# Equine Laryngeal Model for Training Surgical Residents

Preliminary Report

BME 200/300 Design
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**Abstract**

Horses move enormous volumes of air quickly from their nose to their lungs. The larynx is one of the narrowest parts in an equine upper airway, meaning that any abnormality in the larynx can diminish airflow and significantly decrease a horse's athletic ability. A specific treatment for upper airway abnormalities is the laser ventriculocordectomy. 1 out of every 24 horses will need a laser ventriculocordectomy in their life to maintain the horse's athletic abilities [1]. Currently, cadavers are used to train veterinary residents for this procedure, however, cadavers can be expensive and scarce.

To address this problem, the team decided to create a model of the equine upper airway that accurately reflects the anatomical structure and contains static and replaceable components. The final proposed design is called the Replaceable Laryngeal Disk.  will be almost completely static except a disk that can be easily replaced after each practice procedure. The disk will house the vocal folds within the equine larynx, which can be disposed of after each use. There will be four different testing done to ensure that the model is an accurate description of the equine upper airway. The model will test its anatomical accuracy and mechanical properties by comparing literature value and experimental value. The similarity test and ease of fabrication will be evaluated through the residents. This model will be able to improve laser ventriculocordectomy techniques and result in better surgical outcomes.

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## I. Introduction

Our client, Dr. Le of the Department of Surgical Sciences in the School of Veterinary Medicine, has realized the need for an anatomically accurate model of a 4-6 year old equine's upper airway. This model would be used for training surgical residents to perform the transendoscopic laser ventriculocordectomy. This surgery treats upper airway abnormalities such as the Laryngeal Hemiplegia, that cause loud noise and exercise intolerance in horses [1]. The surgery works by resecting or altering the vocal folds in the horse opening the airway. There are about 3200 veterinary residents every year that need to practice surgeries performed in the equine upper airway [2]. Residents need to practice this surgery on models before they perform it on live animals because the lack of adequate practice may lead to harming the horse. Currently residents practice on cadavers there are two main problems: lack of similarity to the living animal, being that the textures of the vocal folds will be different, and the scarcity of cadavers. This means that cadavers are not very effective in teaching residents about the upper airway and are not sustainable. To help mediate this, the team is looking to create an anatomically correct model of the equine upper airway There are similar anatomical models, such as the SynDaver Canine Model shown in Figure 1, but this is a model of a canine and it focused around using sensors and not a replication of the native anatomical tissues of the animal [3]. Biosphera shown in Figure 2, has an online anatomical model of the entire equine body [4]. This model allows one to learn and go through the anatomy of the horse layer by layer. This is not a physical model, so it is not helpful to surgical residents for practicing the surgery. As of right now, there are no other equine models on the market that allows surgeons to practice any upper airway surgeries. Within this model, the materials used are going to replicate exact tissues, textures, sizing, and spacing in the upper airway. The model will also entail replaceable vocal folds that can be reinserted each surgery.

***Figure 1:*** *This is the SynDaver anatomical canine model. This model is focused around using sensors and hard plastic to help surgical residents practice procedures [3].*


***Figure 2:*** *This is the Biosphera anatomical model of the equine body. This model is online and is focused around detailing every layer of the body, which helps to understand the anatomy of the horse [4].*

## II. Background

*Equine anatomy; Transendoscopic Laser Ventriculocordectomy*

The Transendoscopic Laser Ventriculocordectomy procedure is performed by passing a diode laser through the upper respiratory tract to reach the larynx where vocal cords are cut and removed. As seen in Figure 3, the diode laser enters the respiratory tract through the right nasal passage and is directed through the nasal cavity to the nasopharynx and into the larynx where the surgery occurs. Incisions are made in vocal folds to remove them from the larynx. When performing this surgery it is pertinent to avoid cutting within 2-3 mm of the vocal process as it may result in nerve damage [1]. Horses are sedated for this procedure, but not put under anesthesia so vocal folds remain in an open position for removal.

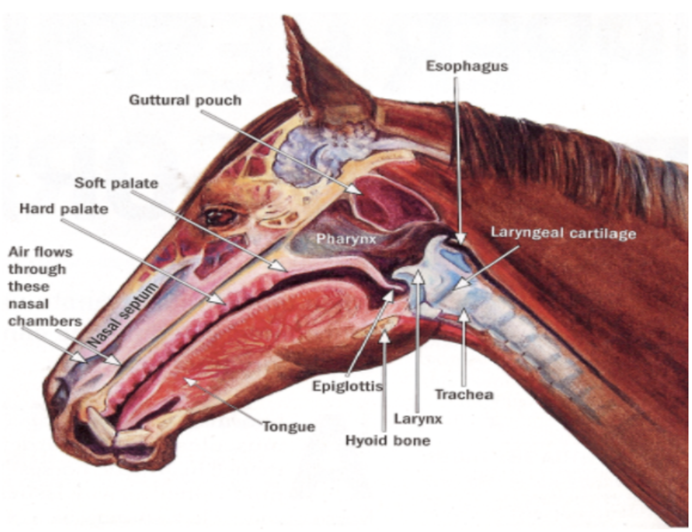


*Figure 3:* Equine Upper respiratory tract in Transendoscopic Laser Ventriculocordectomy procedure [5]

*Importance of Anatomical Surgical Models*

Anatomical models help to greatly reduce the risk of complications during a live surgery [6]. These models can look like many different things, but specifically, 3D models are helpful for students to learn with their hands. 3D models imitate the dimensions, size, shape, and mechanical properties of the animal it is replicating. 3D models are also helpful to help specifically diagnose a patient with the correct ailment because one can compare the normal anatomical structure to the diseased. [6] The 3D models also help with preoperative planning so the surgeon can come up with a plan of what to do in the OR. This can help to save time in the operating room which will limit the amount of trauma brought to the animal's body. This will lower the risk of harm to the animal during surgery because the surgery has been practiced before. Anatomical models can also help to explain relationships between tissues and structures that cadavers would not be able to discern adequately [7]. These factors make it imperative to create a 3D model of the equine upper airway.

*Existing Devices*

Currently there are very few anatomical models for the equine upper airway. The models in circulation are hard plastic models that do not accurately depict the tissues or structures that are in the upper airway. There is, however, an online software that one can purchase to learn horse anatomy in total. This software takes you through all parts of the equine body and aids to teach one of all the structures involved [8]. There are no further physical models made for the equine upper airway.

*3D Materials used for anatomical models*

For many human anatomical models, 3D printing is a popular fabrication method used. For example, two BME 200/300 design projects are using 3D printers for fabrication: one team is fabricating a heart and one is fabricating the hip and hind leg of a canine [9][10]. At the UW Makerspace, they have 4 different 3D printers used to fabricate many different devices [11]. To make the anatomy the most accurate in size, shape, and mechanical properties, the Formlabs Form 3s is the best 3D printer for the fabrication process. From talking to the staff at Makerspace, it was found that Formlabs Form 3s is the most time efficient, can pertain to the most detail, and has the best resin that can relate to the mechanical properties needed to match the equine. The only downside found is that the resin cartridges can be a bit wasteful so the cost is a little higher than using the Ultimaker (FFF) 3D printer, also found in the Makerspace. Therefore, when 3D printing detailed anatomy structures of the equine, the Formlabs Form 3s will be used, as shown in Figure 4.

Regarding different resin cartridges for a Formlabs 3D printer, it is important that the mechanical properties match that of cartilage and bone. Flexible 80A resin has been used to simulate tissues in other studies. For example, Flexible 80A was used to manufacture animal blood vessels that can imitate real animal blood vessels so more testing and research frequencies can be increased [12]. As shown in Appendix B, the mechanical properties table for Flexible 80A are within 5% range of the mechanical properties of the larynx cartilage in a mature equine, found in Appendix A. Therefore, Flexible 80A resin will be used for all cartilage aspects of the model. Similarly, Biomed White Resin has been used to simulate bones in anatomical structures. For instance a 3D-printed spine was fabricated with Biomed White resin and it was found that the mechanical characterization of the 3D model and a fragment of a human spine was 15% different from each other [13]. As shown in Appendix C, the mechanical properties for Biomed White Resin are within 10% range of a mature equine's bone mechanical properties. Furthermore, Biomed White Resin will be used to create bones in the nasal cavity.

The Ultimaker (FFF) 3D printer is known for printing large, less detailed parts at a cheap price, especially when using PLA filament [14]. PLA is a cheap plastic filament that is super easy to 3D print, environmentally friendly, safe for use in medical devices, and comes with a wide range of compost to provide various properties and appearances [14]. Because of its low cost, all other static components of the model will be printed in PLA through an Ultimaker (FFF) 3D printer.

***Figure 4:*** *Formlabs Form 3s printer used to print small, detailed parts of the model [15]*

*Clinical Significance*

There are 3200 residents that are trained for the equine upper airway procedure each year [2]. One in every 24 horses will require laser ventriculocordectomy in its lifetime [1]. However, each veterinary school usually only receives two cadavers per semester. The invention and integration of the equine upper airway model will allow the residents to receive adequate practice without having to worry about limited resources.

*Client*

The client for the equine laryngeal surgical model is Dr. Kayla Le, a Veterinarian of the School of Veterinary Medicine here at the University of Wisconsin, Madison. The client will be using this product for educational and resident surgical training purposes.

*Product Design Specifications*

The client has tasked the team to design a model that is able to provide veterinary residents accurate practice for equine upper airway surgeries, more specifically laser ventriculocordectomy. The device must have an accurate representation of a mature equine upper airway anatomy in terms of mechanical properties, texture, dexterity and dimensions. The model should also contain static and replaceable components, with the vocal fold being the replaceable part. Each resident is expected to practice this procedure one to two times every week during the semester, meaning that each model will be used anywhere from 14 to 28 times per semester. The vocal fold (replaceable component) will be disposed of after each practice procedure, however, the static component must last at least 20 years. As for safety, since the model will be interacting with a diode laser, any material used for the fabrication of the model must not produce harmful chemicals when the laser is used. The model should adhere to codes pertaining to anatomical models and laser safety guidelines. The current budget for the project is $1000, however, clients can provide on a need basis. The main competing designs on the market right now are the synDaver canine model and the Erler Zimmer Foot of a Horse Model [3][8]. The synDaver, although accurate and detailed, cost an astounding $23,000 for the complete set. The Erler Zimmer Foot of a Horse Model is accurate for the foot of the horse but it is not the equine larynx and it is just a 3D file. For more information, refer to Appendix A for the PDS.

## III. Preliminary Designs

*Design #1: Replaceable Gelatin Vocal Folds*

The first design is the Replaceable Gelatin Vocal Folds Design. As seen in Figure 5, this design is an upscaling of a current human laryngeal model used for training surgical residents in endoscopic phonomicrosurgery [16]. Ultimately, design 1 is an upscaling of the human model with altered dimensions to accurately replicate equine anatomy. In the model, the nasal passage to the top of the larynx is static and made of plastic, while the larynx is removable. Based on literature, the dimensions of this design that will accurately replicate the larynx are 7.62cm in diameter and 5.87cm in length [Appendix A]. However, these dimensions may change once our client provides CT scans that will be used to accurately print the size and shape of the equine anatomy. The equine larynx would be made of 3D-printed Flexible 80A with modified lateral cavities to house the vocal folds. The laryngeal portion is split medially in order to have access to the cavities for frequent replacement of the vocal folds. The vocal folds would be made of gelatin due to its cost efficiency and biomaterial representation of equine vocal cords [17]. In order to achieve semicircle gelatin pieces, a reusable silicone mold is required for the fabrication of the vocal folds. The advantages of these silicone molds are heat resistance, soft material, and retain all the specific details of what they are molding [18].

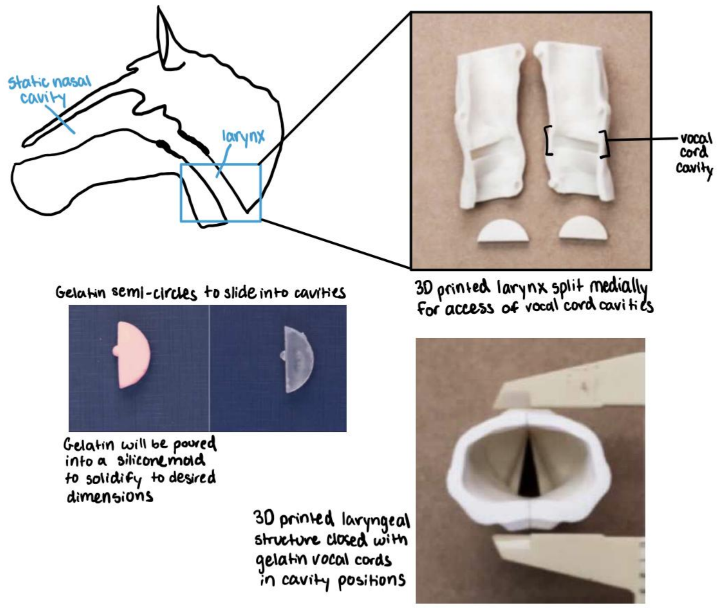


***Figure 5:*** *Open and closed view of 3D printed larynx with modified lateral cavities*

*Design #2: Replaceable Laryngeal Disk*

Building upon the first design, the Replaceable Laryngeal Disk utilizes the replaceable gelatin vocal folds but reduces the work needed to interchange them. It does so with a removable cartridge that can be inserted into a thin cross-section of the static portion of the model, snuggly behind the epiglottis and before the trachea (Figure 6). As such, this design maximizes the number of static components, allowing the model to be even more life-like. Instead of the static components excluding the trachea behind the larynx, the trachea, along with the horse's head and the nasal cavity will all be static. The disk itself will be 3D printed from PLA material with approximate dimensions 20 x 12.5 x 2 cm. These dimensions may be adjusted by CT scans provided by Dr. Le.

The static components will be fabricated in the same way as the first design. The exterior horse head will be made from PLA plastic with a 20% infill. This makes the design lightweight but strong. The vocal cords are fabricated the same way as in the first design and are slid into pockets in the disk. The disk itself is then inserted into the model. It is held horizontally between the walls of the model as the cut is extruded inwards but not across. The disk is held in place vertically by a pin mechanism. At the bottom of the disk, there is a small hole that aligns with two L brackets fastened to the very outside of the model. The pin, threaded through the brackets and hole in the disk holds the disk firmly in place. When the disk is inserted into the model it will align perfectly with the rest of the larynx.

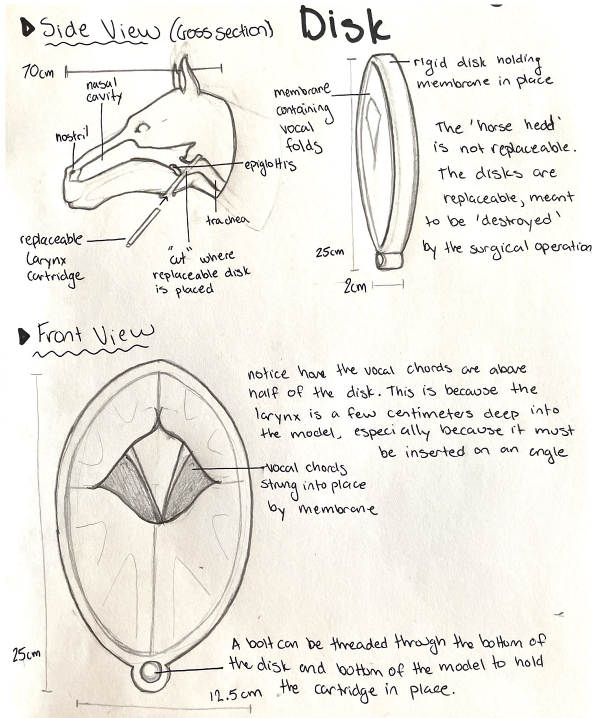


***Figure 6:*** *Front and side view of the replaceable disk cartridge*

*Design #3: Replaceable Laryngeal Tissues with Sensors*

The third design is the Replaceable Laryngeal Tissues with Sensors model. As seen in Figure 7, this model was inspired by the competing SynDaver canine and human model [3]. This design is a static horse head model representing the equine upper respiratory tract from the nose to larynx. Static horse head will be 3D printed from PLA and the static respiratory tract will be made of Flexible 80A Resin to represent cartilage and BioMed White Resin to represent bone. The model will have removable and replaceable laryngeal cartilage and vocal folds. These replaceable tissues will be made of salt, water and fibers similar to that of the SynDaver model that simulate live tissues. Removable and replaceable cartilage and vocal folds are important as the Transendoscopic Laser Ventriculocordectomy surgery cuts out the vocal folds from the larynx using a diode laser. Tissues can be removed and replaced through an opening at the bottom of the model. Dimensions of anatomical features will be based on researched dimensions and CT scan of horse head. Design 3 includes sensors on the laryngeal cartilage that will indicate via LED light if vocal fold is cut within 2 mm of cartilaginous wall. These sensors are important for training surgeons to avoid cutting nerves in surrounding tissues. This design is advantageous as it closely mimics equine anatomy and the surgical residents of UW Veterinary hospital are familiar with SynDaver canine model similar to this design. The disadvantage of this design is that cartilage and vocal fold tissues will be expensive to replace which is required following each surgery.

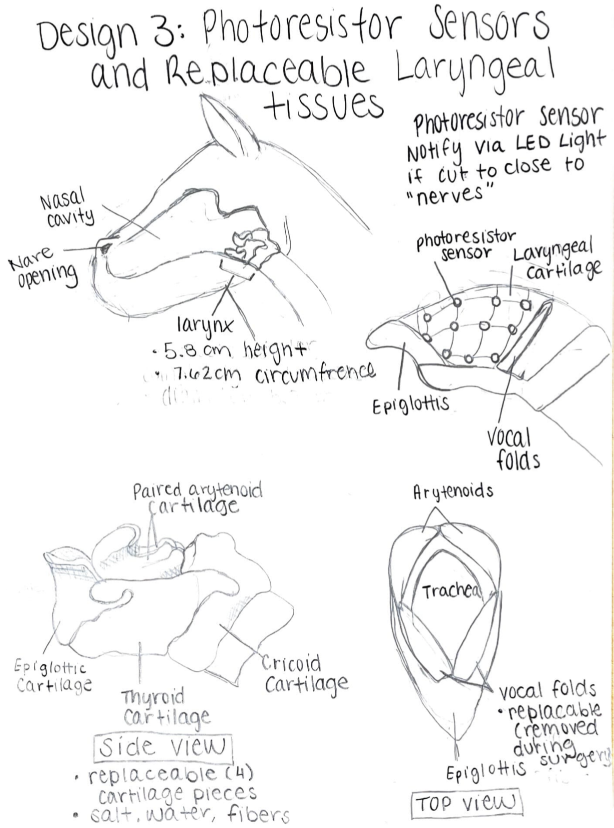


***Figure 7:*** *Side and top view of replaceable laryngeal tissues with cross section of sensors*

**IV. Preliminary Designs Evaluation**

*Design Matrix*

***Table 1:*** *Design Matrix with all methods scored on replaceability, ease of fabrication, accuracy and reliability, safety, cost, and life in service.*

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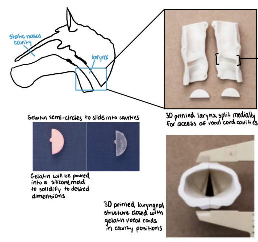
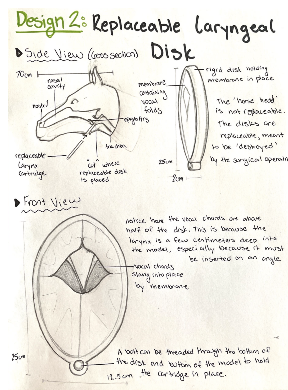
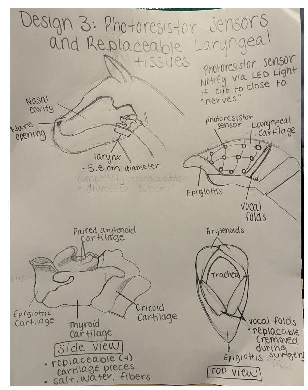
| | |  | |  | |  | |
| | | **Replaceable Gelatin Vocal Folds [17]** | | **Replaceable Laryngeal Disk** | | **Replaceable Laryngeal Tissues with Sensors[3]** | |
| Criteria | Weight | Score (5 Max) | Weighted score | Score (5 Max) | Weighted score | Score (5 Max) | Weighted score |
| Replaceability | 30 | 4 | 24 | 3 | 18 | 1 | 6 |
| Ease of Fabrication | 20 | 3 | 12 | 4 | 16 | 1 | 4 |
| Accuracy and Reliability | 20 | 4 | 16 | 5 | 20 | 5 | 20 |
| Safety | 15 | 4 | 12 | 5 | 15 | 2 | 6 |
| Cost | 10 | 5 | 10 | 4 | 8 | 1 | 2 |
| Life in Service | 5 | 3 | 3 | 4 | 4 | 5 | 5 |
| **Total** | 100 | **Total** | 77 | **Total** | 81 | **Total** | 43 |

*Scoring Criteria:*
**Replaceability** (30%) - It is important to identify which parts of the anatomical model that will be static and replaceable. At minimum, the replaceable aspect of this model should include the vocal folds. The residents should be able to take out the replaceable parts of the model without tampering with the static parts. Additionally, the replaceable parts should not be time consuming to remove and insert; anything less than 10 minutes becomes inefficient use of time for busy surgical residents.

**Ease of fabrication** (20%)- Ease of fabrication includes efficiency and simplicity to fabricate the replaceable parts since the parts will have to be replaced after every practice operation performed.

**Safety** (15%) - The product needs to adhere to ISO standard and regulation 13485:2016. Because the model will be interacting with a diode laser, the model should also adhere to IEC-60825. Since the design is an anatomical model, the design should also adhere to ISO/Ts 23541-1:2021 and FDA Code of Federal Regulations Title 21, volume 8. For more information, look at Appendix A for the PDS.

**Accuracy and Reliability** (15%) - The materials chosen for both the replaceable and static parts should represent accurate dimensions and mechanical properties of equine upper-airway anatomical feature, specifically, from the nostril to the back of the larynx, as found in PDS, Appendix A. Residents should be able to insert a diode laser and a surgical tong into the model and reach the larynx, In addition, residents should be able to practice a laser ventriculocordectomy without any of the static parts being damaged. The accuracy and reliability of the model will be monitored by providing a testing protocol for surgical residents to compare the model to a cadaver.

**Cost** (10%) - The total cost of the product has a budget of $1000, although the client has said that more funds may be provided based on need. It is important to consider that the total budget needs to include the static portion of the model and at least 14 replaceable pieces.

**Life in Service** (5%)- The removable part should at least last for one complete surgical procedure. However, the static portion of the design should be able to last 20 years with at least 14 replacements of the replacement parts per semester.

*Proposed Final Design*

After evaluating the three proposed designs using the design matrix, the team chose to move forward with the second design, the Replaceable Laryngeal Disk. Although the Replaceable Gelatin Vocal Folds design excelled in replicability and cost, the design didn't have an efficient way to remove and insert the vocal folds without compromising some of the accuracies of the anatomy in the larynx. The Replaceable Laryngeal Tissues with Sensors tied with the Replaceable Laryngeal Disk in accuracy and reliability, scored low on safety and ease of fabrication because the sensors are very sensitive and could cause more harm to both the replaceable and statics components of the model if hit incorrectly by a diode laser. It would also be very costly to fix this design. In regards to the second design, it scored high in accuracy and reliability because of the mechanical properties, texture, and dexterity of the gelatin folds compared to that of an equine larynx. The third design also scored high accuracy and reliability because of the fully modular design with sensors that allows the residents to understand the interaction between the surgical tool and other tissues in the equine upper airway.

Unlike the Replaceable Laryngeal Tissues with Sensors, the first two designs had higher biocompatibility with the diode laser which caused both designs to score higher in safety. The Replaceable Laryngeal Disk design scored higher than the Replaceable Gelatin Vocal Folds design because the disk components contain the replaceable parts in a firm position that also attach more sturdily to the model with the pin mechanism. Therefore creates less contact between the statics and the replaceable components.

Overall, the Replaceable Laryngeal Disk Design came out on top due to its ease of fabrication, accuracy and reliability, and safety factors. The Replaceable Laryngeal Disk design will proceed to fabrication and testing.

## V. Fabrication/Development Process

*Materials*

Static Components

The static components of this model will include an anatomical horse head that holds a vocal fold disk. The outer equine head model from nose to larynx will be 3D printed from PLA in an Ultimaker. The inner upper respiratory tract anatomy that the diode laser passes through will be made of Flexible 80A Resin to represent cartilage and BioMed White Resin to represent bone. Between the inner respiratory tract and outer horse head, will be filled in with styrofoam.

Replaceable Components

There are three static components to the design: two gelatin folds and one reusable disk. The gelatin folds are molded from a mixture of gelatin and water. The ratio will be tested until it is adequately representative of the horse's vocal folds. The disk cartridge, both outer rim and inner pockets, will be constructed from 3D printable PLA or tough PLA.

*Methods*

Fabrication methods begin with the acquisition of equine CT scans from the University of Wisconsin School of Veterinary medicine. Using Solidworks, a 3D modeling software, the nasal cavity, larynx, and upper trachea will be isolated. The cartilage aspects of the nasal cavity, the entire larynx, and the upper trachea will be printed with Flexible 80A resin in a Formlabs 3D printer at the UW Makerspace. The bone aspect of the nasal cavity will be printed with BioMed White Resin also in a Formlabs 3D printer at the UW Makerspace. The 3D-printed vocal folds, made within the larynx component, will be isolated and used to make silicone molds. These molds will be filled with gelatin.

The disk portion will be designed in Solidworks where it then is printed with PLA in the UW Makerspace. The slot for the cartridge will be included in the design of the molds and the 3D print of the outside of the model. Two L brackets and 4 screws will be drilled into the outer model. These will provide the holes through which the pin slides and secures the disk into place.

While the primary focus of this model is on the interior, an outer horse head form will be fabricated from a lightweight material such as PLA with 20% infill. The horse's head will be 3D printed and assembled. It may happen for ease of fabrication that two halves are cut (or printed in halves) and carved separately then glued together with a two-part activating glue from the UW Makerspace. The detail in the horse's face will be embellished as time allows.

*Final Prototype*

Final prototype has not been fabricated yet.

*Testing*

The team, veterinary surgeons, and surgical residents will be testing the accuracy of the proposed design in the UW School of Veterinary Medicine in order to determine if the model is an accurate representation of equine properties for the performance of a transendoscopic laser ventriculocordectomy.

1. *Anatomical Accuracy test:* This test will be completed by the team to assess how the structures of the proposed model are replicants of equine anatomical structures. The different variables tested will be the trachea's diameter and length, the larynx's diameter and length, the nostril's width, and the distance from the cheek to the back of the jaw bones. These measurements will be collected from the CT scans and the 3D printed model and compared to those of the literature values. The percent error will be calculated and used to determine if accuracy is achieved. Anatomical accuracy is defined by having a percent error less than or equal to 10%.
2. *Mechanical Properties test:* The mechanical properties of the design will be tested through compression testing. This testing will be completed by the team and will be done on the parts of the model that replicate equine laryngeal cartilage, bone, and muscle. After completing the design testing, the goal is to compare the results to the literature

values: Young's Moduli of equine laryngeal cartilage, bone, and muscle, yield strength of equine bone, and ultimate strengths of equine laryngeal cartilage and bone. The percent error will be calculated and compared to our initial ranges. Test is passed if laryngeal cartilage has less than or equal to 5% error and if bone and muscle have less than or equal to 10% error.

3. *Similarity test:* The model will be tested by 6-8 current surgical residents and/or veterinary surgeons on their personal ranking of the model's biomaterial texture, anatomical shape, relative size, and procedural accuracy. Each category will be ranked on a 1 to 5 scale by the user. A score of 1 indicates zero to no similarity, a score of 2 indicates slight similarity, a score of 3 indicates fair similarity, a score of 4 indicates considerable similarity, and a score of 5 indicates highly similar. A passed test is defined as a score of 4/5 or higher to keep the percent error similar to that of other tests.
4. *Ease of Fabrication and Replacement test:* The model will be tested by 6-8 current surgical residents and/or veterinary surgeons on their ability to fabricate and replace the vocal folds. This procedure will assess two tests that both have to pass in order for the overall test to be considered passing. For the first part, test 1 is passed if the user is able to create gelatin folds using a reusable silicone model in 30 minutes or less [19]. For the second part, test 2 is passed if the user is able to remove the laryngeal disk, remove old vocal folds, replace new gelatin vocal folds, and insert the fresh disk back into the model in 10 minutes or less. If test 1 and test 2 are able to be passed, the Ease of Fabrication and Replacement test is passed.

## VI. Results (Future Work for Now)

Now that a final design has been proposed, the prototyping and testing stages of the project can begin. The group plans to break into two teams statics and replaceable components which will each work independently to streamline the design process. The static component group will fabricate everything but the vocal folds. The replacement group will work on the fabrication of the replacement vocal fold disk and the mold used to make multiple vocal folds.

After testing has been completed, the results can be evaluated to determine the accuracy of the model. The best measure to get a quantitative evaluation would be through statistics, specifically an ANOVA test. ANOVA stands for Analysis of Variance. In general, ANOVA shows if there are any statistical differences between three or more independent groups. The three groups used in this study are: literature values, CT scan values, and then 3D printed model values. An ANOVA test will be used specifically to analyze the anatomical accuracy and mechanical properties test.

## VII. Discussion

Discussion will be written once results have been collected.

**Conclusions**

The guidelines established above will be used to create an equine laryngeal model that will allow for vocal fold replaceability while maintaining the established equine properties. The design chosen will have replaceable laryngeal disks that when inserted, will line up with the static larynx and complete the model's surgical pathway. The product will be tested for its ability to replicate equine anatomy, uphold equine mechanical properties, and have ease of fabrication and replacement. Results will be analyzed to adjust the design for optimal efficiency. Moving forward, the team will begin the prototyping and purchasing stages of the design process, before moving to the testing phase.

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## IX. Appendix

**Appendix A:** Product Design Specification

**Function:** The function of the upper airway is crucial to the athletic ability of horses. However, 1 in every 24 horses experiences hemorrhage from the vocal cord site [1]. This condition calls for laser ventriculocordectomy, a common upper airway surgery performed on horses. As of 2020, according to the AAVMC report, there are 14000 total vet students enrolled in vet schools [2]. However, only one or two cadavers are used per year for vet school to learn about equine upper airway procedures [3]. A model must be designed that accurately mimics the anatomy of the equine upper airway for veterinary residents to practice. The device should contain a replaceable vocal fold that will be replaced after every practice procedure. This model can address the lack of cadavers and can provide veterinary surgical residents with more practice for equine upper airway surgeries.

**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 replaceable part will include the two vocal folds of the larynx which will be replaced per laser ventriculocordectomy surgery.
  - All other aspects of the model will be static and will last at least 24 surgeries for one semester
- The materials should be as close in texture and strength as possible to the vocal cords, cartilage, and tissues of a live horse.
  - View the mechanical properties table and dimension table for more information
- 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 the true anatomical size of an adult horse. The model must consist of reusable parts and replaceable parts. Specifically, the replaceable part will be the vocal fold and all other anatomical parts will be static. The portions that will be replaceable are the vocal folds. These replaceable parts must reflect the 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*****:** The model should not produce toxic products when interacting with the diode 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's larynx and throat. The exact dimensions will be taken for a CT scan of a 4-year-old horse to make sure that our error is less than 5%. 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 [4]. The strength of the vocal folds will need to be able to be cut by this same laser. Refer mechanical properties table, in section j, for specific measurements and error approximations that the model will adhere to.

**d.** ***Life in Service*****:** The static part of the model should be able to last one semester or 10 years. The replaceable parts in total should be able to last at least 14 surgeries per semester. 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 [5]. 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, the model may also be in storage. So the average operating temperature would be around 20 ºC and the average humidity would be around 30% - 50%.

**g.** ***Ergonomics*****:** This model should not weigh more than 15 pounds so that it is easily transportable to different learning environments. The product should not have any sharp edges and should allow for comfortable surgical positioning [6]. 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 [7]. 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 7.62 centimeters in diameter [8].The model will mimic the realistic dimensions of a horse with a 63.5 cm nose circumference, 25.4 cm cheek, and 114.3 cm head measurement [9][10]. These measurements will be crossed and evaluated with our CT scans provided by Dr. Le. If the CT scan dimensions are close to the literature values found, our team will move forward using the CT scan dimensions.

| Anatomical Feature for a mature horse (4-6 years of age) | Dimensions |
|---|---|
| Trachea | 5.5cm diameter, 70 cm length |
| Larynx | 7.62 centimeters in diameter, height around 5.87 cm |
| Nose | 63.5 cm (circumference) |
| Head | 114.3 cm (circumference ) |
| Distance from cheek to the back of jaw bones | 25.4 cm |
| Nostril | 1.9 cm in width |

*Table 1. Approximate dimensions of anatomical features of the equine head to the back of the larynx. [11] [12] [13] [14]*

**i.** ***Weight*****:** A live adult horse's head weighs approximately 18 kg [15]. 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 [16]. The removable component will be a 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 [17]. Cartilage can be replicated using a polymer made of nylon in powder form such as polyamide [17].

| Anatomical features | Young's Modulus | Yield Stress | Ultimate Strength | Error Approximations |
|---|---|---|---|---|
| Equine laryngeal cartilage | 0.42 ~ 2.51 MPa | x | 9.1 MPa | 5% error |
| Bone | 16 GPa | 110 MPa | 226 MPa | 10% error |
| Muscle | 1186 KPa | x | x | 10% error |

*Table 2. Mechanical properties of equine laryngeal cartilage, bone, and muscle.* [18][19][20]

Since the bones and muscles will remain static in the model, the error for the model will be at 10%. On the other hand, since the equine larynx is the primary target for the surgical residents to practice the procedure, the design must remain anatomically accurate to the native tissue, thus having a smaller 5% error.

**k.** ***Aesthetics, Appearance, and Finish*****:** The aesthetic of this model should give the same look and feel as 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 where the model will be used up to two times a month by three students each. Therefore the client has requested 24 sets of replaceable parts.

**b.** ***Target Product Cost*****:** The target product cost for this device is $1000. It will be paid for via UW School of Veterinary Medicine Departmental teaching funds.

## 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 devices. Regarding the equine laryngeal model, this standard specifies that for a technical support device, it must consistently meet customer and applicable regulatory requirements [21]. 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 [22]. In regards to the model being cut with a laser, the model and laser must follow IEC-60825 which provides requirements and specific guidelines for safe operations and maintenance while cutting various materials with a laser [23]. Lastly, The model would also need to follow the FDA's Code of Federal Regulations Title 21, Volume 8 which outlines the requirements for anatomical model devices [24].

**b.** ***Customer*****:** The client, Dr. Kayla Le, is a graduate professor for the Department of Surgical Sciences in the School of Veterinary Medicine at the 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 among 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. Additionally, 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. This model is for training surgical residents and gives them a chance to perfect a Transendoscopic Laser Ventriculocordectomy so that when they go into the veterinary field, their procedural success rate will be as high or higher than the average rate of 63% [1]. Therefore if the model is beyond a 5% error in the dimensions or the materials don't withstand the proper mechanical properties, that can lead to improper training.

***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 complications occur. The current purchase price of a SynDaver Canine would be $28,500 and every time the model needs to be refurbished costs $3500 [25].

**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 [26].

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**Appendix B:** Flexible 80A Materials Property Data [1]

## Flexible 80A Resin Material Properties Data

| | METRIC[1] | | IMPERIAL[1] | | METHOD |
|---|---|---|---|---|---|
| | Green | Post-Cured[2] | Green | Post-Cured[2] | |
| **Mechanical Properties** | | | | | |
| Ultimate Tensile Strength[3] | 3.7 MPa | 8.9 MPa | 539 psi | 1290 psi | ASTM D 412-06 (A) |
| Stress at 50% Elongation | 1.5 MPa | 3.1 MPa | 218 psi | 433 psi | ASTM D 412-06 (A) |
| Stress at 100% Elongation | 3.5 MPa | 6.3 MPa | 510 psi | 909 psi | ASTM D 412-06 (A) |
| Elongation at Break | 100% | 120% | 100% | 120% | ASTM D 412-06 (A) |
| Shore Hardness | 70A | 80 A | 70A | 80 A | ASTM 2240 |
| Compression Set (23 °C for 22 hours) | Not Tested | 3% | Not Tested | 3% | ASTM D 624-00 |
| Compression Set (70 °C for 22 hours) | Not Tested | 5% | Not Tested | 5% | ASTM D 395-03 (B) |
| Tear Strength[4] | 11 kN/m | 24 kN/m | 61 lbf/in | 137 lbf/in | ASTM D 395-03 (B) |
| Ross Flex Fatigue at 23 °C | Not Tested | >200,000 cycles | Not Tested | >200,000 cycles | ASTM D1052, (notched), 60° bending, 100 cycles/minute |
| Ross Flex Fatigue at -10 °C | Not Tested | >50,000 cycles | Not Tested | >50,000 cycles | ASTM D1052, (notched), 60° bending, 100 cycles/minute |
| Bayshore Resilience | Not Tested | 28% | Not Tested | 28% | ASTM D2632 |
| **Thermal Properties** | | | | | |
| Glass transition temperature (Tg) | Not Tested | 27 °C | Not Tested | 27 °C | DMA |

[1] Material properties can vary with part geometry, print orientation, print settings and temperature.

[2] Data was obtained from parts printed using Form 3, 100 µm, Flexible 80A settings, washed in Form Wash for 10 minutes and postcured with Form Cure at 60 °C for 10 minutes.

[3] Tensile testing was performed after 3+ hours at 23 °C, using a Die C specimen cut from sheets.

[4] Tear testing was performed after 3+ hours at 23 °C, using a Die C tear specimen directly printed.

## Solvent Compatibility

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

| Solvent | 24 Hour Weight Gain (%) | Solvent | 24 Hour Weight Gain (%) |
|---|---|---|---|
| Acetic Acid, 5 % | 0.9 | Hydrogen Peroxide (3 %) | 0.7 |
| Acetone | 37.4 | Isooctane (aka gasoline) | 1.6 |
| Isopropyl Alcohol | 11.7 | Mineral Oil, light | 0.1 |
| Bleach, ~5 % NaOCl | 0.6 | Mineral Oil, heavy | <0.1 |
| Butyl Acetate | 51.4 | Salt Water (3.5 % NaCl) | 0.5 |
| Diesel | 2.3 | Sodium hydroxide (0.025 %, pH = 10) | 0.6 |
| Diethyl glycol monomethyl ether | 19.3 | Water | 0.7 |
| Hydrolic Oil | 1.0 | Xylene | 64.1 |
| Skydrol 5 | 10.7 | Strong Acid (HCl Conc) | 28.6 |
| Tripropylene Glycol Methyl Ether | 13.6 | | |

[1] “Flexible 80A Resin,” Formlabs. https://formlabs.com/store/flexible-80a-resin/ (accessed Oct. 12, 2022).

**Appendix C:** BioMed White Resin Materials Property Data [1]

MATERIAL PROPERTIES DATA — **BioMed White Resin**

| | METRIC [1] | IMPERIAL [1] | METHOD |
|---|---|---|---|
| | Post-Cured [2] | Post-Cured [2] | |
| **Tensile Properties** | | | |
| Ultimate Tensile Strength | 45.78 MPa | 6640 psi | ASTM D 638-14 (Type IV) |
| Young's Modulus | 2020.16 MPa | 293 ksi | ASTM D 638-14 (Type IV) |
| Elongation | 10% | 10% | ASTM D 638-14 (Type IV) |
| **Flexural Properties** | | | |
| Flexural Stress at 5% Strain | 74.46 MPa | 10800 psi | ASTM D 790-15 (Procedure B) |
| Flexural Modulus | 2020.16 MPa | 293 ksi | ASTM D 790-15 (Procedure B) |
| **Hardness Properties** | | | |
| Hardness Shore D | 80 D | - | ASTM D2240-15 (Type D) |
| **Impact Properties** | | | |
| Notched IZOD | 15.11 J/m | 0.283 ft-lbf/in | ASTM D 256-10 (Method A) |
| Unnotched IZOD | 269.03 J/m | 5.04 ft-lbf/in | ASTM D 4812-11 |
| **Thermal Properties** | | | |
| Heat Deflection Temp. @ 1.8 MPa | 52.4 °C | - | ASTM D 648-18 (Method B) |
| Heat Deflection Temp. @ 0.45 MPa | 67.0 °C | - | ASTM D 648-18 (Method B) |
| Coefficient of Thermal Expansion | 90.1 μm/m/°C | - | ASTM E 831-13 |
| **Other Properties** | | | |
| Water Absorption | 0.40 wt% | - | ASTM D570-98 |

| Sterilization Compatibility | |
|---|---|
| E-beam | 35 kGy E-beam radiation |
| Ethylene Oxide | 100% Ethylene oxide at 55 °C for 180 minutes |
| Gamma | 29.4 - 31.2 kGy gamma radiation |
| Steam Sterilization | Autoclave at 134°C for 20 minutes<br>Autoclave at 121°C for 30 minutes |

For more details on sterilization compatibilities, visit formlabs.com/medical

| Disinfection Compatibility | |
|---|---|
| Chemical Disinfection | 70% Isopropyl Alcohol for 5 minutes |

Samples printed with BioMed White Resin have been evaluated in accordance with the following biocompatibility endpoints:

| ISO Standard | Description [3] |
|---|---|
| ISO 10993-5:2009 | Not cytotoxic |
| ISO 10993-10:2010/(R)2014 | Not an irritant |
| ISO 10993-10:2010/(R)2014 | Not a sensitizer |
| ISO 10993-11: 2017 | No evidence of acute systemic toxicity |
| ISO 10993-11: 2017/ USP, General Chapter <151>, Pyrogen Test | Non-pyrogenic |

The product was developed and is in compliance with the following ISO Standards:

| ISO Standard | Description |
|---|---|
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |

[1] Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.

[2] Data were measured on post-cured samples printed on a Form3B with 100um BioMed White Resin settings, washed in a Form Wash for 5 minutes in 99% Isopropyl Alcohol, and post-cured at 60°C, 60 minutes in a Form Cure.

[3] BioMed White Resin was tested at NAMSA World Headquarters, OH, USA.

[1] "BioMed White Resin," Formlabs. https://formlabs.com/store/materials/biomed-white-resin/ (accessed Oct. 12, 2022).