Development of a Soft Robotic Tongue Prosthesis

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Abstract:

Instances of oral cancer that prove resistant to radiation treatment or chemotherapy often necessitate glossectomies, the surgical removal of the tongue. The main detriment resulting from glossectomies is the loss of the tongue as an aid in deglutition and mastication, which makes consuming meals a lengthy and arduous process that limits patients to liquid based diets. Existing tongue prosthetics are static and used only for aesthetic purposes. There are no dynamic prosthetic tongues currently available for patient use. This project explores the creation of a dynamic prosthesis actuated by pneumatic networks (pneunets). These networks were implemented in three areas of the tongue, and then inflated for the purpose of creating a wave-like motion that mimics the motion of a tongue during deglutition. The prototype was subjected to a number of tests including displacement, internal pressure, ease of manufacture, and sterilizability. A finite element model was used to predict displacement values and the relationship to the applied pressure to validate the real life model. An oral cavity was constructed using MRI images and additive manufacturing to test the efficacy of the prosthetic's mechanics in aiding in deglutition. A system was also established to integrate the prosthetic tongue with a removable wire retainer. Design requirements for miniaturization were set based on the dimensions of the human tongue and oral cavity, and design requirements for mechanical actuation were set to imitate the mechanics of the tongue. Recommendations for implementing and validating the finalized design are presented.

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Glossary

Actuation - activation of a device
Anterior - towards the front of the body
Aspiration - the act of breathing in a foreign substance into the airway
Cephalometry - anatomical measurements of the interior and exterior of the head
Deglutition - the act of swallowing
Dysarthria - difficulty speaking
Dysphagia - difficulty swallowing
Glossectomy - the surgical removal of all or part of the tongue
Mastication - the act of chewing
Medial - near the centerline of the body
Prosthesis - artificial device that restores the appearance and/or function of a missing body part
Posterior - towards the back of the body

FEM - Finite element model
FEA - Finite element analysis
PLA - Polylactic acid, a material commonly used in 3D printing.
PVA - Polyvinyl alcohol, a water soluble material sometimes used to 3D print scaffolds for 3D prints
RPD - Removable partial denture
TTC - Triphenyltetrazolium chloride, a white, water soluble powder that turns bright red in the presence of metabolically active cells.

1. Introduction

The burgeoning field of healthcare has seen a proliferation of prosthetic devices meant to restore partial function of a body part that has been lost. Prosthetic legs help patients walk after an amputation and advanced robotics are even being developed to serve as prosthetic arms that can grasp cups and respond to user controls. Yet little progress has been made in developing a functional prosthesis for a tongue.

Oral cancer is the eleventh most common type of cancer in the world. There has been a slight decline of oral cancer globally, but the rates of tongue cancer is increasing. In 2012, 369,200 new cases of oral cancer were reported worldwide [1]. According to the World Health Organization and The Oral Cancer Foundation, the annual diagnosis rate of oral cancer is now close to 450,000 people [2]. Oral cancer is expected to afflict 53,000 people and kill 10,000 people in 2020 in the United States alone [3]. It is estimated that 90% of all oral cancers are caused by tobacco use and excessive alcohol consumption [4]. Treatment of oral cancer is typically a multidisciplinary approach that involves surgeons, radiation and chemotherapy oncologists, and dental practitioners [2]. Radiation therapy and chemotherapy are used in combination with surgery to remove cancerous cells in patients. Oral cancer diagnoses often result in a glossectomy, which is the surgical removal of all or part of a patients' tongue [3]. Glossectomies often lead to a loss of speech and critical impairment of deglutition and mastication in patients [5].

There are several types of static prostheses that mimic the appearance of a tongue in a glossectomy patient, but do not aid the user in swallowing or speaking. These prostheses are shown in Figure 1 below. Figure 1A is a silicone denture prosthesis, which consists of a silicone "tongue" and acrylic dentures [6]. Figure 1B is a maxillary obturator prosthesis, which is used when the user retains some of their teeth [7]. Figure 1C is a magnetic cast prosthesis, which has magnets implanted into the user's oral cavity and a silicone tongue is attached using those magnets [8]. Figure 1D is an implant supported prosthesis, which is the most invasive method as it is attached to the user's jaw. It has funnel shaped contours to direct food into the user's mouth [9].

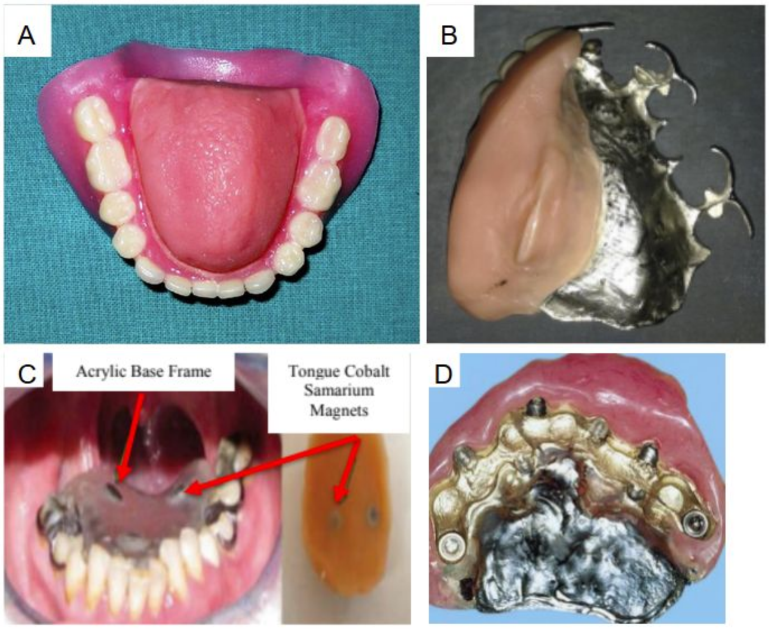

Figure 1: Different types of tongue prostheses. (A) Full denture prosthesis, reproduced as is from [6]. (B) Maxillary obturator prosthesis, reproduced as is from [7]. (C) Magnetic cast prosthesis, reproduced as is from [8]. (D) Implant supported prosthesis, reproduced as is from [9].

Glossectomy patients are able to adapt to these prostheses over time to regain speech and deglutition functionality, but there are no prostheses currently available that seek to aid users in these functions. Araya [10] developed a proof of concept model of a soft robotic tongue that mimicked the motion of the tongue to aid in deglutition, creating the first dynamic prosthetic tongue. Araya's work serves as the basis for this project. We hoped to expand on the original prototype by scaling it down to fit inside a 3D printed oral cavity, fixate the tongue prototype into the mouth using a retainer, and create a control module that can reliably actuate the tongue and record motion data. We verified the design of the tongue by simulating the model in abaqus[11], and planned to test the final prototype. We also maintained Araya's original goal of creating a prosthesis that can actuate in 1 second, which is the approximate time it takes a human to swallow [12]. Thus, the goals of the project are as follows:

1. Design: Create a tongue prosthesis that can actuate in 1 second.
2. Fixation: Integrate the retainer and prosthesis into the oral cavity
3. Safety: The prosthesis must be safe to put in a human mouth.
4. Control: Create a control and testing module for the tongue prosthesis.
5. Model: Validate the tongue model through simulation and testing of the physical prototype.

With these five goals met, we would establish that a prosthetic tongue could be made that would aid in deglutition. Future goals are to miniaturize a more advanced prototype that could feasibly be used by a patient while the current work focused on creating a bench prototype and the system to test it.

The report is organized as follows: Chapter 2 discusses the findings of a literature review on the anatomy and physiology of the tongue, an overview of oral cancer and glossectomies, a brief introduction to soft robotics, and a summary of previous work. Chapter 3 outlines the project requirements and methodology for creating the prosthetic tongue. Chapter 4 describes the design process of the tongue prosthesis, and Chapter 5 describes the design of the control module created to evaluate the prosthesis. Chapter 6 discusses the final design verification for the tongue prosthesis and the results of simulations conducted in abaqus. Chapter 7 discusses the final design validation, including the economic and environmental impact of the prototype. Chapter 8 evaluates the tongue prosthesis and control module against the project goals stated above. Chapter 9 provides recommendations for future work on the tongue prosthesis and control module, as well as the conclusion of our work.

2. Literature Review

In this chapter, we present our background research. We first start with a discussion of the anatomy and physiology of the tongue. We then provide an overview of oral cancer and the current rehabilitation methods used to help patients after glossectomy, followed with patient experiences with and without a prosthesis. Afterwards, we provide a review of previous work done on this specific project.

2.1 Native Anatomy & Physiology of the Tongue

When designing prosthetics to replace the function of a natural body part, the best place to start is with an understanding of both the form and function of the lost anatomy. Accompanying this are the design constraints presented by the remaining portion of the native organ, if there is any left. While the tongue is a highly functional organ, the restoration of deglutition was of principal importance, and so the particular anatomy associated with that process received special attention. Other functions such as aiding in mastication and speech were considered, but proved too complex to be within the scope of the project at this time. In terms of the dimensional constraints presented by the mouth, these can vary greatly from patient to patient. Surgeons attempt to remove as little tissue as possible, but sometimes the whole of the tongue and its associated musculature must be removed. This was the case considered for this project, as it presented both the most generous available dimensions, and the greatest loss of functionality. [13]

2.1.1 Intrinsic and Extrinsic Muscles

Anatomically, the tongue is generally bisected medially and treated as two halves, each with mirrored innervation, vasculature, and musculature. The musculature is of chief importance as it is the restoration of its function that represented the primary goal of the project. The muscles on each side of the tongue can be further divided into two groups, the intrinsic and extrinsic muscles. The intrinsic muscles, shown in Figure 2, lie within the body of the tongue itself and are named for the directions in which they run, being the superior and inferior longitudinal, transverse, and vertical muscles.

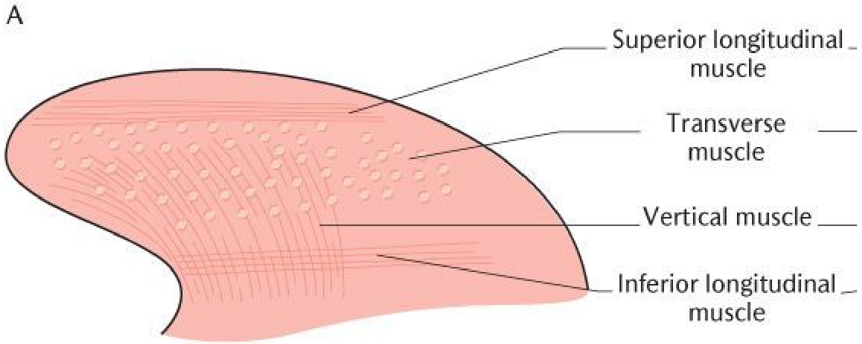

Figure 2: Intrinsic tongue musculature. Reproduced with modifications from [14].

The extrinsic muscles lie outside the tongue proper and are affixed to bony processes of the skull and hyoid bone, shown in Figure 3. There are many extrinsic muscles, such as the geniohyoid seen in Figure 3, but only the largest and most involved were considered for this project. Firstly there is the genioglossus, which begins just inside the chin, running posteriorly and down to the hyoid bone just above the larynx. The styloglossus begins near the back of the tongue and runs up to terminate at the skull anterior to the ear. The hyoglossus starts in roughly the same place as the styloglossus but runs down instead of up, terminating at the hyoid bone. Finally the palatoglossus straddles the tongue, which defines the arch at the back of the mouth and interacts with the soft palate.

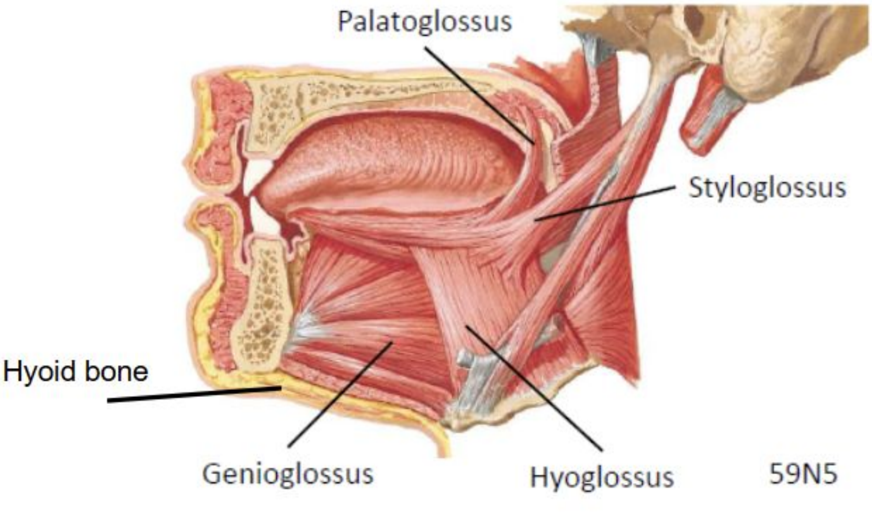

Figure 3: Extrinsic tongue musculature. Reproduced with modifications from [15].

In general, the intrinsic muscles perform the smaller more nuanced movements of the tongue, particularly those involved in speech, and the extrinsic muscles are responsible for gross motor movements such as raising the entire body of the tongue or sticking it out past the teeth

[16]. In actuality the physiology is more complex and subtle than this, but for the purposes of this project, the simplified paradigm was sufficient.

2.2 Oral Cancer, Glossectomy, and Rehabilitation Approaches

In the case of oral cancer, it is common that patients will experience relapse as most oral cancers are neither caught nor diagnosed until later stages, increasing the chance of metastasis and spread to other areas of the body [2]. While there are only approximately 53,000 new cases diagnosed in the United States per year, worldwide, this cancer is much more widespread, impacting 450,000 new individuals per year. When early-stage oral cancer patients are treated, a combination treatment of radiation and chemotherapy is most common and there is a small likelihood that these patients will experience any major anatomical changes to the oral cavity or tongue. For patients who are treated for later-stage oral cancers, the probability that glossectomy will be required to limit future metastasis is much higher, leading to significant life changes such as difficulty swallowing and speaking. After surgical intervention, these patients will often require rehabilitation to assist them in adjusting to their new lifestyle.

2.2.1 Glossectomy

While glossectomy is a common treatment method for later stages of oral cancer, there are three main forms of glossectomy and many different approaches to this surgery [2]. In the case of a small tumor, a partial glossectomy is often performed, removing less than half of the tongue. Larger tumors often warrant removal of larger portions of the tongue, with a hemiglossectomy removing half of the tongue and a full glossectomy removing the entire tongue and its base. As full removal of the tongue can lead to complications such as difficult or unclear articulation of speech, difficulty or discomfort while swallowing, and inhaling foreign objects, patients may also undergo procedures such as reconstructive surgery, surgical removal of some or all of the larynx (laryngectomy), an insertion of a breathing tube (tracheotomy), removal of lymph nodes and surrounding tissue from the neck (neck dissection), or the removal of all or part of the jawbone (mandibulectomy) [17]. Regardless of other surgical procedures performed, full glossectomies often warrant more advanced rehabilitation than either a partial or hemiglossectomy to help patients adjust to life and learn how to eat and communicate without the use of their tongue.

When a glossectomy is performed, surgeons can choose from a number of techniques, depending on the size and severity of the tumor. Small tumors can typically be removed transorally, or solely through the mouth. In cases where surgery is required at the base of the tongue, transoral surgery can be performed with lasers or robotic assistance. In cases where the base or back of the tongue need to be removed, it is common for a mandibulotomy to be performed, during which the mandible is split so that it can swing to the side while the surgeon removes the tongue, shown in Figure 4. After this procedure, the surgeon affixes the jaw back in place using plates and screws. In cases where surgeons or patients wish to avoid splitting the mandible, a transcervical approach with pharyngotomy is performed by making an incision through the neck and pharyngeal wall and accessing the tongue through this incision. While glossectomy patients may undergo any of these surgeries to remove tumors, each cause is unique, leading to the wide variety of surgical techniques for tumor removal and rehabilitation [17].

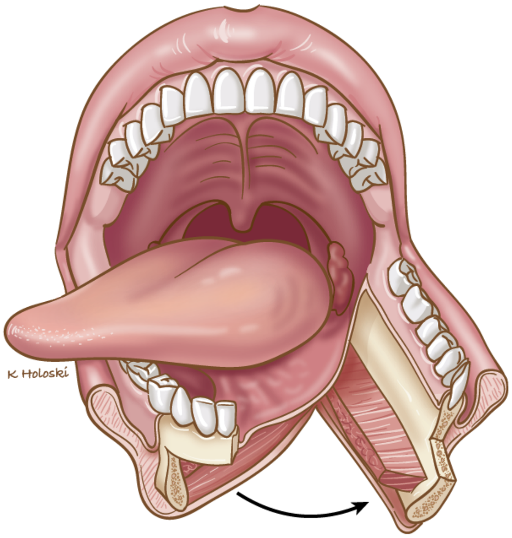

Figure 4: Example of mandibulotomy as a surgical procedure. Reproduced as is from [18].

2.2.2 Current Surgical Rehabilitation Approaches

After a total glossectomy is performed, patients often require reconstructive surgery in an effort to prevent complications and assist the patient in maintaining a more normal lifestyle [17]. The goal of the surgical reconstruction of the floor is to aid in the retention of fluids and food, and is typically done with flesh from other parts of the body

These reconstructive surgeries are often planned and carried out by a team of specialists focused on head and neck surgery and reconstruction, as well as speech pathology. During the planning process for reconstructive surgery, patients discuss their options with doctors to determine if they would prefer surgical reconstruction of the tongue or the use of an oral prosthesis. This determination is often based upon the patient's health record as reconstructive surgeries can be lengthy and require longer recovery times. Surgical reconstruction methods can include skin grafts and flaps [17].

The double tongue technique is one option for glossectomy patients who have their pharynx intact. This surgery involves using parts of the abdominal muscle to create a double layer flap that fills the bottom of the oral cavity [19]. However, other techniques must be explored for other glossectomy patients who were unable to retain their pharynx.

One surgical option for partial glossectomy patients is the mushroom shaped flap technique. In this particular surgery, the surgeon uses the anterolateral thigh perforator flap to reconstruct the bottom of the mouth as well as the tongue for aesthetic purposes [20]. Yet, the reconstructed tongue does not have any of the functionality of the one that was removed.

While various flap reconstructive surgeries are available, patients may also undergo reconstructive surgery via skin grafts. For this type of reconstruction, a split-thickness or full-thickness technique may be used. In the split-thickness technique, the epidermis and dermis are removed from a donor site, such as the thigh, upper arm, or buttock. In the full-thickness technique, all layers of the skin are removed from the donor site, such as from behind the ears or on the inside of the upper arm [17].

While these surgeries do increase the quality of life slightly, they do not replace the functionality or movement of the tongue. Surgical reconstructions do not provide the proper motion needed to move a bolus from the front of the mouth to the back of the mouth, nor do they provide the adequate pressure needed to move the bolus [19]. Such reconstructions can also restrict the pharyngeal opening, causing more difficulty in swallowing. It is also important to note that the possibility of surgery is dependent on the severity of the cancer. In very severe cases, surgical reconstruction of the mouth floor and tongue may not even be an option at all.

2.2.3 Static Prostheses

Static prostheses are used when too much of the oral cavity has been removed for reconstructive surgery to be an option for rehabilitation. Such devices only serve aesthetic purposes.

2.2.3.1 Full Denture Prosthesis

One such prosthesis is the full denture prosthesis, which serves as a reconstruction of the tongue and the teeth as seen in Figure 4. This particular model was made for a patient who had undergone a total glossectomy and a mucocutaneous flap reconstruction. The denture itself consists of a silicone tongue with acrylic teeth, and is held in place with suction between the denture and the floor of the mouth that is further facilitated by saliva. After six months of use, there were noticeable improvements in comfort and oral function. However, the denture does require several trials and readjustments in order to get the best fit and improve effectiveness [6].

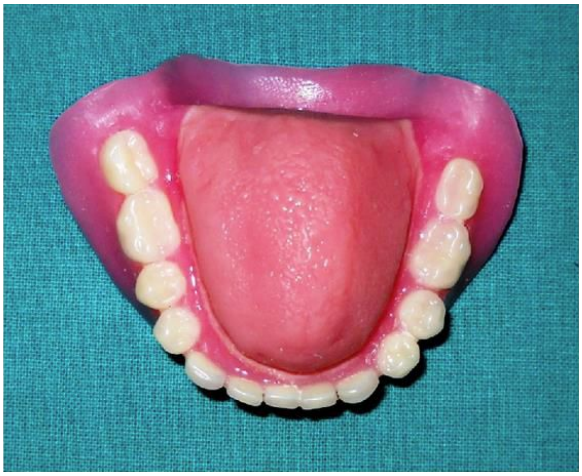

Figure 5: Full denture prosthesis. Reproduced as-is from [6].

2.2.3.2 Maxillary Obturator

In the event that some of the teeth are still intact, a maxillary obturator is an option. Made of acrylic and stainless steel, obturators are supported by the remaining teeth and palate with Adam's and C clips. An apt device for restoring chewing, swallowing, resonance, and speech with the aid of therapy, the use of the device is dependent on the severity of the maxillofacial defect and the recovery of the affected tissues. An image of the device can be seen in Figure 5 [7].

Figure 6: Maxillary obturator. Reproduced as is from [7].

2.2.3.3 Magnetic Cast Prosthesis

A similar option to the maxillary obturator is the magnetic cast prosthesis, shown in Figure 6, which is made out of a polished cobalt removable partial denture (RPD) with a resin base. The device also has a tongue component, made of silicone, attached to the base with cobalt-samarium magnets. With the aid of said tongue component, the prosthesis is able to improve swallowing and speech. Furthermore, the tongue component can be removed for cleaning. However, the magnets are still prone to corrosion and wear. Pathologist evaluation of the prosthesis is required to evaluate patient speech in conjunction with the use of the prosthesis [8].

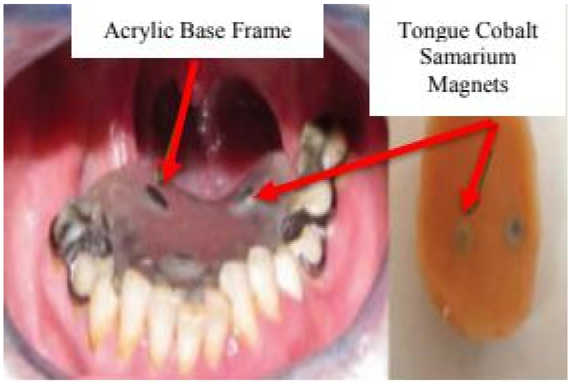

Figure 7: Magnetic Cast prosthesis. Reproduced as is from [8].

2.2.3.4 Implant Supported Prosthesis

The final and most invasive option is the implant supported prosthesis, shown in Figure 7. The prosthesis itself has semi-anatomic resin teeth and funnel-shaped contours that serve to direct food into the esophagus. The entire device is supported by five endosseous implants that have been secured to the patients jawbone. In order for the patient to maintain proper oral hygiene, the prosthesis is removable.After two years of use, one patient was able to eat semi-solid food. While being able to consume a non-entirely liquid diet is beneficial and a stark improvement, speech is not improved due to no tongue-like structure in this particular prosthesis [9].

Figure 8: Implant supported Prosthesis. Reproduced as is from [9].

In general, these current static prostheses do not provide the dynamic functions of the tongue such as facilitating swallowing and speech. As a result, in order to improve the quality of life of a glossectomy patient further, it is crucial to develop a device that takes into account the missing dynamic motions of the tongue as well as the static function.

2.3 Glossectomy Patient Experiences

As a glossectomy can pose a threat to an individual's lifestyle and basic functioning, some may be hesitant to undergo surgery to treat oral cancer before exhausting other treatment methods. While chemotherapy and radiation can be effective in some cases, advanced stage oral cancers often necessitate surgery as such therapies are less likely to be effective for tumors that have already begun to metastasize. Patients who choose to forego glossectomy often find themselves needing to have the procedure done after a different treatment has started, potentially leading to complications as chemotherapy and radiation take their toll on the patient's body and overall health [21]. While each glossectomy case is unique, surgeons may try to limit how much of the tongue they remove in order to limit any aesthetic or functional changes. However, as advanced-stage cancers are likely to metastasize, this may not be possible, leading to a need for a prosthesis that will serve as a functional tool to assist the patient in their day to day life [22].

2.3.1 Experiences with and without Prostheses

Although reconstruction is common and static prostheses are available, some individuals may find these devices are cumbersome and uncomfortable, highlighting the need for prostheses that are both more functional and wearable. Typically prostheses simply function to decrease the space between the upper palate and the residual or reconstructed tongue, helping increase tongue to palate contact. While this helps many individuals, the usefulness is dependent on a patient's tongue mobility. In cases where patients practice chewing, swallowing, and speaking soon after surgery, it may be easier to continue to practice these skills without the use of a static prosthesis so that they do not have to relearn how to complete all these tasks once they are fitted for the prosthetic. Patients who begin rehabilitation soon after surgery have a higher likelihood to build muscle strength and adjust to anatomical changes in the oral cavity, making the use of static prostheses unnecessary.

2.3.2 Swallowing without a Prosthesis

After glossectomy, it is common for patients to experience difficulty chewing and swallowing as the tongue plays a crucial role in helping to move food through the mouth. While some partial glossectomy patients are able to work back up to eating some solid foods, this is very difficult for those who have had a full glossectomy. Patients noted that, without the help of the tongue, they essentially had to relearn to eat or resort to maintaining a liquid-based diet [21]. In cases of a liquid based diet, a patient is typically restricted to substances that are thin enough to pour through a funnel. These patients have to pour these liquids into the mouth while tilting the head back so that the mouth acts like a funnel to direct the fluid on its path to the digestive system. Those restricted to liquid based diets must not only be careful of how thick the liquid is, but also of how hot the liquid is as too hot liquid can make it much more difficult for the patient to swallow [23]. Glossectomy patients who do not have enough mobility to relearn to eat or who do not find static prostheses easy to use often are forced onto a long and difficult path of learning how to swallow, or even eat, without the presence of the tongue.

2.4 Introduction to Soft Robots

Soft robotics is a subfield of the robotics industry that focuses on developing robots from compliant materials [24]. Such materials include shape memory alloys, electroactive polymers, flexible plastic sheets, and silicone rubbers. Soft robots can actuate more smoothly and in more directions than traditional rigid-bodied robots. Our project is focused on soft bodied robots that actuate through the use of fluidic elastomers, also referred to as pneumatic networks or pneunets. Pneunets are a type of soft actuator that consists of a series of channels that have been embedded in an elastomer. When pressurized, the channels inflate to create motion. Some examples of pneunet actuated robots include an autonomous bio-inspired snake robot created by Onal and Rus [25] and a parabolic soft actuator whose movement was inspired by a caterpillar created by Liu, Wang and Cong [26]. The goal of Onal and Rus's work was to develop a soft robotic snake that was able to undulate in a similar way to its biological counterpart using four bi-directional pneunet actuators in series. The robot also had passive wheels between segments to generate frictional anisotropy [25]. An image of the final robot is shown in Figure 9A.

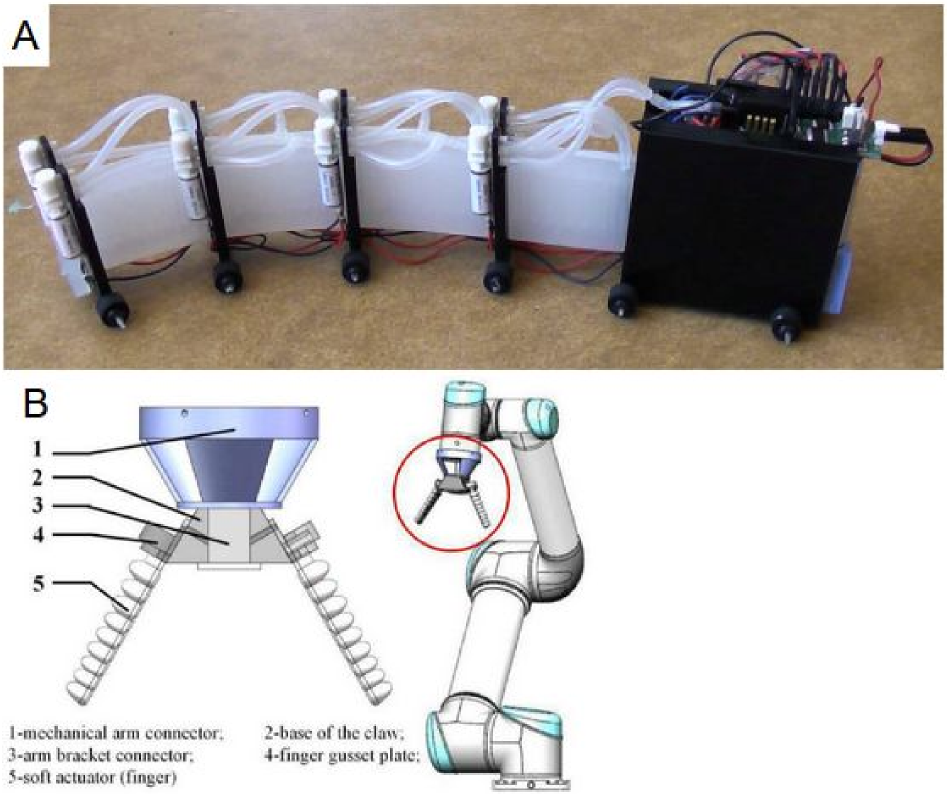

Figure 9: Examples of pneumatic-actuated soft robots. (A) Soft robotic snake capable of mimicking the motion of a biological snake. Reproduced with permission from [25]. (B) Components of caterpillar-inspired soft robotic gripper. Reproduced with permission from [26].

The caterpillar-inspired soft robotic gripper developed by Liu, Wang and Cong was designed to reduce stress concentration and increase surface area grip, which are common problems among pneunet actuators. An image of the soft robotic gripper is shown in Figure 9B. In order to increase the surface grip, pneunet channels were designed based on the geometric structure of a caterpillar. The soft actuator was cast in silicone rubber using 3D printed molds. The first layer of the actuator was made of a non-extendable material, which forced the actuator to curve inward as the pneunets expanded. This is a common feature of pneunet actuated robots, and was used in the initial iteration of this project. Chapter 2.5 will discuss the previous work of Araya [10] and Chen [27] in further detail.

2.5 Previous Project Iterations

This project is the continuation of two previous projects aimed at creating a dynamic tongue prosthetic. The first, a master's thesis by Francis Darmont Araya [10] established the ability of the pneunet actuator to create a motion similar to the tongue. A related Major Qualifying Project (MQP) by Logan Chen [27] developed a miniaturized cam system to actuate the tongue prosthesis but discovered that a mechanical solution was not feasible due to the amount of vibration that a user would experience.

2.5.1 Araya Thesis, 2019

Araya [10] established a proof of concept prototype of a tongue prosthesis that was actuated via pneunets to create a wave-like motion similar to a human tongue. The following sections discuss the design of the tongue and the results of his work.

2.5.1.1 Design

Araya developed a silicone tongue design which consisted of a rectangular body and a semi-circle front, as shown in Figure 10. The tongue actuated via pneunet channels, which were divided into three discrete segments. The segments were inflated via channels on the back of the tongue, which enabled the segments to be inflated one at a time in order to create a wave-like motion. The channels were molded in a thick silicone layer, and a second, thinner silicone layer was attached onto the first to create a series of chambers with the only environmental exposure being at the end of the shaft. The initial prototype Araya created was 11.7 cm long, 7.5 cm wide and 1.3cm thick, was made of Silicone EcoFlex 00-30 [28], and weighed 110.5 grams.

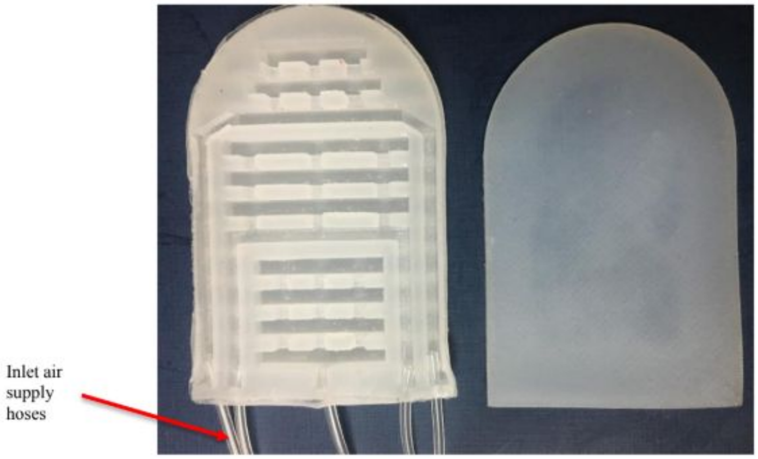

Figure 10: First iteration of the tongue prosthesis. Reproduced as is from [10].

The next generation of the prosthesis, shown in Figure 11, was half the size of the original prototype. The number of pneunet chambers was significantly reduced, and a single shaft connected each section to the rear of the tongue.

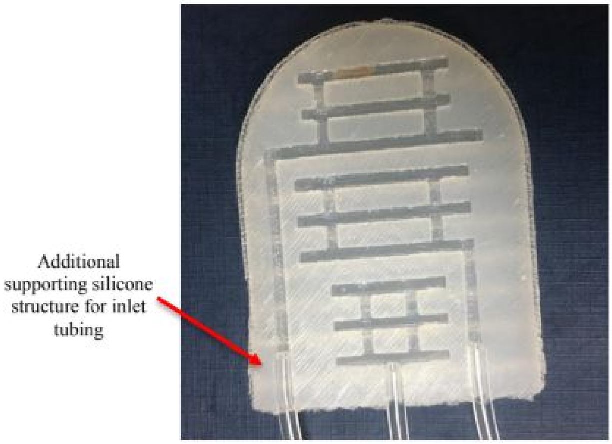

Figure 11: Internal structure of the second generation of Araya's prosthesis. Reproduced as is from [10].

A third generation of the prototype was designed by measuring the dimensions of a dental mold of a mouth so that the tongue could fit inside the oral cavity. Each section of pneunet channels was reduced to two channels and the overall prosthesis was closer to a triangular shape. The new prosthesis was now only 6.5cm long, 4.8cm wide, and 0.6cm thick and weighed 5.5 grams but did not account for tubing, so holes were poked into the bottom of the tongue to insert the tubes that would supply the air. This prototype is shown in Figure 12.

Figure 12: Third generation of Araya's prosthesis. Reproduced as-is from [10].

2.5.1.2 Controls

Araya created a test bench to inflate each pneunet channel, shown in Figure 13. It was controlled via an Arduino UNO [29], three 5V air pumps and three 2-position, 3-way solenoids to direct air into the channels. The air pumps were connected directly to the 5V power supply on the UNO so they were always on. The solenoids were connected to digital pins on the UNO to direct air into each pneunet channel. The test bench was used to test the inflation time of the prototype and measure the displacement of each section of the tongue.

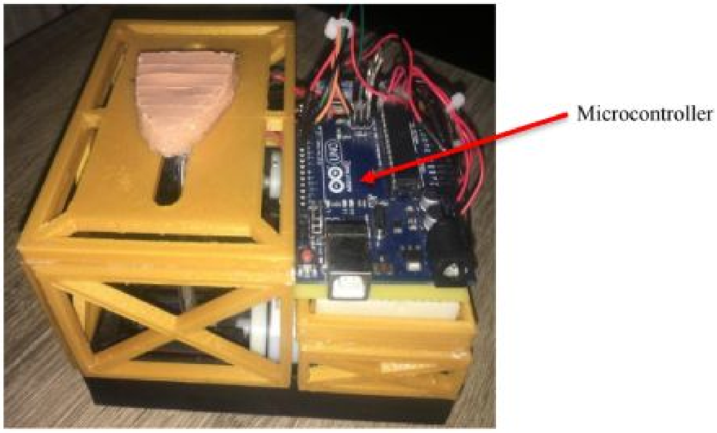

Figure 13: Test bench set up, including the tongue and the Arduino UNO microcontroller. Reproduced as-is from [10].

2.5.1.3 Results and Limitations of Data

Araya's work established a proof of concept prototype for a human-tongue sized pneunet actuator that was capable of producing a wave-like motion similar to the movement of a tongue. However, there are some limitations to this prototype. The most notable limitation is the size of the tongue prosthesis. While the tongue was designed to be able to fit into a human mouth, it is still slightly too large to do so. Future prototypes will have to be further condensed for in vivo applications. Additionally, Araya was unable to develop a method to integrate the prosthesis into a mouth. Integration into a mouth is an important aspect of any prosthesis and must be considered in the future.

The next limitation is that the model did not demonstrate the necessary expansion characteristics. As seen in Figure 14, the T1, T2, T3, and T4 points of the tongue have particular displacements in the motion of a normal tongue. The soft robotic tongue prototype contained the equivalent of the T2, T3, and T4 data points, each of which were less than the values reported by Tasko et al [12]. These values were found by having participants swallow 2mL and 10 mL volumes of water while the motion of the tongue was recorded with the aid of attached gold pellets. The front (T2), middle (T3), and back (T4) sections of Araya's prototype reached displacements of approximately 10.6 mm, 11.4 mm, and 6.35 mm respectively as shown in Figure 15.

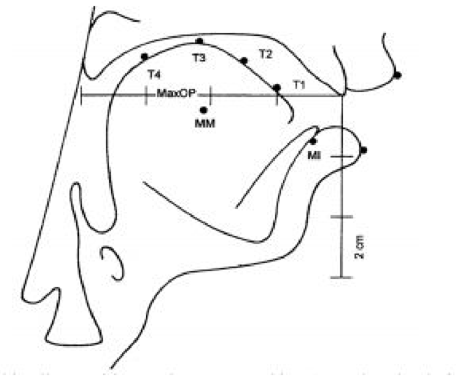

Figure 14: Position of T1, T2, T3, T4. Reproduced as from [12].

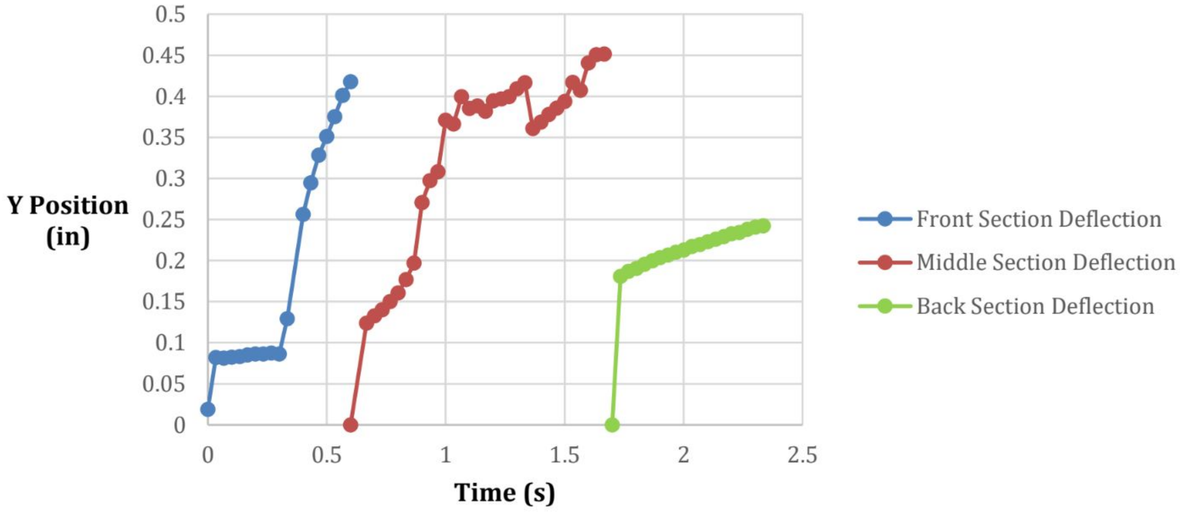

Figure 15: The displacement vs time graph generated by Araya's prototype. Reproduced as is from [10].

The displacement data found for Araya's prototype is not aligned with the data found by Tasko et al; different sections of the prototype fall in different ranges of displacement data for both male and female subjects. The results of Tasko et al.'s findings and Araya's experimental data are shown in Table 1. Arya's T2 experimental data matches reported data for 10mL male, which is the state representing the maximum necessary range. The T3 experimental data matches 2mL male and 10mL female reported data, which is the middle range. Meanwhile, the T4 experimental data is outside the range of acceptable values found by Tasko et al. The displacement of T3 and T4 for Araya's prototype is insufficient for a prosthesis. This could be due to limitations of the displacement measurement software that was used to gather data but it is likely a result of two factors: material and design. The material and related pressure applied to the material could have been insufficient to produce the necessary deflection, waranting discovery of a new material with a lower modulus but higher yield strength.

Table 1: Tongue displacement data collected from [12, 10].

	Mean Displacement (mm)			Mean Duration (ms) of half movement		
	T2	T3	T4	T2	T3	T4
2ml Female	4.7	6.1	12.0	147	131	146
10ml Female	6.4	10.0	14.1	139	152	151
2mL Male	5.3	9.6	15.0	137	167	169
10mL Male	10.5	15.2	19.1	193	179	192
Araya Prosthesis	8.9	11.4	6.4	600	1100	700

Throughout the design process, several prostheses broke or fractured during fabrication or actuation, and as a result the walls of the prototype were made thicker. Thicker material requires more input pressure to achieve the same level of displacement as the thin-walled prototype. A material with a higher yield strength would allow the wall thickness, and therefore the necessary input pressure, to be reduced. Secondly, the design allowed for displacements in the directions other than what was being measured. The vertical displacement of the tongue prototype determines whether the artificial tongue reaches the top of the mouth during expansion to move the bolus backwards. Araya's soft robotic tongue also experienced lateral expansion, due to the fact that the pressure in the chambers was applied equally to each side of the chamber walls, and that the chambers were square. It is unknown if the lateral expansion was significant enough to measurably alter the magnitude of the vertical displacement, but no such testing was done to confirm this. In order to reduce lateral expansion, the sides of the prototype should be constructed out of an inextensible material.

The next limitation of the prosthetic tongue was leakage. The mold used to create the soft robotic tongue consisted of two molded silicone parts that were glued together. When air flowed through the pneunet channels, it applied force on the glued layers and often caused ruptures within the tongue. When we retrieved the prototypes Araya created and analyzed them for current use, we found that only two prototypes were able to inflate, and only one was able to fully inflate. We examined the prototypes that did leak air and found that all but one had a leak that occurred at a glued connection.

The primary result from this work was that a pneunet actuated tongue can replicate a wave-like motion that is akin to that of an ideal tongue. Future designs should explore improved materials and material related design, better connections between the pneunets and the tubing, and miniaturization of the prototype. Additional tests should be conducted on future prototypes. These tests include but are not limited to: measuring the input volume and pressure of air within the pneunet channels, measuring the output force that the prototype is able to exert on the oral cavity, and evaluating whether or not the prosthetic tongue is capable of moving a bolus of food from the front of the tongue to the back of the mouth. Since these tests were not conducted on Araya's soft robotic tongue, it is difficult to know if the existing system will work as it is or if improvements need to be made in future work. For example, despite the vertical displacement of the T2,T3, and T4 points of the prosthesis being lower than associate literary values, the bolus could still move to the back of the tongue, or the differences in displacement could be significant enough to prevent proper function of a prosthesis. The limited amount of data available also presents difficulties in measuring and simulating the forces that act upon the prototype tongue and that the actuation system needs to exert in order to complete the wave-like motion.

2.5.2 Chen 2019 MQP

Chen [27] explored several iterations of a linkage driven tongue prosthesis, including a slider crank and a camshaft. Chen was able to create a model of a camshaft based actuation mechanism using 3D modeling software shown in Figure 16. Chen did not create a physical prototype of the camshaft due to its small size and time constraints.

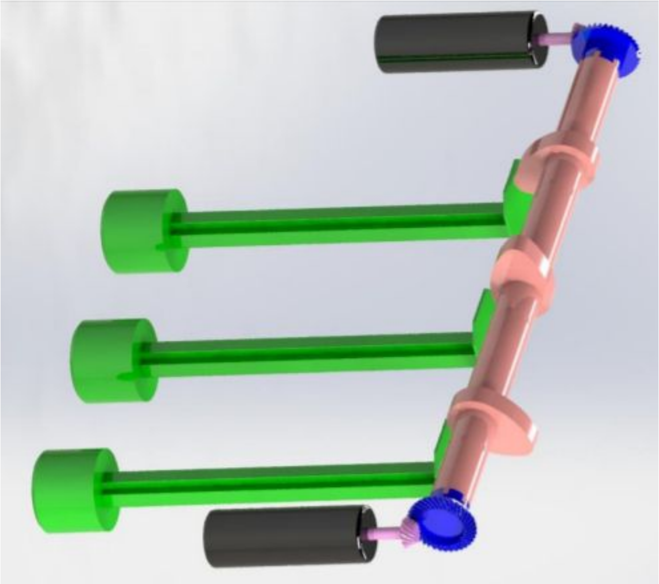

Figure 16: Isometric view of camshaft mechanism without denture. Reproduced as is from [27].

Chen also attempted to create a centrifugal pump to inflate the soft robotic tongue using the Pneu-Net channel design from [10]. A 200% scale prototype was created by machining an 8 blade impeller out of aluminum and 3D printing a housing. However, the centrifugal pump would have to run at approximately 480 rotations per minute in order to generate enough volume flow to actuate the soft robotic tongue. Chen determined that this speed would “create an uncomfortable vibration sensation inside the mouth” [27] and was therefore not appropriate for use in patients.

Chapter 3. Project Requirements and Methodology

This chapter will go into the specific design requirements used as metrics for the success of this project. The knowledge gaps and areas for improvement with respect to the previous work on this concept will be presented, as will the parameters for improvement and how they were decided upon, both conceptually and quantitatively. Procedures set forth for meeting the established design standards will also be laid out.

3.1 Initial Client Statement

The client needs a prosthesis that will help them swallow food at a pace that allows them to eat a full meal in a respectable amount of time. When patients use existing prosthetics, meals take a sizable amount of time. Thus, they need this prosthesis to be able to move food to their throat at a pace closer to that of the tongue than previous prostheses.

3.2 Missing Knowledge and Goals of the Project

Concluding from the work of Araya and Chen, a feasible replacement for the tongue has been created. However, there are still improvements that can be made. To begin, neither Araya nor Chen measured the internal pressure of the pneunets needed to actuate the motion of the tongue. As such there is currently no ability to assess the relation of pressure and displacement. This means simulations can not currently be used to validate design decisions accurately or predict failure in a model and more importantly, there is no data to support selection of controls such as pumps or selection of pressure gauges.

Identifying the relationship between the internal pressure and the displacement of the points on the aforementioned points is important because the relationship helps identify problems with the tongue. For example, a sign of a leak in a pneunet could be a point reaching a lower displacement than expected for the given pressure. Additionally, we were unable to find pneunet actuation studies that reported pressure testing as well as recorded pressure measurements. Finding the relationship between pressure and displacement also allows us to determine how much pressure is required to inflate the pneunet to the desired height and then create design constraints based on the pressure.

Furthermore, the current design of the tongue is not made to be integrated into the oral cavity; there is no existing mechanism to integrate the tongue into the mouth of a patient. Additionally, the components of the control system are currently too large to be comfortably integrated into the mouth or carried by the user externally.

As stated in Chapter 1, the overarching goals of this project are to:

1. Design: Create a tongue prosthesis that can actuate in 1 second.
2. Fixation: Integrate the retainer and prosthesis into the oral cavity
3. Safety: The prosthesis must be safe to put in a human mouth.
4. Control: Create a control and testing module for the tongue prosthesis.
5. Model: Validate the tongue model through simulation and testing of the physical prototype.

These goals guide the creation of safe and functional components that will together make a complete prosthesis. The following sections will assess needs and requirements to achieve these goals.

3.3 Standards

The International Organization for Standardization (ISO) has a set of standards for prosthetics and orthotics, ISO/TC 168. These standards focus on limb prostheses and orthoses and do not include information for non traditional prostheses such as a prosthetic tongue [30]. The testing procedures outlined in this standard were referenced as a general guide but not directly implemented. ISO 10139-2:2016 specifies requirements for softness, adhesion, water sorption and water solubility for soft denture lining materials that may be used for maxillofacial prostheses. These requirements were taken into account when designing the tongue prosthesis [31].

ASTM D575-91(2018) outlines standard test methods for rubber properties in compression, which were used as a guideline for material testing done on the soft robotic tongue [32]. We were unable to find standards for rubber properties in extension to reference for testing.

3.4 Needs Analysis

The ultimate goal of the prosthetic tongue is to aid an individual in swallowing food. To do this, it has many needs relating to form, function, control, and implementation. For form it needs to be able to fit into a mouth with room for food to be inserted. The human mouth is variable and the size is different from person to person, so this project has modeled a mouth from MRI images and will fit the prosthesis inside of this particular mouth. For function the prosthetic has to be able to aid in deglutition by moving a bolus of food backwards to the throat. For controls, the prosthetic needs to be able to reliably actuate on command, and for implementation the prosthetic needs to be able to be put into the mouth, used in the mouth, and removed for cleaning. These last three are critical as if it is not removable the tongue can not be cleaned, and little cleaning may lead to infection or uncomforting bacterial growth. We also considered specifying a certain weight range as consideration of user comfort, but we could not establish an appropriate weight or mass of tongue removed during a glossectomy due to the variability of the surgical procedure and limited data on tongue mass.

The problems previous projects had in creating a mechatronic tongue included leakage, insufficient displacement, and sizing. The air regularly leaked, which led to loss of function over a long term and a strain on actuation devices in the short term due to more air being pumped to replace what was leaking out. A new system needs to be designed to minimize seams and junctions where these leaks occur. The prosthetic tongues tested did not have sufficient displacement due to fundamental design, material properties, and displacement in directions other than the desired vertical direction. As mentioned previously, the system needs to be able to operate within a human mouth. Further requirements are discussed in Chapter 3.5 below.

3.5 Design Requirements

The tongue needs to be able to function, needs to be safe for patients, and needs to be easy to use. While material considerations help with safety and a removable prosthetic attached to a retainer makes it easy to use, definition of sufficient function is harder to define. This project will seek to imitate the only other object that currently helps with deglutition: the tongue. It is possible that imitating the function of the human tongue is not necessary for successful deglutition, but not enough data exists on what technical requirements are sufficient. Thus current requirements will be compared to a real tongue. There are 6 general requirements for the success of a prosthesis according to the needs analysis above in section 3.3. These are presented in Table 2 as follows: duration of actuation, displacement of different sections of the tongue prosthesis, size of the prosthesis, integration of the prosthesis into the mouth, performance of the prosthesis over time as characterized by fatigue, and safety for any patients who might use this. Table 2 shows the listed characteristics with valuation compared to others. A value of 1 indicates a higher level of importance and a value of 0.5 indicates equal levels of importance. Each requirement and their respective priority will be discussed in depth in the following sections.

Table 2: Design Requirement Values

	Duration	Displacement	Size	Integration	Fatigue	Safety	Total
Duration	X	0	0	0	0.5	0	0.5
Displacement	1	X	0	0	1	0	2
Size	1	1	X	1	1	1	5
Integration	1	1	0	X	1	1	4
Fatigue	0.5	0	0	0	X	0	0.5
Safety	1	1	0	0	1	X	3

3.5.1 Size

The size of the prosthesis is the most important aspect of this project. Previous projects have developed bench prototypes that were not yet accurately sized so this project must address this requirement first. Additionally, if the prosthesis is too large and can not fit into a person's mouth all other performance metrics are inconsequential as it will not work as a prosthesis.

Many of the dimensional restraints for the prosthetic came from cephalometric data regarding the average morphology of the mouth. The first examination conducted was regarding the size and shape of the tongue itself. While the whole of the tongue and its associated soft tissue is not removed if possible during a glossectomy, cases where this occurs represent both the largest volume available to house the prosthetic. More importantly, it represents the greatest quality of life impact to patients. Thus this is the context under which this iteration of the prosthetic was designed [13]. The volume of the tongue varies greatly from person to person depending on a variety of factors, most people fall within the 70-100ml range although 140ml and above is not uncommon. [33, 34]. Between 50-75% of this volume is the body of the tongue itself, although the prosthetic need not necessarily meet that proportion [35]. The specific width, length, and height of the tongue are not widely reported, but Sander et al. was able to perform measurements on tongues, including the extrinsic muscles, from cadavers and their measurements are reported below in Table 3 [36]. Note that these measurements represent the maximum value for the given dimension, for example the tongue is narrower than 6.4 cm at various points but never wider, meaning so long as the prosthetic does not exceed 6.4 cm in width it will not be too wide for the mouth.

Table 3: Maximum Tongue Dimensions, from [36].

Dimension (cm)	Length	Width	Height
Value	9	6.4	1.7

The other set of important measurements were the height and width of the mouth when fully opened. These figures were necessary to ensure that the prosthetic could be removed and inserted into the mouth without difficulty, as a device which on paper would fit into the oral cavity may be too tall or wide to pass between the teeth. Generally the maximum distance between the top and bottom teeth is just under 50 mm, but this tends to decrease with age [37, 38]. Interestingly this figure is the same as the width of the first three fingers on a person's hand, as shown below in Figure 17, which makes it very easy to find on an individual basis. Note the longer line in the bottom image denotes the extent some people can open their mouths to, but this represents less than 10% of the population [37].

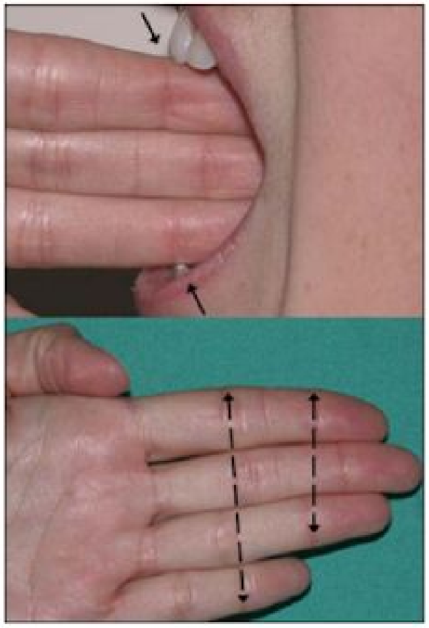

Figure 17: The relationship between finger width and maximum mouth opening, reproduced as is from [37].

The width of the mouth is not as well reported as its height, but is generally considered to be in the low to mid 50 mm range [39, 40]. It is important to note that while this is smaller than the 64 mm width available to the prosthetic, the cheeks are pliable and would be able to accommodate a wider prosthetic.

3.5.2 Integration

The second most important feature of the prosthesis is the integration of the prosthesis. This describes the extent to which the tongue itself can be placed inside of the mouth and still be properly controlled. Again this receives high importance as a prosthesis that can not consistently exist in the mouth is not sufficient. Reliability and sufficiency of any testing depend on the consistent location of tongue within the mouth.

As further testing of the miniaturized tongue model would be required to determine the forces and pressures at work when the tongue was in use, it is unable to determine quantitative requirements for the retainer. Overall, the retainer should be able to withstand any pressures created by the tongue when in use, as well as by the teeth during chewing. The retainer should also be able to remain in place during eating, while also allowing patients to remove it, along with the tongue, for cleaning or maintenance.

3.5.3 Safety

Patient safety is third most important as any prosthesis used by a patient needs to be safe for that patient. It has an importance below size and integration as the safety of a prosthesis is inconsequential if it can’t even fit and be used by the patient in the first place.

The safety of the prosthesis is difficult to measure. Data is lacking for relations between soft robotics and a human interface, but there are two components of safety that can be assessed: the pressurized air inside the tongue and the materials the tongue is made out of. The pressurized channels must not be actuated by high pressures, nor should they require large volumes of air in order to actuate. These requirements are needed so that in the event of a pneunet rupture, the patient is not injured. The material must then not be toxic or harmful to the patient.

We also considered specifying a weight requirement for the prosthetic tongue. Two issues prevented this. First, the weights of tongues are not commonly recorded or at least not provided to an accessible database. Second, while the density of the tongue can likely be found, the volume of tongue that needs to be replaced is also not known. This is because the variation in patient size and the variation in the size removed during a glossectomy greatly affects the mass of the tongue that would be missing from a patient that might use this product.

3.5.4 Displacement

Once the prosthesis can be integrated into the mouth and is safe, it needs to perform correctly. The most important performance metric is displacement of different sections of the tongue as the vertical movement of the tongue determines its ability to push a bolus of food backwards.

The tongue moves up towards the roof of the mouth in a wave, pushing the bolus of food back. To do this each area of the tongue moves a certain distance upwards. This motion has been quantified by separating the tongue into distinct points as was discussed in Chapter 2.5.1. Here our specification is to reach the average tongue displacement as defined by smaller male and larger female parametric data. The displacements in the T2, T3 and T4 sections of the tongue should be 6.4mm, 10mm, and 14.1 mm respectively as seen in Table 4 [12]. Through this same study, we aim for the tongue to be able to move a 10 milliliter bolus as this is the size of the bolus for collected data. The times that each of these sections take to move during the swallowing action are shown in Table 4. The collected data originally measured the time for one movement of each section towards the roof of the mouth but the data shown in Table 4 is doubled to account for the time it takes each section to progress back down to resting position.

Table 4: Height and Time Constraints

Section of Tongue	Corresponding Pneunet	Minimum Displacement (mm)	Maximum Displacement (mm)	Mean Duration of whole cycle (ms)
T4	Back	14.1	19.1	384
T3	Middle	10	15.2	358
T2	Front	6.4	10.5	386

This displacement requirement for the tongue will eventually have an associated pressure requirement for the control module as the pumps need to be able to apply the pressure necessary to completely actuate the prosthesis. The relation between pressure and displacement will be explored through simulation in Chapter 6 to allow for this additional requirement in future projects.

3.5.5 Duration

The displacement and duration data describe the tongue’s movement over a period of time. This is less important than displacement, as a prosthesis that operates slower than a normal tongue will still help a patient swallow faster than if there was no prosthesis at all.

The total movement of the tongue takes approximately one second [12]. The duration of actuation for T2, T3, and T4 sections of the tongue are presented in Table 4. Each section of the tongue, while separated into 3 parts, must actuate up and down in 0.35 to 0.4 seconds. Failure to meet these specifications will likely still result in a successful prosthesis. More importantly, this is a major requirement for the control module. The coding and the mechanical systems of the control module must be able to complete a cycle in these specified times.

3.5.6 Fatigue Life

The fatigue life describes the performance of the prosthesis over time and is important for any product. It is less important than the ability of the prosthesis to function correctly in the first place as described by the previous requirements and therefore receives final priority.

To determine the necessary fatigue life, we must first look at the steps needed to create the wave-like motion. In the first step, the front of the tongue inflates. In the second step, the front pneunet deflates while the middle inflates. In the third step, the middle deflates while the back inflates. In the fourth and final step, the back deflates. Assuming that we want the tongue to complete the swallowing motion within one second, each step would need to be completed in 250 milliseconds. We define one cycle as one inflation and one deflation of the pneunet, which here takes two steps and would thus span 500 milliseconds.

The average person uses their tongue to swallow meals about 500 times a day [41]. If we relate swallowing to fatigue, each section of the tongue would need to “swallow” 500 times a day, or undergo 500 cycles daily. Our goal is for the tongue to last for two years of daily use before a crack forms in any section, or for each section to last 365,000 cycles.

3.6 Revised Client Statement and objectives

The client needs a prosthetic tongue that can move a bolus of food to the back of the mouth in close to one second. To do this the prosthesis must have three discrete sections with displacements and actuation times equaling experimental values of the T2, T3, and T4 sections of the tongue described in Table 4. The prosthesis must also fit within the dimensions of the mouth presented in Table 3. It must then be integrated into a retainer and sustain integrity under cyclic loading for 365,000 cycles.

We planned to achieve these goals through the following objectives:

1. Design: Create a tongue prosthesis that can actuate in one second.
2. Fixation: Integrate retainer and prosthesis.
3. Safety: The prosthesis must be safe to put in a human mouth.
4. Control: Create a control and testing module for the tongue.
5. Modeling: Validate the tongue model through simulation and internal pressure testing.

3.7 Project Methodology

This project was conducted in two main phases: production and testing. During production we designed and manufactured the tongue prosthesis, the retainer and associated fixation components, and the control module. During testing we assessed the abilities of the test bench and validated design through simulation of pressure and displacement in the tongue prosthesis. Due to time constraints we did not complete all testing or achieve all objectives, so future work is precisely laid out to guide what still needs to be done. This section briefly describes the method of our actions.

3.7.1 Production

This section serves as a guide to the production of the tongue, the retainer and the control module. Further details are discussed in Chapters 4, 5, and 6, respectively.

We developed four variations of Araya's original pneunet-actuated prototype. We first altered designs by Araya to create a new two component silicone rubber tongue. This serves as the initial prototype upon which further variations were created. The first variation focuses on material, concluding that polyurethane and silicone rubber are the most apt materials for this prosthesis. The second design creates a polyurethane tongue and assesses the safety of polyurethane and silicone elastomer. The third design is a single part design that uses PVA channels to eliminate the need to glue two parts together as in Araya's and the initial prototype.

We dismissed the initial design modified from Araya with two parts glued together. While it was able to be manufactured successfully, it suffered frequent and rapid failure at the glue seams of the part. The single component design that utilised PVA to form the pneunet channels performed better under initial informal testing. This prototype burst less frequently because there was no glue used during assembly. As such we selected the single component design as the primary design that we focused on for the rest of the project.

We further explored other design options with different actuation systems. We explore the possibility of magnetic actuation via a soft robotic system and mechanical actuation via a linkage system. Chapter 4 discusses the design of each of these prostheses as well as the manufacture and final design selection. We deemed the linkage prosthesis, magnetic prosthesis, and polyurethane prosthesis infeasible due to manufacturing and performance concerns.

To complete creation of a basic prosthesis, we needed to create a system to integrate the prosthetic tongue into a mouth. We selected a retainer for this purpose as the retainer can be used by patients with teeth but can also be used with a denture if the patient does not have teeth. Both scenarios are common among glossectomy patients. To integrate the soft robotic tongue with the retainer, we created a 3D printed PLA casing that holds the tongue in place and can be subsequently attached to the retainer.

We also modeled and created an oral cavity based off of dimensions of a real mouth in which we could place and test the prosthesis; this is further discussed in Chapter 4.4. Finally, we created a control module. This control module contains pumps and solenoids to actuate the prosthesis, along with the necessary control components. The control module is discussed in Chapter 5.

3.7.2 Testing Required

There were six tests deemed necessary to determine if all objectives were met. First, the full prosthesis must be evaluated using ISO 10139-2:2016 to ensure that the chosen materials were safe for use in vivo. Then, we need to measure the displacement and internal pressure for each pneunet channel within the tongue to determine the relationship between the two quantities and compare the data to simulation data. This relationship will improve the accuracy of the control module. The inflation time of each section needs to be measured to ensure that the full prosthesis is able to actuate within one second.

Once each pneunet of the tongue is tested, we must test whether the tongue can successfully move a bolus of food or liquid towards the back of the mouth. We also need to determine the life cycle of the prosthesis by inflating and deflating it repeatedly using the control module.

In parallel with these six tests, we conducted simulations in Abaqus to assess the expected performance of the prosthesis and develop better estimates for the pressures required for each pneunet to meet the height requirements described in Chapter 3.5.4.

3.8 Conclusion

In this chapter, we established the client statement and the goals of our project. Additionally, we established the methodology that was used. First we created prototypes of multiple different concepts. This required redevelopment of the pneunet tongue from Araya at a smaller scale. Alternative materials and concepts also had to be tested to form a more exhaustive approach to the creation of a mechatronic tongue. We then created systems with which we can test the prototypes, including an oral cavity to represent an actual human mouth during testing and a control module to actuate the tongue while measuring displacement and pressure. We simultaneously tested the material's ability to be cleaned, its resistance to bacterial growth, and its biotoxicity.

At this point the existing prototypes demonstrated a susceptibility to leakage and rupture such that it was difficult to measure data before they failed. A subsequent progress of prostheses led to one which we believe will be most successful. In parallel with this approach, we developed a finite element model (FEM) of the tongue in order to measure the vertical displacement of the top of the tongue for a given pressure applied to the inside of the pneunet. The following chapters 4 and 5 will discuss design and manufacture of the tongue prosthesis and the control module respectively. Chapter 6 will discuss the final design verification and Chapter 7 the final design validation. Finally discussion and conclusions will be discussed in Chapters 8 and 9.

Chapter 4. Prosthesis Design

In this chapter we will review the process through which we designed and created several different iterations of the prosthetic. We developed several different prototypes to compare to the two component silicone elastomer prototype actuated by pneumatic networks developed by Araya. To address the leakage and durability concerns associated with Araya's prototype we created a version that could be manufactured in one piece rather than two. In an attempt to address displacement we created an iteration made of a different material. To address size constraints we developed a magnetically actuated and linkage based design. First, feasibility experiments were performed to determine whether dissolution of PVA could be used to create the single component prototype and whether magnets could actuate a prototype with sufficient displacement. This chapter will discuss the feasibility experiments, the primary design from Araya and alternate designs, and finally the actual creation of the prototypes. It will then proceed to present the oral cavity, tongue casing, and retainer that integrated the tongue into a prosthesis that can operate in a mouth.

4.1 Feasibility Study/Experiments

Several of the alternate concepts raised questions upon initial design. Experiments were done to assess whether these concepts were feasible or whether they should be disconsidered. Pneumatic networks as an actuation method had been established by Araya so no feasibility tests were done relating to this, but tests were done for PVA dissolution in the single component prototype and for the repulsion strength of the magnetic prototype.

4.1.1 PVA Dissolution Test

To create a seamless prototype with the goal of preventing leakage, we created PVA inserts that were wholly immersed in the liquid polymer except for two support channels. This resulted in two 2.54x5.08 mm holes for each insert that could be exposed to water and dissolved. The dissolution process needed to be tested to ensure it could be completed in a reasonable amount of time. We acknowledged that dissolving the PVA would be faster given a heated and agitated solution combined with frequent replacement of water to prevent saturation. This set of conditions is space intensive for the heating system and stirring system and work intensive for frequent replacement of water. Thus we instead created a test for the dissolution time necessary given room temperature water replaced only once every 24 hours without agitation by a stir bar.

Uncured silicone was poured over PVA inserts with varying amounts of exposed surface area. The smallest insert had an exposed channel which was 1.27x1.27 millimeters and the largest was 3.81x5.08 mm with those in between varying by increments of 1.27 mm. These were left to dissolve in room temperature water, which was replaced every day. After 13 days the channels had partially dissolved to some extent, but none had fully dissolved. The ends exposed to water became soft and saturated but did not fully dissolve away although scraping these off allowed for new unsaturated PVA to be exposed. We then created a second test using the single component prototype. We printed the PVA inset version 1 as described above in section 4.5.2 and cured silicone around these to make a single component tongue.

We placed this cured prototype into water at room temperature and replaced the water every 24 hours. When the water was replaced, forceps were used to scrape away saturated PVA from the exposed part of the inserts. Figure 18 shows the profiles of the channels as they were embedded in the silicone elastomer. Part 1 represents the model when the channels are completely filled with PVA. On the third day, as shown in part 2 of Figure 18, we scraped the saturated PVA from the horizontal bars, now shown in grey. We then bent the silicone elastomer of the tongue as necessary to push the remaining PVA out of the tongue, resulting in the PVA free channels as in section 3. On the fourth day we squeezed each channel of the tongue to remove any leftover PVA residue resulting in a PVA free channel shown in section 4. On the fifth day no saturated PVA came out when we squeezed the tongue, indicating the prototype was cleared of all PVA. This meant the final time for the creation of a prototype was 6 days, 1 day for curing the silicone and 5 days for removing the PVA insets. The human involvement with the prototype during these 6 days was no more than 15 minutes per day.

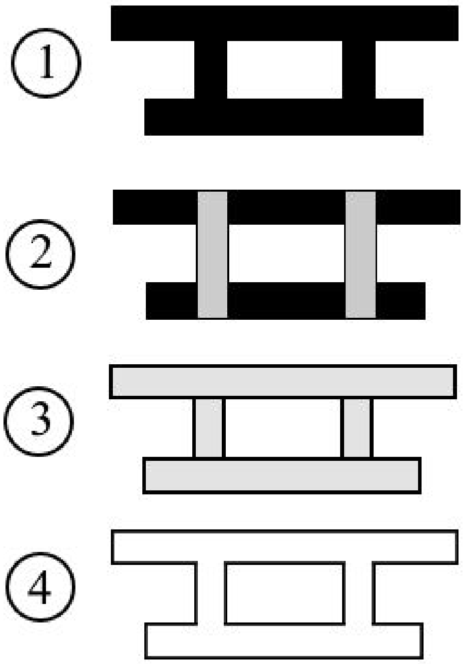

Figure 18: PVA Dissolution Process

4.1.2 Magnetic Actuation Test

To test whether magnetic actuation was feasible, molds of silicone elastomer embedded with magnetic particles and exposed to powerful permanent magnets. Iron oxide microparticles [42] were used, as described in Appendix A. These magnetic microparticles were mixed at 20% by mass into a two millimeter thick silicone rubber slab to test the repulsion, but unidirectional polarization of microparticles could not be achieved. When secondary magnets were moved by the test material, attraction was observed towards both poles and with no visible repulsion. We observed significant magnet attraction between the microfilament loaded silicone elastomer and other magnets for the four months the test was reserved. It is possible this magnetic microparticle preparation method can be used to hold a tongue into a retainer, but it does not produce enough repulsion to be sufficient for a primary actuation method.

A similar test was performed to assess large magnets embedded in silicone as opposed to dispersed particles. A single magnet was placed into 4mm of silicone polymer. When the part had cured, a plastic bead was glued to the top of the tongue right over the magnet. This allowed for the use of software to track the displacement of the bead and by extension the tongue. A single magnet was then moved back and forth underneath the silicone to repel the integrated magnet. The resulting average displacement of 11 mm and maximum displacement of 15 mm can be seen in Figure 19. This equals the minimum displacement in males for the T4 section of the tongue and the maximum displacement for the T3 section of the tongue, which establishes the use of large scale magnets as a potential method for actuation of a dynamic tongue prosthesis.

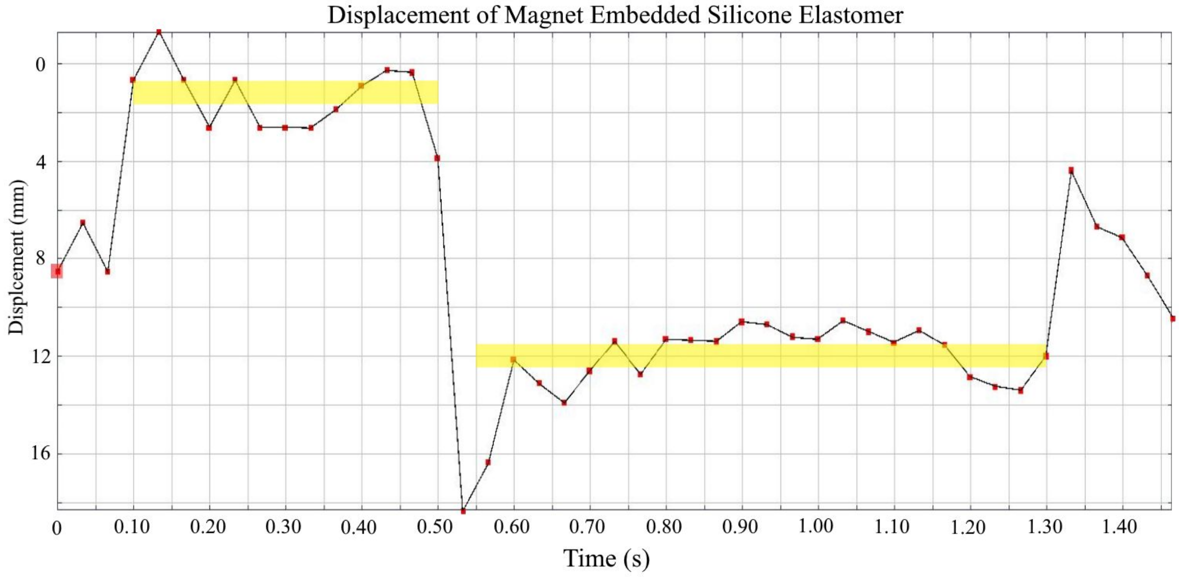

Figure 19: Displacement of magnet embedded silicone elastomer over time. Average displacement for maximum and minimum displacement highlighted in yellow. Data produced using Tracker [43].

4.2 Conceptual Designs

The primary design made during this project is the two component pneunet tongue made of silicone elastomer as created by Araya. We did change this primary design from Araya's design in two notable ways: altered dimensions for a shorter and smaller design and addition of designed holes in which to add tubes for control integration. This primary design and subsequent alternative concepts will be discussed in detail in this chapter. Figure 20 presents the process flow of design and creation of each tongue prototype. Some designs add, alter or subtract steps. Alterations or details of this process will be discussed in each section.

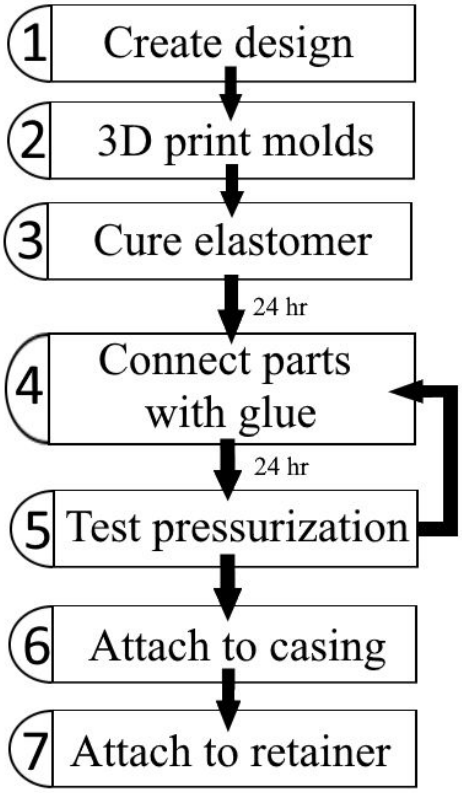

Figure 20: Design Flow

4.2.1 Two component Silicone Rubber

This design was originally created by Araya and served as the initial design for this iteration of the project. There are two components molded using three parts. The top part of the tongue is made with the middle and top mold seen in Figure 21 and 22 below. The top of the tongue had ridges to increase friction between the surface of the tongue and the bolus. The height of the part is controlled by the top mold while the interior channels are formed by the middle mold. The bottom part of the tongue is made from the single mold in Figure 23 below. The following writing details modifications made to these designs by Araya and the creation of our initial prototypes.

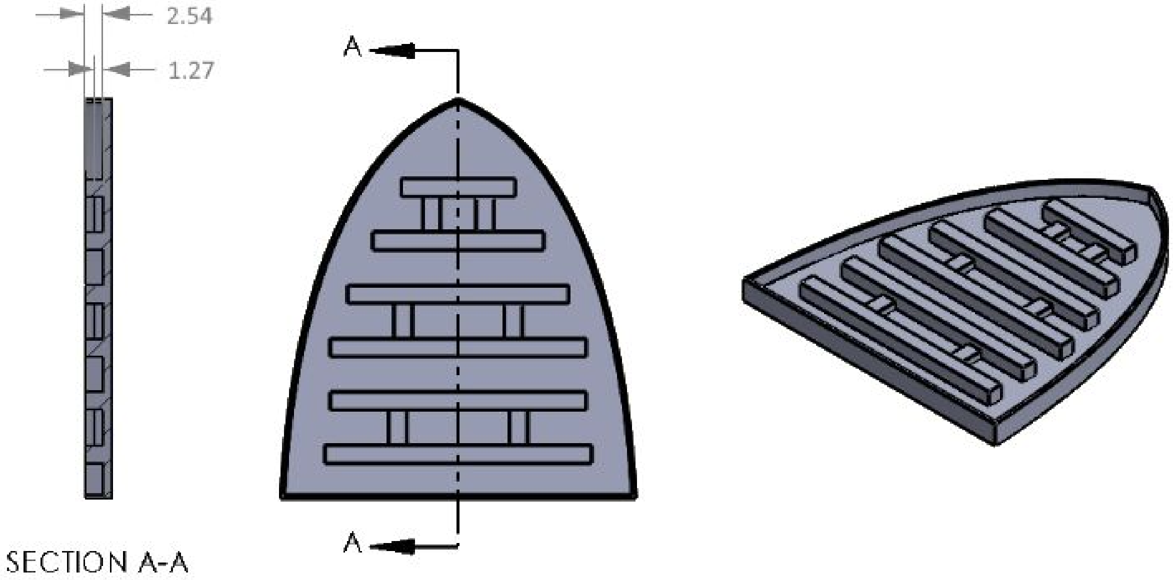

Figure 21: Araya Mold Middle

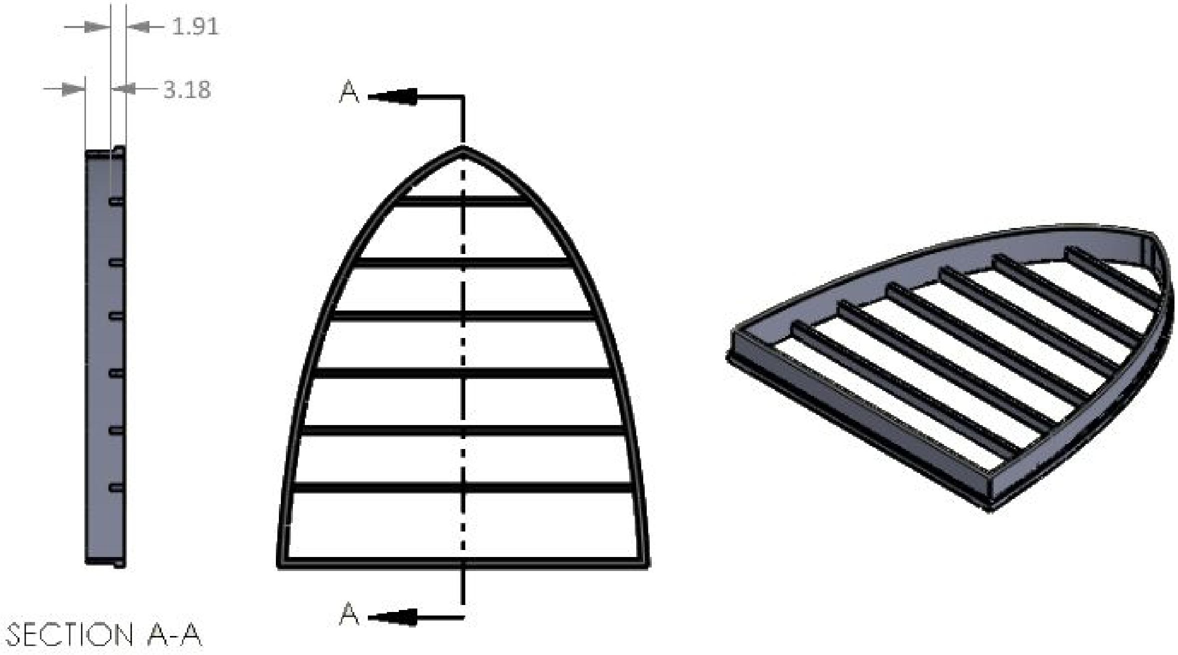

Figure 22: Araya Mold Top

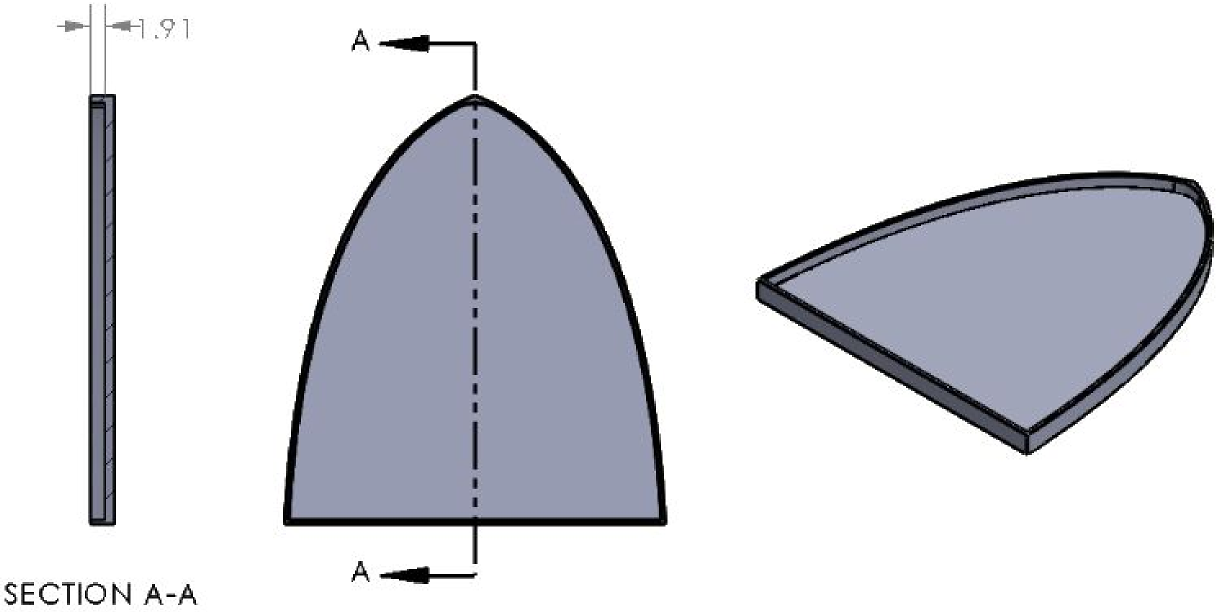

Figure 23: Araya Mold Bottom

4.2.1.1 Initial Two Part Silicone Design

The very first modification made to the design was to shorten the pneunet chambers. These were reduced to 1.02 mm in height as shown in Figure 24. Other dimensions were shortened as noted in Figure 25 through 26 below. These modifications made the part thinner, especially in the areas that needed to expand. This makes the part take up less space inside the mouth, but also theoretically decreases the force, and the pressure, needed to expand the tongue while also decreasing the volume of air needed to apply this pressure. It is currently unknown what volume of air and what pressure produces sufficient displacement. Section 6.2 and 6.3 discuss a simulation of the pressure versus displacement. However, these values will need to be quantified through physical testing. This design has interior channels with a volume of 706.45 mm^3, 55.1% smaller in volume than Araya's design, which takes up 1281.47 mm^3. This means a smaller pump can be used. Testing and simulation will be necessary to verify these expected changes.

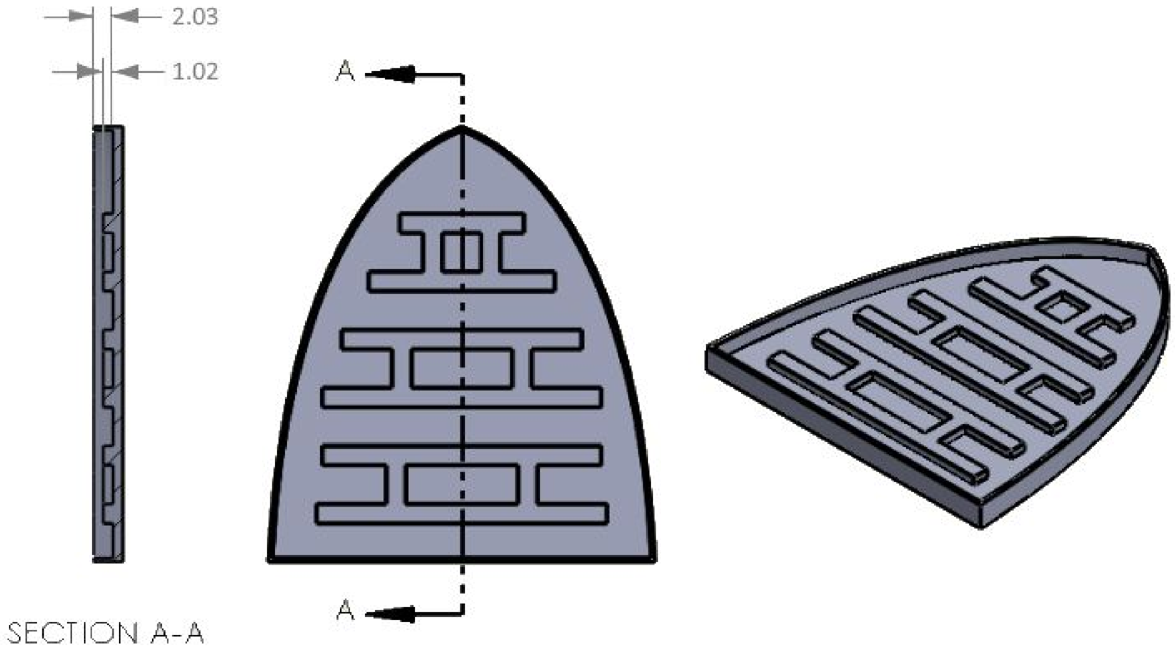

Figure 24: Primary Design Middle mold

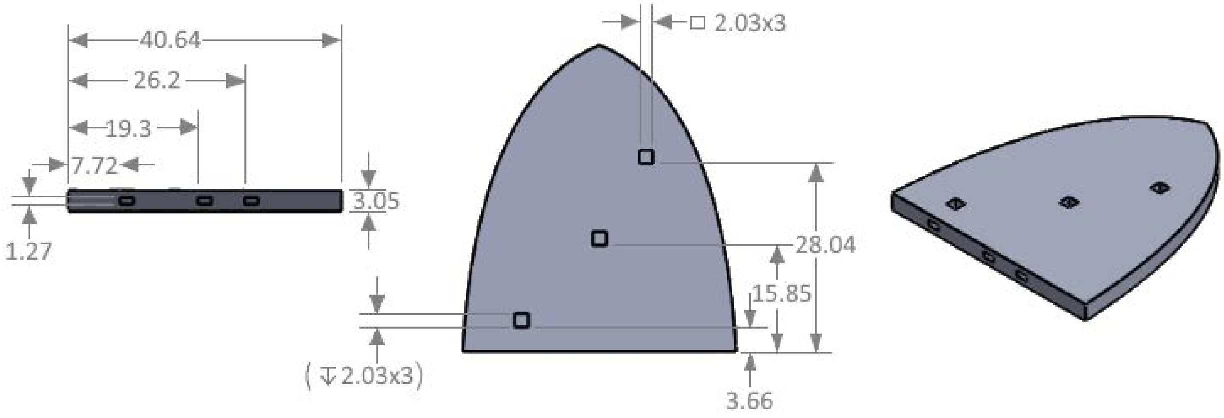

Figure 25: Primary design bottom rear entrance

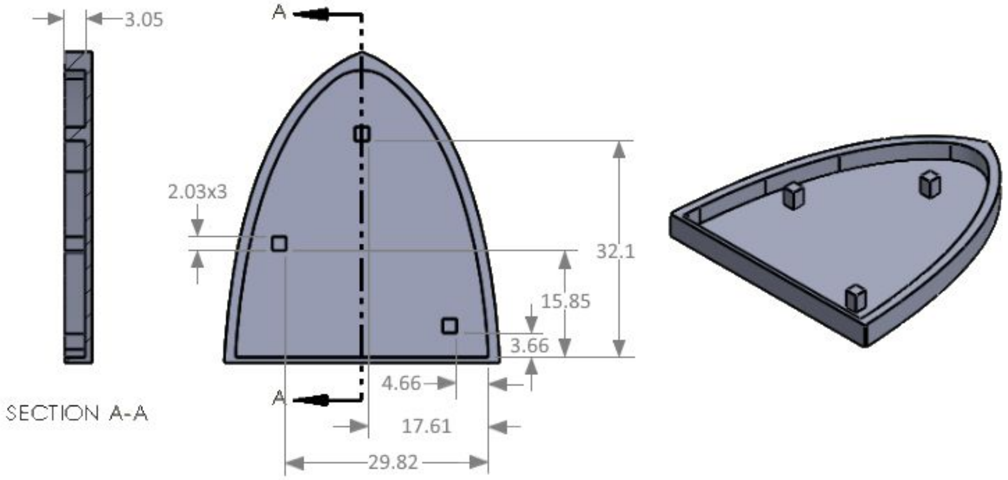

Figure 26: Primary design bottom entrance mold

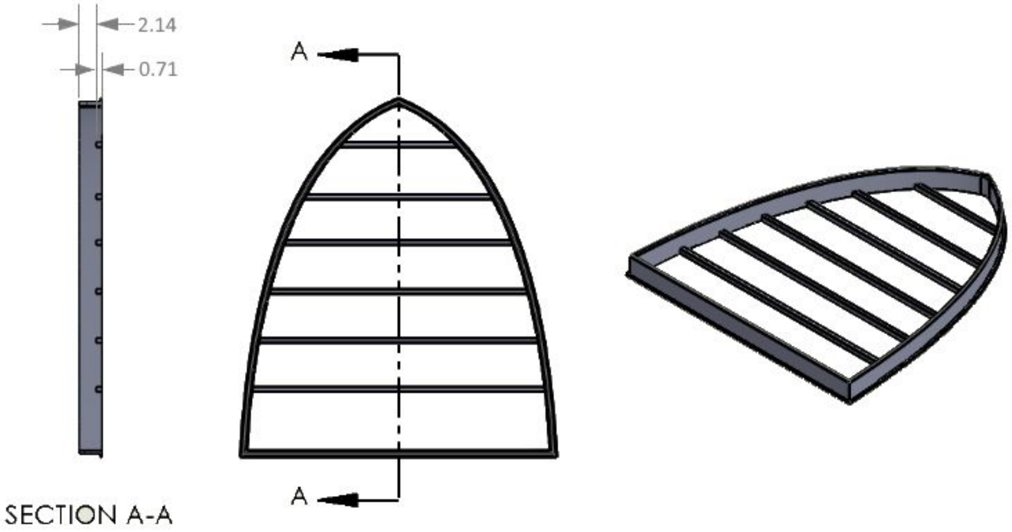

Figure 27: Primary Design Top mold

We redesigned the bottom component of the tongue into two versions, termed the “rear entrance” design, shown in Figure 25, and the “bottom entrance” design, shown in Figure 26. These names refer to where the tubes connected to the body of the tongue. Figure 28 highlights the difference between these two parts. In the bottom entrance design, holes in the silicone elastomer extend through the entire y axis at the areas highlighted in orange. In the rear entrance design the holes at the orange locations extend only 2.03 mm deep. These connect to a 2.03mm wide by 1.02 mm high tube that connects straight along the z axis to the back of the tongue, as highlighted in yellow in Figure 28. The resulting rear entrance design of the tongue is pictured in Figure 29 below.

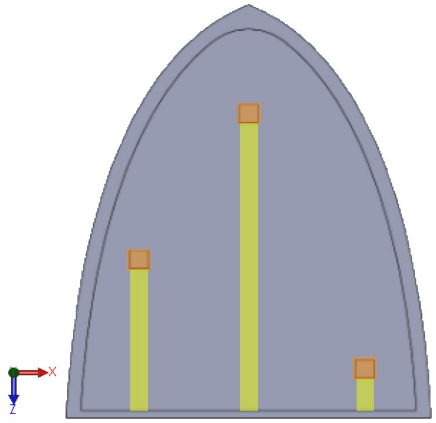

Figure 28: Tubing Integration Channels: An image showing the general shape of the mold as well as the location of each of the holes that tubes would be inserted into.

Figure 29: Image of rear entrance design prototype

4.2.1.2 Silicone Rubber Prototyping

All PDMS prototypes were created by mixing equal parts A and B of Ecoflex 00-30 Silicone Rubber from Smooth-On. These molds cured on a flat surface for at least 12 hours, after which time the parts could be removed from the molds.

We made a total of five prototypes using the rear entrance two component design, shown in Figures 23, 24, and 26, and five prototypes using the bottom entrance two component design, shown in Figures 23, 25, and 26. All two component prototypes took a large amount of effort and time to glue the two parts together, glue in tubes for air supply, identify and fix leaks, and then mount to casings. During part 3 and 4 of the process shown in Figure 20, we cured each part for one day then glued them together using silicone sealant [44], detailed in Appendix A, and let the sealant cure for an additional day. We then glued 2mm tubes into the holes in the back of the tongue by placing the tubes in the hole and covering the seam between the tongue and the tube with Loctite glue [45], which we then let cure for another 24 hours. During stage 5, we attached the loose end of each tube to a 10 mL syringe, submerged the tongue in water and depressed the syringe. Bubbles would form at any areas of leakage, allowing rapid identification and reapplication of sealant. The new glue cured for 24 hours and then we repeated the submersion step until the part was completely sealed as shown in Figure 20 progressing from step 5 back to step 4. The final process took two to five days to complete depending on the prototype.

We experimented with three separate attachment methods to attach the two parts of the prototypes to one another: silicone sealant, Loctite glue, and plasma bonding. Specifications for the glue and sealant are presented in Appendix A. They were each added to the surface by manually applying a thin layer of silicone sealant to the contact surface of the top part of the tongue. The interior channels were left clean but adhesive was applied to the entire surface around the channels. The bottom and top part of the tongue were then placed together such that holes in the bottom component, such as seen in Figure 25, connected to the chambers of the top part and not the glued surfaces of the top part. The edges of the two parts were lined up, and the glue was left to cure for 24 hours.

The Loctite glue did seal the tongues initially, but these prototypes were more prone to rupture and leakage more than other options. Both prototypes where Loctite glue was the primary glue were separated, cleaned, and reattached using silicone sealant. The silicone sealant more often developed a strong connection that did not leak. The plasma bonding did not work and components did not bond. One possibility to explain this failure is that the parts were handled too much before plasma treatment such that the bonding surface was compromised. However, it is also possible that the formulation of silicone elastomer used was simply not conducive to effective plasma bonding. Whatever the cause, the most appropriate bonding agent is still silicone sealant.

Every prototype with which we completed this process and entirely sealed the pneunet channels failed within five pressurization cycles. At this preliminary stage, one cycle was defined by a 100 mL syringe pushing 20mL of air into a pneunet of the prototype and withdrawing the air after the pneunet was fully inflated. Failure was defined by rupture of the glue boundary or of the elastomer itself such that the prosthetic can no longer hold hair in the intended manner. This means none of these prototypes could be pressurized five times without breaking. The displacement associated with this 20 mL pressurization was visually estimated to be around 1cm, but it is important to note that this was not an official test. No measurements were taken, as these prototypes failed before a test setup could be orchestrated.

Important observations were taken as to the location of failure, which tended to occur in one of three spots.The most common location for failure for this prototype was in the interior channels that connected the pneunet channels to the back of the tongue, highlighted in yellow in Figure 28. This failure location was present only in the rear entrance design. These channels represent the thinnest areas of silicon walls. Breakage at this location prevented the different sections of the tongue from being pressurized discretely. This breakpoint could be reinforced with thicker material, but is more efficiently addressed by removing the channels going to the back of the tongue entirely, resulting in the bottom entrance two component version. Even when the part did not fail, this location was a site of improper expansion. In Figure 30, the image on the left shows the back section of the tongue expanding. The middle section should have a similar expansion just in front of and separate from the back section. The image on the right shows the pressurization of the middle section, with a significant area of expansion occurring in the channel connecting the middle section to the tube. The area of expansion is too far back and overlaps with the expansion of the back section.

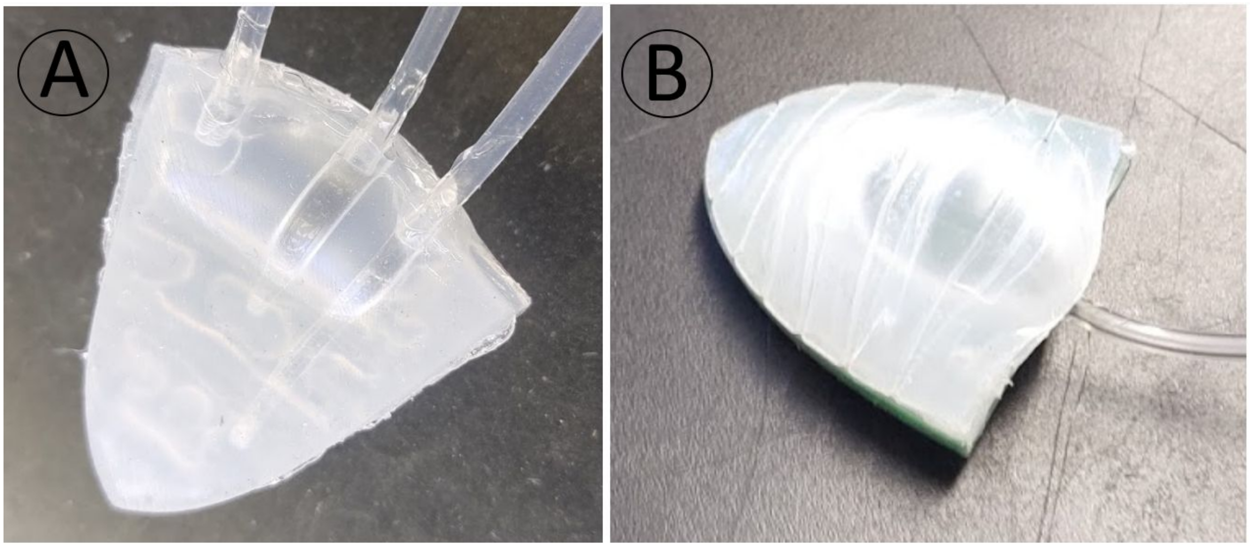

Figure 30: Rear entrance design prototype. A) Upside down tongue with inflated back section. B) Upright tongue in a casing with inflated middle section.

The second most common area was at the seams between the top and bottom components where the glue was applied. This area can be seen as highlighted in orange in Figure 31. Failure at these parts was fixed by an application of sealant, but this is not feasible during long term product use. This location of failure occured in both rear entrance and bottom entrance designs.

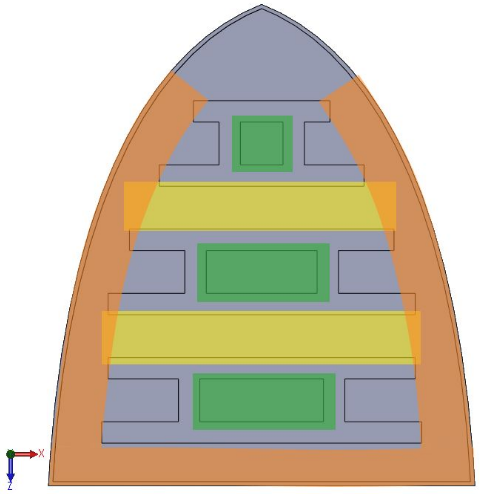

Figure 31: Common areas of failure

The third area of failure also occurred in both two component designs and was located at glue seams between sections, as highlighted in yellow and green in Figure 31. Failure at the green highlighted areas changed the internal forces of each section but did not prevent each section from pressurizing discreetly. For the two component prototypes, failure at this area was always associated with concurrent failure at the yellow highlighted areas. If these seams began to leak, pressurization of one section of the tongue would also pressurize another section, making the wave-like motion created by staggered pressurization impossible.

The bottom entrance two component prototypes, shown in Figures 23, 25, and 26, required an identical manufacturing process and time. Prototypes were more successful; pneunet channels displaced under the applied pressure as desired instead of in the connection tubes as in Figure 30 due to thicker walls. Breakages were still common in the partitions between the three sections of the tongue, highlighted in yellow in Figure 31, which led to indiscrete expansion of the sections.

We observed that expansion occurred primarily in the front to back channels as highlighted orange in Figure 32 of each pneunet section as opposed to the horizontal bars as intended, highlighted yellow in Figure 32. The expansion of each pneunet section is supposed to create an upwards force to push the bolus backwards. As the highest point of the roof of the mouth is in the center, it is appropriate that the area of the tongue that is expanding reach maximum height in the middle. With this model, the upwards expansion occurred in the areas denoted by the orange bars in Figure 32, instead of the yellow bars as was intended.

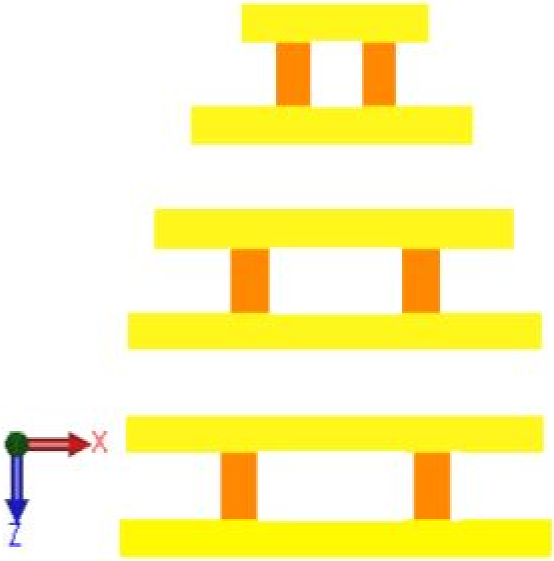

Figure 32: Original Interior pneunet Design

We next created two new designs for interior channels to improve the expansion in the middle of the pneunet. These two new designs are shown in dotted lines overlaid onto the original design in Figure 33. These two new designs featured a larger area, colored gray, upon which air pressure could exert force. Additionally, the interior square, colored green in Figure 31, no longer connected the top and bottom parts as had restricted that area from vertical expansion. We made a preliminary prototype of the second redesign, shown in Figure 33 B, and connected tubes to pressurize the front and back section. Initial observations established that this interior channel design produced a more centrally distributed expansion that would be ideal for bolus movement. We did not conduct further testing on this prototype and the third design was never fully prototyped due to limited lab access.

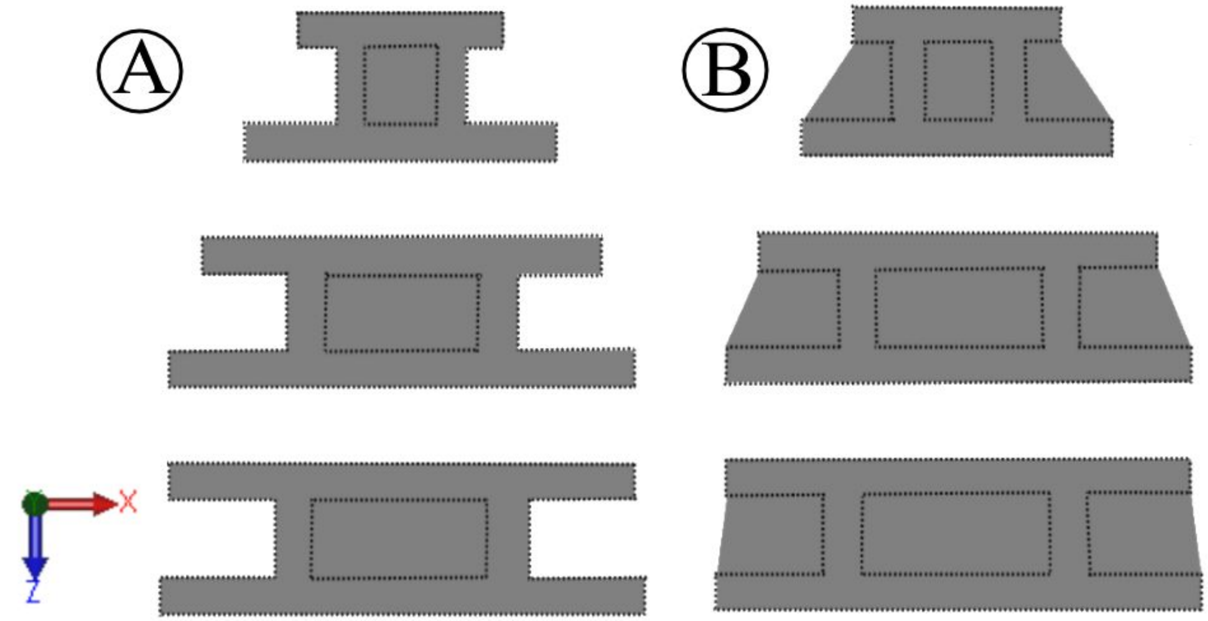

Figure 33: Shown here is the design for each of the two new interior channel designs. The dotted overlay is the original channel design.

4.2.2 PolyUrethane

The previous pneunet prosthesis designed by Araya used the silicone elastomer detailed in Appendix A. Araya faced restrictions due to the thickness of the silicone material necessary to prevent rupture. Araya started with a prototype over twice the size of the current prototype. Portions of smaller prototypes were made of thin material and broke easily. Araya consistently redesigned the layout of the channels in order to allow for thicker walls. We theorized that a material with a higher Young’s modulus would achieve similar strain with less cross sectional area and constant applied force, thus allowing for thinner material sections and more freedom of design. There are material properties other than Young’s modulus which are important for this prosthetic, namely fracture toughness. To determine the optimal material for this soft robotic tongue, we performed the following material selection review.

4.2.2.1 Material Selection Review

Given the nature of the pneunet actuation system and the required movement of the tongue, it was clear the material used needed to be elastomeric in nature. There are many materials that meet this requirement. However, elongation data for materials usually is presented in the form of uniaxial strain, but the pneunet system actuates the material in a multi-axis strain, creating a disconnect that prevents simple comparison of elongation numbers to tongue motion data. As such, we had to consider a wide variety of aspects to determine the best material. The most important attributes for an elastomer include fracture toughness and Young's modulus [46].

The former quantifies the material's ability to resist fracture due to flaws, which would occur in the mouth such as from teeth or other wear, and the latter relates the strain to applied force. Logically the best material will have a high fracture toughness and low modulus of elasticity, although the modulus does not describe to what extent the tongue will expand, so elongation and yield stress are necessary to supplement the modulus data. Next, the desired material should have a long fatigue life to reduce the frequency and associated cost of replacement. Much of the data for fatigue is presented as fatigue stress at 10^7 cycles. Lastly, it is necessary to consider the practicality of a material. It should be cheap and easy to manufacture within the capabilities of prototype manufacture, so injection molding based elastomers are nonoptimal, and it should be biocompatible but not biodegradable as it potentially needs to stay in the mouth for long periods of time.

General classes of elastic materials include silicone elastomers [47], thermoplastic elastomers, which include polyurethane [48], polyvinyl chloride [49], and polyolefins [50], polybutylene adipate terephthalate (PBAT) [51], and hydrogels [52].

To assess all collected data, we developed a material selection decision matrix, displayed below as Table 5. The weighting is based on the importance of that property, with all the weights adding up to ten. The materials are rated out of ten, so a material with good properties where the weight is 2 would get 20 points, making the maximum score 100. We established fracture toughness as the most important consideration as the tongue experiences a great deal of tensile stresses. Young's modulus is second most important as it describes the amount of force necessary to produce a desired displacement with a lower modulus being more favorable and receiving a higher score. The smaller the necessary force, the less strength needed to be applied by the air pumps. Fracture toughness and Young's modulus have a weight of 3 and 2 respectively. Elasticity and strength describe the maximum expansion and maximum stress that the material can sustain and receive lesser but still significant weights of 2 and 1.5. Lastly fatigue resistance and ease of manufacture affect the viability of a prosthesis but not its ability to achieve the necessary specifications and earn lower weights of 1 and 0.5.

Table 5: Material Assessment Matrix

Material	Elasticity	Ease of Manufacture	Modulus	Strength	Fatigue Resistance	Fracture Toughness	Score
Weighting	2	0.5	2	1.5	1	3	10
Hydrogels	6	3	14	3	3	12	41
Silicone Polymer	18	5	14	10.5	6	27	80.5
Polyurethane	16	4.5	12	15	10	27	84.5
LDPE Foam	4	1	20	1.5	1	3	30.5
PBAT	20	1.5	8	10.5	5	21	66
PVC elastomer	6	2	18	9	4	9	48
Polyolefin Elastomer	12	1.5	16	7.5	2	18	57

It can clearly be seen from Table 5 that polyurethane and silicone polymers are the best options for the body of the prosthetic itself with scores of 84.5 and 80.5. While PBAT is somewhat close with a score of 66, there is a sizable gap between the two front runners and any other material. We concluded from the closeness of the values of silicone polymers and polyurethanes that the success of the material would likely be attributable to the manufacture, post processing, skills of the team handling the material, and specific formulas used rather than general material selection itself. While we have already considered the use of a silicone polymer, this materials review clearly establishes that polyurethane has significant potential in the soft robotic application.

4.2.2.2 Polyurethane Design

We formed an alternate concept to the original silicone tongue concept that still used pneumatic networks for actuation but replaced the material with polyurethane [53]. This concept has the same design as the two component prototype but a thinner top section shown in Figure 34. Polyurethane has a higher Young’s Modulus than silicone elastomer, meaning it takes more stress to produce an equivalent strain. The pumps applying pressure to the prototype produce the same pressure so the force that generates the stress is constant. To increase the stress, the cross sectional area of the part needed to be reduced. This made the surface geometry, otherwise created in the top mold component such as in Figure 27, too small. Thus, the top of the polyurethane prototype had to be smooth and lacked the grooves present in its silicone counterpart.

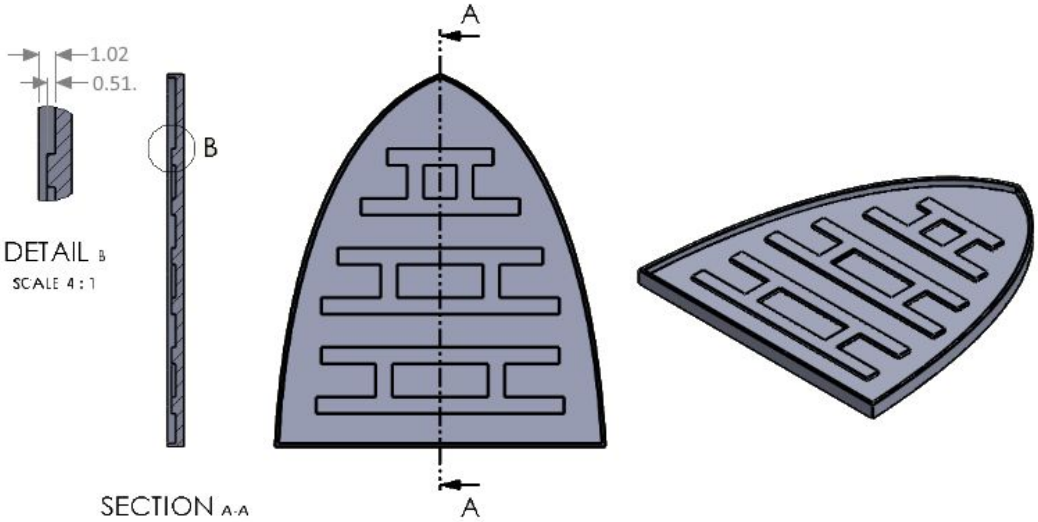

Figure 34: Polyurethane Top Component

4.2.2.3 Polyurethane Prototyping

We attempted to create three prototypes of this polyurethane concept but completed only one prototype. We used Loctite glue, silicone sealant, plasma bonding, and the addition of more uncured polyurethane at the seams to attach the top and bottom parts but none of these methods totally worked and most failed to proceed past step 4 of the manufacturing process, shown in Figure 20. The one prototype that was successfully completed was bonded together using plasma bonding, but this did not provide enough strength to resist the force of pressurization and failed during step 5 of the manufacturing process. It is possible a detailed review of adhesives would provide alternatives that can bond to polyurethane but such a review was not conducted during this project. We were able to do no tests with this prototype due to its inability to be assembled properly. This means it is not known if polyurethane can perform better than silicone elastomer as Table 5 suggests. At this time future developments are needed for this concept to be deemed viable.

4.2.3 Single Component Prototype

One of the primary challenges of the prototypes created by previous projects, described in section 2.5.2 and 4.2.1, is leakage. A significant source of leakage was the boundary between the two sections of the tongue. The glue connecting these components can potentially have gaps where leakage will occur and was often where the prototype failed, as seen in Figure 35. In the single component version two molds were used: a PLA mold to cure the elastomer and a set of PVA inserts to mold interior channels. This prototype is so named as there is one component to the tongue itself, rather than two that need to be glued together as with previous prototypes.

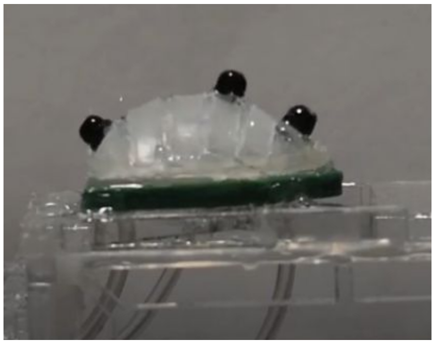

Figure 35: Tongue Actuation after Failure

4.2.3.1 Single Component Design

We ideated an alternate design to address leakage by fabricating the tongue in one piece. This prototype operated under the same pneunet actuation method, but was designed without the two sections that needed to be glued together. The prototype was instead created in a single step in one mold, shown in Figure 36. To create the pneunet channels inside the tongue, PVA inserts in the shape of the previous design's pneunet channels, shown in Figure 37 below, were placed in the silicone as it dried. The feasibility tests described in section 4.1.1 supported the design that these PVA inserts would be removed after the silicone had cured by dissolving them in water.

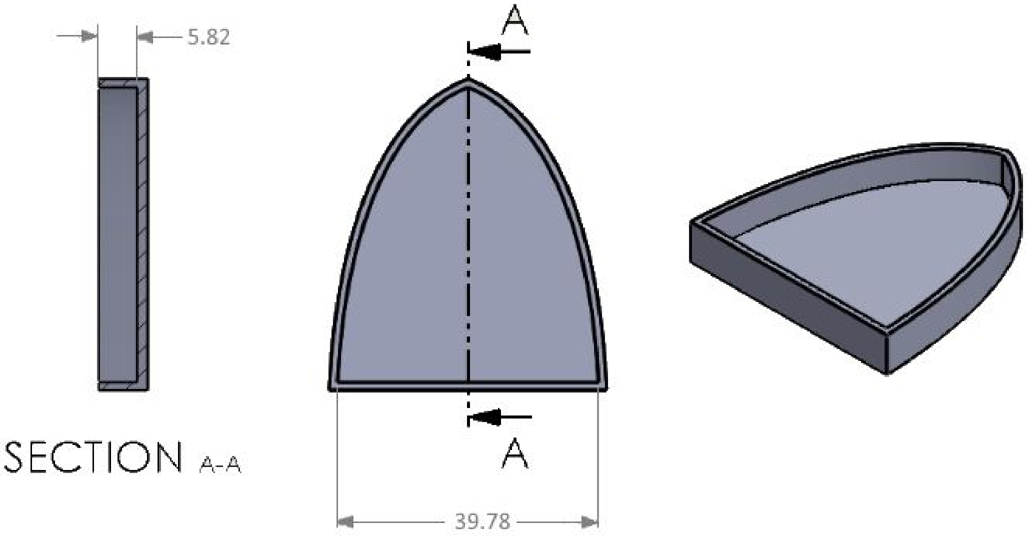

Figure 36: Single Part Mold

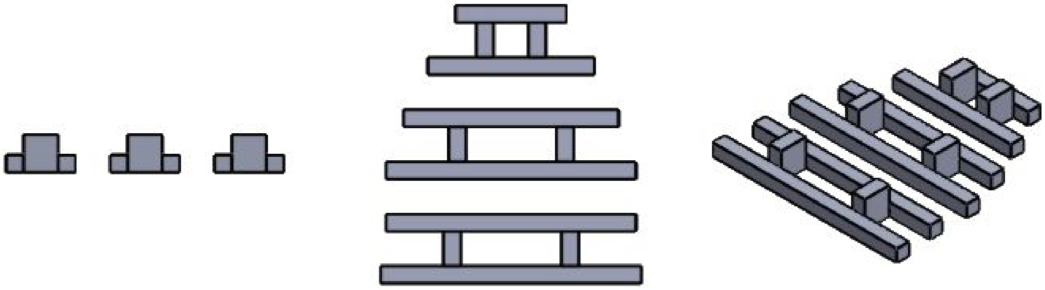

Figure 37: PVA Channel Inserts

4.2.3.2 Single Component Production

We created the first functional single component prototype as the last stage of the PVA dissolution feasibility test. The manufacturing process for this stage is very similar to that of the two component prototypes and still follows the block diagram shown in Figure 20. An image of the prototype curing is seen in Figure 37. The notable difference is that in between stages 3 and 4 the PVA has to be dissolved. Additionally, during the glueing at step 4, there are not two components glued together. Instead, there are holes in the bottom of the tongue that need to be glued due to the supports for the inserts. The isometric view of Figure 37 shows these supports extending vertically from the channels. During manufacturing these protrusions face downwards to hold the PVA inserts at the necessary height. After curing these were the only exposed surfaces of the PVA inserts and after dissolution there are holes left behind where they once were. There were two holes per section of the tongue, one of which had a 2mm tube glued to it while the other was closed with silicone sealant. As the layer of glue applied to these holes can be thicker than the thin layer between the two components pressed together of the previous prototype, we found this prototype performed better and experienced less frequent failure at higher pressures than previous prototypes.

We created only two prototypes of this design but the second was not ready to be tested when physical experiments were halted. The first prototype did provide some initial observations. We found that manufacturing was quicker as no bubbles formed during stage 5 of the manufacturing process in Figure 20. Initial observations showed that this prototype was able to hold a greater volume of air than previous prototypes. While previous prototypes reached maximum displacement around 20 mL of air, this prototype reached maximum displacement around 35 mL of air. Additionally, this prototype was pressurized for at least 20 cycles without failure. It is important to note that these are informal numbers and official testing is needed to confirm these numbers with standardized and controlled conditions. During the first integration of this prototype and the test bench described in chapter 5, there was too much pressure applied to the tongue and the middle pneunet broke. As this occurred during a demonstration and pressure equipment was not attached, it is not known at what pressure the failure occured, but we know the solenoid was powered at 5V. This failure occurred at one of the sealed holes on the bottom of the prosthetic , was easily repaired and the power on the test bench pumps was adjusted.

We designed a subsequent prototype in which all interior channels are made of PVA and held in place by being pressed into holes in the curing tub. This type of prototype was a natural next step for considerations of manufacturability and consistency in a product. The current placement method for the interior channels of a single component prototype allows variation in the placement between prototypes, subject to human error, as the PVA inserts slide around slightly whenever the prototype is bumped and may not even be placed in the correct spot to start. The built in holes of the new curing tub would force the channels to consistently be in the exact same place, increasing reproducibility as well as reducing time necessary for preparation. The ultimate goal will be full automation but for now this new prototype is a natural intermediate step. This was intended to be part of our methodology with manufacturing observations and results but for now will have to remain as future work. As such it will be discussed more in section 9.1 with images included as possible.

4.2.4 Magnetic Actuation

Pneumatic networks tend to take a large amount of space as they require many components and the pumps tend to be bulky as smaller pumps become expensive very quickly. For example, the current pumps we use, discussed more in chapter 5, are approximately 5.5cm long and 2 cm in diameter and cost $8. A breast pump we researched as a potential replacement is smaller but cost $46.99. Magnets stand as a potential replacement to the entire actuation method of pneumatic networks. A magnetic prototype would be able to employ the same type of vertical displacement driven by the repulsion between magnets, which can be much smaller than pumps. A magnetically actuated tongue could then operate by imbedding either magnetic microparticles [54] or full size magnets into the tongue then moving a separate magnet underneath the tongue to repel the tongue upwards.

As magnetic microparticles were determined to be insufficient in Chapter 4.1.2, this design embedded 5mm magnets into the tongue. These were designed to be embedded into the pattern shown in Figure 38. The prototype also had a space within the tongue but underneath the main area of embedded magnets, which can be seen in Figure 39. This area allows a secondary magnet to be moved underneath the main line to repel the tongue upwards. The only actuation method necessary is a motor to move the bottom magnet back and forth, which is much smaller than the pneumatic systems of the pneunet prototype.

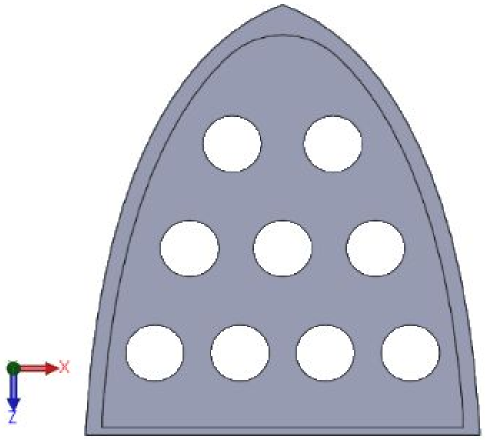

Figure 38: Magnet Inset Pattern. The shape of the mold for the magnetic prototype as well as the pattern of magnet placement to be embedded within the tongue.

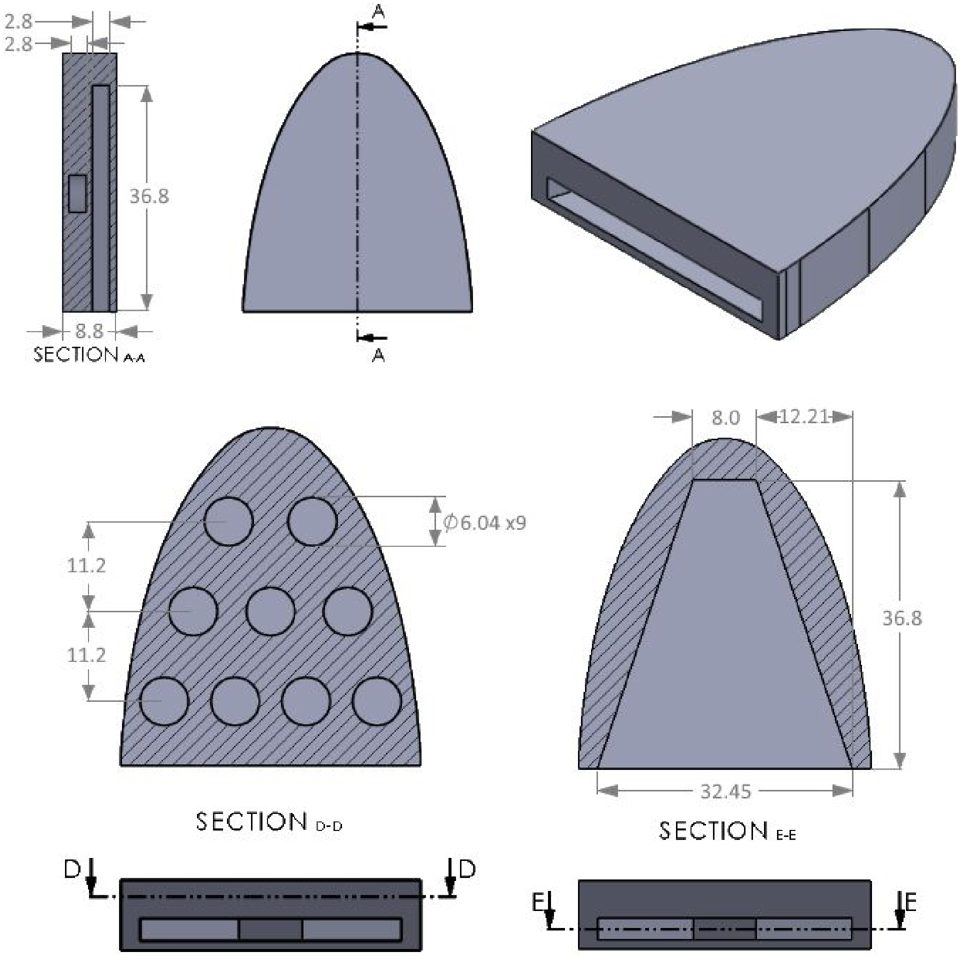

Figure 39: Magnetic prototype drawing, created in Solidworks.

We proceeded through step 2 and into step 3 of the manufacturing process in Figure 20. In step 3 there were several different steps of curing the silicone and then curing more silicone around the first layer. This was meant to produce a tongue with magnets embedded inside the silicone by holding them in place until the silicone cured. During this step the magnets would not hold in place and would bend cured silicone to align poles. It is possible that with more time, a better method to hold the magnets in place while being embedded into the tongue could create a successful prototype. For now, it is not feasible as the magnets are too strong for the material and compromise the integrity of the tongue's structure even if successfully embedded into the tongue.

4.2.5 Linkage Actuation

In continuing to explore other prototypes, one option was a linkage prototype that could be entirely 3D printed. Thus, a model based off of the traditional hard robotic four-bar linkage system was designed in SolidWorks (See Figure 40) [64]. The model consists of a flat surface with two flat pieces on the bottom with cutouts in for an axle. The flat surface standing in for the tongue sits on top of three columns and is secured to the base in the back with another axle and two collars. Two linkages are secured to either side of the back column with another axle and two more washers. The axle in the cutouts of the tongue slide into the linkages. More collars aid in connecting the linkages to the washer and the tongue. Design Specifications for the components can be seen in Appendix B.

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

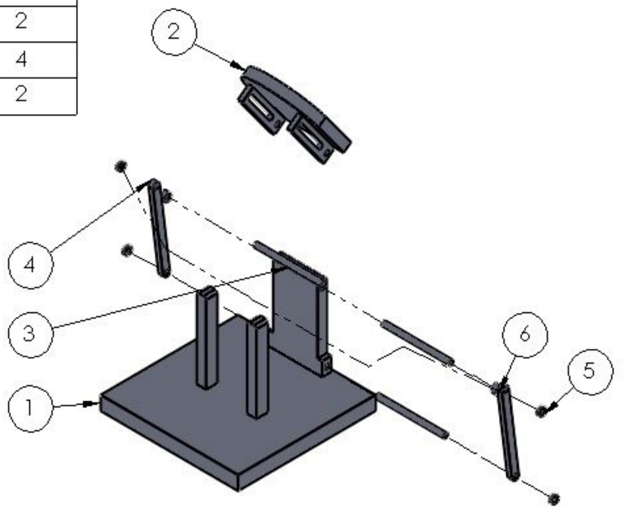

Figure 40: Drawing of Linkage Prosthesis with Labeled Components

In simulation, a motor is attached to the axle connecting the linkages and the tongue and is set to rate towards the back of the thing. As a result, the motor moves the axle backwards, and the tongue angles up as a result of a decreased angle between the linkages and the back column. The motion is demonstrated in Figure 41 and Figure 42. However, future iterations of the design could integrate an attachment to the linkages that the patient can bite on to provide a torque that moves the linkages backwards, making the system purely mechanical and eliminating the need for a control system.

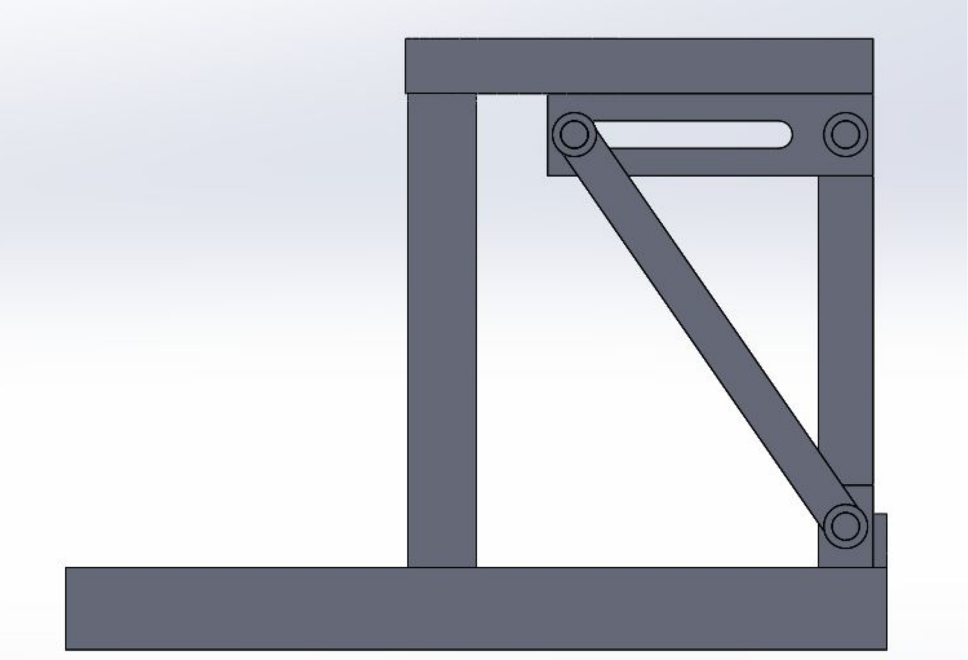

Figure 41: Linkage Prosthesis in its resting state

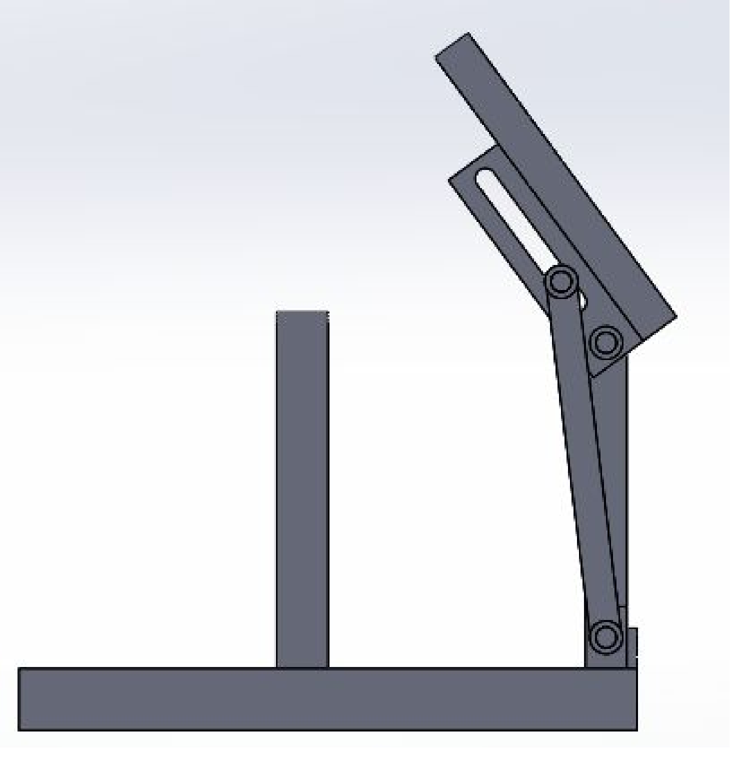

Figure 42: Linkage Prosthesis actuating to its full height

Other benefits of the linkage system come from the fact that it is 3D printed. Because the miniaturized device would be 3D printed, it would be cheap to produce and save material. Furthermore, the current design is more customizable to the patient. Dimensions can be edited based on the measurements from the patient, and create a fit that is tailored to the patient and their needs.

Unfortunately, many of the drawbacks of a linkage system come from the fact that it is 3D printed. To begin, the axles would be difficult to 3D print because printing a miniaturized axle of a very small diameter, as smaller parts have a greater chance of warping when 3D printed. Additionally, the smaller parts of the model (more specifically the collars and the axles) are more likely to break due to their small size, and creating a choking hazard if they break in-vivo. Furthermore, integrating the linkage into a retainer would be more difficult than simply attaching just a prosthetic tongue to a retainer, as the retainer would need to be deeper than the average retainer in order to accomodate all of the parts. If a control system were required, that would also need to be integrated into the retainer.

With these concerns in mind, the focus on a linkage model was swayed with the successful manufacture of a seamless silicone prototype.

4.3 Final Design Selection

If a design was created with dimensions that could fit in a mouth as specified in section 3.3.1 then the concept received a check under size. If the part could be manufactured at all it received a check underneath manufacturing. If the part could be pressurized with air inside it’s chambers, this not being applicable for magnetic or linkage concepts, it received a check for pressurization. If the prototype was able to produce displacement in the vertical direction, it received a check. Finally if the prototype could be subjected to repeated actuation or pressurization without consistent failure, it received a check under cycling. It is important to note that these constitute an assessment of the basic functionality of a prototype and do not state if the prototype meets performance specifications. The best candidate, as demonstrated by Table 6 is the single component prototype. Future sections will use this single component prototype as a basis for testing and analysis. These tests will then determine if the design meets it’s performance specifications.

Table 6: Design Selection Matrix

	Size	Manufacturing	Pressurization	Displacement	Cycling
Linkage	N/A	✖	N/A	-	-

Magnetic	✔	✖	N/A	✔	✔
Polyurethane	✔	✔	✖	-	-
Two Component Silicone	✔	✔	✔	✔	✖
Single Component Silicone	✔	✔	✔	✔	✔

4.4 Prosthesis Integration

With a functioning tongue prototype, we need to perform tests. Ultimate design validation comes from the bolus test which assesses the prototype's ability to move a bolus backwards in an oral cavity to mimic the swallowing process. This requires an oral cavity and the required integrations that allow the tongue prototype to operate within this oral cavity. This section discusses the creation of the oral cavity and the steps taken to integrate the tongue into this. We created a PLA casing that holds the tongue and is in turn held in place in the mouth by a retainer. This casing and retainer connected to the tongue will serve as a complete prosthesis.

4.4.1 Creation of Oral Cavity

The location for full prosthesis validation will eventually take place in an oral cavity. The function of the prosthesis can be tested without direct human contact for an initial stage. As mouth measurements are very difficult to come by and vary largely from person to person, we modeled the oral cavity off of an MRI or a specific patient, seen in Figure 43.

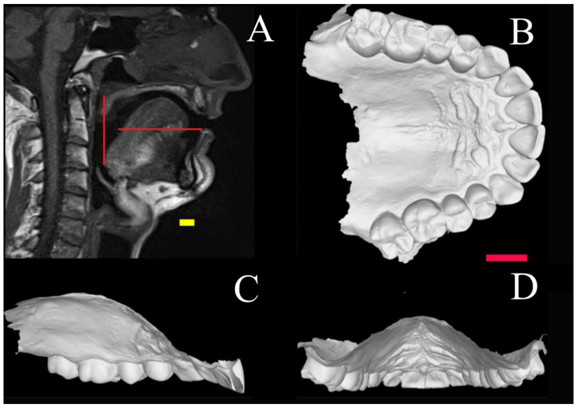

Figure 43: MRI of an Oral Cavity. Scale bar at 1cm. Image reproduced with modifications from [55].

We created an oral cavity matching dimensions from Figure 43 as closely as possible. We digitally integrated this model with a model of teeth received from Cohen et al [56]. and 3D printed the model.

4.4.1.1 Digital Modeling of Oral Cavity

We first searched the following sites for publicly available models of a mouth: Yeggi.com, Free3D.com, Turbosquid.com, Sketchfab.com, and CGTrader.com. We required a model that had an accurate roof of the mouth, an easily removable tongue as we are simulating a patient with no tongue, and a throat to allow for exit of a test bolus. Some of the listed sites, particularly Yeggi and Turbosquid, had realistic models of the mouth, but the bottom component never fit our needs to simulate a patient without a tongue and the roof of the mouth was flatter than dimensions found from Figure 43. Models were most often realistic in image, the teeth, or the tongue, none of which are important for our oral cavity.

The oral cavity itself was created by measuring the dimensions of several planes of the hard palate, creating sketches of each of these planes, and lofting them together. We measured the following dimensions of each cross section, as illustrated in Figure 44: the height (B) from Figure 43C, the width from tooth to tooth (A) from Figure 43B, and the profile of the curve at the very top from Figure 43D. We combined this spliced section with a curvature at the back to produce a vertical wall instead. This produced the model as seen in Figure 45. The bottom of the mouth had unknown dimensions as this depends on how much material the surgeon removes from the tongue and can vary wildly from patient to patient. Figure 43 contains a vertical height of 3 cm from the bottom teeth to the bottom of the soft tissue of the mouth. A space on the bottom was created at this depth in the shape of the mouth above it.

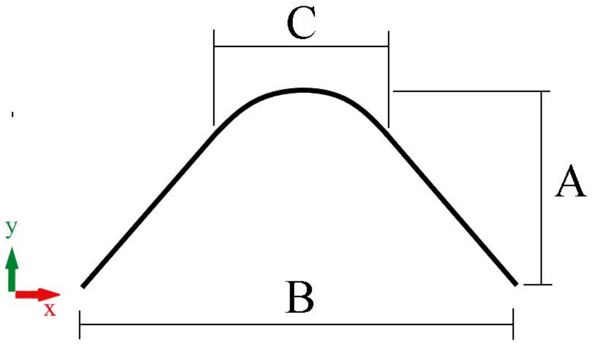

Figure 44: Oral Cavity Cross Sectional Area

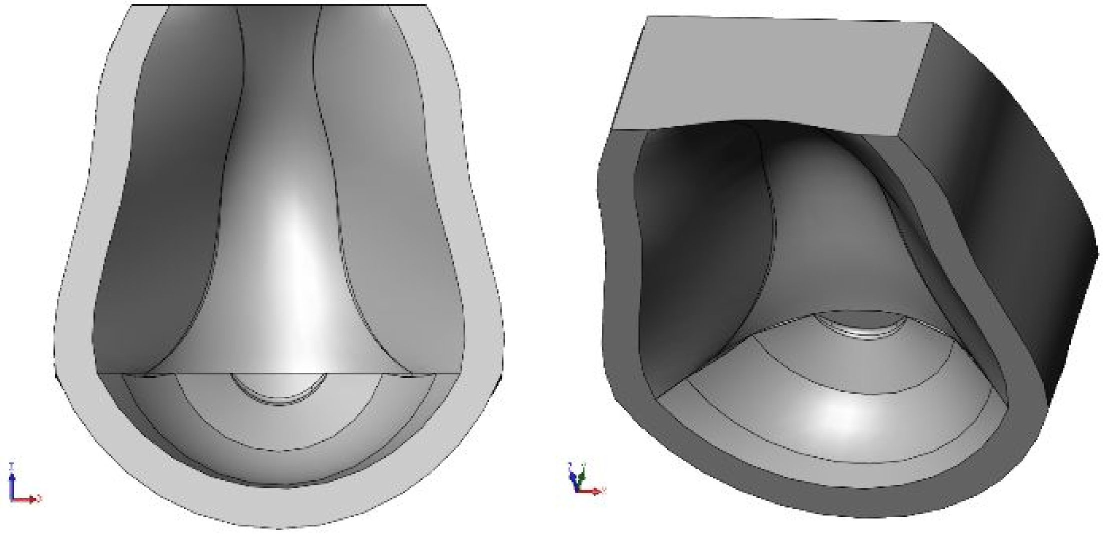

Figure 45: Oral cavity roof

Lastly, we created an opening to represent the esophagus. The throat is about 2.54 cm [57] in diameter, but wider when swallowing. As we can not create a variable width with the time and budget of this project, we created an opening approximately 2.54 cm in width highlighted in yellow in Figure 46. No relevant research was found on the depth of the throat opening. This resulted in the bottom oral cavity as seen in Figure 46, which we consider to be an overestimation of the available space. The dimensions of the bottom of a human mouth vary widely as they are dependent on how much of the tongue an individual surgeon chooses to remove. Approximate dimensions assess 9 x 6.4 x 1.7 cm to be average as stated in Table 3. The dimensions of the bottom of our oral cavity are 5.2 x 3.8 x 2.22 cm.

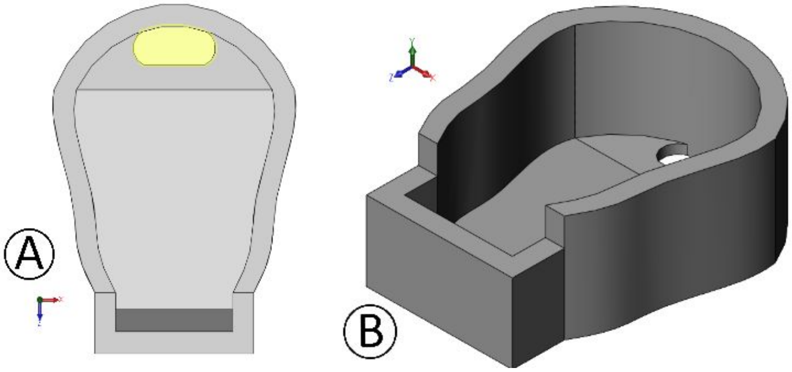

Figure 46: Oral Cavity Bottom. A) Top View. B) Isometric View.

The teeth model received from Cohen et al. exists in two parts, the top and the bottom, shown in Figure 47 and 47 respectively. We received these teeth models as STL files and imported them into Blender for integration into the oral cavities.

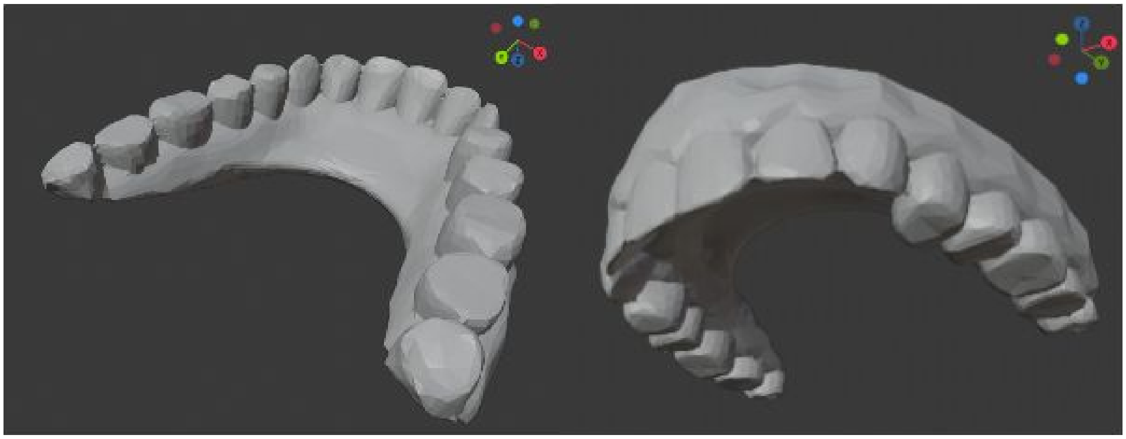

Figure 47: Teeth Top

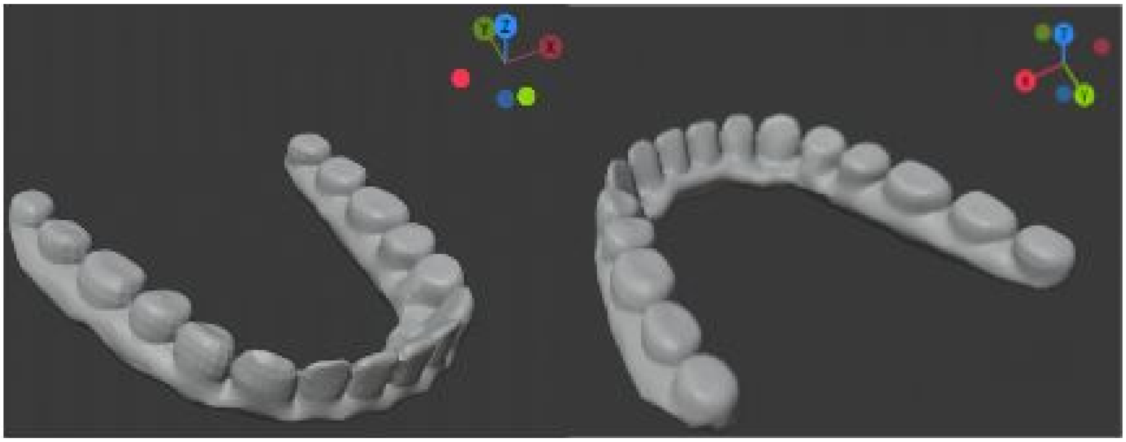

Figure 48: Teeth Bottom

In Blender we merged the teeth and the oral cavity models. This required point by point connection to create a continuous mesh. This was exported into an STL file and then imported into a g code generating program to translate the STL file into a 3D printer readable format. The g code generating softwares used include PrusaCrontrol [58], Slic3r [59], and Ultimaker Cura [60]. Problems developed at this point as PrusaControl interpreted errors in the model and could not process the entirety of the bottom mouth. The program Slic3r was able to fix some of these errors but not all of them, and after several iterations of importing one program's repaired file into the other program and vice versa, we were able to generate a model that could print in a Prusa Mark 3 printer without major error. The main problem was that the programs sometimes did not recognize a facet created by Blender [61] and thus would fail to recognize that entire layers of the model existed. For example, it might generate code to print layer 0 to 20 of a 100 layer print and then 60 to 100, passing by layer 20 to 60. This can not be printed as layer 60 needs to be physically printed on layer 59, which is air in this instance.

4.4.1.2 Prototyping the Oral Cavity

The two printed oral cavity components can be seen in Figure 49. This prototype has one outlying issue: there is a tooth missing in the bottom prototype. For unknown reasons, there is a single tooth missing in the bottom section of the oral cavity. The g code writing programs (Slic3er, Prusa Control, and Ultimaker Cura), did not process the presence of surfaces on one particular tooth. We found no inconsistencies in the prototype between this tooth and others but we were unable to develop a 3D print that was not missing the tooth. However, as the performance of this oral cavity is dependent on the interaction of the tongue and the roof of the mouth and not the teeth, we determined that this missing tooth will not affect testing in the oral cavity. Similarly, we did not proceed to create cheeks for this prototype as the cheeks are outside of the oral cavity and will not affect the performance of our prosthesis. The cheeks may be important to keep large amounts of liquid within the teeth, but this prosthesis is intended to aid in semi-solid based bolus movement. As a result, the presence of cheeks is not important for this project.

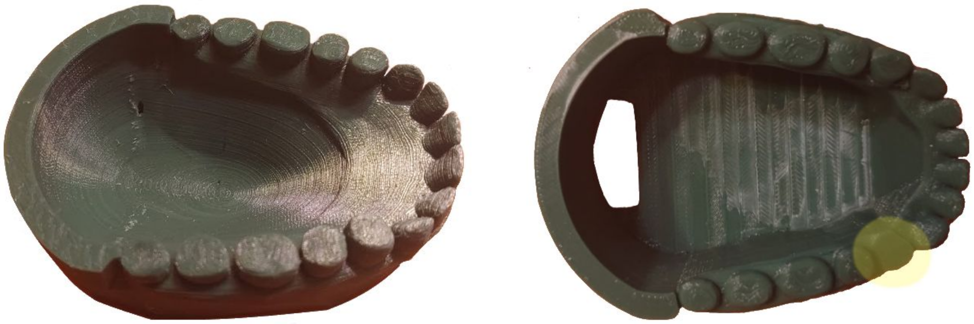

Figure 49: 3D printed oral cavity. Top of the oral cavity (inverted) is on the left and the bottom oral cavity is on the right.

The top teeth in the prototype, specifically the two in the front shown in Figure 47, visually appear smaller than normal teeth but the structure of all the teeth together has the correct dimensions and the size of the teeth will not affect testing as it is only the roof of the mouth that the tongue will contact.

To create a translucent prototype to be able to see inside the oral cavity during use, we created oral cavities made of epoxy [62] as specified in Appendix A. The manufacturing process is written in Appendix C. The initial epoxy oral cavity that we created can be seen in Figure 50. It can be clearly seen that these prototypes are not entirely translucent. Objects are visible through this oral cavity but details are indiscernible. Interior performance of the tongue and movement of a bolus can be visible if both are vibrantly colored. A translucent prototype is optimal for ease of visibility to everyone. As such we recommend that future projects use clear resin in a form2 [63] printer to recreate this oral cavity.

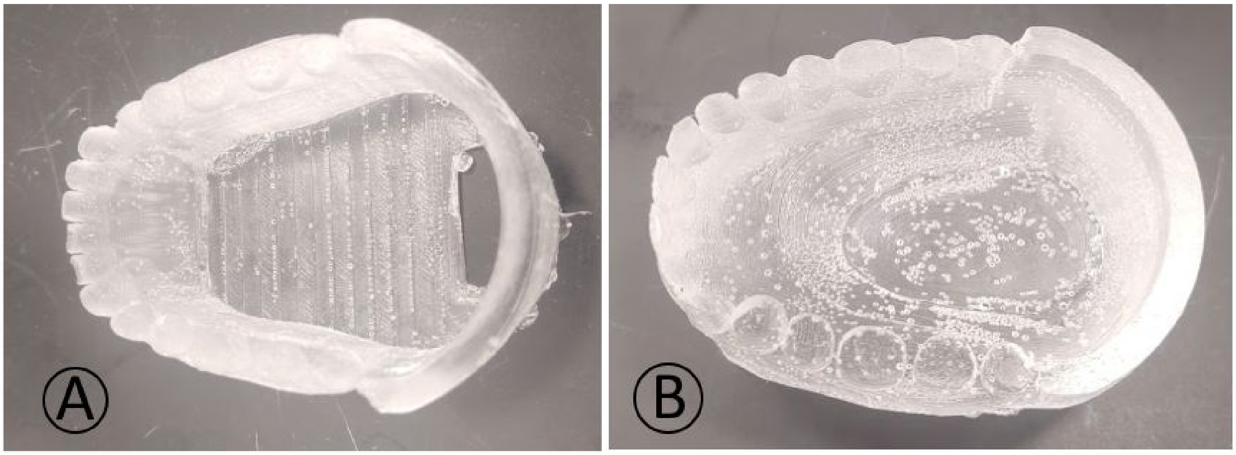

Figure 50: Epoxy oral cavity. A) Bottom. B) inverted oral cavity top.

4.4.2 Casings

The design by Araya demonstrated a clear lateral displacement. This is a problem as the desired displacement is vertical, and displacement in other axes will reduce the displacement in the desired axis. We created PLA casings to hold the tongue prosthetic in place in a mouth. The casings provide structural containment of the sides of the tongue, restricting lateral displacement. It also allows for integration between the prosthesis and the retainer as attachment of the metal and epoxy of the retainer is more stable with the hard PLA casing rather than the hard, distensible silicone elastomer. The casing, shown in Figure 51 and Figure 52, was designed simply to have a band of plastic around the outside of the tongue that is half the height of the tongue. The bottom is a flat layer with a missing area where the tubes are attached. Material is minimized in this section to reduce production time during 3D printing. The tongue and the retainer are attached with loctite glue around the entire casing rim.

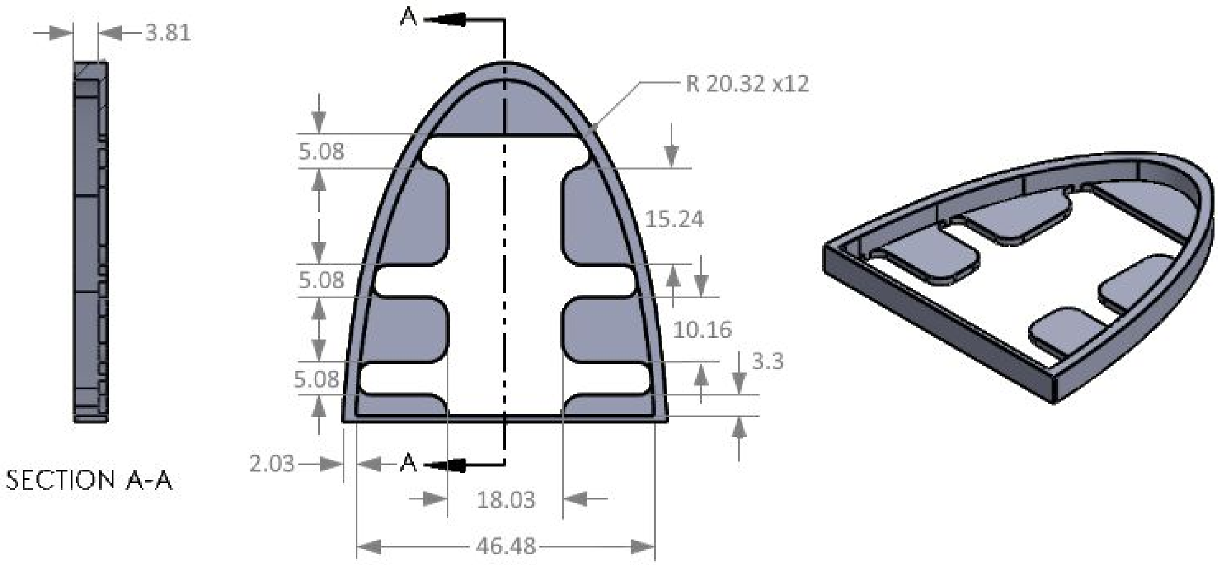

Figure 51: Casing Design

Figure 52: 3D Printed Casing

4.4.3 Retainer Development and Integration

During the initial miniaturization stage of the tongue, it was determined that, if the tongue was to be miniaturized, a method for attachment of the tongue to the oral cavity must be found. Initial discussions of the topic resulted in the conclusion that the tongue could be affixed to either a denture-like structure or to some type of removable retainer. While research of other prosthetic tongue designs showed that one option of fixation was to permanently wire the tongue to the back teeth, this option was ruled out as easy removal of the tongue for cleaning and maintenance would be necessary [65]. As removal of the teeth only occurs in oral cancer cases where there is a risk of the cancer metastasizing into this area, it was determined that a removable retainer design would have the most benefits as these devices are custom fit for each patient, making it easy to add a removable retainer to a denture in the case that a patient does have some or all of their teeth removed.

After deciding that a removable retainer was the best option for fixation, retainer designs were studied so that necessary materials and fabrication methods could be determined. While it was found that the most common removable retainer is the Hawley retainer (see Fig. 52), this design relied upon the use of both orthodontic wire and a powder-based acrylic, making fabrication of this type of retainer nearly impossible as orthodontic acrylic powder is very difficult to purchase without an orthodontic licence [66]. With this in mind, acrylic-free retainer designs were investigated, leading to the discovery of the Sarhan acrylic-free type removable retainer. This retainer, made fully of orthodontic wire, consisted of an outer labial bow and Adam's clasps around the molars, both of which are found in Hawley retainers. Rather than relying on an acrylic base, an inner lingual bow was shaped with orthodontic wire, providing the structure needed along the posterior side of the teeth without requiring use of acrylic [67].

Figure 53: A Hawley removable retainer. Reproduced from [68].

As Hawley retainers are typically the standard devices used in orthodontics, plans and instructional guides for development of an acrylic-free retainer were limited. However, as these two retainer types share common features, it was possible to form wire components for the retainer with the help of Hawley retainer wire bending guides in addition to photographs of Sarhan acrylic-free retainers [69, 70, 67].

In an effort to better ensure safety and stability, stainless steel orthodontic wire was purchased to be used in the development of the retainer. Based upon specifications found for acrylic-free retainers, it was determined that it would be best to purchase both 19 and 20 gauge wire [67, 71, 72]. Along with this, a pair of three prong orthodontic pliers were purchased to aid in wire bending [73]. The 3D printed oral cavity was used as a model so that the retainer could be used with this oral cavity when testing the tongue. As the retainer was designed to hold the tongue in place in the lower portion of the oral cavity, only the 3D printed piece for the mandible was required. With these supplies, as well as additional wire cutters and pliers, development of the main components of the retainer began, resulting in the pieces seen in figures 53 through 55.

Figure 54: Labial bow

Figure 55: Adam's clasps

Figure 56: Lingual bow

Typically, wire and wire-acrylic retainers are soldered at wire to wire connections to ensure that the retainer is stable and only consists of one component [67]. With this in mind, the developed components of the retainer were taken into the rapid prototyping lab where soldering irons were available so that the retainer could be bonded together before attaching the tongue to the retainer. However, during this process, it was discovered that the tools available did not provide enough heat to allow for soldering of the wire, even when flux was used and the surface of the wires were sanded down to increase surface roughness. As soldering was no longer an option, other methods of affixing the retainer components to one another were investigated and a steel-reinforced epoxy [74] was purchased as it had the highest likelihood of binding to the stainless steel wire. As this substance is not suitable for internal use, it was determined that further investigation and recommendations would be required in order to develop a system safe for use in the human mouth.

Although the steel-reinforced epoxy proved to bond very easily to the wire, the size of the wires and the amount of epoxy required to ensure a strong bond impacted the retainer design, causing many issues with the fit of the retainer onto the oral cavity as the wires were shaped with soldering in mind, thus leaving little space between the oral cavity and wires, making it hard to encase the full wire connections in epoxy. Once the epoxy was dried and trimming and sanding was complete, the sample tongue and plastic casing were obtained. Due to the size of the casing, the space taken up by the retainer, and the size of the oral cavity, the initial bond between the tongue and the retainer was difficult to develop as the tongue casing had to effectively rest on top of the wire from the Adam's clasps. Due to this placement when epoxy was applied, it was found that based upon the placement of the tongue, retainer, and epoxy to bind these components together, it would be impossible for the oral cavity to be closed during testing. As the epoxy was sanded down, it popped off of the tongue casing, showing that the epoxy was not a suitable material for attachment of the retainer and tongue casing as it did not bind well with plastics. In addition to this, the retainer went through many iterations due to the epoxy cracking and separating the wire components from one another. Due to these difficulties, other retainer designs were developed. These alternative designs were found to be ineffective as they did not provide enough grip between the oral cavity and retainer to allow for the fixture to remain affixed in the mouth. Due to time constraints and the need to create a design that would not get in the way of the tongue, there are no current alternative retainer prototypes.

4.5 Chapter 4 Summary and Conclusion

This section has discussed the design and production of several prototypes for the tongue. It has concluded that the single component silicone elastomer prototype is currently the most apt for testing and analysis and is the most likely to succeed and meet the requirements specified in chapter 3. It has lastly described the process by which this can then be integrated into an oral cavity for testing. The next chapter will discuss the design process for the control module that will actuate this prosthesis.

Chapter 5. Design process for Control Module

This section discusses the test bench that was created to power the soft robotic tongue and collect data on its performance. Previous work had produced a test bench for associated prototypes, but a significant redesign took place over the course of this project to improve and refine functionality. More nuanced motion control will be addressed, as well as the integration of equipment associated with measuring force and pressure. Finally the design process for the most current test bench prototype will be laid out, from conception to manufacture.

5.1 Needs Analysis and Design Requirements

The test bench created for this project is based on the original design created by Araya. The test bench consisted of three miniature air pumps and three miniature 3-way solenoids powered by an Arduino UNO microcontroller. The test bench was used to inflate the soft robotic tongue in order to measure displacement.

Araya’s design relied upon time based programming to inflate the tongue, and was only able to inflate all three chambers at once. The test bench did not contain any sensors other than an on/off switch, therefore external software was used to measure displacement. No other data was gathered for Araya’s prototype.

The improved test bench must be able to inflate individual sections of the tongue, preferably relying on distance based programming rather than time based so that it is more accurate. Multiple programs must be created to operate different sections of the tongue. The test bench also must be able to collect qualitative data on the tongue such as internal pressure and displacement. This information must be displayed on an LCD screen for ease of use. The test bench must also be able to accommodate additional sensors that may be needed for future testing. Future tests may include measuring the force applied by the tongue, and inserting a miniature camera inside the 3D printed oral cavity to observe the interaction between the prosthesis and the mouth. Miniature components such as air pumps, solenoids and microcontrollers must be used where possible to aid in the eventual miniaturization of the entire system.

Since soft robotics is a relatively novel field, these tests may be conducted using non-traditional methods. These methods are explored in further detail below.

5.1.1. Measuring Tongue Motion

Measuring the motion of the soft robotic tongue is important for mimicking the motion of the human tongue. The motion is also an important component to bolus testing, different tongue movements may move the bolus towards the throat differently.

The motion of the tongue was evaluated in previous work using a camera and motion-capture technology, which is a simple and inexpensive way to analyze motion. Araya conducted this test by gluing black beads onto the top of the prototype tongue to serve as tracking points, shown in Figure 57. Tracker, an open source tracking software, was used to analyze video footage of the tongue's motion. Araya observed some inconsistencies in the motion tracking but hypothesized that they could be resolved by filming the motion against a white background [10].

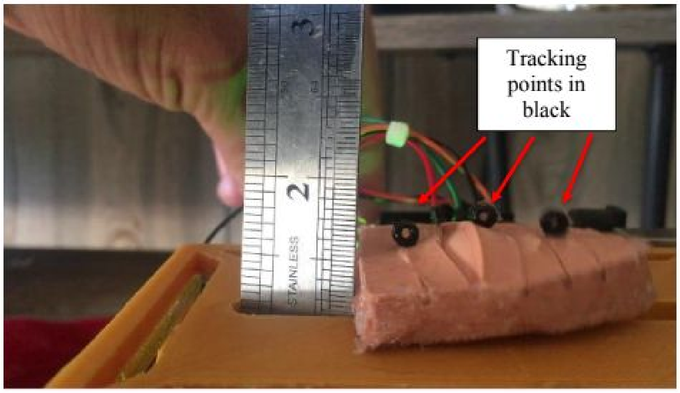

Figure 57: Displacement testing of Araya's prototype. Reproduced as is from [10].

This software was re-examined by the team and determined to be an accurate method for measuring tongue displacement. The tests were conducted on a solid white background and a 12.2 megapixel camera mounted to a tripod was used for filming, shown in Figure 58.

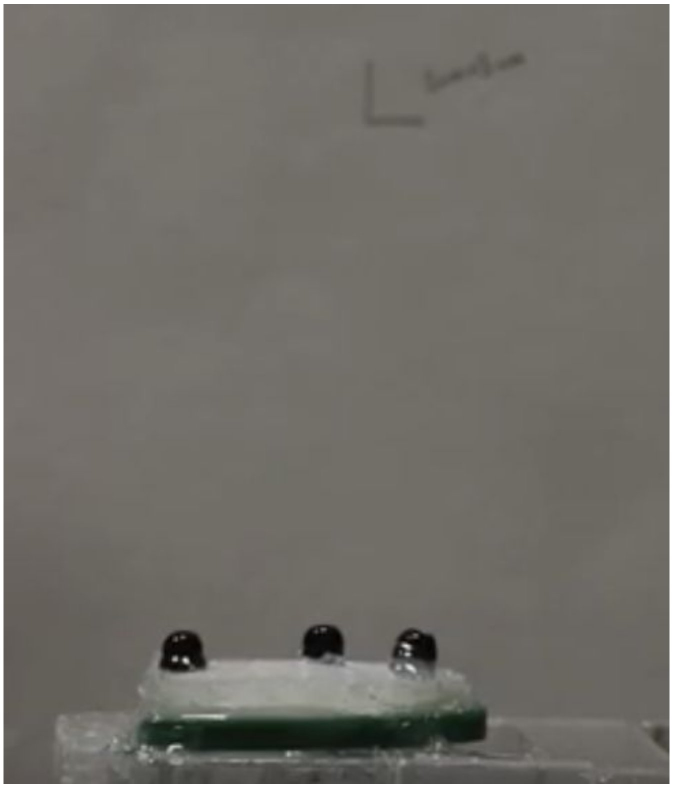

Figure 58: Experimental set up of displacement testing, for method verification only.

External measurement methods are useful for early prototyping, but the amount of set up required is time consuming and not ideal for repetitive measurements. An internal measurement method such as a flex sensor may be appropriate for later models of the robot when repetitive testing is required.

A Composite Soft Bending Actuation Module with Integrated Curvature Sensing by Ozel et al. [75] discusses the usage of resistive flex sensors and Hall effect sensors in order to measure the curvature of a soft bodied snake robot. Two robotic snakes were created for this research, one with a flex sensor from Spectra Symbol and another with a custom fabricated Hall effect curvature sensor, both embedded into the inextensible layer of the robots. A Hall effect sensor was chosen based on its accessibility, ease of fabrication, accurate sensor readings and lack of external circuitry requirements. The sensor was created by placing a Hall effect sensor, specifically AD22151 from Analog Devices, and a small magnet on a flexible PCB, as shown in Figure 59.

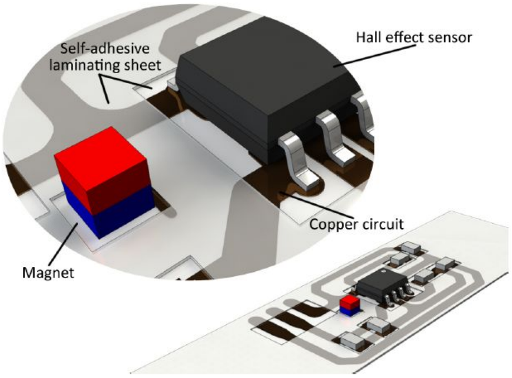

Figure 59: Hall effect sensor schematic. Reproduced as is from [75].

Ozel et al. determined that the flex sensor was subject to minor inaccuracies and significant overshoot when the position of the robot changed. Conversely, the magnetic flex sensor produced accurate readings but was subject to noise when the robot was at rest. The authors proposed a low-pass filter be used to reduce noise in future applications of the magnetic flex sensor.

This paper does not address the impact that the two sensors have on the overall motion of the soft robot, which is a limiting factor of using an embedded sensor to measure robotic motion instead of motion-capture. Additionally, since the sensors are embedded into the inextensible layer of the soft robot, this method is not suitable for rigid bottomed robots such as the soft robotic tongue. The sensor would be mounted on the underside of the tongue and therefore would not measure deflection caused by the expansion of fluid chambers.

5.1.2. Measuring Pressure Inside Tongue

It is important to know the internal pressure of the soft robotic tongue because it is correlated to the displacement of the tongue. In order to measure the pressure inside each pneunet channel, small, low-pressure sensors were integrated into the test bench. The basis for this design element was inspired by The Soft Robotics Toolkit. [76] Honeywell ABPDANN030PGAA5 analog pressure sensors were chosen because it operates on 5 Volt logic and has a measurement range of 0 to 30 psi, or approximately 0 to 207kPa. The air pump used on the control module has an output pressure of 100kPa.

5.1.3. Additional Measurements

We initially planned to measure the force applied by the tongue during actuation, but were unable to establish an accurate method to do so. We considered embedding a flexible strain gauge between the extensible and inextensible layers of the tongue, but this method would not have measured the desired force because it would be mounted on the underside of the tongue.

We also considered mounting force gauges inside the 3D printed oral cavity to measure the impact force of the tongue on the mouth to make sure that the force applied is within a safe range. We were unable to find small enough force gauges, both in size and measurement range, and were concerned about the overall accuracy of force gauges for this application.

We expect the force applied by the tongue prosthesis to be less than the human tongue, therefore we decided to omit this measurement. Small limit switches could be embedded into the 3D printed oral cavity in order to understand the placement and actuation of the prosthetic tongue.

5.2 Conceptual Designs and Early Prototypes

Araya designed a test bench to inflate the soft robotic tongue using low-voltage air pumps and three-way solenoids to direct the flow of air into the pneunet channels, shown in Figure 60. This design served as the basis for our initial test bench designs.

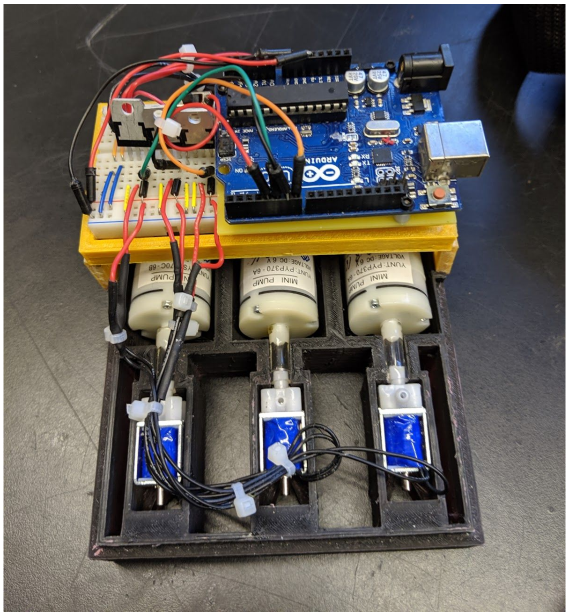

Figure 60: Test bench created by Araya to evaluate the tongue prototype.

The initial design did not provide adequate space to connect additional components such as an LCD screen and pressure sensors. These requirements were taken into consideration when we developed conceptual designs for the new control module.

5.2.1 Layout and Components

Two versions of the control module were drawn: a “stacked” design that was similar to the original device built by Araya, and a “flat” design where all components were mounted to a pegboard for ease of access and improved wire control. Both designs are shown in Figure 61 below.

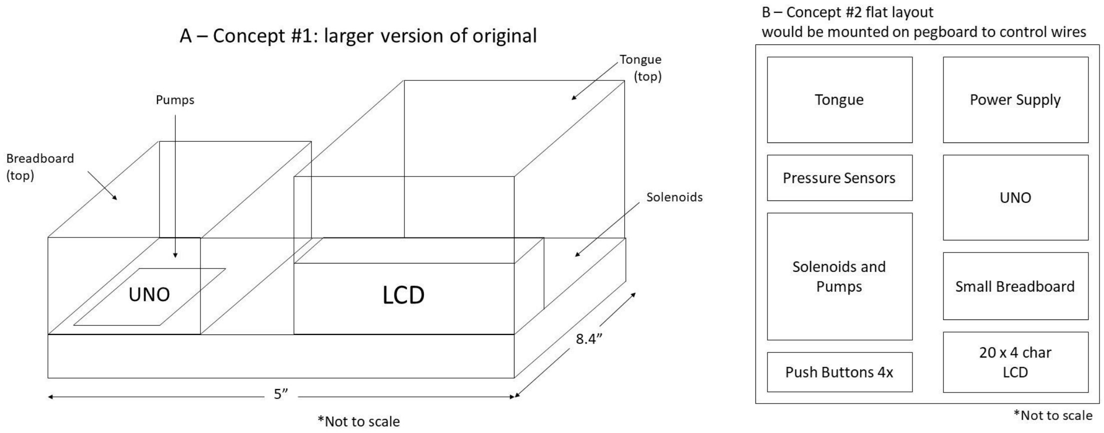

Figure 61: Conceptual designs for control module. (A) “Stacked” design, (B) “Flat” design.

We decided to pursue the stacked design because it took up less space than the flat prototype and could be manufactured using a 3D printer and laser cutter. The initial CAD model of the design was created in Solidworks and is shown below in Figure 62.

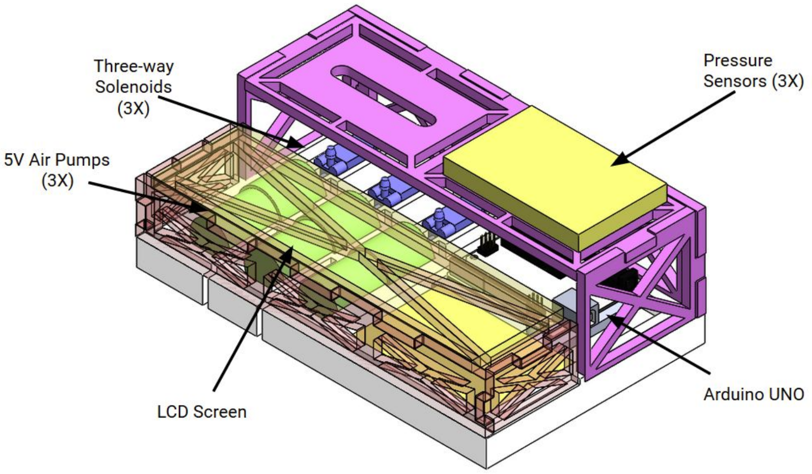

Figure 62: CAD model of initial control module design, created in Solidworks.

The base of the control module, shown in white, was based on the original design by Araya, but was made wider to accommodate a larger breadboard and allow room for additional electronics beneath the frames. The support frame for the tongue, shown in pink, and the support frame for the breadboard, shown in translucent red, feature interlocking tabs for stability and ease of assembly. There are cutouts on the sides of the frames to conserve material because the parts were 3D printed.

The air pumps, shown in green, and the solenoids, shown in blue, are from Araya's original model. The three-way solenoids are controlled by the Arduino UNO using a Bipolar Junction Transistor (BJT) motor driver to switch between open and closed states. The air pumps are powered directly from the V_{OUT} port of the UNO, meaning that they are always on. The other components on the control module include: four two-prong digital push buttons, three Honeywell low pressure sensors, one 20x4 character LCD screen, and an I2C SPI serial monitor to control the screen. The electrical components and circuit design are further discussed in Chapter 5.2.2.

The initial prototype of the control module was 3D printed on a LulzBot TAZ 6 [77], but the frames were not toleranced correctly so the tabs did not fit together properly and had to be glued together. The frames were re-cut in quarter-inch acrylic using a Universal Laser PLS6.60 [78] which greatly improved its stability. This also allowed us to see the electronics that were contained underneath the frames. In the final iteration, the cut outs were removed to reduce the time it took to laser cut them, and clearance holes were added so that they could be fastened together with M3 screws. Figure 63 below shows the acrylic frame, the oral cavity, and prototype of the soft robotic tongue without the retainer mount. The slot on the top of the frame allows for the tubing to pass through the oral cavity, but this meant that the tongue had to be disconnected from the solenoids for easier access. Additionally, there was no method to attach the oral cavity to the frame at this time.

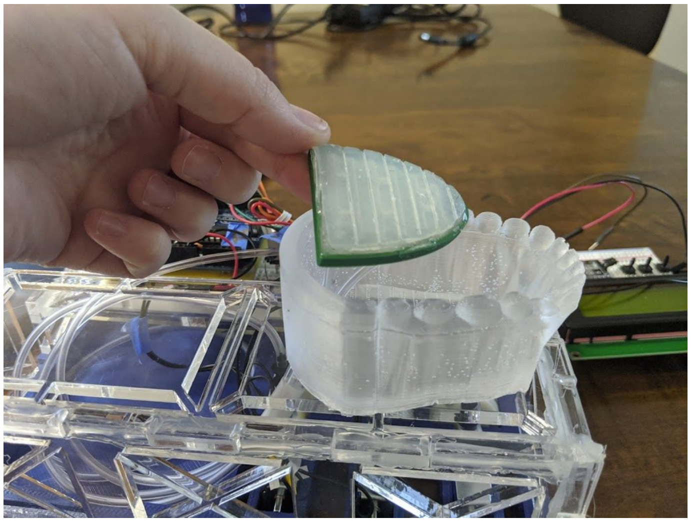

Figure 63: Acrylic frame of control module with oral cavity and tongue attached.

We made an approximate model of the oral cavity in Solidworks to design a way to attach it to the frame. A different model had to be created because the oral cavity was created in Blender as an STL file without dimensions. The first version of the oral cavity mount is shown in Figure 64 below. It consisted of a 3D printed adapter (pink) that could be permanently attached to the bottom of the oral cavity with tabs on all sides for easy attachment to the frame. Small cams (red) were laser cut and attached to the screws to fasten the mount to the frame (blue).

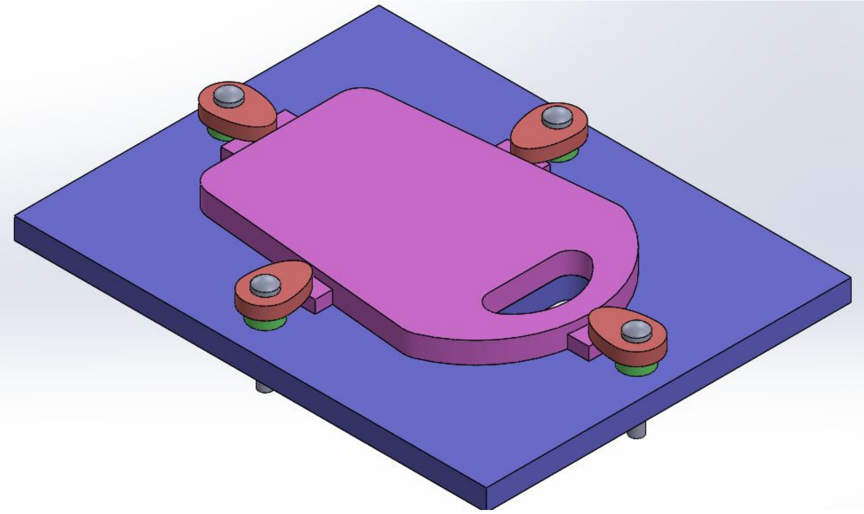

Figure 64: Initial design of oral cavity mount, created in Solidworks.

This design was modified in the final design so that the oral cavity and tongue were able to slide into place without having to thread the tubes through the frame. Additionally, the cams were removed and instead the mount was attached directly to the frame using M3 screws. This design is shown in Figure 65.

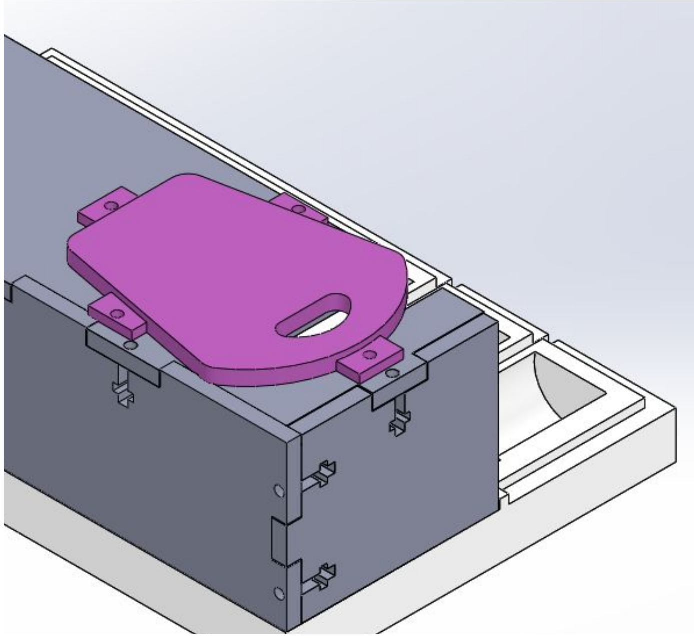

Figure 65: The final design for the oral cavity mount, created in Solidworks.

The next section discusses the electrical components used on the control module.

5.2.2 Electrical Components

This section discusses the electrical components used on the control module and their functionality. Table 7 below lists all the components used, and Figure 5 is the schematic of the control module.

Table 7: Components for control module

Part No.	Component	QTY	Description
U1	Arduino UNO	1	Arduino UNO microcontroller
U2	I2C adapter	1	I2C adapter for LCD
P1	Air pump	1	5V 100kPa air pump
S1, S2, S3	Solenoid	3	2 position, 3 way solenoid
LCD	LCD screen	1	20x4 char LCD screen
PS1, PS2, PS3	Pressure Sensor	3	Honeywell 0-30PSI analog pressure sensor
SW1, SW2, SW3, SW4	Push button	4	2-prong digital push button
R1, R2, R3, R4	Resistor	4	10kΩ pull down resistor
C1, C2, C3	Capacitor	3	0.1µF ceramic capacitor
Q1, Q2, Q3	NPN Transistor	3	PN2222 TO-92 transistor
D1, D2, D3	Diode	3	1N4001 diode

The 5V air pump was originally connected directly to V_{OUT} on the UNO, so it was always on. However, running all three pumps off the Arduino was a significant current draw, so they were moved to an external 9V power source controlled by a voltage regulator [79]. The regulator allows the strength of the pump to be adjusted. The solenoids are controlled using a binary junction transistor (BJT) motor driver, which is created by connecting a diode in parallel with the solenoid and an NPN transistor connected in series [80]. The pressure sensors are connected in parallel with a 0.1µF capacitor to create a low pass filter.

The momentary push buttons are used to select different inflation programs on the Arudino and are connected to digital ports [81]. The signal is stabilized using a 10KΩ pull down resistor. The LCD screen is connected to an I2C driver which is then connected to the UNO [82].

We used an I2C driver because it drastically reduced the number of output pins used on the UNO.

5.2.3 Program Design

The original program that Araya used to inflate the tongue was purely time based and was turned on and off using a two position switch. This limited the amount of inflation that the tongue could achieve. The redesigned control module features four different programs, one to inflate each channel, and one program to inflate all of them in sequence. The desired program can be selected by pushing one of the four buttons that are connected to the Arduino Uno. Multiple programs loaded onto the Arduino allowed us to test displacement for multiple channels without having to change the programming. It also allows us to vary the inflation time for each channel in order to achieve specific height or pressure.

The pressure sensor readings are outputted onto the LCD screen in close to real time to provide an accurate measurement of the internal pressure within the tongue. In order to effectively compare the internal pressure of each channel to the displacement data gathered using the tracker software the pressure readings must be printed and stored in a CSV file.

5.3 Pump and Input Pressure Testing

This section discusses tests that were conducted on the control module components and overall design before the final design was established.

The initial prototype of the control module consisted of three air pumps, which connected directly to the three-way solenoids. The first time we tested inflating the tongue with the control module, the inner channels of the tongue burst. Although this was partially due to the construction of the tongue, the input pressure was much too high and caused several other prototype tongues to burst. This is shown in Figure 66.

Figure 66: One of several tongues with burst interior channels.

We first attempted to reduce the pressure by reducing the input voltage to the air pumps using a voltage regulator, but the impact was negligible. At this point of the project the pressure sensors were not fully integrated so we were unable to get exact values for the change in input pressure.

We then decided to reduce the system one pump, which drastically reduced the input pressure. all three solenoids then had to be connected using tee connectors in order to run them all off of one pump. Although this layout is somewhat awkward and bulky the input pressure is now an appropriate amount to inflate each channel of the tongue. Based on the measurements from the onboard pressure sensors the necessary pressure to actuate one channel is approximately 35 kPa. Since the connection method between the pumps and the solenoids was changed, the base of the testbench needed to be redesigned. This reduced the size of the control module base and allowed it to be further condensed. Appropriate grooves were created on the base so that the tubing and tee connectors are properly sealed and not disturbed during testing.

Once the pumps were tested and the appropriate output pressure was reached, the final control module was assembled. This process is discussed in Chapter 5.4.

5.4 Final Design and Performance

This section discusses the final design of the control module, including CAD models of the design and the electrical schematic. Further information is included in Appendix I.

As mentioned in Chapter 5.3, the control module was reduced to one pump. The input ports on the solenoids were connected to the pump using a series of tee channels, and the output of the solenoids were connected to the pressure sensors and the tongue. The base of the control module was redesigned to accommodate a single pump and multiple tee connectors, but a physical prototype was never created due to limited access to a 3D printer in the later part of this project. A CAD model of the final design is shown in Figure 67. The electrical schematic for the final design is shown in Figure 68.

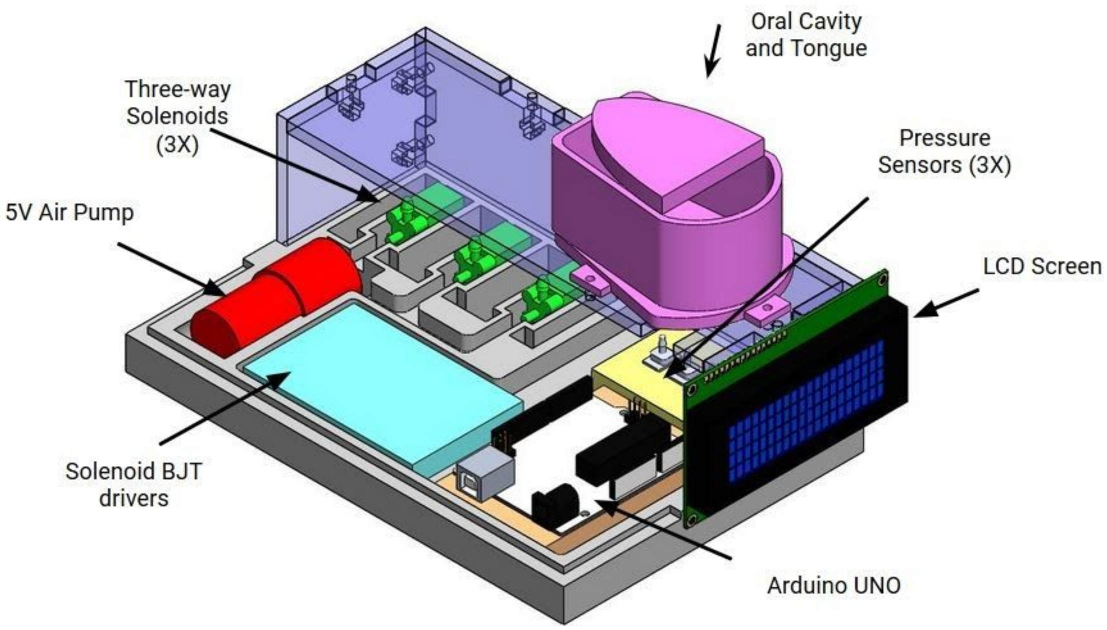

Figure 67: Final design of control module, created in Solidworks.

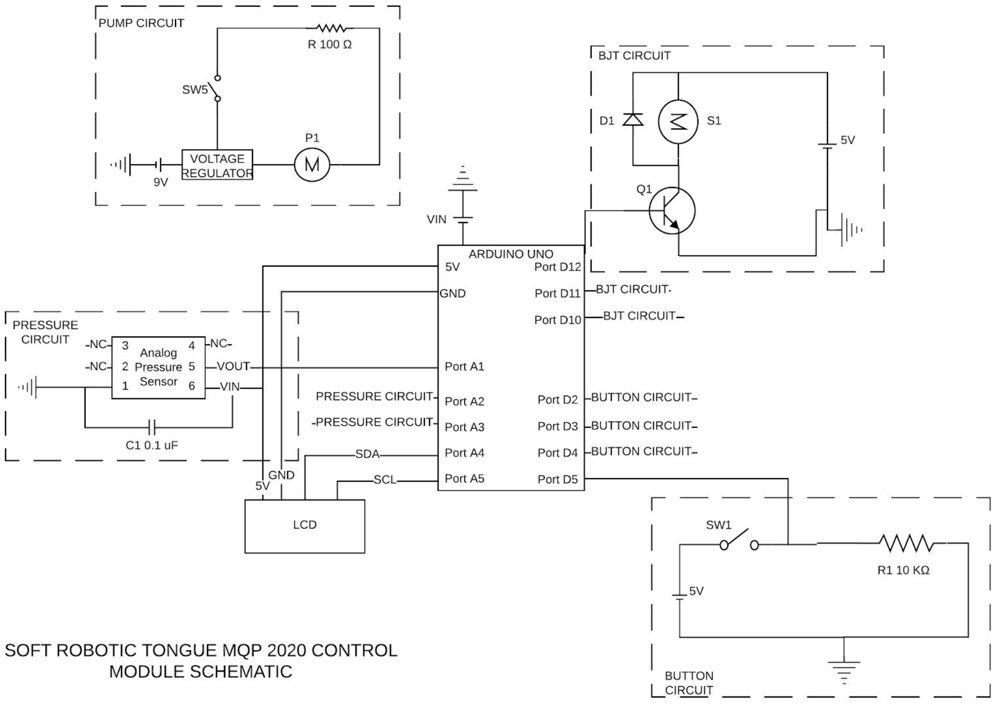

Figure 68: Electrical schematic for the updated control module.

We were unable to build the final design of the control module due to limited resources, so the original base was modified to support the new layout, as shown in Figure 69.

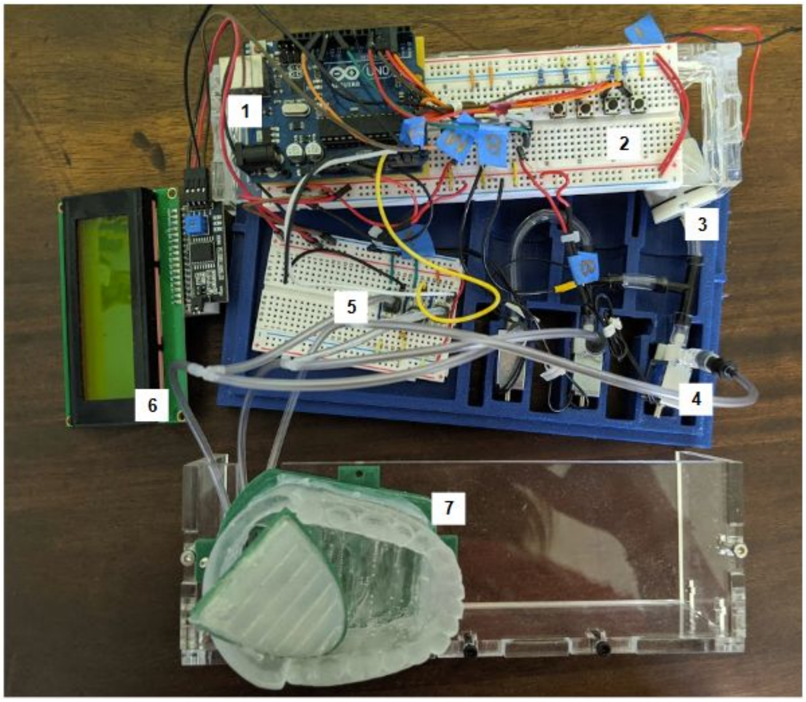

Figure 69: Modified design of control module for one pump and three solenoids. The components are: (1) Arduino UNO, (2), 4 momentary push buttons, (3) 5V air pump, (4) three way solenoids, (5) 3 pressure sensors, (6) LCD screen, (7) oral cavity mount and tongue.

The final control module has seven key features, which are numbered in Figure 69. The first component of the control module is an Arduino UNO, which controls the entire system. The second component is 4 momentary push buttons that allow the user to select an inflation program when testing the tongue. As previously mentioned, programs were written to inflate each pneunet channel individually and one to inflate all three channels in sequence. The third component is the 5V air pump, which has an output pressure of 100kPa. The fourth component is three 2-position 3-way solenoids, which direct air from the pump into the pneunet channels. The fifth component is the three 0-30 PSI pressure sensors, which measures the input pressure of each pneunet channel. The sensor readings are displayed on the sixth component, a 20x4 character LCD screen with an I2C module attached to interface with the UNO. The final component of the control module is the oral cavity mount and the tongue itself. Note that the retainer is not shown in this image because resources were divided at the end of the project, one teammate had the control module and another person had the retainer.

Additional CAD models of the final design, as well as the code and a detailed Bill of Materials are included in Appendix I.

5.5 Planned Improvements

It is evident from the final CAD model and the actual control module that many planned tasks for the control module design were not accomplished.

The most important improvement to the control module is replacing the base part so that the pump and solenoids are properly laid out and easier to connect together. Using smaller tee connectors will help further condense the control module. The LCD module also needs to be mounted to the side of the control module. In order to accomplish this, the I2C pins need to be desoldered and mounted directly to the LCD screen. The LCD screen can be mounted to the side of the oral cavity frame using 3D printed brackets. We also considered replacing the Arduino UNO with an Adafruit METRO M0 Express. [83] The METRO microcontroller is the same size as the UNO but features an ATSAMD21G18 chip and an ARM Cortex M0+. This increases the Flash and RAM on the control module, but the logic level is 3.3V which would require replacing the pressure sensors because they operate on 5V logic.

Further recommendations for the control module outside of what was originally planned are discussed in Chapter 9.2.

5.6 Chapter 5 Summary and Conclusion

In this chapter, we discussed the requirements for the updated control module that was used to actuate the tongue and gather data on its displacement and the internal pressure of each pneunet channel. The design of this control module was based on Araya's original design [10]. The design was first created in Solidworks, and was then manufactured using 3D printers and a laser cutter. The control module was designed to be simple to reproduce and assemble, and could be manufactured using only a 3D printer if necessary. The control module uses an Arduino UNO and three 2-position, 3-way solenoids to control airflow into the tongue. The air pump is run on a separate power source, which was done to reduce the current draw of the control module and lessen the load on the Arduino UNO. There are three low pressure sensors connected to the solenoids to measure the input pressure of each channel on the tongue. These measurements are displayed on an LCD screen that is also connected to the UNO. Users have the option of four different inflation programs, one for each section and one to inflate all sections in sequence, in order to easily test the displacement of the tongue and conduct bolus testing. The oral cavity and tongue prototype are mounted to the control module using screws for easy removal.

There are a number of planned improvements for the control module, including reprinting the base of the module so it is able to better accommodate one pump and three solenoids instead of three pumps directly connected to three solenoids. We also plan to mount the LCD screen to the side of the module for better visibility. Other recommendations for the control module are made in Chapter 9.2.

Chapter 6. Final Design Verification

This section details the tests and evaluations designed to measure the success of the prosthetic, both those that were planned and those that were performed. The principal areas for discussion will be the interactions between cells and the material used and the computer simulation of the prosthesis. Tests that were planned but not completed include the testing of bolus movement and fatigue analysis.

6.1 Tongue Material Safety

Given the fact that the prosthetic is intended to spend a substantial amount of time in the mouth, it was crucial to ensure the materials used in its creation were not dangerous in any way. Three tests were performed to this end. Firstly, it was tested whether bacteria are capable of adhering to the polymers used for the body of the tongue, as this could lead to the introduction of harmful microbes to the body. Secondly denture cleaning tablets were evaluated as a means of cleaning the tongue, and finally the polymers were tested for deleterious chemical effects with respect to the growth and survival of cells.

6.1.1 Bacterial Adhesion Testing

For the purposes of testing the chances of bacterial adhesion leading to infection a number of tests were performed using *Escherichia coli* and *Staphylococcus epidermidis.* These two microbes were chosen for ease of access, long history of study, and representation of the Gram-negative and Gram-positive cell wall modalities respectively, the cell wall being where a microbe interacts with its environment and therefore being the trait most associated with adhesion characteristics. Initially both species were streaked onto plates lined with silicon elastomer and polyurethane to be compared to control groups growing on LB agar. As expected, no bacterial growth was visible on the experimental plates, and any amount present was considered negligible in comparison to the bacterial populations present in all human mouths naturally. Both groups of plates were incubated for 24 hours and then reexamined a day later with no change in the results.

We concluded from the previous test that some kind of nutrient broth would need to be added to the polymer plates if there was ever going to be any appreciable amount of bacterial growth. This was deemed realistic as the use of the prosthesis in eating would expose any bacteria growing there to food and other nutrients on a regular basis. The broth used consisted of generic chicken broth mixed with a portion of white cane sugar. This broth was used in place of conventional cell culture media as the ingredients were cheap, readily available, and more closely reflected a human diet than laboratory media.

Initial tests resulted in the broth of the experimental plates becoming cloudy and pungent, indicating the viability of the improvised broth as a means to support cells. The broth was poured off the plates as any bacteria not attached to the polymer itself were considered too transient to present a serious issue. Following this there was still no visible growth on the experimental plates, and it was determined a metabolic assay would be needed to verify the absence or presence of microbes. It should be noted that some of the silicon elastomer plates were dyed blue, shown in Figure 70, in an effort to make any bacterial cultures stand out more, but this ultimately did not prove to be relevant.

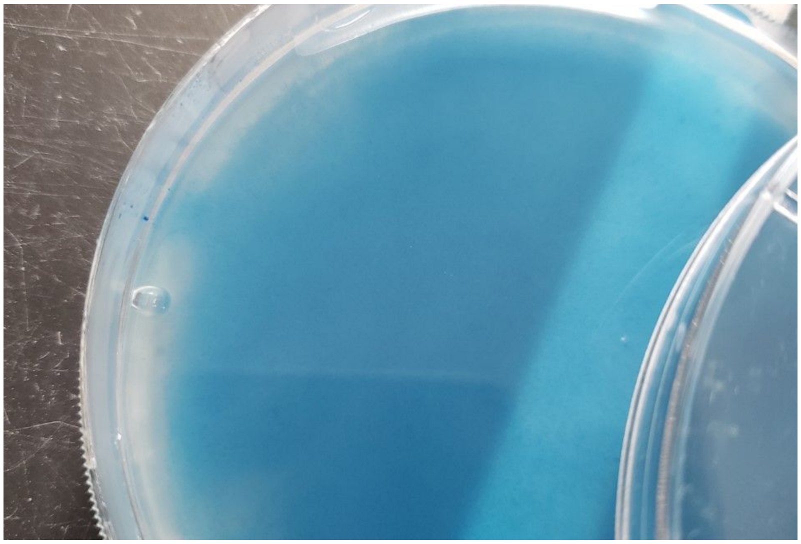

Figure 70: Plate of PDMS with blue food dye added for contrast.

Triphenyltetrazolium chloride (TTC) from Millipore Sigma [84] was chosen both for its sensitivity and the existence of a protocol [85] for its use with *E. coli* and another kind of *Staphylococcus* closely related to *S. epidermidis*. It was very important to get the concentration of TTC correct, as too little would lead to false negatives and too much would hamper bacterial growth. The concentration of TTC used was 0.01 mg/ml and that was found to provide good results, as illustrated with a control test shown below in Figure 70. New plates were prepared as before and allowed to culture for a day. After the period of incubation, the broth was poured off the experimental plates and they were washed three times with Dulbecco's Phosphate Buffered Saline DPBS to ensure only adhered cells would influence the assay results. Broth containing the reported concentration of TTC was then added to the experimental plates, while the control plate received DPBS with an equivalent amount of TTC. The plates were examined after three hours of subsequent incubation, at which point the control plate was very noticeably red due to the action of the TTC, while the experimental plates were still the characteristic slightly brown color of chicken broth. The plates were examined again a day later and no change in results was noted. An additional test was performed using an agar plate with the experimental broth in place of DPBS to determine if the broth affected the action of the TTC, which it did not.

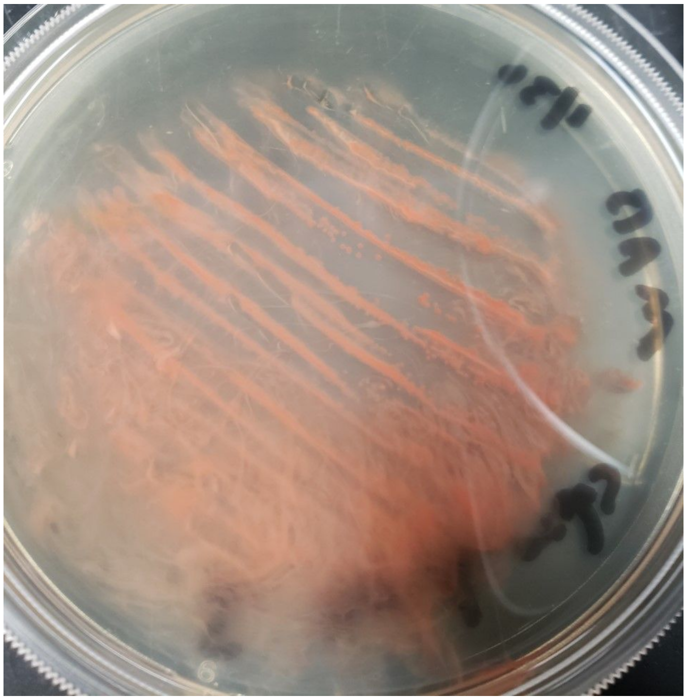

Figure 71: Control test to illustrate efficacy of TTC, which was initially a white powder that dissolved totally into solution but caused the red coloration visible after incubation.

6.1.2 Sterilization Testing

Following the adhesion tests, sterilization testing was performed to establish the efficacy of soluble Polident denture tablets in removing bacteria from surfaces. This was largely precautionary given the results of previous tests, but was considered as a resolution to periods of poor hygiene or as a means of reassuring patients worried about sickness. Denture tablets were chosen as the cleaning method of choice due to their wide availability and established use to clean artificial objects placed into the mouth. Populations of both species were cultured on agar plates, as culture on the polymers increasingly seemed impossible. The plates were placed into warm water with a dissolved tablet for five minutes as instructed by the tablet manufacturer. After this time, the plates were removed and rinsed several times with water from a spray bottle. It appeared as though almost all the bacteria could be removed with enough time and water, but only a few rinses were performed to simulate a patient who was not particularly thorough and didn’t have large colonies of microbes to direct their efforts. A control was performed by rinsing an agar plate of both species in the same manner, only these plates were not exposed to the cleaning tablets beforehand. The efficacy of the tablets was reported by measuring the area of the plate obscured by bacterial growth before and after the washes and is reported below in Figure

72. Note that the control wash was only performed on an *E. coli* plate as the *S. Epidermidis* plate became dessicated and fouled, rendering it unusable. Given that the experimental plates behaved exactly the same, both seeing a 72% reduction in surface area coverage, it was determined that had the control test been performed with *S. epidermidis* it would have looked similar if not identical to the *E. coli* control.

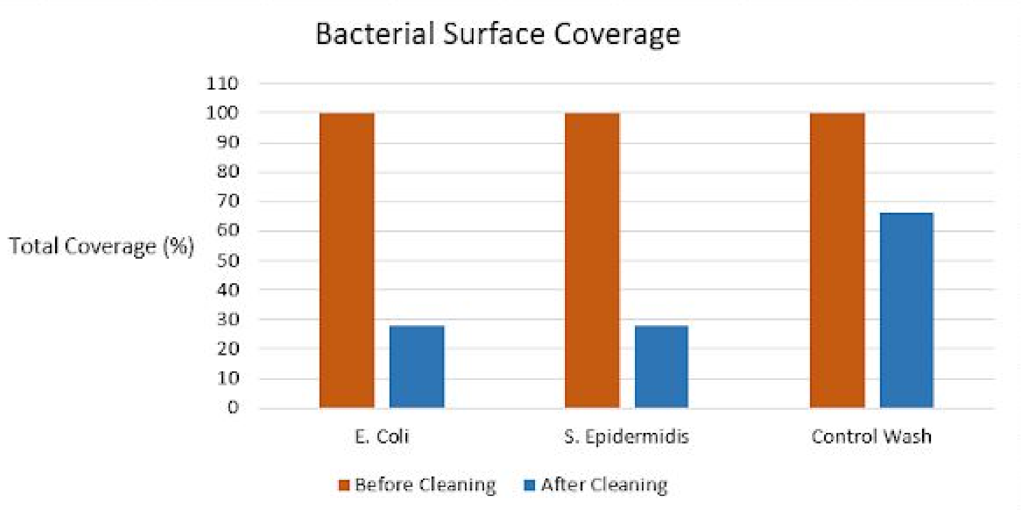

Figure 72: Characterization of denture tablet efficacy.

6.1.3 Biotoxicity Testing

A biotoxicity test was performed following sterilization testing laying a piece of both kinds of polymer over streaks of bacteria which had been previously culturing on nutrient agar, and then letting them culture for 24 hours beyond that before removing the polymer and examining the cells beneath. The cells suffered no deleterious effects from the presence of either polymer and did not appear dissimilar from adjacent, untouched cells. This was to be expected as both silicone elastomers and polyurethane are regularly used in internal implants in humans [86, 87]. A notable flaw occurred with the polyurethane. The piece used was cut from a petri dish and the underside was exposed to the cells. This side had not been exposed to air as the top had and was still tacky as a result. This means that when the polyurethane was removed for examination it pulled the cells underneath it off the plate. The cells appeared no worse for wear and given that the most current iteration of the prosthetic does not use polyurethane it is a moot point regardless. There was one major problem, found not with the polymers but with the silicone sealant. The sealant was not tested in the biotoxicity work as it was believed that testing the polymers was of greater importance, but the data sheet did later reveal that the sealant has the potential to cause birth defects. This is ultimately of little consequence to the function of the prosthetic, as it just means a different method of sealing the holes into the tongue must be found, but the bulk of the prosthetic can remain unchanged.

6.2 Simulation of Tongue in Abaqus

Our team had three purposes for creating a finite element model (FEM) of our prototype. First, we wanted to determine if our current design was able to meet the height requirements set by our literature review. Second, we wanted to determine what the maximum pressure we could apply to our pneunet design before the pneunets failed. Finally, we wanted to determine a mathematical relationship between the height of a pneunet and the applied pressure, so that we can predict the height of the pneunet when given a pressure.

6.2.1 Creation of the Model and Analysis

For the sake of simplicity, the model was created as if it would behave perfectly using the following assumptions:

1.) The pressure applied to a pneunet is even throughout the cavity.
2.) The model does not leak.
3.) Gravity does not provide resistance against the actuation of the tongue and can be neglected.
4.) The effects of atmospheric pressure acting externally provide little resistance against the actuation of the tongue and can also be neglected.
5.) The model is frictionless.

The Soft Robotics provided the basis for our procedure, and we modified steps so that the model would represent the real life scenario as much as possible [88]. To develop a finalized model of the soft robotic tongue, a model of Araya's initial design, as shown in Figure 73, was created in Solidworks and imported into Abaqus, where the needed materials were defined. The silicone material elastosil was created in the material database, and all of the elements except for those on the floor of the pneunets were assigned to elastosil. Hyperelasticity was modeled using the Yeoh model, which models describes rubber-like materials that are isotropic and incompressible with the strain energy potential of the material [89]. Constants for modeling elastosil with the Yeoh model were taken from the Soft Robotics Tool Kit [88]. In the analysis, the elements of the model will behave as elastosil would under the same conditions in real life. The elements on the bottom floors of the pneunets were modeled as paper in order to represent a silicone with a stiffer elastic modulus.

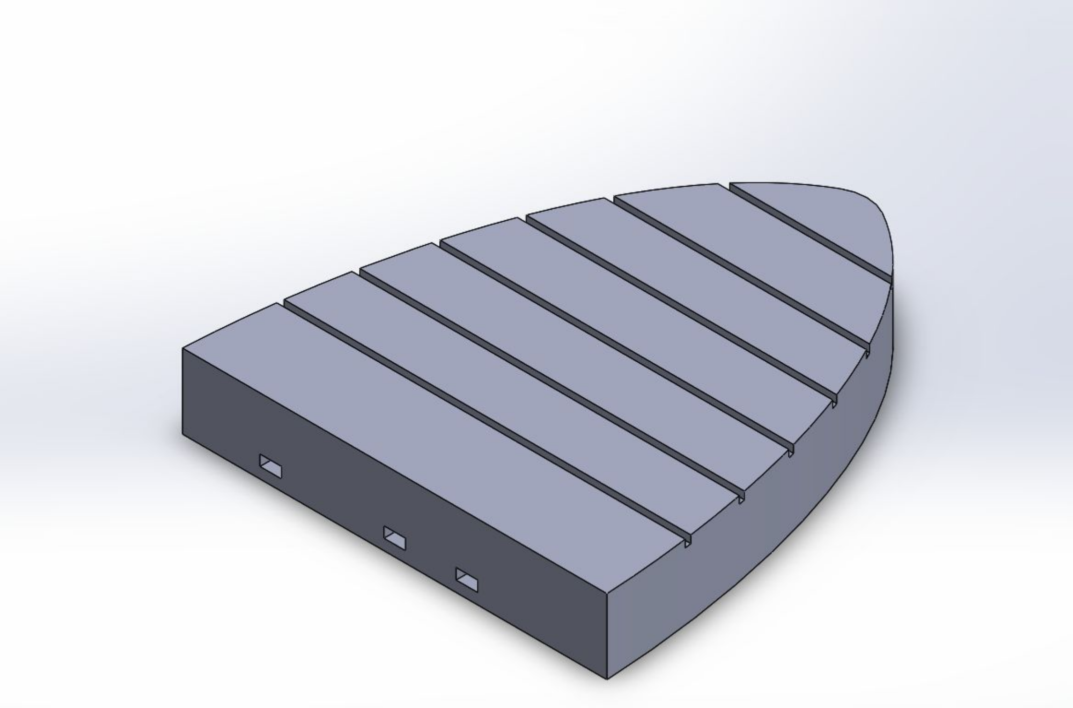

Figure 73: Solidworks model of Araya's prototype.

When the real life testing among several different iterations of the silicone model revealed that a seamless model with no ridges yielded the best results in terms of displacement and ease of manufacturability, a new Solidworks model was created to reflect the changes. As the model was made of all of the same material and did not include a silicone with a different elastic modulus, the paper material was omitted from the final model and all elements of the material were modeled as elastosil. The entire model was then meshed with tetrahedral elements, as that particular shape has the most flexibility with large, non-linear displacements, shown in Figure 74.

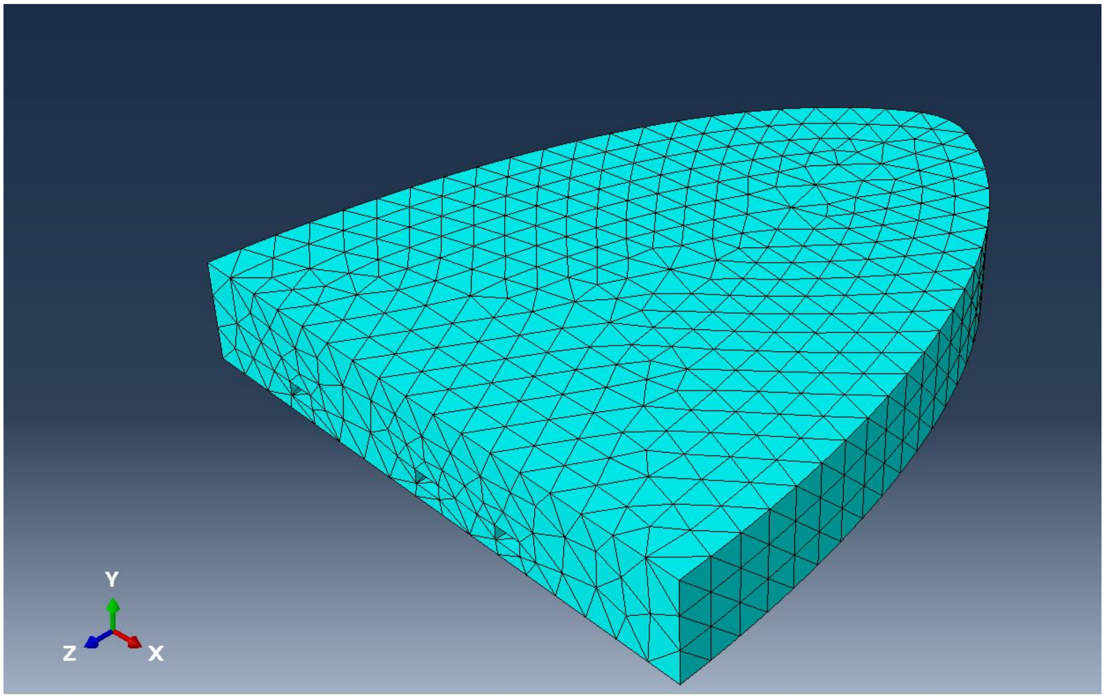

Figure 74: Meshed Finite element model (FEM) of the single component prototype.

Following the meshing, the steps of the analysis were created, along with specified loads for each step of the process: front pneunet inflation, middle pneunet inflation, back pneunet inflation. In the initial step of the analysis, the entire bottom of the tongue is fixed with an "encastre" condition, meaning that every element on the bottom of the tongue cannot move translationally or rotationally in any of the six degrees of freedom. This is to represent how the bottom of the seamless model is cased, only allowing expansion upwards instead of throughout the entire model. In the next step, a uniform pressure is applied to the inside cavity as well as the tubing channel of the front pneunet. When the designated pressure value is reached, the analysis moves to the inflation of the middle pneunet. In that step, the pressure in the front pneunet is suppressed or is removed completely and the middle pneunet inflates. The process repeats for the back pneunet, with the middle pneunet pressure suppressed.

As selecting every single inside the pneunet can be tedious, we created a separate model of the original design with the bottom removed, exposing the pneunets and repeated the aforementioned steps. The purpose of this model was to see if the simulation would yield deformations similar to that of a full model. However, we found through preliminary results that pressurizing additional channels running through the bottom of the tongue as with the preliminary design had an effect on how much displacement the top of the tongue is able to achieve. Thus, a model of the final design of our project which has tubing out of the bottom was created and modeled.

With the proposal of two new pneunet redesigns for the tongue, shown in Figure 75, the same steps to model the seamless prototype were repeated.

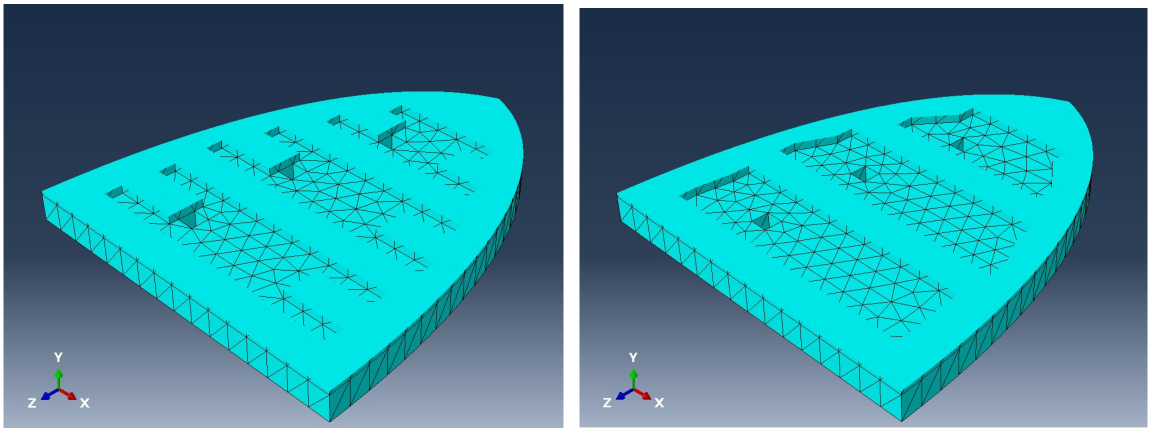

Figure 75: Meshed FEM of proposed future prototypes (Redesign 1 on the left, Redesign 2 on the right)

For each prototype, uniform pressures were applied in each pneunet and a static analysis was run. Afterwards, the vertical displacement was recorded on the nodes indicated in Appendix C, the pressure was increased, and the process was repeated until the model failed to converge a solution for the model. Afterwards, pressures thousandths of a megapascal smaller than the failure were applied until a solution converged to determine the maximum pressure that the model can withstand.

6.2.1 Observations

Upon applying a pressure to the early design of the pneunet, we found that the deformation in each pneunet was uneven. For example, Figure 76 shows the side channels of the pneunet inflating the most out of any channel in the pneunet. The front and the back channels both share a deformation that is slightly lower than that of the side channels. However, the exact middle of the pneunet exhibits the smallest deformation of the pneunet. The phenomenon is due to the solid silicone structure in the middle of the pneunet, which anchors the top of the tongue to the bottom and limits how much deformation can occur in that area. Thus, removal of the structure will allow more deformation in the middle of the pneunet and eliminate the creation of the pocket.

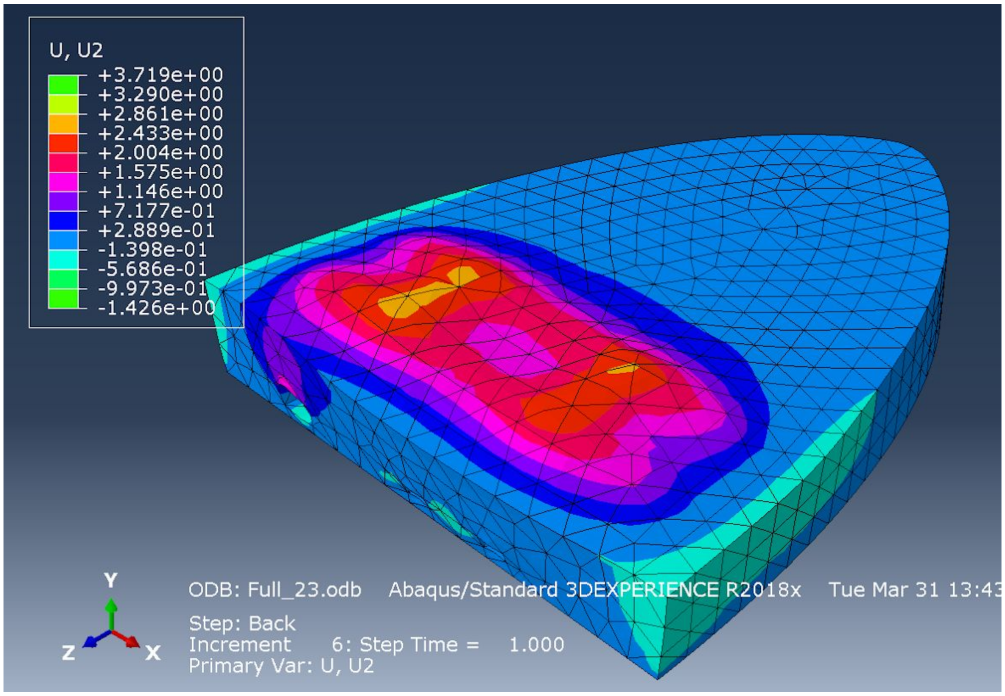

Figure 76: Vertical displacement of the back pneunet in the early design.

The half model in Figure 77 shows the same deformation trends as the full model in Figure 76. Looking at the legend in the upper right corner of both figures, we see that the maximum deformation of the elements on top of the tongue for the full model ranges from 2.433 mm to 2.861 mm. For the half model, the maximum deformation on top of the tongue ranges from 1.786 mm to 2.045 mm. Given that these are the displacements for the same applied pressure of 0.23 MPa, we concluded that structure plays a factor in the amount of deformation. Furthermore, the early design model failed at a pressure of 0.242 MPa while the half model failed at a pressure of 0.816 MPa due to a time error. With these differences in height, as well as the differences in failure pressures, we concluded that a half model does not serve as a comparable alternative to the full model. Thus, we decided not to report the data from the half model.

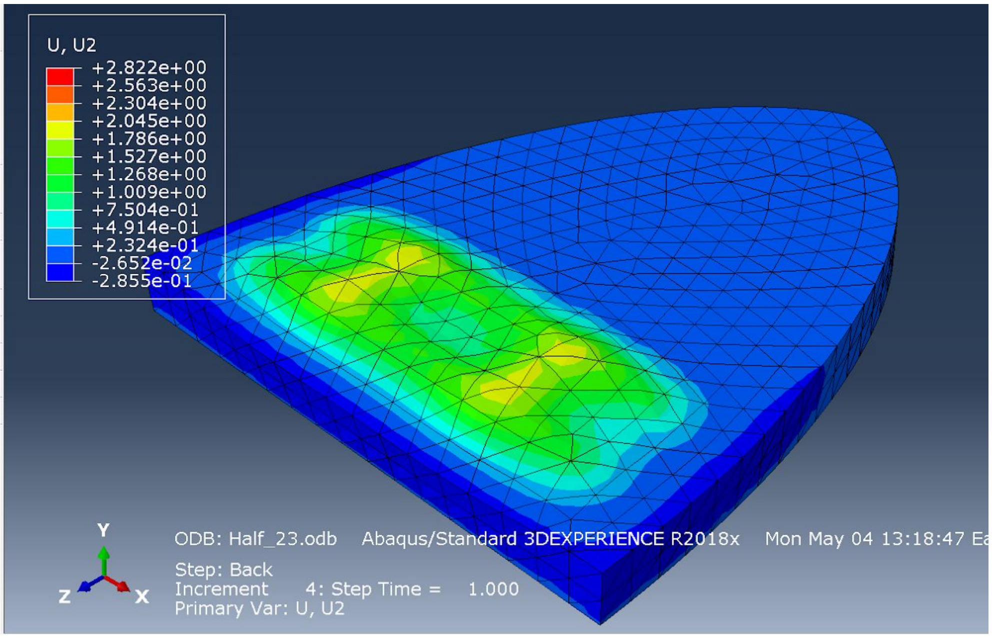

Figure 77: Vertical displacement of the back pneunet in the final model

Redesign 1 had a similar pneunet structure to that of our preliminary design but with one major difference: there was no structure to anchor the top to the bottom. The results from Redesign 1 proved our theory from the observations of the preliminary design: removing the anchor improved the displacement in the middle of the pneunet, as shown in Figure 78. However, the displaced area is in the middle of the tongue, and does not span the entire length of the tongue. While it is an improvement from the original pneunet design, there needs to be more displacement along the width of the tongue in order to properly mimic a human tongue.

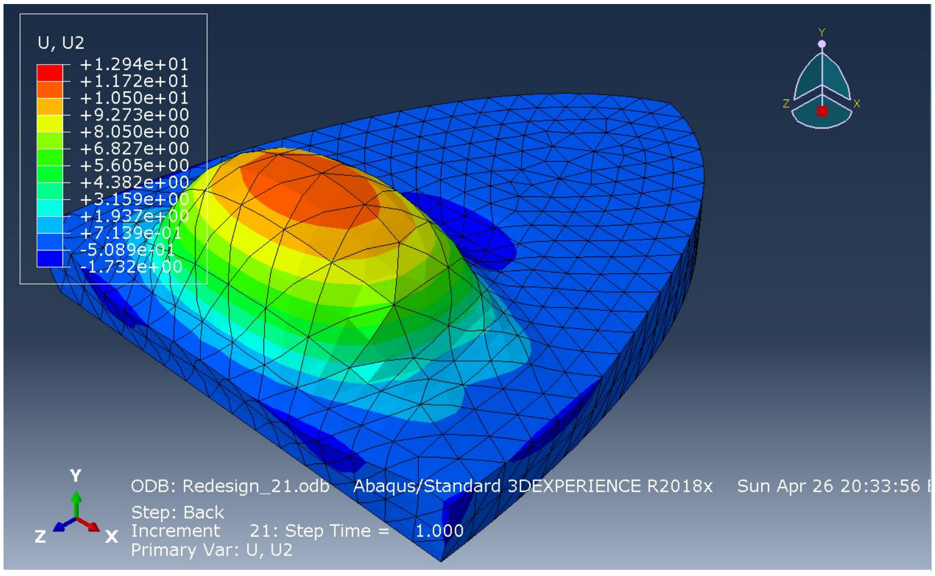

Figure 78: Vertical displacement of back pneunet in Redesign 1

When we simulated Redesign 2, which has no small side channels and an overall greater surface area, we see that the deformation is even throughout the entire pneunet. This is shown in Figure 79. The deformation is spread out through the entire width of the tongue, which would make this particular redesign better suited for moving a bolus rather than simply removing the middle structure from the original pneunet design.

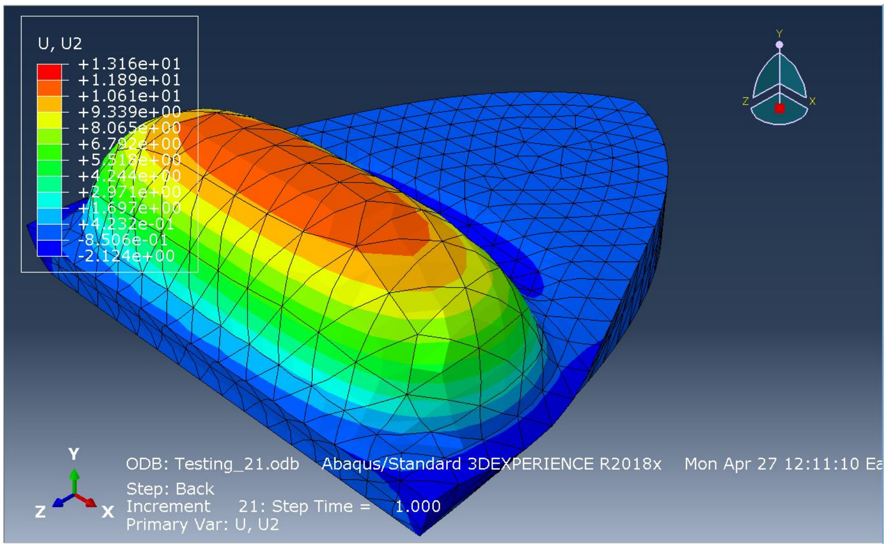

Figure 79: Vertical displacement of back pneunet in Redesign 2

6.2.3 Results: Maximum Pressure

The simplest way to discuss the results of the simulation is by beginning with the maximum pressure. Here, the maximum pressure is defined as the greatest pressure that is run with a converged solution. In this case, Redesign 2 failed with the lowest pressure of 0.221 MPa (see Table 8).The preliminary design model withstood the greatest pressure of 0.524 MPa, while the early design failed at a pressure of 0.32 MPa and Redesign 1 failed at a pressure of 0.32 MPa.

Table 8: Maximum Pressure of Model before Failure

Model	Early Design	Redesign 1	Redesign 2	Preliminary Design
Maximum Pressure (MPa)	0.242	0.32	0.221	0.524

6.2.4 Results: Displacement

Additionally, we look at the height at the maximum pressure for each model. The results are displayed in Figure 80. We calculate the total height from the bottom of the tongue by adding the displacement to the height of the uninflated model. We performed the calculation this way because of the nature of the retainer, which we observed would set the tongue prosthesis where the top surface of the human tongue was pre-glossectomy. Figure

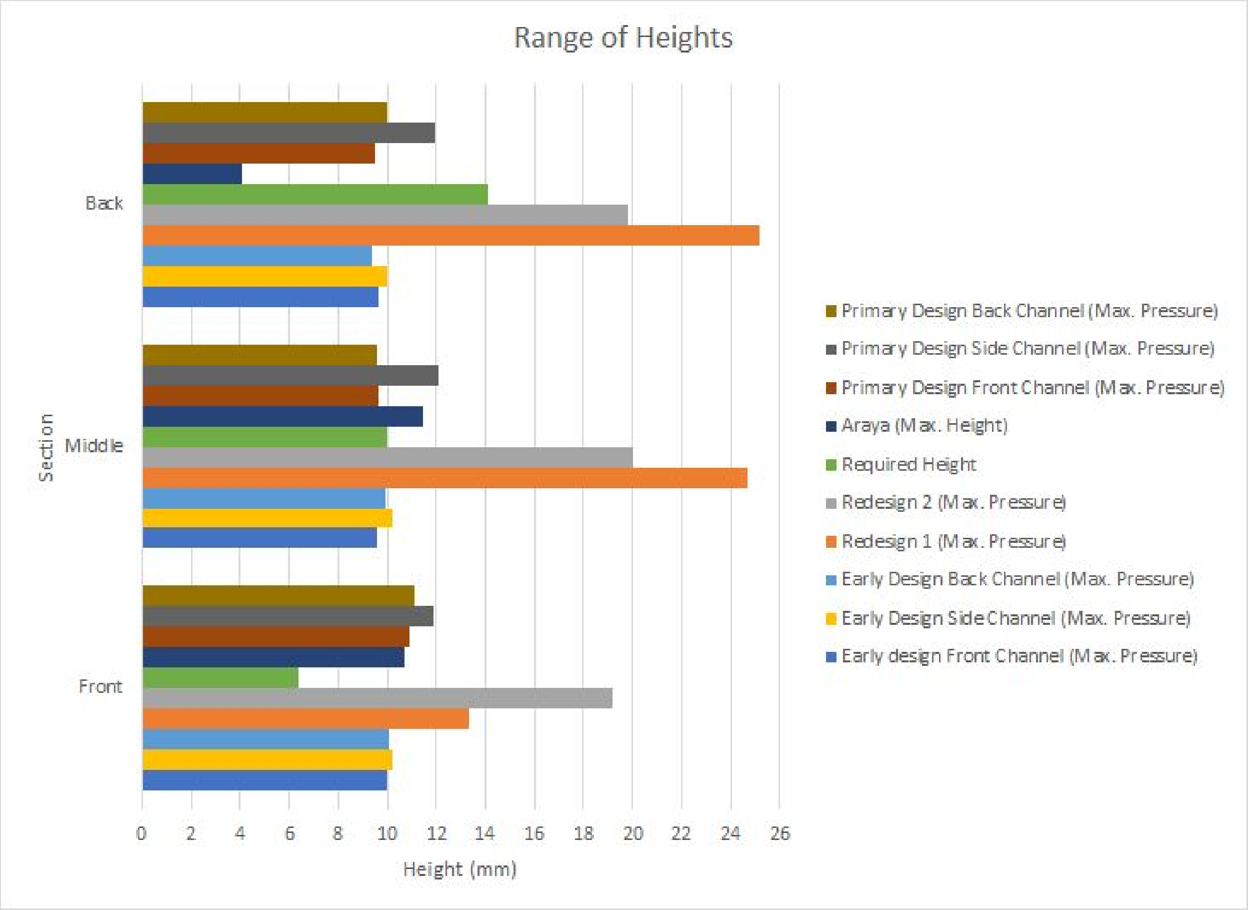

Figure 80: Height data gathered from modeling prototypes in Abaqus.

As the channels of the early and preliminary design deformed unevenly, we had to collect data from each channel, which we have defined in Figure 81. The front section of the early design model met the requirements at the maximum pressure. However, the middle and back sections of that same model did not. The front, side, and back channels of the front pneunet reached heights of 9.986 mm, 10.178 mm, and 10.0743 mm respectively. Those channels in the middle pneunet reached heights of 9.6087 mm, 10.1955 mm, and 9.9139 mm respectively. The respective channels in the back pneunet met heights of 9.6824 mm, 10.0245 mm, and 9.3603 mm.

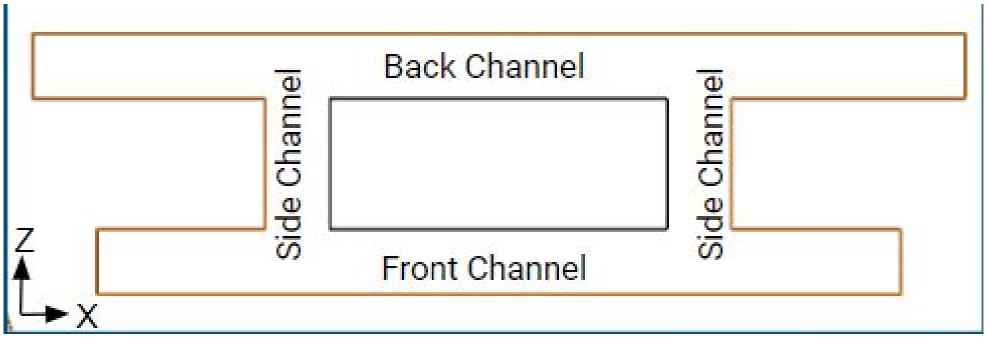

Figure 81: Channels of pneunet design

As seen in Figure 80, Redesign 1 had the greatest total height for the back and middle sections, but had the second greatest height for the front section. The front section must meet a height of 6.4 mm, and Redesign 1 succeeds the requirement with a height of 13.362 mm. Meanwhile, the middle section succeeds the height requirement with a height of 24.6845 mm. Furthermore, the back section exceeds its requirement with a height of 25.161 mm.

Redesign 2 had the greatest front pneunet deformation, but had the second greatest middle and back pneunet height. The front section surpassed the height requirement with a height of 19.219 mm, surpassed the middle section requirement with 20.0365 mm, and surpassed the back section requirement with a height of 19.219 mm.

6.2.5 Results: Extrapolated Pressures Required to Meet the Height Requirements

Using the line of best fit equations from the data presented in Appendices E through H and the *goalseek* function in excel, we were able to extrapolate the pressures that would be needed to meet the height requirements. The results can be seen in Table 9.

Table 9: Extrapolated Pressures Required for the Pneunet Section

Model	Front Pneunet Required Pressure (MPa)	Middle Pneunet Required Pressure (MPa)	Back Pneunet Required Pressure (MPa)
Early Design	N/A	0.2796	0.6054
Primary Design	0.0670	0.5709	1.5669
Redesign 1	N/A	0.0338	0.1211
Redesign 2	N/A	0.0298	0.1140

As previously mentioned, the early design pneunet deformed unevenly and we had to develop three equations for each pneunet, one for the front channel (one for the side channels, and one for the back). In order to determine the required pressure, we used *goalseek* to solve each equation for the pressure needed to meet the required height. We used the maximum pressure out of the three, because we want to assume that every pneunet will exceed or meet the pressure requirement. The process was repeated for the primary design.

We were unable to calculate the required pressure for the front pneunet to meet a height of 6.4 mm because the height of the uninflated model exceeds the required height at 7.62 mm. For the middle and back pneunets to inflate to their required heights, they would need pressures of 0.2796MPa and 0.6054 MPa respectively. Unfortunately, these pressures are greater than the 0.242 Mpa maximum pressure that the model could withstand.

The front pneunet of the primary design requires 0.0670 MPa pressure to inflate to its required height is below the maximum pressure of 0.524 MPa. This is a reasonable pressure for real life actuation. However, the 0.5790 MPa and 1.5669 MPa pressures required for the middle and back pneunets are much greater than the model's maximum pressure. Since both the early design and the primary design share the same pneunet design and the back and middle pneunets in both models require pressure greater than what the model can stand in order to meet the required heights, it can be concluded that the use of these models as an aid in swallowing is infeasible.

Simply removing the internal structure from the pneunet design in the early and primary model pneunet design lowers the pressure required for the pneunet to meet the height requirements. This is exemplified with the results of the Redesign 1 model. Once again, the height of the uninflated tongue is 7.37 millimeters, which is greater than the required 6.4 millimeter height for the front pneunet to move a bolus backwards. The middle and back sections require pressures of 0.0338 MPa and 0.1211 MPa to meet their requirements. These pressures are lower than those of both the early and primary models, and they are also lower than the model's maximum pressure of 0.32 MPa. Thus, Redesign 1 is feasible from a pressure and height standpoint.

The height of the uninflated Redesign 2 was also 7.37 millimeters, which surpasses the front pneunet height requirement once more. In order for the middle and back pneunets of Redesign 2 to meet their height requirements, they would need pressures of 0.0298MPa and 0.1140 MPa respectively. These values are all lower than the required pressures for Redesign 1. Additionally, they are lower than the maximum pressure of 0.221 MPa. While we have concluded that the pressures of the original design were not a danger to the patient due to the low volumes and pressures of air, we do favor pneunet designs with a lower required pressure input in order to lower any potential risks for the patient. As such, Redesign 2 is the favorable design out of the five models analyzed.

6.3 Physical Displacement Testing

In order to gather displacement data through motion capture, we first had to glue black craft beads to the tongue in the middle of each pneunet. At first, we simply used hot glue. Unfortunately, as the glue hardened, there was a strain difference between the glue and the inflated silicone that caused the beads to fall off. We tried to remedy the situation by using Loctite to anchor the beads to the tongue. However, the same phenomenon occurred due to the same reasoning. The problem was remedied by inflating the pneunets while the glue was still tacky, but this solution limits how many times we can inflate the tongue and record data before the beads need to be reattached. A more effective solution to attaching the beads was silicone glue. While the beads did stay on entirely, the bond of the bead to the tongue is permanent. Thus, if future projects wish to reuse the tongues for bolus testing, they should use one of the aforementioned methods of temporary fixation.

After attaching the beads, we planned to inflate the tongue with known pressures and film. The pressure sensors in the circuit will be used to record the values of air that goes into each pneunet. In post-processing, Tracker is used to calculate the maximum displacement of each bead. To calculate the maximum height, the maximum displacement is added to the height of the uninflated tongue. The calculated maximum heights are then compared to results from our modeling, as discussed in 6.2.2.

While we were unable to obtain physical displacement data, we did finalize methodology for future groups to do so.

6.4 Fatigue Testing

Following the finalization of the pressures required to actuate each pneunet to its required height, fatigue testing is required. Due to the large number of cycles we have set for the tongue to undergo before a crack forms, the problem has become a high cycle fatigue problem.

The most simple way to test fatigue is to inflate and deflate the pneunets of the tongue at its operating pressure until the pneunet ruptures. This must be done for each pneunet as each one will be undergoing a different pressure and will be subjected to different stresses.

We did perform informal fatigue testing on the tongue by inflating and deflating the pneunets of the tongue with a syringe. The single component model was able to survive 20 cycles of being inflated with 35 milliliters of air. When the same test was performed on the two-component tongue (both models with rear and bottom entrances for tubing) with 20 mL of air, it lasted a maximum of five cycles. The single component prototype ruptured a pneunet when inflated using the control module.

6.5 Bolus Testing

Bolus testing was planned as a “real world” examination of the efficacy of the prosthetic. The tongue would be affixed to the artificial oral cavity with the retainer in order to stand in for an actual human mouth. In terms of the material used for the bolus, several were considered including a lump of semi-solid silicone gel, putty, and beads. How close any of these are to actual food was a cause for concern as a review of the literature reveals that, unsurprisingly, there isn’t a precedent for feeding people lumps of silicon and the impact the characteristics of such a substance have on the physiology of the tongue. For this reason, it was decided that generic instant mashed potatoes would be an ideal candidate for a bolus. There were a couple reasons for this, firstly, even if using beads or silicone was found to be acceptable, they would still be standing in for the actual food that the tongue is intended to move. While they may still have perhaps been a suitable initial testing bolus given their superior cleanliness when compared to food, a bolus test with something edible was always going to happen anyway. Additionally the consistency of instant mashed potatoes is very easy to alter by adding or subtracting water. This would have proved beneficial to establish a profile of the prosthetic’s behavior as a function of bolus rigidity, placing it somewhere between the fully liquid diets glossectomy patients are currently prescribed and totally solid food.

Mashed potatoes of varying consistencies, starting close to liquid and becoming increasingly viscous until it began to prevent actuation, would have been spooned onto the tip of the tongue in a predetermined volume, around 5-10ml as reported in literature [90]. The prosthetic would then be actuated externally and the amount of material that reached the back of the tongue near where the throat could be used to characterize how effective the prosthetic is at moving substances of a given consistency. In order for direct observation of the passage of the bolus to establish an understanding of its movement from the beginning to the end of the wave-like actuation, the intent was to use a clear epoxy for the upper portion of the oral cavity as described in 4.4.1.2. Given the mixed results of that endeavor, the idea of drilling a hole in the roof of the mouth to allow the insertion of a small camera was considered, but similar to the bolus testing itself was not attempted.

6.6 Chapter 6 Summary and Conclusion

The adhesion testing proved that no bacteria adhered to the tongue after a precursory wash. However, if patients do desire a more extensive cleaning process for peace of mind, Polident denture tablets proved to be effective. Furthermore, it was determined that PDMS would not cause harm to the cells in the mouth, and thus is safe to use as a material for the prosthetic tongue.

We evaluated five models using FEA, three of which had Araya's original pneunet design. Unfortunately, that pneunet design was deemed impractical for use in future iterations of the prototype due to the middle structure anchoring the top to the bottom. Removing the middle structure in Redesign 1 yielded improved heights, while Redesign 2 yielded more deformation throughout the length of the tongue and required the lowest pressure to reach those heights.

We further established protocol for physical displacement testing, fatigue testing, and bolus testing.

Abaqus job files and model file can be found here:
https://drive.google.com/drive/folders/1ylnNBdK_RWeDZTEFylBlZf0KePNsWR0v?usp=sharing

Text documents of the data extracted from Abaqus can be found here:
https://drive.google.com/drive/folders/1fTwShzeTG7FcKaDX1BNs9r33wTI78PMS?usp=sharing

Chapter 7. Final Design Validation

This chapter goes into various standards and considerations that needed further discussion following the completion of previous chapters. We will extend beyond the engineering involved in the prosthetic itself to explore its potential impacts on wider topics such as the environment and the global economy.

7.1 Economics

Anyone related to the production, sales, or development of this would seek to earn a salary at least partly with this product. Anyone treating patients of oral cancer would have to consider this, and most importantly anyone with oral cancer would consider this. At the source, this product can save patients money by eliminating the need for reconstructive surgery.

There is more at stake for anyone seeking a profit. It would be entirely feasible as the product stands for a production kit to be sent to anyone distributing these tongues to patients. This kit would require that the tongue be molded and cured, possibly the mold could even be printed with files included in the kit. The PVA would be removed, the tubing inserted, the retainer attached, and then the electronics would be hooked up as provided in the kit for prosthesis that is ready for use. Alternatively, production lines could be set up to mass produce and ship out these tongues of various sizes, delivering to the distributor everything up to the retainer.

This project had access to a total of $1250 for development of this prosthesis. However, a single tongue produced for a patient will not cost nearly this much. We estimate that the cost of the tongue prototype we developed is approximately $37 in raw materials. The 3D printed PLA and PVA together cost under $5 and the elastomer used to make the tongue costs $5 for the amount used in a single tongue. The control module costs $27 for the acrylic and 3D printed components. The electrical components, including the Arduino UNO, solenoids, air pump, pressure sensors and LCD screen cost approximately $140. The total cost for the control module is $167. However, the electrical components were one-time purchases that can be used for future testing.

It is difficult to estimate the cost of a retainer, as retainers are custom made for each patient. Additionally, it would be up to the orthodontist to attach the tongue to the retainer at this stage of development. One wire retainer can cost anywhere from $175 to $300 [91].

The only recurring cost for this product is the denture tablets required for cleaning the prosthesis every night. A pack of 120 dental tables costs about $15 [92]. This results in a nightly cost of $0.13, or $45 per year.

Between the initial cost of the prosthesis and the recurring cost of operation, we estimate a total cost of $267 for a product that lasts two years.

7.2 Environmental Impact

We do not believe this product would have any effect on the environment. The product is small and does not require much energy to make and does not produce much waste. The only part of the process that could have any negative influence on the surrounding environment is the materials used, and even this is unlikely to have a negative impact. The product uses 3D printed molds of PVA and PLA, both of which are biocompatible. The tongue uses silicone elastomer produced through mixture and curing of two components, one of which alone can cause irritation. Otherwise this is not a toxic substance except that it is very hydrophobic and cells have difficulty growing on or adhering to this surface. The glue is similarly a silicone based glue and the tubing is silicone tubing.

The process of manufacturing this product does not consume a significant amount of energy or release pollutants. The manufacture will not affect the environment. This product may produce waste if discarded, but such waste would be equivalent to any piece of consumer plastic that is discarded. As such it may not decompose or break down for a very long time, but the size of the waste produced is small and is not a reoccurring waste, so it will not measurable affect the environment.

7.3 Societal Influence

For patients who use this product, the quality of life could be greatly increased by making deglutition easier. For those directly involved in their treatment or the product's manufacture and sale, this would be the same as any other product or prosthesis and would not alter their behavior meaningfully. If the product became widespread such that the general population knew about it such as if this or a similar device reached general news, oral cancer awareness could be raised. Otherwise this would have no influence on the lives of anyone not affected by oral cancer or helping those suffering from it.

7.4 Political Ramifications

We do not foresee any likely abnormal effects on politics originating from this product. It is meant to aid glossectomy patients in deglutition. This means eating food would be more attainable for such patients. The current prosthetic tongues require patients adhere to a liquid based diet which largely consists of waiting for the liquid to reach the throat before swallowing. A prosthetic tongue that helps them eat should not be any different than a prosthetic limb that helps an amputee walk from a political viewpoint. The only areas where a prosthetic tongue and legislation likely overlap is in potential subsidies, such as if there are any political subsidies, tax breaks, or therapy programs that help recipients of other prosthetic devices, and in legislation relating to manufacture, if this product were manufactured in a different country. Even these two possibilities are unlikely to have any political ramifications different than similar products already in the market.

7.5 Ethical Concerns

A prosthetic tongue that helps patients swallow more solid food would drastically increase the variety of diet from the liquid based subsistence to which patients that would use this prosthetic are currently limited. This variety would potentially reduce the effort necessary to ensure balanced nutrition as well as provide a bolster to emotional strength. This product clearly has the potential if properly developed to greatly improve the quality of life for a patient who has had a glossectomy. There is an ethical concern of whether this product might affect the frequency of glossectomies.

The three major treatments of oral cancer are chemotherapy, radiation treatment, and a glossectomy. While the first two are traditionally extreme measures on the human body, the glossectomy is still seen as a last choice as it drastically limits the patient's ability to eat or speak and greatly reduces their quality of life. This product is not designed to aid in speaking and can not return full functionality of the tongue, helping only with deglutition and neither speech nor mastication.

If patients know that this product exists, they may be more likely to pursue the option of a glossectomy without considering the full reality of loss of speech and mastication. An increase in glossectomy frequency, given that this product allows patients to retain deglutition ability, could be positive or negative. More glossectomies could mean fewer deaths, less cost and health effects from chemotherapy or radiation treatment, and less time that patients use space in the hospital. It could also mean more people who are left without a tongue who could have undergone a different treatment in which they would have the tongue. It is impossible to tell which would occur if not both. The likelihood that this product would alter such a heavy decision is a very serious ethical concern of this product.

One other ethical consideration applies to prostheses as a whole. Patients receiving these tend to be more self conscious and are more susceptible to depression [10]. The foreign shape and weight of a prosthesis can then feel strange and patients may have a difficult time adjusting to its presence. As such use of this prosthesis must be carefully considered to ensure it is not overvalued. It can have significant effects on the mental health of a patient and thus must not be selected hastily. Future projects can address this by attempting to make the prosthesis look and feel more like a tongue to help with self image.

7.6 Health and Safety Concerns

Integrating any prosthesis or mechanism into the body comes with some inherent risk, but such dangers were small so far as this project was concerned. The two areas that did draw focus were the regarding the risk for physical injury should the body of the tongue rupture or otherwise fail, and the potential of the tongue to serve as a means to facilitate bacterial colonization that could potentially lead to sickness. Addressing the former, a literature survey was performed regarding injury reports concerning cases of injury strictly due the movement of air. Information regarding this is limited, mainly concerning explosive shockwaves as case studies in military medicine or demolition safety.

It was found that relatively small pressures can lead to injury when paired with appropriately large volumes of air [93]. Given the small volume of air associated with the actuation of the tongue, it was concluded that there was not a significant risk of injury due to failure at the pressures used. Furthermore, the small volume of air is moving at a very low speed, thus lowering the risk of injury if the tongue ruptures.

It should also be noted several models of the tongue failed during testing and the resulting burst of air was very mild, being notably quieter than a balloon filled to the point of popping. Additionally, only the internal pneunet structure was damaged.

In terms of cleanliness, bacterial adhesion testing was performed with species from both of the major cell wall cohorts. The results from this showed the chance of any more than a negligible amount of bacteria sticking to prosthetic was essentially nonexistent, and further testing justified the use of over the counter denture cleaning tablets as an effective, although ultimately cautionary, cleaning method.

7.7 Manufacturability

The prototype developed during this MQP is not ready for mass production. Several improvements can easily be made that would drastically increase reproducibility. The production method as used for the final prototype requires careful preparation by an individual and has several steps that are prone to error. The soft rubber portion of the prototype is made by mixing two materials together to make silicone rubber, a process that can be done in bulk followed by pouring of the uncured rubber into a 3D printed reusable mold.

The two major aspects of manufacturing the soft tongue that need to be standardized are the placement of the interior channels and the height of the tongue. The interior channel placement can be made uniform by adding grooves in the mold to force the PVA inserts to snap into place while the silicone rubber is poured. In order to ensure that the height of the tongue is consistent, a set amount of silicone should be poured into the mold each time.

It is also very important that the PVA inserts are fully dissolved to ensure that the pneunet channels are clear from debris. Placing the tongue in a water bath removes most of the PVA, but it is time consuming and difficult to ensure that all the material is dissolved. The process of attaching silicone tubes to the tongue varies between prototypes but could be standardized by integrating tubing attachments into the 3D printed tongue casing.

In addition to the prosthetic prototype, the retainer prototype for fixation is not ready for mass production. Currently there are no known ways to mass produce wire retainers as these are custom built so that they snugly over an individual’s teeth. Future work on a retainer could be made easier by enlisting the help of an orthodontic technician as these individuals work on creating removable retainers on a frequent basis. Alternative retainer designs should be investigated and, if a retainer could be designed from a form fitting polymer, such as is done for Invisalign® treatments, mass production may become much more feasible.

7.8 Sustainability

The current product requires use of PLA, PVA, and silicone rubber during production. PLA can be produced from raw materials that are renewable, and silicone rubber is not made using critical nonrenewable sources like oil. PVA is produced from vinyl acetate monomers that require ethylene, derived from non-renewable sources, for production [94]. The amount needed is small for each tongue at 824 mm^3 per tongue. If these hydrocarbon sources have not been depleted entirely, the supply should not be an issue. Should this become a problem, PVA can be 3D printed and then will dissolve in water so any other formable, water-soluble material will be a capable replacement. As a result, sustainability of material sourcing is not of issue. The energy required for this is similarly low with the raw materials able to be mass produced and the product manufacture requiring very little energy input. It is unknown how much energy the manufacturer of the 3 materials discussed in this section produces during manufacture. Production of the tongue itself requires very little energy, consuming only 1.5 hours of electricity through a 3D printer totaling 0.3 kWh [95]. Thus this product is not of concern with energy.

The control module is less sustainable. It requires several types of metal to create pumps and a circuit, but the processors that control everything will require rare earth elements which are finite. This applies to any electronic system so this is also not of any concern as long as general electronics can be made.

Chapter 8. Discussion

This chapter will expand upon the data generated by the work discussed in past chapters. It will be evaluated to determine how thoroughly the previously described goals, such as those relating to prosthetic fixation and safety, were accomplished. Limitations of the collected data will be addressed where relevant, and their implications discussed.

8.1 Meeting objectives and constraints

This section evaluates the tongue prototype against the objectives outlined in Chapter 3. Those objectives are:

1. Design: Create a tongue prosthesis that can actuate in one second.
2. Safety: The prosthesis must be safe to put in a human mouth.
3. Fixation: Integrate retainer and prosthesis.
4. Control: Create a control and testing module for the tongue.
5. Modeling: Validate the tongue model through simulation and internal pressure testing.

8.1.1 Design: Create a tongue prosthesis that can actuate in one second

Unfortunately, we were unable to test any version of the prototype with the control module due to divided resources. One teammate had the control module, and others had some prototype tongues that had burst previously. They were repaired but no concrete data was gathered from them. Additionally, the simulation allotted one second for each pneunet to be fully inflated with the applied pressure instead of simulating the motion over one second. Thus, whether or not the prosthesis will be able to actuate in one second is inconclusive.

8.1.2 Safety: The prosthesis must be safe to put in a human mouth.

As the use of prosthetics is so intimately tied to the human body, the health and safety of users is paramount. While this particular device is not exposed to blood or other visceral fluids, it does come into and go out of the mouth, which raises concerns regarding how clean the prosthetic is. Overall, the elastomer used for the body of the tongue itself was found to be very safe for use in close quarters with living tissue. No bacteria could be found adhering to the polymer after only a cursory wash, and denture tablets were found to be a very effective option should the need for cleaning arise. These results indicate it is very unlikely the prosthetic could serve as a vehicle for the introduction of pernicious bacteria into the digestive draft or respiratory system, even without rigorous cleaning practices. The polymer was found to have no harmful chemical impacts on living cells, but it is important to note the sealant used to plug the holes on the base of the prototype has been associated with birth defects, which is certainly an issue that would need to be resolved by changing the kind of sealant used or modifying the manufacturing or design of the prosthetic.

8.1.3 Fixation: Integrate retainer and prosthesis

As is discussed in section 4.4.3, the integration of the retainer and prosthesis was unsuccessful due to the limitations of the materials available and the sizing of the components. While different retainer designs were investigated and additional methods of fixation were discussed, this area needs much more investigation in the future in order to develop a safe, stable, and space efficient design. Due to the complications encountered during the fixation stages of this project, it cannot be concluded that fixation via a retainer is an effective way to incorporate the prosthesis into the mouth.

8.1.4 Control: Create a control and testing module for the tongue prototype

A control module was developed in order to test the tongue prototype based on the needs analysis in Chapter 5.1. The control module inflated the tongue using a 5V air pump and three 2-position, 3-way solenoids. The control module included three separate inflation programs, which were used to measure the displacement of each channel as well as all three channels in sequence. Pressure sensors were integrated into the control module in order to measure the input pressure of each pneunet channel. Although the final tongue prototype was never formally tested, preliminary versions of the tongue were tested to make sure that sensor readings were accurate. Therefore, this objective was met but further development of the control module and additional testing of the tongue prototype is required.

8.1.5 Modeling: Validate the tongue model through simulation and internal pressure testing

Our team did successfully create a finite element analysis of the tongue that was used to evaluate the pneunet designs presented and validate that they would be able to actuate to the required height. The original pneunet design used in Araya's work will not meet the requirements. While the front section was able to surpass its requirement, the back and middle sections require a greater pressure than what the material can withstand. This was proven through two separate models. Furthermore, we were able to use the model to prove that the two pneunet redesigns exhibit better displacement than the original design.

Unfortunately, we were unable to further validate the design of the tongue through internal pressure testing and therefore did not meet that portion of the objective.

8.2 Limitations of data

The work presented in this report describes the production of a bench prototype. This prototype is not ready to be incorporated into an actual living system. Rather, this is an extended proof of concept. Araya completed a proof of concept that established that pneumatic neworks could actuate a silicone elastomer prototype to imitate the motion of a swallowing tongue. This project is limited to the scope of establishing the potential for this pneumatic actuation method to be made into a viable prosthesis. As such it is not a working prosthesis.

The data from the simulation, while it is an accurate representation of how the tongue will behave faces one primary flaw: there are many different types of silicone with properties that may vary. We modeled all of the designs as elastosil primarily because the properties were known, including the constants for modeling the tongue with the Yeoh model for hyperelastic materials. In reality, silicone rubber will not necessarily behave the same as elastosil due to differences in the Yeoh model and may not follow the curves we have previously generated for the material at each section. Additionally, the sides of the model were not constrained, and thus does not take into account the constraint provided by the casing.

Additionally, we have defined the maximum pressure in simulation as the greatest pressure that can be applied and converge on a solution. Abaqus may fail to give a solution if it cannot apply the given pressure during a given time constraint. It may also fail to yield a solution for the problem if the given pressure creates stresses and deformations that violate the fixed boundary conditions. As such, the only way to determine the true maximum pressure would be through physical displacement testing.

Additionally, we do not have data from physical testing, including physical displacement as well as fatigue testing. Without this data, it is difficult to determine if the real life prosthesis is able to meet our design constraints.

Based upon the difficulties encountered during the retainer to tongue integration phase, future considerations may need to be made in terms of the size and shape of the tongue prosthesis. While working with the model and oral cavity, it was discovered that the tongue casing could barely fit into the oral cavity in terms of width, but fell short in length, suggesting that the dimensions could be reevaluated. Reevaluation of the dimensions, if possible, could allow for the prosthesis to fit into the oral cavity more easily and may allow for easier integration of the prosthesis and the retainer.

Lastly, all data collected is limited by the manufacturability of the prosthesis. All production is currently performed by hand. Performance of different models of the same type will vary significantly. Designs need to be made that increase the automation or reproducibility of manufacture. Until then, current prototypes will be subject to flaws created by the individualistic production such as through inconsistent glue application or interior channel placement.

Chapter 9. Conclusions and Recommendations

Previous chapters have presented the work completed during this project. However, much remains to be done to finish design and analysis of a functioning prosthesis. This section will discuss future recommendations that we think are worthwhile for future projects to reach a functioning prosthesis.

9.1 Conclusion

The goal of this project was the creation of a dynamic prosthetic capable of restoring deglutition functionality to patients whose tongues have been removed to stop the spread of oral cancer. There were many facets to improving the previously designed prosthetic model, such as a more exhaustive materials survey which identified polyurethane and silicone elastomers as the ideal materials for the body of the soft robotic tongue, although the elastomer was ultimately chosen due to its ease of manufacture. Designs using these materials underwent a number of iterations to improve upon shortcomings such as air leakage and size, and were examined for physical and chemical safety as well as overall practicality. A synthetic oral cavity for the purposes of testing was produced using additive manufacturing based on anthropometric data sourced from MRI images, and a wire retainer was designed and constructed to integrate the tongue into the artificial mouth. A retainer was chosen over the use of a denture as not all oral cancer cases necessitate the removal of teeth, and in instances where teeth are removed the retainer would still function as it could be fitted over an independent set of replacement teeth.

The control module used to actuate the prosthetic from the previous projects was redesigned to allow for more nuanced control over the prosthetic and measurement systems were integrated directly. Data from computer modeling was used to assess the behavior of the prosthesis, predict performance as a function of air pressure, and serve as a benchmark for the results provided by the test bench. Through our modeling, we were able to determine that Araya’s pneunet design is impractical for future iterations, and highlighted the promise of one of the proposed redesigns.

There is still a substantial amount of work which could be put into the restoration of deglutition, such as validation via physical testing, refinement of the test bench, and reevaluation of certain aspects regarding the pneunet design and manufacturing. Additionally, testing that the tongue can move a bolus from the front of the mouth to the back within one second is crucial to further refining the prosthesis. Significant strides were made in all these areas over the course of the project’s duration which resulted in a more refined, practical device that is markedly closer to meeting its design goals than when this iteration of the project began.

9.2 Recommendations for Future Work

Several steps need to be taken in the future before a complete tongue design can be chosen. First of all more testing is needed to connect the design, manufacturing, and simulation. Second, alternative concepts that were dismissed due to time or cost constraints need reconsideration. Lastly more considerations are needed to incorporate manufacturability and integration of the mechanics into the prosthesis.

The future of this project calls for advancements in response to data that will be collected. Certain displacement values of the tongue during deglutition have been cited (See Table 4) and testing should verify if a prototype is able to reach these values. If it does not meet these values, we would alter dimensions until they were closer to the targeted value. Alternatively, rigorous testing should establish what displacement is truly needed to produce a bolus movement towards the back of the mouth to determine whether the specified ranges from section 3.3.1 are necessary for proper functionality. The control module should then be progressively miniaturized until the complete prosthesis can fit inside of a mouth.

9.2.1 Testing Recommendations

We recommend that future projects complete several types of testing. These will provide more information to establish if there are design changes that would make a stronger and more durable prosthesis.

Bolus testing has not been done and must be done with all future models. This project has assumed that the tongue prosthesis needs to have displacements similar to a real tongue during the swallowing process to effectively move a bolus. Bolus testing combined with physical displacement testing will help establish if this assumption is correct and further determine the actual effectiveness of the prosthesis. We recommend a similar comparison between the displacement of the prosthesis predicted displacement of the simulated model. The ideal conditions provided by the model combined with variations in input young's modulus create a likely divergence from experimental displacements.

The next two tests predict the structural integrity of the prosthesis and allow for future modifications to a design to make a stronger and more durable prosthesis. We recommend a structural test for the retainer, in which extreme and repeated actuation of the tongue as well as outside forces to simulate food and other forces in the mouth. This test would assess the quality of the retainer-prosthesis integration. The second test is a fatigue life test in which the tongue is inflated and deflated at its operating pressure until it breaks. This will provide information as to how long the prosthesis is expected to last.

9.2.2 Pneunet Redesign Recommendations

We recommend future projects pursue the alternate pneunet design presented in Figure 33 of section 4.2.1.2. While no prosthesis was made that used the pneunet design presented in Section 4.2.1.2, initial observations suggest a better form of expansion that is more centralized. Through simulation in Figure 77 and 78 of section 6.2.3, we saw that the second version of the pneunet interior channels required less pressure to meet displacement specifications. In addition to a more uniform deformation, the lower pressure is safer to put in the mouth. These qualities will help improve the design of the tongue and increase the likelihood that it is able to actively move a bolus. Furthermore, simulation showed that this redesign allowed for more expansion throughout the width of the tongue and thus was a better representation of a human tongue.

9.2.3 Manufacturing and Integration

The final set of recommendations we suggest to future projects concerns manufacture and integration of the model. The manufacturing of the tongue is currently variable and dependent on the individual that is responsible for manufacturing the part. The PVA inserts currently lie in the mold while the silicone cures around it. The placement of these inserts can vary such that the interior channels will be inconsistent distances from any side of the tongue between different models. Incorporating grooves to guide placement into the molds for future models will improve reproducibility as seen in the mold picture in Figure 77. The associated inserts shown in Figure 81 and 83 would then be fit into place rather than simply allowed to lie anywhere. Additionally, the process of dissolving and removing the PVA insets and attaching the tubes can still use new ways to be made more reproducible and more easily manufacturable.

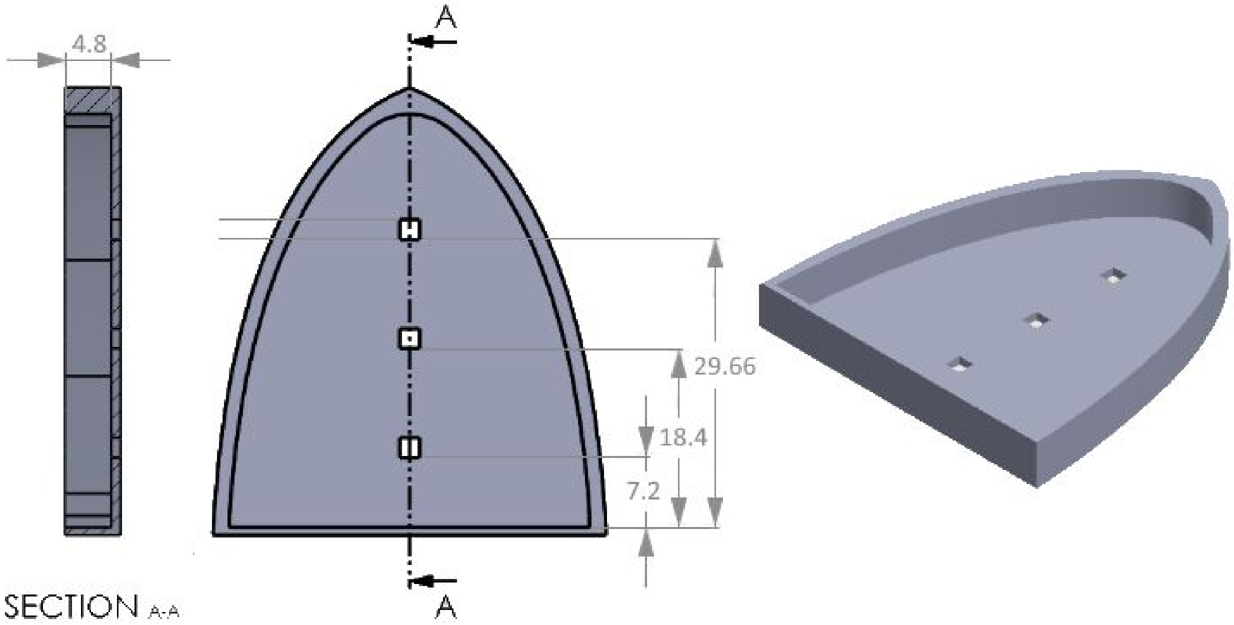

Figure 82: PLA casing for tongue.

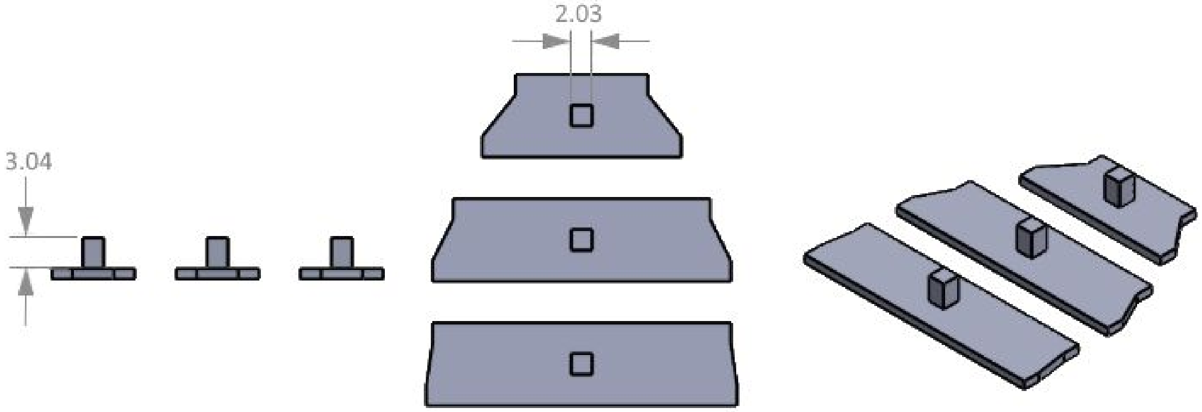

Figure 83: Solidworks drawing of inserts for the recommended pneunet design.

We created several design concepts that were either infeasible at the time or did not progress far enough due to time constraints. The material study presented in Section 4.5.1 established polyurethane as a strong candidate for replacement of the silicone elastomer. Polyurethane parts are more difficult to manufacture because bonding between polyurethane parts has been insufficient to resist the force from pressurization. The PVA mold for single component models proved promising for molding silicone elastomers. A combination of this method of manufacture and a glue more appropriate and specific to polyurethane should be pursued before any conclusions can be drawn as to the most appropriate material. It is possible that a different form of polyurethane is appropriate, but variations in polyurethane can quickly increase in cost, difficulty to manufacture, or even toxicity. This redesign has the potential to increase manufacturing reproducibility for both silicone and polyurethane models. It does still require glue at the connection between the tongue and tubing, so it is appropriate that a review of potential glues be performed to find adhesives that are safer than the current silicone sealant or can be used with polyurethane.

There is limited reproducibility and manufacturability in attachment of the tongue to the retainer. The process is currently to place the silicone tongue into the 3D printed PLA casing and then glue it into place. This glue barrier provides a lot of room for error and a space for food, saliva, and bacteria to get caught underneath the tongue. Future work should develop a more consistent attachment or use a removable tongue with magnetic filament

While magnetic actuation was not feasible during manufacturing stages, future projects should create a design that uses the potential of magnets and magnetic filaments to hold the magnet to the retainer. The current design glues the tongue into the casing. This eliminates the potential for manual cleaning. Use of magnets for integration will allow for patient's to separate the tongue from the retainer more easily to clean the retainer. This would need to follow ISO standard 13017:2012: Dentistry - Magnetic attachments [97].

As many difficulties were encountered when developing a wire retainer, alternative materials and designs should be investigated. Reinvestigation of orthodontic acrylic powder may be useful as attachment of the tongue casing to the retainer may be made easier with the use of acrylic powder. Other options include the use of a thermoplastic similar to that used for Invisalign® [96] products. This would allow for much quicker development of a retainer that is custom fit for a patient's oral cavity, and may provide easier attachment to the tongue casing as bonding of plastic to plastic is much easier to accomplish than bonding plastic and metal. Different types of orthodontic wire should be investigated to determine if a different material would allow for the retainer to be soldered. Investigation of flat wire, rather than round wire may also be useful as the flat surface may make it easier to affix the wire pieces together as well as the wire components to the tongue casing.

9.2.4 Alternative Soft Robotic Actuation Methods

Given that the eventual goal of this project is to condense the tongue prosthesis to fit within a human mouth, other methods of actuation commonly used in soft robotics should be investigated as alternative means to actuate the tongue. Dielectric elastomer actuators (DEAs) are commonly referred to as artificial muscles because they have a high actuation speed, low energy density, and silent operation, mimicking many desirable physical properties of muscles [98]. DEAs have the potential to generate rich motions with many translational and rotational degrees of freedom without the need for complex mechanisms and drive systems. Unfortunately, many materials commonly used as DEAs such as carbon black and graphite powder are not safe for in vivo use

[98]. An in depth study of DEAs would be required before using them to actuate the soft robotic tongue.

9.3 Control Module Recommendations

This section discusses potential improvements for the control module as well as recommendations for condensing the entire system to fit into the oral cavity.

As stated in Chapter 5.5, there are a number of planned improvements on the control module based on the design developed during this project. However, there are several other aspects of the control module that could be improved. The module could be condensed by replacing the existing solenoids with manifold solenoids. This would eliminate the need for tubing to connect the three solenoids together and reduce sources of air leakage on the control module. The size of the control module can also be reduced by using smaller pumps, potentially those found in breast pumps or insulin pumps.

The design can also be further streamlined by moving portions of the electronics on the control module from breadboards to a solderable protoboard. The bipolar junction transistor motor drivers, discussed in Chapter 5.2.2, used to control the solenoids are one such example of this. Soldering the components in place would also reduce the sources of error in the control module because they become unplugged frequently.

We also recommend that future teams re-examine the overall design of the control module in order to make it more streamlined and user-friendly. Currently the electronics are connected on breadboards, which are well suited for prototyping but wires unplug easily, which took hours to identify during troubleshooting. The UNO and air pump should each have a dedicated power supply instead of running the UNO off a USB connection. Additionally, since the final base was never 3D printed, the air pump and solenoids are not fully constrained into the base and can be removed easily. As a result, tubing connections are not always fully sealed and can disconnect easily. The Soft Robotics Toolkit [76] provides a design for a fluidic control board that is well-organized that can serve as inspiration for an updated control module.

9.4 Miniaturization

Further miniaturization of the control system is required to make this prototype a functional prosthesis. The current control module is bulky and would be cumbersome to carry on a day to day basis. Breast pumps and insulin pumps or other infusion pumps are potential options that may help to reduce the size of the control module.

9.5 Team Reflection

Our entire undergraduate career has concluded with MQP. We are very fortunate to have had the opportunity to test the skills that we have learned the past four years in our classes. This MQP also served as an example of an engineering project in industry: several engineers that provide a unique skillset to accomplish a set of goals over a long term period.

Biomedical Engineering Design (BME 3300) and Introduction to Engineering Design (ME 2300) helped to guide the process of specifying design specifications. These classes also helped to narrow down the important qualities that our design should include. Additionally, the introductory design classes introduced the idea of a design matrix and how to use them to evaluate different prototypes.

The material review conducted as part of the design of a polyurethane component drew from BME 4814 for information about polymers in biomedical applications. Furthermore, it also discussed materials that are able to be 3D printed, as well as the concepts of biocompatible materials. This knowledge, paired with the knowledge from design classes, resulted in the material assessment matrix in Table 5.

During initial stages of prosthesis development, it was important to make considerations for the stakeholders involved. Experience in Rehabilitation Engineering (ME 3506) and in shadowing at a clinical prosthetic facility allowed for interaction with both industry professionals and patients. This helped guide the design and thought process to include considerations to enhance comfort and ease of use. Shadowing experience with prosthetic and orthotic technicians helped guide hand-modeling of the retainer designed as an attachment method for the prosthesis into the mouth. Furthermore, Introduction to Computer-Aided Design (ES 1310) as well as Manufacturing Science, Prototyping, and Computer Controlled-Machining (ME 1800) helped provide experience in CAD modeling. Solidworks served as the primary design platform for the tongue and the control module. It also served as the platform for the linkage model.

Prior experience gained in the Cellular Engineering Lab (BME 3813) provided the practices necessary to handle, incubate, and observe the cells used in sterilization testing. More broad laboratory training such as in the Biomaterials (BME 3811) and Circulatory & Respiratory (BB 3514) labs allowed safe and efficient use of the Goddard Laboratory equipment in manufacture and evaluation of the various prosthetic iterations. Background regarding the human body necessary for evaluation of cephalometric data and an understanding of the tongue's anatomy was predicated by Physiology & Engineering (BME 3111).

Previous experience with FEM through a structural engineering internship in the aerospace industry provided the basis for using FEM softwares such as Abaqus. This internship also provided structural knowledge that helped to define our fatigue testing protocol and as well as helped to identify the type of fatigue the tongue is expected to undergo. Continuum mechanics (ME 3501), Biomechanics (BME 4504), and the Solid Biomechanics lab sequence (BME 3505, 3506) provided the basis for undering if the data we obtained from the model would be accurate to the real world phenomenon.

The soft robot we developed during this project is vastly different from the robots discussed in the RBE sequence, but the programming and electronics skills covered in Unified Robotics I and II (RBE 2001, RBE 2002) were useful in designing the control module. Future students would also benefit from the topics covered in Introduction to Electrical and Computer Engineering (ECE 2010). One of the most interesting courses related to this project is Soft Robotics (RBE 530), which discusses the many types of soft robots and their applications. Although not necessary, this course did provide insight into alternative soft robotic actuation methods that could be applied to the soft robotic tongue.

References

[1] Y. Ghantous, I. Abu Elnaaj. “Global Incidence and Risk Factors of Oral Cancer,” *Harefuah*, vol. 156, no. 10, Oct. 2017.

[2] “Oral Cancer Facts,” The Oral Cancer Foundation, 28-Feb-2019. [Online]. Available: https://oralcancerfoundation.org/facts/. [Accessed: 17-May-2020].

[3] “Key Statistics for Oral Cavity and Oropharyngeal Cancers,” American Cancer Society, 08-Jan-2020. [Online]. Available: https://www.cancer.org/cancer/oral-cavity-and-oropharyngeal-cancer/about/key-statistics.html. [Accessed: 17-May-2020].

[4] “Global data on incidence of oral cancer (maps),” Oral Health, 26-Sep-2016. [Online]. Available: https://www.who.int/oral_health/publications/cancer_maps/en/. [Accessed: 17-May-2020].

[4] B. R. Pauloski, A. W. Rademaker, J. A. Logemann, et al. “Surgical variables affecting swallowing in patients treated for oral/oropharyngeal cancer,” *Head and Neck*, vol. 26, no. 7, 2004. [Online], Available: doi: 10.1002/hed.20013.

[6] P. Bhirangi et al. “Technical Considerations in Rehabilitation of an Edentulous Total Glossectomy Patient,” International Journal of Dentistry. February 2012. [Online] Available: https://doaj.org/article/183fa34888fa46b2a06efe2bbac706da

[7] M. N. Alhajj, I. A. Ismail, N. Khalifa. “Maxillary Obturator Prosthesis for a Hemimaxillectomy Patient: A Clinical Case Report,” *The Saudi Journal for Dental Research*, vol. 7, no. 2.

[8] A. A. Sabouri et al., “Prosthodontic Rehabilitation for Total Glossectomy with a Magnetic Detachable Mandibular Tongue Prosthesis: A Clinical Report,” *Journal of Prosthodontics*, vol. 21, no. 5.

[9] M. Penn, *et al.*, “Implant-retained feeding aid prosthesis for a patient following total glossectomy and laryngectomy: A clinical report,” *The Journal of Prosthetic Dentistry*, vol. 97, no. 5.

[10] F. D. Araya. “Investigating the Design and Manufacture of PneuNet Actuators as a Prosthetic Tongue for Mimicking Human Deglutition,” M.S. thesis, Mechanical Engineering, Worcester Polytechnic Institute, 2019. [Online], Available: https://digitalcommons.wpi.edu/etd-theses/1300

[11] *Abaqus*. Dassault Systèmes. 2020

[12] S. M. Tasko, R. D. Kent, J. R. Westbury. “Variability in Tongue Movement Kinematics During Normal Liquid Swallowing,” *Dysphagia*, vol. 17, no. 2.

[13] M. Ansarin, R. Bruschini, V. Navach, *et al.* “Classification of GLOSSECTOMIES: Proposal for tongue cancer resections,” *Head & neck*, vol. 41, no. 3, 2019.

[14] Mrzezo, “25 The oral cavity and related structures,” Pocket Dentistry, 03-Jan-2015. [Online]. Available: https://pocketdentistry.com/25-the-oral-cavity-and-related-structures/. [Accessed: 17-May-2020].

[15] J. T. Hansen, “Anatomy Flash Cards,” *ICON Learning Systems.*

[16] M. Kayalioglu, V. Shcherbatyy, A. Seifi, & Z. J. Liu. “Roles of intrinsic and extrinsic tongue muscles in feeding: electromyographic study in pigs,” *Archives of Oral Biology*, vol. 52, no. 8, 2007 [Online] Available: Science Direct, https://www.sciencedirect.com/science/article/pii/S0003996907000271

[17] “Surgery for oral cancer,” www.cancer.ca, 2020. [Online]. Available: https://www.cancer.ca/en/cancer-information/cancer-type/oral/treatment/surgery/?region=on. [Accessed: 17-May-2020].

[18] “Glossectomy,” THANC Guide, 12-May-2020. [Online]. Available: https://thancguide.org/cancer-basics/treatments/surgery/ablative/glossectomy/. [Accessed: 17-May-2020].

[19] Y. Hamamoto *et al.*, “The Double-Tongue Method: A new reconstruction technique for oral floor reconstruction after total glossectomy,” *Journal of Plastic, Reconstructive & Aesthetic Surgery*, vol. 68, no. 11.

[20] B. Longo, M. Pagnoni, G. Ferri, R. Morello, & R. Santanelli, “The Mushroom-Shaped Anterolateral Thigh Perforator Flap for Subtotal Tongue Reconstruction,” *Plastic and Reconstructive Surgery*, vol. 132, no. 3. [Online], Available: http://doi.org/10.1097/prs.0b013e31829acf84

[21] S. Tzoore, “Patient Stories: Kate B. ,” UCSF Health, Aug-2011. [Online]. Available: https://www.ucsfhealth.org/patient-stories/kate-brown. [Accessed: 17-May-2020].

[22] Memorial Sloan Kettering Editorial Staff, “Alyssa's Story,” Memorial Sloan Kettering Cancer Center. [Online]. Available: https://www.mskcc.org/experience/hear-from-patients/alyssa. [Accessed: 17-May-2020].

[23] brettholomeau, “Technique for Swallowing After a Total Glossectomy,” YouTube, 19-Nov-2015. [Online]. Available: https://youtu.be/HkKwNz89GUc. [Accessed: 17-May-2020].

[24] P. Polygerinos, N. Correll, S. A. Morrin, *et al.*, “Soft Robotics: Review of Fluid-Driven Intrinsically Soft Devices; Manufacturing, Sensing, Control, and Applications in Human-Robot Interaction,” *Advanced Engineering Materials*, vol. 19, no. 12, 2017. [Online], Available: DOI: 10.1002/adem.201700016

[25] C. D. Onal, D. Rus, “Autonomous Undulatory Serpentine Locomotion Utilizing Body Dynamics of a Fluidic Soft Robot,” *Bioinspiration & Biomimetrics*, vol. 8, no, 2, Mar. 2013.

[26] D. Liu, M. Wang, M. Cong, “Design and application of integrated parabolic soft actuator,” *The Industrial Robot*, vol. 46, no. 6, 2019. [Online], Available: https://wpi.primo.exlibrisgroup.com/permalink/01WPI_INST/1pchs3f/proquest2314534812

[27] L. Chen. “Investigating the Design and Manufacture of PneuNet Actuators as a Prosthetic Tongue for Mimicking Human Deglutition,” M.S. thesis, Mechanical Engineering, Worcester Polytechnic Institute, 2019. [Online], Available: https://digitalcommons.wpi.edu/etd-theses/1300

[28] Smooth-On, “Safety Data Sheet,” 823A, Jan. 2020.

[29] “Arduino Uno Rev3,” Arduino Official Store. [Online]. Available: https://store.arduino.cc/usa/arduino-uno-rev3. [Accessed: 10-Feb-2020].

[30] “Standards by ISO/TC 168,” ISO, 14-May-2020. [Online]. Available: https://www.iso.org/committee/53630/x/catalogue/. [Accessed: 12-May-2020].

[31] “ISO 10139-2:2016,” ISO, 10-Jun-2016. [Online]. Available: https://www.iso.org/standard/70317.html. [Accessed: 12-May-2020].

[32] “ASTM D575 - 91(2018),” ASTM International - Standards Worldwide. [Online]. Available: https://www.astm.org/Standards/D575.htm. [Accessed: 12-May-2020].

[33] I. A. Humbert, S. B. Reeder, E. J. Porcaro, S. A. Kays, J. H. Brittain, and J. Robbins, “Simultaneous estimation of tongue volume and fat fraction using IDEAL-FSE,” Journal of Magnetic Resonance Imaging, vol. 28, no. 2, pp. 504–508, 2008. [Online] Available: https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.21431 [Accessed Aug. 9, 2019]

[34] W. Ajaj, M. Goyen, B. Herrmann, S. Massing, S. Goehde, T. Lauenstein, and S. G. Ruehm, “Measuring tongue volumes and visualizing the chewing and swallowing process using real-time TrueFISP imaging-initial clinical experience in healthy volunteers and patients with acromegaly,” European Radiology, vol. 15, no. 5, pp. 913–918, 2004. [Online] Available: SpringerLink https://link.springer.com/article/10.1007/s00330-004-2596-6

[35] X. Ding, S. Suzuki, M. Shiga, N. Ohbayashi, T. Kurabayashi, and K. Moriyama, “Evaluation of tongue volume and oral cavity capacity using cone-beam computed tomography,” Odontology, vol. 106, no. 3, pp. 266–273, 2018. [Online] Available: SpringerLink https://link.springer.com/article/10.1007/s10266-017-0335-0 [Accessed Aug. 10, 19]

[36] I. Sanders, L. Mu, A. Amirali, H. Su, and S. Sobotka, “The Human Tongue Slows Down to Speak: Muscle Fibers of the Human Tongue,” The Anatomical Record, vol. 296, no. 10, pp. 1615–1627, Sep. 2013. [Online] Available: https://anatomypubs.onlinelibrary.wiley.com/doi/full/10.1002/ar.22755

[37] K. H. Zawawi, E. A. Al-Badawi, S. L. Lobo, M. Melis, and N. R. Mehta, “An Index for the Measurement of Normal Maximum Mouth Opening,” Canadian Dental Association, vol. 69, no. 11, pp. 737–741, 2003. [Online] Available:https://cda-adc.ca/jcda/vol-69/issue-11/737.pdf

[38] N. Khare, S. B. Patil, S. M. Kale, J. Sumeet, I. Sonali, and B. Sumeet, “Normal Mouth Opening in an Adult Indian Population,” Journal of Maxillofacial and Oral Surgery, vol. 11, no. 3, pp. 309–313, 2012. [Online] Available: SpringerLinkhttps://link.springer.com/article/10.1007/s12663-012-0334-1

[39] C. N. Stephan, “Facial approximation: An evaluation of mouth-width determination,” American Journal of Physical Anthropology, vol. 121, no. 1, pp. 48–57, 2003. [Online] Available:https://onlinelibrary.wiley.com/doi/full/10.1002/ajpa.10166

[40] C. N. Stephan and S. J. Murphey, “Mouth width prediction in craniofacial identification: cadaver tests of four recent methods, including two techniques for edentulous skulls.,” Journal of Forensic Odontostomatol, vol. 21, no. 1, pp. 2–7, 2008. [Online] Available: https://pdfs.semanticscholar.org/7329/49d4533bb7d5be4cbc312243a08a64c37812.pdf

[41] Advanced Solutions International, Inc, “Swallowing Awareness Day,” Speech Pathology Australia. [Online]. Available: https://www.speechpathologyaustralia.org.au/SPAweb/whats_on/Swallowing_Awareness_Day/SPAweb/What_s_On/SAD/Swallowing_Awareness_Day.aspx?hkey=d40795b9-eba6-413b-939a-c3eb9a69084c. [Accessed: 17-May-2020].

[49] S*ynthetic Black Iron Oxide*. Alpha Chemicals

[43] *Tracker 5.1.3*. Tracker. 2019

[44] *Silco RTV 4500 High Strength Silicone Sealant.* Silco

[45] *Go2 Glue*. Loctite

[46] S. Coyle, M. Carmel, P. LeDuc, K. Hsia. “Bio-inspired soft robotics: Material selection, actuation, and design,” *Extreme Mechanics Letters*, vol. 22, pp. 51-59, 2018.

[47] AZOMaterials, “Properties: Silicone Rubber,” AZoM.com, 14-May-2020. [Online]. Available: https://www.azom.com/properties.aspx?ArticleID=920

[48] H.J. Qi, M.C. Boyce. Stress-Strain Behavior of Thermoplastic Polyurethane. MIT and Cambridge. 2004.

[49] *Ces Edupack 2019.* Granta Design. 2019

[50] T. Wang, and M. Hillmyer. “Oxidatively Stable Polyolefin Thermoplastics and Elastomers for Biomedical Applications,” *ACS Macro Lett*, vol. 6, pp.613-618, 2017

[51] G. Bheemaneni, S. Saravana, R. Kandaswamy. “Processing and Characterization of Poly(butylene adipate-co-terephthalate)/Wollastonite Biocomposites for Medical Applications,” *materialstoday: Proceedings*, vol. 5, no. 1, pp. 1807-1816. 2018.

[52] J. Odent, T. Wallin, W. Pan, K. Kruemplestaedter, R. Shepherd, E. Giannelis. “Highly Elastic, Transparent, and Conductive 3D-Printed Ionic Composite Hydrogels,” *Advanced Functional Materials*, vol. 27, 1701807, 2017

[53] V*ytaFlex 30 Urethane Rubber Compo*und. Smooth-On

[54] M. Schmauch, S. Mishra, B. Evans, O. Velev, J. Tracy. “Chained Iron Microparticles for Directionally Controlled Actuation of Soft Robots,” *ACS Applied Materials & Interfaces*, vol. 9, no. 13, 2017

[55] Dediu, D., Janssen, R., & Moisik, S. R. (2019). Weak biases emerging from vocal tract anatomy shape the repeated transmission of vowels. Nature human behaviour, 1-9.

[56] G. Cohen, O. Kiritsis, E. Lauer, *et al.*, “Humanoid Animatronic Learning Simulator for Medical Interactive Training (H.A.L. S.M.I.T),” Undergraduate Major Qualifying Project, Mechanical Engineering, Worcester Polytechnic Institute, 2020.

[57] Lee, J., Huprich, J., Kujath, C., Ravi, K., Enders, F., Smyrk, T. C., ... & Alexander, J. A. (2012). Esophageal diameter is decreased in some patients with eosinophilic esophagitis and

might increase with topical corticosteroid therapy. Clinical gastroenterology and hepatology, 10(5), 481-486.
[58] *PrusaControl*. Prusa3D. 2017
[59] *Slic3r Prusa Edition 1.41.2*. Slic3r. 2018.
[60] *Ultimaker Cura 4.3.0*. Ultimaker. 2019
[61] *Blender 2.80*. Blender. 2018
[62] Ep*oxAcast 690*. Smooth-On
[63] *Form2 3D Printer*. Formlabs
[64]*Solidworks*. Dassault Systèmes, 2018.
[65] T. Otake, "Japanese team invents movable tongue prosthesis to enable speech for cancer victims," *The Japan Times*, 01-Feb-2016.
[66] RetainerDesigner, *Retainer Acrylic Trimming*, Feb. 9, 2013. Accessed on Nov. 1, 2019. [Video file]. Available: https://www.youtube.com/watch?v=APRw1wgvwy8
[67] A. F. Alhuwaizi, "A Comparison between Hawley and Acrylic-Free Retainers (A clinical trial)," *Journal of the College of Dentistry*, vol. 12, pp. 115–121, 2002.
[68] T. Upword, "The Difference Between Essix and Hawley Retainers," *SportingSmiles*, 15-Nov-2019. [Online]. Available: https://www.sportingsmiles.com/blog/the-difference-between-essix-and-hawley-retainers/. [Accessed: 10-May-2020].
[69] RetainerDesigner, *Wirebending 101*, Aug. 27, 2012. Accessed on: Nov. 1, 2029. [Video file]. Available: https://www.youtube.com/watch?v=lotA3UyZ17s&t=131s
[70] RetainerDesignwe, *Adam Clasps: How to Bend*, Jul. 7 2012. Accessed on: Nov. 1, 2019. [Video file]. Available: https://www.youtube.com/watch?v=YSzU2A6cq6A
[71] "Dental Orthodontic Lingual Retainer Spooled Wire Stainless 19GA 0.9mm x 9m 50gr," *eBay*. [Online]. Available: https://www.ebay.com/itm/Dental-Orthodontic-Lingual-Retainer-Spooled-Wire-Stainless-19GA-0-9mm-x-9m-50gr/222465502036?hash=item33cbfa2b54:g:KSwAAOSwmgJY5m72. [Accessed: 18-Jan-2020].
[72] "Dental Orthodontic Lingual Retainer Spooled Wire Stainless 20GA 0.8mm x 11m 50gr," *eBay*. [Online]. Available: https://www.ebay.com/itm/Dental-Orthodontic-Lingual-Retainer-Spooled-Wire-Stainless-20GA-0-8mm-x-11m-50gr/322475595109?hash=item4b150b1565:g:KSwAAOSwmgJY5m72. [Accessed: 18-May-2020].
[73] "3 Prong Pliers Orthodontic Dental Instruments," *eBay*, 30-May-2017. [Online]. Available: https://www.ebay.com/itm/3-Prong-Pliers-Orthodontic-Dental-Instruments/401266385841?epid=527700641&hash=item5d6d5723b1:g:HzIAAOSwilpenyQn:sc:USPSFirstClass!01420!US!-1. [Accessed: 18-May-2020].
[74] "B Weld Twin Tube," *J*. [Online]. Available: https://www.jbweld.com/product/j-b-weld-twin-tube. [Accessed: 18-May-2020].

[75] S. Ozel, E. H. Skorina, M. Luo, W. Tao, F. Chen, Y. Pan, and C. D. Onal, “A composite soft bending actuation module with integrated curvature sensing,” 2016 IEEE International Conference on Robotics and Automation (ICRA), 2016.

[76] Z. Wang, P. Polygerinos, A. Alazmani, and A. Campo, “Fluidic Control Board,” Soft Robotics Toolkit. [Online]. Available: https://softroboticstoolkit.com/book/control-board. [Accessed: 17-May-2020].

[77] “LulzBot TAZ 6,” LulzBot, 20-Jun-2019. [Online]. Available: https://www.lulzbot.com/store/printers/lulzbot-taz-6. [Accessed: 17-May-2020].

[78] “Manufacturing Labs - Laser Cutter,” Google Sites. [Online]. Available: https://sites.google.com/site/wpimanufacturinglabs/schedule/laser-cutter. [Accessed: 01-May-2020].

[79] “Ultra-Small LM2596 Power Supply Module DC/DC Buck 3A Adjustable Buck Module Regulator Ultra LM2596S Compatible with Arduino by Atomic Market,” *Amazon*. [Online]. Available: https://www.amazon.com/Ultra-small-adjustable-Compatible-Atomic-Market/dp/B00TMFKJ9Q/ref=asc_df_B00TMFKJ9Q/?tag=hyprod-20&linkCode=df0&hvadid=198062682203&hvpos=1o1&hvnetw=g&hvrand=18325460662492879627&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9001843&hvtargid=pla-319814629648&psc=1.

[80] “TransistorMotorControl,” *Arduino*. [Online]. Available: https://www.arduino.cc/en/Tutorial/TransistorMotorControl. [Accessed: 18-May-2020].

[81] “20 Pcs 6 mm 2 Pin Momentary Tactile Tact Push Button Switch Through Hole Breadboard Friendly for the Panel PCB by QTEATAK,” *Amazon*. [Online]. Available: https://www.amazon.com/Momentary-Tactile-Through-Breadboard-Friendly/dp/B07WF76VHT/ref=sr_1_5?crid=TKZ0TIPL3VFW&keywords=2 pin push button switch&qid=1580491382&s=industrial&sprefix=2pin pus,industrial,147&sr=1-5.

[82] “AiTrip IIC/I2C/TWI 1602 Serial 2004 20x4 Blue Backlight LCD Module Shield for Arduino Uno Mega2560,” *Amazon*. [Online]. Available: https://www.amazon.com/AiTrip-Serial-Backlight-Arduino-Mega2560/dp/B07HRD8655/ref=sr_1_4?crid=2PJ4M3SXS1MZL&dchild=1&keywords=20x4 lcd&qid=1589431802&s=industrial&sprefix=20x4 ,industrial,168&sr=1-4.

[83] “Adafruit METRO M0 Express - designed for CircuitPython,” Adafruit Industries Blog RSS. [Online]. Available: https://www.adafruit.com/product/3505. [Accessed: 17-May-2020].

[84] “2,3,5-Triphenyltetrazolium chloride T8877,” Sigma Aldritch. [Online]. Available: https://www.sigmaaldrich.com/catalog/product/sigma/t8877?lang=en®ion&gclid=EAIaIQobChMIgtaVge246QIVCIbICh25DADpEAAYASAAEgLB3PD_BwE. [Accessed: 16-May-2020].

[85] Tengerdy, R. P., Nagy, J. G., & Martin, Barbara (1967). Quantitative measurement of bacterial growth by the reduction of tetrazolium salts. Applied microbiology, 15(4), 954.

[86] E. P. Melmed, “Polyurethane implants: a 6-year review of 416 patients.,” Plastic and Reconstructive Surgery, vol. 82, no. 2, pp. 285–290, 1988.

[87] D. H. Deheer, S. R. Owens, and A. B. Swanson, “The host response to silicone elastomer implants for small joint arthroplasty,” The Journal of Hand Surgery, vol. 20, no. 3, 1995.

[88] “Modeling,” *Soft Robotics Toolkit*. [Online]. Available: https://softroboticstoolkit.com/book/pneunets-modeling. [Accessed: Nov-2019].

[89] C. Renaud, J.-M. Cros, Z.-Q. Feng, and B. Yang, “The Yeoh model applied to the modeling of large deformation contact/impact problems,” *International Journal of Impact Engineering*, vol. 36, no. 5, pp. 659–666, 2009.

[90] Hori, K., Hayashi, H., Yokoyama, S., Ono, T., Ishihara, S., Magara, J., ... & Inoue, M. (2015). Comparison of mechanical analyses and tongue pressure analyses during squeezing and swallowing of gels. Food hydrocolloids, 44, 145-155.

[91] T. Upword, “How Much Do Dental Retainers Cost?,” Sporting Smiles, 15-Nov-2019. [Online]. Available: https://www.sportingsmiles.com/blog/how-much-do-dental-retainers-cost/. [Accessed: 12-Mar-2020].

[92] *Overnight Retainer and Denture Cleaning Tablets*. Dental Duty. [Online]. Available https://www.amazon.com/Overnight-Retainers-Invisalign-Dental-Appliances/dp/B07W3KPYDT/ref=sr_1_1_sspa?dchild=1&keywords=denture+tablets&qid=1589768148&sr=8-1-spons&psc=1&spLa=ZW5jcnlwdGVkUXVhbGlmaWVyPUFORU1BMzgwWFNFN08mZW5jcnlwdGVkSWQ9QTAwMTQzMDBQQkMyVzhXWDlYOUkmZW5jcnlwdGVkQWRJZD1BMDU3ODk1NzJPSFBIT1c0T0M2QVomd2lkZ2V0TmFtZT1zcF9hdGYmYWN0aW9uPWNsaWNrUmVkaXJlY3QmZG9Ob3RMb2dDbGljaz10cnVl. [Accessed 12-May-2020]

[93] R. K. Zipf and K. L. Cashdollar, “Effects of blast pressure on structures and the human body,” CiteSeerX, 2006. [Online]. Available: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.691.7547. [Accessed: 15-May-2020].

[94] “What is Vinyl Acetate Monomer?,” Solventis. [Online]. Available: https://www.solventis.net/products/others/vinyl-acetate-monomer/. [Accessed: 05-Apr-2020].

[95] “How Much Power do 3D Printers Use and What Does that Cost?,” 3D Printing Mentor. [Online]. Available: https://3dprintingmentor.com/how-much-power-do-3d-printers-use-and-what-does-that-cost/. [Accessed: 17-April-2020].

[96] “FAQ,” Invisalign. [Online]. Available: https://www.invisalign.com/frequently-asked-questions. [Accessed: 17-May-2020].

[97] **ISO 13017:2012: Dentistry — Magnetic attachments**.

[98] I. A. Anderson, T. A. Gisby, T. G. Mckay, B. M. O’Brien, and E. P. Calius, “Multi-functional dielectric elastomer artificial muscles for soft and smart machines,” Journal of Applied Physics, vol. 112, no. 4, p. 041101, 2012.

Appendices

Appendix A: Material Specifications

Item	Manufacturer	Identity
Silicon Sealant	Silco	Silco RTV 4500 High Strength Silicone Sealant
Loctite Glue	Loctite	Go2 Glue
PolyUrethane	Smooth-On	VytaFlex 30 Urethane Rubber Compound
PDMS	Smooth-On	EcoFlex 00-30 Silicone Rubber Compound
Magnetic Filament	Alpha Chemicals	Synthetic Black Iron Oxide
PLA Filament	MatterHackers	
	Hatchbox	
PVA	Matterhackers	
Epoxy	Smooth-On	EpoxAcast 690
Release Agent	Smooth-On	Ease Release 200
TTC	Millipore Sigma	2,3,5-Triphenyltetrazolium Chloride

Appendix B: Design Specifications of Linkage Actuated Prosthesis

All dimensions are in mm unless otherwise noted.

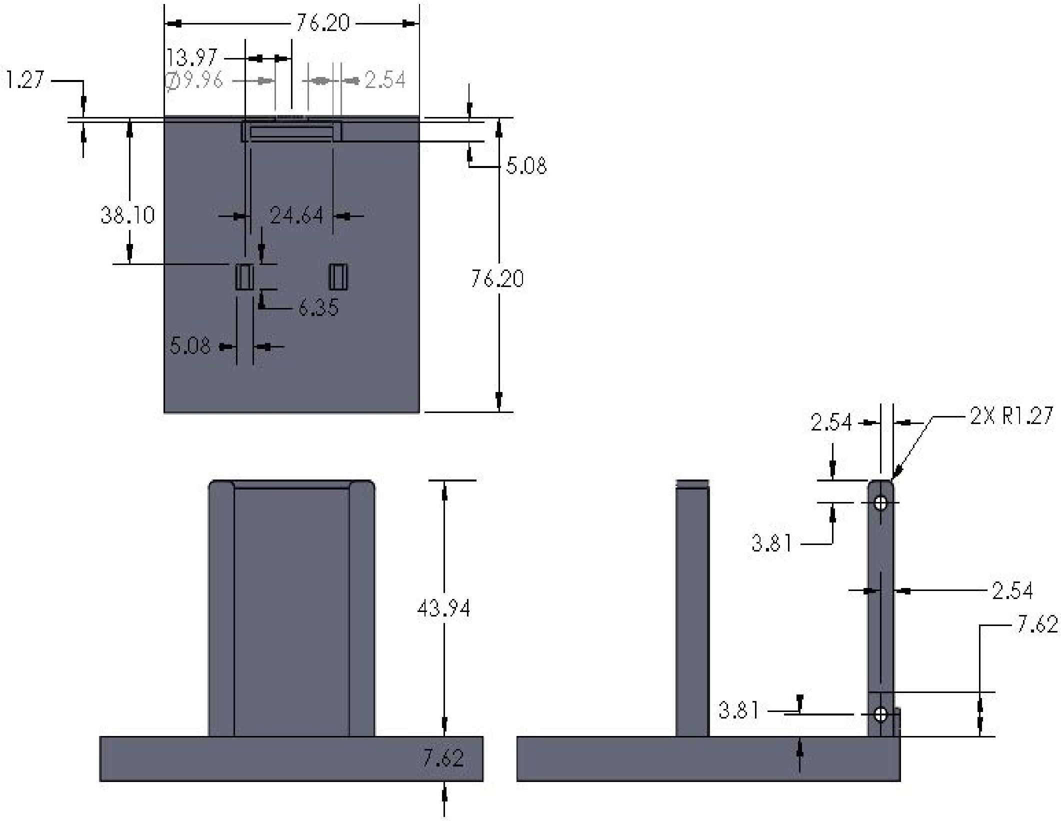

Figure 84: Base of linkage actuator.

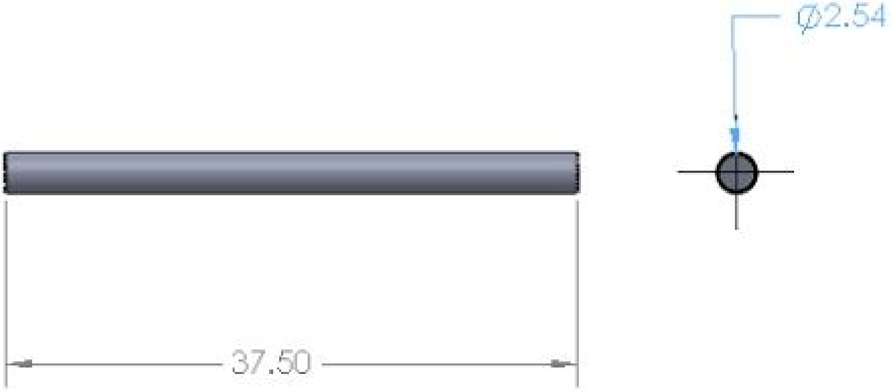

Figure 85: Axle for linkage actuator.

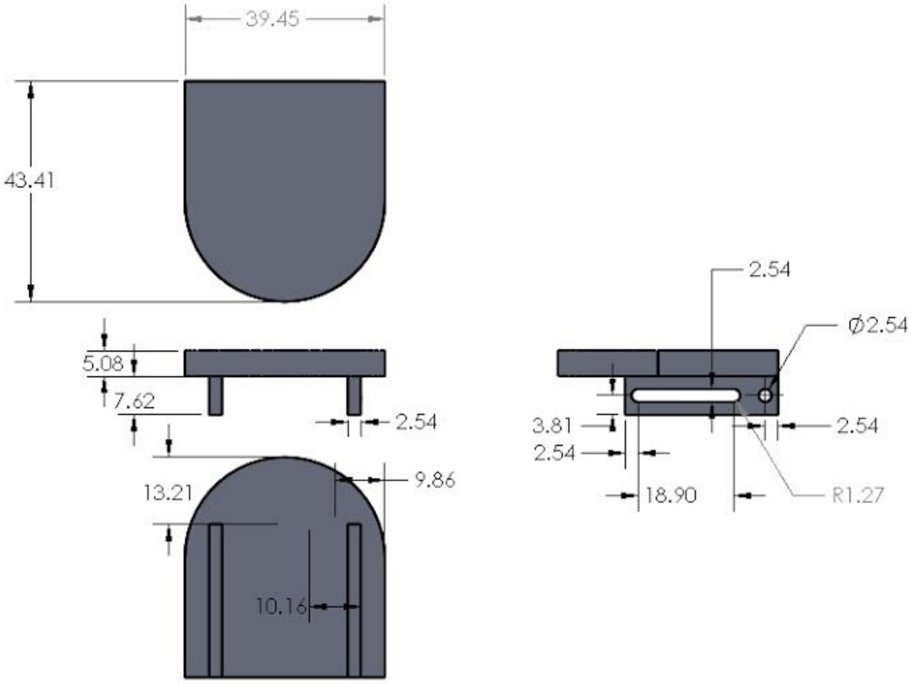

Figure 86: Tongue used in linkage actuator.

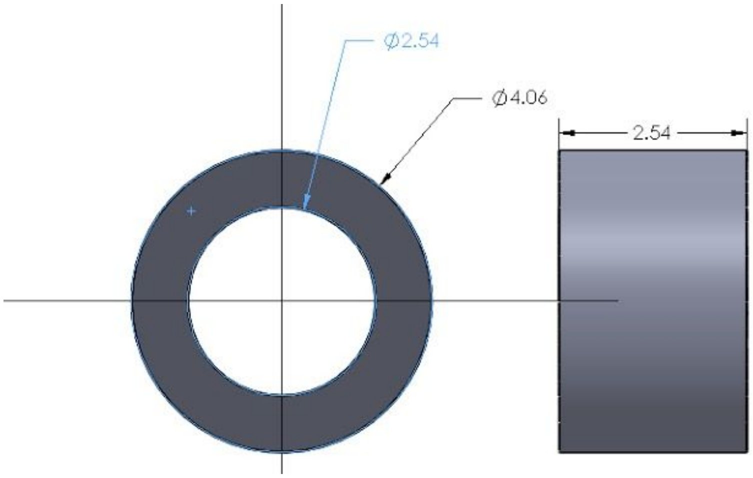

Figure 87: Large collar for linkage actuator.

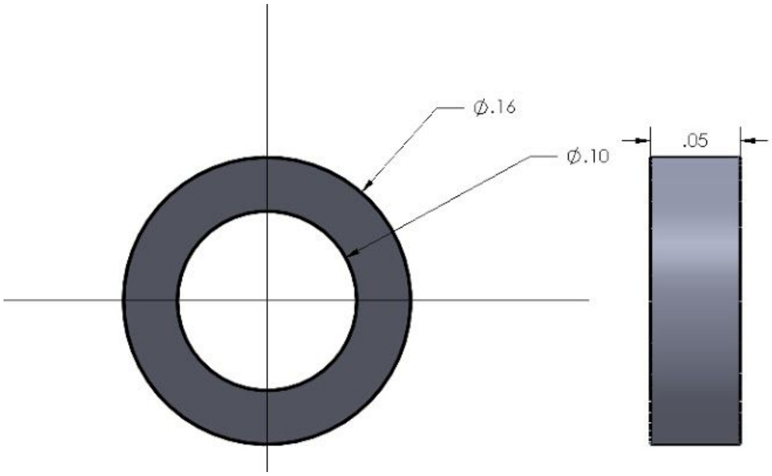

Figure 88: Small Collar for linkage actuator.

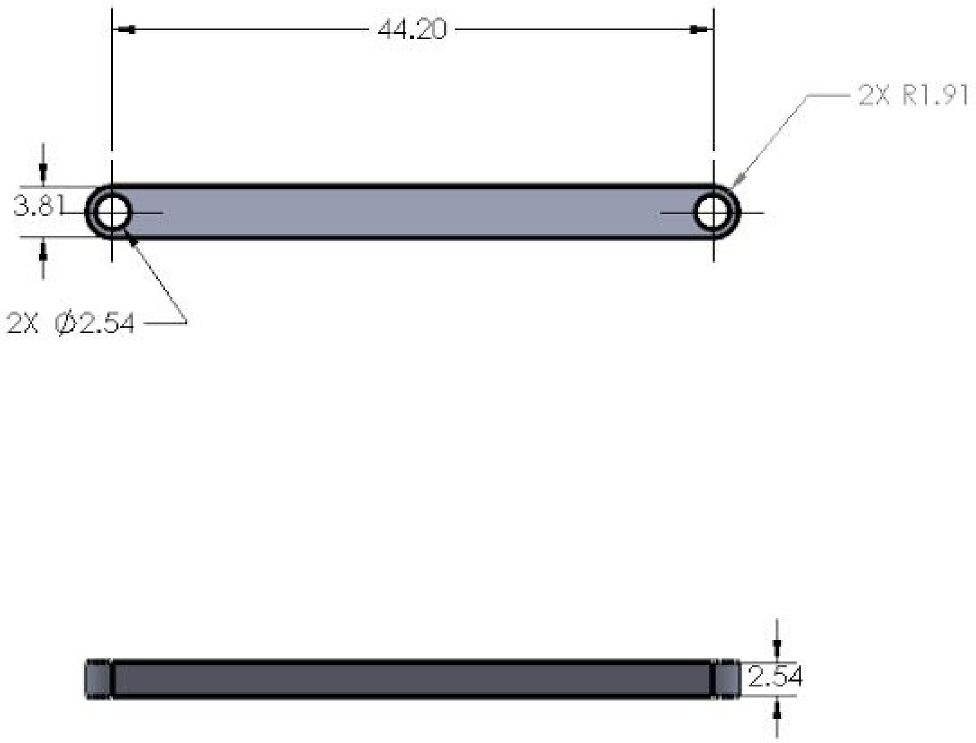

Figure 89: Linkage used in linkage actuator.

Appendix C: Manufacture of Epoxy

To create the Epoxy Oral Cavity, we created a silicone elastomer mold. We put the 3D printed PLA oral cavities into a bucket. The size of this did not matter as long as the oral cavity fit completely inside. We then poured the silicone elastomer into the bucket and let it cure around the oral cavity for 48 hours. This was greater than the 24 hours normally given for curing as this mold had thicker sections that could potentially take longer to cure. We then removed the 3D printed oral cavity. To do this we attempted to leave one surface of the oral cavity open to the uncured section so it could more easily be removed, but we had to cut away excess silicone elastomer on top of the bottom model to get it out.

The top mold had developed a pocket of air at the roof of the mouth so we poured silicone into the inverted top oral cavity where the pocket of air had been. We then glued this onto the total mold using silicone sealant. This replicated the shape of the part with the exception of a noticeable seam, which we attempted to smooth using more silicone sealant.

Next we mixed and poured epoxy into this mold. This epoxy is detailed in Appendix A. We sprayed the molds with a release agent as described in Appendix A,prepared 130 grams of epoxy in a fume hood according to manufacturer instructions in a disposable plastic cup, and then poured the epoxy into the silicone molds. These cured for 24 hours. We then Pulled the silicone molds off of the epoxy parts. It is important to note that at this time the molds were still slightly soft and could be moved. This is a critical point of time as it allows for excess epoxy to be cut off, but it also allows for the part to slightly change shape. Either great care should be taken while removing these molds to not accidentally alter the shape, especially in the bottom part, or these should be left in the mold for another 24 hours, reaching 48 hours in total.

The resulting epoxy oral cavities did not appear as translucent as we wanted. We tried following designs where we mechanically agitated and heated the epoxy after mixing but before curing to try to degas the epoxy. This did not noticeably affect the opacity. We then noted that the molds had a significant texturing from the 3D printed parts that made the mold. We tried to create a prototype in which we coated the mold with silicone sealant to change the surface texture. This prototype had a similar opacity. We finally tried to use sandpaper to smooth the surface but this too did not make the component translucent.

First, we immersed the PLA molds created in the previous step were immersed in Silicone Rubber, which cured around them to make negatives of the oral cavity. These were then filled with the epoxy. This epoxy came in two parts which were mixed in a 100:30 weight ratio. These cured for 24 hours and were removed from molds 48 hours after mixing. As seen in Figure 50 reproduced below these were not as transparent as desired due to the pattern caused by the printed pattern of the original PLA parts. Another prototype was created by rubbing silicone sealant across the surfaces that needed to be transparent. While this sealant was supposed to be a glue, when spread into a thin layer, it instead created a smoother pattern that was more transparent when molded onto the epoxy.

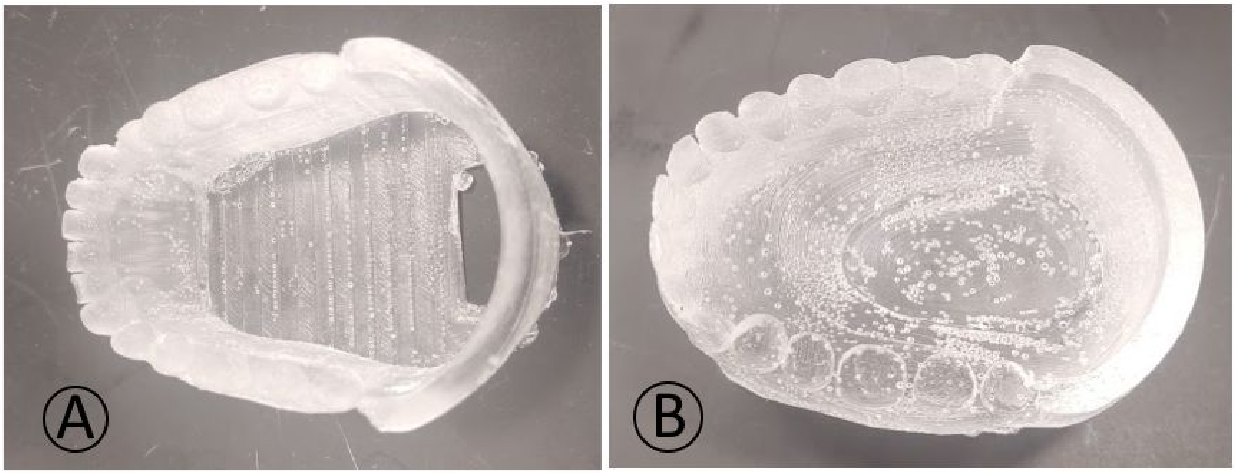

Figure 50 (reproduced) : Epoxy oral cavity. A) Bottom. B) inverted oral cavity top.

Appendix D. Nodes Probed for Data Collection from Abaqus

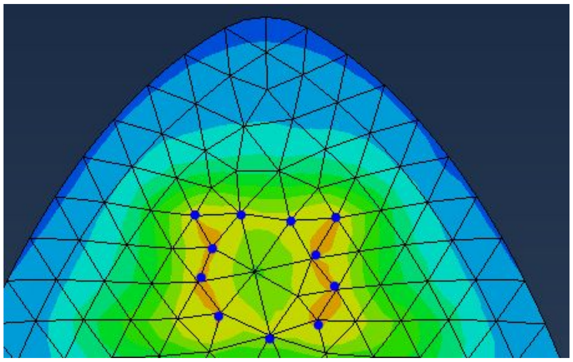

Figure 90: Early Model - Front Pneunet

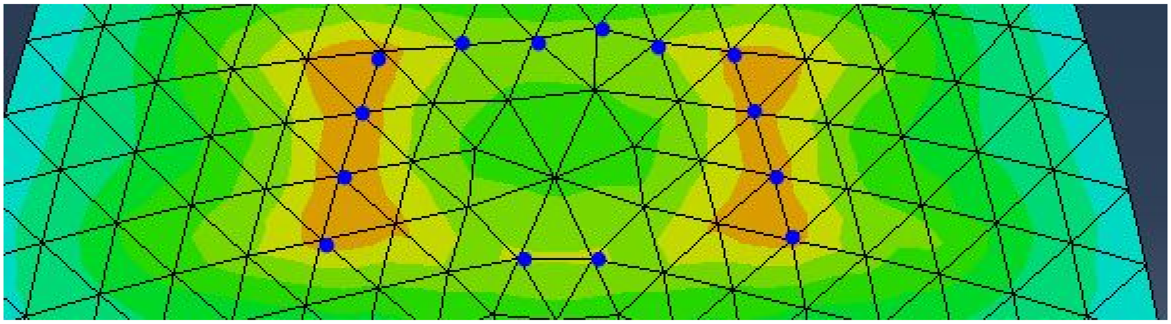

Figure 91: Early Model - Middle Pneunet

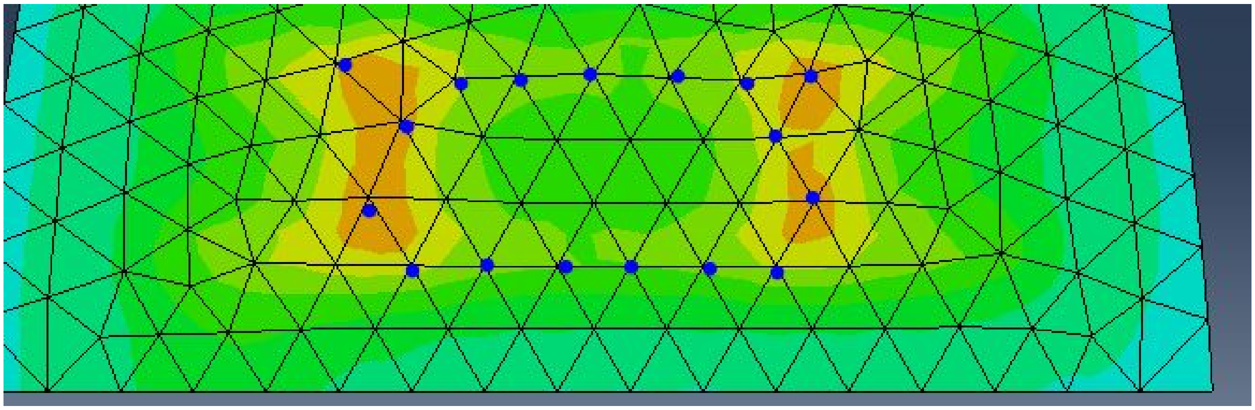

Figure 92: Early Model - Back Pneunet

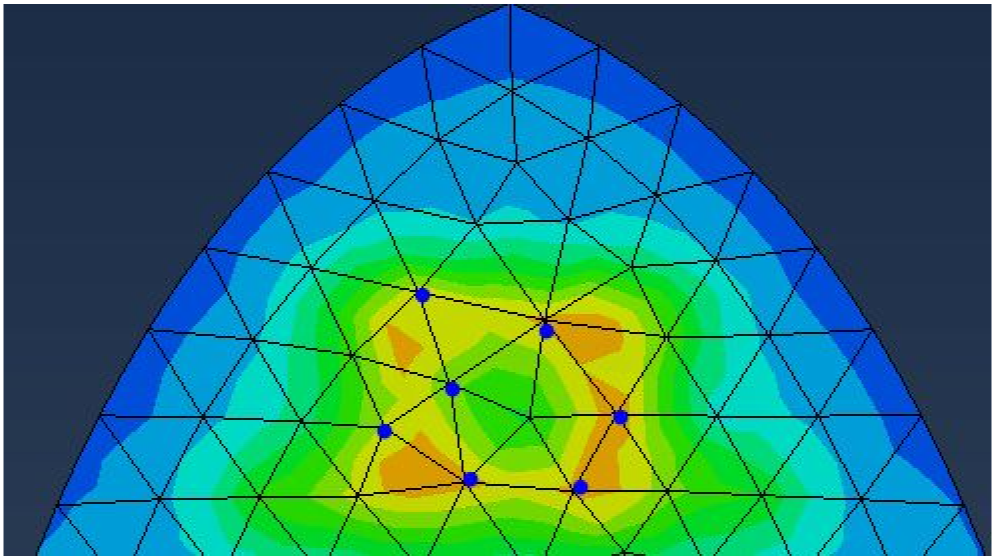

Figure 93: Primary Design - Front Pneunet

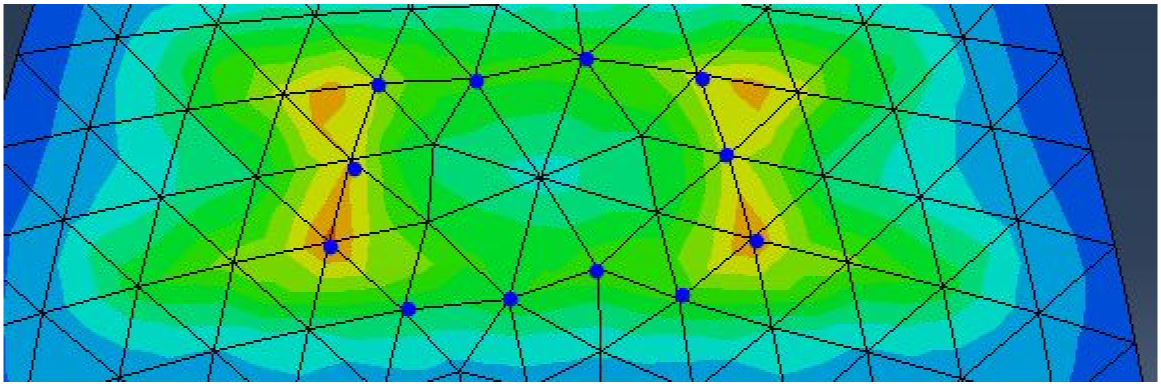

Figure 94: Primary Design - Middle Pneunet

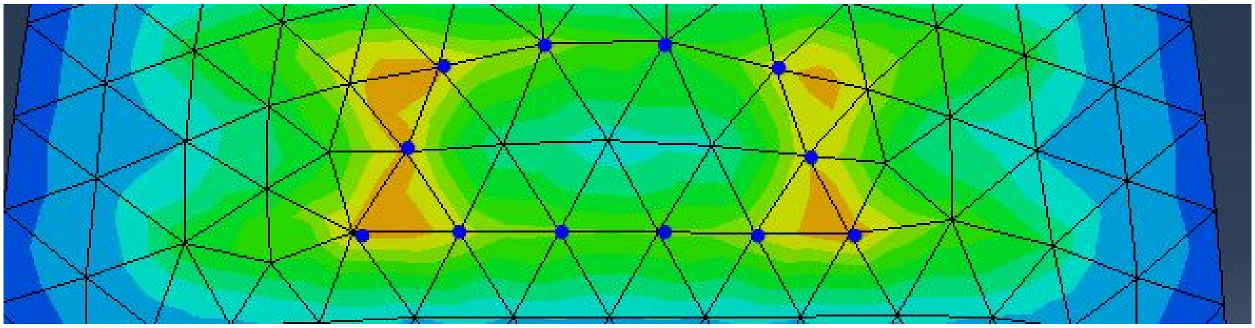

Figure 95: Primary Design - Back Pneunet

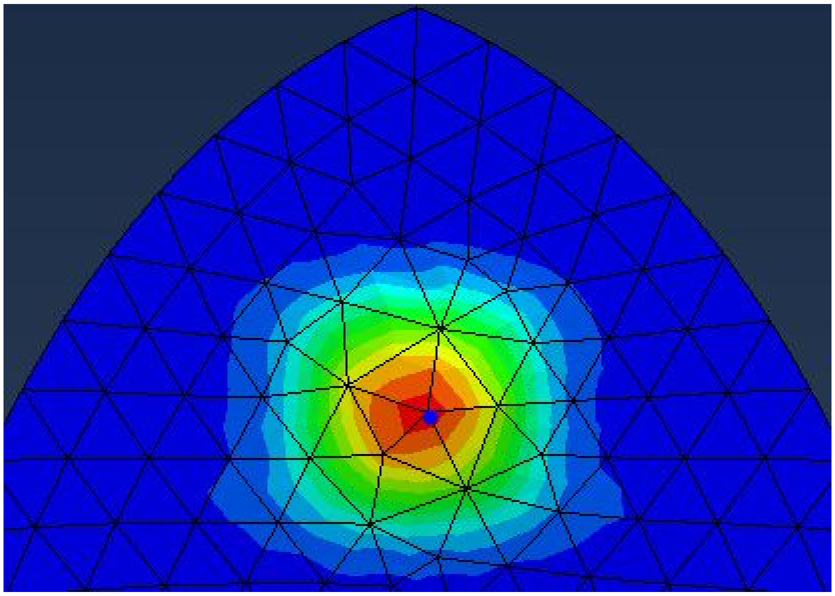

Figure 96: Redesign 1 - Front Pneunet

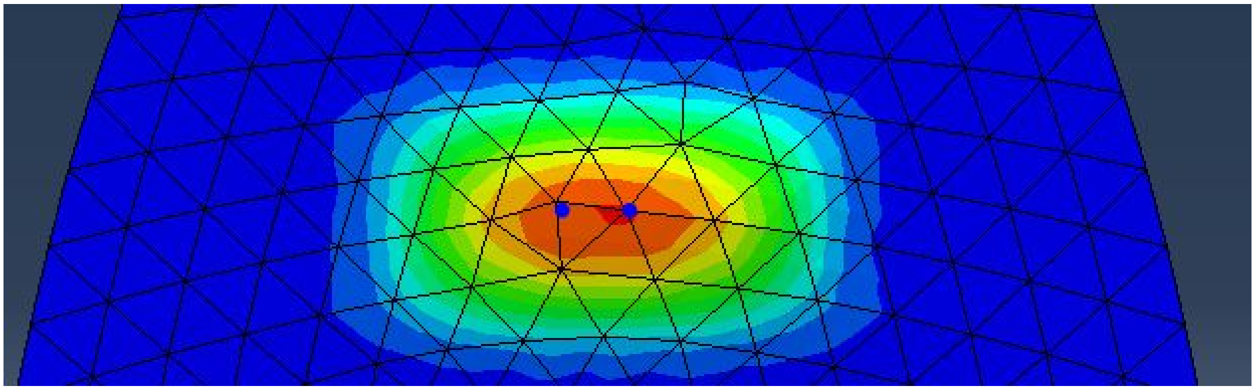

Figure 97: Redesign 1 - Middle Pneunet

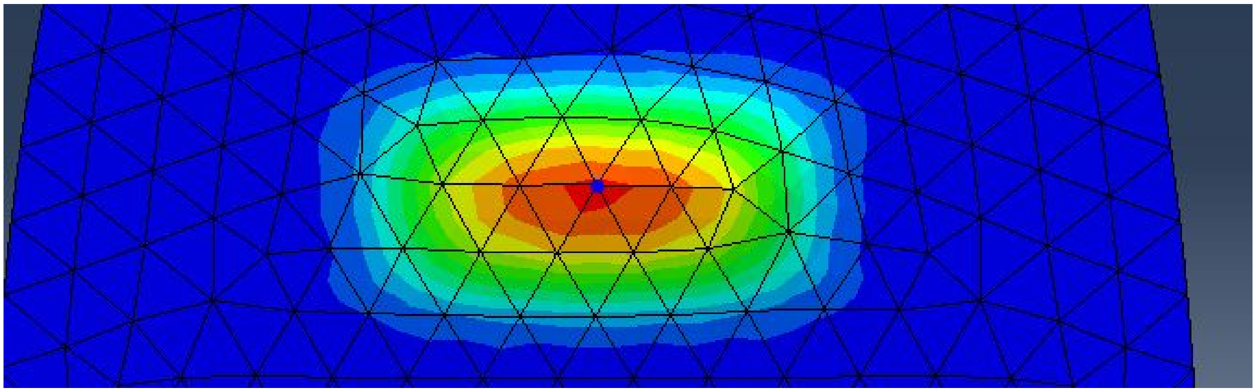

Figure 98: Redesign 1 - Back Pneunet

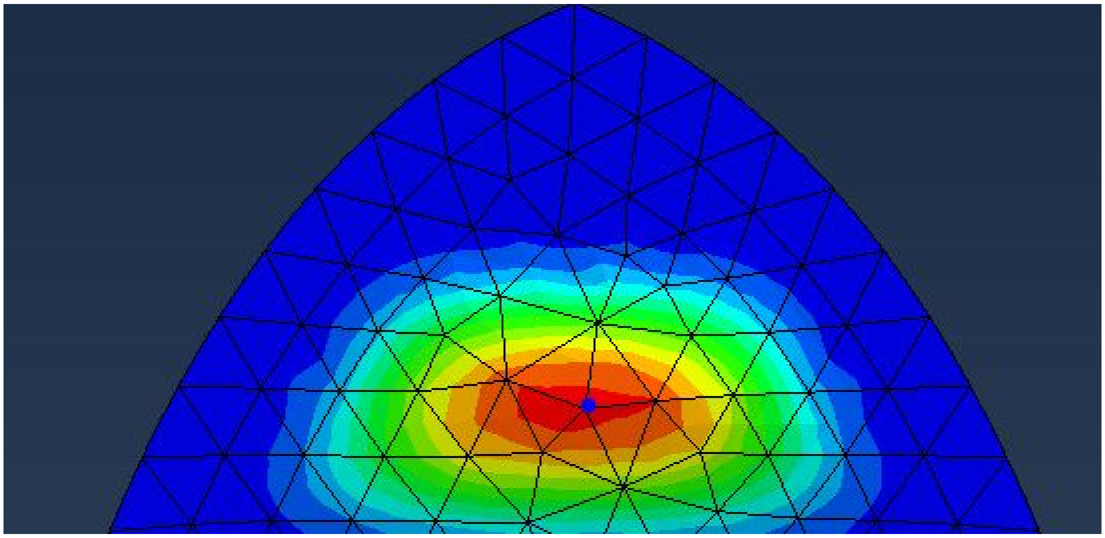

Figure 99: Redesign 2 - Front Pneunet

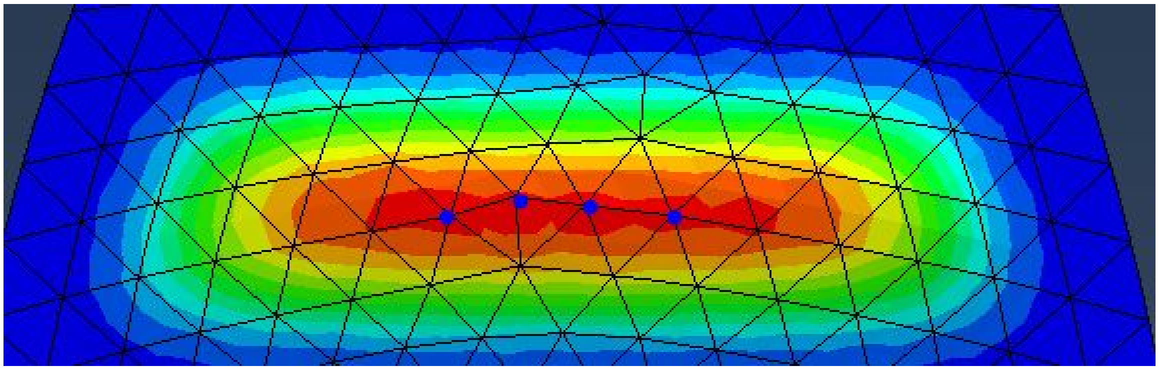

Figure 100: Redesign 2 - Middle Pneunet

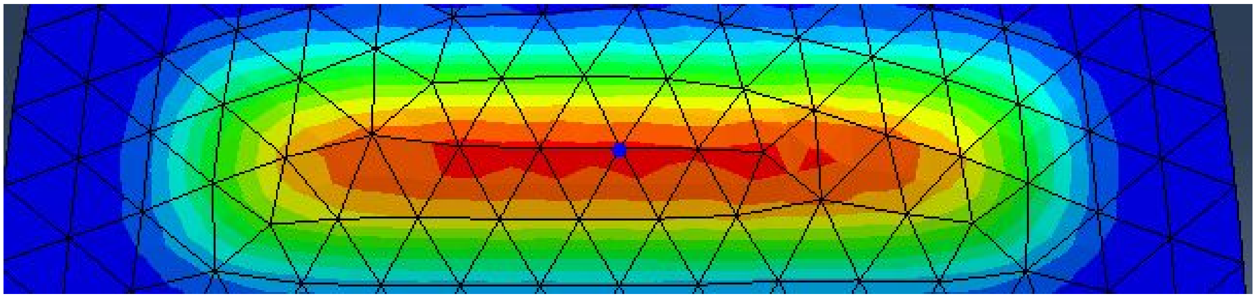

Figure 101: Redesign 2 - Back Pneunet

Appendix E. Height vs. Pressure Curves from Simulation (Early Design)

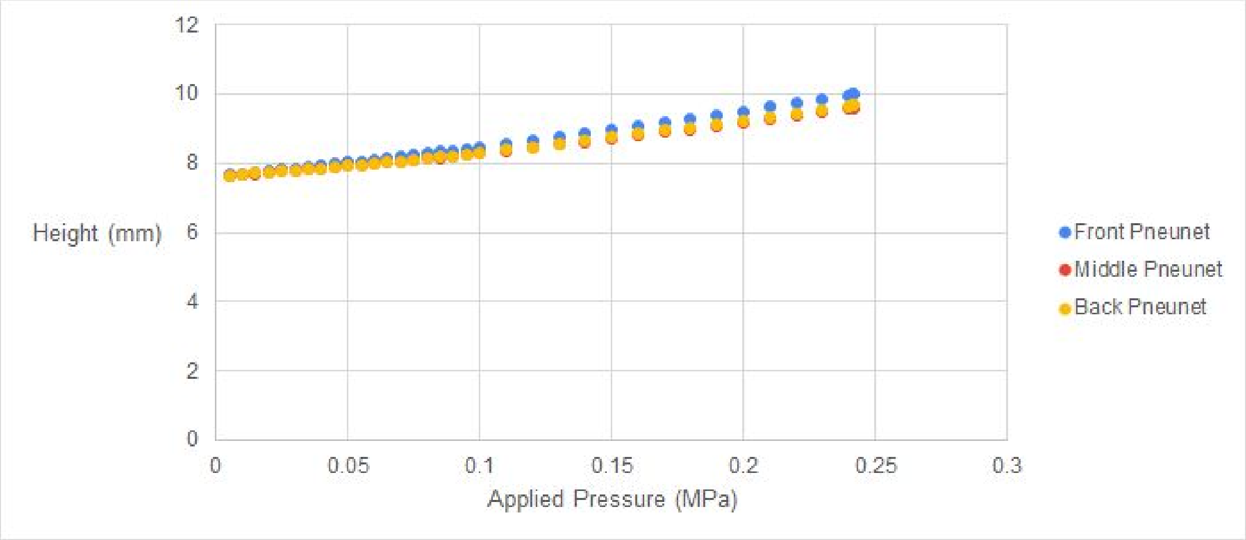

Figure 102: Front Channel Average Height Vs. Applied Pressure, Early Design

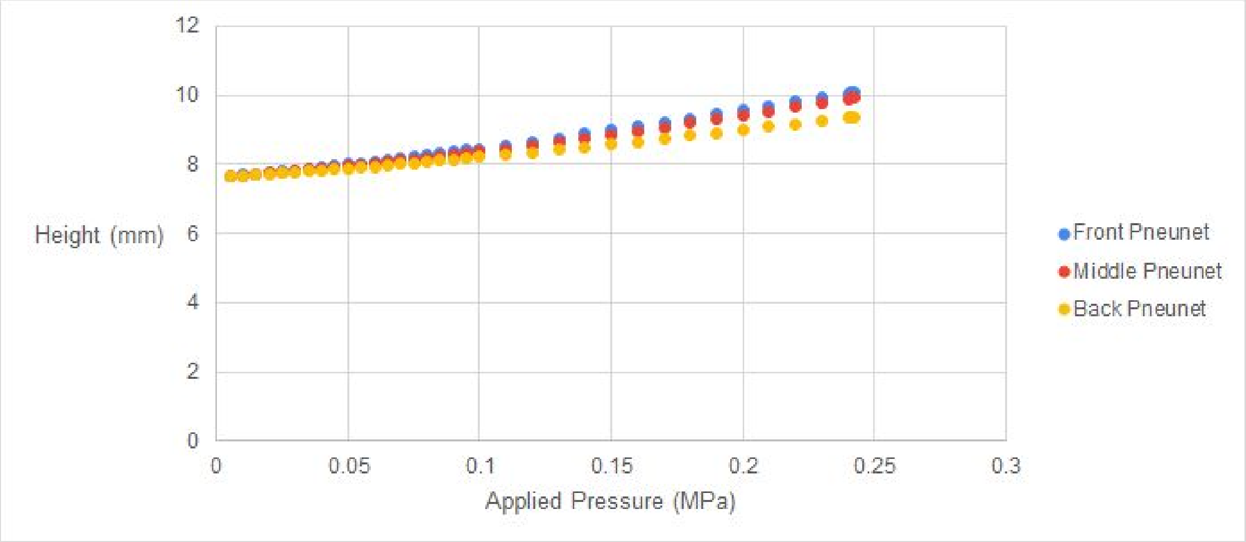

Figure 103: Back Channel Average Height Vs. Applied Pressure, Early Design

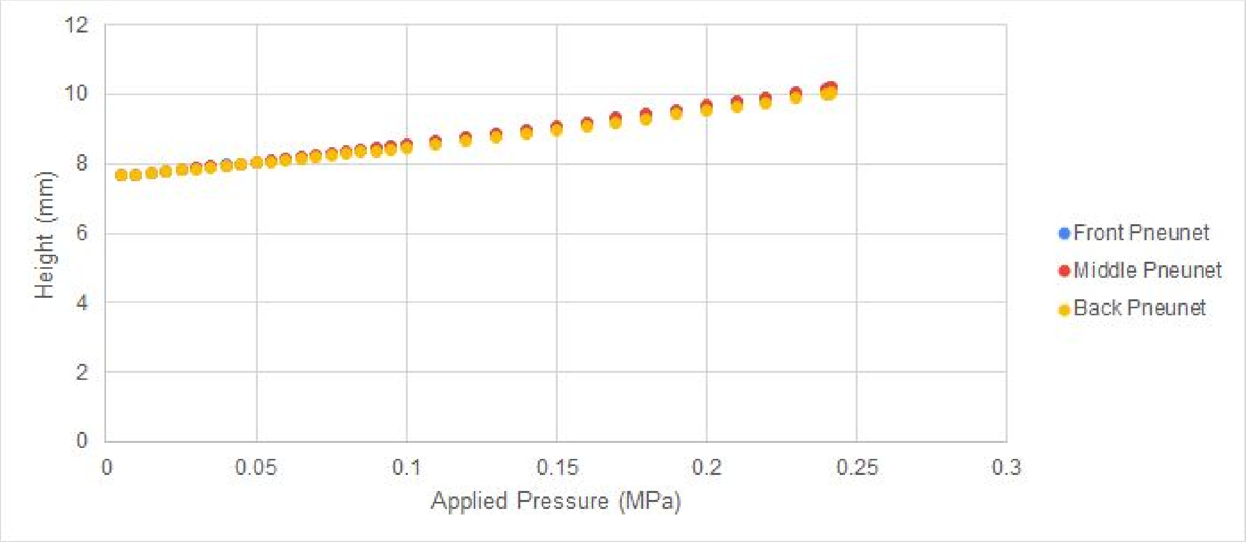

Figure 104: Side Channel Average Height Vs. Applied Pressure, Early Design

The line of best fit equations for each curve are as listed in Table 10. Note that here, y is height and x is applied pressure.

Table 10: Line of Best Fit Equations from Early Design Simulation Data

Pneunet	Channel	Equation
Front	Front	$y = 8.9195x^2 + 7.6725x + 7.6109$
	Back	$y = 12.197x^2 + 7.2777x + 7.6072$
	Side	$y = 9.3718x^2 + 8.325x + 7.615$
Middle	Front	$y = -20.784x^3 + 18.713x^2 + 4.8925x + 7.6239$
	Back	$y = -19.705x^3 + 21.468x^2 + 5.4216^x + 7.6245$
	Side	$y = 10.489x^2 + 8.1409x + 7.614$
Back	Front	$y = 11.595x^2 + 5.8267x + 7.6056$
	Back	$y = 9.5257x^2 + 4.9503x + 7.6117$
	Side	$y = 10.341x^2 + 7.468^x + 7.6153$

Appendix F. Height vs. Pressure Curves from Simulation (Preliminary Design)

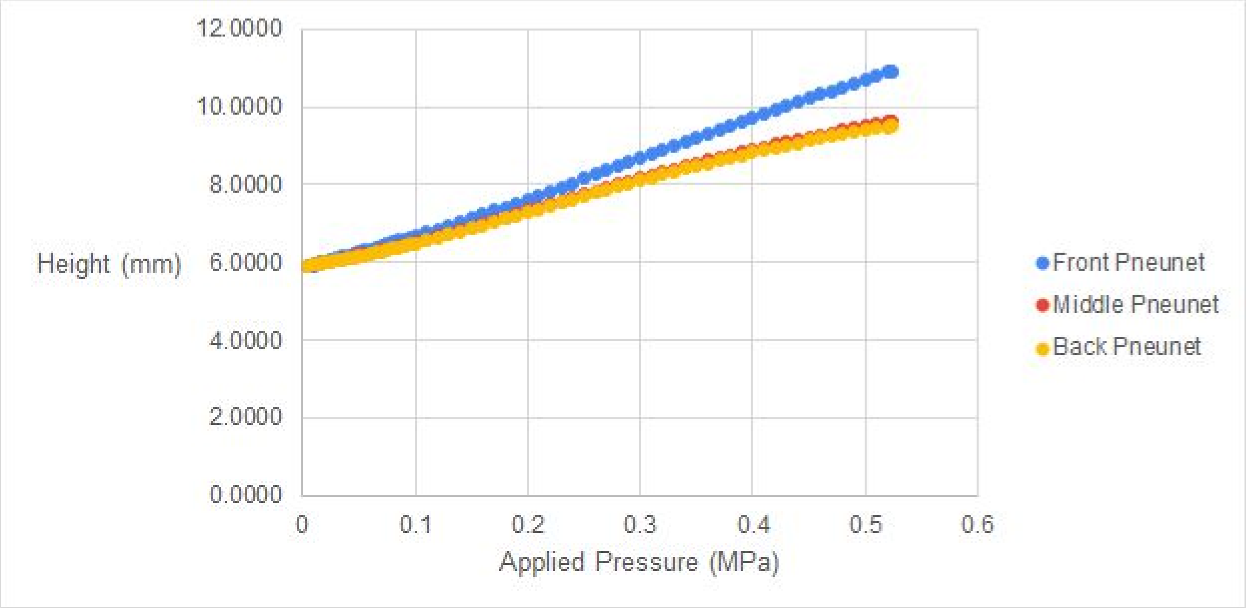

Figure 105: Front Channel Average Height Vs. Applied Pressure, Preliminary Design

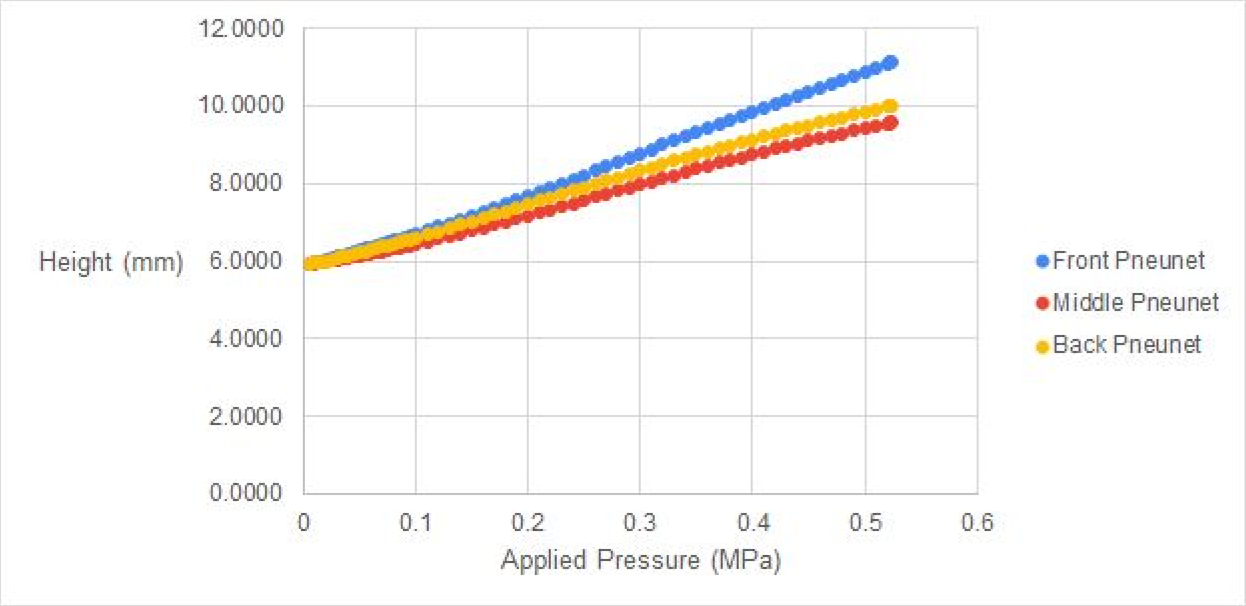

Figure 106: Back Channel Average Height Vs. Applied Pressure, Preliminary Design

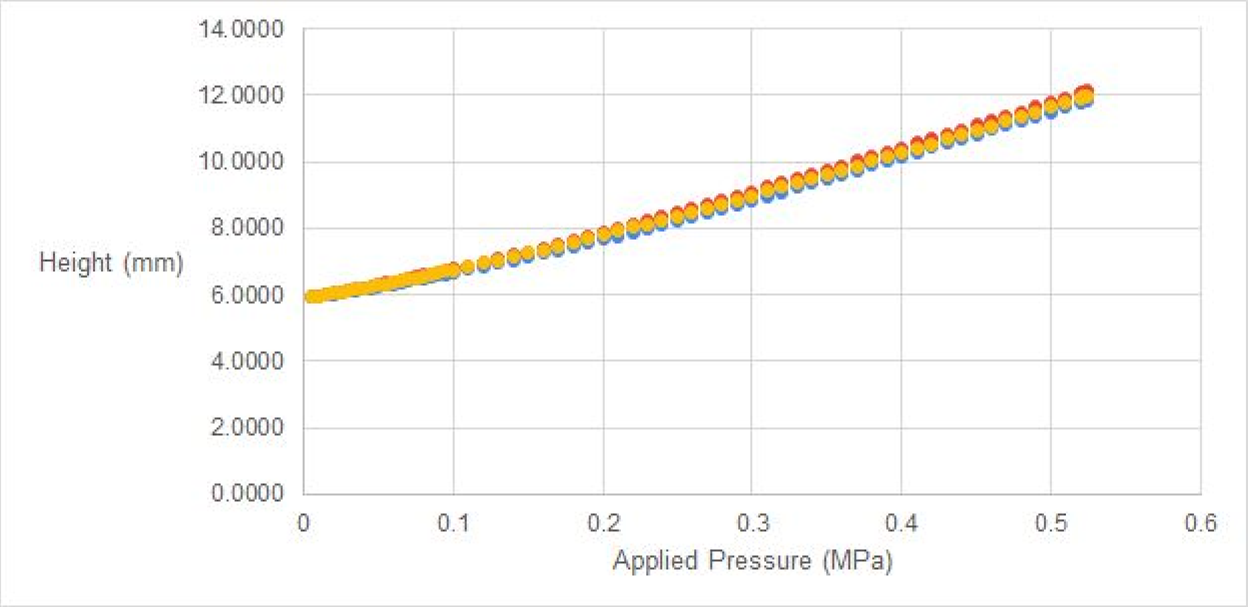

Figure 107: Side Channel Average Height Vs. Applied Pressure, Preliminary Design

The line of best fit equations for each curve are as listed in Table XX. Note that here, Y is height and x is applied pressure.

Table 11: Line of Best Fit Equations from Preliminary Design Simulation Data

Pneunet	Channel	Equation
Front	Front	$y = 1.6566x^2 + 9.0268x + 5.8046$
	Back	$y = 2.1081x^2 + 9.1542x + 5.8014$
	Side	$y = 7.0336x^2 + 7.888x + 5.8398$
Middle	Front	$y = 7.5196x + 5.8241$
	Back	$y = 0.5946x^2 + 7.0492x + 5.7819$
	Side	$y = 5.5679x^2 + 9.1583x + 5.8305$
Back	Front	$y = 7.316x + 5.828$
	Back	$y = -1.133x^2 + 8.7407x + 5.7822$
	Side	$y = 5.9244x^2 + 8.6485x + 5.8457$

Appendix G. Height vs. Pressure Curves from Simulation (Redesign 1)

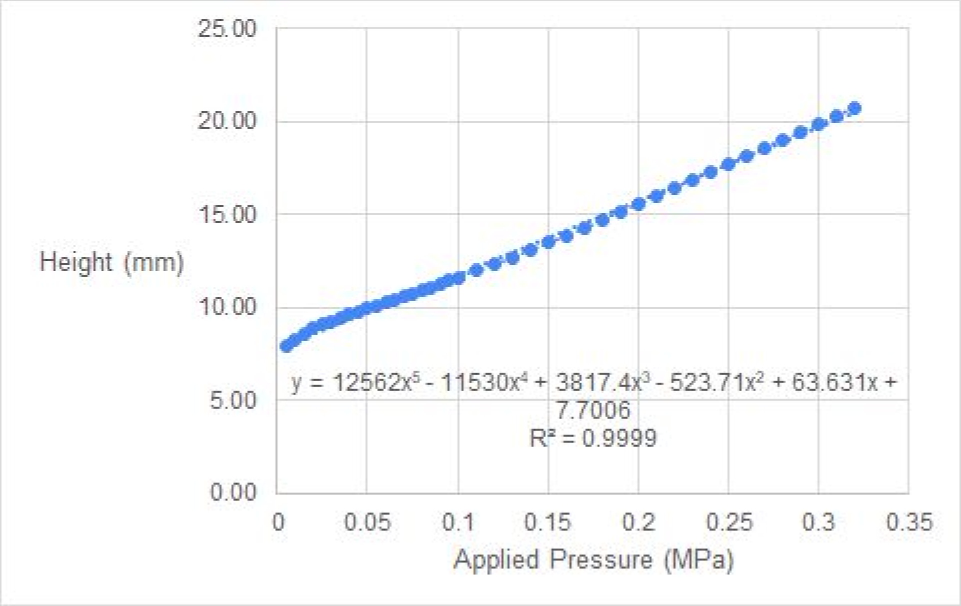

Figure 108: Front Pneunet Average Height Vs. Applied Pressure, Redesign 1

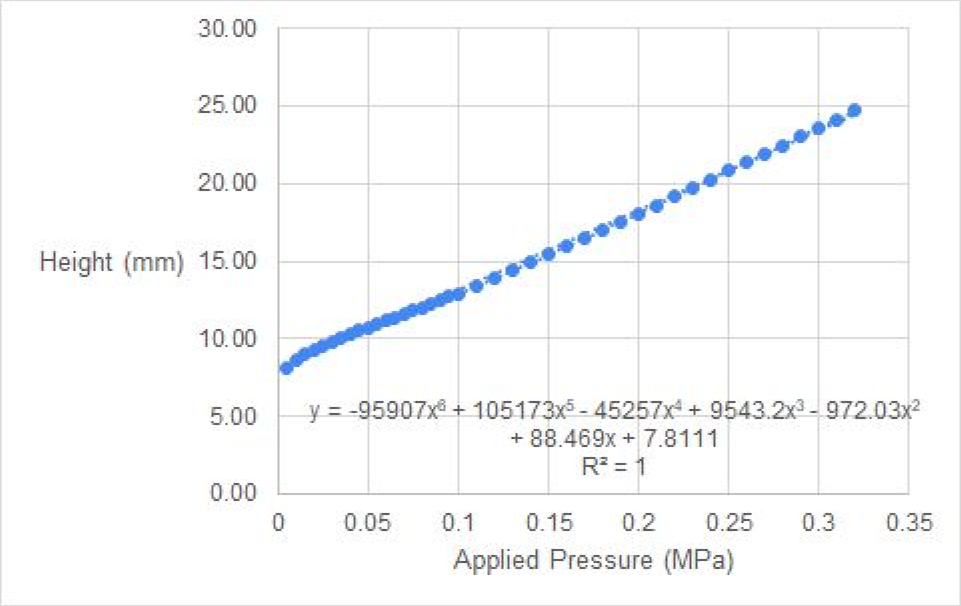

Figure 109: Middle Pneunet Average Height Vs. Applied Pressure, Redesign 1

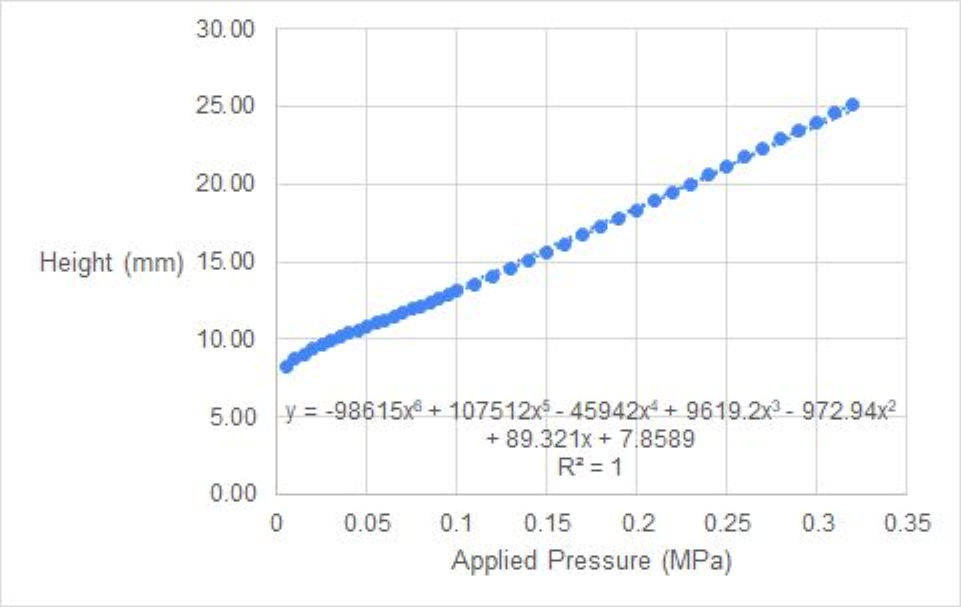

Figure 110: Back Pneunet Average Height Vs. Applied Pressure, Redesign 1

Appendix H. Height vs. Pressure Curves from Simulation (Redesign 2)

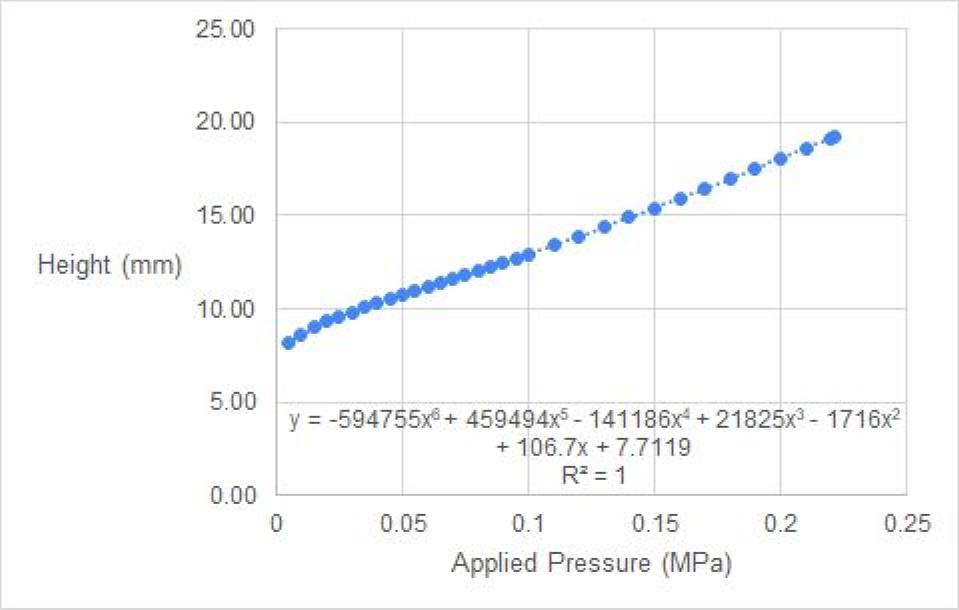

Figure 111: FrontPneunet Average Height Vs. Applied Pressure, Redesign 2

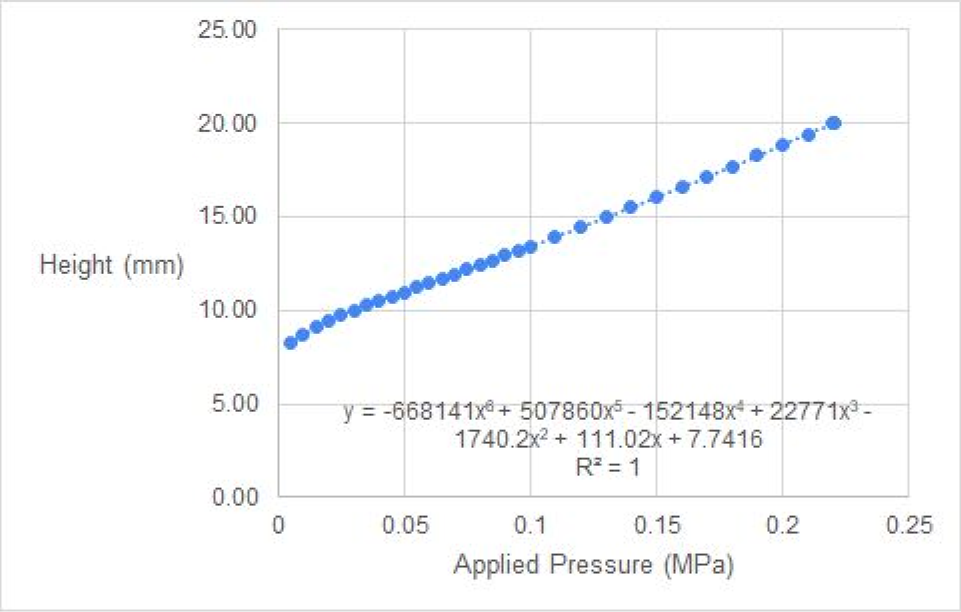

Figure 112: Middle Pneunet Average Height Vs. Applied Pressure, Redesign 2

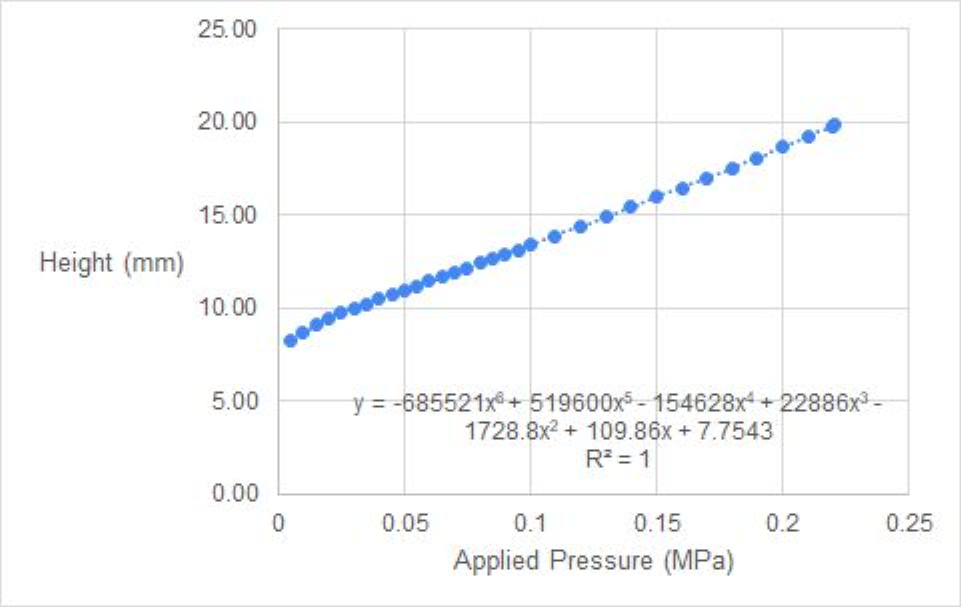

Figure 113: Back Pneunet Average Height Vs. Applied Pressure, Redesign 2

Appendix I: Additional Control Module Designs and Schematics

The Solidworks drawings for the control module parts are shown below, units are in mm unless otherwise specified. They are also available online at the link below.
https://drive.google.com/drive/folders/1YNvXpdD2Qb-UY4s4nKIIM0osFif8E76M?usp=sharing

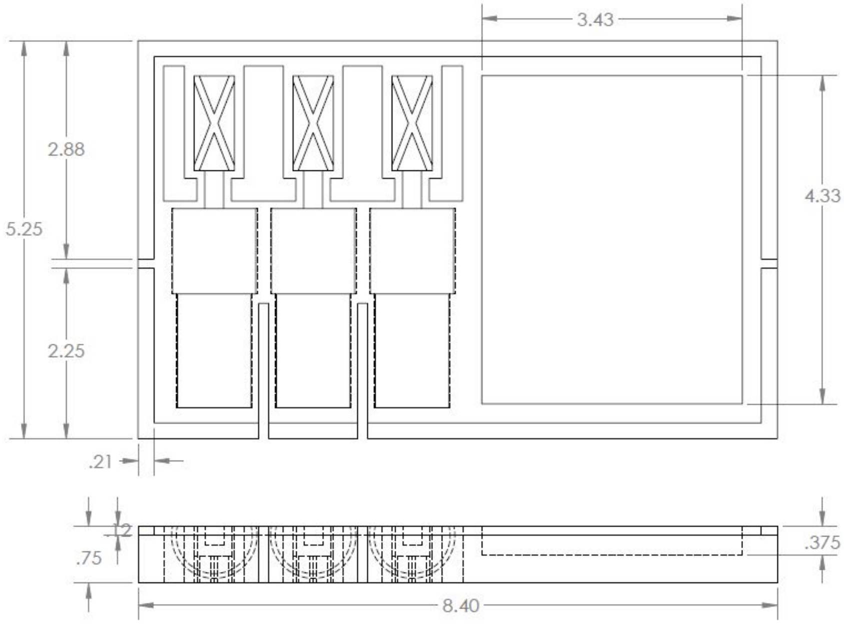

Figure 114: Original stacked base design, units in inches.

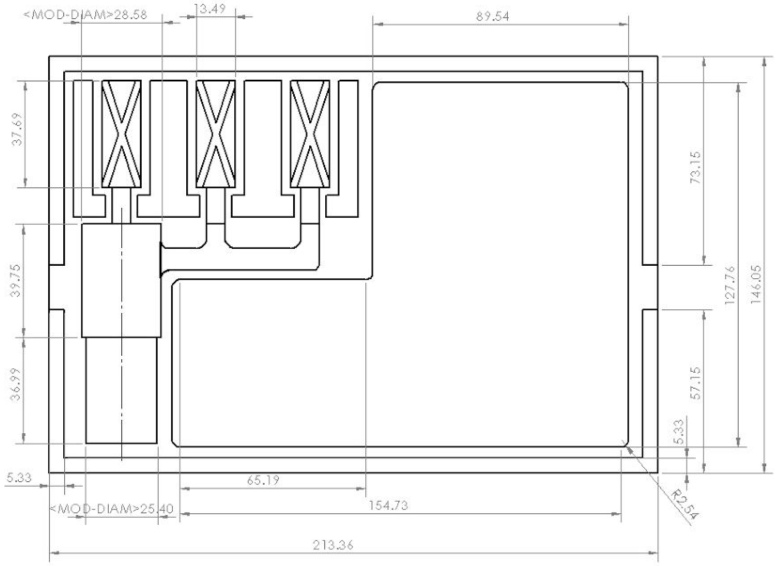

Figure 115: Updated base design with only one pump and grooves for tubes to connect solenoids.

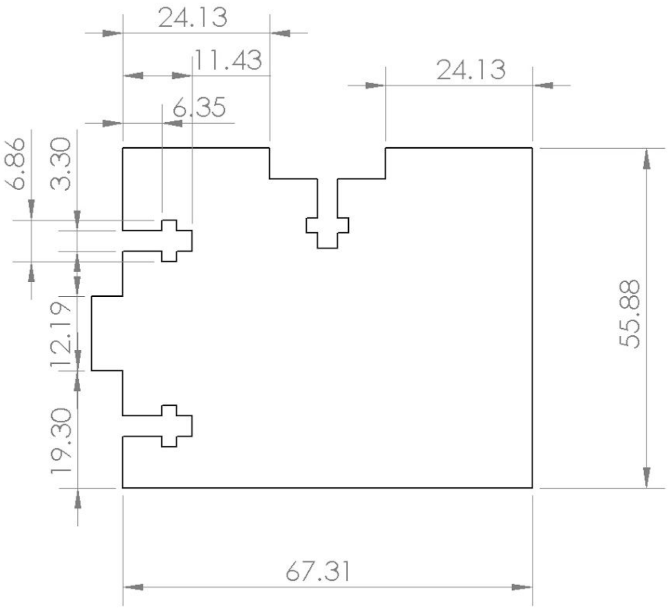

Figure 116: Side part of acrylic frame.

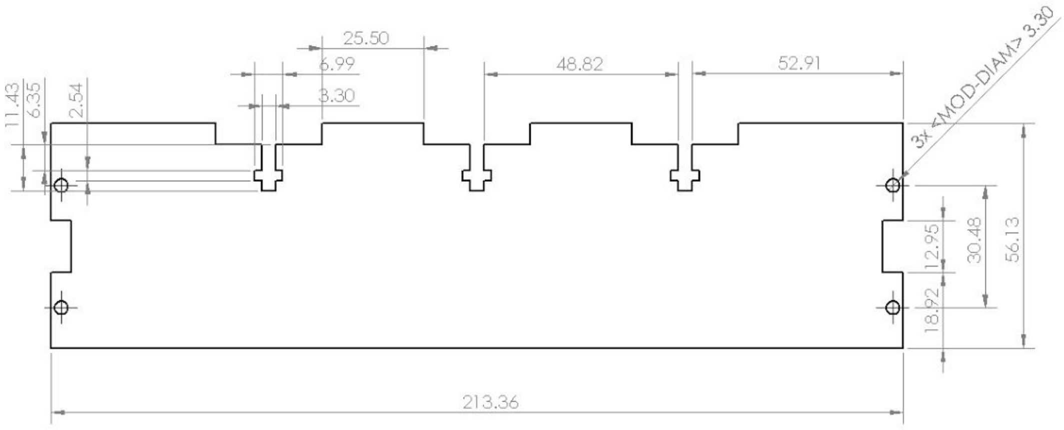

Figure 117: Back part of acrylic frame.

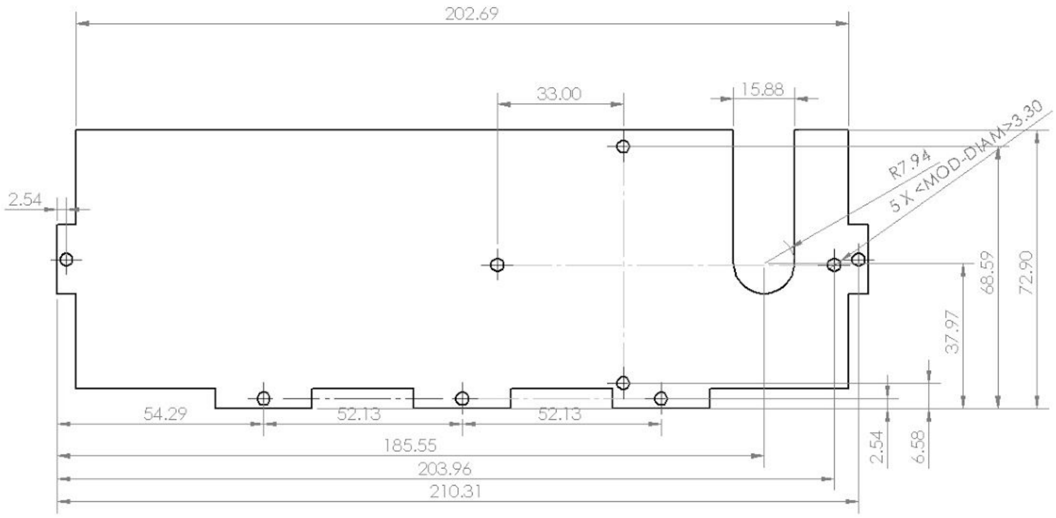

Figure 118: Top part of acrylic frame.

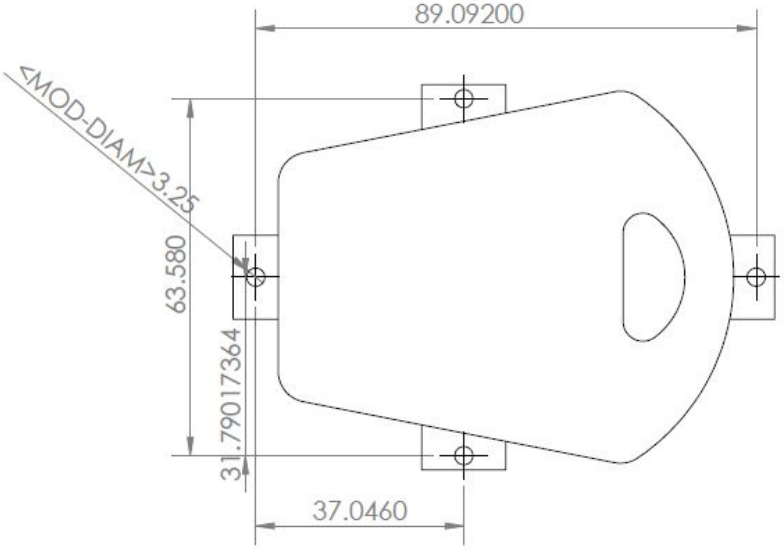

Figure 119: Solidworks drawing of oral cavity mount.

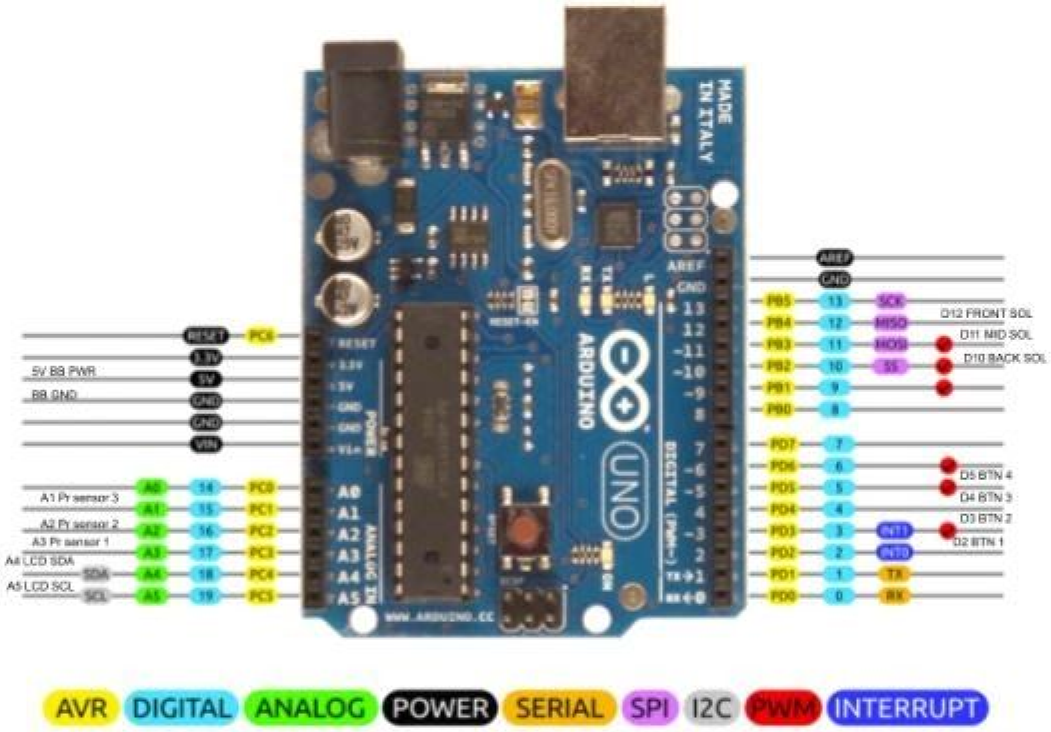

Figure 120: Pinouts on Arduino UNO for control module.

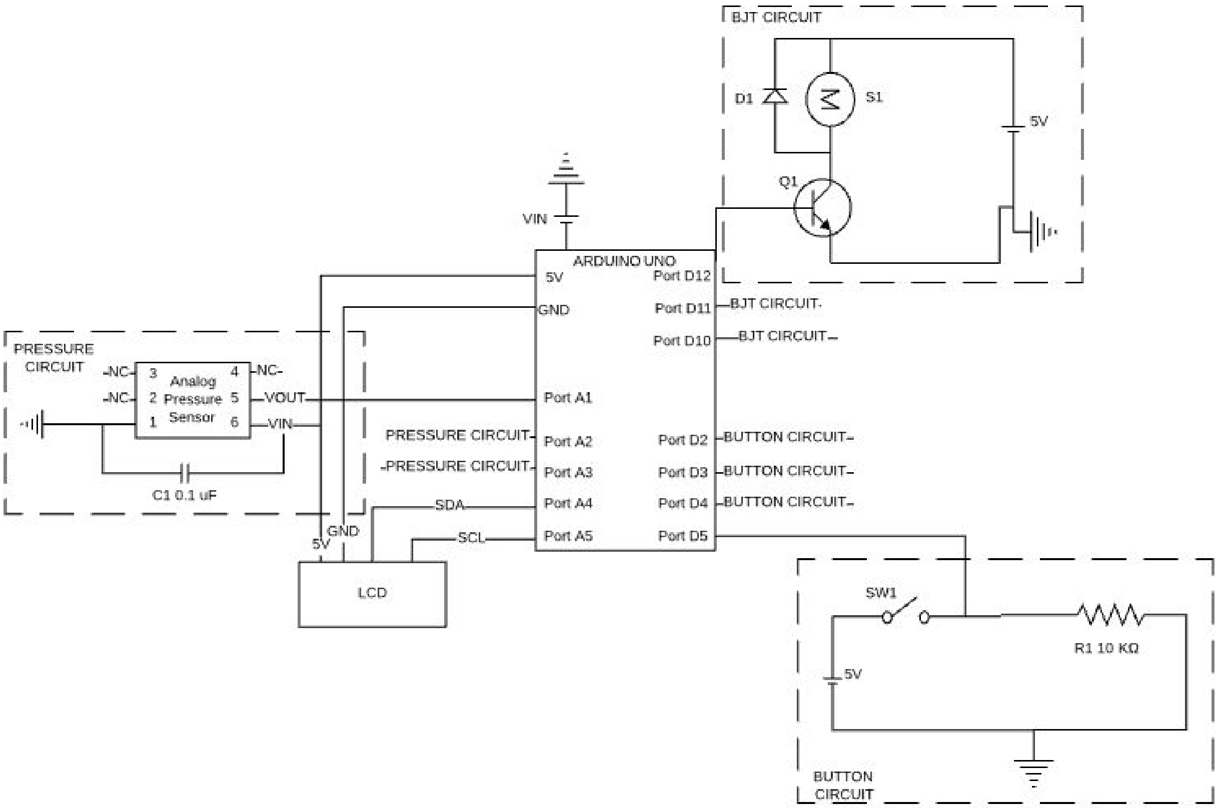

Figure 121: Control bench schematic, UNO connections only.

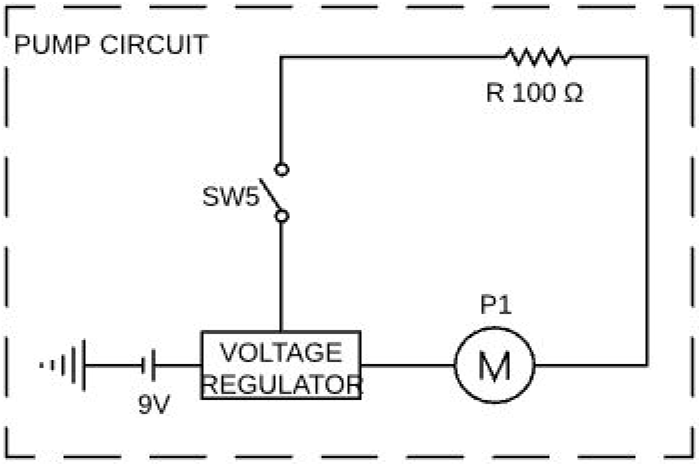

Figure 122: Control bench schematic, air pump connection only.

Table 12: Bill of Materials for Electrical Components

Electrical Components						
Part No.	**Component**	**QTY**	**MFR**	**Description**	**Unit Cost**	**Total Cost**
U1	Arduino UNO	1	Arduino	microcontroller	$23	$23
U2	I2C module	1	Atomic Market	I2C adapter for LCD	N/A	
P1	Air pump	1	Uxcell	5V air pump	$8	$8
S1, S2, S3	solenoids	3	uxcell	5V, 2-position, 3-way	$8	$24
LCD	LCD Screen	1	Atomic Market	20x4 char LCD, includes I2C module	$8.99	$8.99
PS1, PS2, PS3	Pressure Sensor	3	Honeywell	ABPDANN030PGAA5, 0-30 PSI analog pressure sensor	$14.95	$44.85
SW1, SW2, SW3, SW4	Push Button	4	Uxcell	Normally off, 2-prong momentary push button	$4.96/20 pcs	$4.96
R1, R2, R3, R4	10K Ohm resistor	4	Adafruit	10K Ohm resistor	$0.75/25pcs	$0.75
C1, C2, C3	0.1uF capacitor	3	Adafruit	0.1uF ceramic capacitor	$1.95/10 pcs	$1.95
Q1, Q2, Q3	NPN Transistor	3	Adafruit	TIP120 Darlington Transistor	$2.50/3pcs	$2.50
D1, D2, D3	Diode	3	Adafruit	1N4001 diode	$1.50/10 pcs	$1.50
VREG	Voltage Regulator	1	Atomic Market	LM2596S Buck Module Regulator	$6.99	$6.99
					Total Cost for Electronics:	**$127**

Table 13: Bill of Materials for Raw Materials and Hardware

Raw Materials and Hardware						
Part No.	**Component**	**QTY**	**MFR**	**Description**	**Unit Cost**	**Total Cost**
N/A	Tongue frame top, sides and back	1	Foisie Innovation Studio	12"x24" Cast acrylic	$20	$20
N/A	Base	1	Foisie Innovation Studio	3D printed part, printed in PLA on TAZ 6	$10	$10
N/A	Breadboard (small)	1	Adafruit	5.5cm x 8.5cm breadboard	$5	$5
N/A	Breadboard (large)	1	Adafruit	5.5cm x 17cm breadboard	$5.95	$5.95
N/A	Breadboard (extra small)	2	Adafruit	4.6cm x 3.6cm breadboard	$4	$8
N/A	M3 bolts	1	McMaster-Carr	91290A117, pack of 100	$8.67	$8.67
N/A	M3 nuts	1	McMaster-Carr	90695A033, pack of 100	$3.51	$3.51
Total Cost for Materials and Hardware:						**$61**
Total Cost of Control Module:						**$189**

Code for Control Module:

Available on GitHub:
https://github.com/casellen/ArtificialTongue19-20

```
/* Test Bench code for Artificial Tongue - V1 (branch 3)
 *  Includes multiple inflation functions - measure this stuff
 *  Buttons
 *  Basic LCD display
 *  Testing pressure sensors/Calibration
 *  MAKE SURE TO UPDATE THIS WITH THE PRESSURE CODE FROM 1a!!
 */
// **** LIBRARIES TO INCLUDE ****
#include <Wire.h>
#include <LCD.h>
#include <LiquidCrystal_I2C.h>

// ****** CONSTANTS AND VARIABLES ******

//	PINOUTS - see pinout diagram in Claire's daily updates
const int backSol = 10;		//Back Section D10
const int midSol = 11;		// Middle section D11
const int frontSol = 12;	// Front section D12
const int btn1 = 2;	// Button 1, D2
const int btn2 = 3;	// Button 2, D3
const int btn3 = 4;	// Button 3, D4
const int btn4 = 5;	// Button 4, D5
const int pres_1 = A3;		// pressure sensor 1 (white wire), A3
const int pres_2 = A2;		// pressure sensor 2 (yellow wire), A2
const int pres_3 = A1;		// pressure sensor 3 (black wire), A1

LiquidCrystal_I2C  lcd(0x27,2,1,0,4,5,6,7); // 0x27 is the I2C bus address for an unmodified backpack

// OTHER MISC CONSTANTS
int Pmin = 0;  // minimum pressure reading on sensor
//	VARIABLES FOR READINGS
int frontBtn = 0;	// Button 1 - inflate front
int midBtn = 0;		// Button 2 - inflate mid
```

```
int backBtn = 0;          // Button 3 - inflate back
int allBtn = 0;           // Button 4 - inflate ALL
float cur_pres[3];        // initialize cur_pres array to store pressure values

void setup() {
  // solenoids
  pinMode(backSol, OUTPUT);         // Back Section D10
  pinMode(midSol, OUTPUT);          // Middle section D11
  pinMode(frontSol, OUTPUT);        // Front section D12

  //buttons
  pinMode(btn1, INPUT);       // Button 1 D2
  pinMode(btn2, INPUT);       // Button 2 D3
  pinMode(btn3, INPUT);       // Button 3 D4
  pinMode(btn4, INPUT);       // Button 4 D5

  // activate LCD module
  lcd.begin (20,4);       // for 20 x 4 LCD module
  lcd.setBacklightPin(3,POSITIVE);
  lcd.setBacklight(HIGH);

  // set up pressure sensors
  pinMode(pres_1, INPUT);   // Pressure sensor 1
  pinMode(pres_2, INPUT);   // Pressure sensor 2
  pinMode(pres_3, INPUT);   // Pressure sensor 3

  // start serial monitor
   Serial.begin(9600);  // print pressure values to serial read out, 9600 baud rate
}
// ****** HELPER FUNCTIONS ******
void lcdMain() {
  /*
   * Prints main menu for LCD screen
   */
  lcd.home ();            // set cursor to 0,0
  lcd.print("Select program:");
  lcd.setCursor (0,1);              // go to start of 2nd line
  lcd.print(" 1- front 2- middle");
  lcd.setCursor (0,2);
```

```
  lcd.print(" 3- back 4- inf all");
  lcd.setCursor (0,3);
  // lcd.print("send help please");
  delay(100);
}

void inflateSection(int section, int sec) {
  /*
   * Takes in section and time, inflates for that long
   */
   lcd.clear();   // clear lcd at beginning
   for (int i = 0; i <= 2*sec; i++) {
          //lcd.clear();   // clear lcd at start of each iteration
          digitalWrite(section, HIGH);
          delay(500);     // inflate for 0.5 sec
          cur_pres[0] = readPressure(pres_1);  //  Read  out  pressure  sensor  WHILE  inflating!  -
Sensor 1
          cur_pres[1] = readPressure(pres_2);  // Read out pressure senor 2
          cur_pres[2] = readPressure(pres_3);  // Read out pressure sensor 3
          delay(100);     // give time to read pressure
          digitalWrite(section, LOW);  // turn off pump
          lcd.print(cur_pres[0]);  // print pressure readouts
          lcd.println(cur_pres[1]);
          lcd.println(cur_pres[2]);
          delay(500);
          lcd.clear();
   }  //for loop
   //return cur_pres;   // Global array, no need to return it
}

void inflateAll(int sec) {
  /*
   * takes in time and Pin Val, inflates all sections for that long, then turns off solenoids
   */
   lcd.clear();   // clear lcd at beginning
   for (int i = 0; i <= 2*sec; i++) {
          //lcd.clear();   // clear lcd at start of each iteration
          digitalWrite(backSol, HIGH);
          digitalWrite(midSol, HIGH);
```

```
        digitalWrite(frontSol, HIGH);
        delay(500);     // inflate for 0.5 sec
        cur_pres[0] = readPressure(pres_1);  //  Read  out  pressure  sensor  WHILE  inflating!  -
Sensor 1
        cur_pres[1] = readPressure(pres_2);  // Read out pressure senor 2
        cur_pres[2] = readPressure(pres_3);  // Read out pressure sensor 3
        delay(100);     // give time to read pressure
        digitalWrite(backSol, LOW);  // turn off pump
        digitalWrite(midSol, LOW);
        digitalWrite(frontSol, LOW);
        lcd.print(cur_pres[0]);  // print pressure readouts
        lcd.println(cur_pres[1]);
        lcd.println(cur_pres[2]);
        delay(500);
        lcd.clear();
  }  //for loop


  //return cur_pres;    //This is a global variable so it shouldn't need to return it. If we do return it,
change the function to void
} // inflate all loop

float readPressure(int pin) {
 /*
  * takes in pressure sensor pin,
  * returns output pressure
  * modified from soft robotics toolkit
  */
  int sensorValue = analogRead(pin);           // reads sensor value

  // convert sensor value to voltage
  float voltage = (float)sensorValue * (5.0f / 1023.0f);

  // convert volts to PSI
  float pressure_Value = ((voltage - (0.10f * 5.0f)) / (0.80f * 5.0f)) * 30.0f;

  // return PSI value
  return pressure_Value;
  }
```

```
// ******** MAIN LOOP *******
void loop() {
  lcdMain();     // Turn on LCD main menu

  frontBtn = digitalRead(btn1);          // Check if button 1 is pressed
  midBtn = digitalRead(btn2);            // Check if button 2 is pressed
  backBtn = digitalRead(btn3);           // Check if button 3 is pressed
  allBtn = digitalRead(btn4);            // Check if button 4 is pressed

  // Inflate Front if button 1 is pressed, inflate for 2 seconds
  if (frontBtn == HIGH)
  {
          inflateSection(frontSol, 3);
          delay(500);
          lcd.clear();
          lcd.setCursor (0,1);            // go to start of 2nd line
          lcd.print("Inflated front");
  }

  // inflate middle if button 2 is pressed, inflate for 2 seconds
  else if (midBtn == HIGH)
  {
          inflateSection(midSol, 3);
          delay(500);
          lcd.clear();
          lcd.setCursor (0,1);            // go to start of 2nd line
          lcd.print("Inflated mid");
  }

  //inflate back if button 3 is pressed, inflate for 2 seconds
  else if (backBtn == HIGH)
  {
          inflateSection(backSol, 3);
          delay(500);
          lcd.clear();
          lcd.setCursor (0,1);            // go to start of 2nd line
          lcd.print("inflated back");
  }
```

```
 // inflate all if button 4 is pressed
 else if (allBtn == HIGH)
 {
        inflateAll(3);
        delay(500);
        lcd.clear();
        lcd.setCursor (0,1);            // go to start of 2nd line
        lcd.println("inflated all");
 }
} // end bracked for main loop
```