Redesigning the Actuation System for a Prosthetic Tongue

Submitted By:

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

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Abstract:

The goal of this project was not only to develop a self-contained prosthetic tongue that could aid in deglutition but also to design a tongue that caters to the human aspect of our project by incorporating our stakeholders as one of the main design influences. Previous iterations of this project explore pneumatic, magnetic, and mechanical actuation methods. We conducted research to identify what aspects of each iteration could be redesigned or improved upon. The testing results that were available to us that were conducted on these previous iterations allowed us to define these concerns. In the development of our prosthetic tongue, the focus was on creating a biomechanically authentic and human-oriented design. The project transitioned from a basic concept to an advanced 'flapper' mechanism using extensive mathematical analysis to determine the optimal lengths and linkages for natural motion, alongside torque requirements for efficient gear actuation. Silicone was our choice for the prosthetic tongue coating. Although exact quantitative design specifications are still in development, our group considers this a critical aspect of our tongue prosthetic. Many different control mechanisms were researched, leading to the selection of Bluetooth over Wi-Fi for remote actuation, prioritizing safety regarding electromagnetic radiation. The design also shared detailed plans on adhering to industry standards for biocompatibility ensuring the prosthetic's safety and functionality, a key consideration for its potential FDA Approval hypothesized to be a Class III device under 510(k) submission guidelines.

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Authorship Table

This report was written by Nicole Sanchez-Jean, to be submitted in completion of her project submission.

Nomenclature

Bolus - partially masticated/chewed food

Total Glossectomy - the surgical removal of all of the tongue including any surrounding tissue in the oral cavity

Cytotoxicity - The quality of being toxic to cells; measures a material's potential to kill or damage cells

Sensitization - The process by which a person becomes, over time, increasingly allergic to a substance through repeated exposure.

Irritation - A localized physical discomfort induced by a non-corrosive material that can occur upon first exposure.

Acute Systemic Toxicity - The harmful effects that result from a single dose or multiple doses given within 24 hours of a substance, affecting the whole body rather than a specific location.

Pyrogenicity - The ability of a substance to induce fever by causing the body to produce pyrogens, which are fever-inducing substances.

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1. Introduction [1][2][3][4]

While prosthetic advancements have significantly aided limb loss, progress in prosthetic tongues for oral cancer and glossectomy patients has been limited. In the U.S., around 54,540 new cases of oral cancer are reported annually, with a global incidence estimated at 377,713 cases. Glossectomy, the partial or complete removal of the tongue, often includes excising surrounding muscles and structures and is typically a last resort for oral cancer patients when treatments like chemotherapy and radiation fail. This surgery leads to difficulties in swallowing, speech, and mastication.

Current prosthetic tongues are static and cosmetic, offering no swallowing or speech support. Our project aims to address this gap within the medical device industry, focusing on patients who have undergone total glossectomies. The project's evolution started with a pneumatic system by Francis Araya, then moved to an improved air pump design by Bridges and team, The third iteration by Vasquez's team introduced electromagnetic actuation but struggled with effective bolus movement. The fourth and fifth iterations by Holod et al and Barthold et al. respectively, used a combination of these with added linkage systems, transitioning to a more mechanical tongue.

Our project combines these advancements, aiming to develop a more human-centric and functional prosthetic tongue. Key objectives include a design that facilitates natural bolus movement, an anatomically accurate size for simulated oral cavities, miniaturized control systems, and a design that prioritizes our stakeholders. This venture aspires to improve the quality of life for glossectomy patients and represents a significant stride in prosthetic technology and oral cancer survivor care.

1.1 Previous Iterations

In this section, we'll be reviewing the previous versions of this project. By doing so, we aim to understand how the project has developed over time and to identify opportunities for further improvements in our work.

1.1.1 Iteration 1: Araya 2019[5]

Francis Araya created the first iteration of this project using a silicone tongue with internal hollow chambers that used pneumatic (air pumps), electromagnetic (solenoids), and an external power supply.

The tongue had dimensions of 45.72mm width, 60.96mm length, and 6.09mm height; it was attached to a control module that externally contained pumps, batteries, solenoids and a microcontroller. The control module was much larger than the tongue and had dimensions of 101.6mm width, 190.5mm length, and 66.8mm height. These can be seen in Figures 1.4 and Figures 1.3 respectively.

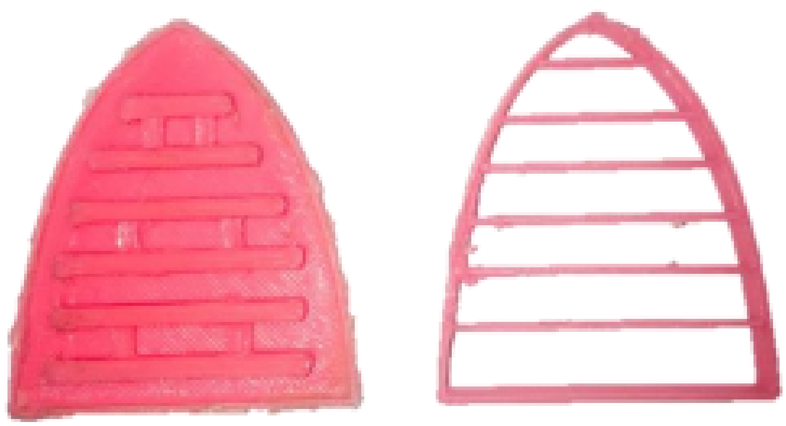


Figure 1.1: 3D printed molds of initial design of the Iteration 1 silicone tongue as reproduced by [5]

Figure 1.2: Pumps, and the microcontroller of Araya's Prosthetic Tongue Design as produced from [5]

Each pneumatic air pump was attached to one of the sections of the tongue: front, middle and back. For the final testing, a structure was 3D printed to hold the control module, the three mini pneumatic pumps, the microprocessor unit and the prosthetic tongue, shown in Figure 2.3. The tongue was mounted by putting the input tubes through the slot in the structure and then the output ends of the tubes were placed on their respective solenoid valves. Due to the open nature of the platform, the tongue was able to be observed at all angles during testing.

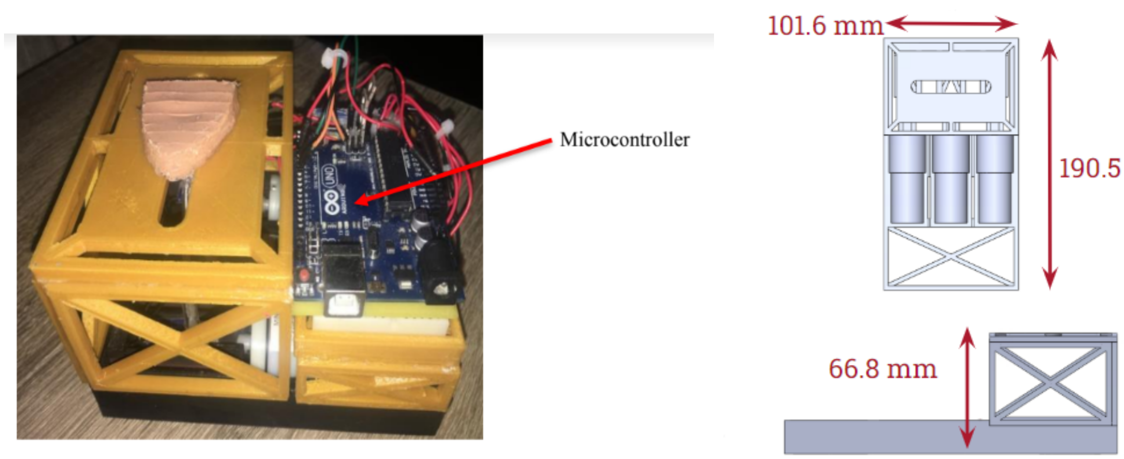


Figure 1.3: Control Module, microcontroller, and prosthetic tongue. The red arrow points to the microcontroller. The dimensions of the control module are on the right. Both as reproduced from [5]

The system didn't incorporate sensors and operated based on a closed-loop system controlled by an Arduino microcontroller. This iteration primarily emphasized achieving a more natural movement of the tongue and the importance of applying the right pressure against the palate.

However, there were some challenges in this phase. These included difficulties in effectively sealing the silicone, designing a system that could comfortably fit inside the oral cavity, experiencing deflection heights that were on average 5.5mm lower than the intended target, and not conducting tests within the actual oral environment, which includes factors like saliva and maintaining the human body's temperature.

A significant issue encountered with the initial design was the tendency of the silicone to split along the seams where the top and bottom layers were bonded. The iteration also struggled with controlling the direction. This led to air escaping and, consequently, disrupted the prototype's operation preventing it from working altogether.

1.1.2 Iteration 2: 2019 - 2020 Bridges et al. Prosthetic Tongue MQP [6]

In their 2020 project, the Prosthetic Tongue team experimented with several methods to create a moving prosthetic tongue but faced numerous setbacks. Their first method involved using air pressure (pneumatic actuation) to move the tongue. However, this approach had problems: the silicone material didn't hold the air well, leading to minor movement. Additionally, the silicone often splits at the seams, causing air leaks.

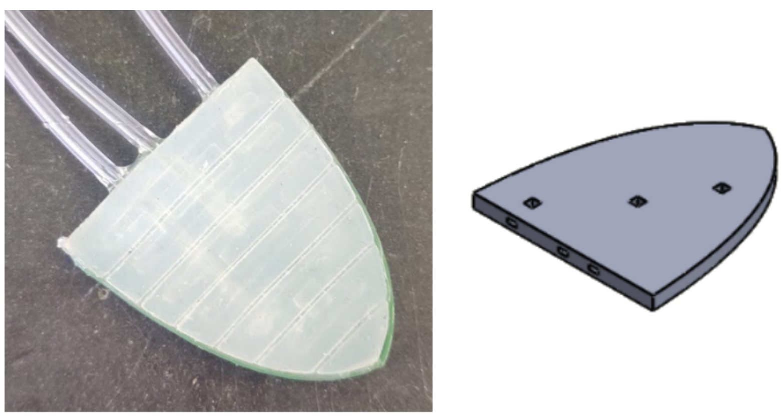


Figure 1.4: Rear entrance design (left), bottom entrance design (right) as reproduced from [6]

The team also tried using magnets (magnetic actuation) by embedding iron oxide particles in the silicone and moving them with magnets. This method caused some movement, but it was mostly uncontrolled twisting and bending, which wasn't suitable for a prosthetic tongue.

Another approach was using a system of small mechanical parts and motors (linkage system) to achieve movement. This system faced issues with the small parts being prone to damage and warping, posing a risk of breaking and potentially being swallowed.

A significant challenge was making the device compact enough to fit inside the mouth. Essential components like air pumps were too large to be incorporated comfortably. The team designed a control module to manage the tongue's movement, but its size and complexity made it impractical for everyday use.

In summary, the 2020 team's exploration into different actuation methods for a prosthetic tongue brought to light several key challenges. The pneumatic method was limited by material issues and inadequate testing conditions. The magnetic approach was hindered by unpredictable material behavior, and the linkage system was compromised by fragile components. The control module's bulkiness further limited the project's practical application. The start of the COVID pandemic, unfortunately, was a major roadblock in conducting testing.

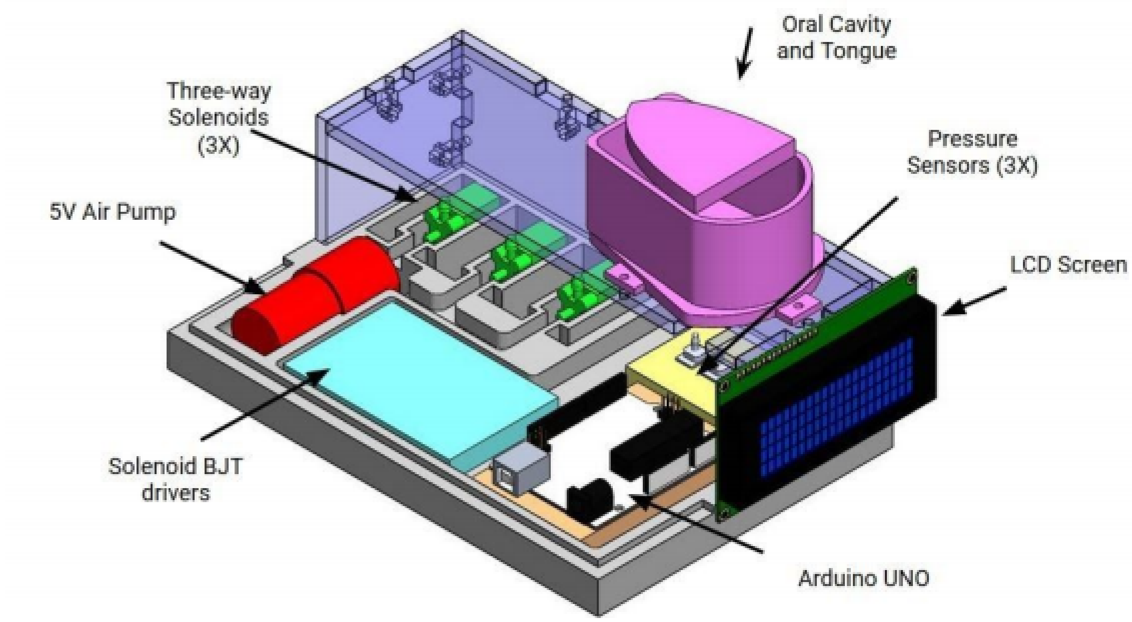


Figure 1.5: 2019-2020 MQP Control Module Testing Setup as reproduced from [6]

1.1.3 Iteration 3: Vasquez et al. Prosthetic Tongue MQP [7]

Building on the work of Bridges et al., the Vasquez et al. team aimed to refine the prosthetic tongue project by reducing the prototype size and enhancing biocompatibility. The team transitioned from a pneumatic to a magnetic actuator system (Solenoids) for tongue movement.

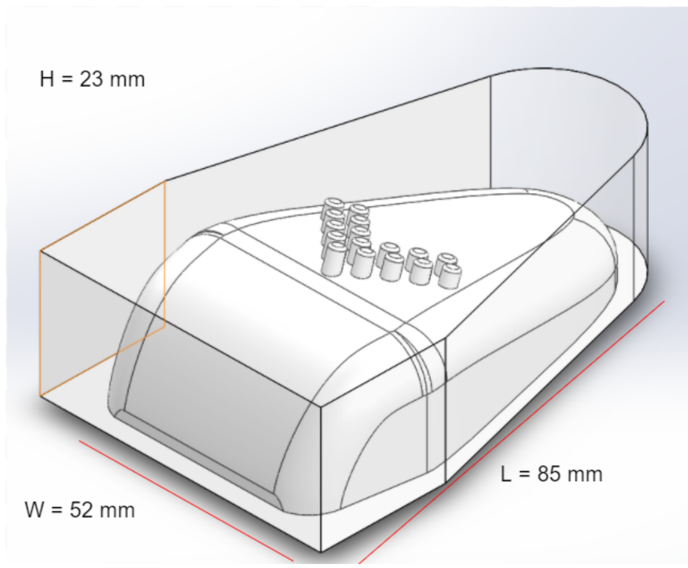


Figure 1.6: Dimensions of the Entire Tongue Prototype 2020-2021 MQP as taken from [7]

The Vasquez team's prosthetic tongue was notably larger, measuring 85 mm in length and 52 mm in width. This design as seen in Figure 1.6, allowed for a more realistic representation and incorporated miniaturized electronics. Notably, the prosthetic featured papillae on its surface, aiding in bolus movement. The elimination of the pump from the design significantly reduced the space requirement for components.

The control module was designed to be minimalistic, focusing on essential data collection and maximizing actuation. A significant aspect of the design was incorporating the TinyDuino and solenoid within the prosthetic tongue, making the system more compact and efficient.

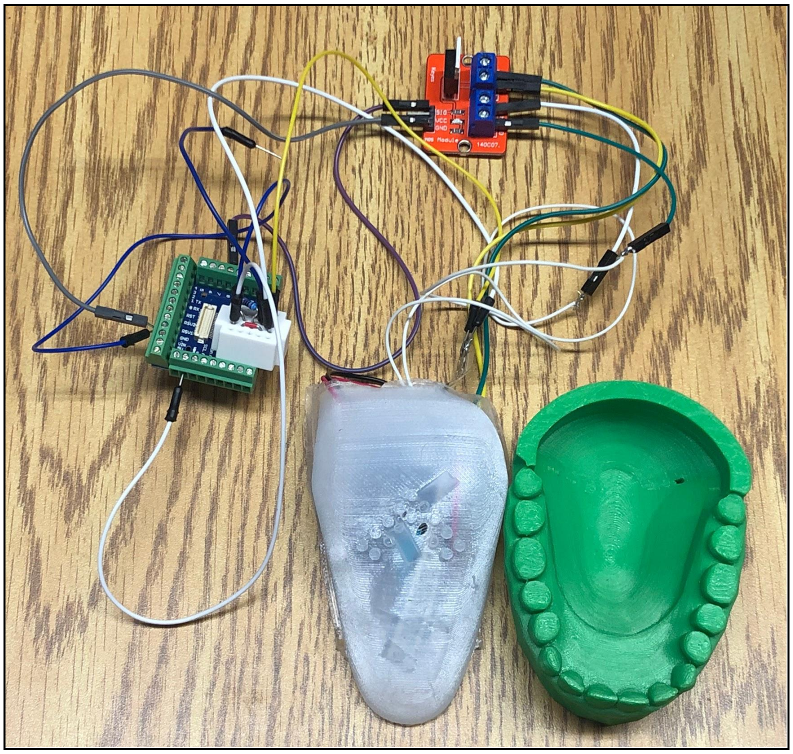


Figure 1.7. Final Circuit of Vasquez et al. MQP from as reproduced from [7]

The control module was designed to be minimalistic, focusing on essential data collection and maximizing actuation. A significant aspect of the design was incorporating the TinyDuino and solenoid within the prosthetic tongue, making the system more compact and efficient.

The 2020-2021 MQP team made significant strides in automating the control of the prosthetic tongue and achieving a more human-like appearance. However, the size reduction led to decreased actuation capabilities. Future improvements suggested by the team include better movement control, material selection for biocompatibility, and continued sensor development. A focus on more sensitive sensors could lead to a more precise and efficient system. This iteration's move away from an air pump circuit to an integrated circuit inside the tongue was a large step toward space-saving design.

1.1.4 Iteration 4: Holod et al. Prosthetic Tongue MQP [8]

Drawing inspiration from the previous iterations, the Holod et al. team set out to refine the prosthetic tongue even further. Previous iterations of the prosthetic tongue relied heavily on pneumatic and magnetic systems for actuation. While these systems were innovative at the time, Holod et al. discovered limitations that reduced the device's functionality. The pneumatic system was bothersome, requiring an air pump that seemed to be impossible to integrate into the compact redesign of their prosthetic tongue. Similarly, the magnetic actuation lacked the necessary force and precision, leading to minimal movement in terms of the natural tongue movement.

To overcome these limitations, the team developed a linkage system. Their design incorporated a gearbox design that featured three gears with a ratio of 2.2. This was chosen to optimize the balance between torque and speed. A string wrapped around a spindle was also added, which would wind or unwind as the gears turned, aiding the movement of the prosthetic tongue. This system is pictured below in Figure 1.8, showing the final iteration of the linkage system.

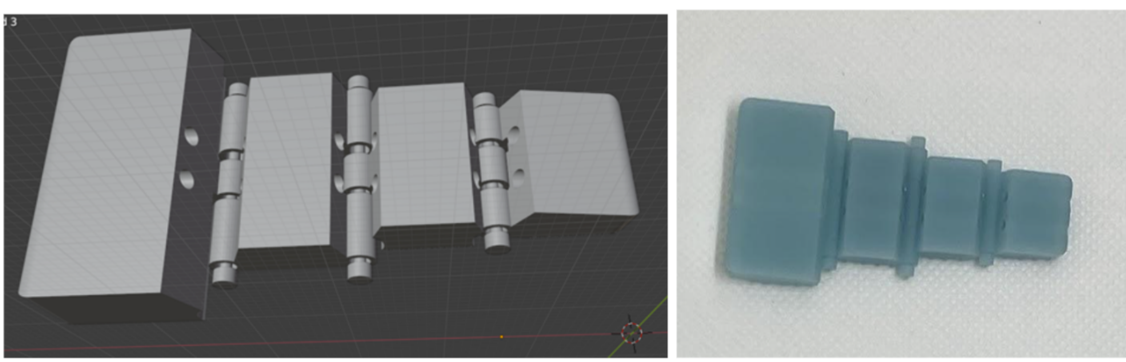


Figure 1.8: Final Linkage System Design as taken from [8]

Looking forward, the project suggests several recommendations to enhance functionality and design. One of the main suggestions is to integrate EMG sensors directly within the jaw muscles, providing a more intuitive control mechanism based on the natural movement in the jaw. Secondly, replacing the TinyDuino with a PCB could improve the system's integration and spacing. Finally, the use of a micromotor instead of the current servo motor is suggested to provide more controlled movement in the tongue, and further reduce the overall size.

1.1.5 Iteration 5: Barthold et al. Prosthetic Tongue MQP [9]

The fifth iteration of the prosthetic tongue project encountered several challenges that highlighted areas for improvement and refinement. A limitation identified was the prosthetic tongue's inability to function with the mouth (Figure 1.9) in a closed position. This issue is a significant concern for realistic applications, as the system must operate in the required conditions, must be acceptable for use, and must be comfortable. This design also was not self-contained.

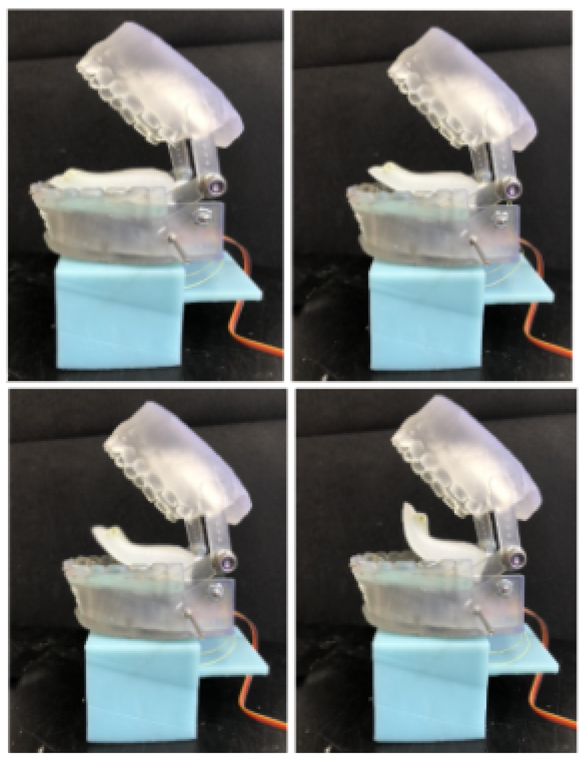


Figure 1.9: Final Circuit of Vasquez et al. MQP from as reproduced from [9]

Another drawback was the inefficient battery system. The batteries used in the prototype were unable to provide the sustained power necessary for prolonged usage, leading to frequent interruptions and less reliable performance. This inefficiency could be a source of frustration for users and would likely impede the adoption of the technology in real-world scenarios. For a prosthetic device, a consistent and reliable power supply is crucial to ensure it can support the user's needs throughout their daily routine.

Upon assembly, several issues were noted within the mechanical components. The gears within the system were found to be very tight, resulting in an increased risk of shear and potential failure points. A more refined gear system that allows for smoother operation could extend the device's lifespan and reduce maintenance requirements. Finally, the use of an external breadboard, while useful for prototyping, would need to be updated to a fully enclosed system.. Transitioning to an integrated circuit would satisfy the design requirements and protect the electronics from damage.

2. Additional Research [10] [11] [12] [13] [14] [15] [16] [17] [18] [19] [20] [21][24]

In this section, we'll delve into more research about materials compatible with the human body, assess potential impacts on human health, and explore different control options.

2.1 Biocompatible Materials

The selection of biocompatible materials in the design of prosthetic devices, particularly a prosthetic tongue, is a crucial aspect of ensuring safety and functionality. In this context, the choice of silicone, specifically Ecoflex™, as the coating for a prosthetic tongue, demonstrates the beginning of our thoughtful consideration of biocompatibility standards.

Ecoflex™ series silicones are known for their super-soft, additional cure properties. Available in various hardness levels from Shore A-5 to 000-35, they cater to a wide range of applications. For prosthetics, their suitability lies in creating appliances that require softness and flexibility, such as a prosthetic tongue. Ecoflex™'s ability to be used in orthotic devices and special effects, particularly in animatronics requiring repetitive motion, highlights its durability and adaptability.

One of the standout features of Ecoflex™ is its independently certified skin safety. Additionally, Ecoflex™ cures to form a rubber that is not only soft and strong but also highly stretchable. It can stretch multiple times its original size without tearing and then rebound back to its original shape without distortion. This characteristic is particularly beneficial for a prosthetic tongue, which needs to mimic the natural flexibility and resilience of human tongue tissues

The choice of Ecoflex™ for a prosthetic tongue coating aligns with the essential requirements of biocompatibility, flexibility, and skin safety. These properties ensure that the prosthetic tongue not only performs its intended function but also does so without causing harm or discomfort to the user. The use of such a material in prosthetic design reflects an understanding of the complex needs of prosthetic devices and their users. It underscores the importance of selecting materials that are not just functionally effective but also align with the health and safety standards necessary for medical-grade devices.

In conclusion, the utilization of Ecoflex™ silicone in the design of a prosthetic tongue is a testament to its flexibility, strength, and skin-safe properties, making it an ideal material for such a sensitive and functional application.

Safety data from the products we received are found in Appendix D.

2.1.2 FDA & Industry Standards

In summary, these collectively ensure that every aspect of our prosthetic tongue is thoroughly evaluated for safety, comfort, and performance. By adhering to these standards, we're committed to providing a device that's reliable and safe for glossectomy patients.

- ➔ FDA (Food and Drug Administration): Ensures public health by regulating food, pharmaceuticals, medical devices, and cosmetics to be safe and effective for their intended use.
- ➔ ISO (International Organization for Standardization): Provides international standards to ensure quality, safety, efficiency, and interoperability of products and services across various industries.
- ➔ ADA (American Dental Association): Sets standards for dental practices and products to ensure the oral health and safe dental care of the public.
- ➔ ANSI (American National Standards Institute): Oversees the creation, promulgation, and use of thousands of norms and guidelines that directly impact businesses in nearly every sector to ensure the safety and health of consumers and the protection of the environment.
- ➔ ASTM (American Society for Testing and Materials): Develops and publishes technical standards for materials, products, systems, and services to ensure quality and safety in performance and manufacturing

2.1.2.1 FDA Approval

We would place this under the 510(k) for a Class III device. However, the FDA will consider whether the prosthetic tongue is sustaining or supporting life, and if it poses a risk of critical injury, ultimately determining the classification.

2.1.2.2 Effects on the Human Body

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – long term (> 30 d)													
Category	Contact		Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity#	Degradation@
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	X	O	X		X					
		C	X	X	X	X	O	X	X	X		X			
	Breached or compromised surface	A	X	X	X	X	X								
		B	X	X	X	X	X	X		X					
		C	X	X	X	X	X	X	X	X		X	X		
External communicating device	Blood path, indirect	A	X	X	X	X	X				X				
		B	X	X	X	X	X	X			X				
		C	X	X	X	X	X	X	X	X	X	X	X		
	Tissue+/bone/ dentin	A	X	X	X	X	X								
		B	X	X	X	X	X	X	X	X					
		C	X	X	X	X	X	X	X	X		X	X		
	Circulating blood	A	X	X	X	X	X		X^		X				
		B	X	X	X	X	X	X	X	X	X				

Table 1: Biocompatibility Matrix taken from ISO 10993-1:2018 [22]

To ensure the safety of our patient we used the ISO 10993-1:2018 biocompatibility matrix found in the FDA guidance document for this standard, which highlights which biological effects (endpoints) that need to be addressed. We classified our device as a surface device, in contact with a compromised surface for a limited duration. Following the matrix, we would need to assess:

- ➔ Cytotoxicity
- ➔ Sensitization
- ➔ Irritation
- ➔ Acute Systemic Toxicity

➔ Pyrogenicity

The assessment of biological effects is vital to the prosthetic tongue project as it ensures the device is safe for human use. The biocompatibility matrix from ISO 10993-1:2018, as mentioned, is used to evaluate potential risks such as cytotoxicity, which involves the material's toxicity to cells; sensitization, which examines the possibility of allergic reactions; irritation, which looks at the material's potential to cause inflammation; and acute systemic toxicity, which assesses the risk of harm when the material is used systemically. Additionally, pyrogenicity, the potential of the material to induce fever, is also assessed.

These evaluations are critical in determining if the material chosen for the prosthetic tongue will be safe for patients with compromised oral surfaces, ensuring the device does not cause adverse effects when in contact with the body for its intended use.

2.1.2.3 Relevant Standards and Regulations

Research led us to identify these as the regulations most relevant to our project. These standards provide us with methods for testing compatibility with the human body, ensuring that our prosthetic tongue is safe to be in constant contact with the climate of the oral cavity.

Compliance with FDA regulations is also pivotal, with an expectation to meet Class 2 or 3 under the 510(k) clearance or approval process, affirming our commitment to the highest safety and efficacy levels.

Furthermore, the implementation of ISO standards, including those specific to long-term implantation, and adherence to the European MDR, ensures global compliance with stringent medical device requirements. Our selection of materials is informed by a comprehensive set of standards, including ADA ANSI, ISO, and ASTM, which guide us in evaluating the silicone's tensile strength and elasticity, essential for the prosthetic's durability and functionality.

In the realm of electronics within the prosthetic, we are guided by standards such as ISO 60601-1-11:2015 and IEC 61000, which set the criteria for medical safety in electrical components.

More detailed information on these standards can be found in Appendix E.

2.1.3 Controls

The effect of different methods of controlling the system and their safety.

2.1.3.1 Wifi & Bluetooth

Information	Details	Comments
Study Distance from Brain	None found	Full research paper may have the distances
Allowed Frequency Range Near Brain	Depends on device and context.	Guidelines vary; safety standards depend on device and application.
Frequency of Common Devices Near Brain	Ranges from MHz (WiFi, Bluetooth) to GHz (mobile phones, some medical devices).	Includes medical devices like MRI, consumer electronics.
Raspberry Pi Pico W WiFi Frequency	2.4 GHz WiFi frequency required for Wi-fi communication	Standard for WiFi-enabled microcontrollers
Adjustability & Stability of Raspberry Pi Pico W Frequency	Typically not adjustable	Limited by WiFi standards.
Accuracy of Raspberry Pi Pico W Frequency	Generally accurate Wi-fi specifications	Compliance with IEEE 802.11 standards.
Comparison with Other Values	Comparable to typical WiFi devices; within	Similar frequency as many household WiFi

	GHz range. Need to find more safety data	routers, required for stable wifi communication
Safety of Raspberry Pi Pico W Frequency Near Brain	Depends on exposure duration and individual sensitivity; generally considered safe but requires specific evaluation.	Proximity and duration are key factors; further research

Table 2: Research table summarizing the findings in this section

When evaluating the safety of wireless frequencies emitted by devices such as the Raspberry Pi Pico W near the human brain, various factors need to be considered.

Safety standards for the allowed frequency range near the brain are device and context-dependent. These frequencies range from Megahertz (MHz), typically used by Wi-Fi and Bluetooth, to Gigahertz (GHz), used by mobile phones and some medical devices, including MRIs and consumer electronics. This indicates a broad spectrum of frequencies that must be monitored for safety near sensitive organs.

The Raspberry Pi Pico W operates at a Wi-Fi frequency of 2.4 GHz, which is a standard for Wi-Fi communication and is common among Wi-Fi-enabled microcontrollers. This frequency is typically not adjustable due to the limitations set by Wi-Fi standards, ensuring uniformity in the function and communication capabilities of such devices.

The accuracy of the Raspberry Pi Pico W's frequency is generally in line with Wi-Fi specifications and complies with the IEEE 802.11 standards, which govern wireless networking. By adhering to these standards, devices ensure reliable and consistent performance.

In terms of safety, the frequency used by the Raspberry Pi Pico W is comparable to that of typical Wi-Fi devices within the GHz range. It matches the frequency of many household Wi-Fi routers designed for stable wireless communication. The safety of such frequencies near the brain is contingent on the duration of exposure and individual sensitivity. Although generally considered safe, specific evaluations are necessary to ascertain the risk for any given individual, taking into account the proximity and duration of exposure to these frequencies.

3. Project Goals

In this chapter, we will go over our patient criteria, improvements planned, and goals for this project.

3.1 Client Statement and Criteria

Post-glossectomy patients face challenges with chewing and swallowing, a gap in functionality that existing prosthetic tongues do not bridge. Our design targets patients post-total glossectomy retaining some of their jaw teeth, aiming for a prosthetic that makes swallowing food a natural experience.

3.2 Improvements Planned From Past Work

Based on our background research and group discussions, we plan on implementing a linkage and gear design using a micro motor, PCB, and 3D printed linkages. We are looking to evolve to incorporate human-centric design principles, seeking a more natural interaction with the mouth's anatomy.

In earlier designs from 2021 to 2023, the prosthetic tongues featured a mechanism that bent the tip toward the throat to propel food toward the digestive tract. These models, however, didn't work when the mouth was shut and lacked a natural motion. Our current endeavor aims to enhance the prosthesis's human-like qualities by emulating the natural push against the palate seen in pneumatic versions from 2019 and 2020. Despite the challenges with the pneumatic systems, our approach is to integrate a mechanical linkage that replicates the natural swelling movement of the tongue. We're also addressing the issue of food displacement by reshaping the prosthesis to form a taco shape that prevents spillage toward the teeth.

3.3 Project Goals

We aim to develop a prosthetic tongue for total glossectomy patients that is completely contained within the oral cavity and is capable of safely and effectively moving a bolus into the esophagus. We aim to have our design, report, and overall ethos of the project honor the struggles faced by oral cancer survivors.

The goals of our project are as follows:

1. Develop a self-contained tongue
2. Be able to move a 1g bolus at least 100 times
3. Fit an oral cavity of 160 cm3
4. Validation: Create and carry out testing protocols to check tongue function.
5. Ambient temperature at 97°F (36.1°C) to 99°F (37.2°C)
6. Works with saliva every single time
7. Battery needs to last at least 100 actuations
8. Can be put in/ taken out within 1 minute

4. Methodology

This chapter will discuss the process that led to our current concept and actuator design. Additionally, improvements in the soft pneumatic actuation were analyzed, but redesigning the previous linkage systems is the current way of action.

4.1 Motor Actuation

Our prosthetic tongue design concepts began with exploring how the tongue moved naturally, not exclusively when swallowing food. This provided a basis for the testing of the final actuation design. This team focused on creating a device that is User-centric. A gear train with a DC motor operating a flapper mechanism is a main component of this design.

4.1.1 Torque Calculations

The actuation of the prosthetic tongue's linkage system will be powered by a compact DC motor, which must meet specific torque requirements. For handling a 1g bolus—our hard goal—the system needs to generate 213.167 gcm of torque, and for a softer target of a 9g bolus, it requires 285.807 gcm of torque. Underlying these specifications are several assumptions: the bolus is considered a singular point for simplicity, and the distance to this bolus is equivalent to one linkage segment. The materials used, silicone and PLA, have densities of 1.041 g/cm^3 and 1.25 g/cm^3, respectively. We're disregarding the weight of the flapper, and the tongue's shape is approximated as a rectangular prism. For our calculations, we're assuming an efficiency of 80%.

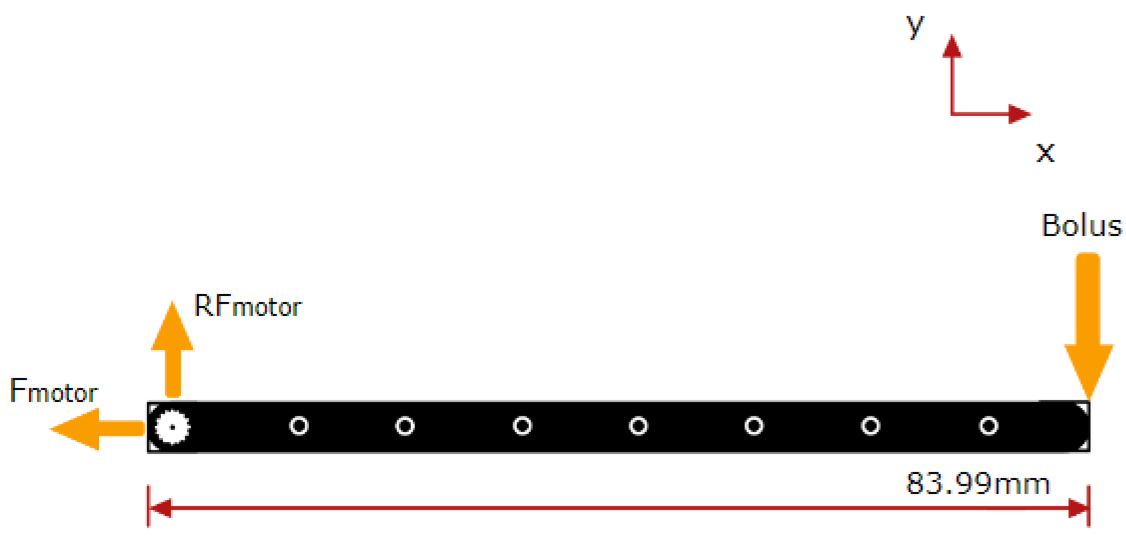


Figure 5.1: The FBD used to calculate the required torque

4.1.2 Flapper Positional Analysis

The prosthetic tongue is designed to rest flat against the oral floor when at relaxed, mirroring the natural state of a human tongue. For the 'Wave' function, the foremost two linkages maintain contact with the upper teeth while the subsequent links execute alternating angles, propelling the bolus toward the back of the mouth. In the 'Arch' mode, the tongue forms an arc, effectively pressing the bolus against the soft palate for swallowing. The precise distances between these linkages, CAD files, and Linkage animation are provided in Appendix B.

4.2 Silicone

The chosen material for our prosthetic tongue strikes a balance between softness and flexibility, crucial for its functionality. It's soft enough for the necessary flexibility, allowing the tongue to

1. prevent spillage
2. form a 'taco' shape around the food bolus

It will also feel more natural to the user and will provide the necessary force without risk to the palate. Although exact quantitative design specifications are still in development, our group believes this is an important aspect of our prosthetic.

Additionally, this softer texture ensures a more natural feel for the user, while still providing the necessary force without risk to the palate. Since previous iterations had trouble sealing sheets of silicone together, we created a mold like a popsicle, so that we don't have to seal the silicone.

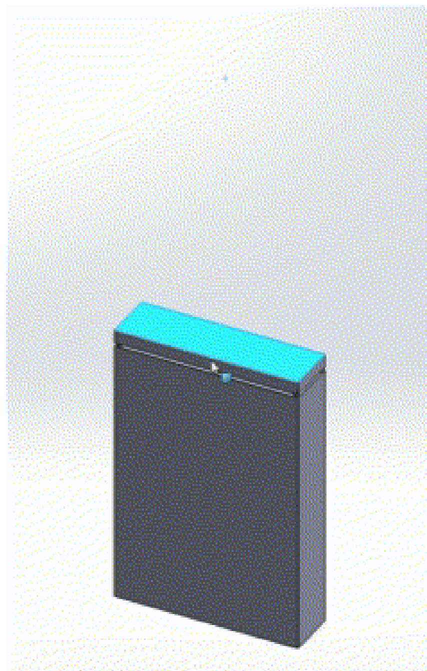


Figure 5.2: Popsicle Mold for the Silicone Casing [8][24]

4.2.1 Shore Hardness

In developing the prosthetic tongue, we are opting for materials that are on the softer end of the spectrum, specifically aiming for a Shore hardness between 00-10 and A-10. The reason behind this choice is to ensure the prosthetic has the required flexibility to wrap around the food bolus effectively and to adapt comfortably to the mouth's contours. The Shore hardness scale is a critical tool in this context as it allows us to quantify the softness of the materials, which is a key factor for the device's performance and the wearer's comfort. We're currently weighing the options between using Ecoflex 30, Ecoflex 10, or a possible combination of both to achieve the right balance of properties for our device.

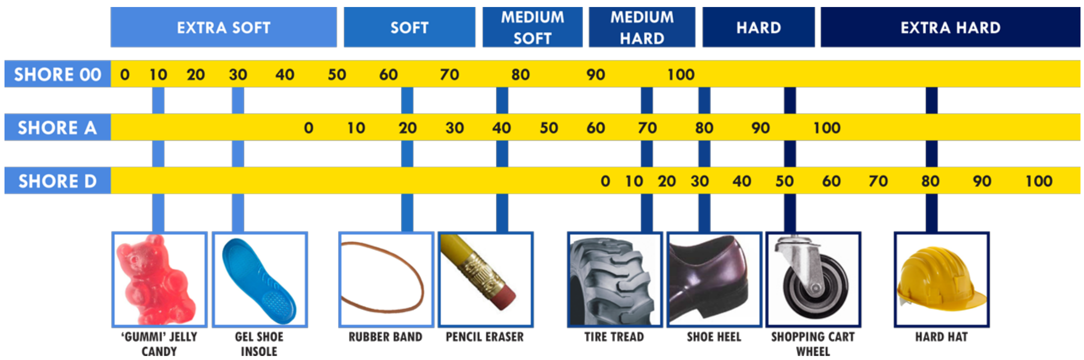


Figure 5.3: Durometer Shore Hardness Scale from Smooth-On Inc. [8]

Technical Data (Smooth-On Inc.)	***Ecoflex 00-10***	***Ecoflex 00-30***
100% Modulus (F @100% elongation)	8 psi	10 psi
Tensile Strength	120 psi	200 psi
% Elongation @ failure	800%	900%
Temp range	-65F - 450F	-65 - 450F
Shore Hardness	00-10	00-30
Cure Time	4 hrs	4 hrs

Table 3: Table comparing the Technical Data of two silicone options [8][9][10][11]

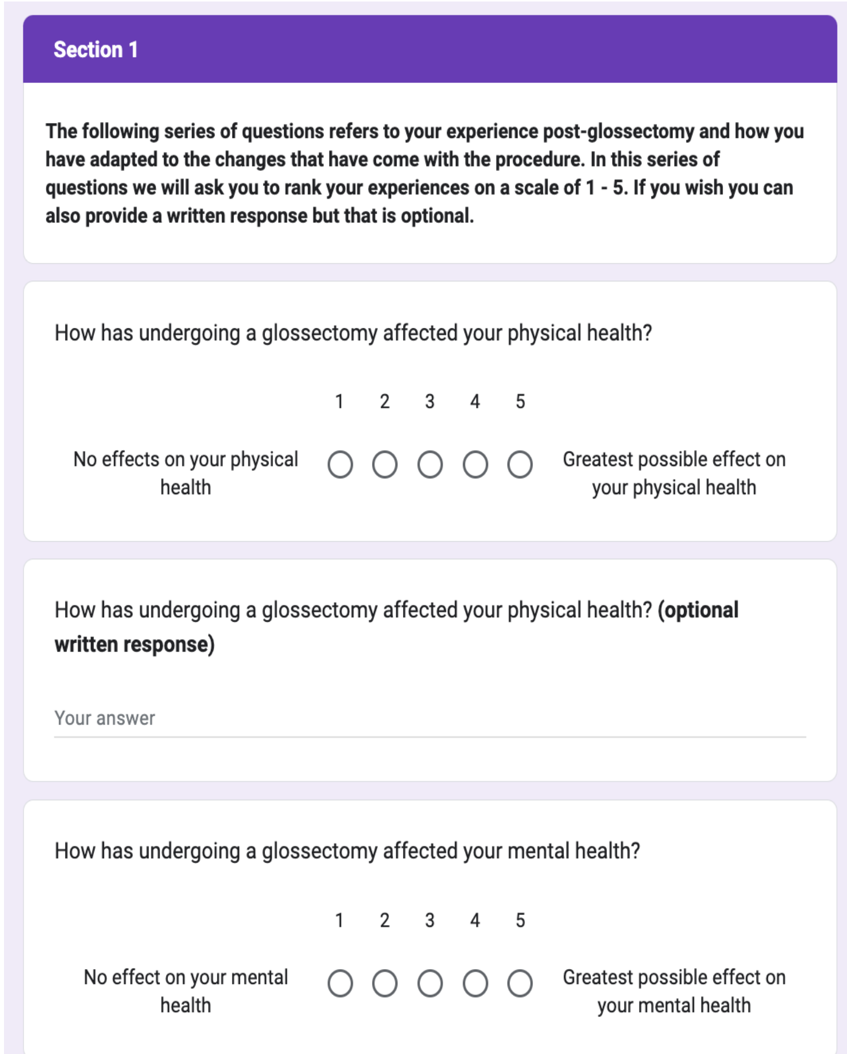
4.3 Interviews

To gather comprehensive insights for our prosthetic tongue project, we're setting up a series of interviews and surveys targeted at both patients who have undergone glossectomy and their healthcare providers. These instruments are designed to capture both the personal experiences of the patients and the professional observations of the physicians. We understand that each patient's journey is unique, and by directly engaging with them, we hope to uncover the nuanced ways in which their daily lives and routines have been altered post-surgery.

Our approach includes both online surveys and in-person interviews, providing flexible options for participation based on the individuals' preferences and availability. The online surveys offer the convenience of completing the questions at one's own pace and allow for anonymity, which can sometimes result in more candid responses. On the other hand, in-person interviews afford us the opportunity for a deeper, more empathetic understanding through face-to-face interaction, where non-verbal cues can be as telling as spoken words.

The survey and interview questions have been carefully crafted and are currently undergoing review by the Institutional Review Board (IRB) to ensure they meet ethical research standards and respect patient confidentiality. This step is crucial in maintaining the integrity of our research process and upholding the trust of our participants.

The ultimate aim of these efforts is to inform the design of our prosthetic tongue so that it doesn't just replicate organic function but also addresses the specific life changes and challenges faced by glossectomy patients. By integrating personal experiences with clinical expertise, we're committed to creating a solution that enhances the quality of life and brings a sense of normalcy to those who have faced significant changes in their ability to perform basic functions like eating and speaking.


Section 1

The following series of questions refers to your experience post-glossectomy and how you have adapted to the changes that have come with the procedure. In this series of questions we will ask you to rank your experiences on a scale of 1 - 5. If you wish you can also provide a written response but that is optional.

How has undergoing a glossectomy affected your physical health?

1 2 3 4 5

No effects on your physical health ○ ○ ○ ○ ○ Greatest possible effect on your physical health

How has undergoing a glossectomy affected your physical health? **(optional written response)**

Your answer

How has undergoing a glossectomy affected your mental health?

1 2 3 4 5

No effect on your mental health ○ ○ ○ ○ ○ Greatest possible effect on your mental health

Figure 5.4: An excerpt from our Patient Survey [24]

4.3.1 Stakeholder Significance

Conducting stakeholder interviews is key for us to truly understand the varied and individual challenges that those who have undergone glossectomy surgeries encounter in their everyday activities. Recognizing the personal and distinctive nature of each patient's journey following glossectomy, we aim to create a device that could significantly enhance their quality of life. This prosthetic has the potential to restore the ability of patients to eat independently, possibly paving the way for future advancements in speech prosthetics. Such an innovation promises to not only foster autonomy for the patients but also alleviate the responsibilities shouldered by family members and caregivers, while also marking significant progress for medical professionals in this specialized area.

5. Conclusions and Recommendations

This chapter will conclude the findings of the project, reflecting on the achievements and suggesting future improvements.

5.1 Design Review

Based on feedback from advisors and experts, several suggestions were made to enhance the design and functionality of the prosthetic tongue.

Recommendations for silicone involved reducing friction to enhance comfort and functionality. The use of silicone with the specified shore hardness levels could hinder the functionality of our mechanical components, now making it an major enhancement focus. We're considering various techniques, including modifying the surface finish or tweaking the texture of the silicone to improve the prosthetic's interaction with both food, the mouth's inner surface, and our mechanics

Integrating peristaltic pump technology is another component that was suggested. This could significantly refine the prosthesis's ability to transport food, mimicking the natural swallowing action using less mechanical parts. Furthermore, manipulating the silicone within the prosthetic design to improve the vacuum within the mouth to assist in swallowing, potentially easing the process for users by guiding food with gentle suction that is natural to the mouth.

For the control mechanism of the prosthetic tongue, Bluetooth Low Energy (BLE) was recommended. BLE was already preferred by the group for its safety profile, especially regarding electromagnetic radiation, and its efficiency in communication. The recommendation to use BLE was based on its widespread application in medical devices and its ability to securely and efficiently transmit data. This technology would allow users to control the prosthetic tongue with precision and ease.

5.2 Future Recommendations

My recommendations for the team as they work to complete a final prototype.

Although an official decision on our control method has not been made, I believe our discussion about BLE will steer the team to consider this method seriously.

5.3 Challenges

Creating the prosthetic tongue involved overcoming many hurdles, from technical issues to working within a diverse interdisciplinary group.

One challenge faced this term was the integration of everyone's designs. This device has a lot of key components, that require different disciplines and background knowledge. Since we are a multidisciplinary group, we all had a lot of great wisdom to add to our Flapper design, however, we spent a lot of time working around and redesigning components to be compatible with others. Once we were on the same page, we were able to simulate a working Linkage and Gear actuator system that the entire group is proud to have designed together. Looking forward we will also need to integrate a gear train and micro gear motor to the system.

5.4 Conclusion

This conclusion summarizes the achievements, challenges, and reflections of this project. It acknowledges the progress made and emphasizes the project's goal to contribute to the field of oral prosthetics.

Our team's approach to designing a human-centric linkage system has proven successful in achieving this project's goal. The development process involved navigating through complex design problems, from motor selection to flapper dimensioning. The integration of the flapper into an improved linkage framework was a major step forward in this design. This integration has resulted in a more lifelike motion than previous iterations—another advancement for user-centricity. This was a crucial step toward creating a tongue that seriously considers stakeholders' well-being.

The project's accomplishments offer new perspectives and lay the groundwork for advancements in oral prosthetics. The experiences and knowledge gained will be passed on to be used by future iterations of this project, aiming to improve the lives of those who depend on these prosthetic innovations.

5.4 Reflection

This MQP fulfills the requirement for the undergraduate engineering degree and challenges students to research and design a device for one year.

The Artificial Prosthetic Tongue Team for the academic year 2022-2023 extends its appreciation for the opportunity this MQP has provided. The project allows the team to participate in a comprehensive research and design process spanning one year. This project has not only expanded our collective academic and social knowledge but has also fine-tuned our practical skills. The project provided the team with the real-world experience of working in a social setting, the freedom to come up with new designs and creative solutions to the problems people face today, and again the space to navigate making mistakes and the importance of learning from them.

5.4.1 Personal Reflection

During my Major Qualifying Project (MQP), I experienced substantial growth beyond the typical classroom environment. This project was not just about applying what we've learned academically; it was a hands-on experience that broadened all of my professional and interpersonal skills.

A crucial part of this journey involved critical thinking and problem-solving in real-life situations. I often leaned on my practical knowledge more than textbook theories, especially when tackling unexpected challenges, like the design complexities of the prosthetic tongue.When creating something that objectively doesn't exist, I appreciated the creative freedom given in the design and prototyping phase. I also ventured into new areas like understanding biocompatible materials and the extensive industry standards that follow. Though challenging, this exploration was incredibly insightful, revealing how medical devices are cleared by the FDA and how materials interact with the human body.

Working in a team setting was another key aspect. Collaborating with a diverse group enhanced my communication skills and taught me the value of different concentrations. Furthermore, the project boosted my public speaking skills. Presenting our work to audiences weekly, from peers to experts, was initially daunting but ultimately improved my confidence in discussing complex topics by the end of this project.

In summary, my MQP was more than an engineering project; it was a journey of personal and professional growth, pushing me beyond my usual boundaries and equipping me with invaluable skills for tackling challenges in the future.

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Appendix

Appendix A - Torque Calculations

$$9.42cm^3 \cdot 1.041g/cm^3 = 9.806g$$
$$9.806g \cdot 1/3 = 3.269g$$
$$8cm \cdot 3.269g = 26.149gcm$$

$$53.382cm^3 \cdot 1.25g/cm^3 = 66.728g$$
$$66.728g \cdot 1/3 = 22.242g$$
$$8cm \cdot 22.242g = 177.938gcm$$

$$2.55cm \cdot 9g = 22.95gcm$$

$$9.08cm \cdot 1g = 9.08gcm$$
$$9.08gcm + 26.149gcm + 177.938gcm = 213.167gcm \text{ SOFT GOAL}$$

$$9.08cm \cdot 9g = 81.72gcm$$
$$81.72gcm + 26.149gcm + 177.938gcm = 285.807gcm \text{ HARD GOAL}$$

Figure A-1: Full Torque Calculations

Appendix B - FBD and Flapper CAD Files

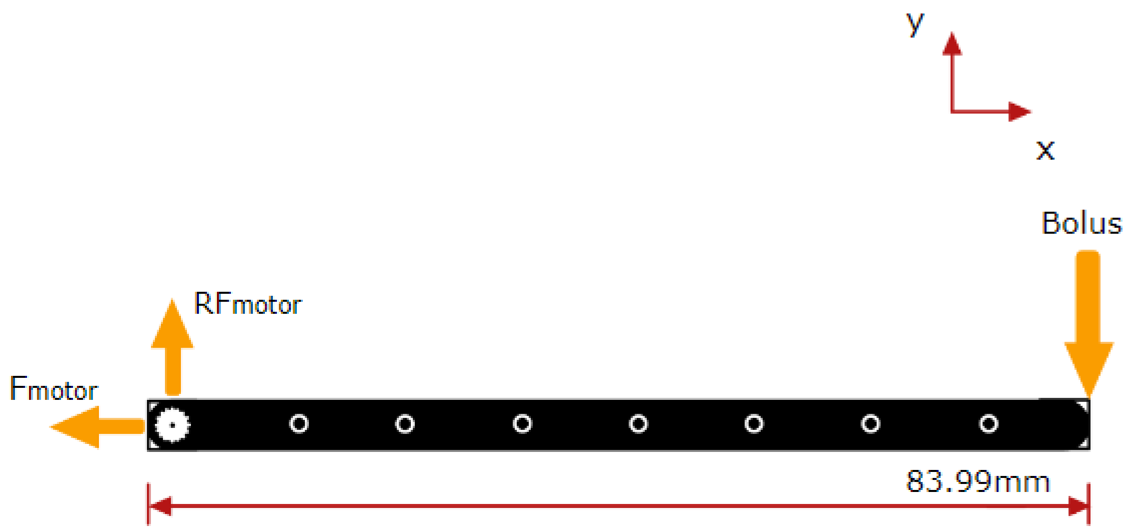

Figure B-1: FBD illustrating how torque values were calculated

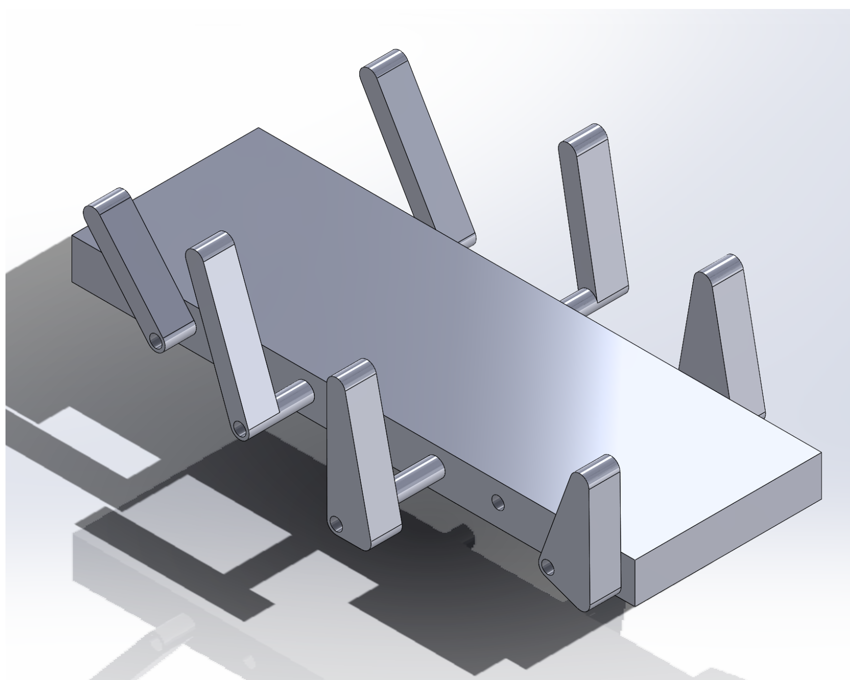

Figure B-2: 3D view of the 'Flapper' mechanism [24]

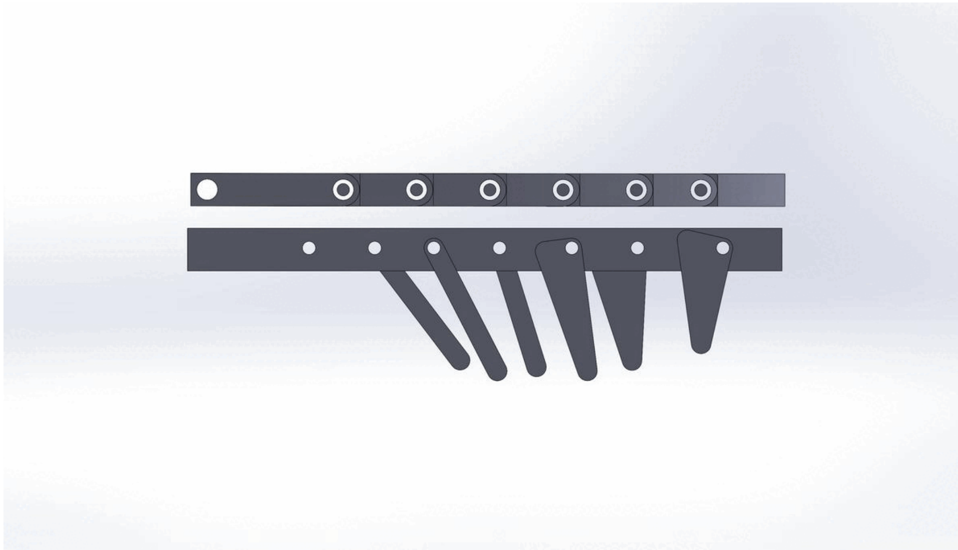

Figure B-3: GIF of the integrated Flapper and Linkage System [24]

File B-1: Flapper CAD File [24]

File B-2: Linkage CAD File [24]

Appendix C - Motor Specifications & Electronic Components

Component Name	Specifications	Size
Arduino Nano 33 BLE	Operating Voltage: 3.3V	Length: 45mm Width: 18mm
6mm Micro DC Gear Motor	Rated Voltage: 3V Stall torque: 1,250g.cm	Total Body Length: 26.1mm Motor Body Length: 16.6mm Shaft Diameter: 2mm
NPN Transistor (BJT) 2n2222	collector-emitter voltage): 40V IC (max collector current): 800mA	5mm x 4mm x 3mm
Battery LR416	1.5V (x3) = 4.5V	4.8x1.6 mm

Table C-1: Electronic Component Specification [24]

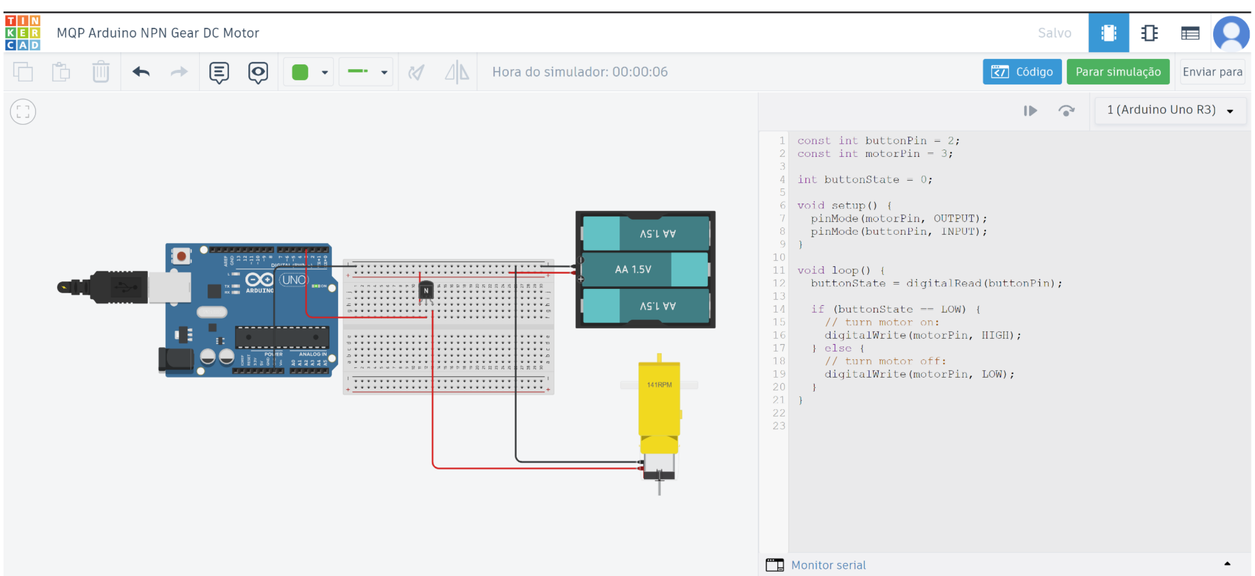

Figure C-1: TinkerCAD Electrical Schematic of the DC Motor [24]

Appendix D - Silicone Technical Data

D-1: EcoFlex 00-10

D-2: EcoFlex 00-30

D-3: DragonSkin 10 Fast

D-5: DragonSkin 10 Slow

D-7: DragonSkin 10 AF AntiFungal Cert

D-9: DragonSkin 10 AF

D-10: V Flex 10

Appendix E - Links to Relevant Safety Standards

E-1: ISO 7405:2018

E-2: ANSI ADA 116:2020

E-3: ISO 57015

E-4: ISO 1633927

E-5:ISO 71503

E-6: ISO 11.040.40

E-11: ASTM F2038

E-12: Products standards technical specifications and technical reports

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