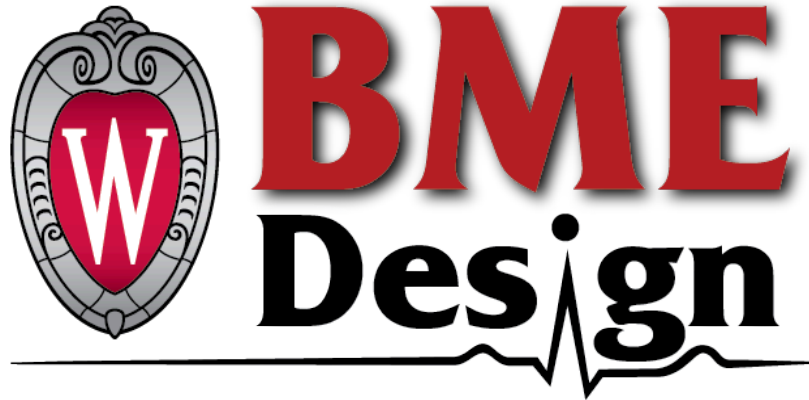# BME Design: Product Design Specification

Manipulative Models of Carnivore and Herbivore Mastication Muscles

BME 200/300 Design Project

Date: September 19, 2024

Team Members:

Jensen Weik (Leader)

Kaiya Merritt (Communicator)

An Hua (BPAG)

Leah Nelson (BWIG)

Noah Kalthoff (BSAC)

Client: Dr. McLean Gunderson

Advisor: Dr. Cameron Casey

Function

The muscles of mastication are important for understanding the complex relationship of animal physiology and behavior including bite force and diet. In veterinary anatomy education, there is a notable absence of interactive, hands-on models that demonstrate the movement, function, and location of the muscles of mastication for both carnivores and herbivores. This gap limits students' ability to engage in effective learning and understanding of the interactions between muscular and bony structures including the importance of teeth shape and mastication directionality. The main goal of this project is to develop two models that accurately replicate the anatomy of mastication muscles in carnivores and herbivores. The models should allow for the visualization and physical manipulation of muscle function and clearly define individual muscles to enhance educational engagement.

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.
      ii. The carnivore model must replicate the muscles of mastication structures of a dog and involve the three muscles.
         1. The three muscles included are the masseter, the temporalis, and the digastricus [2].
      iii. The herbivore model must replicate the muscles of mastication structures of a horse and involve the four muscles involved.
         1. The four muscles involved are the masseter, the temporalis, the digastricus, and the pterygoid [3].
   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 [4].
      ii. Use biocompatible and non-toxic 3D printed materials as it will be in contact with the skin. The materials should not be prone to releasing harmful chemicals or particles.
   c. *Accuracy and Reliability*
      i. The model needs to be reliable in showing the location and mimicking the muscles of mastication.
      ii. The muscle materials must be able to withstand multiple manipulations by several different students and return back to the resting state.
      iii. The printed skulls must be accurate in size to confirm that the students have the correct visualization to enhance their understanding.
   d. *Life in Service*
      i. This model is expected to withstand its structural soundness with every educational use. It is expected that the fabricated joints and muscles are also able to function with each use. The model will be handled in a classroom, undergoing tension and compression from tugging at the muscles. On a typical day, a professor can demonstrate muscle movement to multiple classes. Therefore, the model should be durable enough to last at least one semester, which aligns with the duration of a typical academic class period.
   e. *Shelf Life*
      i. The model will be stored in a classroom setting, with minimal environmental factors needed to be considered. It should be able to withstand common wear and tear.

     f. **Operating Environmen*t***

        i.   The model must be able to withstand the disinfectant and cleaning solutions used in a classroom lab, for optimal safety. There will be no extreme case of pressure, humidity, temperature, or corrosion from fluids as it will be stored in a classroom laboratory.

     g. **Ergonomics**

        i.   The model should accommodate the size of the user, making it comfortable to hold as horse skulls are very large compared to other animals, evident by relating amygdala volume to the size of the animals' brain [5]. Therefore, the model will be scaled down to a handheld tool for professors and students.

     h. **Size**

        i.   Our two 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.   The products do not need to be life-size. Adequate space is available for storing the two products, but portability is the main concern. Maintenance should be easy to access, as the models will likely need moderate levels of maintenance.

     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^3 [6], 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.

     j. **Materials**

        i.   For this project, materials that wear quickly should be avoided, as the models will be in constant use.

        ii.   Material such as magnets and velcro should be avoided, as they have proven to be inconvenient.

        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.   As talked over with our client, the appearances of the models can be rudimentary, but should still be of high enough quality to be used in a university setting.

        ii.   Muscles can be color-coded, although the client said this isn't a necessity.

        iii.   The skull shape and the muscles don't have to be anatomically exact, but students should be able to easily understand the model.

2. **Production Characteristics**

      a. ***Quantity***

          i. Two models of mastication are needed by the client, one each for a carnivore and herbivore.

          ii. There is only needing to be one model of each animal but separate parts that would possibly break down should be easily replaceable and on hand.

      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 the purchasing of any STL files that may be required to aid with the 3D printing of the skulls.

3. **Miscellaneous**

      a. ***Standards and Specifications***

          i. ISO 9001:2015 Quality Management Systems Requirements [7]

              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 [8]

              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 [9]

              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. As the models could be used for demonstrations with children, they should be safe to handle and easy to use correctly.

          ii. The models should accurately demonstrate the correct movement of mastication, reducing unrealistic motion.

      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 [10]

        1.   This model shows the four muscles of mastication for a human. The material is a hard plastic with removable muscle pieces.

Appendix

[1]   S. E. Kim, B. Arzi, T. C. Garcia, and F. J. M. Verstraete, "Bite Forces and Their Measurement in Dogs and Cats," *Front. Vet. Sci.*, vol. 5, Apr. 2018, doi: 10.3389/fvets.2018.00076.

[2]   S. Tomo, T. Hirakawa, K. Nakajima, I. Tomo, and S. Kobayashi, "Morphological classification of the masticatory muscles in dogs based on their innervation," *Annals of Anatomy - Anatomischer Anzeiger*, vol. 175, no. 4, pp. 373–380, Aug. 1993, doi: 10.1016/S0940-9602(11)80047-6.

[3]   P. M. Dixon, N. du Toit, and C. Staszyk, "A Fresh Look at the Anatomy and Physiology of Equine Mastication," Veterinary Clinics of North America: Equine Practice, vol. 29, no. 2, pp. 257–272, Aug. 2013, doi: https://doi.org/10.1016/j.cveq.2013.04.006.

[4]   F. Brocal, C. González, G. Reniers, V. Cozzani, and M. Sebastián, "Risk Management of Hazardous Materials in Manufacturing Processes: Links and Transitional Spaces between Occupational Accidents and Major Accidents," Materials, vol. 11, no. 10, p. 1915, Oct. 2018, doi: https://doi.org/10.3390/ma11101915.

[5]   T. Takeuchi and S. Sugita, "Histological Atlas and Morphological Features by Nissl Staining in the Amygdaloid Complex of the Horse, Cow and Pig," Journal of Equine Science, vol. 18, no. 1, pp. 13–25, Jan. 2007, doi: https://doi.org/10.1294/jes.18.13.

[6]   "UW Makerspace," UW Makerspace. https://making.engr.wisc.edu/

[7]   14:00-17:00, "ISO 9001:2015," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/62085.html

[8]   "ISO 13485:2016(en), Medical devices — Quality management systems — Requirements for regulatory purposes." Accessed: Sep. 19, 2024. [Online]. Available: https://www.iso.org/obp/ui/en/#iso:std:iso:13485:ed-3:v1:en

[9]   14:00-17:00, "ISO 14971:2019," ISO. Accessed: Sep. 19, 2024. [Online]. Available: https://www.iso.org/standard/72704.html

[10]   "QS 8/3M 14-Part Coloured Model of the Skull with Muscles of Mastication," Biomedical Models. Accessed: Sep. 19, 2024. [Online]. Available: https://biomedicalmodels.com/product/qs-83m-14-part-coloured-model-of-the-skull-with-muscles-of-mastication/