Investigating the use of Magnetic Actuation for a Self-Contained Functional Tongue Prosthetic

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Abstract

Oral cancer can result in the loss of the tongue through surgical removal known as glossectomy. Patients who have undergone this procedure face challenges during speech, mastication, and deglutition. Currently, tongue prosthetics lack functionality and are mainly cosmetic. Many of these prosthetics are made of wax and connected to a retainer which attaches to the back molars of the patient. The goal of this project was to develop a self-contained mechatronic tongue prosthesis that can fit within the oral cavity and aid in deglutition. Investigations into various techniques and sensors supporting miniaturization were carried out and magnetic actuation was found to be the most promising technique. The development process involved redesigning the silicone cast to house sensors, selecting sensors and components for magnetic actuation, magnetic field quantification and miniaturizing various other electrical components. Force sensors were selected as a method to detect external stimuli on the tongue such as a food bolus to signal magnetic actuation to begin. The tongue prosthesis was tested, and the displacement was comparable to a normal human tongue at 1 cm of tip actuation. Alterations made to the design of the tongue mold itself increased biocompatibility through an improved anatomical shape and addition of papillae.

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Glossary:

Actuation - movement or activation of the tongue prosthesis.
Compartments - hollowed out space within the tongue prosthesis mold for addition of electrical components.
Keys - 3D printed inserts to be placed into the tongue mold during the silicone curing process to create compartments.
Magnetic Solenoid - long coils of wire wrapped around a ferromagnetic core to produce a magnetic field with an applied current.
N52 Magnet - Neodymium magnet of grade 52 (highest).
PCB - Printed Circuit Board
TinyDuino - miniaturized Arduino Uno microcontroller.
M - a linear mapping of a column-vector
I - currents
$\mu0$ - permeability of a vacuum
p - dipole field at any point
B - magnetic field
T- torque on magnet
F - force on magnet

1.Introduction

As technology has evolved, so has the ability to implement this technology within the realm of healthcare. Advancements have been made within prosthetic devices which help to restore an individual's missing limb or help restore bodily functions. For example, prosthetic limbs are being developed to be robotically controlled and include sensory feedback from the individual user [1]. Despite recent advancements in prosthetic limbs, an often-overlooked area of prosthetics are within the oral cavity for tongue movement.

About 54,010 people will be diagnosed with oral cancer in the United States in 2020 [2]. According to the World Health Organization, the rate of oral cancer is about 650,000 cases per year with half of these resulting in death [3]. The main causes for oral cancer include tobacco use, alcohol use, and from the human papilloma virus (HPV). Treatments for oral cancer include chemotherapy, radiation therapy of the affected area, targeted drug therapy, and immunotherapy [4]. A common consequence of oral cancer is the surgical removal of the tongue known as glossectomy [5]. There are three types of glossectomy performed which are partial, hemi, and total glossectomy. Partial glossectomy only removes the area of the tongue affected by cancerous cells. A hemi glossectomy only removes one side of the tongue and total glossectomy is the complete removal of the tongue to treat oral cancer.

Removal of the tongue through glossectomy impacts an individual's ability to speak and to masticate. In addition to bodily function being impacted, patients also experience psychological impacts and often have difficulty adjusting after the procedure [6]. Since patients experience difficulty speaking, they are unable to connect with family members and friends. Therefore, these patients become isolated after cancer treatment which highlights the need for a more robust tongue prosthetic to restore speech and feeding functionality within the oral cavity.

Tongue prosthetics have been largely static and lack the ability to mimic anatomical movements during feeding and speech [7]. Typical static prosthetics involve a denture system to be attached to the surrounding teeth and includes a wax tongue. Issues with static prosthetics include tooth decay around surrounding areas and do not provide any additional functionality to the user. Recently, a tongue prosthetic was created by a team in Japan which allows the user to utilize a resin prosthetic connected to the back teeth with a wire [8]. The prosthetic is controlled by what is left of the user's back tongue to move the prosthetic tongue up and down to aid with speech. Bridges et. al [9] was able to develop and prototype a prosthetic tongue that utilizes a pneumatic actuator to inflate the tongue for feeding. A 5V air pump supplied the air to inflate the tongue and the controls module allowed for user-controlled inflation settings. This team was able to achieve different inflation settings for the prosthetic tongue to try and emulate anatomical movement patterns during feeding. The limitation of the prototype was the large controls module which was not portable nor could fit into the mouth of the patient with measurements of 8.4 inches in length and 5.25 inches in width. Additionally, the tongue actuation was mainly in the center of the tongue and would inflate to a balloon like shape. The height of the actuation reached about 20 mm with pneumatically controlled tongue prosthesis. Due to some of the limitations of the previous design, new objectives were created to improve this prototype by miniaturizing the electrical components, more accurately replicate tongue movements, and to fit our prototype within a 3D printed oral cavity. From the previous year’s prototype, our team tested the initial prototype through motion and Abaqus testing to develop a baseline for what our prototype should work to improve.

The goals of our project include:

1. Design: Create a tongue prosthetic to mimic anatomical movements more accurately.
2. Size: Develop a more anatomically correct tongue mold and fit prosthetic into the 3D printed oral cavity.
3. Safety: Tongue prosthetic must prevent users from electric shock, leakage current, and be biocompatible.
4. Controls: Miniaturize electrical components
5. Validation: Develop clear test protocols to validate tongue functionality and biocompatibility.

Completion of these goals would allow our team to develop a more usable tongue prosthetic, which mimics anatomically correct movements and can fit into the oral cavity.

The report is organized as follows: Chapter 2 presents research findings from a literature review on the anatomy of the tongue, an introduction to glossectomy and those affected, current tongue prosthetics, and a brief overview of magnetic actuation, and a summary of previous work on this project. Chapter 3 establishes the project objectives and the methodology for developing the self-contained tongue prosthesis. Chapter 4 explores the design of the tongue prosthesis, and Chapter 5 describes the design process for miniaturizing the electrical components. Chapter 6 reveals the results of the displacement and preliminary bolus testing performed with the tongue prosthesis. Chapter 7 brings awareness to the project in a more worldly context including ethical concerns and societal influence. Chapter 8 compares the performance of the prosthesis and control module to the previously outlined project goals. Chapter 9 addresses future improvements and recommendations for future work and the conclusions of the accomplishments made this year.

2. Literature Review

This chapter will explore all the necessary background research conducted by the team to understand the project and develop a prosthetic tongue. Our research will be presented starting with an in-depth view of the anatomy of the tongue and continue into psychological effects. An introduction to silicone molds and electrical components will also be presented. Additionally, previous work on this project will be presented.

2.1 Anatomy & Physiology

This section will explore the anatomy and physiology of the human oral cavity and tongue to gain an understanding of the tissues and intricate muscles within the system.

2.1.1 The Oral Cavity

The oral cavity in humans includes oral structures such as the tongue, palette, cheeks, teeth, gums, and other tissues. Each of these structures perform functions relating to speech or consuming food. Some of these major structures are described below.

The gingiva, or gums, are the tissues surrounding the teeth on top of the alveolar bone. There is typically a 2-3 mm crevice between the gingiva and teeth. Inflammation of the gingiva due to infection is known as gingivitis. Gingivitis is often the result of poor oral hygiene habits. If poor hygiene continues gingivitis can worsen into periodontitis. This more severe infection can lead to damage of the gingiva and the dentin, the outermost layer of the tooth, which is permanent [10]. The gingiva can also develop keratinized mucosa, where the thin membrane along the gingiva produces keratin in its cells as a result of continuous physical trauma. This results in firm fibrous tissues in the gingiva. One study observed the development of keratinized mucosa in patients with oral implants and found that patients without keratinized mucosa had higher levels of plaque and gum recession. In some cases, gum recursion was successfully combated through surgery [11]. This indicates that this fibrous tissue is important to the oral health of patients with oral prosthetics or implants. Proper oral hygiene can combat the formation of plaque so good hygiene practices are very important for these patients.

The palate or “roof of the mouth” is located on the top of the oral cavity. This is divided into two structures, the hard palate, and the soft palate. The hard palate is located behind the front teeth and is firm due to its proximity to the palatine bone. This is important both to speech and eating because the tongue presses against it to push the bolus in eating, and to make some sounds in speech [12]. The hard palate features small ridges directly behind the incisors which are integral to speech [10]. The soft palate is located behind the hard palate closer to the throat. It extends from the midline, usually in line with the molars, to the back of the throat [12]. The soft palate separates the oral and nasal cavities and is made of softer tissue [10].

The floor of the mouth is located on the bottom of the oral cavity and consists mainly of soft tissues. Many veins run through the floor of the mouth to supply the tongue with adequate blood. These soft tissues are also extremely sensitive [13]. One of the main salivary glands in the oral cavity is located in the floor of the mouth. It can also store saliva under the tongue to keep the mouth lubricated [10].

2.1.2 The Human Tongue

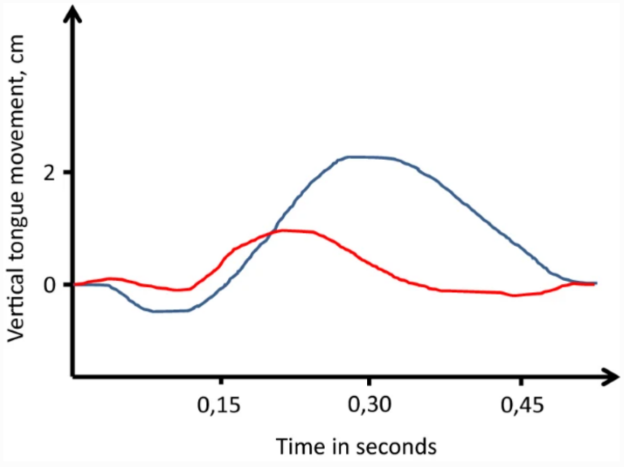
The goal of this project is to make tongue prosthetic as anatomically correct and functional as possible. Therefore, it is important to understand the main functions of the tongue and the attributes of the tongue that help us to eat and swallow. The tongue is separated into five sections namely the tip, lateral surface, ventral, dorsal, and tongue base. Beginning in the anterior region or towards the front is the tip of the tongue. The tongue starts and helps digestion within the mouth and helps to keep swallowed foods and liquids out of the lungs to prevent possibly fatal pneumonias and other harmful effects [14].

There are two different types of muscle groups which move the tongue in both change in shape and directionally which are intrinsic muscle groups and extrinsic muscle groups, respectively. About the midsagittal plane, the tongue is symmetric and has a thin line of connective tissue which divides the tongue in lateral halves. This line of connective tissue, or medial septum, runs along the tongue from the tip of the body to the hyoid bone. The hyoid bone is located at the base of the tongue and is the only bone in the body that is not articulated with another bone. It is also believed to play an important role in speech. Some tongue muscles are attached directly to it [15].

The surface of the tongue is rough and covered with many small bumps. The small bumps near the front of the tongue are taste buds which are responsible for detecting flavors in food and drink. Towards the back of the tongue there are larger bumps known as papillae. The papillae form a “V” shape pointing down the throat to guide the bolus while swallowing. The rough texture of the tongue allows for adequate friction needed for the formation and swallowing of the bolus [13].

Though there have been attempts to measure the size of the tongue in the past, there have been many varying results. One 1986 study by R. G. Grover and S.P Evans attempted to measure the average size of the tongue using two methods [16]. The first was to ask volunteers to stick their tongue out into water to measure the displacement and the second was to take length, width and height measurements of each volunteer's tongue and calculate the volume assuming it was a rectangular prism. Researchers found wise variation in tongue size by gender and by operator taking the measurements. The average dimensions found in the study were 33.3mm in length, 43.7mm in width, and 10.4 mm in height [16]. Many factors could have influenced the variation in the results of this research, but one notable aspect is the tension in the tongue. When the muscles in the tongue relax or contact the shape and size of the tongue can change. This can introduce significant variation into this and similar research methods.

Fig. 2



Comparison of M-mode ultrasound images in younger and older women. Schematic change of the vertical tongue movement when swallowing water (30 ml) in younger (blue) and older (red) women

Figure 1: Vertical Movement of the Tongue During Swallowing (reproduced as is from [17])

The tongue itself goes through a wave motion in the act of swallowing. One study from Nienstedt et. al uses M-mode ultrasounds to view the changes in the motion of the tongue [17]. The focus for this study was towards the aging of the tongue and how that affects its actuation levels. Through a test involving water swallowing, two groups were tested and the M-mode ultrasound that was gathered from this study was used to graph the vertical tongue movement of one group of younger women and one group of older women. The findings in Figure 1 above show the average height for younger women was around 2 cm and for older women it was 1 cm [17].

2.2 Tongue's Role in Feeding Functions

Generally, feeding has four main stages which are Stage I Transport, processing, Stage 2 Transport, and bolus formation & deglutition [18]. State I Transport involves moving the food towards the back molars for chewing. When the jaw closes, the tongue will rise and start to move the food from the back molars towards the front of the mouth [18]. Processing involves tongue movements within the sagittal and coronal planes. The food processing stage is important for ensuring the food is okay to swallow without choking. During this stage, the jaw and hyoid bone move rhythmically. The tongue and soft palate move in relation to the jaw and hyoid bones located below the oral cavity. Additionally, no sealing of the posterior oral cavity occurs and movement of tongue and jaw push air up, so we can smell the food we are eating. In order to prevent us from biting our tongue, when our jaw opens the tongue is moved outward and down. Alternatively, when our jaw closes the tongue moves backward. Our hyoid bone plays an important role in feeding and is connected to our cranial base, and mandible. Due to these connections the hyoid bone helps to control the movement of our tongue and jaw.

Stage II transport involves the action of swallowing the food or liquid being ingested [18]. The process of swallowing involves the anterior portion of the tongue coming in contact with the hard palate or "roof" of the mouth. From there, the contact between tongue and hard palate increases and food is squeezed backwards towards the oropharynx. Next, there is Bolus formation & deglutition which has mainly been studied with swallowing liquids. For liquids, most people will form a bolus from the surface of the tongue to the palate. However, some hold liquid towards the bottom of the mouth which is called "dipper" swallows. The tongue has the ability to form more shallow or deeper cavities as needed to accommodate the liquid or food. To swallow, the tongue squeezes the bolus towards the back of the throat for ingestion.

2.3 Oral Cancer, Glossectomy, and Current Prosthetics

Approximately, 54,010 people are diagnosed each with oral cancer in the United States [2]. World-wide, there will be able 650,000 cases of oral cancers per year with half resulting in death. Risk factors for developing oral cancer include tobacco usage, human papillomavirus (HPV) and alcohol use. Non-surgical treatment of oral cancer includes chemotherapy, radiation therapy of the affected area, and immunotherapy. However, when the cancer becomes malignant treatment begins to take a more surgical approach known as glossectomy [19].

Patients that have undergone glossectomies may have replacement tongues constructed from human tissue normally taken from their forearm or thigh. Patients that had this surgery done were able to have diets taken solely by mouth and with mild to moderate difficulty. Around half of these patients were able to eat regular or soft diets. Psychologically, patients cannot understand what they will be going through until the procedure is completed. They cannot talk which leads to lack of communication between friends and family members and it may also lead to job loss. These patients also may have to feed using a stomach tube which does not allow them to socialize with others over food and drink, isolating them from a lot of society [14].

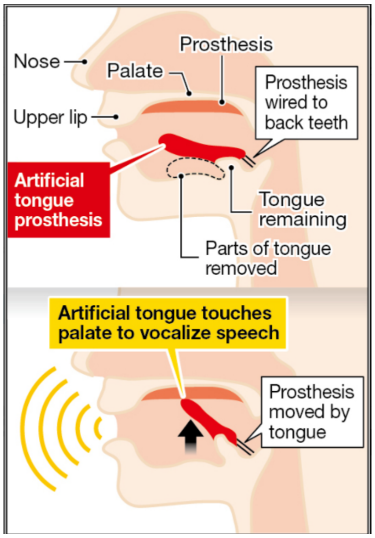


Figure 2: Graphic Depicting the Okayama Prosthetic (reproduced as is from [8])

A Japanese team of dentistry researchers from Okayama University created a movable tongue prosthesis to help oral cancer patients as shown in Figure 2 [8]. The prosthesis helped the patient to be able to speak despite tongue loss. The team was led by Shogo Minagi, who was inspired by the work of his colleague, Kenichi Kozaki. Kozaki had lost his tongue to oral cancer and asked Minagi to help him speak again through an oral prosthesis. However, tongue prosthetics are largely static so a functional prosthesis had yet to be developed. Minagi began developing an oral prosthesis, working with Kozaki, who would try out the prototypes and give feedback on them and how they could improve [8]. The main problem with speech is that the tongue needs to touch the palate and without a tongue, one cannot touch the palate and therefore had trouble speaking. From this problem, Minagi and his team made a prosthesis made from resin that could move up and down in the mouth, allowing the user to control the device using the remaining bit of their tongue. A resin filling is placed within the roof of the mouth so that the device can touch the palate. Minagi hopes for the device to become more readily available to people as they used widely available materials so that it can be easily made by any dental technician [8].

2.4 Electronics & Effects on the Body

Small scale electrical components are integral to fit into the oral cavity for a more advanced tongue prosthetic. Components that aid miniaturization are microcontroller, transceivers, small batteries such as those in hearing aids. Microcontrollers play an integral role in modern day medical devices such as in blood pressure monitoring devices [20]. Unlike microprocessors, microcontrollers allow for less external circuitry which is optimal for our purposes. Additionally, microcontrollers have a central processing unit or CPU, which allows the device to send signals to control the circuit using code from the user [21]. Programming microcontrollers is typically done in the coding language of C. Written code by the user essentially gives the microcontroller instructions on how to function and interact with attached components. The microcontroller has a memory component that can save these instructions and continue to perform the desired actions. Transceivers are also commonly utilized in medical devices such as pacemakers and other wearable medical technologies. These devices allow for wireless transmissions of data, which is useful to the user as a feedback mechanism of the activity being detected by the circuit. For our project, this is important to understand how the tongue is moving in response to external stimuli.

A concern with electronics implanted or worn on the user is electric shock and leakage currents. Typically, these devices will have an isolation amplifier to prevent electric shock to the user. Leakage currents are particularly undesirable and are a result of improper ground of the circuit. These currents can flow through the components and result in damage or a shorter life span for the battery. Additionally, leakage currents can flow through the human body and affect functions of the heart. To mitigate these risks, it is important that electronics are properly grounded and enclosed in a resin to shield the electronics from interacting with the body. Pacemakers are a good representation of successful electronic safety practices due to its implantation and placement within the body. Typically, pacemakers encase the electronics within epoxy resin and vacuum sealed [22]. Vacuum sealing the electrical components prevents degradation and exposure to bodily gases. These methods ensure patient safety and can be used for further applications for other implantable medical devices.

Another concern is with the magnets affecting the oral cavity. The magnets chosen for this project were N52 magnets which are composed of neodymium. Previous work with neodymium magnets has been done for orthodontic applications for motion actuation, molar distillation, and palate expansion [23]. The magnetic fields produced by these magnets have also allowed for a stimulation bone formation. Cardiovascular effects of magnets have been seen in altering blood flow. When the body is subjected to strong magnetic fields, red blood cell flow decreases. However, studies show there is no significant damage observed within the cranium, indicating that magnetic fields on the area are not inherently negative. Additionally, magnetic simulation of the brain has been used as a treatment against depression. In terms of skeletal effects there is not a lot of evidence to suggest any advantages or disadvantages [23]. A neodymium magnet placed on the tooth of a patient with the pole facing towards the buccal mucosa, shown in Figure 3, shows no significant differences after long periods of time with interactions between the two [24].

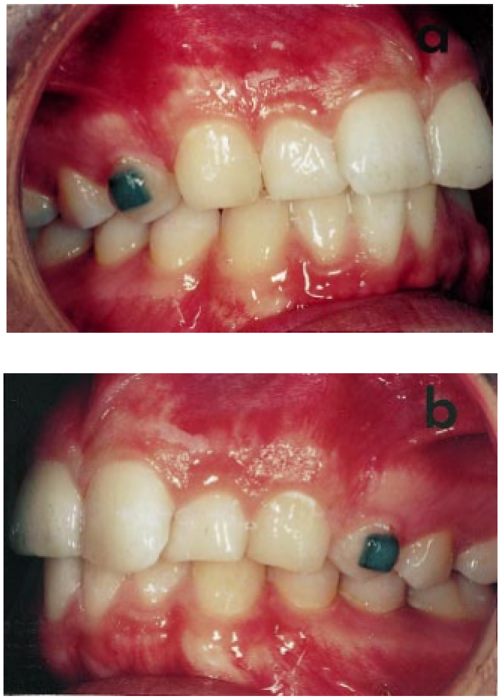


Figure 3: Magnet Placed on Tooth Towards Buccal Mucosa (reproduced as is from [24])

2.5 Introduction to TinyDuinos & MOSFETs

Previously, Bridges et. al. had utilized a full-size Arduino Uno as the primary microcontroller to store and execute the functions of the tongue prosthetic. The disadvantage of a full-sized Arduino board is that it cannot be stored within the oral cavity. The dimensions of the Arduino Uno board are 68.6 mm in length and 53.4 mm wide, which is too large to comfortably fit within the oral cavity of the user [25]. Therefore, other alternatives were explored to condense the size of the microcontroller while also maintaining equal functionality. Since Arduino is a familiar platform and microcontroller for most users, our options were kept to those within the Arduino family. Many manufacturers such as Adafruit and TinyCircuits have begun to create smaller microcontrollers for small scale applications such as fitness trackers and portable GPS monitors [26,27].

The TinyDuino is a smaller version of the Arduino Uno developed by a company called TinyCircuits. These TinyDuino microcontrollers operate similar to the Arduino Uno and are much smaller in size to fit within the oral cavity [27]. Dimensions of the TinyDuino are advertised as being smaller than a quarter and are specifically 20mm x 20mm in size as shown below in Figure 4.

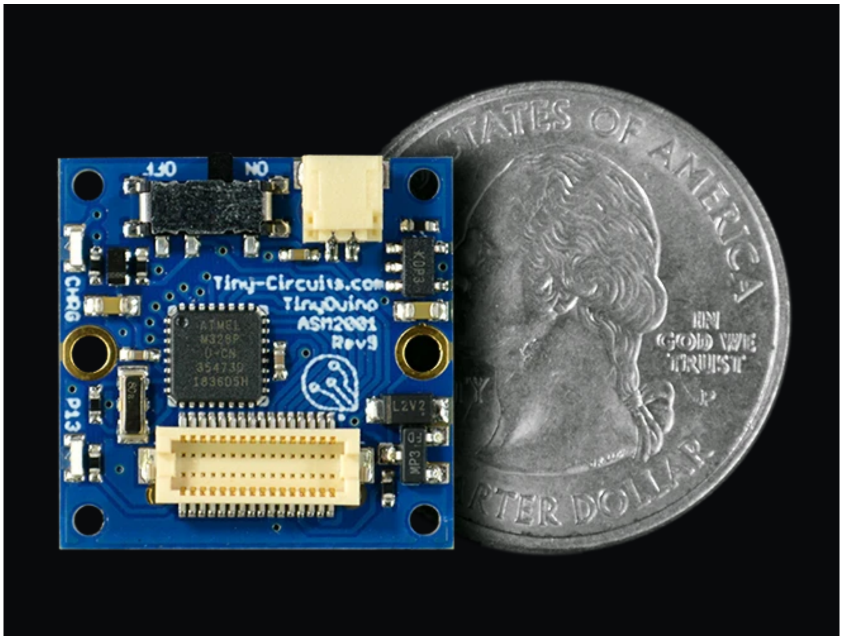


Figure 4: TinyDuino Processor Board (Dimensions 20mm x 20mm) (reproduced as is from [27])

Due to the small size of the TinyDuino, not all the components will be able to fit on one shield or board. To compensate for this issue, the TinyDuino are stackable by the pin connector and allows the user to choose the applicable shields for a specific project (Figure 5). Typically, the set up will require a USB shield to connect to the computer and upload the code and the processor shield to load the code onto. After these two shields, the customization is up to the user and various sensors can be added to the TinyDuino for specific projects.

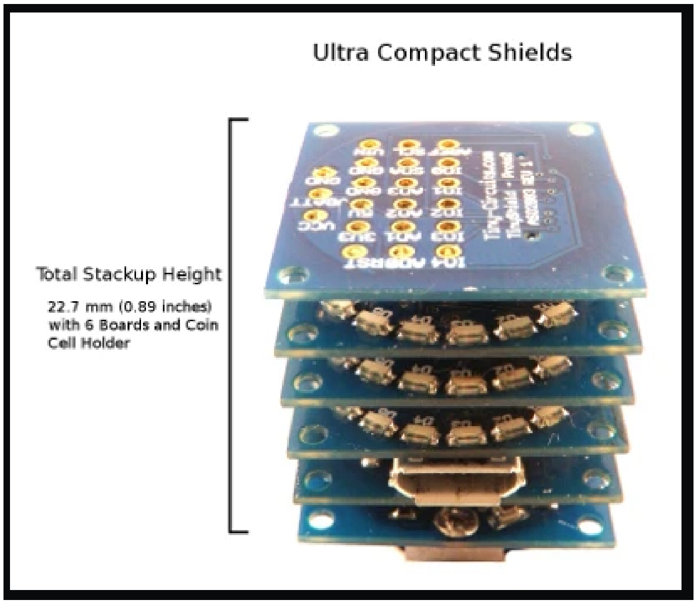


Figure 5: TinyDuino Shields Stacked (Stack height 22.7mm) (reproduced as is from [27])

The TinyDuino has the same Atmel Atmega328P microcontroller as the Arduino Uno and accepts the same 14 digital I/O pins [27]. However, the difference between the two boards is that the Uno utilizes an 8MHz resonator while the TinyDuino uses a 4MHz resonator which allows for lower power usage. A TinyDuino can be operated using only a 3.3V coin cell battery which can be inserted on the back of the processor board to supply power to all the shields. All of the TinyDuino designs are open source and can be freely altered and adapted for the user's projects. A special consideration when utilizing the TinyDuino is that since this is a specialized board it has different libraries created by TinyCircuits which will need to be manually added to the Arduino IDE software.

2.6 Soft Robotics

Soft robotics is a specific subsection of robotics that brings automated robotics closer to humans. A soft robot is defined as a robot that mimics a living organism's characteristics beyond actions, namely it is constructed out of material that is similar to organic material such as silicone rubber. In soft robotics, silicone rubber is some of the most widely used materials to mimic organic material, it can have a large amount of force applied to it and change its shape. The material is also a low conductive, and long-lasting weather resistant substance that can be smooth like skin [28]. A study on creating a robotic hand that can grip and pick up objects like a normal hand concluded that sensory deformation is necessary to register accurate actuation [29]. The measurement of elastic deformation is proportional to the force applied to the surface of the material, that can then be converted using a flex sensor and control laws to provide exact actuation by moving the soft robot [28]. Any specific amount of elastic deformation can register a response, while when deformation is not desired a dome shape can be used to test slip and grip capabilities of a robot.

For the precise movements and elastic properties of silicone rubber, our team chose to pursue researching this material for the outer coat of the tongue. Silicone rubber is a very soft and smooth material, it creates smooth shapes and avoids making inorganic movements due to its properties [29].

Further research on magnetic actuation in soft robotics provided a separate study with a robot made to explore the use of linear and turning locomotion in a fully 3D printed soft robot. This multi-material robot has a 3D printed body structure made from magnetic particle-polymer plastics; the shape of this specific robot is meant to mimic the locomotion of an inchworm shown in Figure 6. The magnets on each end of the body actuate while limited by the cooling time of the shape memory alloy (SMA) coils. This makes the overall motion of the robot and steering slow. The robot is designed for use in the medical field, specifically a drug delivery system, so while its body is significantly smaller than a tongue (only taking up a 40mm x 5mm x 4mm space), we can still analyze the creation method for our project. By using multi-material fabrication and 3D printing the magnetic polymer in structures layer by layer allows control of different segments of the soft robot body. From independent segment control, the user can handle complicated tasks with the soft robot. We aimed to mimic this movement and shape created by this robot for our tongue prosthesis. A magnetic polymer can also be used as an actuation within the silicone [30].

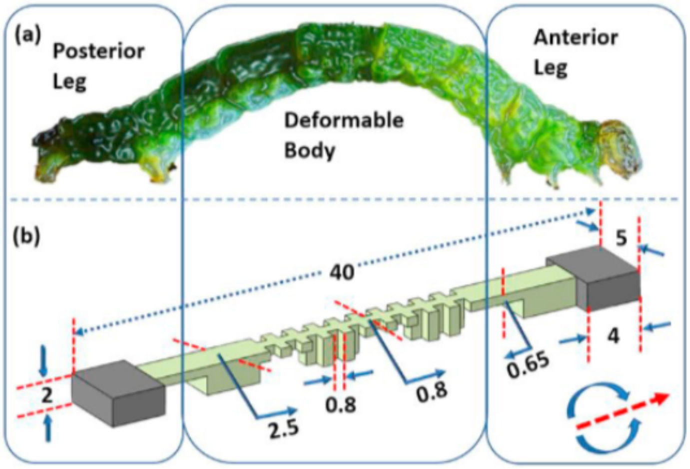


Figure 6: Particle Polymer Composite Soft Robot (reproduced as is from [30])

2.7 Magnetic Actuation

Understanding magnetic fields and the capabilities of electronic magnetic systems was necessary for success. The Biot-Savart law of magnetism states that magnetic fields generated by currents can be related to the magnitude, direction, length, and proximity of the electric current. This current can be controlled to alter the magnetic field to create actuation. Couple this with Ampere's Law where an equation relates magnetic fields to electrical currents, this law is as follows:

$$B = \mu N I \qquad (1)$$

When utilizing this magnetic field manipulated by a current, a force and torque acting on the actuator is needed. A magnetic dipole can produce a torque about its center. For force on a current carrying magnet, it will feel a force in the presence of a magnetic field for a permanent magnet. A permanent magnet is an object made from magnetized material and produces continual magnetic fields. Everyday examples include refrigerator magnets used to hold notes on a refrigerator door. While objects made of material that are strongly attracted to a magnet is a ferromagnet, an example of this is iron. The actuator magnet must be a permanent magnet with a controller electromagnet manipulating them with a current. When a magnet is brought near a previously unmagnetized ferromagnetic material, it causes local magnetization of the material with unlike poles closest as shown in Figure 7 below. A permamagnet will exhibit its own poles as is, there are always two poles to every magnet, as a single pole magnetic material does not exist. If you were to split a magnet down to the molecular level, the magnet's atoms would exhibit a North and South polarity. The magnetic pole lines move from north to south as shown in Figure 8, some general rules for identifying magnetic fields are as follows:

1. The direction of the magnetic field is tangent to the field line at any point in space. A small compass will point in the direction of the field line.
2. The strength of the field is proportional to the closeness of the lines. It is exactly proportional to the number of lines per unit area perpendicular to the lines (called the areal density).
3. Magnetic field lines can never cross, meaning that the field is unique at any point in space.
4. Magnetic field lines are continuous, forming closed loops without beginning or end. They go from the north pole to the south pole. [31]

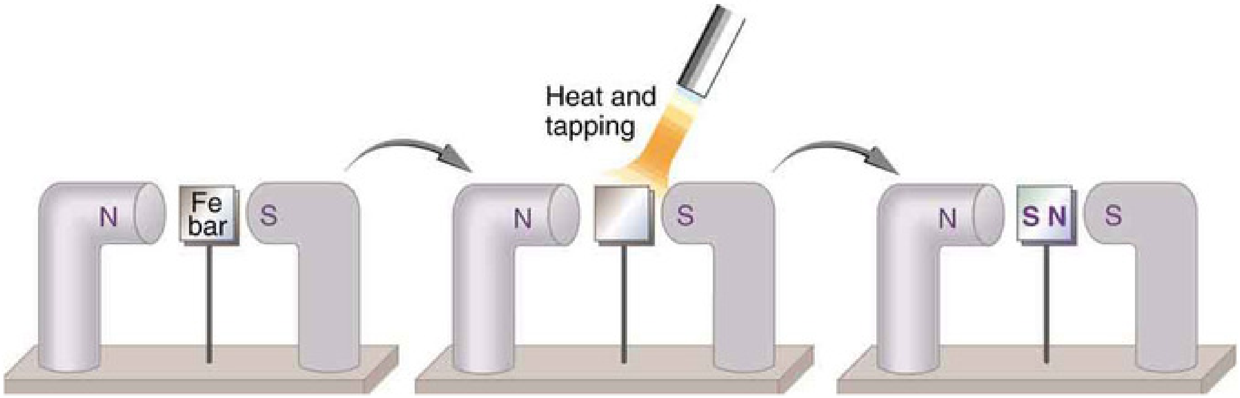


Figure 7: Polarization of a Ferromagnet (reproduced as is from [31])

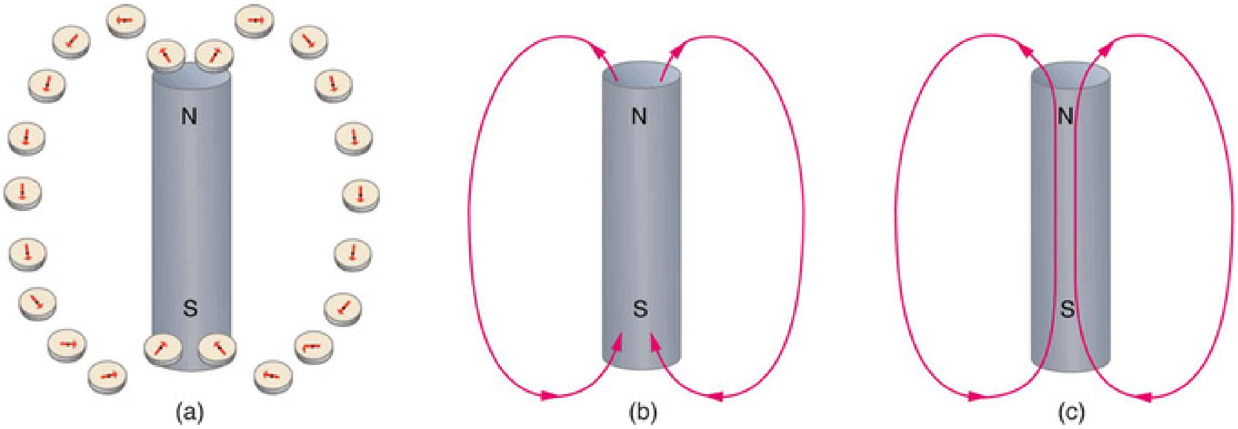


Figure 8: Magnetic Field lines (reproduced as is from [31])

Magnetic forces and torques application are important for successful robotic actuation. In Figure 9 below, examples and graphics of magnetic material aligning to magnetic field lines are shown. By having a permamagnet offset from the direction of the magnetic field, a torque is generated, while when the poles are aligned with the direction a force is applied. To manipulate these magnets, a current driven electromagnet should be used as discussed above with Ampere's Law. Examples of potential coils that create different magnetic fields are explained:

- **Helmholtz coil** - composed of two coaxial circular coils with the same radii r, and the interspacing between the coils is equal to r. A nearly uniform magnetic field parallel to the coaxes is produced at the center when equivalent currents flow in the same directions.
- **Maxwell coil** - another specialized coil pair generating an almost uniform field gradient parallel to the coaxes at the center. A Maxwell coil also contains two identical coaxial circular coils with radii r, but the interspacing is 3__√ r and the equant currents are in opposite directions.
- **Saddle coil - comprises** two identical coils in saddle shape, which coincide with the side surface of a cylinder and symmetric about the coaxes. By parameter optimization, a saddle coil can produce an approximately uniform magnetic field perpendicular to the coaxes when charged with currents.
- In Figure 10, different systems of these coils are used to create different actuations [32].

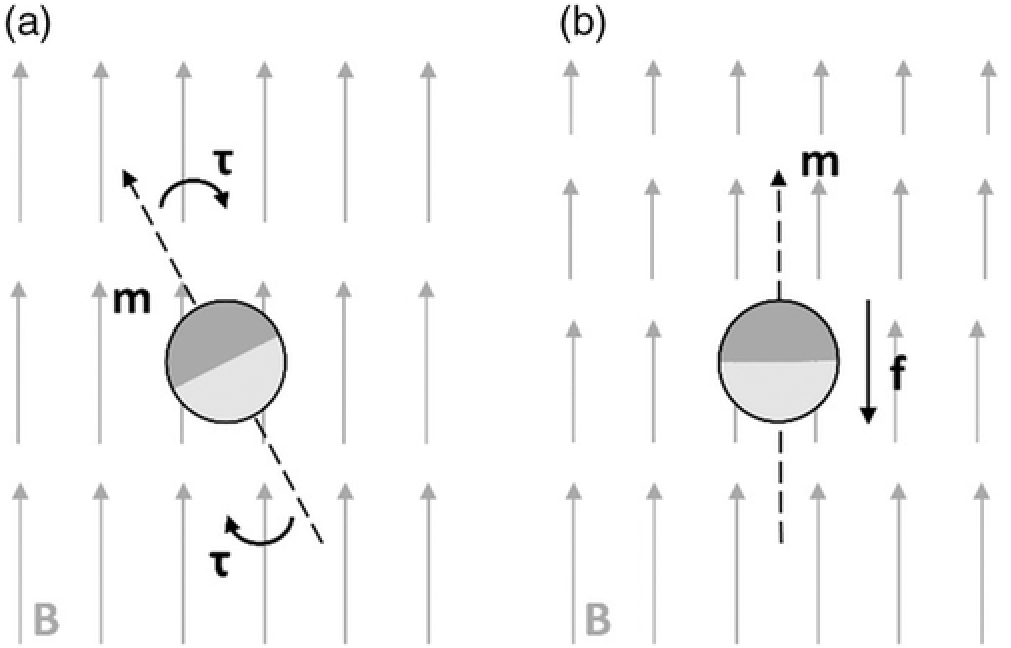


Figure 9: Magnetic Torque and Force alignment (reproduced as is from [32])

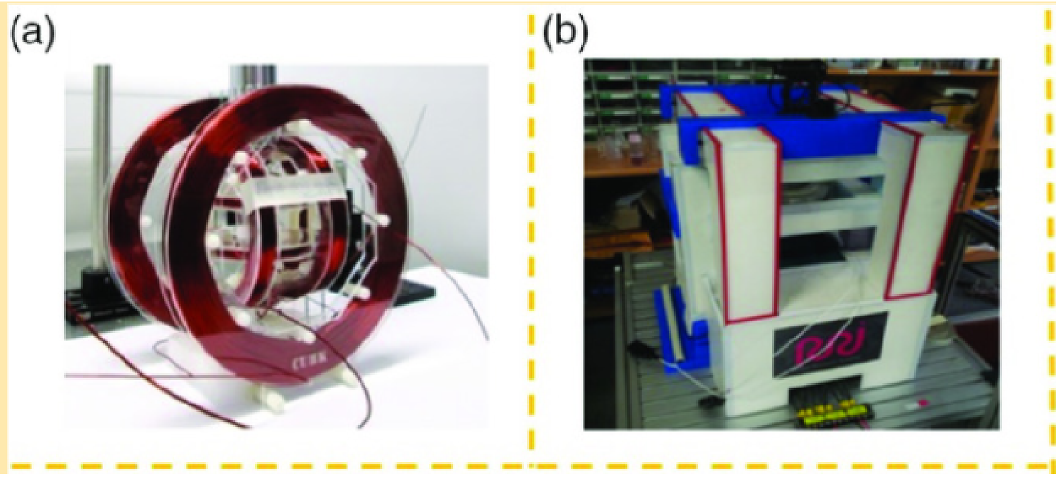


Figure 10: Magnetic actuation systems with paired coils a) triaxial circular Helmholtz coil b) triaxial square Helmholtz coil (reproduced as is from [32])

These coils can generate specific magnetic fields that would allow a permamagnet to perform specific types of actuation. The Helmholtz and Maxwell coil can even be combined to produce a square shaped magnetic field [32].

To achieve appropriate actuation utilizing electromagnets with coils, some calculations need to be done. As shown below, equations 2, 3, and 4 are the calculations for finding the force on the magnet (x and y movement) and torque on the magnet (rotation about z axis) can be found with the known values of: m - the dipole moment of an electromagnetic source, M - a linear mapping of a column-vector, I - currents, u0 - permeability of a vacuum, p - dipole field at any point, B - magnetic field, T- torque on magnet, F - force on magnet. With many of these known values either acting as inputs or known specifications of the controller or magnet, calculating the torque and force on the magnet will determine the actions the magnet executes.

To utilize electromagnets to act upon the law when an unconstrained magnetic tool is placed within a magnetic field, it will align with the applied field because of the magnetic torque. So if the field has a rotating factor, the tool will attempt to keep up with the rotation as well and will be limited in its rotation to the amount of magnetic torque exerted by the controller. The other degrees of freedom manipulation can be done by changing the field gradient at the position of the tool to apply a controlled force for pushing and pulling. Shown below in Figure 11 is a tri directional electromagnet used to manipulate a ball about a maze. With changing directions in the magnetic field from different electromagnets operating, torques and forces are achieved that can be based on Ampere's Law and the equations shown in the list below.

Force and Torque Equations [33]:

$$m = MI \qquad (2)$$

$$B = \mu_0/4\pi||p||^3\,(3pp^T-I)m \qquad (3)$$

$$F = (m*\Delta)B \qquad (4)$$

$$T = m \text{ x } B \qquad (5)$$

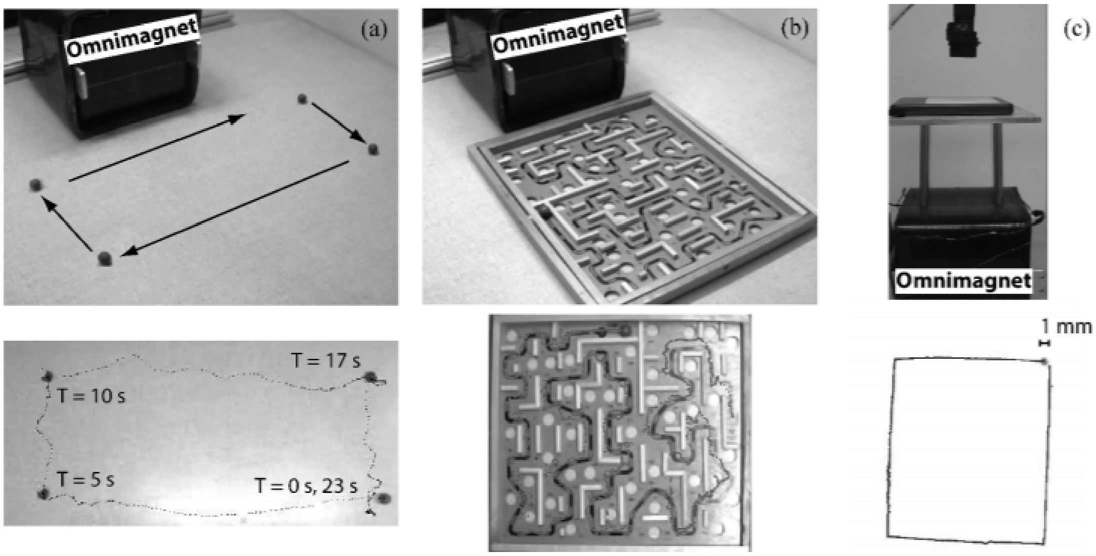


Figure 11: Dynamic magnetic ball rolling with a stationary controller (reproduced as is from [33])

An omnimagnet shown in Figure 11 above is three electromagnets centered at the same point in space but point in different directions. A picture of exposed coils for the electromagnets is shown in Figure 12 below. By controlling these with a current passing through each coil, it will generate a magnetic dipole of desired strength in any direction and can actuate a magnet remotely. One current operating through the omnimagnet will create desired magnetic fields in any direction therefore only having one input control. The purpose of producing magnetic fields in any direction is to apply a force and torque to the device without maintaining a mechanical connection, by producing a rotating field the magnet will then rotate with the field and can move based on its size and features. Several videos are available that explain and show the use of an omnimagnet with a magnetic ball to navigate through a maze and through a liquid using rotational torque along with manipulating the position of a magnet floating on water using magnetic force. The way these operators achieve a force actuation instead of a torque is by having the magnet rigidly attached to a nonmagnetic object that can still freely move in a two-dimensional plane (x and y), along with manipulating the actuator's magnetic dipole to face upwards. This means that when operating with an omnimagnet, one magnetic actuator might need to be utilized or magnets that behave in a precise way in relation to one another where their differing dipoles will create different movements [34].

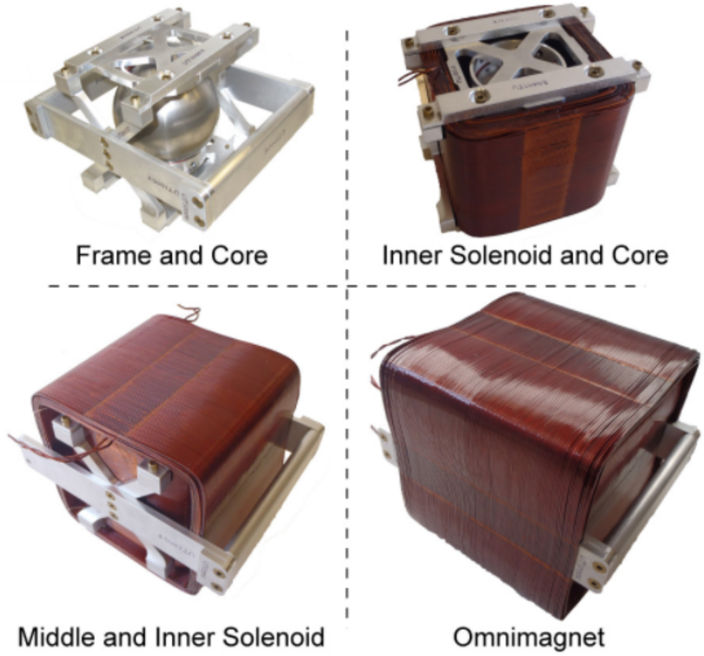


Figure 12: Design of an Omnimagnet (reproduced as is from [34)]

An Omnimagnet consists of three orthogonal opposing direction solenoids surrounding a ferromagnetic core. When designing an Omnimagnet, a few requirements must be determined. First, the shape of the solenoids, then the core shape, in this article the team chose a square solenoid shape for density packaging and a sphere shape for the core because:

1. A sphere does not have a preferential magnetization direction.
2. When placed in a uniform field (similar to the field in the center of a solenoid), a sphere produces a pure dipole field.
3. The average applied magnetic field within a sphere is equal to the applied magnetic field at the center of the sphere.

The dipole-moment generated in each direction consists of the contribution of both an individual solenoid and the magnetization of the core due to that solenoid. It can be calculated that both the magnetization of the core and solenoid should be the same when an equal electrical current density is applied through each solenoid. In this experiment, the team decided to constrain their design to use a single wire gauge for all solenoids, meaning an equal electrical current density is proportional with an equal current; current and current density are related by the cross-sectional area of the wire used. It would be wise for us to use the same method for our omnimagnet.

With a current going through a single wire gauge, the solenoids will produce differing magnetic fields. Their field shapes and strengths are represented in Figure 13 below. Since each solenoid in the Omnimagnet has a different geometry, the magnetic field produced by each solenoid will not have the same shape for positions close to the Omnimagnet. An Omnimagnet is a source for magnetic fields with three inputs from the current applied to the three solenoids that then generate a magnetic field in a specific location in space. This is too large for it in the oral cavity. A design for this purpose would need to have the patient sit still while chewing in order to prevent poor actuation. Instead utilizing a single electromagnet with this in mind will be more beneficial to achieve simpler actuation [35].

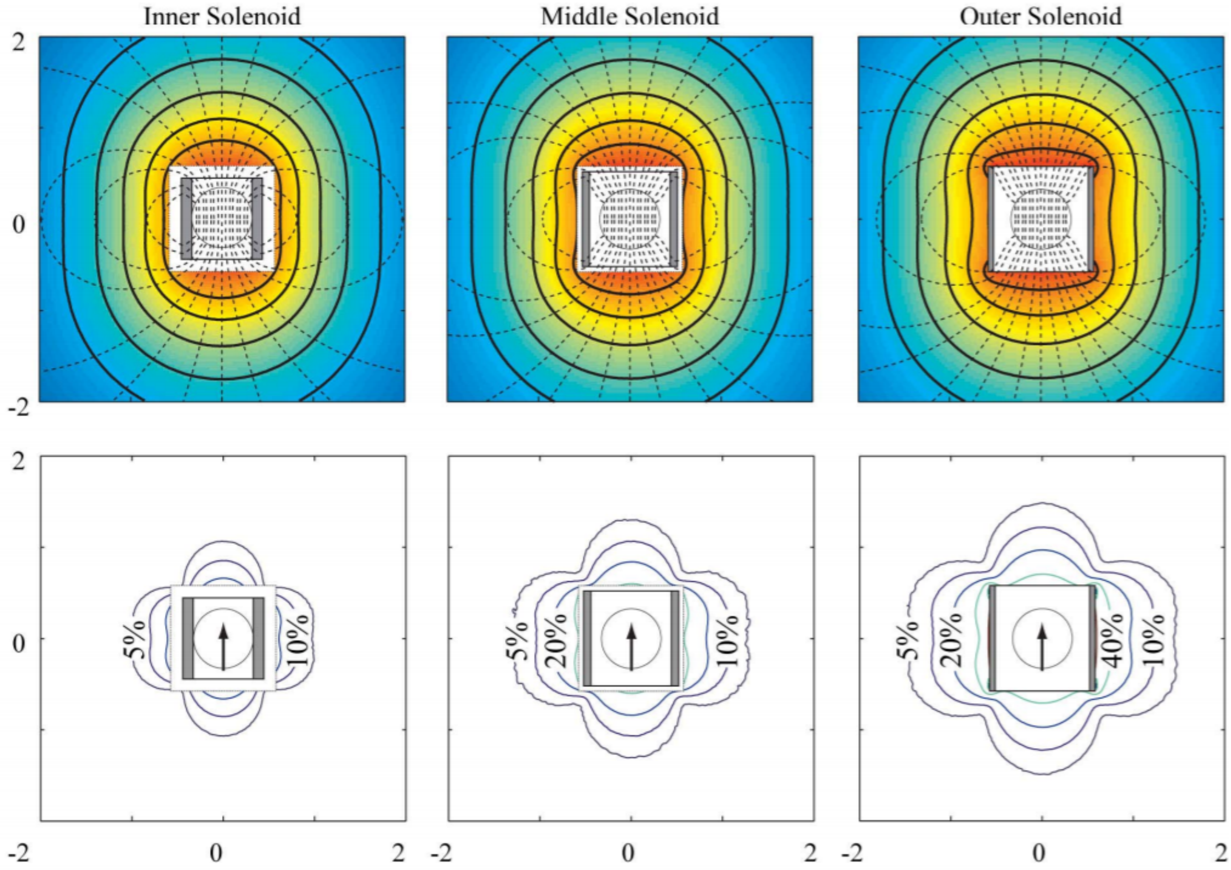


Figure 13: Solenoid Magnetic Field Analysis (reproduced as is from [35])

2.8 Previous Project Iterations

Previous projects have approached the goal of creating a functional tongue prosthetic differently through pneumatics. This project is a continuation of a previous master's Thesis and Major Qualifying Project (MQP). The Master's Thesis was by Francis Darmont Araya [36] and focused on utilizing PneuNets as the actuation mechanism for the tongue. Last year's MQP was able to decrease the number of pneumatic pumps and attempted to allow for various inflation settings.

2.8.1 Bridges et. al. 2020 MQP

Bridges et al. created a pneumatically actuated tongue prosthetic with various inflation settings with the goal of moving the bolus towards the back of the throat [9]. The following sections will address the previous team's design and their results.

2.8.1.1 Prosthetic Design

Bridges et al. developed a silicone tongue prosthetic based on the previous work of Araya in his Master's thesis [9]. This tongue was made much smaller at 40mm length and 35mm width, to potentially fit within the oral cavity. The shape of the tongue was also modified to be more triangular, which more accurately represented the shape of a human tongue. The tongue contained chambers which were meant to be inflated with air pumps so the flat tongue would emulate a swallowing motion. Similarly, to Araya, these chambers were created by pouring silicone with a 3D printed chamber insert to create a void. Two of these silicone pieces were then adhered together creating a gap where the inserts were present. The chamber inserts used by this team are shown in Figure 14 below.

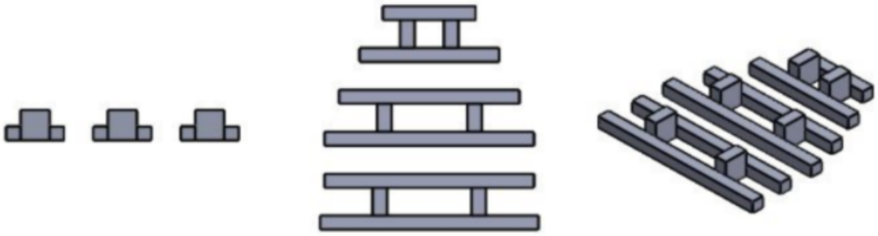


Figure 14: Chamber design used by Bridges et al. (reproduced as is from [9])

Originally, three pumps were used to inflate the tongue by section, but Bridges et al. were able to reduce the system to a single pump. The air was pumped into the silicone tongue via three tubes. These tubes were connected to the air pump on one side and attached to the tongue with silicone adhesive on the other side.

The team investigated two methods of attachment for this tubing. The first method connected tubes at the rear seal between the chambers and the second connected via ports in the bottom of the tongue similar to Araya's method of tube attachment. The team chose to continue with the first method. Figure 15 shows where the tubing is inserted and fixed in the rear of the tongue.

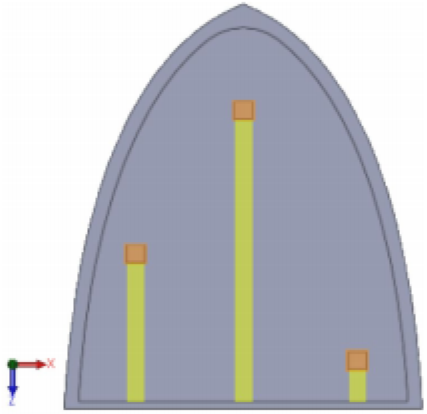


Figure 15: Tubing attachment via rear of the Bridges et al. prosthetic (reproduced as is from [9])

The prosthetic developed by Bridges et. al [9] was held in place with a retainer based on a typical Hawley retainer. A retainer was chosen as the stabilization method because it was able to support the prosthetic and allow for a patient to wear over natural teeth or dentures. The team created a retainer system using orthodontic wire and epoxy. They found that epoxy was prone to cracking and separating the wires.

2.8.1.2 Controls Module

The previous MQP team developed a control module and 3D printed housing components to store the pneumatic pumps, solenoids, and tubing connected to the prosthetic tongue as shown in Figure 16. This module was able to downsize from Araya's work from three to one 5V air pump to supply air to the tongue prosthetic. Additionally, this unit integrated pressure sensors to provide an air pressure reading to the LCD screen for the user. An Arduino Uno was utilized as the microcontroller and supplied the 5V to the air pump and connections to the LCD and external circuitry. This module allowed for various inflation settings for the tongue by supplying the air towards the tip, middle, or back of the tongue.

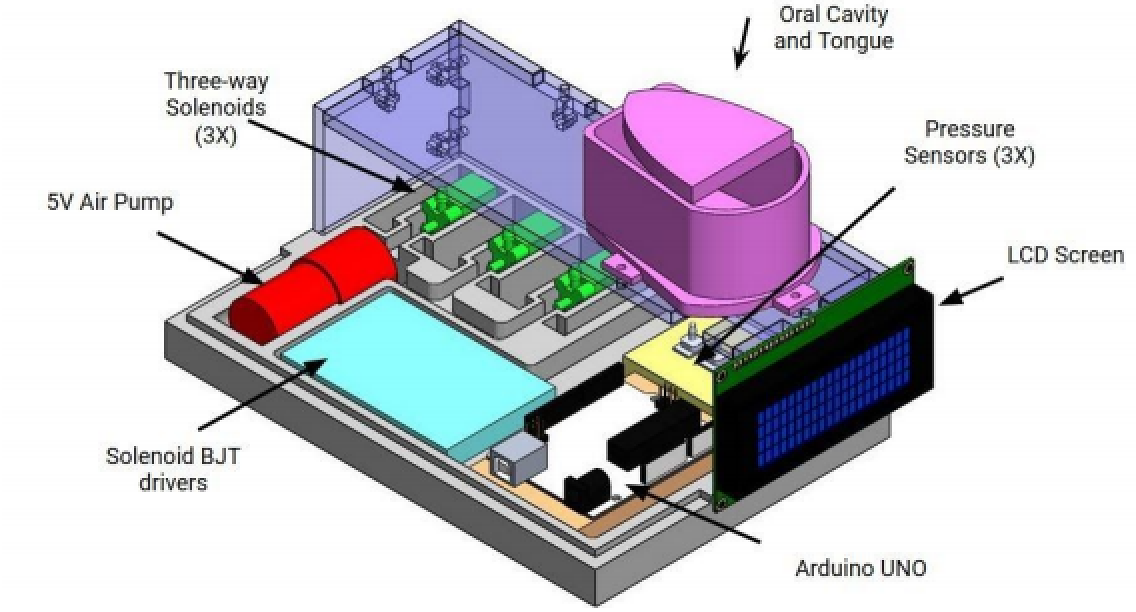


Figure 16: MQP 2020 Final Control Module Components (reproduced as is from [9])

2.7.1.3 Results & Limitations of MQP 19-20

This MQP team was able to develop a working prototype through pneumatic controls that was able to inflate the tip and middle areas of the tongue prosthetic. However, the limitations of this prototype were apparent in the size and method of actuation. The size and shape of the tongue developed was too triangular and small to be natural for a human tongue. Additionally, the electrical components and pumps are much too large to fit into an oral cavity. The previous retainer ideas were promising but had to be altered for a prototype that is able to be placed within the oral cavity. Unfortunately, this team was unable to fully integrate these components within the oral cavity.

A limitation of utilizing pneumatics as the primary mechanism of actuation is the issue of air leakage and the possibility of the mold rupturing. Typically, the air leakage was found to be along the outside edges of the silicone mold. Additionally, pneumatically controlled devices have a max air pressure before the mold will burst and be unusable. Another issue observed with the pneumatically controlled system is that the air pressure supplied would cause the tongue to form more of a ball shape during inflation which does not help the bolus move towards the back of the throat. The maximum pressure of the final tongue before failure was 0.524 MPa which was significantly higher than previous designs the team tried which experienced failure at 0.242 MPa.

The displacement of the tongue was measured using a video software and a light background with a scale bar for the software to reference. The team measured the front, side, and back heights for each of the top, middle, and ending PneuNet in the tongue. The tongue displacement values reached between 9.5 mm to 10 mm for front, middle, and back of the tongue. Unfortunately, the team did not have any values or results for bolus testing due to the global pandemic but had planned to utilize mashed potatoes as the food choice for the pneumatic tongue to move.

3. Project Requirements & Methodology

This chapter will discuss the design requirements defined by our team as the measurement of success of the artificial tongue prosthetic. Areas of improvement from previous work on this project will be presented and evaluated. Additionally, all design requirements will have an explanation for why and how these were identified. All design objectives will have a measurable method for testing which will either be theoretical or practical.

3.1 Initial Client Statement

Patients need a functional tongue prosthetic to aid in speech and mastication to improve their quality of life. Currently, tongue prosthetics lack functionality and cannot be controlled by the user. Therefore, the prosthetic tongue needs to be able to move a bolus to the back of the throat and aid in basic speech.

3.2 Improvements from Past Works

Previous work conducted by the Bridges et. al [9] team revealed challenges with pursuing pneumatics as the mechanism for the prosthetic tongue's actuation. Pneumatics require the usage of pumps, solenoids, tubing, and tee connectors, which is cumbersome when having to respect size constraints. Additionally, the control systems of this prototype had multiple breadboards and were far too large to integrate into the oral cavity. Last year's research team did explore the idea of magnetic actuation but used magnetic dust within the silicon causing the material to scrunch in on itself instead of actuating. The prototype created last year did not have any sensors to detect food or weight on the tongue to trigger the actuation. Instead, four push buttons were used to provide different inflation settings. Overall, the previous work revealed the need for miniaturized electrical components, a more efficient actuation method, and a more anatomically correct tongue size and shape.

3.3 Goals for this Project

Overall, it is important for the tongue prosthetic to be small enough in size to fit comfortably in the oral cavity and protect the user from electric shock or leakage currents. Magnetic actuation is important to integrate into this project since it allows us to eliminate more cumbersome electrical components. Further, a new silicone tongue mold is needed to better replicate the size and shape of a human tongue. The theoretical relationship between magnetic fields is important for the scope of this project to predict movement within the oral cavity. An overarching goal of this project is to integrate the functional tongue prosthetic into the oral cavity securely with minimal discomfort to the patient. The goals for this project are as follows:

1. Design: Create a functional tongue prosthetic to actuate the tip of the silicone tongue.
2. Size: Develop a more anatomically correct tongue mold and fit prosthetic into the 3D printed oral cavity.
3. Safety: Tongue prosthetic must prevent users from electric shock, leakage current, and be biocompatible.
4. Controls: Miniaturize electrical components and implement magnetic actuation into the final prototype of the tongue
5. Validation: Develop clear test protocols and theoretical simulations to validate tongue functionality and biocompatibility.

These project goals led our team through design iterations and formulation of the appropriate testing to ensure a successful prosthetic.

3.4 Standards

The medical device industry is heavily regulated by external bodies such as the International Standards Organization (ISO). Additionally, many regions around the world have their own regulatory bodies such as the Food & Drug Administration (FDA) in the United States and the European Union Medical Device Regulation (EU MDR) for European countries.

Relevant standards for our project include those regarding silicone material, prosthetics, and electromagnetic compliance standards for medical devices.

Dental implants have their own ISO regulations under ISO 19429:2015, which address testing needed to be performed on these implants and general guidelines. ISO13485 is the standard for all medical devices which includes implants and products. Additionally, IEC 60601-1-2 is the test requirements for electromagnetic compliance which includes radiated emissions and immunity testing.

Electronics integrated into medical devices have specific ISO/IEC standards which are ISO/IEC 60601-1-11:2015 which outlines standards for basic medical electrical equipment [37]. Since this device would be implanted within the oral cavity, another applicable standard could be IEC 61000 which is for active implantable medical devices [38]. Testing that must be performed with this standard is RF radiated immunity, radiated magnetic immunity, and radiated emissions which are important for patient safety.

Some standard biocompatibility testing protocols include ISO 10993-5 (cytotoxicity), ISO 10993-4 (hemocompatibility), ISO 10993-6 (implantation), ISO 10993-10 (irritation and sensitization), ISO 10993-11 (pyrogenicity and systemic toxicity), and ISO 10993-18 (chemical characterization) [39]. Cytotoxicity would be completed after the full prototype, but there has been research done that states that the magnets have no negative effects on the oral cavity and the medical grade silicone that is suggested for final use would be biocompatible already. Genotoxicity does not apply as the prosthetic would not be in contact within the cells. Hemocompatibility also does not apply as the artificial tongue would not be in contact with blood. Implantation, irritation, and sensitization was researched in that the magnets have no effect on the surrounding tissues and the silicone would be biocompatible so it also would not affect the surrounding tissue. Pyrogenicity and systemic toxicity would have to be monitored and chemical characterization would also have to be tested for [39].

3.5 Needs Analysis

An artificial tongue prosthetic is needed to help aid patients in mastication and deglutition to improve their quality of life. This prosthetic will need to have food sensing abilities and be safe for the user to wear and clean. In addition to safety precautions, the prosthetic needs to be able to fit comfortably in the oral cavity and be secured to the user during mastication activities. Our team was able to find the average measurements of the oral cavity and tongue through ultrasound and other biomedical imaging techniques. The main goal and need for this project is to allow the user to move a bolus to the back of the throat for eating and drinking purposes. Implementation of this design must have a silicone tongue mold that accurately represents the size and shape of the human tongue. The silicone mold must be safe for the user and biocompatible. Controls of this prototype must be able to begin the actuation of the tongue once the force of the food is sensed.

Previous prototypes lacked the ability to regulate the air flow to the pneumatic tongue to create accurate displacements. These past works had innovative PneuNets for this application but were unable to minimize the pneumatic pumps and solenoids to fit within the oral cavity. The controls of previous works could not sense when any external stimuli was on the prosthetic tongue. Therefore, our work seeks to improve previous works on this medical device and validate our prototype.

3.6 Design Requirements

The prosthetic needed to be designed with the project goals, and methods of meeting those goals in mind. In order to accomplish this the design of the tongue and retainer system needed to meet its own set of requirements. The tongue would need biocompatibility allowing it to blend with the patient's flesh for the most comfortable and effective use. The tongue must also allow for maximum magnetic actuation despite the magnetic field inhibiting property of silicone. The design must also promote oral health with the patient. Based on the research conducted, oral prosthetics can damage the surrounding tissue if they are too hard and/or cause too much friction or are not cleaned properly. To combat this, the tongue bust be gentle on the oral cavity and be removable for regular hygienic maintenance. Given the choice of magnetic actuation to prevent the patient from having tubes pass out of the mouth, the electronic components should also not pass out of the mouth. For this reason, the design must be able to house these components within the oral cavity safely. A list of all these requirements can be seen below:

1. Biocompatibility: The shape and size of the prosthetic must be compatible with the oral cavity of a glossectomy patient.
2. Actuation: The tongue must allow for maximum actuation.
3. Promotion of Oral Health: The tongue and retainer system must not cause further irritation or damage to the teeth, gums, or surgical area and must be removable for regular cleaning.
4. Electric Component Housing: The design must be able to encompass all electric components inside the oral cavity.

When reviewing our design requirements, we assigned values relative to each other to determine the most important quality of the design. We ranked the row characteristic relative to the column characteristic, with a 1 denoting more important, 0.5 denoting a similar importance level, and zero denoting less important. After a row is completed, the column shows the complement of that row, where a 1 turn to a 0 and vice versa. The value 0.5 stays the same as the importance is unchanged relative to the direction it is compared. As shown in Table 1 below, miniaturization proved to be our most important characteristic, while integration and displacement tied afterwards. This means during our design process we had to consider each requirement in this order of importance.

Table 1: Design Requirements Pairwise Comparison

	Miniaturization	Integration	Displacement	Sensors	Safety	Total
Miniaturization	X	1	0.5	1	1	3.5
Integration	0	X	0.5	1	0.5	2
Displacement	0.5	0.5	X	0.5	0.5	2
Sensors	0	0	0.5	X	0.5	1
Safety	0	0.5	0.5	0.5	X	1.5

3.6.1 Size

For optimal biocompatibility, the prosthetic tongue would need to be custom made for each patient due to the varying size of the oral cavity. The team decided to base the size of our prototype off average size data collected through research and measurements taken by the team.

To combat the size constraint necessary to fit the tongue in the oral cavity, the team began by taking measurements of our own tongues. The data collected from these measurements can be found in Table 2 below. The two team members with access to their own calipers conducted this measurement on their own tongues. The calipers were sanitized and then used to measure the tongue in a resting position within the oral cavity. The palatoglossal arch, which is the thickest point of the tongue, is located between the back molars. This guide was used when measuring any data at the "arch". All measurements referencing the tip were taken 6mm from the end of the tongue. The was done by first measuring the 6mm from the tip, then rotating the calipers to take necessary measurements. The measurement of the gag reflex was taken to the nearest mm due to the difficulty in taking this measurement.

Table 2: Measured data of team members' tongues

	Length to gag reflex (mm)	Length to arch (mm)	Width at arch (mm)	Height at arch (mm)	Height at tip (mm)	Width at tip (mm)
Person 1	72	44.2	45.7	23.4	9.74	20.8
Person 2	80	62.3	46.2	25.2	7.9	31.5

An updated model of the tongue was developed using the measurement data collected and anatomical models of the tongue such as that shown in Figure 17. This model was used as a baseline for the team to better understand the space available in the oral cavity while more research was being conducted. Karibe et. al. did a study regarding the gag reflex and how far back a tube can go before hitting the gag reflex, which was used for a study regarding the length of the tongue [40]. Because subjects would stick their tongues out during data collection, the height measurements from these studies are not accurate for our purposes. When the muscles in the tongue contract to push the tongue out of the mouth, the height is diminished. For this reason, the height measurement taken by one of our team members was used rather than the averages reported in the aforementioned studies.

Figure 17: Academic diagram of the human tongue (reproduced as is from [41])

With this information compiled the final tongue design was made. The final version extended slightly down the throat to replace the tongue muscle removed during a glossectomy and to make swallowing easier. This aspect of the design would have to adapt to the particular patient depending on the amount of their original tongue remaining. The team decided to assume a total glossectomy when creating the rear of the tongue. Due to the varying sensitivity of the gag reflex, the total length of the tongue was close to 80 mm, the assumed length until the gag reflex is triggered. The final prototype is slightly larger than this to accommodate for the force sensor and to fill the space past the gag reflex left behind after the glossectomy. The final measurements of the prosthetic can be found in Table 3 below.

Table 3: Final measurements of the tongue prototype

Total Length (mm)	Length to arch (mm)	Width at arch (mm)	Height at arch (mm)	Height at tip (mm)	Width at tip (mm)
85	62	52.87	23.2	9.74	23.8

3.6.2 Integration

The tongue and controls modules were integrated through two methods. The first was by using compartments in the tongue itself. These compartments were made by inserting a 3D printed piece called a “key” into the silicone mold while it was curing. This key was of similar size and shape to the component that was meant to be put into the tongue. When the tongue was demolded, the key could be popped out and an inner compartment would be left behind. These compartments were used for the force sensor, solenoid, and magnets.

The other components were integrated using the second method. This was by placing them into the space left from the retainer. The retainer was designed to be able to hold all other electronic components and wires. These would be directly under the tongue so the wires could feasibly reach all parts of the controls.

3.6.3 Safety

The safety of the oral cavity is of utmost importance. The main overall concern is the biocompatibility of the tongue with the body of the patient. If materials are used that are harmful to the body or they are affected by the body, then that compromises the function of the tongue and the effectiveness of the tongue. Bringing harm to the body sets back the progress that is being made with the prosthetic.

In order for the oral cavity to be safe, the components of the tongue must be biocompatible. One main component of the tongue was the magnets that were used for actuation. The magnets that were best for the tongue prosthetic are N52 which are composed of neodymium. It was found from previous work that neodymium does not negatively affect the oral cavity [23,24].

3.6.4 Displacement

Once the tongue prosthesis has been analyzed for safety to the patient and integrated into the oral cavity, it must be functional while eating. Therefore, it is important to analyze how much displacement is achieved by magnetic actuation at the tip of the tongue. During feeding, the tongue works to push a food bolus back towards the throat and involves many complex movements. Mimicking the anatomical function of the tip of the tongue helps to begin the movement of the bolus. For the purpose of this project, only the measurement of the tip of the tongue was analyzed. Our goal was to have a displacement value similar to that of older women as previously mentioned in Chapter 2, which was 1 cm of vertical movement. Various placements and orientations of the magnets were tested to improve displacement values with each design iteration as shown in Table 4.

Table 4: Displacement Constraints

Section of Tongue:	**# of Magnet(s):**	**Maximum Displacement (mm):**
Tip	1	5
Tip	2	10

As shown in Table 4, the number of magnets positively correlates with an increase in actuation of the prosthesis. This relationship along with the strength of the magnetic field will be explored further in the following Chapter 4.

3.6.5 Duration

The duration of the tongue's movement is begun by the force sensor detecting an external stimulus. This is important as the duration of time the tongue is in a certain position can affect eating habits and affect how the patient uses the prosthesis. However, the total movement of the tongue upwards is indefinite due to the current placement of the magnets in relation to the magnetic solenoid. Once actuated the tongue prosthesis holds its position until disconnected from the solenoid manually by the user pushing down the tip of the tongue. Although this may be inconvenient, the prosthesis still helps to aid in swallowing and helps increase variety in the patients diet. However, the software of the control module has been developed to help mitigate this lack of disconnection by not switching on the magnetic solenoid when a force is no longer detected on the sensor.

3.7 Revised Client Statement and Objectives

The client requires a self-contained tongue prosthesis that can store the miniaturized electronics within the tongue mold and functions autonomously. Therefore, the prosthetic must incorporate sensors to detect external stimulus and integrate smaller electrical components into the final design. Additionally, the prosthetic tongue mold must be anatomically correct in size and aid in movement of the bolus towards the back of the throat.

The following are the revised objectives:

1. Design: Develop a tongue prosthetic to mimic anatomical features more accurately and actuate the tip of the tongue upwards.
2. Size: Develop a more anatomically correct tongue mold size and fit the prosthetic into the oral cavity.
3. Safety: Tongue prosthetic must protect users from electric shock, leakage current, and be biocompatible.
4. Controls: Miniaturize electrical components and implement magnetic actuation into the final prototype of the tongue for a targeted displacement of 1 cm.
5. Validation: Develop clear test protocols to validate tongue functionality and biocompatibility.

3.8 Project Methodology

This section will provide an overview of the methods used to develop, produce, and test the final design. Therefore, the two main sections of this chapter will describe the production of the prosthesis and the testing after it was completed. The production of the prototype involved the silicone mold of the prosthesis, development of the retainer, and the final control unit. Testing of the final design confirmed the detection of external stimuli on the tongue and quantified maximum displacement during demonstrations. Additionally, testing on the magnetic components revealed the strength of the fields for actuation.

3.8.1 Production

The production of the prosthetic had two main components, the silicone tongue and the retainer system. The means of producing these elements were different in order to accomplish all goals of the design.

3.8.2 Silicone Tongue Mold

The silicone tongue was made using SmoothOn Ecoflex® 00-30 silicone. This silicone was chosen by Bridges et al. in the 2019/2020 project because it is accessible and affordable unlike medical grade silicones. The SmoothOn Ecoflex® 00-30 silicone is a two-part silicone that cures in a few hours at room temperature.

The mold used to pour the silicone into was 3D printed in PLA at 15% fill density. This created a study mold that could survive the transportation necessary to complete this project without lab access due to COVID-19. The mold was also inexpensive and easy to produce. This allowed for many iterations of the design to be made and cast in silicone.

The design of the tongue featured compartments to insert the electronic components. These compartments were made using 3D printed parts called “keys”. These keys were the shape and size of components such as the solenoid used for actuation. When the tongue was demolded these “keys” could be removed, leaving behind a compartment that the component could be slid into. During the curing process these keys were taped in place on the mold to prevent them from floating or moving. This allowed for accurate placement of the components within the tongue.

3.8.3 Denture and Retainer

The tongue prosthetic is held in place with a retainer attached to dentures. Dentures were chosen as the primary means of attachment with a retainer piece covering the floor of the mouth for additional component housing and to create stability for the prosthetic. Due to the sensitive surgical tissue the retainer piece would have to be custom made for each patient to ensure comfort and prevent damage to the oral tissue. Without a patient to base the retainer on, an anatomical model was referenced.

The initial retainer was made from polymer clay based on the model and size of the tongue. This clay retainer was then encased in silicone to create a mold of the retainer piece. The retainer was then cast in UV resin to emulate the plastic used for dental retainers. The denture portion was then attached using 3D printed teeth and adhering them with additional UV resin. Jewelry wire was heated up and inserted through the 3D printed teeth. These wires would then be threaded through the silicone tongue to maintain proper position and attachment.

3.8.4 Required Testing

The testing involved to determine if the project objectives were met involved quantifying the tongue's maximum displacement, magnetic field mapping, and preliminary bolus testing. However, since this design took an entirely new approach to actuation and miniaturization, testing of various components was also needed before the final prototype. Additional testing was performed to identify the minimum thickness of the silicone tongue mold achieved before ripping occurred. Previous works by Bridges et. al proved the biocompatibility of the tongue mold under ISO 10139-2:2016 [9].

Initially, testing of various electrical components was performed to select more miniaturized items for the final prototype. This testing involved various trials on sensor sensitivity to detect external stimuli on the tongue such as food or liquid. Due to the use of magnetic actuation, testing of an electromagnetic module and magnetic solenoids was performed to determine which had the stronger magnetic pull of the magnets placed within the tongue mold. Once the final determination of components was made, silicone ripping tests were performed to determine how thin the tongue mold could be to house the various electronic components.

Displacement testing was conducted to determine the amount of actuation that is exhibited by the tongue prototype without using an external measurement device such as a ruler. Therefore, the accuracy of the measurement is increased by utilizing a sensor placed within the prosthetic tongue itself. Preliminary bolus testing was conducted by creating a food sample that accurately represents the diet of patients who have undergone glossectomy. This goal of this testing was to validate that the integrated sensors could detect a food bolus.

Lastly, the magnetic field of the magnetic components such as the magnets and solenoids were quantified through magnetic field mapping techniques. This quantification provides a basis for how to orient the components within the tongue mold and can influence future design iterations.

3.9 Conclusion

Over the course of this chapter, the steps taken to finalize our project design were discussed. As the project progressed throughout the 20-21 academic year, initial design and testing protocols were finalized. Using SmoothOn Ecoflex® 00-30 silicone our team was able to create an anatomical model tongue that had cavities to house electronics and actuators for testing. We recommend shifting to a medical grade silicone for better integration. A denture was created for integration of the tongue to the oral cavity, while this changes between each patient, the remaining oral tissue will be sensitive, and this allows for smooth integration. The new electronic system allowed for individual part validation testing and proved to make troubleshooting issues simpler. Without magnetic actuators in the tongue, the force sensor could register external stimuli generated by a bolus, we also were able to test the displacement of the tongue with just the battery pack and no force sensor system. With the accelerometer displacement testing, the actuation and electronic systems proved to be a viable solution.

From the work we have done, our existing prototype demonstrated adequate actuation and anatomical properties and dimensions to a normal tongue. Our testing led us to believe the prosthesis would perform successfully.

4. Prosthesis Design

This chapter will address and review the various design iterations developed leading to the final prototype. The decision to pursue magnetic actuation will be addressed based on a decision matrix and flow chart. Insight into the evolution of the shape of the tongue mold to become more biocompatible will be explored. Preliminary designs for a retainer to attach the tongue prosthesis will also be explored.

4.1 Feasibility Study

With changing design and actuation methods, feasibility testing needed to be done. The previous work of Araya and Bridges et al. allowed this team to forgo testing the silicone material itself; however, feasibility of its interactions with other design elements were necessary.

4.1.1 Thickness Testing

With the actuation method changing to magnetic actuation, components would need to be embedded in the tongue itself. In order to effectively and safely embed these components testing needed to be done to determine the minimum thickness needed for the silicone to withstand the friction and bending of the prosthetic. To complete this testing, we performed a test called thickness testing on the silicone.

For this test, weights were hung from the silicone strips and allowed to hang for a few seconds. The length of the strips was then measured and compared to original to assess if any deformation occurred. The strips were also rubbed against an Arduino Uno to determine if friction against the electronics will cause deformation. This allows one to test the different thicknesses of silicone for the ideal prosthetic wall.

4.1.2 Magnetic Field Testing

Initial testing methods were required to understand the effects the prosthesis would have on the oral cavity. Prior to creating a final model, we analyzed these results to help refine the model itself.

Looking at magnetic field capabilities, we performed some initial testing to identify potential issues and design ideas for the tongue prosthesis. From our literature review and previous experience with magnets, we identified that the force applied between the magnets increases with a decrease in distance between the magnets. We looked at how the magnets could interact with each other to create actuation similar to an anatomic tongue. Two initial testing methods were performed using a solenoid and magnets to identify their interactions.

The testing of magnets was conducted in two phases. Phase I is called a "paper test." In this experiment, we aimed to introduce the fundamentals of the magnets and solenoids and how they interact with each other. As shown in Figure 18 and 19, a piece of paper is taped to a magnet and tested to find the operating distance with the solenoid. We used the paper test to show how the magnet poles affect the solenoid and how the solenoid creates a visible difference in length when on vs off. This is a simple test where you place the solenoid next to the magnet and wait for the magnet to move to the solenoid, this is the closest the solenoid can be to the magnet. Then with the solenoid on the furthest operating distance can be determined when the magnet moves to it. If the distance is shortened from the off state, the current direction needs to be flipped. The piece of paper is a uniform thin material that can bend easy, and tape can be used to temporarily attach the magnet. We chose not to have silicone in this testing phase because we initially struggled to find a way to test the actuation at all with the silicone as tape does not effectively stick to it. Later we found Loctite bonding glue worked well for temporary testing, but this testing was an opportunity to introduce magnetics actuation with a solenoid and magnets. Appendix X is the full procedure and materials needed. The magnet poles and solenoid poles can conflict with each other and create a negative distance where the solenoid has to be closer to the magnet for them to interact instead of further away. When the plunger in the solenoid pulls in, the magnetic field moves through the rod with the north end on the inside of the body and the south end at the exposed end of the rod, this means north sides of the magnet will be attracted to the solenoid and south ends will be repelled. The size of the stroke length of the solenoid will also determine the range of the solenoid, as we look for the distance the magnet will move to the solenoid when it is off and then when the solenoid is on. The stroke length makes the magnetic field extended for the permamagnet, the area determined is where the solenoid should operate to create desired actuation.

This test gave definitive results and helped determine what other testing needed to be done so the tongue could function. This testing creation is a dynamic process and I encourage changes to be made as needed for better results.

We then moved on to phase II of the magnetic field testing. The purpose of this test was to understand how the silicone moves when magnetic fields actuate around it. Since silicone is a non-uniform material, it shifts easily but also has difficulty bonding to other materials. This process uses a hole in the silicone to place a magnet inside while the solenoid remains outside and aims to show how the artificial tongue will actuate and how natural the bending of the material can be. Figure 20 shows the magnet inside the tongue mold with the solenoid sitting on top, when the solenoid is switched on the magnet should actuate towards the core without making contact. This test helped define our final prototype by utilizing cavities inside the tongue. Appendix I is the necessary materials and protocol to perform this test.

Figure 18: Paper Test "OFF" State

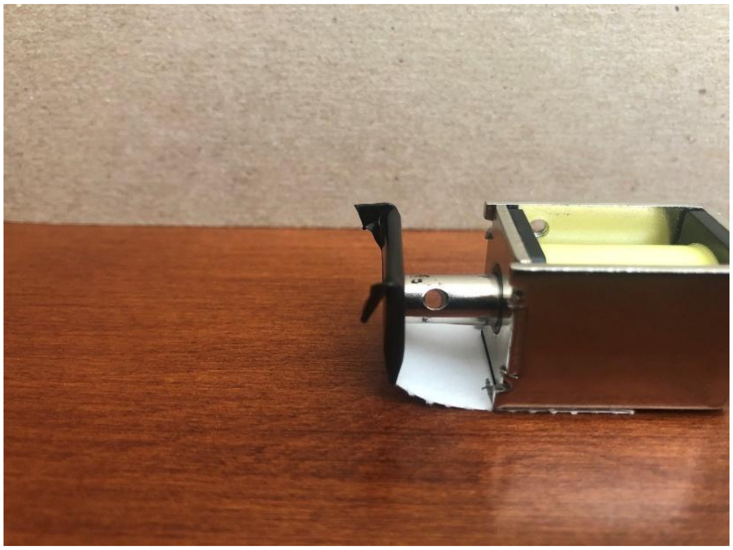


Figure 19: Paper Test “ON” State

Figure 20: Silicone Test

The following data shown in Table 5 are the results of both testing phases.

Table 5 Initial Magnetic Testing Results

		Smallest Magnet (¼” Cube)		**Medium Magnet (¾”L)**		**Large Magnet (1 1/2 “ L)**	
		No Current	**Current**	**No Current**	**Current**	**No Current**	**Current**
Paper Test	**Large Electro-Sideways**	7.25-7.5mm	8.5mm	N/A	N/A	10mm	11mm
	Large Electro-Forwards	16.75mm	20mm	14.75mm	15mm	18.5mm	20.5mm
	Small Electro-Sideways	N/A	N/A	N/A	N/A	N/A	N/A
	Small Electro-Forwards	8.25mm	9mm	9mm	6.8mm	6.8mm	8mm
Thru Silicone	**Large Electro-Forwards**	4mm x 1mm	4.5mm x 1mm	N/A	N/A	1mm x 2mm	1mm x 1mm
	Small Electro-Forwards	2mm x 3mm	2 mm x 4mm	N/A	N/A	“-” 4mm x 3mm	“-” 3mm x 3mm

The above results in Table 5 determined the operating distances for the various solenoids at different orientations with different magnets. These different orientations and magnets helped determine conceptual designs. We found the larger solenoid to have a larger operating area with the core facing forwards instead of sideways. The magnet used for the actuation also changed the operating distances, specifically for the silicone testing, the larger magnets required the solenoid to be closer due to the increased weight of the silicone. From this test, we determined that the larger solenoid with a smaller magnet would produce the best results for actuation.

4.2 Conceptual Designs

Primary designs were created over the course of the term utilizing magnetic actuation. Several silicone molds were created to perform initial testing and validate the movement capabilities. Before any molds were created, we analyzed our design options and the previous methods. Shown in Figure 21 below, the design originated from a three-pump actuation system to a one pump pneumatic system, all using Silicone. Our conceptual designs would involve the silicone while having anatomical dimensions and shape. The potential actuation methods varied between a breast pump and magnetic actuation, through our decision matrix, Table 6 in Chapter 4.3, we pursued designs with magnetic actuation capabilities.

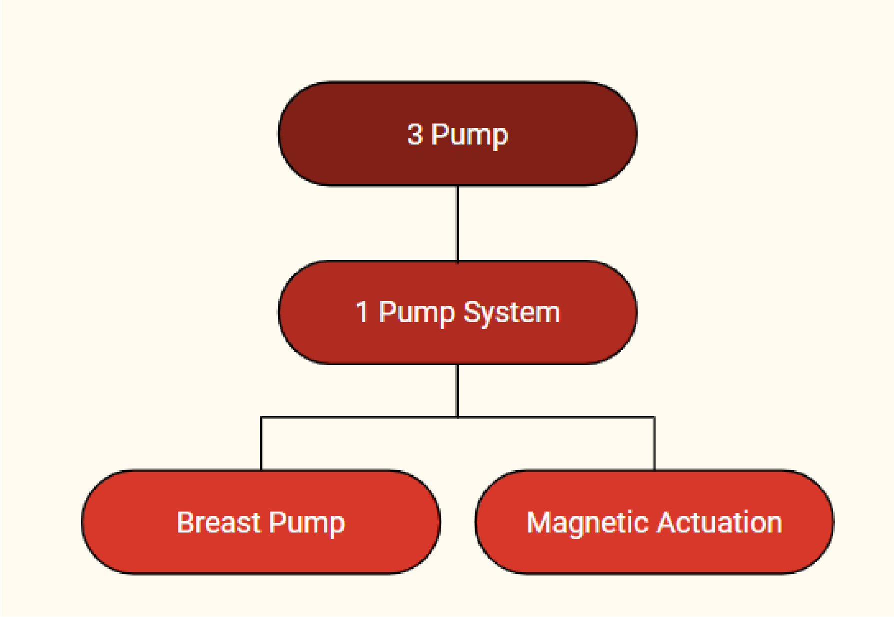


Figure 21: Development of Actuation Methods

With the actuation method in mind, we created a sequential process to create molds and designs of our system. With a new actuation system, we deviated from the Bridges et. al [9] to fit the needs for creating anatomic movement. Below in Figure 22, we followed this step process to create a final model. Each design iteration will be discussed in this chapter and alterations between each design will be discussed. While looking at types of magnets to use, the grading system of each can determine the strength of the magnetic fields produced. Magnets are graded by the magnetic material from which they are manufactured. The grades can range from

N35 to N52, where the number relates directly to the pull force of the magnet. We chose to use N52 for their increased strength in a small volume. When looking at types of solenoids to use, we could utilize a push or pull type. With aligned magnetic field lines and attracting poles, a pull type solenoid was best fit for this project. A pull solenoid utilizes a plunger where the magnetic fields go inwards through the core.

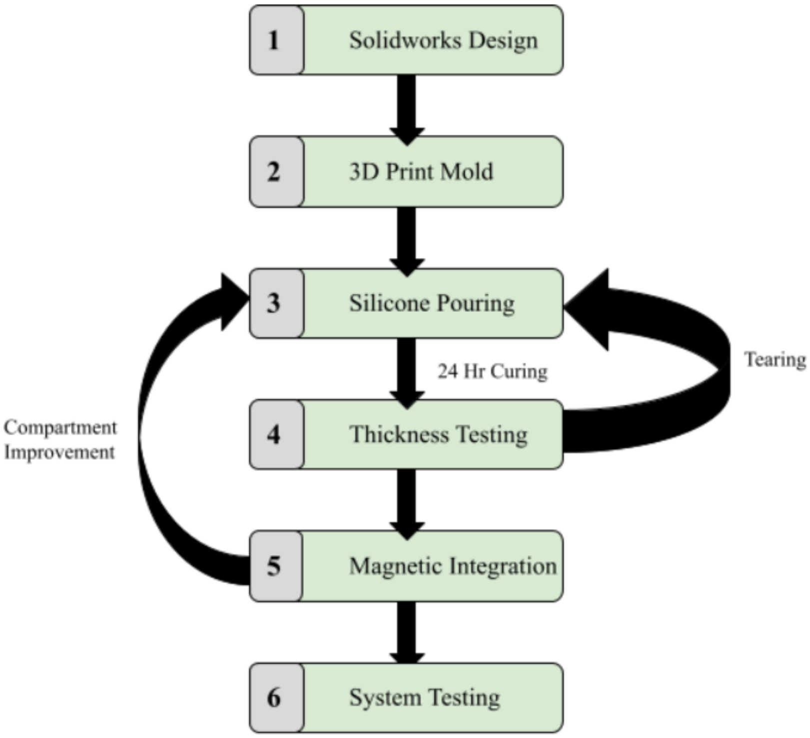


Figure 22: Process Taken to Develop Final Model

The initial design focused on creating an anatomic model, shifting from the flat prosthesis from last year's design. The choice behind this decision is because no air will be expanding this tongue, allowing a 3D printed mold to be created to cast the silicone. The casting outline was created in SolidWorks, shown in Figure 23, then printed out using PLA and 15% infill density. This primary model served the purpose of providing a general shape of what we desire for the prosthesis rather than accuracy, the dimensions did not reflect our research of tongue measurements and instead was based on a team member's tongue size. This design also had no intention of a retainer integration, with a complete flat back where food would drop; this also meant the tongue would house all components which was infeasible as the size constraint was very limited.

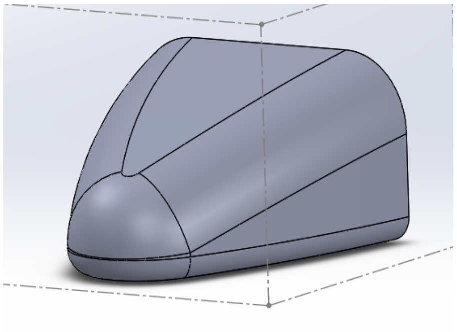


Figure 23: Version 1 of Anatomical Tongue

Based on the design shown in Figure 23 above, modifications were made to make it mimic the anatomy of a tongue and have better integration with the mouth. Shown in Figure 24 below, a back was added, and the dimensions were changed. Several thicknesses were created for this mold to determine the forces that can be applied to various tongues during our thickness testing discussed in Chapter 4.1.1 and Appendix I. A. More room was created with increased dimensions and papillae to guide the bolus and make our tongue function better. No interior pockets were created yet, simply a hollowed version of this tongue was created for integration with the magnetics. The magnetic solenoid and permamagnets need to be precise distances away, when each test was conducted, they would shift in the open cavity, providing inaccurate data. We then looked at solid molds to then cut spaces out, but this proved to be difficult with the distance between the magnet and solenoid being a guess. The solid tongue was also hard to flex, allowing very limited movement by the solenoid.

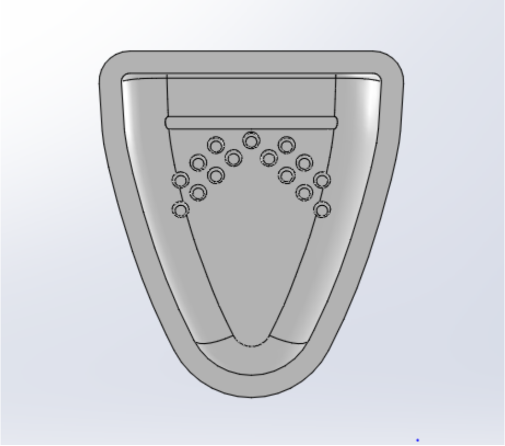


Figure 24: Version 2 of Anatomical Tongue

The third and final silicone mold design shown below depict the final dimensions of our tongue prosthesis. This design moves the sloped back to a more shallow angle for easier swallowing and retainer integration. The papillae have an increased height of 2mm and were changed to allow easier formation during the casting process. Our model was still completely solid, to circumnavigate this issue we developed compartment 3D printed molds to be placed inside the silicone as it was casted. It would then have hollowed out spaces that were used to place the solenoid and magnets consistently in the same spot during our testing. All testing described in Chapter 6: Final Design Verification was conducted on the model shown in Figure 25.

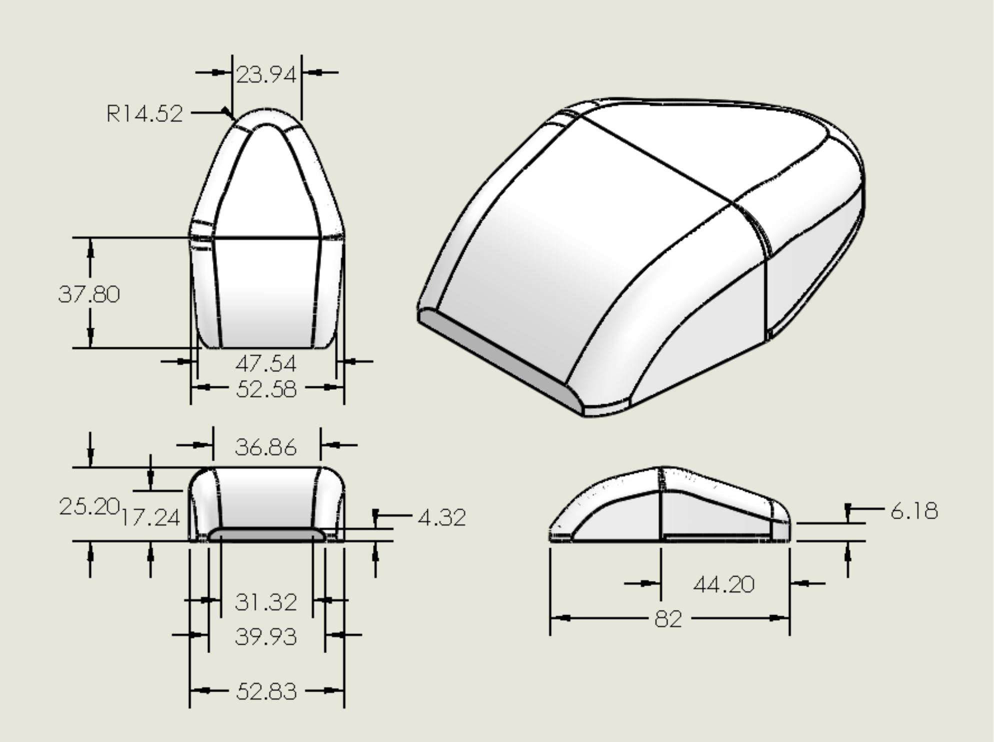


Figure 25: Final Tongue Prosthesis (Dimensions in mm)

Through magnetic field calculations using equations 1- 4 discussed in Section 2.6 of the literature review, the distance between the magnet and solenoid where the solenoid would interact with the magnet when in the “ON” state and not interact in the “OFF” state was determined to be approximately 6 mm. To keep this distance consistent without relying on external measuring sources and the effectiveness of adhesive materials, compartments were created to manage this separation. The dimension of each mold is shown in Figures 26 and 27, these compartment models were held in place with tape to prevent floating during curing and had extended braces that would prevent them from sinking too deep into the silicone. When the silicone has fully cured, the components are then removed and compartments for placing electronics and actuators are available. The connectors between the horizontal brace and body of the compartment mold creates a 2 mm thick flap of silicone which allows the tongue to close but still have easy access to internal components.

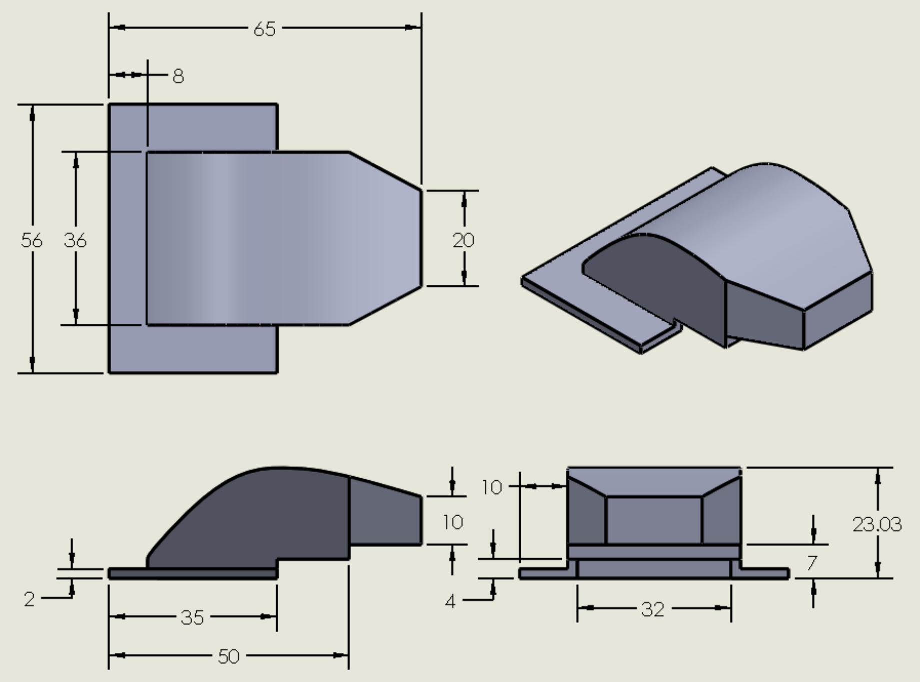


Figure 26: Magnetic Solenoid Compartment (Dimensions in mm)

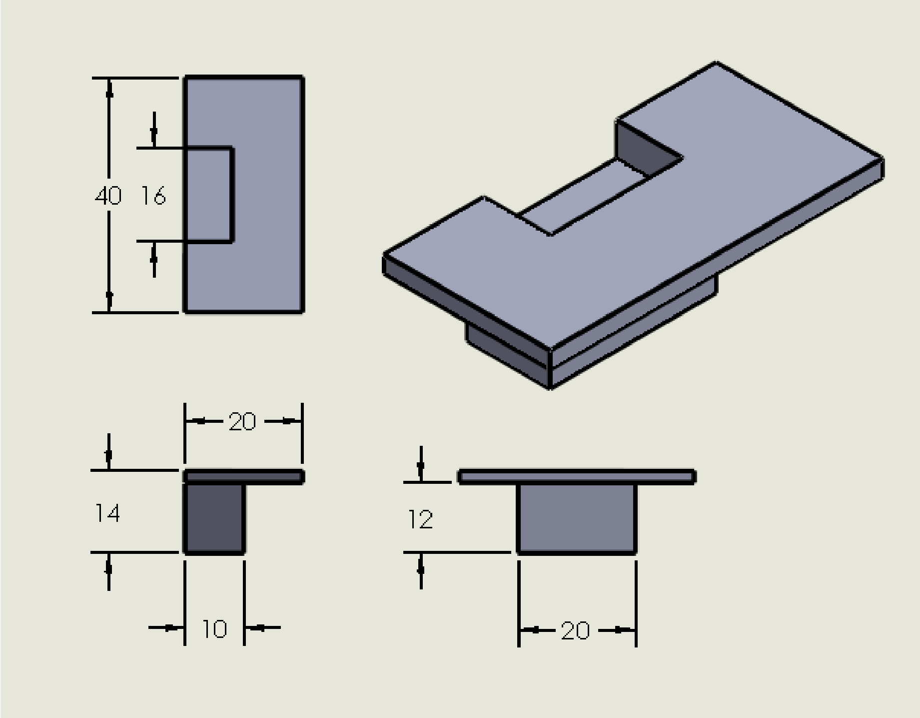


Figure 27: Magnet Compartment (Dimensions in mm)

4.3 Final Design Selection - Actuation Methods

With the potential to pursue two types of actuation methods, we employed a decision matrix to determine the best route to pursue. We analyzed the characteristics of each method and employed a weight to each characteristic. Shown in Table 6, the two highest weight characteristics are miniaturization and electronics safety. The desired system needed to be as small as possible, preferably fitting entirely in the oral cavity. We also had to make sure there is no potential for shocking the patient as electronics in the mouth with high currents could pose a large risk for injury.

Biocompatibility of the artificial tongue system is important for the health and safety of the patient. We looked at safety for the patient when considering the biocompatibility of each system. When utilizing a control system in a project that will continue in the future, it is important to make the controls simple to understand or assemble, this also tied into potential improvements where we looked at what work could be done to further improve the final prototype we would create. Finally, the feasibility and actuation capabilities were our least important characteristics as the feasibility of each system are high and can be easily pursued. While the actuation capabilities were relatively unknown to us at the start of the project, we based this characteristic from our literature review and this uncertainty made us weigh this less.

Table 6: Decision Matrix for Actuation Methods

	Weight	Breast Pump Rank	Magnetic Actuation Rank	Breast Pump	Magnetic Actuation
Miniaturization	5	3	5	15	25
Control System	3	3	4	9	12
Potential Improvements	3	2	4	6	12
Feasibility	2	5	4	10	8
Actuation capabilities	1	4	3	4	3
Biocompatibility	4	4	4	16	16
Electronics Safety	5	3	2	15	10
Score				**75**	**86**

As shown above, magnetic actuation proved to be the most effective method for us to pursue this project. Magnetic actuation shows to be the best method with a score of 86 compared to the breast pump with a score of 75. The biggest differences to note between these two systems is the miniaturization and electronics safety. The capabilities of miniaturization in magnetic actuation are far better than a pump system which has tubes coming out of the mouth in almost every design concept. Electronic safety is important when a high amperage is running through the system in the oral cavity, with the magnetic solenoid housing everything in the mouth the currents are a large concern, but we can take precautions with having no exposed wiring. Overall, we found the magnetic actuation capabilities and potential to be better for a final product and pursued this method.

4.4 Integration

A 3D printed mold was modeled on SOLIDWORKS, a CAD software made by Dassault Systèmes, to mimic the shape of the human tongue. The general shape was modeled after images from other prosthetics, medical scans, and anatomical drawings. This shape included the thicker arch of the body of the tongue along the rear molars and the thinning of the body of the tongue near the apex. The shape was further refined through the use of measurements of the tongue from various studies [40] [42] [43]. The final height we used was from measurements the group took of our own tongues because we found that when the tongue's height was measured in these studies, the subject would stick out their tongue. This flattens the tongue which in turn reduces the maximum height. For this reason, we used our own data for this measurement and data from studies for all other possible measurements. The final measurements of the tongue at its thickest point were 85mm long, 52mm wide, and 23mm tall (Figure 28) [40] [42] [43].

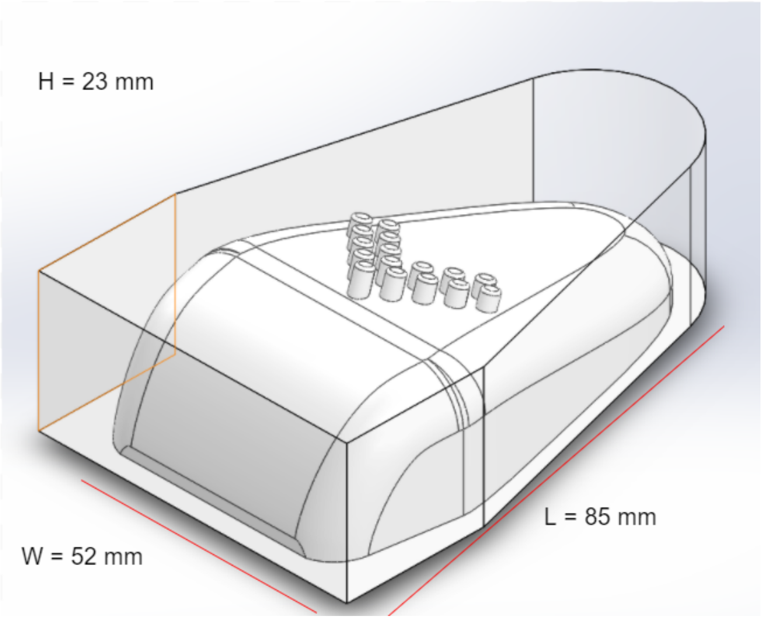


Figure 28: Final Tongue Mold with Dimensions

For increased biocompatibility, the tongue mold extends into the throat area of the patient and has the papillae in a V shape pointing down the arch of the tongue. This allowed for easier swallowing for a potential patient. The V-Shaped vallate papillae, which can be seen in Figure 29, help guide the bolus down the center of the throat [41]. The extended root of the tongue allows for a smooth integration between the prosthetic and the flesh of the patient. This would need to be adjusted for the individual patients based on the amount of the root of the tongue remaining after glossectomy.

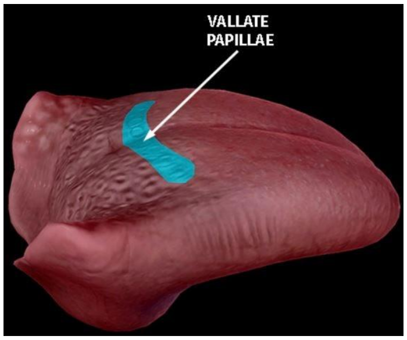


Figure 29: Anatomical Image of the Tongue (reproduced as is from [41])

The N52 magnet and solenoid were embedded in the silicone tongue by creating compartments in the silicone. This was accomplished by 3D printed "keys" with a similar shape to the magnets and solenoid with a stem that comes out of the silicone and rests on the sides of the mold in Figure 30. These "keys" were held in place with tape to prevent floating during curing. When the silicone had been fully demolded, these components could be easily inserted into the tongue for actuation.

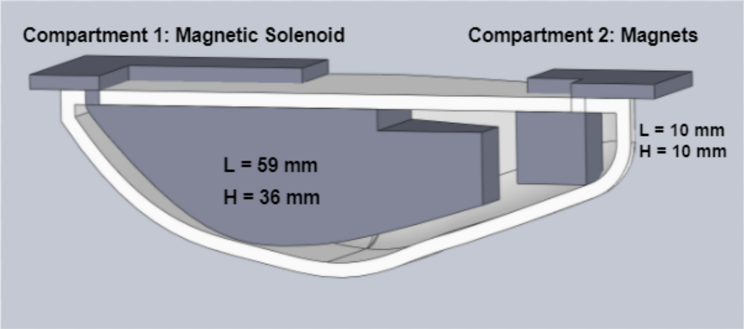


Figure 30: SolidWorks Drawing of Component Compartments

The tongue was created by 3D printing a mold of the tongue and pouring SmoothOn Ecoflex® 00-30 silicone into this mold. This material was chosen because it was able to mimic flexibility of human flesh while being easily accessible. Additionally, biocompatibility was promoted through implementation of papillae on the tongue's surface as shown in Figure 31.

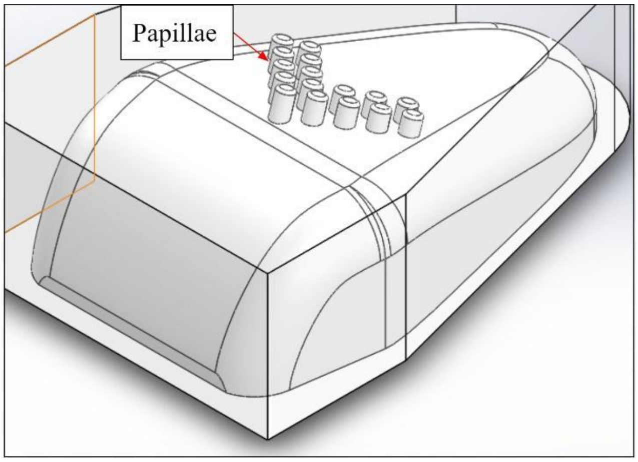


Figure 31: Interior of the 3D Printed Mold Showing the Tongue Surface with Papillae

4.4.1 Retainer

A retainer was developed to house additional electric components such as wires as shown in Figure 32. The use of a retainer and denture system would be necessary for patient use to hold the prosthetic in place and protect sensitive tissue at surgical sites. In an interview with Dr. Lilia Fiat DMD, we learned the importance of attaching the tongue via a denture rather than traditional retainers. Retainers damage teeth and surrounding tissue if the patient is chewing, while dentures are designed for use while chewing. A retainer plate across the floor of the mouth would still be necessary for additional electronic housing, and support for the prosthetic. The retainer would be attached at its sides to a set of dentures for the rear teeth. This would protect the patient's oral cavity and provide the stability necessary.

For the prototype, this retainer was made based on the design of a Hawley retainer, which covers the palette [44], using anatomical models as a guide. This prototype was made larger with a back lip that would not be present in a retainer used by patients. This was done to ensure all wires and electrical components were held properly. The retainer was made from polymer clay using tongue measurements and an anatomical model of the floor of the mouth as reference.

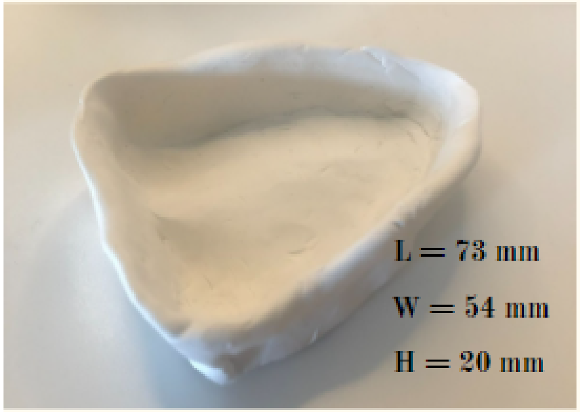


Figure 32: Polymer Clay Retainer for Prototype

The clay retainer was then cast in silicone and allowed to cure. This created a silicone mold that could be used to make the retainer from UV resin which can be seen in Figure 33. The resin retainer would more accurately simulate the plastic used in orthodontic retainers. The UV resin was then used to adhere epoxy teeth to the retainer to indicate the denture attachment. These teeth would have wire passing through them to the tongue prosthetic for attachment. However, due to time constraints with testing, we were unable to perform the attachment to the tongue.

Figure 33: Final Resin Retainer Prototype

5. Design Process for the Control Module

This chapter will address the design process for the control module and the electrical component functionalities in order to power the magnetic solenoids and allow for magnetic actuation. As mentioned in Chapter 2, previous designs utilized pneumatics with 5V pumps and solenoids. The previous control module was approximately 8 inches by 6 inches, which is too large to successfully fit within the oral cavity. Therefore, a major redesign was performed to miniaturize and decrease the electrical components needed in order to fit within the silicone tongue mold and into the oral cavity. The design process and iterations will be discussed from initial designs to the final components used in the functional prototype.

5.1 Needs Analysis and Design Requirements

Development of the control module first involved identifying the needs associated with the system in order to best create further requirements.

The needs of the control module are as follows:

1. Miniaturization
2. Accessibility of Components
3. Autonomous Functioning

Miniaturization was identified as a need of this project in order to create a self-contained system which could be used in vivo for a patient. The accessibility of the components selected is important to ensure future works can continue on the project beyond the scope of this MQP. It was important to select components which were easily accessible through electrical components providers such as DigiKey or Amazon. Components needed to be cost efficient to ensure easy purchase for future teams and researchers. Lastly, the control module must be able to function autonomously. This means that it would not need to be human controlled through a button press or switch. Instead, the control module needs to be able to detect food or liquid within the oral cavity and trigger actuation. The control module must integrate a method to quantify tongue displacement during feeding. From the specified needs, the requirements of the system were developed which influenced the project activities to meet the goals set for the controls module.

5.1.1 Miniaturization

The need for miniaturization influenced the requirement of the electrical components being able to fit into the tongue prosthetic and if needed connected to the retainer. The average size of the tongue is 79-85 mm in length, 50-64 mm in width, and 17 mm in height at the middle of the tongue [40] [42] [43]. This influenced the components chosen to fit within this space. This project chose to forgo pneumatic actuation previously explored by Araya [36] and Bridges et. al [9] to drastically reduce the components needed to actuate the tongue. Additionally, by eliminating the air pumps and solenoids, all the external circuitry and pneumatic tubing was no longer needed. The traditional Arduino Uno used for previous project iterations measures 68.6 mm in length and 53.4 mm in width [25]. Therefore, the size of this microcontroller is outside of the scope of an average sized oral cavity and could not fit within the tongue prosthesis developed by our team. After extensive research into miniaturized microcontrollers available on the market currently, the TinyDuino was chosen as the microcontroller due to the benefits in size and usability for future works. Advantages of the TinyDuino involved the smaller size of 20 mm X 20 mm and the ability to stack the TinyDuino shields on top of one another [27]. Thereby utilizing vertical space within the tongue mold or easy enclosure into a small box attached to the retainer. Additionally, the TinyDuino has the same Atmega328P microcontroller and utilizes the Arduino IDE software which has many resources online and is easily accessible for future researchers who investigate this project. TinyCircuits, the provider of TinyDuino, specializes in selling miniaturized components such as micro breadboards which are 5 mm X 5 mm and Wireling Sensors which are 10 mm X 10 mm. The TinyDuino allows for a 3V coin cell battery to power the microcontroller which would eliminate the need for a USB connection as the power supply. These components met the requirements for miniaturization and were thus integrated into the final prototype. The MOSFET module utilized the switch on the magnetic solenoid aided in miniaturization with measurements of 33.5 mm x 25.5 mm. By utilizing this module, a larger MOSFET breadboard circuit was eliminated and allowed for the magnetic solenoid to be powered by its own 12V source.

5.1.2 Accessibility

Accessibility is an important requirement to ensure components are cost effective, easily obtained, and are easily understood by the programmer. The Arduino platform is widely known and resources are available to understand basic programming and set up. TinyCircuits provides step-by-step instructions specifically for the TinyDuino and Wirelings on the website. Therefore, the system is user friendly and easily learned.

An integral part of accessibility is cost of the components which is important when abiding by a project budget. The TinyDuino starter kit includes all the shields needed to begin a project and starts at $50. The micro breadboards are $5 each and the MOSFET modules retail for $7 for a set of 6. Additional components such as the jumper wires, soldering iron, and resistors can be purchased in kits for a total of approximately $20. Therefore, the control module is cost effective for prototyping and could be even more accessible with mass production in the future.

5.1.3 Autonomous Function

The control module must meet the requirement of functioning autonomously. For this project, this is measured by the system's ability to detect external stimuli, activate the magnetic solenoid, and to quantify the motion of the tongue prosthesis. In order to achieve these requirements, a force sensor measuring 100mm or 3.9 inches is able to have a detection area from the tip of the tongue to the back of the tongue. This allows for detection of the bolus as it moves towards the back of the throat and to signal the MOSFET module to switch on when a force such as food is detected on the tongue. When the MOSFET switches on it will allow the magnetic solenoid to be powered by a 12V source and actuate the tongue upwards. Once external stimuli is not present and the force sensor does not detect any stimulus the MOSFET is switched off and the magnetic solenoid is not on until the next force reading is detected.

Quantifying motion is an important requirement as it evaluates how well the project objectives of actuation were met and allows for comparisons to published research. To meet this requirement, an Accelerometer Wireling was integrated into the front compartment of the tongue mold to measure displacement in the Y-Axis direction during prototyping [45].

5.1.4 Measuring Tongue Motion

In order to understand the true motion or displacement of the magnetically actuated tongue prosthetic, our team utilized an onboard accelerometer sensor located at the tip of the tongue. By capturing the motion measurements, these can be used to further conduct the bolus testing as the food moves towards the back of the throat.

The displacement of the tongue was measured using an accelerometer sensor placed at the tip of the tongue as shown in Figure 34 where the magnetic actuation is occurring. By utilizing a sensor, this eliminates less accurate forms of measurement such as rulers or video motion capture. The TinyDuino platform supports more miniaturized sensors referred to as Wirelings. A 5-pin connector was attached to the TinyDuino Wireling Board with an accelerometer shield and placed through the mold opening to fit inside the key at the top of the tongue. An accelerometer is used to measure acceleration or motion in the x and y directions. The axis of interest for the magnetic actuation would be the x and y direction as the sensor is moved upwards and back with actuation.

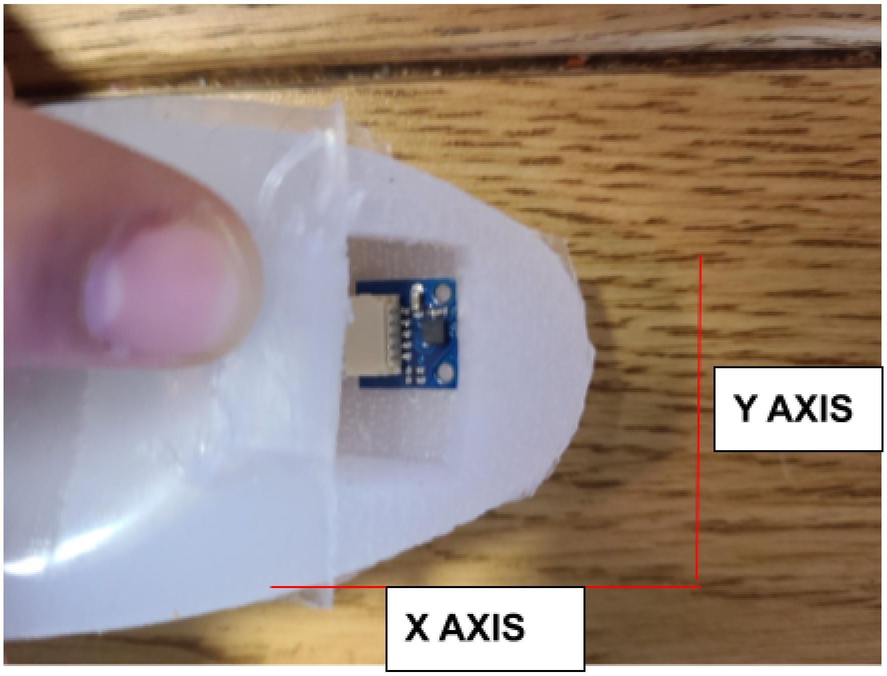


Figure 34: TinyDuino Accelerometer Wireling placed at the tip of the tongue mold

The TinyDuino has sample code for all Wireling Sensors which allows for the use of the Serial Plotter and Monitor in the Arduino IDE software [45]. Sample code for the accelerometer and the BMA250 library for the sensor was imported into the Arduino IDE software. This accelerometer is able to measure temperature, which can be helpful for ensuring the devices within the mold are not becoming too high in temperature which can harm the patient.

As recommended by Bridges et al., flex sensors were explored as a method to measure displacement of the tongue. However, these sensors posed many challenges since the sensor would detect bending as it rests within the tongue mold due to the silicone mold curvature. Additionally, flex sensors did not have a sensitive enough detection range for external stimuli. Trials were conducted to test sensitivity by placing a flex sensor inside a silicone tongue and placing a 5-gram bolus on top of the tongue. However, it was discovered that the silicone beared some of the weight of the bolus and therefore the sensor did not bend in response to external stimuli. All of these reasons influenced the team to explore more compact options that could be placed at various points in the tongue as the project progresses.

5.1.5 Measuring the Magnetic Field of Solenoids

In order to preliminarily quantify the magnetic fields of the magnetic solenoids and compare components for the final prototype, an analog hall effect Wireling sensor was used in conjunction with the TinyDuino. As shown in Figure 35, the Wireling is connected to a 5-pin connection wire which can be placed a distance away from the TinyDuino. This allowed for the Analog Hall Wireling to be placed near the magnetic solenoid as it was powered on by a 12V source.

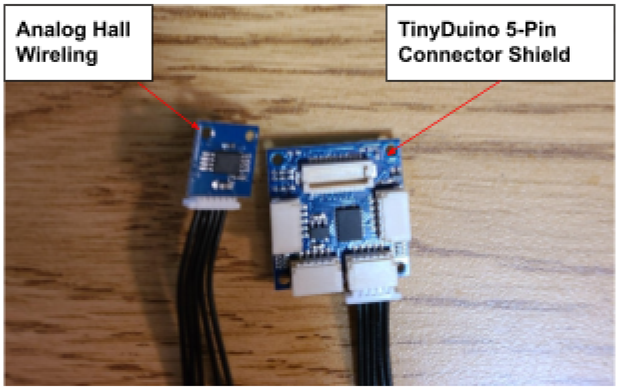


Figure 35: Analog Hall Wireling Connected to TinyDuino Shield

5.2 Conceptual Designs and Early Prototypes

Over the course of the academic year, multiple prototypes and conceptual designs were considered when constructing the tongue prosthesis. This section will discuss the sensors and electrical components used for testing our prototypes.

5.2.1 External Stimuli Sensor Selection

Although this MQP is a continuation of previous thesis and undergraduate works, a very different approach was taken towards the controls system. Therefore, many early prototyped designs involved a focus on sensor selection to detect food and to measure bolus movement. Initially, a flex sensor was tested to see if various items could trigger an analog code reading and decrease resistance. However, it was noticed that the silicone mold would reduce the impact of the mass on the flex sensor and not give an accurate reading. When placing external stimuli on the flex sensor, no analog reading was shown on the Serial Monitor within the Arduino IDE software. The flex sensor can only bend in one direction, which means in order to capture movement in both directions, two flex sensors would have to be placed together in the same position in the mold. This early prototype involved the flex sensor detecting bending in the downward direction as shown in Figure 36. Due to the lack of sensitivity to external stimuli placed on the tongue, a flex sensor was not utilized in the final prototype.

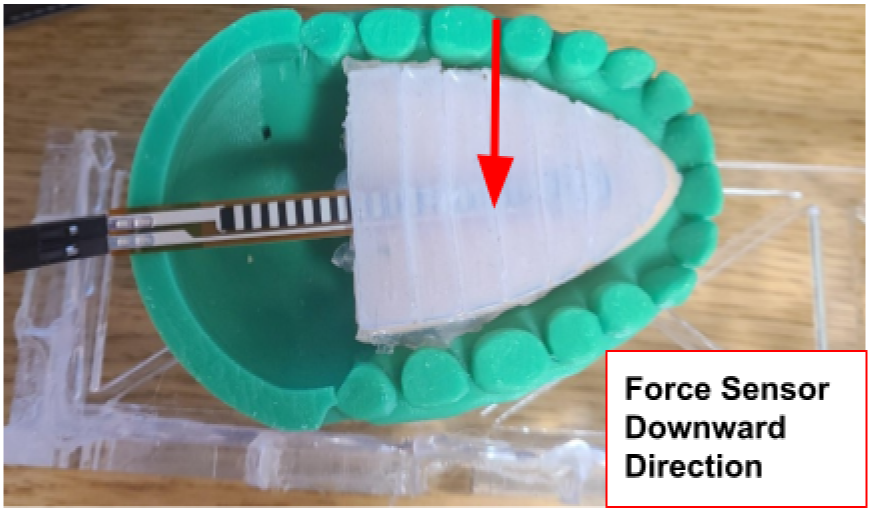


Figure 36: Early Prototype involving Flex Sensor for Food Detection

Another promising sensor explored was a force sensor, which generates an analog reading when force or a pressing down motion is placed on the sensing area as shown in Figures 37 and 38. Initial prototypes involved a force sensor with a circular shape which could capture force at almost any point on the tongue as shown in Figure 37 below. This force sensor had a detection range of 0-30 kg and was 60 mm X 5.8 mm.

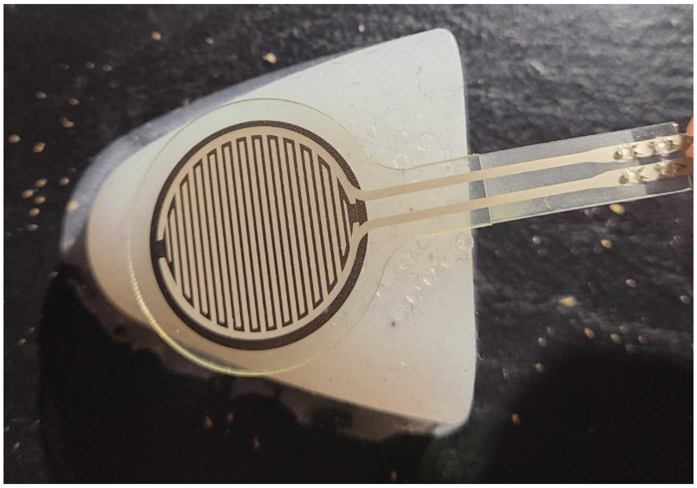


Figure 37: Early Prototype involving Circular Force Sensor for Food Detection

As the size of the tongue evolved, so did the size and shape of the force sensor for the final prototype. For the final prototype, a long force sensor was integrated into the tongue prosthesis as shown in Figure 38. This sensor had a more minute detection range of 0-500g and is 100 mm X 10 mm with a thickness of 0.25 mm. Advantages of the long force sensor was an increased area of detection which could be used as the bolus moves towards the back of the throat. This sensor was more ideal than a flex sensor since human eating patterns typically involve utensils which would apply a downward force on the sensor as food is being put into the mouth. As stated in section 2.1, it was found that instinctually the bottom hard palate moves towards the top palate which creates a force for the sensor to read.

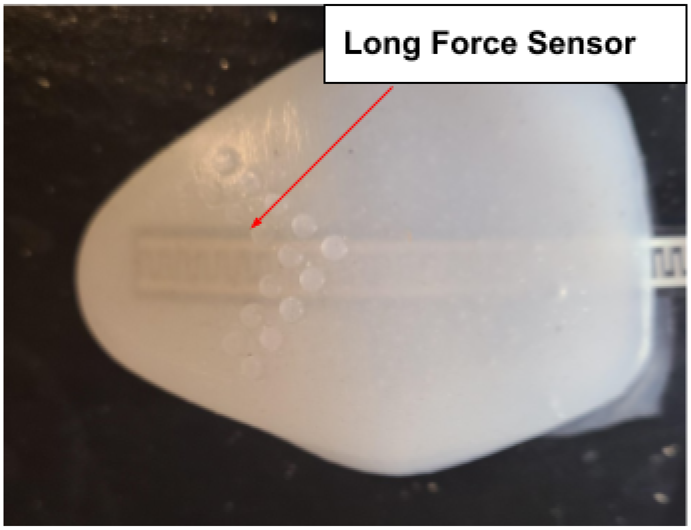


Figure 38: Long Force Sensor Placed within the Tongue Prosthesis

5.2.2 Electrical Component Selection For Miniaturization

Several ideas were prototyped that involved larger breadboards and MOSFETs to control the magnetic solenoids. An early prototype featured a small forces sensor and a large Keyesstudio KS0320 Electromagnet Module which would be placed in the back of the tongue mold to control the magnets and move them for actuation (Figure 39 and 40). This prototype had many flaws since the module is 40 mm X 20 mm X 19 mm which is larger for the tongue prosthesis, and only had a field strength of 25N. This force was not enough to attract multiple magnets together and would not be suitable for obtaining actuation greater than a few millimeters. This module required a 3.3-5V source for the Vcc pin and was controlled by a digital pin on the Arduino to provide the signal to turn on the magnet.

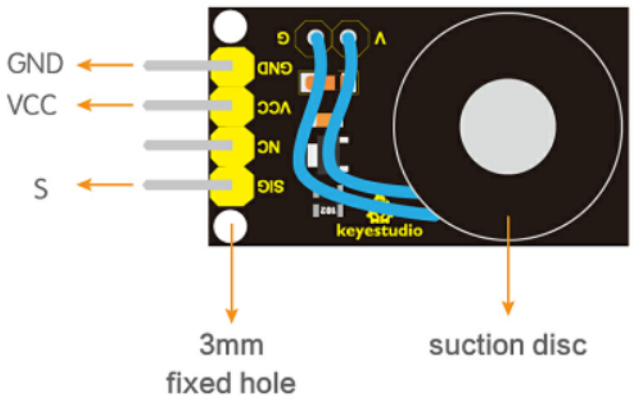


Figure 39: Keyestudio KS0320 Electromagnet Module Pin Out Diagram

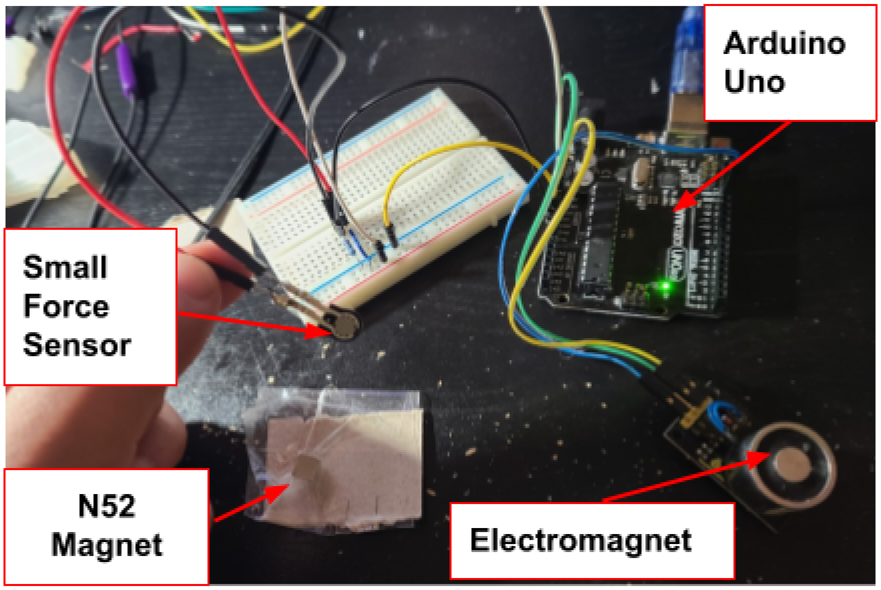


Figure 40: Initial Prototype with Keyestudio KS0320 Electromagnet Module

5.2.3 Electrical Components

This section will address the electrical components used in the final control module and the respective component functionality. Table 7 lists all the components utilized, and Figure 46 shows a schematic of the final design. All specifications for final components can be found in Appendix III. The final code for the control module can be found in Appendix II.

Table 7: Components List for Final Control Module

Component	QTY	Description
TinyDuino Processor Board	1	Arduino Uno Microcontroller
TinyDuino USB Board	1	USB Connection Board
TinyDuino Protoboard	1	External circuitry connections
TinyDuino Wireling Board	1	Connects to TinyDuino Wirelings
5-Pin Connector Cable	1	Connects Wireling to TinyDuino
MicroUSB Cable	1	Connects TinyDuino to Power Source
12 Volt Batteries	2	Powers Magnetic Solenoid
Battery Holder	1	Holds 12V Batteries
Magnetic Solenoid	1	Generates Magnetic Field
N52 Rectangular Magnets	2	Magnets for Actuation
MOSFET Module	1	Switching on Magnetic Solenoid
Force Sensor	1	Food detection on tongue
Accelerometer Wireling	1	Measure Tongue Displacement
Micro Breadboard	1	Circuitry for Force Sensor
Resistor	1	10kΩ pull down resistor

The TinyDuino boards were all able to be stacked on top of one another to minimize the space used in the tongue mold as shown in Figure 41.

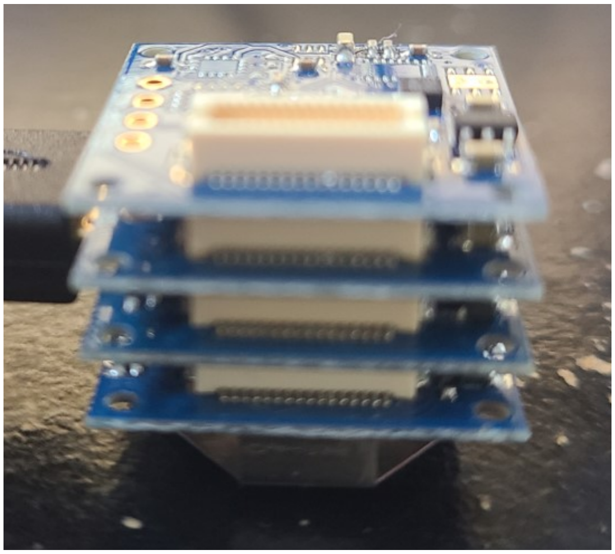


Figure 41: TinyDuino Shields Stacked together

A Keyes MOSFET module was used to allow the magnetic solenoid to be powered by its own 12V batteries and to act as a switch which was turned on as food was detected on the tongue by the force sensor as shown in Figure 42.

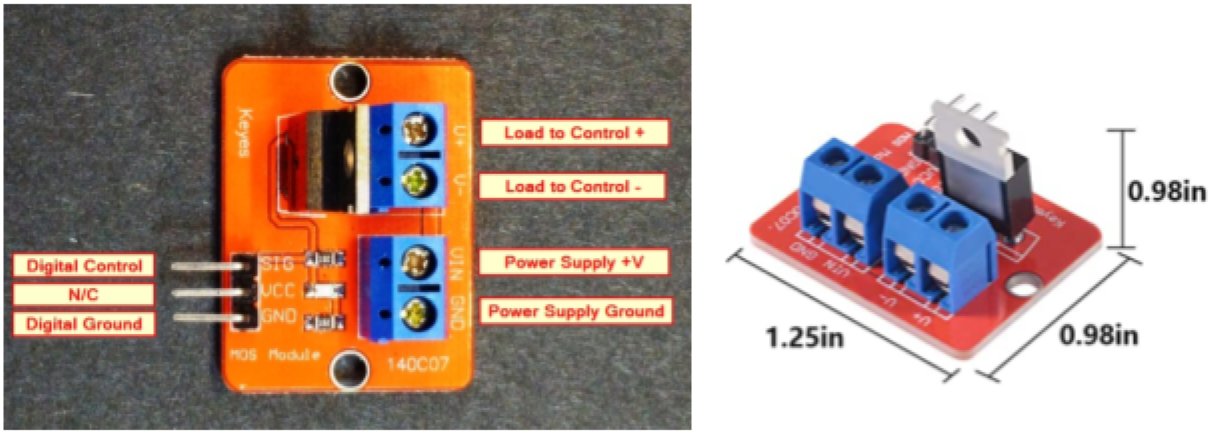


Figure 42: MOSFET Module Function and Dimensions

A micro breadboard was used to hold the external circuitry and pull-down resistor needed for the force sensor while conserving space within the tongue mold. This breadboard has a different interconnectivity than the traditional 5.5 cm X 17 cm breadboard as shown in Figure 43. The force sensor dimensions are shown in Figure 44. This extra circuitry was needed for the force sensor to send an analog reading to the TinyDuino board as shown in Figure 45.

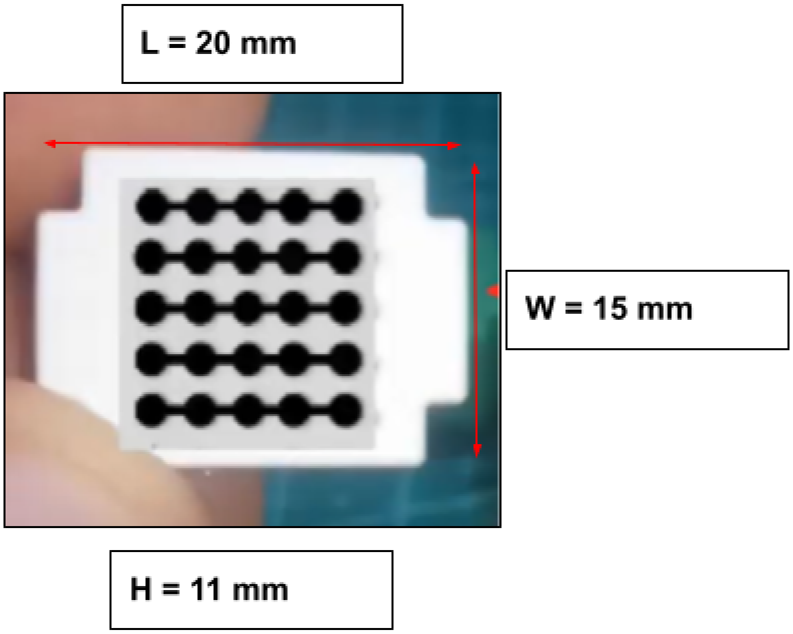


Figure 43: Dimensions of 25 pin Micro Breadboard

Figure 44: Dimensions of Long Force Sensor

5.2.4 Program Design

The program design of the control module is based on whether the force sensor detects external stimuli or not. When stimuli are not detected this indicates the lack of a food bolus within the oral cavity which means the microcontroller will not switch the MOSFET on and power the magnetic solenoid. Therefore, the TinyDuino microcontroller will continue to monitor the force sensor until an analog reading is detected. Once the sensor detects a force, the MOSFET module is switched on and allows the magnetic solenoid to be powered on by a 12V battery to generate a strong magnetic field to attract the magnets within the tongue mold.

In order to measure displacement of the tip of the tongue, an accelerometer wireling is connected to the TinyDuino 5-pin connections shield. The TinyDuino has sample code for all Wireling Sensors which allows for the use of the Serial Plotter and Monitor in the Arduino IDE software. Sample code for the accelerometer and the BMA250 library for the sensor was imported into the Arduino IDE software.

5.3 Final Design

Several ideas were prototyped that involved larger breadboards and MOSFETs to control the magnetic solenoids. An early prototype featured a small force sensor and a large Keyesstudio KS0320 Electromagnet Module, which would be placed in the back of the tongue mold to control the magnets and move them for actuation. This prototype had many flaws since the module was very large and lacked a strong enough magnetic field when powered on to attract the magnets at the tip of the tongue. This module required a 5V source for the Vcc pin and was controlled by a digital pin on the Arduino to provide the signal to turn on the magnet.

The electrical components in the final system were the force sensor, TinyDuino shields, accelerometer sensor, MOSFET module, magnetic solenoids, and 12V batteries (Figure 46). The force sensor was placed 2mm under the tongue mold and was connected to a micro breadboard with a 10 KOhm pull down resistor with connections to ground and the analog pin 0 on the TinyDuino protoboard.

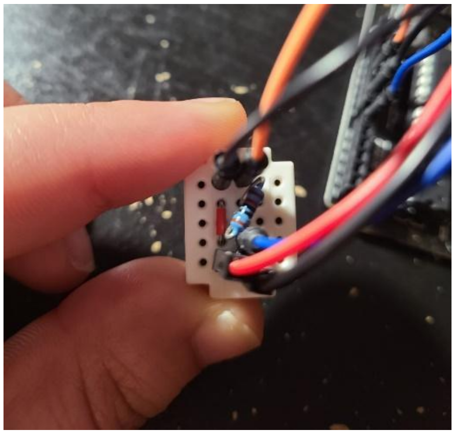


Figure 45: Micro Breadboard with Force Sensor Circuit

The TinyDuino stack consisted of the microcontroller board, USB board, Wireling 5-pin connection board, and prototype wiring board. The USB connector board allowed for the TinyDuino to be connected to a computer to provide power and for programming. The Wireling board connected to the accelerometer Wireling sensor which was placed at the tip of the tongue mold to measure displacement in the x, y, and z axis. The Arduino IDE software was utilized to program the microcontroller and to receive measurements from the Serial Monitor and Serial Plotter. The MOSFET module was used to connect two 12V batteries and the magnetic solenoid to the TinyDuino prototyping board. This module when switched on, supplied 12V to the magnetic solenoid so the device would be working with the voltage specified on the data sheet. The TinyDuino was programmed to monitor the force sensor for an analog reading. If an analog reading was detected, then the digital pin would send a signal to power on the MOSFET module and power the magnetic solenoid to attract the magnets towards the solenoid. The final magnets used were 3/4 in. length x 3/8 in. width x 1/16 in. height with two connected to produce larger actuation. As shown in Figure 47, a practical view of the electrical components and wiring is shown in relation to the tongue prosthetic inside a 3D printed oral cavity.

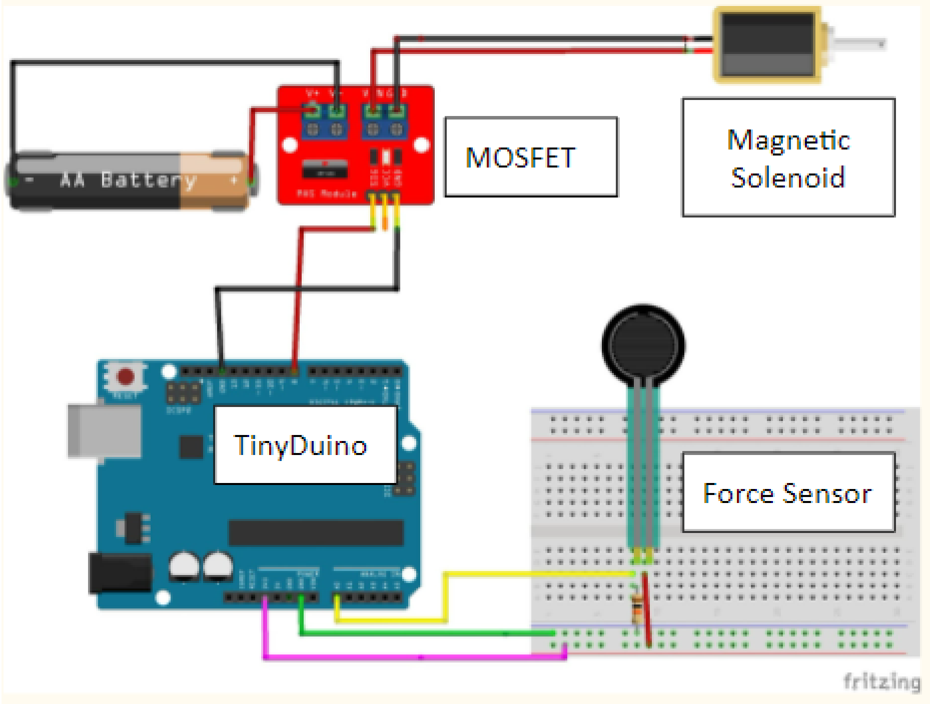


Figure 46: Schematic of Miniaturized Control Module

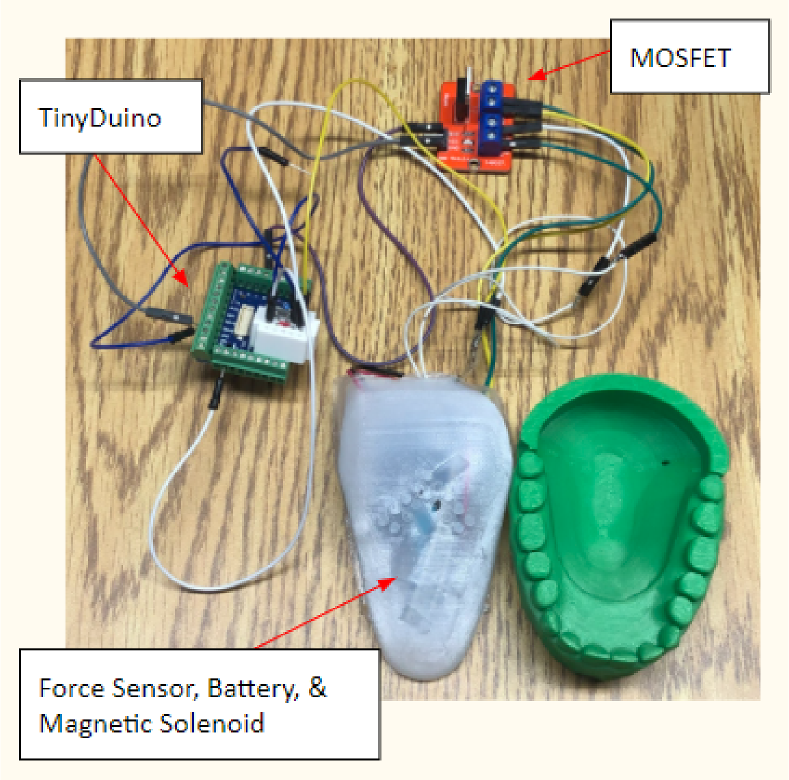


Figure 47: Final Prototype of Prosthetic Tongue with Labeled Components

5.4 Planned Improvements

All requirements created for the control module were met which involved miniaturization, accessibility, and autonomous function. However, to promote increased miniaturization, Printed Circuit Boards (PCBs) should be explored to continue to minimize the size of the components. MOSFETs and Resistors are much smaller in size when printed on circuit boards which could eliminate both the MOSFET module and micro breadboard that currently supports the force sensor. PCBs would help to aid in wire management within the oral cavity and reduce shock risks to the patient. Although the accessibility of the current system is cost effective and easy to obtain, the reduction of components will also provide reduced costs to the patient. Improvements regarding autonomous function include improved sensor selection for detection of the bolus. Additionally, increasing the strength of the magnetic field to attract more magnets and develop more complex tongue motion. This could involve the addition of more magnetic solenoids and magnets placed within the tongue prosthesis. Onboarding sensors for temperature and displacement integrated into the prosthesis that goes into the patient increase safety and continuously monitor the tongue prosthesis performance.

5.5 Summary and Conclusion

This chapter discussed the design process for developing the control module of a self-contained tongue prosthetic. Prior works by Araya and Bridges et. al. focused on pneumatic actuation but faced many challenges when striving towards miniaturization. The improved control module underwent significant miniaturization through a reduction of components to actuate the tongue utilizing magnets instead of pneumatics. The use of a TinyDuino board with the ability to be stacked allowed for easy integration within the tongue mold for self-containment. The micro breadboard and miniaturized MOSFET module further promoted the ability for electronics to fit within the tongue mold or attached to the developed retainer. Additionally, the module incorporated a force sensor to detect a food bolus and promote autonomous function. Overall, the control module for this MQP underwent significant and much needed improvements to achieve an initial prototype for a self-contained tongue prosthetic.

6. Final Design Verification

This chapter explores the various testing protocols to evaluate and quantify the success of the final developed tongue prosthesis. The main focus to measuring success included magnetic field mapping and displacement testing to quantify the actuation of the tongue. Initial testing and set up was developed for bolus testing but were not fully completed during the scope of this project.

6.1 Simulation of Magnetic Fields in ANSYS

To further show the magnetic field lines from the solenoid, we utilized ANSYS Maxwell magnetostatic simulation. We modeled the solenoid in the software based on caliper measurements and assigned materials to each component. The core was assigned to iron and the wire was copper. To simulate the field, we had to place the solenoid in a vacuum and apply a current to the copper cross section. With 0.4 A applied and measurements taken at planes 0 mm, 5 mm, 12.5 mm, and 30 mm away from the end of the iron core. The results showed to range between 0.8 and 0.0002 A/m as shown in Figure 48 below.

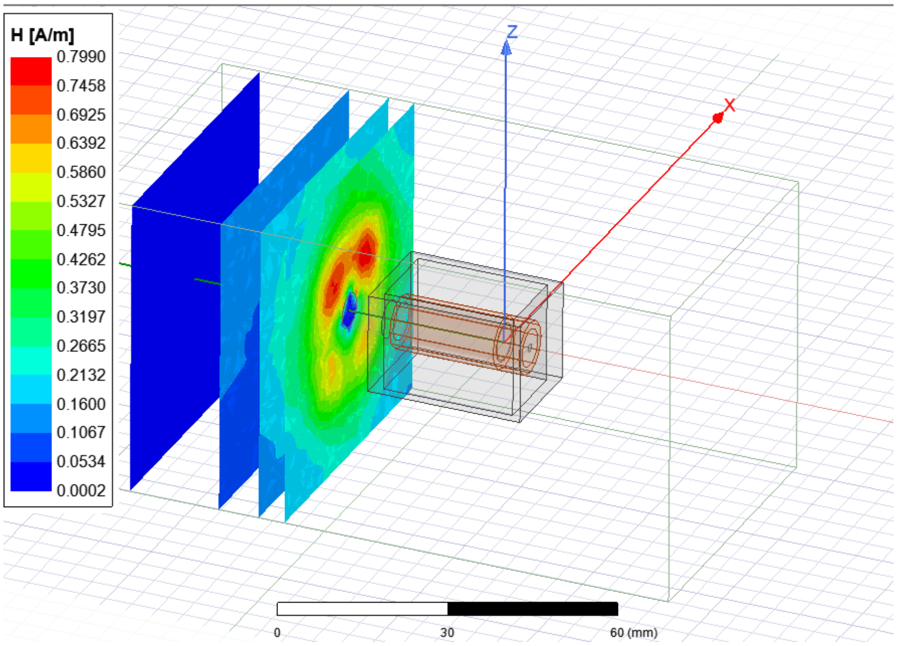


Figure 48: ANSYS Simulation of Magnetic Solenoid

6.2 Magnetic Field Mapping

To provide supporting data to the magnetic field calculations, our team reached out to a professor at WPI to aid in the quantification of magnetic fields for the solenoid. Below in Figure 49 is a Quantum Diamond Microscope (QDM) in the physics department at WPI. The QDM acts as a microscope for magnetic fields, quantifying them to the microTesla. This device operates with a nitrogen vacancy synthetic diamond on the upper level. The diamond is then placed on or above the magnetic field of interest where the microscope captures images of the magnetic field. Color rays are passed through the diamond and captured to create a map of the exposed magnetic field in Gauss. 10,000 Gauss is equivalent to 1 Tesla and can measure to the nanoTesla.

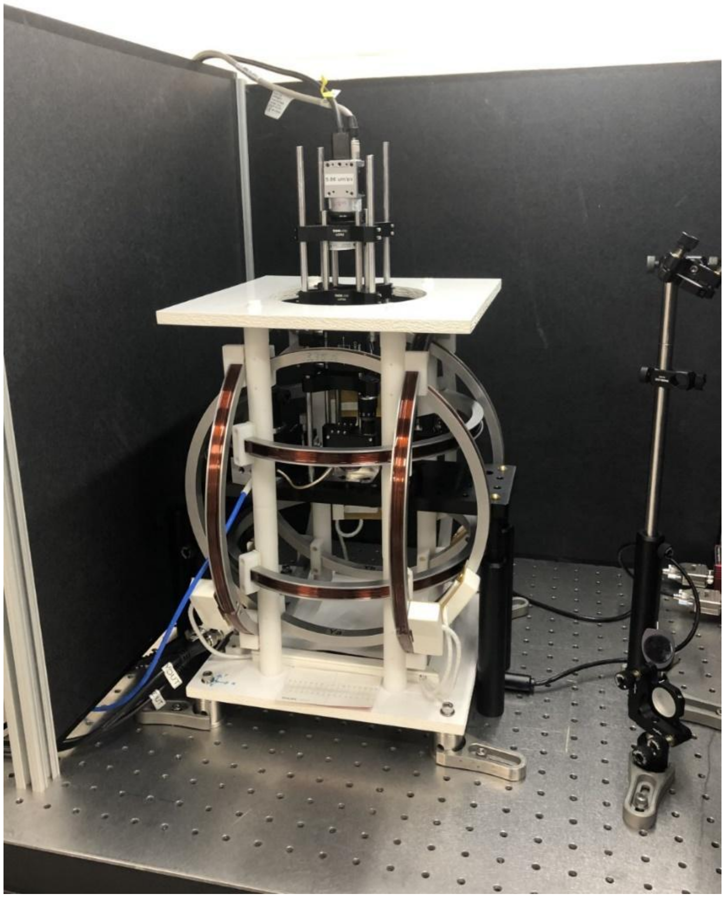


Figure 49: Quantum Diamond Microscope for Magnetic Field Mapping

Tests were conducted to quantify the magnetic field on the solenoid at 11mm and 15mm away from the diamond. From initial testing the solenoid proved to be too powerful to be placed directly on the iron core. These are initial testing results and should be continued in the future with varying currents and distances to get a current/distance graphic relationship.

For the testing, the solenoid was placed vertical with its iron core upwards, this is where the magnetic field strength that we utilized in our design is projected. Then a base magnetic field was taken with the solenoid off, only holding a small magnetic field; a separate measurement was taken with it turned on. The results are shown below in Figure 50(a), 50(b), 50(c) and 50(d). Figure 50a and 50c map the magnetic fields at 11mm and 15mm off positions respectively. The average value mapped is 13.13 Gauss which equals 1313 microTesla with a standard deviation of 0.0906 Gauss or 9.06 microTesla. Figure 50b depicts the solenoid turned on 11mm away from the diamond with 90mA of current.

The difference between the two values registered is 75.45 microTesla with a standard deviation of 8.33 microTesla. Figures 50c and 50d depict the 15mm measurements, the off position is still 1313 microTesla while the result is a decreased value. This is due to the voltage flip of the battery, therefore creating the inverse magnetic field but with the same magnitude. The results from this testing with the current at 130 mA is -88.78 microTesla with 7.52 microTesla standard deviation. With an increased current for this test compared to the 11 mm the field can be considered larger despite being at a further distance. This is due to the equation for calculating magnetic fields of a solenoid, known as Ampere's Law, see equation 1 in section 2.7. The magnetic field is proportional to the current running through it along with the number of turns and permeability of free space. With the current flipped in the solenoid during the 15 mm testing the "off" state in Figure 48c appears to be higher than in Figure 48d as the solenoid is now generating an inverted magnetic field compared to when it is off.

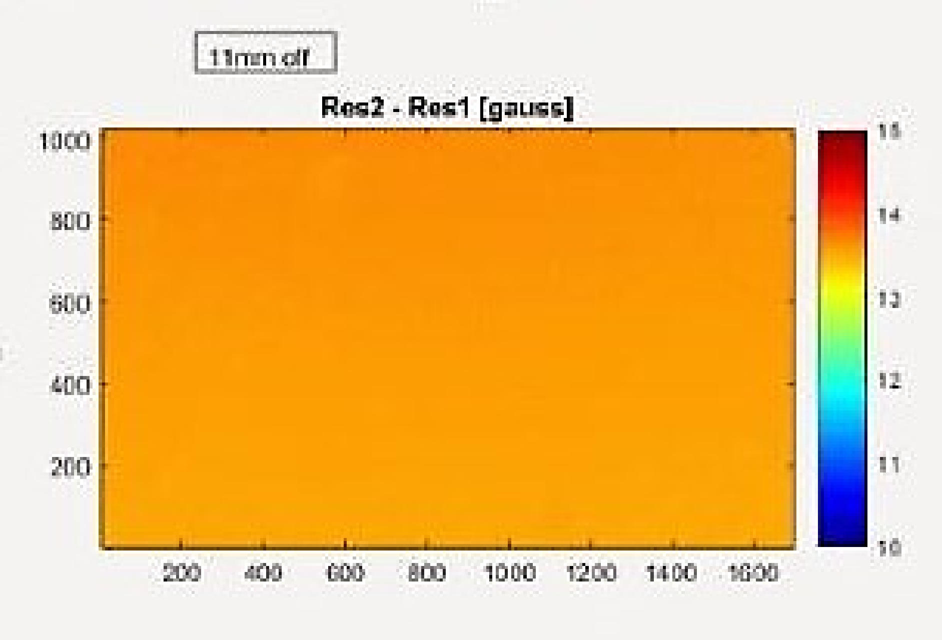


Figure 50a: 11mm “OFF” State

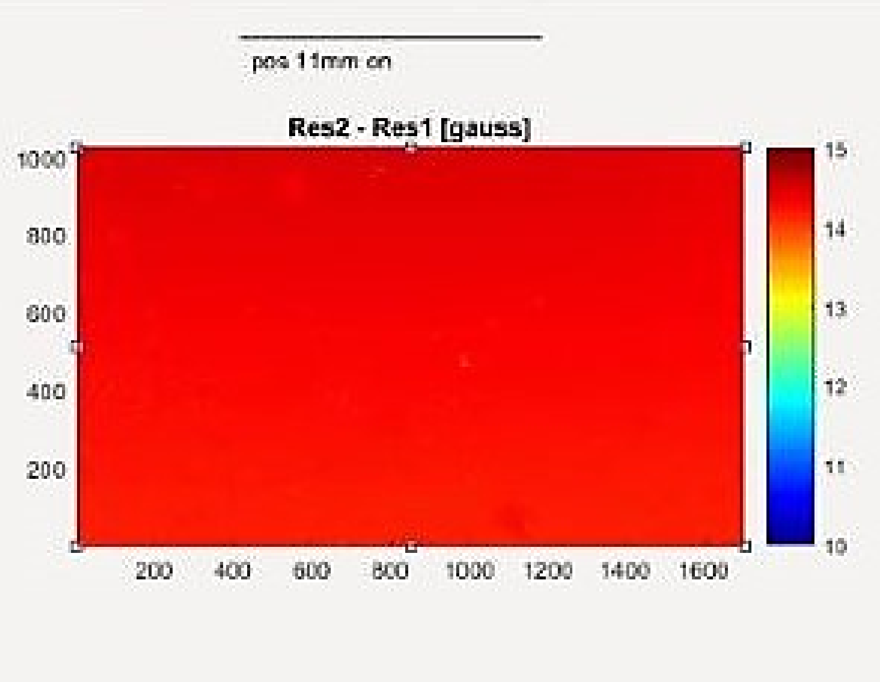


Figure 50b: 11mm “ON” State

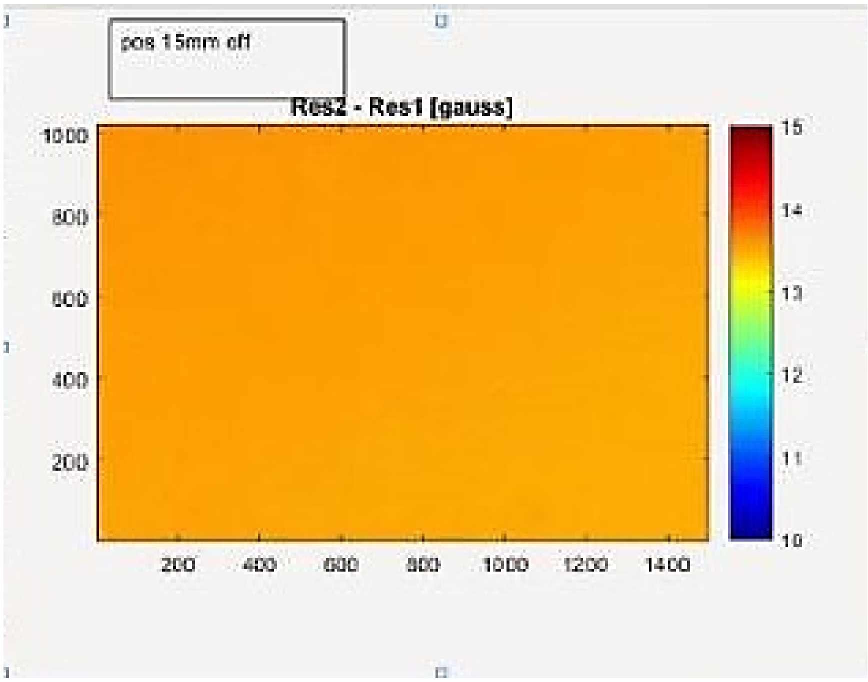


Figure 50c: 15mm “OFF” State

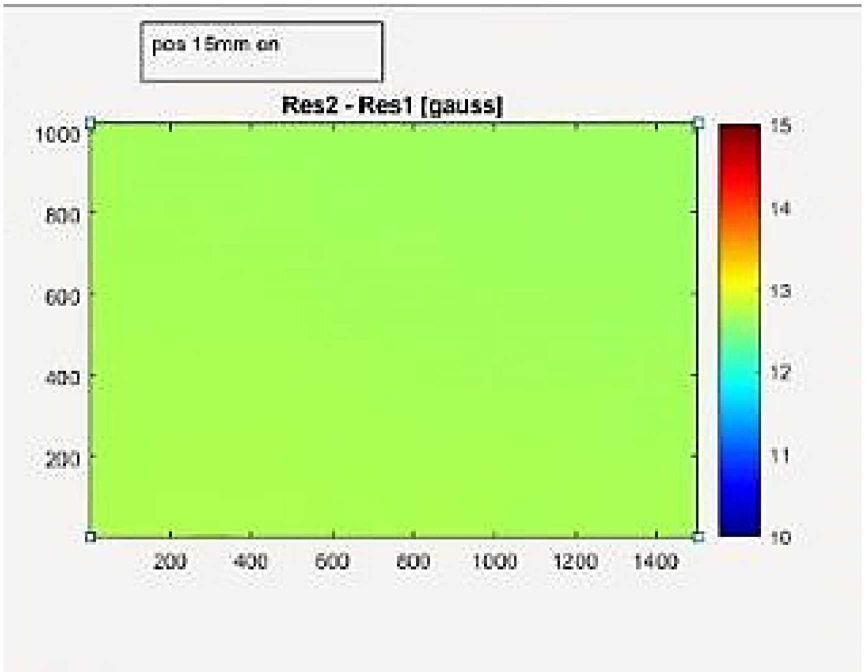


Figure 50d: 15mm “ON” State

From this data, with additional data points at a desired current, a plot can be created to correlate distance between magnets with the desired magnetic field and force applied to the magnet.

6.3 Displacement Testing & Results

Initially, the displacement testing was performed using an external measuring device which was a ruler. However, due to inaccuracies that can occur using this method, a sensor was deemed more appropriate for this testing. In order to measure displacement within the tongue prosthesis an accelerometer was placed within the front compartment of the tongue mold above the magnets. This sensor was able to quantify the motion of the tip of the tongue in the vertical or Y-axis direction.

Three trials were conducted to measure the displacement of the tip of the tongue where the magnetic actuation is occurring. An accelerometer wireling was placed at the tip of the tongue to observe measurements in the Y-Axis which is representative of the displacement in the vertical direction, the testing of this is shown in Figure 51. As shown by the graph in Figure 52 below, the regions at the beginning are constant and when movement occurs, the measurements reach 100 on the y-axis. These 100 mm measurement correlates to about 1 cm of movement which was measured from the top of the silicone mold. Therefore, the total displacement from the bottom of the tongue can be measured by adding the thickness of the tip of the tongue at the bottom.

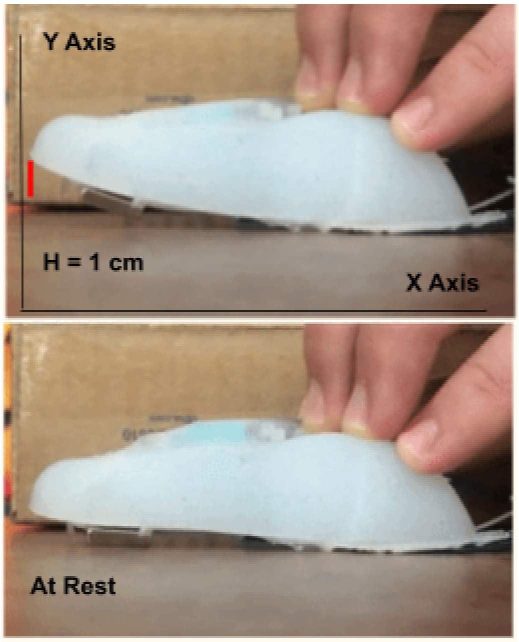


Figure 51: Tongue Displacement from Rest to 1 cm

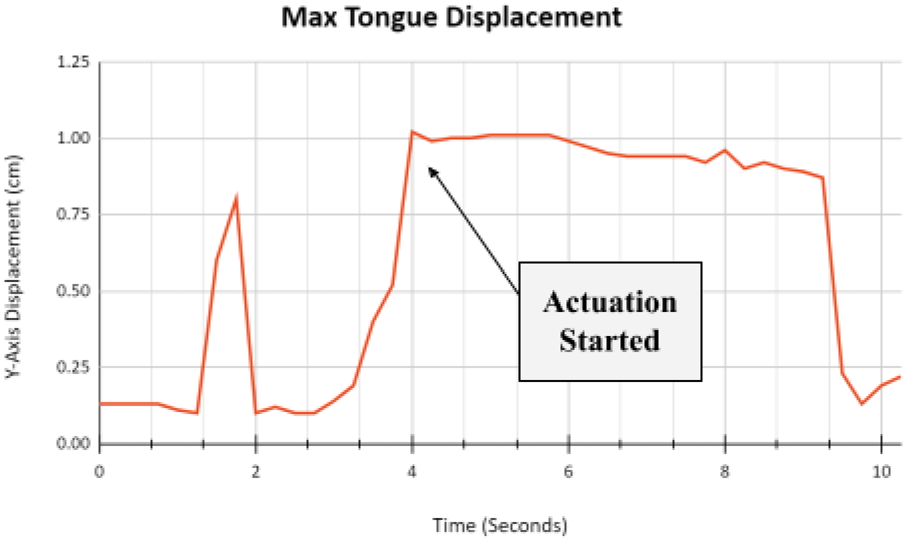


Figure 52: Tongue Displacement Graph

6.4 Bolus Testing

In the literature, there was a study regarding bolus testing and what was most comfortable as a bolus. They used custard and the most comfortable size for one swallow was 5 grams. The viscosity of the custard used in testing was 1.5 Pa*s and the shear rate was 50/s. This gave the conclusion that the substance used was classified in the honey-like group according to the National Dysphagia Diet guidelines. From this, more research was done regarding the density of honey which could be used as a substitute for the density of the custard used in the article [46].

Because of the need of a bolus for testing, instant mashed potatoes with cornstarch used to thicken them. This does not correlate to the density found in the article; however, it does match the average diet of a glossectomy patient. First, a bolus of instant mashed potatoes without the thickening agent was placed on the tongue. From that, a spoon with a mashed potato/cornstarch mixture was placed on the tongue shown in Figure 53. We were able to receive an analog reading that increases between the two tests showing that the flex sensor reads the pressure put on the tongue which mimics eating, which would turn on the solenoid to actuate the tongue.

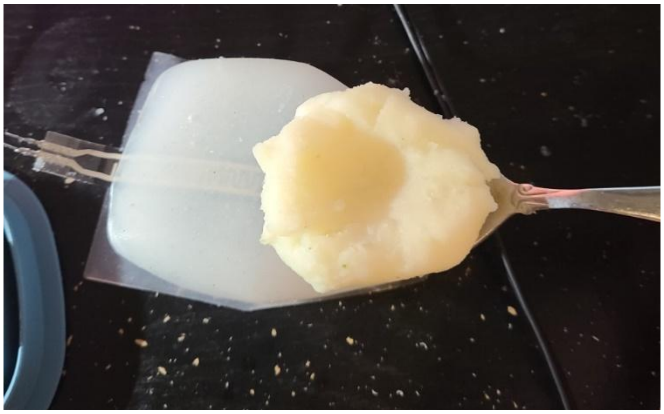


Figure 53: Test Case 2-Instant Mashed Potatoes with 1 Tbsp of Cornstarch

6.5 Summary & Conclusions

Overall, the testing verification revealed the success of the current prototype and where improvements could be made. Silicone thickness testing concluded that 2 mm of thickness was sufficient to protect the silicone from puncturing and protect the patient from the electronic components. However, further testing and design solutions would be needed to verify patient safety before any in vivo testing could occur.

The ANSYS simulation revealed that the solenoid could produce a magnetic field that reached approximately 30 mm away from the end of the iron core, the largest portion of the strength is within the first 12.5 mm away from the solenoid. Through this simulation we were able to map the fields shown around the end and how we could integrate this solenoid into our tongue prototype. Later we looked at magnetic field mapping to further investigate the optimization of the solenoid system. The solenoid is not perfect and could fluctuate its magnetic field based on the current running through it. With variable currents we could work backwards in our calculations from the required force and desired distance to get a current value and associated resistor. The magnetic fields are easy to view on the QDM and essential real-world data can be concluded from these tests.

Analysis of the tongue prosthesis displacement revealed 1 cm of actuation in the Y-Axis or virtual direction. This value was comparable to baseline displacement values from research studies discussed in Chapter 2.12. Therefore, the magnetic actuation for this preliminary prototype proved to be successful and hold promising for greater movement and increased functionality. Preliminary bolus testing was able to confirm the sensitivity of the long force sensor in response to external stimuli. This testing confirmed that stimulus could be detected when mimicking human eating patterns of pressing a utensil on the tongue prosthesis. As the project continues and makes strides toward more complex movements, additional bolus testing will need to be performed to verify the prosthesis is aiding in swallowing. All testing protocols used over the course of this project can be found in Appendix I.

7. Final Design Considerations

This chapter will discuss the project in the context of more worldly applications and considerations. These additional considerations include various impacts to the environment, economy, and impacts on health and safety. Additionally, the political ramification, ethical concerns, manufacturability, and environmental and sustainability applications.

7.1 Economics

The medical device industry is very profitable and could help to further the project and increase accessibility. Those involved at the professional level to improve upon this project would receive compensation in the form of a salary. Additionally, if a company were to market and sell this product to those who suffer from oral cancer a profit could be made. The costs of the device could be fully covered or partially covered by health insurance to allow individuals to purchase the device. Ideally, the electrical components would last for over a year and the silicone molded tongue would be replaceable and sold individually to the patient as needed.

This project had a budget of $800 to purchase components and develop the prosthetic tongue and retainer. The final tongue prosthetic electrical components had a final cost of about $70 which includes the sensor, MOSFET, TinyDuino shields, micro breadboard, and batteries. Magnetic materials such as the magnets and magnetic solenoids had a combined cost of about $30. Lastly, the materials to develop the tongue mold include the EcoFlex silicone, 3D printed molds, and clay for the retainer formation. The 3D printed molds cost about $5 to produce and the Ecoflex cost per tongue mold was $3. Retainer costs are harder to estimate due to the intricating fitting and professional help to ensure the device is fit for each patient.

7.2 Societal Influence

This tongue prosthetic will have the societal influence of bringing more visibility to the realm of oral prosthetics and this unique unmet need. Additionally, the prosthetic if in practice would positively impact the quality of life for those that suffer from oral cancers. These works could influence medical device companies to expand their product lines to include dental solutions. Lastly, this work may influence other researchers to approach the task of mimicking human tongue movement and further the prototype designed by this team.

7.3 Political Ramifications

Overall, the team does not anticipate any negative political ramifications associated with the tongue prosthesis. The tongue prosthetic developed can be comparable to limb prosthesis, which also have no direct political ramifications. However, legislation or policy may occur within the health insurance realm on if the prosthesis would be covered by insurance or by a government program to help those who need health insurance assistance. Possible regulators at the governmental level could include the FDA or the EU aboard. However, these agencies are mainly concerned with the safety and efficacy of a medical device.

7.4 Ethical Concerns

In order to move the project forward, at one point, a final prototype will have to be tested within a human to ensure the capabilities of the tongue itself. However, the tongue itself would have to have been tested in multiple different ways to ensure biocompatibility and safety to the user. While there will be a lot of precautions and tests that will be done before human trials, it is still an issue of if it is ethical to test on human patients. All precautions will be taken, and tests will be done in vitro to ensure safety before undergoing tests in human trials.

7.5 Health & Safety Concerns

Health and safety are major concerns for this project as it relates directly to someone’s health and quality of life. The biocompatibility of the tongue is a major factor when it comes to this. Without the tongue reacting to the body in an appropriate and safe way, the project ends up not working and a re-evaluation needs to be done on what can and cannot be used in the making of the prototype. In order to ensure the health and safety of the users, many tests will be done as well as research on tests done using the same components within the oral cavity. Some research has been done regarding the N52 magnets being used as well as a future recommendation of using medical grade silicone and biocompatible adhesives for the continuation of the project.

It also needs to be taken into consideration the idea of the tongue malfunctioning in the mouth and how that could affect the patient. It needs to be clear that even if one thing stops working, the safety of the patient is put first before the prototype continues its work while malfunctioning. The tongue must be able to alert of the malfunction or issue or stop completely so no damage can be done to the patient.

7.6 Manufacturability

In the prosthesis current state, it is not ready for mass production and distribution as a prosthetic for glossectomy patients. Due to the highly manual process implemented to create and develop the tongue mold, there is no quality control. The magnets and solenoids required to reliably actuate the system need to be in precise locations, lack of quality control will result in a poor functioning product. Therefore, a uniform precise process would need to be implemented by various machinery to ensure each tongue mold is made the same and cures for the same amount of time. Higher quality medical grade silicone would need to be used during manufacturing since this is an implantable device in the oral cavity.

The electrical components currently require soldering to secure most connections, but this could be mitigated with PCBs. Using a PCB would continue to miniaturize components and automate the process for developing the electrical components to have good quality and be easily reproduced at a low cost. A large decrease in production cost would also result from reduced 3D printed housing present in previous iterations of the project. While this prosthesis currently lacks 3D parts, the addition of them would be simple and cost effective given how small the system is. Reduced printing time would also contribute to better manufacturing capabilities.

Fitting retainers is a highly manual and custom process performed by those in the dental field. Therefore, a one size fits all retainer does not exist and would be challenging to manufacture in advance for patients utilizing the tongue prosthetic. Customization of the retainer which allows the prosthesis to connect enhances comfort to the patient.

7.7 Environmental Impact and Sustainability

The sustainability of the prosthetic is unfortunately not very good. The use of silicone is not a sustainable practice as there is no way to recycle or reuse it, especially in a medical setting. The same is true of the resin retainer being used for the prosthetic. These non-recyclable elements would need to be disposed of as trash and would likely go to a landfill.

Similarly, to the resin and silicone, it is likely that the 3D printed elements of the prosthetic used in manufacturing would be thrown away. However, there is a growing push for makers to find uses for their discarded 3D printing filament. Many have created at home methods to turn old filament into new spools or send their filament scraps to companies for recycling. This type of recycling is known as closed-loop recycling in these makers circles and is a key to improving the sustainability of 3D printing [47]. For this project, old 3D prints were saved for reference for future iterations of the process, so no 3D printed material has been thrown away.

The United States Environmental Protection Agency, or EPA, provides clear instructions to recycle electronic waste. These instructions are available on their website where they suggest bringing your electronics to a R2 certified Electronics Recycler. These are recyclers who have met the R2 electronics recycling standards and have been certified for doing so. These standards map out proper categorization, processing, and management procedures for these facilities. The standards have been updated as of October 2020 to include new detail and information. The EPA provides information on how to find a certified recycler for your electronics on their websites [48].

Overall, because only a small portion of the prosthetic has potential to be recycled this is not an environmentally sustainable prosthetic.

8. Discussion

In this chapter, the data collected from validation testing and prior work will be evaluated. The evaluation will be based on how well the data supports and achieves the project goals. Data limitations will be discussed and the impacts it has on the project.

8.1 Meeting Objectives and Constraints

This section will compare the final prototyped tongue prosthesis to the objectives developed and outlined in Chapter 3.

The objectives are as listed below:

1. Develop a tongue prosthetic to mimic anatomical features more accurately and actuate the tip of the tongue upwards.
2. Size: Develop a more anatomically correct tongue mold and fit prosthetic into the 3D printed oral cavity.
3. Safety: Tongue prosthetic must prevent users from electric shock, leakage current, and be biocompatible.
4. Controls: Miniaturize electrical components and implement magnetic actuation into the final prototype of the tongue for a targeted displacement of 1 cm.
5. Validation: Develop clear test protocols to validate tongue functionality and biocompatibility.

8.1.1 Design: Create a tongue prosthetic to mimic anatomical movements more accurately.

Our team was able to develop a tongue prosthetic that can actuate the tip of the tongue in response to external stimuli. The tip of the tongue prosthesis was able to actuate to 1 cm in height or vertical motion during prototype testing as discussed in Chapter 6.3. Actuation of the tip of the tongue is more functional than current static tongue prosthetics widely available today. Previously, Bridges et. al [9] only accomplished 22 mm in actuation of the front of the tongue prosthesis with pneumatic controls. Therefore, our prosthesis was able to actuate almost 5 times as much as previous works which accomplished our goal of greater tongue displacement and mimicking anatomical movement at the tip of the tongue.

8.1.2 Size: Develop a more anatomically correct tongue mold and fit prosthetic into the 3D printed oral cavity.

The tongue shape and size was developed by referencing anatomical models of the human tongue and oral cavity and referencing data and measurements of the human tongue. Our final prosthetic was within the range of measurements found from data collected by researchers though slightly larger than the average measurements for these. Most notably the maximum height of the tongue is 23mm which is much larger than what is seen in the data from research as discussed in Chapter 3.6.1. This is due to the methods used in the studies conducted but is still plausible as can be seen from the measurements taken by the team. This model was then placed into the 3D printed oral cavity from the Bridges et al. project for some of the early testing and design. Based on this the team was able to successfully develop a more anatomically correct tongue mold and fit the prosthetic into the 3D printed oral cavity.

8.1.3 Safety: Tongue prosthetic must prevent users from electric shock, leakage current, and be biocompatible.

In order to fulfill the safety requirement, research on the components was done and further recommendations will continue the safety goal. Bridges et. al performed tests that validated the safety of the tongue [9] These include bacterial testing on the silicone used and denture tablet cleaning. The denture tablet proved that the tongue could be cleaned regardless of what bacterial growth was there [9] Overall, the components of the tongue used for this years' team were researched for biocompatibility. The N52 magnets used were found to not negatively affect the oral cavity as discussed in Chapter 3.6.3. In order to house the electronics correctly, a box would be placed under the tongue in the remaining oral cavity. To ensure these components would not harm the patient, the components would be encapsulated in acrylic so seal off any leakage and prevent any damage that could occur. The tongue would also be cleaned which would be done through heating the tongue. The silicone would have to encapsulate the electronics so that they would not be damaged by the heat. There was also research done on what kinds of materials could be used that are biocompatible, such as medical grade silicone and biocompatible adhesives that could be used for the electronics. The medical grade silicone we would use would be Factor II medical grade silicone which was researched to be a good biocompatible material for the artificial tongue as it is widely used and has the highest tensile strength which makes it safe for removal without getting damaged [49].

8.1.4 Controls: Miniaturize the electrical components.

The control module for this project was significantly miniaturized compared to the previous iterations which involved a pneumatic approach. Bridges et. al [9] final prototyped electrical control module was 8.4 inches in length and 5.25 inches wide. Our control module was able to achieve integration into the tongue mold itself to become a self-contained system. The TinyDuino Boards were only 20 mm in height when stacked on top of each other. Component selection focused on the integration of a smaller microcontroller, reducing external circuitry, and implementing sensors to detect food on the prosthesis. A long force sensor measuring 3.9 inches was incorporated along the tongue mold to detect stimuli as the bolus moves towards the back of the throat. TinyDuino Shields were stacked on top of one another to aid in miniaturization. The shields stacked on top of each other included the microcontroller shield, USB connection shield, temperature sensor shield, and prototyping shield to connect all of the wires to for connection. Once a force reading is recognized by the microcontroller, then the MOSFET component acts as a switch to power on the magnetic solenoid with its own 12 V power source. When the magnetic solenoid is powered on, the strength of the magnetic field increases and attracts the magnets from the tip of the tongue upwards towards the solenoid. Therefore, this objective involving miniaturization was met from our discussion in Chapter 5.2 and the system could be self-contained within the tongue mold. More miniaturizations could be achieved through Printed Circuit Boards (PCBs) which would decrease the size of the MOSFET and resistors within the system.

8.1.5 Validation: Develop clear test protocols to validate tongue functionality and biocompatibility.

In order to validate the tongue, we developed different protocols for different functions of the tongue. As shown throughout Chapter 6, we performed many tests that gave results for the thickness of the silicone results, magnetic field simulation, and actuation of the tongue. The silicone thickness allowed for testing to see what force the silicone could withstand and see if the thickness would affect that force. The magnetic field that was modeled supported the calculations made about the magnetic field which were used in the design of the prototype. The actuation of the tongue tested the amount the tongue could move and mimic the movement of a human tongue. We also developed clear protocols for bolus testing (Appendix I. C.), for accelerated aging at 55oC (Appendix I. F.), and for body temperature simulation (Appendix I. G.) that can be used for future testing to further validate the tongue's functionality and biocompatibility.

8.2 Limitations of Data

All work presented in this report addresses the development of a self-contained functional tongue prosthesis. Although the prototype is not yet refined enough to be integrated into a human oral cavity, it still provides a basis for future works and advancements. Araya and Bridges et. al investigated a pneumatic approach to actuation whereas our team utilized magnetic actuation to aid in miniaturization of the controls system. This led to a major redesign of the control module and significant research into magnetic actuation. Due to the time spent researching actuation methods and changing the system, data is limited for bolus testing and methods to create more complex movements of the tongue.

Thickness testing data is only accurate to the SmoothOn EcoFlex 00-30 silicone and may not be representative of medical grade silicones. The tongue mold was developed using EcoFlex 00-30 due to prior biocompatibility research performed by Bridges et. al and due to accessibility of the material. In the future, when a medical grade silicone is used, the thickness testing would need to be performed again to ensure proper wall thickness between eclectic components and the patient.

Magnetic mapping has the limitation of its field of view. The diamond in the Quantum Diamond Microscope is smaller than the iron core of the solenoid and can only map the areas that overlap. This provides only a small scale of the overall mapping that can be acquired where multiple recordings are needed to get the full view. With the necessity to take multiple images, the current and battery voltage must remain constant throughout the entirety of each measurement. If insufficient batteries are used during this measurement, the data collected is rendered useless. To get the best data possible it is important to use fully charged batteries and keep the solenoid from receiving a surge of current with a resistor.

The displacement data has the limitation of only focusing on motion related to the Y-Axis and not in conjunction with the X-Axis. During testing it was noted that the accelerometer wireling and tip of the tongue moved slightly along the X-axis but this data was not analyzed. For our purposes, only the displacement in the vertical or Y directions was important. Once the project is expanded to include more complex movements in the X direction these measurements must be analyzed. Bolus testing had major data limitations since the bolus could not be moved all the way to the back of the throat. The measurements obtained for bolus testing only confirm detection of external stimuli by the long force sensor integrated into the tongue mold.

Variations in data collected also depended on the development of each prosthesis. Since all of the prototypes are developed by a person compared to a machine, there is possible variation in values. For example, curing of the silicone molds and the quality is subject to curing time, storage temperature, and pouring method. In regard to the electrical components, the performance was affected by the battery supplying power to the magnetic solenoid. It was noted that during testing if the battery voltage fell below 12V, the magnetic field decreased and minimized actuation.

9. Conclusions and Recommendations

Previous sections leading up to this chapter explored the importance of a tongue prosthesis, design iterations, and validation testing of the final prototype. Progress was made within the areas of miniaturization and biocompatibility. This chapter will discuss suggested future improvements and conclusions of the current project state.

9.1 Conclusion

Overall, the goal of this project was to develop a self-contained functional tongue prosthetic to aid oral cancer patients in swallowing a food bolus. This approach proved magnetic actuation could pave the way for more advanced and functional oral prosthetics. Additionally, miniaturized electrical components were integrated into the final design to allow the control module to be self-contained within the oral cavity. The integrated microcontroller boards were only 20 mm X 20 mm and could be stacked vertically to maximize space within the prosthesis. Sensor integration allowed for a stimulus-controlled system to actuate with the presence of food during patient feeding. Improved versions of the original tongue prosthetic allowed for a final iteration that is within average human tongue measurements and shape. Addition of the papillae not only made the mold more human-like but could aid in bolus movement in the future. To connect the tongue prosthesis within the oral cavity, preliminary design ideas were explored for a retainer to connect the tongue to the patient and store some of the electrical components.

Magnets and solenoids were carefully and precisely integrated within compartments of the tongue mold to allow for the tongue tip to actuate upwards. Two magnets were placed inside the tip compartment with one placed outside of the compartment. For testing purposes, the magnets would clip onto the opening cover for the compartments and move the tongue when actuated. Various trials and testing confirmed this to be the best placement for actuation during our testing. When the solenoid is turned on in the other compartment, the magnets are attracted to it and turn towards the core to align itself with the field lines. Magnetic field mapping helped to prove the strength of the field around the solenoid was sufficient to attract and hold magnets when powered on. Since the magnetic components were used, the large pneumatic system was not necessary. Therefore, the miniaturized control module integrated smaller microcontrollers, reduced external circuitry, and utilized sensors to detect external stimuli. Increased biocompatibility resulted from an improved tongue prosthesis size and shape.

Although there is still much work to be done to refine the magnetic actuation mechanism, initial work showed promise for future design iterations and prototypes. Testing of the prosthesis evaluated displacement, sensor detection, and thickness of the tongue prosthesis. Displacement testing revealed 1 cm of actuation at the tip of the tongue which was greater than tongue displacement of Bridges et. al [9]. Despite initial bolus testing, further testing and research must be performed within this area. This project was able to achieve and completely redesign a pneumatic system to utilize magnetic actuation and have the potential to become self-contained within the silicone tongue and retainer.

The size and shape of the tongue was drastically improved for this type of actuation. Unlike the pneumatic controls of previous iterations of this project, the height would be unchanging during actuation. The size and shape of the tongue was completely altered to replicate human anatomy. The final measurements of the tongue at maximum were 85mm in length, 52mm in width, and 23 mm in height. These measurements were found using both research and measurements taken by team members. The creation of an anatomically correct tongue allowed for increased biocompatibility. This is especially true because for patient use the tongue size and shape would likely be altered to reflect their own natural tongue. The ability for customization only furthers the biocompatibility and is a major success of this project.

9.2 Recommendations for Future Work

Future improvements to the work on this project should focus on materials selection for biocompatibility, increased movement control, and continued sensor exploration. Research into medical grade silicones should be a priority to increase biocompatibility and safety to the patient. Additionally, more trials of various magnet combinations and placements should be performed to see what will allow for maximum displacement based on the magnetic field quantification. Further sensor explorations could aid the patient triggering tongue movement with less food placed on the tongue. Bolus and displacement testing should first verify the values shown in this report and continued with each design iteration. _

9.2.1 Testing Recommendations

This section discusses suggestions for testing that should be done to gather data that suggest that these steps moving forward are successful.

Testing was mainly focused on measuring tongue displacement as a result of magnetic actuation and force sensor sensitivity. Although the force sensor was tested for its ability to detect the bolus, more comprehensive testing must be performed on bolus movement. Moving the food bolus is a priority for this tongue from the goal of helping the patient to swallow. From the literature, an average food bolus for a comfortable swallow is around 5 grams with a thick density [46]. It is suggested that a food bolus of the same mass and a similar density is used, first as recognition for the flex sensor to get the solenoid to turn on, and then as a theoretical food bolus that mimics the bolus of an actual person. Instant mashed potatoes thickened with cornstarch was used as a bolus for the flex sensor testing and it is recommended to use that or a similar material for bolus testing. A protocol for bolus testing was made and can be found in Appendix I. C.

It is also suggested that the biocompatible components be used for testing of future tongue prototypes such as the medical grade silicone and biocompatible adhesives. For biocompatibility reasons, medical grade silicone must be used for the final product. It is recommended to test medical grade silicone to evaluate changes to the curing method and thickness testing. The silicone itself must also be tested for strength and fatigue so that the lifespan of the tongue can be determined before it is no longer usable and must be replaced. That testing also is needed for calculating the force needed to lift a food bolus upwards of 1+ cm so that it can accurately help a glossectomy patient to swallow. The biocompatible adhesives must be able to hold the components of the tongue in place and be safe for the body. If the adhesives are not tested for strength and capacity, then the adhesives could fail to perform and cause a failure in the tongue because the components are not secured.

Another aspect that must be tested for is shelf life and usage life. Age is one main aspect of failure that can be tested for shelf life or overall usage life. In order to test through fast aging, the whole prototype of the tongue in a controlled oven at 55°C for shelf life and 37.5°C for body temperature simulation. Both of these are important to know and therefore should be done in future testing as to better understand the limitations of the tongue and how to manage the tongue and what to expect from the tongue. Protocols have been made for these tests and are in Appendix I. F. and Appendix I. G.

A final suggestion for the tests that should be performed would be the cleaning testing of the components of the tongue. As done in last years' MQP, a denture tablet was used and shown to be successful in cleaning the tongue component (Bridges et. al). Future recommendations would include testing such as this to show that the tongue can be made sterile despite any bacteria or other unsterile components the tongue could get. Testing regarding these unsterile components should also be done beforehand to show what kind of growth could be on the tongue and how the experimental procedure will clean the tongue successfully.

9.2.2 Magnetic Actuation

This section will discuss the improvements and conclusions based on magnetic actuation testing.

The purpose of exploring magnetic actuation was to validate the miniaturization of the entire system and evaluate the capabilities of using magnets to move a bolus. From testing and theoretical calculations, it was noted that magnetic fields increase as distance decreases between the magnets. Therefore, the magnet is attracted to the solenoid and moves towards the ferromagnetic core when a current is applied. From experimentation, it was realized that the magnet would not detach from the solenoid once the current was turned on. To avoid this issue, we looked at utilizing a stationary permamagnet outside of the tongue prosthesis. If the stationary magnet attracts the actuation magnet, when the solenoid is turned off, the magnet can return to its resting position. Doing this will require a lot of testing and magnetic field calculation as three magnetic sources are involved instead of two. However, this method could allow for patient control with movement of the outside magnet during feeding.

As shown in the testing and magnetic mapping simulations, the magnetic solenoid only creates a small magnetic field of about 1 milliTesla. Due to the lack of strength in the field, the bolus movement capabilities are limited. At 15 mm away from an actuator magnet, around 1 milliTesla is generated, thereby resulting in an almost nonexistent force. Even if the magnet on its own could move from the force, it is doubtful the solenoid could move the magnet and bolus with such a small force from that point. To create more actuation force, a stronger magnetic field should be controlled. While we pursued the solenoid for its simplicity with the control system, an oscillating magnet can provide a better solution when moving a larger bolus. With the new tongue mold, a small servo motor and sliding linkage system could be utilized to move the tip upwards and backwards like a normal tongue. The oscillating magnet capabilities can also provide expanding the magnetic movement beyond just the tip of the tongue.

For the bolus to move seamlessly from the front to the back of the tongue, more magnets should be implemented to move the bolus beyond the tip. The integration of more magnets and actuators could prove to be the final necessity for the prosthesis to be fully functioning. Placing a magnet in the back with an oscillating magnet in the front and actuating magnet at the tip could be a viable method for creating this actuation. Whatever method is implemented, further exploration is needed for the magnets in the tongue.

With the further exploration into magnetic actuation, we would like to recommend getting assistance from Professor Trubko to continue mapping generated magnetic fields.

9.2.3 Manufacturing and Integration

This section will discuss recommendations for manufacturing and integration of components in the final prosthetic.

The most notable recommendation for manufacturing in future iterations of this project is the use of medical grade silicone for the tongue. The SmoothOn Ecoflex 00-30 currently in use is adequate for testing the size and shape, but does not perform the same as a medical grade silicone. This year our team won a Women's Impact Network grant for $2,500, which can be used for medical grade silicone in the future of this project. We recommend using Factor 2 silicone, which we believe will adequately meet the needs of this project.

We also recommend continuing to refine the integration with the controls unit. Currently the electronics are not enclosed in the tongue and therefore would not be suitable for patient use. Some ways this could be done is through using smaller lengths of wires or soldering rather than using removable wires. This would allow the controls to take up less space and be more seamlessly integrated into the tongue and retainer. Changes to the retainer design would need to be made to properly encase these electronics.

Lastly, we recommend making the denture and retainer system more biocompatible. Currently, the size and shape allow it to work well for the prosthetic but would not be usable for a patient. Notable the back lip and depth of the retainer portion are not biocompatible. Designing a smaller retainer would be very helpful for the biocompatibility of future iterations.

9.3 Control Module Recommendations

This section will explore further improvements to the control module and address efforts to fully integrate the electronics within the oral cavity.

Although the control module was significantly miniaturized, many wires are involved to connect the system and may be an issue when trying to contain the electronics within the tongue. The amount of wires made it difficult to test the device since the connections would become disconnected with the slightest movement. Therefore, it is recommended that future teams solder all connections to the TinyDuino prototyping shield. Since the current design has to be connected via USB cable for power, it is recommended that future work explores the use of 3V coin cell batteries to run the TinyDuino to increase portability.

More research into appropriate sensors to detect external stimuli is recommended as a more sensitive sensor could be utilized to detect liquids such as soup or water to help the patient swallow. Additionally, continued integration of onboarding sensors within the tongue such as temperature and displacement to protect the patient and quantify the complex motion of the tongue prosthesis. Our team began to explore bluetooth as a feedback mechanism to the patient wearing the device to monitor temperature and motion. However, future teams will need to further integrate this to establish the wireless connection and communications.

An enclosure for the electrical components should be developed for attachment within the retainer to maximize storage space within the oral cavity. It is recommended that the enclosure be biocompatible and coated in acrylics similar to pacemakers. Lastly, it would be important for future works to explore Printed Circuit Boards (PCBs) in order to continue efforts towards miniaturization and self-containment within the prosthesis. By further miniaturizing the electrical components, additional magnets and solenoids could be placed within the tongue mold to achieve more complex and anatomical movement.

9.4 Team Reflection

This MQP fulfills the requirements for the undergraduate engineering degree and challenges engineering students to research and design an innovative year-long project. Our team was very grateful for the opportunity to apply our knowledge from various courses and personal experiences in order to develop an improved prosthesis for oral cancer patients. This project provided real world experience similar to a design team within the industry and how to navigate new ideas and design iterations.

Various courses aided our project in understanding the design process and determining design requirements through decision matrices. For the biomedical engineers on the team, these skills were learned through Biomedical Engineering Design (BME 3300). Mechanical engineers on the team obtained these skills through Introduction to Engineering Design (ME 2300). Both courses provided insight into how to go through the design process which helped the team throughout this process. The combination of the BME and ME class allowed the team to approach the problems from different angles and solve them effectively. Having a well-rounded team was a key to our success in designing the prosthetic throughout the project.

Materials selection knowledge was provided by Introduction to Material Science (ES 2001) which all members of the team had taken during their undergraduate careers. This course allowed the team to have introductory knowledge to material properties and how these can affect biocompatibility. All members of the team participated in Physics - Electricity & Magnetism (PH 1120) which provided a basic understanding of magnetic fields and how magnets interact with each other. The knowledge brought by Sarah Vasquez, the only Electrical and Computer Engineering major in the team allowed us to better work with the controls module of the prosthetic.

The validation and other testing done throughout the year was benefited by the team's course work such as Engineering Experimentation (ME 3902) and Biomedical Engineering Design (BME 3300). Both these courses prepared team members to set up experiments and test results. This allowed the team to assess our prosthetic more confidently and accurately.

Not only did previous courses teach the team useful skills, but this Major Qualifying Project also offered many learning opportunities for the team. With short term projects when something goes wrong, the team often explains the problem and never fixes it due to time constraints. With the additional time taken for this project, the team was faced with more problem solving and design decisions that we did in previous projects. Unlike many project courses, the team was able to decide which areas we felt would be the most important and should be given the most attention. This allowed us to fully explore ideas such as magnetic actuation. These skills of problem solving, needs analyses, and time management allowed the team to grow as engineers in ways that were not gained from previous work.

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Appendices:

I. Test Protocols

I. A. Thickness Testing

Objectives: To determine the minimum thickness of silicone for walls of tongue mold through deformation testing.

Phase I: Tensile Force Deformation

Materials :

- 3D printed thickness mold
- SmoothOn EcoFlex 00-30
- Load cell
- Arduino Uno
- Carabiner clip
- Small bag with handles
- Objects of known weight up to 10 lbs
- Calipers

Procedure:

1. Pour silicone into the thickness testing mold and allow to cure. Demold when fully cured.
2. Connect the load cell to the Arduino Uno and begin running code to read the load cell in lbs. Depending on the load cell being used this code could vary slightly but open-source code can be found easily online.
3. Hang one side of the load cell from a table or drawer for stability.
4. Put the carabiner on the hole on one side of a strip of silicone and put the other side on the load cell.
5. Attach the bag to the carabiner clip and recalibrate the load cell to ignore the weight of the silicone, clip, and bag.

6. Place the object of lowest weight into the bag and allow it to hang for 5-10 seconds.
7. Remove the weight and use calipers to measure the length of the silicone.
8. Repeat steps 6 & 7 for all weights up to 10lbs.
9. Repeat steps 4-8 for each thickness of silicone strip.

Phase 2: Friction Deformation

Materials :

- 3D printed thickness mold
- SmoothOn EcoFlex 00-30
- Arduino Uno
- Digital Scale
- Tape

Procedure:

1. Pour silicone into the thickness testing mold and allow to cure. Demold when fully cured.
2. Place the Arduino Uno on the scale and tape down the edges so it is secure. Tear the digital scale.
3. Rub the silicone strip over the surface of the Arduino Uno with 5 lb of force as read from the scale. Continue this for 1 minute.
4. Observe the surface of the strip for any deformation from the friction against the electronics.
5. Repeat step 3 for each of the silicone strips.

I. B. Magnetic Field Testing

Objective: To test the distances and placements at which the solenoid is effective.

Phase I: Paper Test

Materials:

- All test magnets
- Electromagnets
- Battery Pack
- Ruler or measuring tape in [mm]
- Construction paper
- Scissors
- Electrical/Duct Tape
- Thin pointed pencil

Procedure:

1. Taking the construction paper, cut a piece of it out the width of the magnet you are testing and length wise at least 40 mm longer than the magnet if it was at the end of the construction paper.
2. Using the electrical/duct Tape, with the magnet on the end of the paper tape it securely to the construction paper without bending or creasing the paper. Make sure your magnetic field is pointing upwards.
3. Now take your electromagnet or solenoid and duct tape the core to the body so it will not exit the solenoid and go to the magnet. We are now ready to begin testing.
4. Slowly sliding the solenoid across the paper moving closer to the magnet, pay attention to the magnet's movement and have a pencil ready to mark the position of the solenoid.
5. Firmly grasping the solenoid and holding the paper as needed, once the magnet moves and connects to the solenoid core, with the thin point pencil mark the position the body of the solenoid is at, this is the closest your solenoid can be to the magnet.

    1. **Note:** Since the magnet touched the core of the solenoid, it is now magnetized slightly - meaning it will attract the magnet from a further distance now - to demagnetize it, touch the solenoid with a ferromagnetic material (material affected by a magnetic field) multiple times until they no longer hold a charge.
    2. **Note**: If the magnet does not move from a further distance on compared to when it was off, then your magnet polarity is flipped. To fix this simply flip your magnet over.
2. Repeat steps 4 and but this time with the electromagnet on. Mark the position of the body of the solenoid again, this is the furthest point your solenoid can interact with the magnet.
3. You now have a distance range in which the solenoid can move the magnet (Try placing the body of the solenoid in between the two lines and turn it on). Using the ruler or measuring tape, find the distances and record them with 0mm at the end of the magnet closest to the middle of the paper..
4. Repeat all steps for each magnet and each solenoid/electromagnet you wish to test.

Phase II: Silicone Testing

Material:

- A silicone mold of any shape with a hole in the center at one end
- All Magnets
- Electromagnets
- Ruler or measuring tape in [mm]

Procedure:

1. Make a hole for your silicone mold about the size of your magnet using an exacto knife or simply during the creation process of the mold. Then when you have the hole in the silicone as large as you would like it, place a magnet with the correct side (as discussed in phase I where the electromagnet can repel the magnet or attract it) facing up at the end of the silicone. Make sure the magnet will not slip out of the hole you created
2. With the electromagnet outside the silicone, we will determine how the silicone moves with a magnet in it and determine the position the electromagnet has to be for proper

actuation. Hover over the end of the magnet facing the center of the mold, now move the electromagnet horizontally away from the magnet until the magnet no longer tries to contact the solenoid.

3. Once you reach this horizontal and vertical displacement position, if you move the solenoid closer vertically or horizontally, the magnet will connect with the solenoid. Now, make slight adjustments to see where the magnet actuates best (creates a curl motion and has both efficient vertical and horizontal movement). This can be entirely horizontal or vertical displacement, the goal is to introduce the tester to silicone movement.
4. Once you find the position you find most efficient, take horizontal and vertical measurements for the end of magnet to end of solenoid and top of silicone to bottom of solenoid. Record your results.
5. Repeat the steps for as many electromagnets and magnets you wish to test. Note that due to the permeability of silicone interfering with the magnetic fields, some of the solenoids/magnets may not create desired actuation.

I. C. Food Bolus Testing

Objective: To use an artificial bolus to test the moving capabilities of the artificial tongue model.

Phase I: Creation of the Artificial Bolus

Materials:

- Measuring cups
- Measuring spoons
- 3+ cups of water
    - 2 cups hot
    - 1+ cup cool
- Instant mashed potato mix
    - Idahoan Brand 4 cheese blend used for this specific experiment
- 8+ cups of cornstarch

Procedure:

1. Heat 2 cups of water to around boiling temperature
2. Measure out 1 cup of cool water with 5 tablespoons of cornstarch
3. Mix cool water and cornstarch into a cornstarch solution
4. Take the solution and add it to the hot water immediately after heating it to thicken the water
5. Once combined, mix the mashed potato mix into the hot water/cornstarch solution and combine until a mashed-potato-like substance is created.
6. Create another cornstarch solution using 3 tablespoons of cool water and 3 tablespoons of cornstarch
7. Add the new cornstarch solution to the potatoes to thicken it further
8. If necessary, create more solutions to thicken the potatoes

Phase II: Tongue Bolus Testing

Materials:

- Artificial Tongue Mold (with components)
    - Solenoids
    - Wires
    - Magnets
    - Flex sensor
- 3-D printed case for the electrical components (below) with silicone mold surrounding it

    - TinyDuino
    - Batteries
- Oral Cavity fixture (bottom jaw)
- Artificial Bolus
- Camera and camera set up
- Ruler
- Flat counter/table with a background that is clear enough to see movement of the tongue
- Lab Notebook

Procedure:

1. Set up the camera to view the actuation of the tongue from the side with a background that shows the tongue clearly. Add a ruler for measurements.
2. Set up the electrical components of the tongue in the 3-D printed case with its silicone mold and place it in the base of the oral cavity. Take a picture to show where all the pieces have been placed. Feed the wires through the slot in the box to be put into the tongue's components.
3. Set up the tongue in the oral cavity in the orientation it would theoretically be within a patient with the wires from the box. Take a picture to show the orientation of the tongue and its components.
4. Once both components are put together in the orientation it would be in the oral cavity (without turning them on), prepare the bolus
    1. For mashed potatoes:
        1. Prepare as said in the protocol*
        2. Weigh the solid to be around 5 -10 grams and record the actual weight

b. For other materials:

        1. Form the material(s) into a solid ball-like format
        2. Weigh the solid to be 5-10 grams and record the actual weight

b. Place the bolus on the middle-tip of the tongue before everything is turned on to ensure the bolus will not fall off before actuation

Turn on all components to prepare for actuation

Start recording

Place bolus on the center of the tongue on the force sensor.

From the ruler in the recording, measure how much the tongue moves and record.

Measure displacement with accelerometer wireling if possible, instead of external measurement devices.

I.D. Displacement Testing

Objective: To determine the displacement of the tip of the tongue due to magnetic actuation.

Materials:

- Tongue Mold (with TinyDuino Electronics)
- TinyDuino Accelerometer Wireling
- Arduino Uno Board
- Breadboard
- 3-pin Wires
- Power Source (USB to Arduino Board and hooked up to laptop)
- Lab Notebook

Procedure:

1. Label each device under test with a unique identifier for traceability purposes.
2. Connect the TinyDuino to your PC with a USB cable
3. Compile the code "Accelerometer Wireling" from TinyCircuits. When the TinyDuino has a green blinking light the upload was successful.
4. Place the Accelerometer Wireling at the tip of the tongue where the magnets are for actuation.
5. Power on the MOSFET Module by pressing on the force sensor and until an Analog Reading appears on the serial monitor.
6. Once the MOSFET is powered on and the tongue actuates, observe the serial monitor for the values in the x, y, and z axis for the measurement of displacement as the magnets actuates.

I. E. Flex Sensor Range Testing

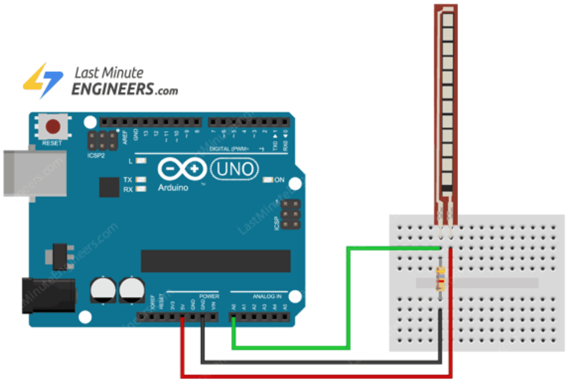
Objective: To determine the range of resistance values produced by the flex sensor on the prosthetic tongue when liquid and food comes in contact with the mold.

Materials:

- Tongue Mold (with TinyDuino Electronics)
- Flex Sensor
- Arduino Uno Board
- Breadboard
- 10KOhm Resistor
- Breadboard Wires
- Power Source (USB to Arduino Board and hooked up to laptop)
- Thickened Water
- Thickened Mashed Potatoes
- Lab Notebook

Procedure:

1. Label each device under test with a unique identifier for traceability purposes.
2. Connect the Arduino Uno to your PC with a USB cable
3. Compile the code “FlexSensorTest” from the teams 20-21 Github located here. When the Arduino Uno has a green blinking light, the upload was successful.
4. Connect the external circuit components and flex sensor as shown in the schematic and picture below:
    1. **Note:** additional help can be found online via this link https://lastminuteengineers.com/flex-sensor-arduino-tutorial/



5. Place the flex sensor under the center of the tongue mold under test.
6. Pipette 5ml of water on the center of the tongue. Careful to not wet any of the electrical components.
7. Record the resistance values in the lab notebook or save the data from the Arduino software.
8. Clean the water off of the tongue with a napkin and ensure the flex sensor has stabilized which means there is no change in resistance values.
9. Place the food on the center of the tongue.
10. Record the resistance values.
11. Remove food and clean tongue molde and ensure the flex sensor is not changing resistance before the final test.
12. Place 5mL of water and the food on the middle of the tongue.
13. Record the resistance values in the lab notebook or save the data from the Arduino software.
14. Remove food and liquid to clean the tongue mold.
15. Perform each test 3 times to run a statistical analysis on the range values of each test case.
16. Take the average, standard deviation, and identify an acceptable range for each condition of the tongue under test
17. Use this data to develop the switch case code for magnetic actuation.

I.F. Accelerated Aging Testing

Objective: To use accelerated aging techniques on the prototyped silicone tongue molds to show how prosthetic will age over time.

Materials:

- Tongue Mold (No Electronics)
- Controlled Lab Heating Oven
- Thermometer
- Flat Metal Pan (Cookie Sheet)
- Sharpie/Marker
- Lab Notebook

Procedure:

1. Label each device under test with a unique identifier for traceability purposes.
2. Preheat a controlled lab heating oven to 55 degrees Celsius.
3. When the oven reaches temperature, check the temperature manually with a thermometer and record the reading.
4. Place the device under test onto the flat metal pan with the tongue mold facing upwards.
5. Place the baking sheet into the controlled temperature heating oven.
6. Leave the samples in the oven for one week to minic approximately two months or eight weeks of accelerated aging.
7. After one week, remove samples and turn the heating oven off.
8. Inspect each sample and record observations (yellowing of device, material feels brittle, etc.)
9. Take pictures of each sample for recording purposes.
10. If able, place the electronic components into the tongue and power on to move the prototype. Record observations in a lab notebook.
11. Compare these samples to samples that are not accelerated aged and record observations.

Citations:

[1] "Accelerated Ageing", MET, 2021. [Online]. Available: https://met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing. [Accessed: 06-May- 2021].

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I.G. Body Temperature Testing

Objective: To use accelerated aging techniques on the prototyped silicone tongue to observe the effects of the body temperature.

Materials:

- Silicone Molded Tongue (No electronics)
- Controlled Lab Heating Oven
- Thermometer
- Flat Metal Pan (Cookie Sheet)
- Sharpie/Marker
- Lab Notebook

Procedure:

1. Label each device under test with a unique identifier for traceability purposes.
2. Preheat a controlled lab heating oven to 55 degrees Celsius.
3. When the oven reaches temperature, check the temperature manually with a thermometer and record the reading.
4. Place the device under test onto the flat metal pan with the tongue mold facing upwards.
5. Place the baking sheet into the controlled temperature heating oven.
6. Leave the samples in the oven for one week to minic approximately two months or eight weeks of accelerated aging.
7. After one week, remove samples and turn the heating oven off.
8. Inspect each sample and record observations (yellowing of device, material feels brittle, etc.)
9. Take pictures of each sample for recording purposes.
10. If able, place the electronic components into the tongue and power on to move the prototype. Record observations in a lab notebook
11. Compare these samples to samples that are not accelerated aged and record observations.

Citations:

[1] "Accelerated Ageing", MET, 2021. [Online]. Available: https://met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing. [Accessed: 06- May- 2021].

[2] "News Detail", MET, 2021. [Online]. Available: https://met.uk.com/Accelerated-Ageing-For-Medical-Device-Packs-What-Temperature. [Accessed: 06- May- 2021].

[3] "Medical Device Shelf Life Testing - Pacific BioLabs", Pacific BioLabs, 2021. [Online]. Available: https://pacificbiolabs.com/medical-device-shelf-life. [Accessed: 06- May- 2021].

[4] ”ASTM F1980 - 07(2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices", Astm.org, 2021. [Online]. Available: https://www.astm.org/DATABASE.CART/HISTORICAL/F1980-07R11.htm. [Accessed: 06- May- 2021].

II. Control Module Code

```
int fsrPin = A0; //Force Sensor Variables
int fsrReading;
int fsrVoltage;
unsigned long fsrResistance; //Voltage converted to resistance value which can be long.
unsigned long fsrConductance;
long fsrForce; //Convert resistance to force

///int electromagnet = 13; //Electromagnet is connected to digital pin 3
#define control 8
//int control = 8;
void setup() {
  // put your setup code here, to run once:
Serial.begin(9600);
pinMode(control, OUTPUT); //Make pin 3 the output
}

void loop() {
  // put your main code here, to run repeatedly:
  fsrReading = analogRead(fsrPin);
  Serial.print("Analog reading = ");
  Serial.println(fsrReading);

  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V (= 5000mV)
  fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);
  Serial.print("Voltage reading in mV = ");
  Serial.println(fsrVoltage);

  if (fsrVoltage > 0) {
    // The voltage = Vcc * R / (R + FSR) where R = 10K and Vcc = 5V
```

```
  // so FSR = ((Vcc - V) * R) / V        yay math!
  fsrResistance = 5000 - fsrVoltage;     // fsrVoltage is in millivolts so 5V = 5000mV
  fsrResistance *= 10000;                // 10K resistor
  fsrResistance /= fsrVoltage;

  digitalWrite(control,HIGH); // turn the MOSFET Switch ON
  delay(2000);// Wait for 2000 ms or 2 second
  digitalWrite(control,LOW);

  Serial.print("FSR resistance in ohms = ");
  Serial.println(fsrResistance);

  fsrConductance = 1000000;
  fsrConductance /= fsrResistance;
  Serial.print("Conductance in microMhos: ");
  Serial.println(fsrConductance);

  if (fsrConductance <= 1000) {
    fsrForce = fsrConductance / 80;
    Serial.print("Force in Newtons: ");
    Serial.println(fsrForce);
  } else {
    fsrForce = fsrConductance - 1000;
    fsrForce /= 30;
    Serial.print("Force in Newtons: ");
    Serial.println(fsrForce);
  }

 Serial.println("--------------------");
 delay(250);
}
```

```
  else {
    Serial.println("No pressure");
    delay(250);
      //digitalWrite(control,HIGH); // turn the MOSFET Switch ON
  delay(8000);// Wait for 2000 ms or 2 second
  digitalWrite(control,LOW); // Turn the MOSFET Switch OFF

 /// delay(2000);// Wait for 2000 ms or 2 second

  }
 }
```

III. Final Electrical and Magnetic Component Specifications

TinyDuino Processor Board:

- Arduino Compatible
- Atmel Atmega328P Microcontroller
- 32KB Flash, 2KB RAM, 1KB EEPROM
- Dimensions: 20 mm X 20 mm
- Power: USB or 3.3V Coin cell battery
- Operating Voltage: 2.7V-5.5V

Source:

"TinyDuino Processor Board", TinyCircuits, 2021. [Online]. Available: https://tinycircuits.com/products/tinyduino-processor-board?variant=14479558087. [Accessed: 06- May- 2021].

TinyDuino Accelerometer Wireling

- 3 Axis Detection (X,Y,Z)
- Operating Voltage: 3.3V
- Current: 139uA
- Dimensions: 10 mm x 10 mm
- Digital Resolution: 10 bit

Source:"Accelerometer Wireling - TinyCircuits", Learn.tinycircuits.com, 2021. [Online]. Available: https://learn.tinycircuits.com/Wirelings/Accelerometer_Wireling_Tutorial/. [Accessed: 06- May- 2021].

Keyes MOSFET Module:

- IFR520 MOSFET transistor
- Weight: 10g
- Dimensions: 1.25 in x 0.98 in x0.98 in
- Max load current: <5A
- Output Load Voltage: 0-24V
- Input Voltage: 3.3V, 5V

Source: Energiazero.org, 2021. [Online]. Available: http://www.energiazero.org/arduino_sensori/arduino%20irf520%20mosfet%20driver%20module.pdf. [Accessed: 06- May- 2021].

Walfront Force Sensor:

- Sensor ZD10-100
- Range: 0-500g
- Operating Voltage: 3.3V
- Dimensions: 100 mm x 10 mm x 25 mm
- Response time: <10ms
- Recovery time: <15ms

Source:

Amazon.com, 2021. [Online]. Available: https://www.amazon.com/gp/product/B07MHTWR1C/ref=ppx_yo_dt_b_search_asin_title?ie=UTF8&psc=1. [Accessed: 06- May- 2021].

Magnetic Solenoid:

- Operating Voltage: 12 V
- Operating Current: 1.26 A
- Resistance: 9.54 Ω
- Power: 15.1 W
- Max Time On: 5 sec.
- Dielectric Strength: 500 VRMS
- Maximum Stroke Length: 0.4 in.
- Applied Force Range: 14.0 - 1.6 oz.
- Outer Body Diameter: 0.25 in.
- Outer Body Length: 1.0 in.
- Core Diameter: 0.185 in.
- Core Length: 0.85 in.

N52 Magnets:

- Dimensions: 3/4 in. Length x 3/8 in. Width x 1/16 in. Height
- Material: NdFeB
- Grade: N52
- Magnetization Direction: Thru Thickness
- Weight: 0.0762 oz.
- Maximum Pull Force Against Gravity: 4.77 lbs
- Surface Field: 1698 Gauss
- Brmax: 14,800 Gauss

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