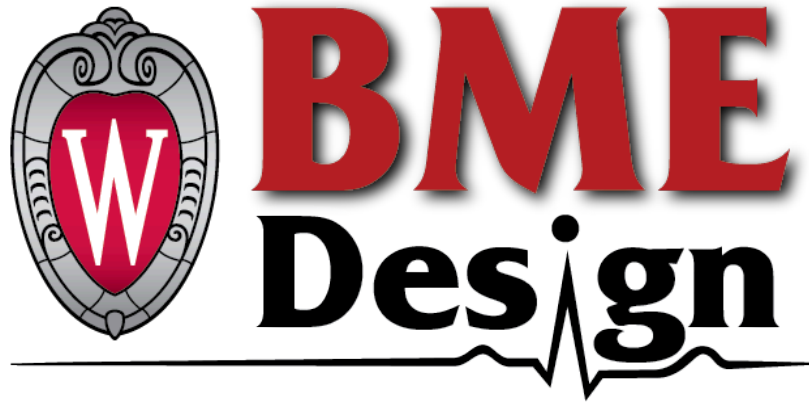


# **BME Design: Preliminary Report**



## **Manipulative Models of Carnivore and Herbivore Mastication Muscles**

**BME 200/300 Design Project**

**Section 305**

**Date:** October 9th, 2024

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**Client:** Dr. McLean Gunderson

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## **Abstract**

Dr. McLean Gunderson, a current professor at University of Wisconsin - Madison School of Veterinary Medicine, has noticed a lack in models that accurately demonstrate the location and function of mastication muscles in carnivores and herbivores. The team's client has requested two models, one each of a carnivore and herbivore, that exhibit anatomically correct muscles of mastication capable of manipulation and articulation to demonstrate the function of chewing and bite force in a classroom setting. Other teams have conducted similar designs, but have been unable to configure a material and attachment that is both elastic for manipulation and durable for repeated use in the classroom. The goal is to implement a 3D printed material that accurately represents muscle in function and aesthetics and design an attachment method to the skull that is durable and removable. The muscle material will be tested using tensile testing and analysis in SolidWorks to ensure accurate elasticity and strength. The skull will be 3D printed and articulated to verify anatomical movement. The muscles will be attached and durability and elasticity will be tested by repeated contraction. A successful prototype will allow veterinary professionals to better understand and treat issues relating to mastication in carnivores and herbivores.

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# Introduction

## Motivation

Understanding anatomy is essential in veterinary medicine, including the complex masticatory muscles that play a crucial role in animal health and wellbeing. Traditional methods of teaching these anatomical structures, such as cadaveric dissection, often come with ethical concerns and accessibility issues that can hinder the learning experience of students [1]. This creates a significant need for innovative educational tools that can effectively convey the intricacies of masticatory anatomy. 3D printing technology, which has been advancing since 1986, presents a viable solution by enabling the creation of detailed models of these muscles. Such models can enhance spatial understanding and provide a more engaging learning experience for veterinary students [1].

While existing research is still limited, the potential of 3D printed models to serve as ethical, accessible and effective learning tools in the veterinary curriculum is promising. By incorporating 3D printed models, educators can better prepare future professionals to comprehend the anatomical and functional needs of animals. These models provide a hands-on learning experience that can serve as an ethical and accessible alternative to traditional methods [2]. This innovation not only enriches the educational experience, but also contributes positively to animal health and welfare, ultimately benefiting society as a whole.

While 3D printed immersive models are slowly being implemented into the curriculum, no models currently exist that show the muscles of mastication. Mastication is an essential part of obtaining nutrition as it is the first step in the digestive process in which bones including teeth and mandibles work together with muscles to perform chewing [3]. Different species exhibit unique chewing adaptations, exemplifying the need for veterinarians to understand these variations to provide species-appropriate care. Furthermore, knowledge of mastication equips veterinarians to educate pet owners about maintaining their animals' dental health and to develop effective treatment plans for dental and gastrointestinal issues. The understanding of mastication is vital in understanding both the digestive system and also in treatment regarding dentition.

## Existing Designs

Currently, there are no existing carnivore or herbivore animal skull models that show and mimic the mastication muscles. However, there are existing human models on the market that highlight mastication muscles. The existing design of the human skull model [4], which includes a replica of the skull and masticatory muscles, offers a valuable resource for studying the locations of the muscles. This model features removable masticatory muscles, allowing for detailed examination of jaw movements such as occlusion, opening, and lateral motions. The skull cap can be easily removed to provide an internal view of the skull's intricate structure.

Assembled by medical professionals, this model is designed for optimal educational use and ensures clear viewing. The versatility of the design makes it suitable for doctor's offices, classrooms, or personal study, enhancing the overall learning experience [4]. However, the model does not show the forces caused by contraction of muscle and is not manipulatable, which are primary objectives from the client.



*Figure 1: Axis Scientific's Life-Size Masticatory Muscles Anatomy Model [4].*

This model depicting human mastication muscles has removable muscles and an adjustable jaw; however, the muscles are rigid and do not demonstrate contractions.

### **Problem Statement**

In veterinary anatomy education, there is a notable absence of interactive, hands-on models that illustrate the muscles of mastication for both carnivores and herbivores. This gap limits students' ability to engage in effective learning and understanding of the complex relationships between muscular and bony structures. The team's goal is to develop two models that accurately replicate the anatomy of mastication muscles in both a carnivore and an herbivore by allowing for the visualization of muscle function and clearly defining individual muscles to enhance educational outcomes.

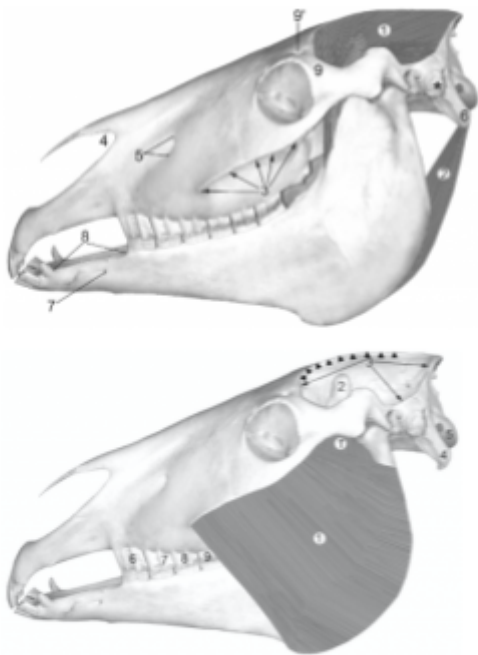
## Background

### Relevant Physiology and Biology

The muscles of mastication are skeletal muscles that originate and insert on osseous structures of the jaw to function in opening and closing the jaw for chewing. While the mastication muscles within both carnivores and herbivores are named the same due to their insertion and origins, they have major differences in size and function due to varying methods of chewing and for obtaining nutrition [5]. The major bony structures include the mandible, maxillae, and teeth [6].

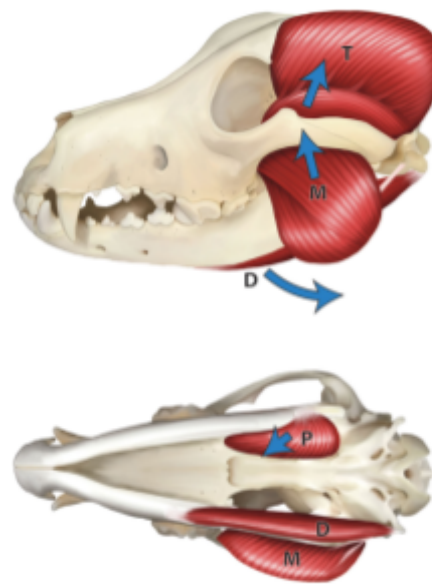
Carnivores, such as dogs, have large temporalis muscles to provide a large bite force during predation [6]. Herbivores, such as horses, emphasize the masseter and medial pterygoid to provide lateral motion of the jaw to grind plant material [5]. Although many muscles and tendons are involved in mastication, the client has placed an importance on the masseter, temporalis, and digastricus in both groups along with an addition of the pterygoid in the herbivore model shown in Figure 2 and 3.

Additionally, because of these different directions of chewing, the shape of teeth varies between carnivores and herbivores. Herbivorous animals grind their teeth in a circular motion to masticate plant material resulting in flat teeth whereas carnivores have sharp teeth that do very little chewing and instead puncture prey with a large bite force [3].



*Figure 2: Horse Muscles of Mastication*

In the top image, numbers related to our project are 1, temporalis m.; 2, digastric muscle. In the bottom image, 1, masseter muscle [7]



*Figure 3: Dog Muscles of Mastication*

In the image, arrows represent the direction of force caused by muscle contraction. M-masseter, T-temporal, P-pterygoid, D-digastric[8]

## Client Information

Dr. McLean Gunderson, BS, DVM is a current Assistant Teaching Professor at UW-Madison's School of Veterinary Medicine in the Department of Comparative Biosciences. Her primary interest is in providing innovative and immersive techniques to demonstrate veterinary medicine in a hands-on manner. Her lab has conducted similar design projects shown in Figure 4 [9] to replicate the movement of muscles by utilizing elastic bands, but she desires to expand on those designs to more accurately represent muscle movement.

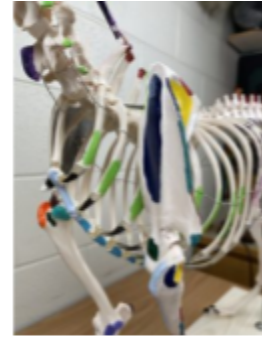


Figure 4: Dr. Gunderson's Painted Skeleton Model [9] This full canine skeleton has hooks for elastic bands to attach to demonstrate muscle movement.

## Design Specifications

The client has requested two models of mastication, one for both a carnivore and herbivore, that accurately demonstrate the location, function, and movement of each muscle while being within a budget of \$1,500. The muscle material must have an elasticity of  $10.4 \pm 3.7$  kPA [10] and be durable to withstand repeated elongation while maintaining its function. The skulls must be lightweight, under 10 lbs, and capable of articulation. Furthermore, the models must be safe to handle by containing non-sharp edges and non-toxic materials for educational purposes. Complete product design specifications are in Appendix A.

## Preliminary Designs

### Muscle Material

#### Design 1: Thermoplastic Polyurethane

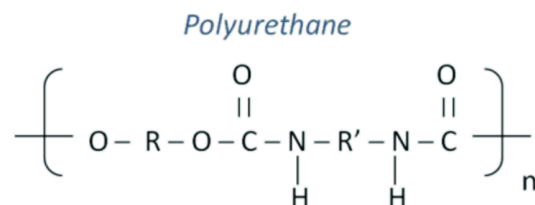
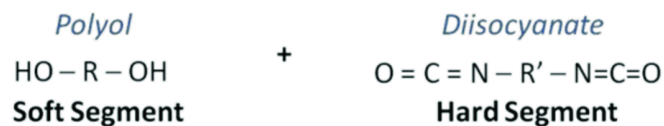


Figure 5: TPU Compound Formula [11]

The first design implements the use of thermoplastic polyurethane (TPU) as a substrate for the 3D printed muscle. TPU is the most elastic 3D printable material available at the MakerSpace, making it an ideal candidate for materials available. TPU was selected due to both its high tensile modulus of 26.0 MPa, and its length of elongation of 55% [12]. With the material capable of being 3D printed, this allows for easy replacement in the case that the muscle breaks in use.

### Design 2: Silicone

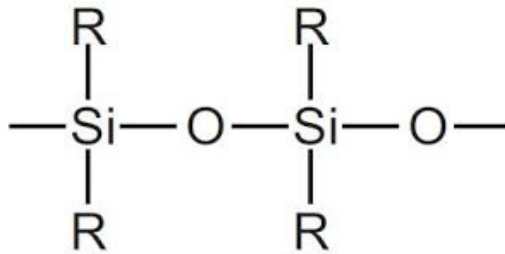


Figure 6: Silicone Compound Formula [13]

The second design implements silicone as the muscle material. Silicone elastomers have a Young's modulus of 5 MPa to 22 MPa and a yield strength of 2.4 MPa to 5.5 MPa [14] while also having a maximum elongation of 700% [15]. Silicone is often purchased in powder form which allows for simple fabrication by shaping the liquid silicone into molds. This would allow the team to shape the silicone into a more realistic representation of the muscle.

### Design 3: Stainless Steel Spring



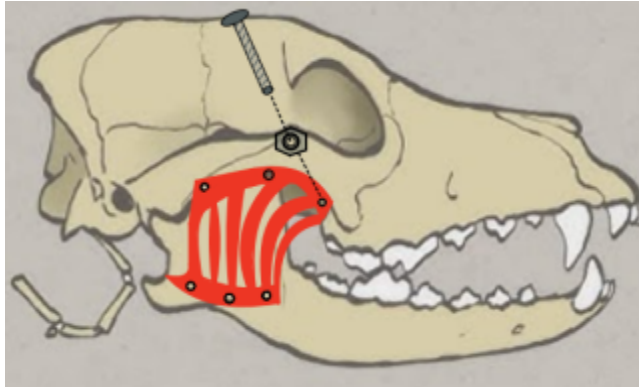
Figure 7: Stainless Steel Springs [16]

The third design entails stainless steel springs. The springs will have hooks on each end, being able to mimic the movement of a natural muscle when attached to the skull. The springs are resistant to corrosion and durable, making them a suitable option for easy replacement. Springs are also readily available to purchase in varying tensile forces to correlate with the difference sizes and force productions of the muscles of mastication [17].



## Muscle Attachment

### **Design 1: Nut and Bolt**



*Figure 8: Nut and Bolt Attachment*

The first design is the nut and bolt method. Nuts and bolts will be screwed in along the top and bottom of the muscle material to secure it in place. This allows for the muscle to easily be replaced for potential breakage. Holes will be drilled into the skull model to allow these nuts and bolts to be inserted into place. This method of attachment was developed off inspiration from anterior cruciate ligament (ACL) repair orthopedic surgery. During this surgery, a tunnel is created in the femur in which the tendon graft is threaded through and secured with a screw [18].

### **Design 2: Epoxy Glue**



*Figure 9: Epoxy Glue [19]*

The second design utilizes epoxy glue to attach the muscle to the skull. Epoxy is an adhesive with a tensile strength of approximately 300 lbs and is resistant to high temperature, UV lights, solvents, and impact [19]. A line of epoxy will be applied along the top and bottom of the muscle, attaching it to the skull model and allowing it to replicate the natural movement of real muscle.

### Design 3: Open Hook

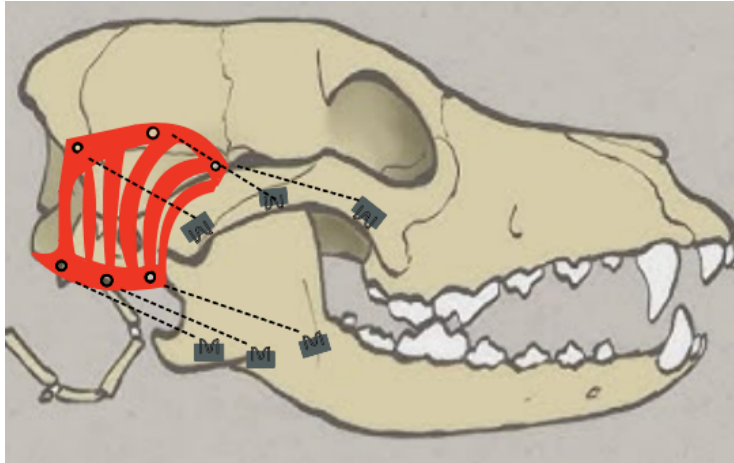


Figure 10: Open Hook Attachment


The third design is the open hook attachment. The muscle material will have holes, so that it can loop onto the hook that will be inserted into the skull. The hooks will be positioned along the top and bottom of where the muscle will rest, securing it in place. The open hooks will allow for the muscle material to be easily replaced if needed. This design was included in the design matrix because the client's similar project with the full body canine skeleton implemented the use of elastic bands attached to open hooks to replicate muscle movement [9].

## Preliminary Design Evaluations

### Design Matrix: Muscle Material

To evaluate the muscle material designs, a design matrix was implemented (see Table 1 below), and designs were compared based on seven criteria and their respective weight. These criteria are elasticity, durability, ease of fabrication, reproducibility, aesthetics, safety, and cost. These criteria were chosen based on the scope of the project for this semester, and for future work.

Table 1: Muscle Material Design Matrix

Criteria:	Design 1: Thermoplastic Polyurethane (TPU)		Design 2: Silicone		Design 3: Stainless Steel Spring	
		<p>Polyol HO-R-OH Soft Segment</p> <p>+ Diisocyanate O=C=N-R'-N=C=O Hard Segment</p> <p>Polyurethane</p> $\left[ \text{O}-\text{R}-\text{O}-\overset{\text{O}}{\parallel}\text{C}-\overset{\text{H}}{\text{N}}-\text{R}'-\overset{\text{H}}{\text{N}}-\overset{\text{O}}{\parallel}\text{C} \right]_n$		$\begin{array}{c} \text{R} \quad \text{R} \\   \quad   \\ -\text{Si}-\text{O}-\text{Si}-\text{O}- \\   \quad   \\ \text{R} \quad \text{R} \end{array}$		
<b>Elasticity (25)</b>	4/5	20	5/5	25	4/5	20
<b>Durability (20)</b>	5/5	20	2/5	8	5/5	20
<b>Ease of Fabrication (20)</b>	4/5	16	4/5	16	4/5	16
<b>Reproducibility (15)</b>	4/5	12	4/5	12	5/5	15
<b>Aesthetics (10)</b>	4/5	8	5/5	10	1/5	2
<b>Safety (5)</b>	5/5	5	5/5	5	3/5	3
<b>Cost (5)</b>	2/5	2	4/5	4	5/5	5
<b>Total: 100</b>	<b>83</b>		<b>80</b>		<b>81</b>	

Criteria Descriptions and Justifications:

**Elasticity** is the highest weighted factor in the design matrix because the client’s primary goal is being able to mimic movement of the mastication muscles. A design high in elasticity must be able to stretch and elongate without tearing during repeated manipulation while remaining in the elastic region. The silicone scored a 5/5 in this section due to its excellent flexibility, with a high elasticity score of 0.96 that closely mimics human skin [20]. The thermoplastic polyurethane (TPU) material scored a 4/5 due to its more rigid nature, as it is not as elastic as silicone, but it is the most elastic material that is capable of being 3D printed at the Makerspace. The stainless steel spring design also scored a 4/5 in this section, because of its ability to return to its neutral position. However, it is also more rigid than silicone, making it slightly difficult to stretch compared to the silicone.

**Durability** is ranked as the second highest factor in the design matrix due to the importance of the model being able to withstand classroom use. The muscles should be capable of elongation without risk of rupture. TPU scored a 5/5 because a study conducted on a TPU specimen determined TPU has high durability, strength, and flexibility [21]. The stainless steel spring also scored a 5/5, since it has high tensile strength and will not rust over time. Although silicone is highly elastic, it has an increased risk of snapping or breaking when overstretched, resulting in a score of 2/5.

**Ease of Fabrication** was weighted the same as durability due to the project's time constraints. The client would ideally like us to complete more than one animal skull model, so designing something easy to fabricate will save time and allow for quick changes or fixes. All materials scored a 4/5 in this section. TPU can be 3D-printed to create the muscles and silicone only requires molding. The springs will need an outer shell to enclose it, after purchasing the individual part. Overall, all the materials are acceptable for this section as fabrication will be achievable.

**Reproducibility** had the third highest factor. Being able to reproduce the muscles on the skull efficiently in case something breaks is important for this project. The models the team will create will be used in classes with large amounts of students, so materials wearing down and potentially breaking is something that could happen. Because of this, reproducibility is important. The stainless steel springs scored the highest at 5/5. If a spring were to break, the client would simply need to purchase another one. The silicone scored a 4/5, as replacing this would require the client to pour silicone into a premade mold to produce another one. When put in a mold, silicone may need up to 24 hours to fully cure [22]. The TPU also scored a 4/5, as you would have to 3D print the muscle you were replacing again, but the STL files used to 3D print could be provided to the client.

**Aesthetics** was not emphasized by the client as a concern, so the team gave the category a low priority. However, it was decided that aesthetics still play an important role in the design due to the model aiding with good educational outcomes. TPU received a 5/5, as 3D printing the muscle enables us to add a good amount of detail. The silicone also received a 5/5, as the team would be able to create an accurate looking muscle using a detailed mold. The spring received a 3/5, as there isn't much leeway to change how it looks.

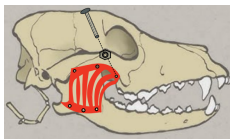

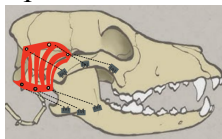
**Safety** is vital, but the other categories have a higher importance in the scope of the project. TPU received a 5/5 due to it having a relatively strong tensile strength of about 30 MPa [23]. Silicone also received a 5/5, as the mold and silicone itself don't raise much of a concern in terms of safety. The spring, however, received a 3/5. This is because it is made of stainless steel and the hooks at the ends of the spring could potentially slip out, causing a potential hazard for anyone who is using the model.

**Cost** had a low rating due to the overall low material usage and high budget. The cost of TPU came out to be the highest at \$3.84 per cubic inch [24] at the design innovation lab which led to the 2/5 rating. Silicone was comparatively more inexpensive at \$32.69 for 2 lbs of powder, resulting in a score of 4/5. The springs are also broadly available at a low cost which the team also rated as 4/5.

**Design Matrix: Muscle Attachment**

To assess muscle attachment designs, the team created a second design matrix (see Table 2 below) that evaluates each design against five key criteria. The evaluated criteria was durability, ease of fabrication, reattachment, safety, and cost. These factors were selected to align with the project’s objectives for this semester, as well as future developments.

*Table 2: Muscle Attachment Design Matrix*

<b>Criteria:</b>	<b>Design 1: Nut and Bolt</b> 		<b>Design 2: Epoxy Glue</b> 		<b>Design 3: Open Hook</b> 	
<b>Durability (30)</b>	5/5	30	3/5	18	4/5	24
<b>Ease of Fabrication (30)</b>	4/5	24	5/5	30	4/5	24
<b>Reattachment (20)</b>	4/5	16	2/5	8	5/5	20
<b>Safety (10)</b>	5/5	10	2/5	4	3/5	6
<b>Cost (10)</b>	5/5	10	5/5	10	5/5	10
<b>Total: 100</b>	<b>90</b>		<b>70</b>		<b>84</b>	

**Criteria Descriptions and Justifications:**

**Durability** was the highest weight on the muscle attachment design matrix, ensuring that the product can withstand repeated use without compromising performance. A design rated 5/5 in durability should exhibit resistance to wear and tear, maintain integrity under various conditions, and ensure reliability over time. This means the attachments used should be robust enough to

endure rigorous handling and other environment factors that may wear down the attachment. Design 1 scored the highest due to this method being the most secure and sturdy for attaching the materials to the skull. Design 3 was the next highest due to the possibility of detachment from the hooks, and Design 2 scored the lowest due to the environmental factors making it more susceptible to failure with holding components together.

**Ease of Fabrication** focuses on the simplicity and efficiency of the fabrication process for the design. A design that highly emphasizes this quality should allow for straightforward assembly and minimal tooling requirements. Design 2 was rated the highest for this criteria since adhering the muscles to the skull with pre-made glue would require minimal fabrication. Design 2 and 3 were then rated the same at 4/5 because they both require minimal materials and can be easily assembled at the Makerspace or TEAM Lab.

**Reattachment** is crucial for the muscles as it guarantees the components can be easily restored in the event of a breakage. A design that presents this criteria would be straightforward in the reconnection process without compromising the structural integrity. Design 3 scored the highest for this as it would be simple to reattach a new muscle to the hook. Design 1 scored the next highest as the process would not be complicated, but it would take more effort in unscrewing the design and then re-fastening it. Finally, Design 2 scored the lowest due to reattaching involving new glue to be present to connect the parts together.

**Safety** was a low weight on the matrix due to the minimal safety risks associated with the model. Design 1 got the highest rating with regards to safety as the attachment would be inside of the skull and secure. Design 2 had the lowest safety rating as uncured epoxy glue causes irritation to the eyes and skin. Cured epoxy is safe for all human use with cytotoxicology results confirming this [25]. Lastly, with Design 3 the hook could be poking out of the skull and could lead to something getting snagged which gave it the 3/5 rating.

**Cost** had a low weight due to the overall inexpensive materials and high budget. All of these materials are at a reasonable price and fits well within the budget. The team can also find all of the materials at the design innovation lab which allows us to not have to deal with outside sourcing. Due to this, the team gave all of the designs a 5/5 rating.

### **Proposed Final Design**

For the final design, the team strategically chose thermoplastic polyurethane (TPU) due to its superior elasticity and durability, making it an ideal material for its application. The incorporation of striations in the TPU muscle models will enhance the elasticity, allowing the structure to better absorb shocks and flex under pressure without compromising integrity. Additionally, utilizing a nut and bolt system ensures optimal durability and facilitates easy

reattachment, providing a reliable and robust connection that can withstand repeated use. This combination of materials and design elements not only improves performance but also extends the lifespan of the product, ensuring it meets the demands of the client.

## **Fabrication**

### ***Materials and Methods***

To begin fabrication of the models, STL files of the canine and horse skulls will be downloaded from online databases. They will then be separated into the upper and lower jaw in SolidWorks, then 3D printed to act as a base for the muscles. Thermoplastic polyurethane (TPU) filament will be 3D printed to form mastication muscles– the designs for each muscle will be individually created in SolidWorks as files are currently available to print from other databases. The muscles will be created with striations to increase the elasticity of the muscle material piece.

For attachment, small holes will then be drilled into the skull to secure nuts and bolts at the locations of insertions and origins of each muscle. The muscles will be fastened to the skull with nuts and bolts by tightening by hand. Further fabrication information will be decided on within the coming weeks and will be included in the final report.

### ***Testing***

Tensile testing will be conducted to analyze the elasticity of the TPU. This will be performed using the Material Testing System (MTS) machine. Tensile testing the TPU will give us information regarding the elastic and plastic regions as well as the force necessary to elongate the TPU. This testing will verify that the TPU will be elastic enough to go through the full motions needed to physically move the jaw outlined in the PDS (Appendix A).

The team will additionally test the articulation of the skull following printing by moving the jaw in all anatomical directions and ensuring full range of motion also included in PDS (Appendix A). This will be done without the muscles attached and will be focusing on how free moving the jaw is as it is connected to the upper skull.

Finally, the team will test that after fabrication, the contraction of each muscle will produce anatomically accurate movements of the jaw as determined by the PDS (Appendix A).

## Discussion

### Ethical Considerations

When creating anatomical models, ethical concerns include inclusivity of the model for representing all varieties of species within the herbivore and carnivore groups will limit a student's understanding for diverse species. Additionally, inclusivity will be limited for various educational training environments due to availability of 3D printers. However, the team plans to combat the availability of 3D printed parts by using inexpensive materials and offering replacement parts with the initial model.

### Future Work

Following the fabrication of the prototype, testing will be conducted which may show changes need to be made to the models. Most specifically, the muscles may need to be made of a more elastic material or vary in size in order to more accurately represent the muscles of mastication. Testing will also verify if the material selection for the skull provides a sturdy yet lightweight structural basis for the muscles.

Since this project is revolving around anatomical models, there are many avenues for future work beyond the semester. The team is primarily focused on designing a model with an existing material and basic fastening methods; however, future work will include refining the muscles to be more anatomically accurate according to the PDS (Appendix A) and advancing the attachment method to be more hidden. The muscles provide many sources of error as the thickness, length, force, and elasticity all vary between animals. The attachment methods may also require additional fastening points that are not anatomically exact in order to properly secure the muscle. The skull size of canines also has high variability, resulting in a source of error.

The team will also like to follow up with students to determine if any changes would be necessary to improve educational outcomes. This may also include additional tendons and muscles to advance the realism of the model. Furthermore, ensuring sustainability is always a goal in engineering, so using recyclable materials and ensuring longevity of the models will also be included in the design process.



## **Conclusion**

In veterinary anatomy education, there's a lack of interactive, hands-on models that demonstrate the mastication muscles in both carnivores and herbivores. Since students have diverse learning styles, including hands-on learning, this lack of practical experience limits their ability to fully grasp the relationships between muscles and bones. The team's objective is to create two models that showcase the mastication muscles in carnivores and herbivores. These models will aid in visualizing muscle function and distinctly defining each muscle, thereby improving educational outcomes.

The final design will feature a fully 3D-printed skull with the four and three main mastication muscles in herbivores and canines respectively. The muscles will be 3D printed using elastic TPU filament and then attached onto the skull using nuts and bolts. The primary focus of this project will be on the muscles and ensuring they work together with their attachments. This aspect of the project will be intricate to make the models as realistic as possible, both in movement and aesthetics, to a functioning jaw. Moving forward, the team will continue with fabrication, testing, and research to develop functional models, allowing improved education for veterinary students.

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# Appendix

## Appendix A: Product Design Specifications

### Function

The main goal of this project is to develop two models that accurately replicate the anatomy of mastication muscles, including their insertion and origins and direction of force, in carnivores and herbivores for educational training. The models should allow for the visualization and physical manipulation of muscle function and clearly define individual muscles to enhance educational outcomes.

### Client requirements

1. Both models must:
  - a. Accurately depict the movement of the mastication muscles
  - b. Exhibit the osseous structures relevant to mastication including the mandibles, maxillae, and teeth [1]
  - c. Construct the muscles of a soft material that is capable of manipulation and is replaceable
  - d. Be within a budget of \$1,500
2. The carnivore model must:
  - a. Replicate the mastication structures of a cat or dog
  - b. Involve three muscles of mastication:
    - i. Masseter
    - ii. Temporalis
    - iii. Digastricus
3. The herbivore model must:
  - a. Replicate the mastication muscles of a horse or cow
  - b. Involve four muscles of mastication:
    - i. Masseter
    - ii. Temporalis
    - iii. Digastricus
    - iv. Pterygoid

# Design requirements

## 1. Physical and Operational Characteristics

### a. *Performance requirements*

- i. The material of the muscles attached must be capable of manipulation to help illustrate the muscle functions.
  1. The material must have an elasticity of  $10.4 \pm 3.7$  kPA as an approximation for the mean elasticity value of the masseter [2].
- ii. The skull must function physiologically by providing support for the muscle attachments and articulate in appropriate directions.
- iii. The carnivore model must replicate the muscles of mastication structures of a dog.
  1. The three muscles included are the masseter, the temporalis, and the digastricus [3].
- iv. The herbivore model must replicate the muscles of mastication structures of a horse.
  1. The four muscles involved are the masseter, the temporalis, the digastricus, and the pterygoid [4].

### b. *Safety*

- i. The material of the skull and muscles of mastication must be smooth as students will be touching and manipulating the material.
  1. This is to ensure that no one gets cut from the material [5].
- ii. Use biocompatible and non-toxic 3D printed materials as it will be in contact with the user's skin. The materials should not be prone to releasing harmful chemicals or particles.
  1. Labels, standards, and warnings may be required depending on the chemical and physical properties.

### c. *Accuracy and Reliability*

- i. The model needs to be reliable in showing the origins and insertions of the muscles on bony attachments.
  1. The masseter originates at the ventral border of the rostral half of the zygomatic arch and inserts at the ventrolateral surface of the mandible and ventral margin of the masseteric fossa of the mandible [6].

2. The temporalis originates at the parietal, temporal, frontal, and occipital bones and inserts on the medial surface of the condyle of the mandible just ventral to its articular surface [6].
  3. The digastric originates at the paracondylar process of the occiput and inserts at the ventromedial border of the mandible [6].
  4. The pterygoid medialis originates at the lateral surface of pterygoid, palatine, and sphenoid bones and inserts at the caudal margin and also on the caudomedial surface of the mandible [6].
- ii. The muscle materials must be able to withstand repeated manipulations in anatomical directions (complete opening and closing of jaw and lateral movement) and return back to the resting state.
  - iii. The muscle materials must accurately replicate morphology of the mastication muscles.
    1. The morphological data of mastication muscles in a domestic dog:
      - a. Whole masseter has a physiological cross section area (PCSA) of  $6.20 \text{ cm}^3 \pm 5\%$  and a fascicle length (FL)  $1.80 \text{ cm} \pm 5\%$  [7].
        - i. Pennation angle of  $30\text{-}40^\circ$  [8]
      - b. Temporalis has a PCSA of  $11.44 \text{ cm}^3 \pm 5\%$  and a FL of  $3.03 \text{ cm} \pm 5\%$  [8].
        - i. Pennation angle of  $30\text{-}40^\circ$ [8]
      - c. Digastricus has unknown PCSA
        - i. Pennation angles of  $0^\circ$ [8]
    2. The morphological data of mastication muscles in a herbivore:
      - a. Masseter has a PCSA of  $83.07\text{-}102.82 \text{ cm}^2$  and a FL of  $2.92\text{-}4.55 \text{ cm}$  [9].
      - b. Temporalis has a PCSA  $47.10\text{-}57.68 \text{ cm}^2$  and a FL of  $4.04\text{-}4.08 \text{ cm}$  [9].
      - c. Medial pterygoid has a PCSA  $48.95\text{-}71.32 \text{ cm}^2$  and a FL of  $2.78\text{-}3.63 \text{ cm}$  [9].
  - iv. The contraction of each individual muscle must produce anatomically accurate movements of the jaw.
    1. In the carnivore [6]:
      - a. The masseter raises the mandible.
      - b. The temporalis raises the mandible.

- c. The digastricus opens the jaw.
  - 2. In the herbivore [10]:
    - a. The masseter causes side to side motion and closes the jaw.
    - b. The temporalis closes the jaw.
    - c. The digastricus opens the mouth.
    - d. The pterygoid medialis causes side movement.
  - v. The printed skulls must be accurate in bone proportions to confirm that the students have the correct visualization to enhance their understanding.
- d. ***Life in Service***
  - i. This model is expected to maintain its structural integrity with every educational use. It is expected that the fabricated joints and muscles are also able to function with each use.
  - ii. The model will be handled in a classroom, undergoing tension and compression from tugging at the muscles.
  - iii. On a typical day, the client can demonstrate muscle movement to multiple classes. Therefore, the model should be durable enough to last at least one whole year before replacement parts are needed.
- e. ***Shelf Life***
  - i. The model will be stored at room temperature (21°C), with minimal environmental factors needed to be considered.
  - ii. The muscle material must not degrade or weaken within the life in service.
- f. ***Operating Environment***
  - i. The model must be able to withstand the disinfectant and cleaning solutions used in a classroom lab, for optimal safety.
  - ii. There will be no extreme cases of pressure, humidity, temperature, or corrosion from fluids as it will be stored in a classroom laboratory.
    - 1. Temperature inside a standard room is approximately 21°C.
    - 2. Humidity inside a standard room is approximately 50% [11].
- g. ***Ergonomics***
  - i. The model should be comfortable to hold and manipulate. Therefore, the model may be scaled down to a handheld tool for professors and students.
  - ii. The muscle material should not be used beyond specified use in the model.
    - 1. Specified use includes anatomical stretching and movement.
- h. ***Size***



- i. Both models should be small enough to be used in a classroom setting. This means that students should be able to hold the models in their hands and easily pass them around to other students.
- ii. The final products should be portable and easy to transport.
- iii. Adequate space is available for storing the two products, but portability is the main concern.
- iv. Attachment locations should be easily accessible for replacement of muscles.

*i. Weight*

- i. The weight of the models should be under 10 lbs for easy maneuvering and transfer.
- ii. The skulls will likely have a density of approximately 1.24 g/cm<sup>3</sup> as approximated by tentative skull materials [12], but they won't be heavy enough to cause complications for travel. This will be accomplished by having a hollow-like structure to minimize weight.
- iii. For the muscles of mastication, light materials should be used for easy setup and demonstration along with ease of use in manipulation.

*j. Materials*

- i. For this project, materials that wear quickly should be avoided, as the models will be repeatedly stretched during demonstrations within the life of service.
- ii. Material such as magnets and velcro should be avoided, as they have proven to be inconvenient in prior models under the guidance of the client.
- iii. Elastic materials should be used to promote durability and accurately illustrate how the mastication muscles move during chewing.

*k. Aesthetics, Appearance, and Finish*

- i. The appearances of the models can be rudimentary but should still be of high enough quality to be used in a university setting for educational benefits.
- ii. Muscles may be color-coded to enhanced educational demonstrations.

**2. Production Characteristics**

*a. Quantity*

- i. Two models of mastication are needed by the client, one each for a carnivore and herbivore.
- ii. Additional parts for replacement of muscle materials after the life of service may be required.

*b. Target Product Cost*

- i. The final cost of the design process should not exceed the client's budget request of \$1,500.
  1. This includes 3D printing the skull, the material used for the muscles and attachment, and the purchasing of any STL files that may be required to aid with the 3D printing of the skulls or muscles.

### 3. **Miscellaneous**

#### *a. Standards and Specifications*

- i. ISO 9001:2015 Quality Management Systems Requirements [13]
  1. A globally recognized standard for quality management. Specifies general guidelines to follow to ensure quality control and customer satisfaction. Guideline topics include leadership, planning, support, operation, performance evaluation, and improvement.
- ii. ISO 13485:2016 Medical Devices – Quality Management Systems [14]
  1. The standard specifies the life-cycle of a medical device such as development, fabrication, distribution, usage, and disposal. The requirements of this standard are recognized by suppliers pertaining to the quality of the materials and other components of the device.
- iii. ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices [15]
  1. The standards detail the principles and processes for managing risks involving medical devices. These risks include, but are not limited to, identifying potential hazards in manufacturing, installing safety software, testing biocompatibility, and regulating usage of a device during its medical life span.

#### *b. Customer*

- i. The model should be easily understandable and usable for demonstrations.
- ii. The client did not have a preference on level of fidelity, but the target muscles and osseous structures should be identifiable.

#### *c. Patient-related concerns*

- i. The force required to contract each muscle may not be physiologically accurate to each animal due to variation in sizes which may impact the understanding of bite force.

- ii. Models should accurately show the correct muscles their direction of force in order for veterinary students to be able to accurately locate and treat issues related to mastication.
- iii. Using these models students should be able to better understand and treat the overall health of carnivores and herbivores.
  - 1. This would help improve oral health and wellness of the animals being treated.

*d. Competition*

- i. Currently the client has multiple models of canine muscles with movement but none of the muscles of mastication.
- ii. No current models of mastication for non-human herbivores and carnivores are available on the market.
- iii. 14-Part Coloured Model of the Skull with Muscles of Mastication [16]
  - 1. This model shows the four muscles of mastication for a human. The material is a hard plastic with removable muscle pieces.

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