Equine Laryngeal Model for Training Surgical Residents
Product Design Specifications

BME 200/300 Design
September 19, 2022

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Function: The client has requested the design team to create an equine laryngeal model for training surgical residents. The design will imitate the anatomy and size of an adult horse's nostril to larynx. The design will describe the different types of tissues that are present in the larynx of a horse. Additionally, these anatomical model parts will be replaceable and reusable to address the lack of cadaver per resident.

Client requirements:

- The model will be life sized and skeletally reflective of a matured horse at approximately 4 to 6 years of age.
    - The model must replicate the entire equine nasal passage to the back of the larynx.
- The model should have removable and replaceable parts so the model can be reused after a single laser practice.
- The materials should be as close in texture and strength as possible to the vocal cords, cartilage, and tissues of a live horse.
- Replicating external features of the model is at a lower priority compared to the vocal cords and other inner features of the model
- Materials provided by the client
    - A budget of $1000
    - CT scans of equine larynx
    - A live demonstration of an upper airway endoscopy with a mock surgery
- Timeline: All final deliverables must be completed by December 14th, 2022

Design requirements:

1. Physical and Operational Characteristics

    a. *Performance requirements*: The product must imitate true anatomical size of an adult horse. The model must be consisted of reusable parts and replacable parts. The portions that will be cut out must reflect texture of real tissue. Finally, the model should extend from the head of the horse to the back of the larynx of the horse.

    b. *Safety*: As the product will interact with carbon dioxide laser, only the appropriate parts should interact with the laser. The model should not produce toxic products when interacting with the laser. The model should also not contain sharp edges and corners due to fabrication. However, sharp edges or corners to imitate the anatomy of the horse is acceptable.

    c. *Accuracy and Reliability*: This model will replicate a structurally mature horse, about 4-6 years of age. This will be a true to size model of the horse larynx and throat. The texture, dexterity, and durability of the vocal folds and throat will need to be exactly replicated. The strength of the materials in the throat will need to withstand a

5,000-10,000 J carbon dioxide laser [1]. The strength of the vocal folds will need to be able to be cut by this same laser.

d. *Life in Service*: This model in total should be able to last one semester, 14 weeks. Likely, there will be about one to two surgeries a week. The durability of the throat material should last the entirety of the semester and not be broken down by usage. The replaceable vocal cord pieces will only last one surgery as they are going to be cut off by the laser.

e. *Shelf Life*: The materials in the model should be able to withstand 20 years of shelf life. The predicted materials used will likely be plastic in nature, so the materials can last between 20-500 years in no sunlight and temperate rooms [2]. We will not want to reach toward the 500 years in safety of degradation of integrity. So the outer material of the model will be able to last 20 years. The replaceable material will only be able to last about 10 years due to the softer plastic being used.

f. *Operating Environment*: The operating environment would be in a veterinary classroom. However, model may also be in storage. So the average operating temperature would be around 20 ºC and average humidity would be around 30% - 50%.

g. *Ergonomics*: The product should not be too heavy and should be easily transportable to different learning environments. The product should not have any sharp edges and should allow for comfortable surgical positioning [3]. Replacement pieces should be easily accessed and changed.

h. *Size*: The surgical model should be life size. The model will represent the upper respiratory tract of a skeletally mature horse of 4-6 years of age [4]. The model will start at the nostril and continue to the end of the larynx. In a skeletally mature horse the larynx should be approximately 3 inches in diameter [5].The model will mimic the realistic dimensions of a horse with a 25in nose circumference, 10in cheek, and 45in head measurement [6][7].

i. *Weight*: A live adult horse's head weighs approximately 18 kg [8]. This is the maximum allowable weight of the model. Realistically, the model should weigh between 7 and 11kg, because the model will only include the components of a horse head pertaining to the upper respiratory system.

j. *Materials*: The model will have 2 main components in which one is static and the other is a removable and replaceable device. The static portion of the model will replicate the equine nasal cavity and will be made of plastic or 3D printed material to ensure its hardness as well as flexibility [9]. The removable component will be replicant of the laryngeal section of the equine throat. No specific material is required for the synthetic

vocal cords, cartilage, and tissue substitutes, however, it must be cost-effective, easy to use, and replaceable. Acceptable suitable materials for vocal cords include silicone, gelatin, and rubber [10]. Cartilage can be replicated using a polymer made of nylon in powder form such as polyamide [10].

k. *Aesthetics, Appearance, and Finish*: The aesthetic of this model should give the same look and feel of a horse head. It should be lighter in weight, but be a size replication of the throat and larynx. This head will be finished both internally and externally. The model will end at the back of the larynx and will be closed off at that point. The model will be able to be taken apart slightly to ease the exchange of the vocal fold removable parts.

2. Production Characteristics

a. *Quantity*: The client has asked for one equine laryngeal model. The model, however, will undergo multiple operations, therefore it is necessary to have many of the replaceable parts. The life in service for the model is one semester (14 weeks) wherein the model will be used up to two times a week. Therefore the client should be provided with 28 sets of replaceable parts.

b. *Target Product Cost*: The full product model will cost around $13,000. This would account for the base model with no replaceable parts. The replaceable parts will cost $2,000 a semester and will need to be replaced after every procedure.

3. Miscellaneous

a. *Standards and Specifications*: The model would need to adhere to the ISO 13485:2016 regulation which outlines requirements for regulatory purposes of medical deivces. Regarding the equine laryngeal model, this standard specifies that for a technical support device, it must consistently meet customer and applicable regulatory requirements [11]. The model would also need to adhere to ISO/TS 23541-1:2021 regulation which makes sure that all 3D structural representations of humans (in alignment with other animals) are consistent and accurate [12]. In regards to the model being cut with a laser, the model and laser must follow IEC-60825 which provides requirements and specific guidlines for safe operations and maintenance while cutting various materials with a laser [13]. Lastly, The model would also need to follow the FDA's Code of Federal Regulations Title 21, Volume 8 where it outlines the requirements for anatomical model devices [14].

b. *Customer*: The client, Dr. Kayla Le, is a graduate professor for the Department of Surgical Sciences in the School of Veterinary Medicine at University of Wisconsin - Madison. Dr. Le is asking for a life-like surgical equine model that can be used by surgical residents to practice upper-airway surgeries. Having a model that can be

reusable, replaceable, and as detailed as possible would result in confidence within the surgical residents and overall better surgery performance.

c. *Patient-related concerns*: The accuracy of the anatomy, size, shape, and material to imitate an adult equine is of the utmost concern for the client. The model only needs to be from the nostril to the larynx, but for the surgical resident to get the best pracitce out of the model, it needs to be as life like as possible. Lastly, it is also important that the parts within the model can be replaced so that if a resident messes up and defects the model, the model can return to its original shape for the resident to try again.

d. Competition:

I. SynDaver Canine: The biggest competition to this project is the SynDaver Canine. This is an anatomical model of a canine used for surgical practices. This anatomical model is able to simulate not only the normal anatomy of a canine during surgery but also when complocations occur. The current purchase price of a SynDaver Canine would be $28,500 and everytime the model needs to be refurbished costs $3500 [15].

II. Erler Zimmer Foot of a Horse as Model: This competitor fabricated an anatomical model of a horse's foot from CT and MR co-registered data, making the model incredibly accurate. The model is 3D printed in full color. The structure also includes removable parts. However, this model may not be practical for surgery practice. The model is priced at $2,155.15 [16].

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