Developing a 3D model of the tongue and mouth to assess pressure generation and predict bolus flow when swallowing

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1. Abstract

Swallowing is an essential function of life. Unfortunately, a large segment of the geriatric population suffers from dysphagia,[7] which is a disorder characterized by difficulty in swallowing. A 3D mouth model is needed for research and educational purposes in order to fully understand normal and abnormal swallowing. Dr. JoAnne Supervised this third semester project. Building upon the tongue prototype developed by previous BME Design teams, we built a stable base to support the tongue and act as the pharyngeal wall. A mouth cavity is also needed to be compatible with the Madison Oral Strengthening Therapeutic (MOST) device. Three designs were evaluated based on accuracy, ease of fabrication, modifiability, client preference, durability, and cost. The Polycarbonate Enclosed Cavity Design was selected as the optimal design. The hard palate and the base were manufactured with 3D printing and a laser cutter respectively. The team tested the prototype with the MOST and found that the data collected were precise but generally lower than the human data provided by the literature.[8]

2. Introduction

2.1 Physiology of the Swallow

The action of swallowing is one that is often overlooked and underappreciated. Swallowing is a complex mechanism that consists of three phases: oral, pharyngeal, and esophageal. [1] The anatomy involved in the swallowing process can be found in Figure 1.

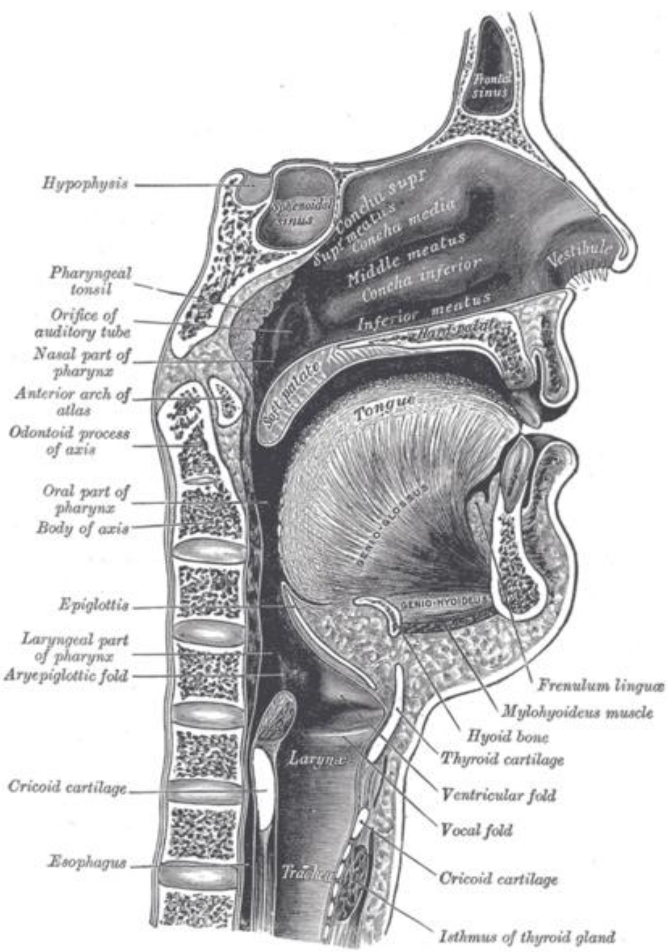

Figure 1: Anatomy involved in Swallowing[3]

The oral phase is a voluntary process in which food is chewed and moistened with saliva to form the bolus. After the bolus is formed, it is pushed to the back of the mouth cavity. The anterior portion of the tongue depresses down while the posterior portion on the tongue lifts up and generates pressure against the hard palate. This pressure forces the bolus to hit the pharyngeal wall. As soon as the bolus reaches the pharyngeal wall, the next phase, the pharyngeal stage, begins.[1]

The second phase of the swallow, the pharyngeal phase, is an involuntary process and begins with the plunger force of the tongue propelling the bolus into the pharynx. The palatopharyngeal folds pull together medially to create a slit in the pharynx that the bolus can slide through. The soft palate also raises and closes the nasopharynx passage to prevent bolus entry into the passage. To prevent bolus re-entry into the oral cavity, the tongue is retracted. Next, three actions happen simultaneously to protect the airway. The first action is the upward and forward motion of the larynx and the hyoid bone to enlarge the pharynx and create a vacuum in the hypopharynx that pulls the bolus downward. The second action is the adduction of the true and false vocal folds. The third action consists of the epiglottis dropping down over the top of the larynx to protect the airway and divert the bolus into the esophagus. There are four factors that cause food to move down the pharynx during the rest of the pharyngeal stage, these include the driving force of the tongue, the stripping action of the pharyngeal constrictors, the presence of negative pressure in pharyngeal stage, and finally, gravity.[1]

Once the bolus enters the esophagus, the last stage, the involuntary esophageal stage, begins. In this phase, the bolus is moved down the esophagus via peristaltic wave motion assisted by gravity.[1]

Dysphagia, or difficulty swallowing, arises after injury, neurodegenerative disease, or stroke. It affects quality of life as well as physical health of an estimated 15%-40% of Americans over the age of 60.[2] This leads to increased hospitalizations, malnutrition, dehydration and pneumonia. Therefore, it is important that the physiology of swallowing be studied and understood to correct the problems that arise to cause dysphagia.

2.2 Project Motivation

Currently, there are no models that replicate the human swallow. A model that could duplicate the physiology of the human swallow would be a great teaching tool as well as a way to measure the forces generated between the hard palate and the tongue during both a normal and an abnormal swallow. The prototype tongue that has been fabricated by previous semesters also has motivated our design. We aim to improve upon this design by replacing the unstable cardboard base with a plastic mechanism that would double as the anatomy of the neck and throat. In addition, to assess the tongue movement already programmed, we aim to construct a hard palate that would be compatible with the Madison Oral Strengthening Theraputic (MOST) device, a device developed by the client and already in use in human subjects to measure pressure generated by the tongue against the hard palate. Dysphagia can severely limit the quality of life as well as threaten it. It often leads to malnutrition, dehydration, and aspiration pneumonia, which is among the leading causes of death in the elderly.[4] For these reasons, it is essential that dysphagia be studied and understood further, and this model will aid in achieving that goal.

2.3 Problem Statement

JoAnne Robbins, Ph.D., the director of the UW/VA Swallowing Speech and Dining Enhancement Program (SWAL-ADE) proposed this project concerning dysphagia, or difficulty in swallowing, which affects many adults and children in the U.S. It often is a result of stroke or degenerative neurologic disease. This project will focus on developing a 3D model of the tongue and mouth that will be used to assess pressure generation within the oral cavity during swallowing. This is a third semester project, and we will concentrate on creating a stable base that doubles as a pharyngeal wall, and designing a mouth cavity compatible with pressure sensors (MOST device).

2.4 Previous Design

This is a third semester project; therefore, there is a prototype, as seen in Figure 2, that is available to improve upon. Currently, the design consists of a moving silicone tongue controlled through a JAVA program written by previous teams. The JAVA program controls eight servos that move eight corresponding metal rods, which move up and down to generate tongue movement. We are currently satisfied with the tongue movement, but wish to conduct testing to determine its accuracy in modeling human tongue movement during swallowing. At present, the tongue rests upon a cardboard base. This base needs to be manually held down while the tongue is moving, and this is another aspect of the design that we hope to improve.

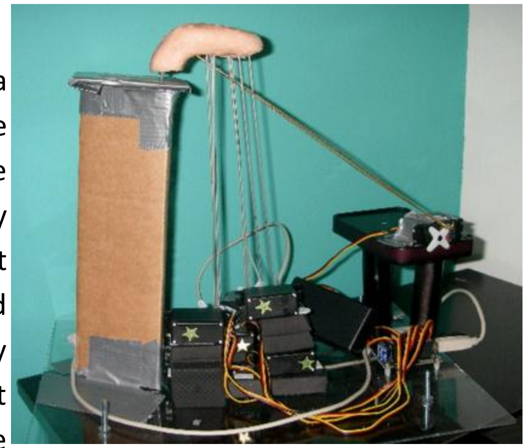

Figure 2: Previous Prototype - tongue constructed of silicone is moved with 8 rods that connect to 8 servos, cardboard base acts as support for tongue

2.5 Design Specifications

Specific design requirements can be found in the Product Design Specifications located in the appendix.

3. Designs

3.1 Design Options

3.1.1 Design 1: Enclosed Cavity Design

The Enclosed Cavity Design incorporates the functional and anatomical aspect of a closed mouth cavity. First, there is the main base support (seen in the figure 3 to the right) for the design that is also used to represent that back of the pharynx. The pharyngeal wall extends all the way towards the top, and has a hook along its side and indentation toward its end for a hard palate connection point. Likewise, it extends toward the actual mouth cavity in order to allow for the back of the tongue to touch it, which is an important step during the process of swallowing.

The hard palate (seen in figure 4 below to the left) is essentially a stiff plastic block that has unique features in order to induce functionality and anatomical correctness. First, it is carved out on its underside such that the tongue can reach it easily enough to create pressures against it. Next, it also is removable from the base and jaw portions so that the user can insert a bolus directly onto the tongue.

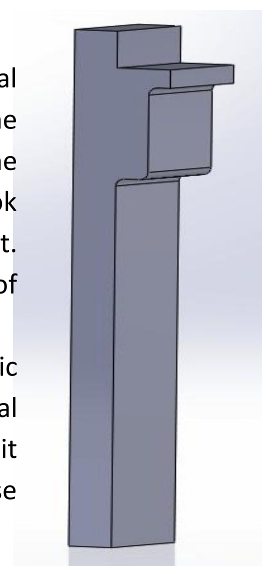

Figure 3: Pharyngeal Wall, wall extends out for contact with the tongue. Ledge provides connecting surface for hard palate piece

The mandible piece (seen in figure 5 below to the right) has been designed to maintain the movement of the tongue, and is joined with a front

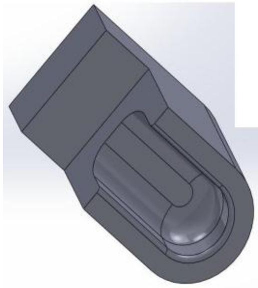

Figure 4: Hard Palate, carved out to mimic human hard palate

support piece to stabilize the placement of the tongue. As seen in the lower figure, the mandible has been hollowed out so that the existing servos still have access to the tongue. This mandible piece fits together nicely with the cut out regions of the front support (seen in 6 figure below to the right). The entire configuration of the mandible and front support is important, since its design allows for easy assembly of both parts around the preexisting tongue.

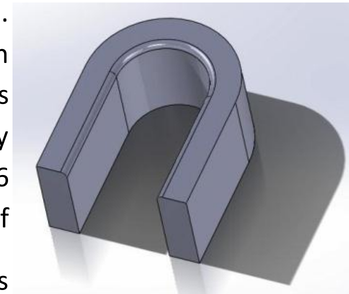

Figure 6: Mandible, constructed to leave gap for servos and to not obstruct tongue movement

Overall, the entire design (seen to the left in figure 7) to the left) can be seen as blocks that have been carved out to surround the tongue and permit current tongue and servo interaction. The design is unique in that it mimics the closed cavity of a real mouth cavity. The enclosed cavity is an important aspect of the design, because it could potentially be beneficial when analyzing pressure generations of the tongue on the hard palate while the model is conducting its swallowing mechanism.

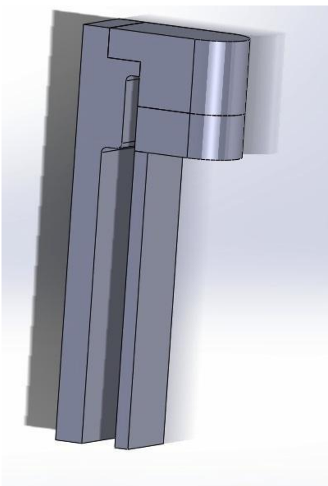

Figure 8: Entire design

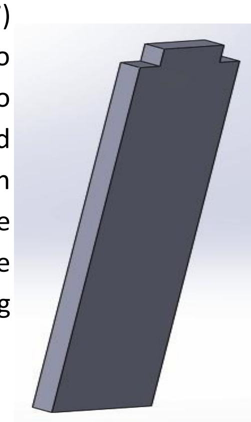

Figure 7: Front Support piece, cut out on top allows for mandible to fit in

3.1.2 Design 2: Purchased Oral Cavity

The Purchased Oral Cavity design is much like the Polycarbonate Enclosed Cavity design, but varies slightly in its pharynx and hard palate details. As figure 9 toward the right shows, the trachea, epiglottis, and esophagus features are the same as the Polycarbonate Enclosed Cavity, yet the back support and pharynx differ slightly. This back support can be made of a material that is rigid yet durable, and will be attached to a purchased hard palate via a screw. Directly behind the hard palate, there is an access that has been drilled out for a servo to connect to a silicone soft palate. When swallowing is occurring, the servo will be programmed to retract its line in order to bring the soft palate back far enough to touch the pharynx. This portion of the design has been included to display the function of the soft palate, as well as adding more anatomical correctness to the model.

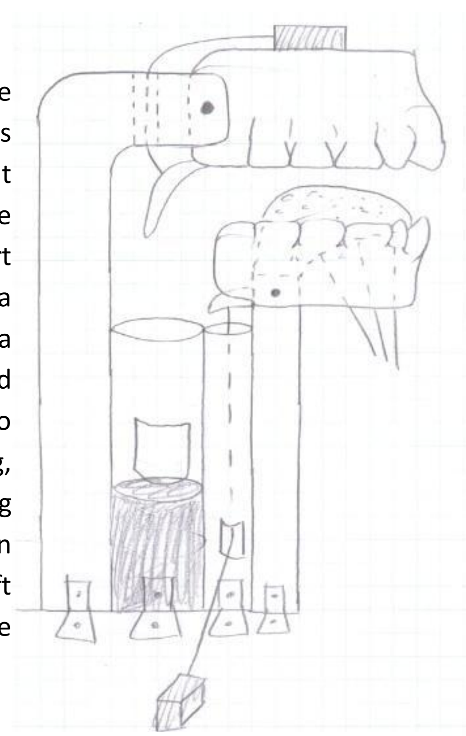

Figure 9: Profile view of the Purchased Oral Cavity Design - Purchased models used for upper and lower jaw, two plastic tubes for trachea and esophagus, servo activated epiglottis

As stated previously, the hard palate within this design will be purchased off the internet, and is expected to have physical qualities such as teeth and ridges in its underside. The lower jaw portion will also have teeth, but the team will work to hollow out its underside to allow for the servo to tongue attachments. This lower jaw is screwed to a front support that will include a flat region for the tongue to rest, as seen in figure 10 to the right.

This design includes a bit more anatomical correctness to it, but the fact that it is not an enclosed mouth cavity makes it less likely to be as functionally accurate as the Polycarbonate Enclosed Cavity Design.

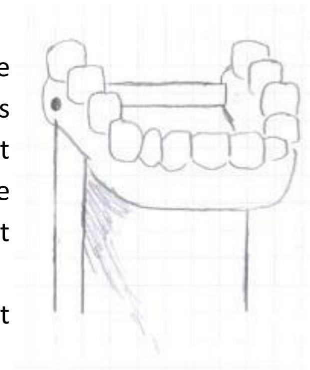

Figure 10: Angled view of the lower jaw portion of the Purchased Oral Cavity Design - purchased lower jaw would rest on base

3.1.3 Design 3: Wood Base Design

Because the client intends to use the model to measure lingual pressure, the model must feature a secured base to which the other model components will be attached. In order to avoid structural failure of the model components, the "Wood Base" design, seen in Figure 11, includes a posterior pharyngeal wall and hard palate that are worked into a continuous block of wood, which serves as a base.

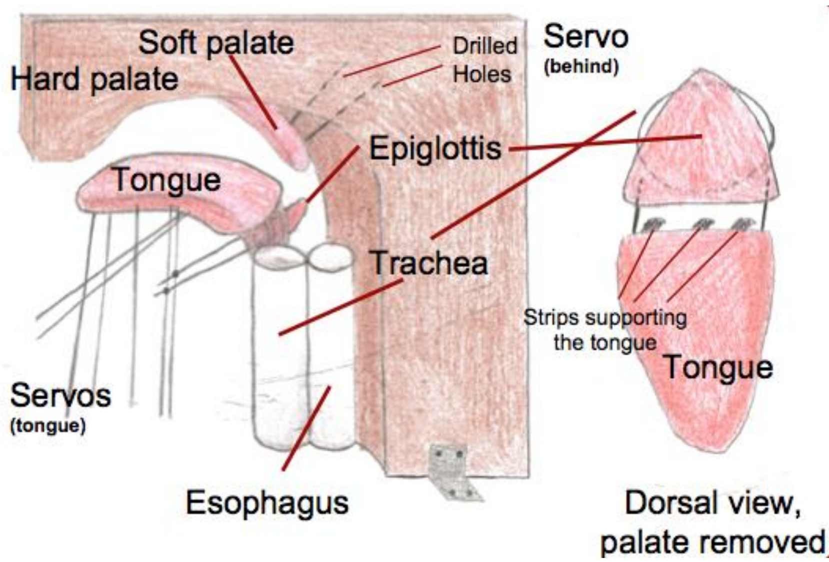

Figure 11: Design 3 - Wood base. A continuous block of wood serves to stabilize the model and provide the surfaces for the palate and posterior pharyngeal wall. The right-hand side image displays the dorsal view of the tongue and epiglottis

Based on feedback given by the client, this design includes a dynamic soft palate, which improves on the rigidity of previous mathematical models. The soft palate's posterior movement (mainly retraction to block the nasopharynx) is regulated by an additional servo (not seen). The soft palate servo originates behind the base and attaches to the soft palate through holes drilled in the base. During swallowing, the soft palate servo retracts while the bolus enters the oropharynx.

The movement of the epiglottis to cover the opening of the tracheal tube does not, however, require an additional servo. Instead, this movement is coupled with the movement of the tongue so that the elevation of the tongue is concurrent with the blocking action of the epiglottis. This is accomplished through a lever-type system in which the metal rods attached to the epiglottis are also fixed to the vertical servos of the tongue. The attachment point allows rotation; it is the fulcrum of the lever. As seen on the right-hand side of Figure X, the metal rods that attach to the epiglottis are positioned around the wires that support the base of the tongue.

3.2 Design Matrix

Categories	Weight	Design 1 - enclosed cavity	Design 2 - purchased oral cavity	Design 3 - wood base
Functional Accuracy	25%	4	4	3.5
Anatomical Accuracy	20%	4	3	3
Ease of Manufacturing	15%	5	3.5	2.5
Modifiable in Future	15%	4	4	4
Client Preference	10%	4	2	3
Durability	10%	4	3	4
Cost	5%	3	2	4
Total:	100%	4.1	3.325	3.35

Table 1. Design Matrix. The three designs were evaluated by seven weighted criteria.

The success of the model is ultimately determined by how accurately it can imitate actual swallowing. Therefore, functional accuracy is of primary concern to the team's design. Because the team recognized problems with the way the epiglottis and soft palate would function in Design 3 (wood base), the design received a lower score. The first two designs are similar in design regarding functional accuracy.

A distinction must be made between functional accuracy and anatomical accuracy; the client would like to use the model to integrate with the MOST device and would also like to use the model as an educational tool. For the model to be used to elucidate the swallowing process and disorder, it must be anatomically (visually) correct. All designs feature the same anatomical features and dimensions; however, only Design 1 (polycarbonate enclosed cavity) displays the anatomically correct sealed oral cavity, while Design 2 (purchased oral cavity) and Design 3 (wood base) have open oral cavities. Therefore, Design 1 was scored higher.

Due to the complexity of the model, the difficulty of fabrication was accounted for in selecting a final design. Determining whether a design would be easy or difficult to build depended on the materials that would be used to construct the model. Although many of the biomimetic materials for all designs have not been selected (e.g. the soft palate, tracheal and esophageal tubes), each design includes the material for which the base is constructed. Designs 1 and 2 are mainly composed of polycarbonate. These designs are much more compatible with other materials; subsequently, the team will look into 3D printing as a potential method of fabrication, which would dramatically decrease the difficulty of manufacturing the model. Instead, Design 3 has a base of wood, which must be modified by hand to fit the dimensions of the oral cavity.

This semester's team anticipates considerable future work for a complete, functioning model. Thus, the ability of all three designs to be modified in the future was a criterion for selecting an optimal design. However, because this semester's high-priority goals include fabrication of a sturdy base and hard palate, there will be opportunities within all designs for modifications.

Initial designs were presented to the clients; based on feedback from those meetings, the team was able to extrapolate the feedback, along with previous expectations, to evaluate the three designs based on client preference. The clients expressed concern regarding the second design's stability, particularly in the pharyngeal area. From this feedback, the polycarbonate enclosed cavity was created, which improved upon the stability and included other innovative features. Similarly, a predecessor to the wood base design (3) that included a hard/soft palate and base constructed with wood was met with criticism: its rigidity did not greatly improve upon the parallel-plate mathematical model used to analyze fluid dynamics of bolus flow. Accordingly, modifications to the design resulted in the addition of a soft palate and controlling servo.

When the model is fully functional, various pressures will be subjected to it that reproduce the forces generated during swallowing. Consequently, the model must be durable—both in resisting structural failure and material deterioration. The structural integrity of design 2 was questioned by the client and recognized as a potential weak point. Design 2 was therefore scored lower than the other two designs.

Finally, cost of the materials involved was considered. Because the raw materials involved will not be expensive, cost was not highly weighted. Design 2 and 3 incorporate purchased model parts and wood respectively; these designs are the most expensive and least expensive designs, respectively, while the first design is between the two.

4. Manufacturing

The team was able to begin manufacturing after submitting a request to have the hard palate and mandible pieces three-dimensionally printed through the FDM Printer, located within the College of Engineering. However, since the pharyngeal wall and front support pieces were quite large, they had to be manufactured through an alternative route. Luckily, both of these pieces were two-dimensional, so they could be constructed through the use of the laser cutter.

Figure 12: Pharyngeal Wall pieces being cut using laser cutter

The pharyngeal wall portion of the design was entered into the computer that was synced with the laser cutter, and a total of 12 cuts were made from 0.22 inch width slabs of acrylic. The front support piece only required 3 cuts from the same dimensional slab. Once these various cuts were made, they were appropriately matched up and adhered to one another through acetone. This process can be noted in the figure 12 above.

Prior to testing however, the team noticed that as the entire structure was assembled, the widths of the hard palate and mandible pieces were constricting the movement of the tongue. Each inner portion of the hard palate and mandible were then shaved down using a dremel, until an appropriate reduced thickness was reached so that the movement of the tongue was no longer constricted.

5. Testing

Because the success of the previous prototype to accurately reproduce pressure generation and movement of the tongue depends on the surrounding structures (hard palate and mandible), a goal of our design was to expand on the physical components of the model to create the necessary environment for testing the robotic tongue. Therefore, the testing conducted focused on the accuracy and precision of lingual pressure generation against the hard palate compared to actual human physiology. The literature concerning swallowing in general is sparse, and testing data could only be compared to research conducted by Banaszynski (2012 - unpublished)[8], who measured maximal isometric lingual pressure of three age groups using the MOST device. Compatibility of our model with the MOST device was another goal of our design—successful integration of the MOST device with the hard palate of our model was also a component of testing.

5.1 Materials

The Madison Oral Therapeutic Device (MOST) developed by Swallowing Solutions LLC was the principal tool used to measure pressures generated along the hard palate. The device included a five-sensor mouthpiece (see Figure 13) and an HP laptop, which displayed and recorded pressures data. Tongue movement and pressure generation for the robotic tongue was controlled by the Java software (referred to here as MInT_program) developed by previous semesters to control the movement of the tongue. MInT_program included classes for individual servo movement to max, min, default, and specified heights, and a class for a concerted swallowing motion.

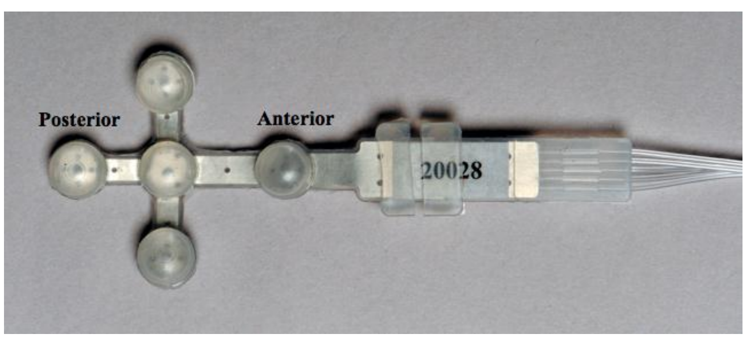

Figure 13[8]: Five-sensor MOST mouthpiece. The sensors are air-filled pockets that increase in pressure when a force is applied.

5.2 Method

The method for testing the maximum isometric lingual pressure across each sensor was adapted from the methods used by Banaszynski[8]. Achieving maximum pressure of the tongue against the hard palate was taken to be the maximum height orientation for the servo in interest (i.e. the greatest pressure occurred when the servos elevated the tongue to the maximum vertical distance). We also ran trials assessing the composite pressure generation of all sensors during an automated swallowing sequence. The general scheme for testing the pressures generated against each sensor (anterior midsagittal, left lateral, middle midsagittal, right lateral, posterior midsagittal) during a normal swallowing sequence is as follows:

1. Start MOST device readings
2. Zero MOST device
3. Fit mouthpiece into hard palate and mold to set flush against hard palate
4. Hook the hard palate to the mandible
5. Run MInT_program concerted movement: generic swallow for ~5 seconds
6. Run MInT_program concerted movement: return all servos to default
7. Stop MOST data collection
8. Unhook hard palate and remove MOST mouthpiece

Testing for maximum pressure against individual sensors followed the same scheme, except for step 5, where the activation of the generic swallow movement in MInT_program was substituted for individual servo movement. Activation of maximum servo height in MInT_program for servos 0, 6, 1, 3, 2 corresponded to the maximum pressure against the anterior midsagittal, left lateral, middle midsagittal, right lateral, and posterior midsagittal sensor, respectively (see Figure 14). Five trials were completed per sensor.

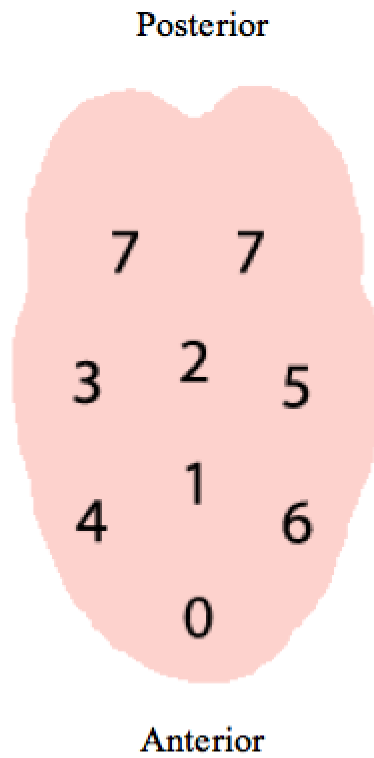

Figure 14: Servo Diagram. Each servo was assigned to a corresponding sensor. 0=anterior midsagittal, 6=left lateral, 1=middle midsagittal, 3=right lateral, and 2=posterior midsagittal.

6. Results/Data Analysis

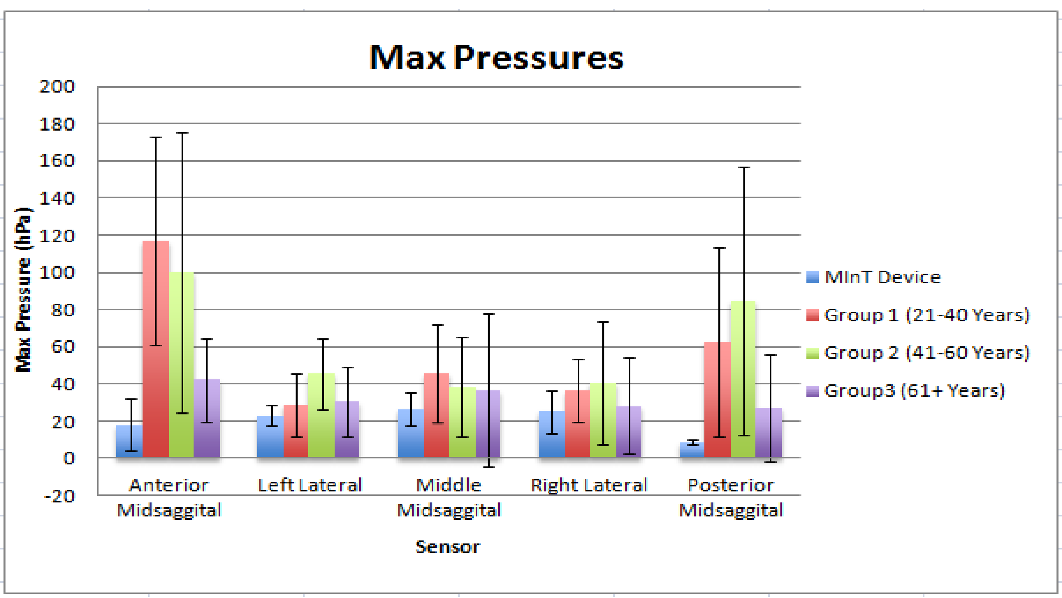

Figure 15: Graph comparing mean max pressures of the MInT device and mean max pressures from human data found in Banaszynski[8]

After the five trials on each sensor were completed, the data was analyzed to find the max isometric pressure of each run. The max pressures were then used to determine the mean max pressure for each sensor. Next, the standard deviation was found and these data points can be found on figure 15. The max means for each sensor were compared to the corresponding max values found by Banaszynski[8], who used the MOST device for human measurement of lingual pressure. The standard deviation of our averages were from the means found in the Banaszynski[8] study were calculated and are listed in table 2. The percentile was also calculated from these standard deviations and can also be found in table 2.

	Standard Deviation from Mean	Percentile
Anterior Midsaggital		
Group 1 (21-40 Years)	-1.794	3.6
Group 2 (41- 60 Years)	-1.083	14
Group 3 (61+ Years)	-1.079	14
Left Lateral		
Group 1 (21-40 Years)	-1.514	6.55
Group 2 (41-60 Years)	-1.183	13.14
Group 3 (61+ Years)	-0.04187	33.8
Middle Midsaggital		
Group 1 (21-40 Years)	-0.7266	23.27
Group 2 (41-60 Years)	-0.4408	33
Group 3 (61+ Years)	-0.2466	40.13
Right Lateral		
Group 1 (21-40 Years)	-0.6469	35.78
Group 2 (41-60 Years)	-0.4604	32.28
Group 3 (61+ Years)	-0.114	45.62
Posterior Midsaggital		
Group 1 (21-40 Years)	-1.0624	14.46
Group 2 (41-60 Years)	-1.0508	14.69
Group 3 (61 + Years)	-0.6388	26.11

Table 2: Standard Deviation from Mean and Percentile for MInT device when compared from human data in Banasynski[8] study

Overall, all max pressures found in our testing are low when compared to the human data. They are all below the 50th percentile. Our model replicated humans 61+ plus years most accurately with the mean percentile rank of 31.93 across the five sensors. Next was the 41-60 year olds with a mean percentile rank of 21.422. Lastly, the youngest group the 21-40 year olds were represented the worst with a mean percentile rank of 16.732. Also, the right lateral sensor consistently had the closest readings to the human readings suggesting that our tongue was most accurate on that side. Although there is no data in the literature to compare the pressures of a normal swallow, three trials were conducted to record such measurements and can be noted in figure 16 below.

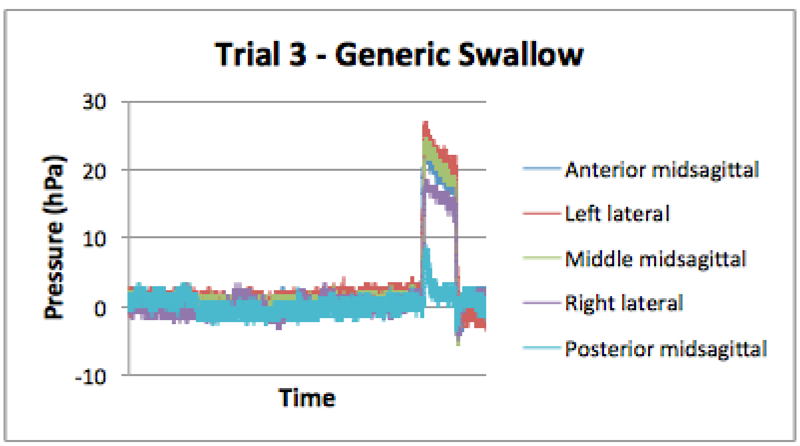

Figure 16: Pressure Generation of all sensors during generic swallow

6.1 Discussion

Our data suggests that the current tongue on our device is not generating accurate human pressures; the pressures are consistently low. However, due to the large standard deviation found in the human data it is difficult to determine what the ideal pressures would be. The human population has a wide range of lingual pressures and it would be unrealistic to have a model perform the mean of a sample population perfectly.

The consistently low maximum pressures across all sensors is due to a number of factors. First, the metal rods connected to the servos at one end and the tongue at the other are not rigid enough to withstand greater forces. When moved to the maximum vertical distance, the metal rods bowed outwards, resulting in lower pressures. Strengthening the rods would most likely have to be accompanied by a similar strengthening in the integrity of the material composing the tongue. We found that even with the weaknesses in the rigidity of the metal rods, the silicone was subject to puncturing. Second, we believe there to be movement of the metal rods within the tongue during trials. The rods are aligned underneath one of three plastic strips that run lengthwise (anterior to posterior) within the tongue to prevent the rods from puncturing during a swallow. When the tongue came into contact with the hard palate, the rods moved along the surface of the protrusion of the sensor from within the tongue. This is evidenced by Figure 16 (generic swallow), which displays a drop-off of maximum pressure even though the max height was held steady for ~5 seconds.

7. Cost Analysis

The following items were obtained or purchased for our project.

Material	Item Cost	Quanity	Total Cost
1"OD Polycarbonate Tubing	$1.62 per foot	8 feet	$12.96
5/8" OD Polycarbonate Tubing	$1.02 per foot	8 feet	$8.16
0.220"x24"x18" Clear Acrylic Sheet	$19.97	2	$39.94
Quart of Acetone	$7.48	1	$7.48
Hook and Staple Brass Connector	$3.79	2	$7.58
Corner Brace 3/4"x1/2"	$3.29	1	$3.29
MOST device	$0.00*	1	$0.00
		TOTAL	$79.38

*Item was supplied by Client and will be returned. Therefore, there is no cost.

Table 3: Itemized cost breakdown

8.Timeline Evaluation

To remain on task in completing the final design, a schedule was composed and followed as strictly as possible, as shown in Figure X. Our biggest deviations from our schedule were mostly in the manufacturing and testing phase. Due to changes to our original manufacturing plan, more time was required for construction of the pharyngeal wall and front support pieces. The setback in the manufacturing phase also pushed back the testing phase. Also, there were more client meetings than expected due to heighten client interest and involvement. Lastly, due to an unforeseen scheduling conflict the poster session was delayed one week, therefore, work on poster was also delayed a couple

Project Schedule:

Task	September				October				November				Dec.	
	9	16	23	30	7	14	21	28	4	11	18	25	2	9
Project R&D														
Background Research	X	X												
Design Brainstorm		X	X	X	X	X								
Final Design Selection					X	X	X							
Manufacturing									X	X	X	X	X	
Testing													X	
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PDS		X				X								X
Midsemester Presentation					X	X								
Midsemester Paper					X	X	X							
Final Poster													X	X
Final Paper														X
Meetings														
Team	X	X	X	X	X	X	X		X	X	X	X	X	X
Advisor	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Client	X	X		X	X				X				X	X
Website														
Updates	X	X	X	X	X	X	X	X	X	X	X	X	X	X

**X indicates a worked on or completed task. Shaded boxes indicate projected timeline*

Table 4: Project Schedule

of days.

9. Future Work

Since this is a third-semester project, improvements on both the tongue created from previous semesters and the hard palate built this semester are discussed here.

During the testing of the prototype, the team planned to collect pressure data from individual servos and noticed the sliding of servo wires in the tongue. The wires also nearly poked through the tongue. In order to avoid such problems, a different material should be considered for manufacturing the tongue. Moreover, the servos were not powerful enough to mimic the movement of a tongue pressing on the hard palate. The data collected by the team were precise but generally lower than the patients' data provided by the client.[8] Also, the wires are constantly coming off of the servos. Therefore, the servos should be replaced with more powerful and stable ones. Reorganization of the servos is also needed for easy and convenient usage of the client.

The team planned to make a transparent hard palate for the tongue. However, this was not possible due to the limited technology available to the team. Transparency of the hard palate is preferred for educational purposes. To be anatomically and functionally accurate, inner coating of the hard palate and lubrication should be considered to simulate the friction produced in the mouth cavity during swallowing. Also, the V-shape of a human jaw should be taken into account accurately. The current model was designed to be a U-shaped jaw and manually trimmed down to fit the tongue.

With the above improvements, the model would be able to simulate swallowing accurately and precisely.

10. Conclusion

Dysphagia is a growing health care concern that affects six hundred thousand people yearly.[7] It is necessary to develop a 3D mouth model to better understand it. With the tongue developed from the previous semesters, the team built a stable base, which also plays the role of a pharyngeal wall, and a mouth cavity compatible with the MOST device. After evaluating three design ideas, the team decided that the Enclosed Cavity Design would be the most ideal design. The design was then manufactured and tested by the team. Although the data collected was precise, further improvement on the tongue and the mouth cavity is needed for obtaining more accurate pressure data.

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12. Appendix

12.1 Project Design Specifications

Developing a 3D model of the tongue and mouth to assess pressure generation in predict bolus flow when swallowing

Project Design Specifications

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Function: JoAnne Robbins, Ph.D., Director of the UW/VA Swallowing Speech and Dining Enhancement Program (SWAL-ADE) will supervise this project concerning dysphagia, or difficulty swallowing, which affects many adults and children in the U.S. It often is a result of stroke or degenerative neurologic disease. This project will focus on developing a 3D model of the tongue and mouth that will be used to assess pressure generation within the oral cavity during swallowing. This is a third semester project, and we will concentrate on designing a mouth cavity compatible with pressure sensors (MOST device), and a stable base that will also represent the pharynx, esophagus and trachea.

Client requirements:

Our client requires a model that fulfills these requirements:

- Develop a mouth cavity with a hard palate:
  - Compatible with force sensors (MOST device)
  - That supports realistic pressure generations
- Develop a pharynx to allow for controlled bolus flow
- Programmed tongue movements that simulate various forms of dysphagia

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The design should allow for full tongue movement (posterior/anterior), be compatible with sensors that are able to detect a range of pressures (MOST device), and permit realistic pressures during testing.

b. *Safety*: This model would not be in direct contact with patients; therefore, typical medically ethical issues do not need to be considered. However, the model's electrical components should be contained as to not harm the operator.

c. *Accuracy and Reliability*: Our model should mirror the physiology and anatomy of healthy and unhealthy swallowing mechanisms found in humans as accurately as possible.

d. *Life in Service*: Our model is expected to last for many years, with continual updates to electrical components as technology advances.

e. *Shelf Life*: Our model will need to be stable on a flat surface and portable.

f. *Operating Environment*: The model should be able to maintain structural integrity when handled and if dropped.

g. *Ergonomics*: Our model is not a hand-held device and so ergonomics does not apply directly.

h. *Size*: Model should be consistent with typical human size. Mouth cavity: ~15 cm x ~15 cm.

i. *Weight*: Model (including electronics) should not exceed 4.5 kg.

j. *Materials*: Tongue is currently made of silicone. Hard palate and lower jaw should be constructed using a hard plastic (polycarbonate). Pharynx should be build of a rigid material. The soft palate should be constructed out of silicone.

k. *Aesthetics*, *Appearance, and Finish*: Model should accurately represent the appearance of a human mouth, and allow for user visibility when running.

2. Production Characteristics

a. *Quantity*: At least one functional prototype is needed. Design should be conscious of possible replication.

b. *Target Product Cost*: Device costs should not exceed 500 dollars.

3. Miscellaneous

a. *Standards and Specifications*: Model will not be in direct contact with patient; only basic safety specifications will be considered.

b. *Customer*: Functionality is a priority to the client.

c. *Competition*: Currently there are no devices that model the swallowing mechanisms of dysphagia.

d. *Modification for the Future*: The design should be conscious of future modifications that will benefit its performance and anatomical correctness.