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VetMed: Affordable Muzzle to Assist in Mandibular Fracture Repair in Dogs

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BME 200/300: Biomedical Engineering Design

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Abstract:

A common injury seen in canines is the fracture of the mandible. Currently, there are several different techniques used to treat these fractures, both invasive and non-invasive. The standard non-invasive method of treatment is a tape muzzle that helps to stabilize the fracture up to and after surgery. These muzzles however can cause further displacement of the fracture site due to the pivot point it generates. The surgery that follows is typically costly and most patient owners can not afford this course of treatment. One solution to promote proper healing and eliminate the costs of surgery would be to create a nylon muzzle that provides adequate support and evenly distributes the bite forces in the jaw to aid in proper healing and, in some cases, eliminate the need for surgery. Our client, Dr. Thatcher, would like our team to design a nylon muzzle with these properties using principles of cantilever and suspension bridge mechanics. It then needs to be quantitatively proven, through finite element analysis, that the nylon muzzle is superior to the tape muzzle. After extensive research, the team developed three designs that would meet the design requirements specified by our client. These designs were then evaluated using a design matrix against criteria that the team thought was most important. It was determined that the design we will focus on moving forward is the mesh design. Using this design, we will create a model in SolidWorks and carry out finite element analysis to determine where the stress concentrations are distributed. These calculations will allow us to numerically prove the effectiveness of the nylon muzzle over the tape muzzle for canine mandibular fracture repair.

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1. Introduction

1.1: Motivation, Global and/or Societal Impact

Mandibular fractures in canines are a costly injury that have many forms of non invasive and invasive treatment. These fractures are common and make up 1.5 to 3 percent of all fractures in canines [1]. With the current treatment options, oftentimes surgeons and several anesthetic events are required in order to heal the fracture. These surgeries can range anywhere from 1000 to 2000 dollars and in certain cases pet owners cannot afford to have their animal undergo surgery [2]. This can be detrimental to the canine leading either to improper fracture healing or in some cases euthanization.

Treatment options include internal fixation and wiring combined with a tape muzzle to stabilize the fracture. Currently, tape muzzles are the standard non invasive treatment for mandibular fracture repairs in canines. Their main purpose is to stabilize the fracture up to and after surgery, but because of the placement, tape muzzles have been known to cause a pivot point around the fracture site that can lead to further displacement of the fracture. Nylon muzzles on the other hand can provide an alternative to surgery or provide greater stability before and after surgery by distributing the bite forces of a canine mandible more evenly than that of a tape muzzle.

Our client, Dr. Thatcher, believes that nylon muzzles are the superior treatment option for mandibular fracture repairs in canines. By quantitatively proving that nylon muzzles more evenly distribute the bite forces in the jaw, costly surgeries can be eliminated and improvement in the stabilization through these nylon muzzles can become the standard treatment ultimately saving and improving the quality of the dogs life.

1.2: Existing Devices/Current Methods

The standard treatment for a mandibular fracture in canines is the tape muzzle. This method is meant to stabilize the fracture up to and after surgery by wrapping around the snout. The typical placement of this stabilizing device has the tape sitting directly over the fracture site with a gap of 0.5 cm to 1 cm between the top and bottom jaw [1].

There are commercial nylon muzzles on the market, most of them being for recreational use and are not meant to be used to treat fractures. There are thousands of patents for these commercial muzzles, most of them aimed to improve the comfort for the dog. One particular patent, number 5299531 aims to improve the breathability while ensuring the stability of the

muzzle is not compromised [3]. While another patent, number US D659,303 S , has a more rigid body in order to improve the security of the muzzle [4]. These muzzles do provide more stability throughout the entire jaw, however further research is needed in order to ensure the support offered by these muzzles is adequate to treat mandibular fractures.

Tape muzzles, which are the most widely used treatment option, create a pivot that can cause further displacement. Commercial muzzles, while they are useful in restraining canines, are not fit to be used in a medical setting. By looking at these factors there is a clear gap in treatment options leaving the opportunity for our team to develop a nylon muzzle that is suitable for medical treatments.

1.3: Problem Statement

In veterinary medicine there is a gap in treatment options for mandibular fracture repairs in canines. The current treatments available require costly surgeries and the tape muzzles that are used to stabilize the fracture up to and after surgery can displace the fracture further. In order to reduce costs and improve the quality of care, our client would like the team to design an improvement upon nylon muzzles using principles of cantilever and suspension bridge construction that can be used as an alternative to the standard treatment options. Using finite element analysis, the team will compare the stress that the improved nylon muzzle places on the fracture site compared to the standard tape muzzle. The muzzle must be able to withstand bite forces of 620.33-1,091.1 N and evenly distribute those forces throughout the jaw [5]. Through these tests the team must quantitatively prove that nylon muzzles are the superior treatment option when dealing with mandibular fracture repairs in canines.

2. Background

2.1: Background Research

2.1.1: Relevant Physiology and Biology

In canines, mandibular fractures make up approximately 90% of maxillofacial trauma injuries. These fractures most commonly occur at the mandibular carnassial tooth, also called the M1 tooth. The M1 tooth has the largest volume of any of the teeth, resulting in the largest force applied to the mandible during a bite [6]. Fracture under the M1 tooth can occur in two general patterns: favorable and unfavorable. Favorable patterns are characterized by the distal end of the

mandible lying above the fracture, and the fracture being under compression as the masseter contracts. An unfavorable fracture will result in the opposite direction, and the fracture will pull apart during a bite [G. Thatcher, personal communication, September 25, 2020]. A cadaver mandible, with direction of force by the masseter, and types of fracture patterns can be seen in Figure 1.

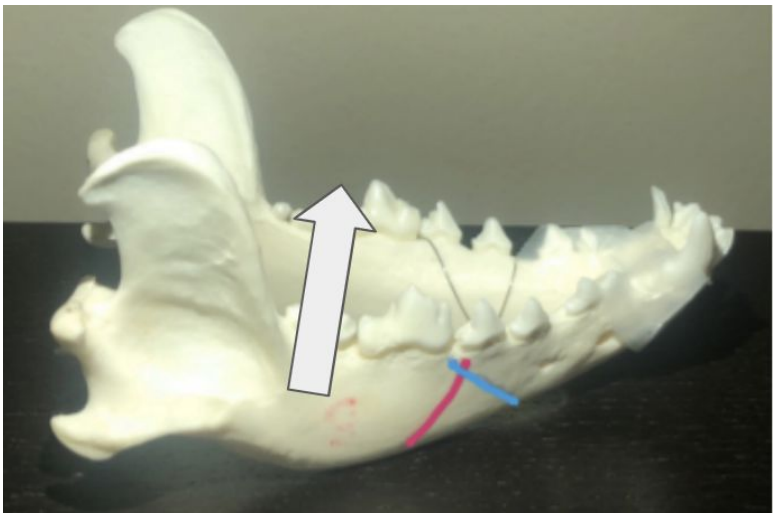

Figure 1: Canine mandible, with favorable fracture pattern in Blue, and unfavorable pattern in Pink.

Bite forces at the carnassial tooth, found through finite element analysis, can range from 620.33-1,091.1 N. The bite force for the dogs can vary based on the size and skull shape of the dog. Bite force will increase as the size of the dog increases, and also increased in dolichocephalic skull shapes compared to brachycephalic [7].

2.1.2: Design Research

The current method to stabilize mandibular fractures before and after surgery is a tape muzzle. Our goal is to create an improvement from this method and provide quantitative evidence to support a new design. The tape muzzle has been taught to veterinary students, without their effectiveness in supporting the fracture being studied. The tape muzzle, seen in Figure 2, only provides rigid structure directly under the fracture site. Lack of support throughout the entire mandible could create a pivot point at the fracture, resulting in displacement of the fracture, increased healing time, and pain. The muzzle should have a 0.5-1.0 cm gap for drinking water and eating soft food, and since these are made individually, there may be difficulty for the owner to achieve this range. They are also only single use, and must be replaced whenever they get dirty.

Figure 2: Tape muzzle design

There are also commercially available muzzles, created to limit barking or biting of dogs. These types of muzzles are designed to be put on and taken off easily, and provide greater range of contact under the mandible. Our design will be created for the purpose of increased support along the mandible. We have researched commercially available muzzles, and talked with our client, to determine requirements to implement, and created three initial designs to be evaluated.

2.2: Client Information

Our client, Dr. Graham Thatcher, is part of the Surgical Sciences at University of Wisconsin- Madison's School of Veterinary Medicine. In his experience, he has encountered many maxillofacial injuries in canines. He has expressed his displeasure with current teachings of the tape muzzle design and would like scientific evidence that shows other designs providing superior support for healing.

2.3: Design Specifications

Currently, the tape muzzle used in the treatment and recovery of mandibular fracture repair in dogs is insufficient in evenly distributing the forces applied by the masseter and biting throughout the mandible. Our alternative muzzle design must support the fractured mandible, while preventing stress concentration or displacement near the existing fracture site at the M1 tooth. A model must accompany the new muzzle design that validates a decrease in stress when compared to the existing tape muzzle options.

The main purpose of the design is to support and distribute the forces throughout most of the mandible's length, in contrast to the fulcrum point that is formed where the tape of the tape

muzzle is wrapped around the dog's jaw. Compressive forces of the jaw can reach up to 5000 N depending on size, breed, and location within the mouth [8], and the bite force of the M1 tooth ranges from 620.33-1,091.1 N [5]. The dog must be able to carry out necessary functions such as eating soft food, drinking water, and panting. A gap of 0.5 cm to 1.0 cm (1.5 cm max) is sufficient in allowing the dog to perform these actions. The design needs to account for common complications of muzzles including moist dermatitis, aspiration of food and hyperthermia due to possible impairment of panting [9]. The muzzle also must not disrupt blood flow to oral tissues, so the fracture can properly heal. The material used should be comfortable and minimize irritation to the dog's skin. The muzzle should be washable, so it is easy to clear away any build-up of dirt or bacteria that could lead to infection.

The design must support the jaw without loss of strength for at least 6 weeks when the jaw is stable. Canine dental fractures are reported to have functionally healed within as little as 2-3 weeks, with average healing time of 5.5 weeks [1]. Fractures often return to 90% of their original stiffness within 6-weeks [10], at which time the dog is able to resume normal activities without risking further damage to the mandible. The design should be able to accommodate dog's of different breeds, shapes, and sizes. It will be made in three different size variations (small, medium, and large), all of which will feature a breathable, lightweight, adjustable strap to allow the muzzle to properly fit and support the jaws of many different dogs.

3. Preliminary Designs

3.1: Zipper Muzzle

The first design considered was a nylon sleeve featuring zippers along the sides of the mouth. (see Figure 3) It bears a great resemblance to many commercial nylon slip on muzzles, save for the added zippers. The zippers can open and allow more movement. There will also be a thin mesh layer underneath the zippers in order to add more support and prevent fur from catching on the zippers. (see Figure 3) If the muzzle is to be a long term treatment alternative to more expensive surgical procedures, the extra movement will allow convenient drinking and eating. The owner will not have to take off the muzzle in order for the dog to eat and drink.

The typical nylon sleeve muzzle's support has also been improved through the addition of sewn in battens. Due to the request of the client for further support in mandibular fractures, there will be 3D printed battens running laterally through the nylon, reminiscent of the battens in a corset or sail. To aid in comfort and prevent wearing on the dogs skin, the team has considered padding the areas with foam. However, that may lead to a possible breathability issue.

The main material of this muzzle will be nylon due to its relatively strong and elastic fibers. Nylon would be able to withstand abrasions and more force than other synthetic materials such as polyester. [11] Though the nylon does have less moisture-wicking capabilities, it is washable.

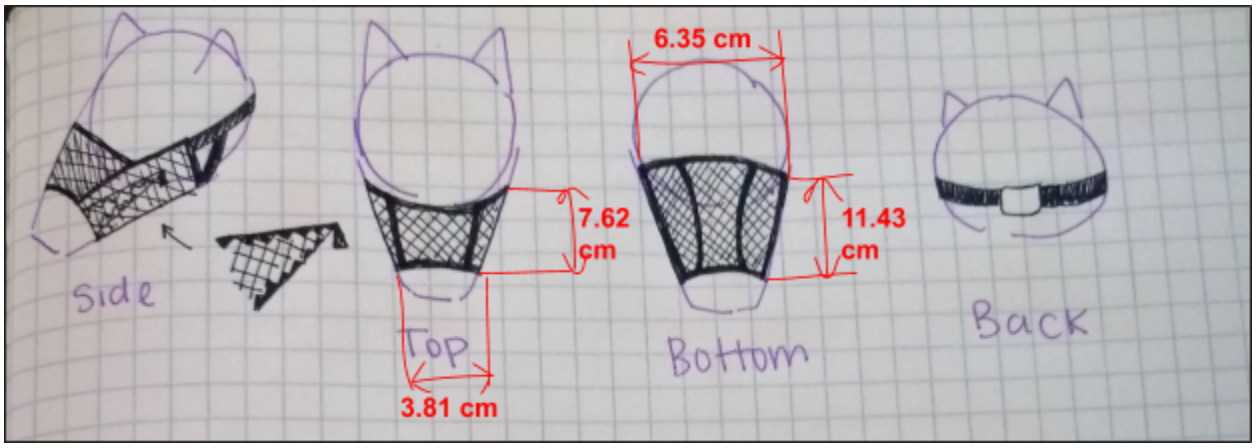

Figure 3: Preliminary zipper muzzle design. Views from left to right: side, top, bottom, and back. Measurements are based on mandible provided by the client.

3.2: Mesh and Nylon Muzzle

The second design combining mesh and nylon materials is the second design the team considered. There will be two main panels of material; a reinforced nylon bottom panel and mesh top panel. The nylon piece will be laterally reinforced with batten supports running through the fabric. The mesh panel will be stitched to nylon straps. If possible, the nylon straps would have flexible battens also running through for added support. There will be an overhead strap which buckles to the back of the head. (see Figure 4) The size of the muzzle will vary with dog skull sizes though the maximum circumference will be no more than 12 inches; 30.48 cm. The muzzle is designed primarily for the use of long snouted dogs such as a labrador and are unsuitable for flat-nosed dogs.

The mesh's primary function is to allow better breathability for the dog. It will allow proper ventilation and prevent any build up underneath the muzzle that may lead to infections. The extra ventilation will also help counteract nylon's poor moisture wicking. The bite force of a dog is majorly affected by body weight and skull size. There is a lesser effect due to oral pain as well [12].Thus as the dog heals and there is less oral pain due to the fracture, the mesh may not hold up to the forces. The nylon straps will help in supporting the muzzle even if the mesh were to rip. Further testing in SolidWorks will be needed in order to find the failure point of the mesh and nylon straps.

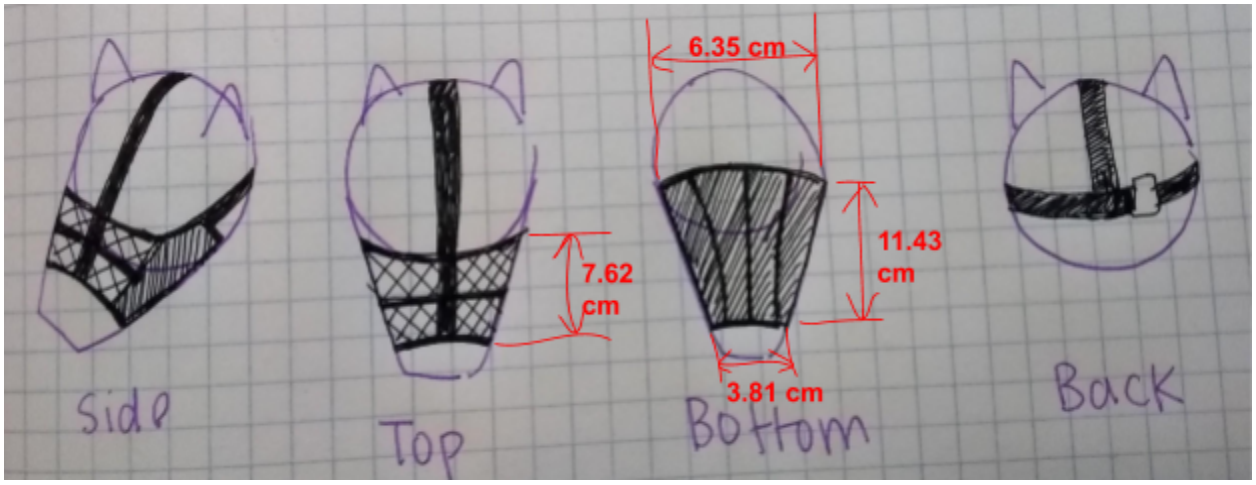

Figure 4: Preliminary mesh muzzle design. View from left to right: side, top, bottom,and back. Measurements are based mandible provided by the client.

3.3: Molar Muzzle

The third design was the Molar Muzzle. There would be an over the top of the head stap oriented horizontally between the ears and the eyes, with a batten reinforced underside and single straps over the muzzle and behind the back of the head with a buckle. The underside of the muzzle would have significant gaps in its structure near the areas of where the molar fracture site would be, enabling this design to disperse the force evenly throughout the rest of the muzzle while avoiding force directly on the fracture site. There would be three distinct sizes of the muzzle, with the largest not being greater than 12 inches, 30.48 cm in diameter.

The nylon used has an increased strength over that of tape, while also offering a greater ability to be adjusted. The over the top straps will stabilize both the mandible and the muzzle on the canine patient, which is further reinforced by the behind the skull buckle strap. The battens located on the underside of the muzzle will help to disperse the force evenly throughout the mandible bar the molar areas of the mandible. The thought process behind this was that if there was a fracture in that position, it would be wise to avoid putting significant force directly onto it. However, we would later come to find out that this thought process would only aid in unfavorable fractures, while potentially being useless or causing side effects in a favorable fracture situation.

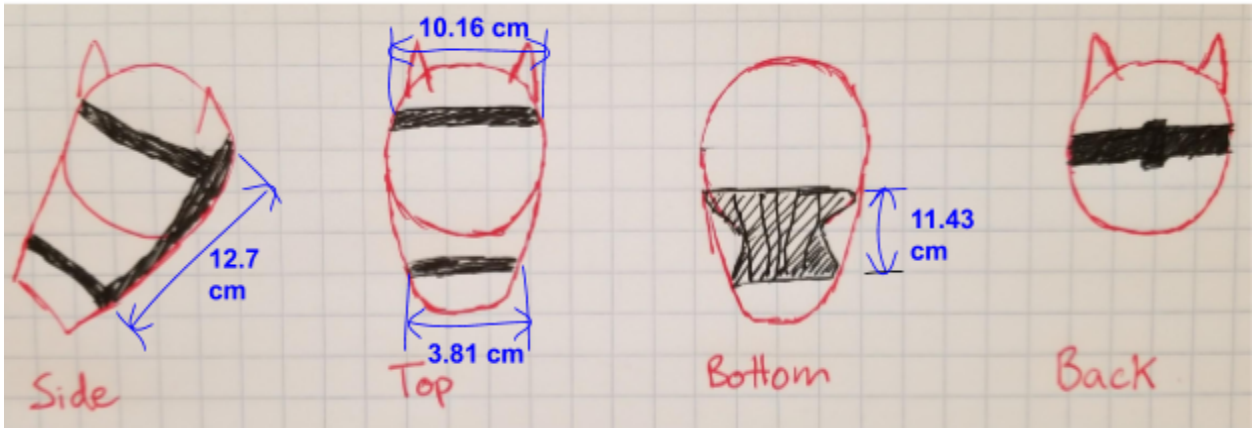

Figure 5: Preliminary molar muzzle design. Views from left to right: side, top, bottom, and back. Measurements are based on mandible provided by the client.

4. Preliminary Design Evaluation

4.1: Design Matrix

Designs Criteria (*weight)	Design One Zipper		Design Two Molar		Design Three Mesh		Existing Design Tape	
Safety (25)	9/10	22.5	4/10	10	9/10	22.5	3/10	7.5
Support (25)	8/10	20	6/10	15	8/10	20	0/10	0
Ergonomics (15)	7/10	10.5	5/10	7.5	8/10	12	1/10	1.5
Size (15)	8/10	12	6/10	9	7/10	10.5	5/10	7.5
Material (10)	9/10	9	9/10	9	9/10	9	2/10	2
Cost (5)	6/10	3	8/10	4	8/10	4	10/10	5
Usability (5)	8/10	4	5/10	2.5	7/10	3.5	3/10	1.5
Total (100)	**81**		**57**		**81.5**		**23.5**	

*Note: When referring to weight it is always *x/100*

Figure 6: Design matrix comparing the three designs

Our design criterion weighed our three designs against the current tape muzzle. Safety and Support are the most important to the construction of our product. Safety is a major concern as it takes into consideration the inherent ability for the canine to be able to actually drink water and eat food in order to survive. Alongside this, factors such as not restricting blood flow to the mandible or the rest of the head and the ability to be machine washed as to aid in the prevention of bacterial growth in the space between fur and muzzle. The zipper design and the mesh design

ranked the highest out of the three due to both of these designs including some type of nylon mesh that would reduce contact surfaces while remaining highly adjustable for the canine. The molar design is still inherently safe, but did not rank as high as a result of full pieces of nylon being used rather than mesh. Tape was ranked poorest out of all designs, since it often has problems with infection and is not adjustable so improper implementation can have harsh side effects.

Support was weighed on account of the ability of the muzzle to offer full and proper support of relevant force throughout the mandible, limiting side effects as much as possible. Once again, the Zipper and Mesh designs ranked highest in our criterion, offering relatively equal support between the two of them. The molar design, while initially ranking higher, was ranked lower than both of the other two new designs. This is due to some input that we received from our client, in that if the fracture is at a "favorable" angle, the design to distribute the forces elsewhere might actually end up hindering the healing of the fracture site. Simultaneously, if the fracture is at an "unfavorable" angle, this design likely offers superior support than that seen in a standard muzzle. The tape offers relatively low if any support throughout the mandible and therefore received a zero.

Next in our criterion was Ergonomics, which takes into account the ability for the muzzle to be adjustable, breathable, and lightweight while taking into account support, comfort, and range of motion. The mesh design won out this criteria due to its focus on the nylon mesh, which would be far more breathable for the canine than any of the other 3 designs. The zipper design was ranked second since it also included some mesh details, but is primarily covered by the zipper. The molar design, having neither mesh nor zipper came in third, since it still offered support, comfort, and range of motion, but was likely not as breathable as the other two designs or as lightweight. The tape, since it offers no adjustability prevents almost all movement of the jaw in the patient and therefore scored the lowest on ergonomics.

Size of the muzzle was ranked equal in importance to ergonomics, and takes into account that the muzzle should not be oversized, remain flush to the surface it is on, and also should not have any major components sticking a significant distance off of the canine's skull, while also including adaptability, The zipper design accumulated the most points as it is the only design to offer not only adjustability in the back, but also adjustability in the front as well. The mesh design then ranked since it is flush with much less material used than the molar design, which was ranked below the mesh design. The tape muzzle, while being the smallest and closest to the canine out of all the designs, was downgraded for not taking adaptability into consideration.

We then weighed material as the next most important aspect. Materials should be non-toxic as well as non-abrasive, avoid metals as they are typically heavier and more rigid, and allow airflow for breathing and prevention of overheating. Since all three designs are going to be made of nylon, all ranked the same, although some designs will feature metal aspects such as a zipper, these are not vital parts of construction and do not weigh very heavily into consideration for this aspect of our criterion. Yet again, the tape was ranked the lowest since it neither allows for airflow and can be abrasive.

At a low weight we then placed cost, since essentially all the materials we will be using are relatively inexpensive. With this accounted for, tape is obviously the cheapest option, with the molar and mesh designs then coming in second. The zipper design, due to its inclusion of a zipper, makes it the most expensive design that is featured and therefore caused it to be ranked the lowest.

Tied with cost was usability, also known as the ability for the product to be used by the owner of the canine patient. The design should not be overly difficult to get off or put on, nor should the adjustability of it be over complex, while remaining relatively easy to clean. The Zipper design was ranked the highest since the zipper would make it the easiest to get on and off of the canine. Then, the mesh design that features the vertically aligned over the head strap. The molar design was ranked the lowest since its horizontal head strap would likely cause trouble for the owner to put on. Tape was yet again ranked the lowest as it is not easy to put on.

4.2: Proposed Final Design

Our proposed final design is the Mesh design. With that said however, it is not yet clear at the moment whether or not we will choose to also implement the zipper design into the final product since it also ranked so highly within our criterion. It ranked highest in 4 separate criterion categories while the zipper ranked highest in 5, only beating it out by .5 points after weighting. Accordingly, we are highly considering a combination of the two designs.

5. Discussion

Based on the weight criteria and overall results of the design matrix, the team has decided to focus on the mesh muzzle design. Proper ventilation over long term use was a key point that this design addressed. However, the close rankings indicate possible combinations of key features of the zipper and mesh designs. For example, the extra mobility granted by the use of the zipper will be convenient to the owner. Though the mesh design aims to improve the

ventilation capabilities of conventional nylon muzzles, that may lead to a support issue. Therefore, further research and testing into the material properties of mesh will be done within SolidWorks. Finite element analysis will be utilized to image the distribution of forces that the mandible will experience using the proposed mesh design. The team will also analyze the tape muzzle and its pivot point as well. If the results prove that nylon muzzles distribute the forces more evenly than tape muzzles, nylon muzzles can be reliably used to stabilize and treat mandibular fractures. The nylon muzzle can then be an alternative treatment to more expensive surgical procedures and conventional tape muzzles.

6. Conclusions

Canine mandibular fractures are a frequent occurrence, and many veterinary professionals, like Dr. Thatcher, recognize there is a lack of treatment options. Apart from the expensive surgeries, tape muzzles are currently being utilized to stabilize the jaw; however, this method can displace the jaw further. Our client would like us to design an alternative, affordable nylon muzzle that uses cantilever and suspension bridge construction to improve the treatment process. With SolidWorks and finite element analysis, the team must quantitatively prove the effectiveness of the nylon muzzle over the tape muzzle. To create this device, the team researched the anatomy behind the fracture, the types of muzzles already available, and the mechanics associated with cantilevers and suspension bridges. Based on these mechanics, the team proposed three preliminary designs which were evaluated using the weighted criteria in our design matrix. The Mesh and Nylon design is our final proposed idea. It contains elastic material, specifically, mesh and nylon fabrics along with reinforcing battens. The main purpose of this design is to improve breathability and support surrounding the fracture site. A zipper may be incorporated to increase mobility and usability. Previously, Dr. Thatcher provided us with a cadaver of a mandible from a medium sized dog with the location of an M1 favorable and unfavorable fracture [G. Thatcher personal communication, September 25, 2020]. Our goal in the coming weeks is to accurately replicate the jaw in SolidWorks and conduct finite element analysis on the mandible to locate the concentration of the typical bite force. Upon completion of our muzzle design, we aim to use SolidWorks to build a prototype with the correct dimensions to fit the cadaver mandible. This should be a testable model of our muzzle design and must evenly distribute the forces produced by a canine bite.

When the SolidWorks model is completed, we will put the appropriate constraints resulting from the muzzle support onto the mandible. Finite element analysis will be carried out

once again in order to determine the difference in stress concentrations and see if our muzzle design reduces the pressure near the fracture site in order to aid in healing without displacing the jaw further.

These calculations will help us prove beyond anecdotal evidence provided from Dr. Thatcher and other professionals that a reinforced nylon muzzle would assist in healing the fractured mandible more effectively than the tape muzzle.

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8. Appendix

8.1: PDS

VetMed: Affordable Muzzle to Assist in Mandibular Fracture Repair in Dogs- BME 300/200

Product Design Specifications

September 18, 2020

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Function: Our client is seeking an improvement in current muzzle techniques during pre- and post-surgery stages for mandibular fracture repair in dogs. The muzzle could also be used as a cheaper alternative to the surgery. Canine mandibular fractures most commonly occur at the M1 tooth, as a result of the large volume of the tooth compared to mandible [1]. Existing methods of repair require surgeons and several anesthetic events, resulting in a high-cost to the patient owner. A suggested way to relieve pain before and after surgery, and a possible cheaper solution, is using a muzzle to support the mandible. The bite force of this tooth ranges from 620.33-1,091.1 N [2], and displaces that force into the jaw. The team is tasked with designing and validating a muzzle that evenly distributes the bite force applied to the mandible away from the fracture site, without completely restricting movement.

Client requirements: The client is expecting the following:

- The muzzle to evenly distribute force throughout the mandible that is applied by the masseter and biting.
- Must properly support the fractured mandible.
- Prevent stress concentrations or displacement near the existing fracture site at the M1 tooth.
- Create a small, medium, and large size, and be adjustable to fit dogs between sizes.
- A model to validate a decrease in stress compared to existing taped muzzle options.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:*

- The muzzle is designed to be used in the treatment and recovery of the mandibular fracture repair of dogs. It will support the mandible by distributing the force throughout the mandible, allowing it to properly heal, and it will limit the motion of the jaw. Compressive forces of the jaw can reach up to 5000 N depending on size, breed, and location within the mouth [3]. A nylon or canvas muzzle provides support and distributes force through most of the mandible's length, whereas a tape muzzle has a fulcrum point where the tape is wrapped around the dog's jaw.
- We will be testing and comparing the nylon muzzle vs. the tape muzzle in its ability to support the mandible and how the stress is distributed on the mandible.

b. *Safety:*

- The dog must be able to eat soft food and drink water. A gap of 0.5 cm to 1.0 cm (1.5 cm max) usually accomplishes this.
- It must not disrupt the blood supply to the oral tissues.
- The muzzle's material should be comfortable and minimize irritation to the dog's skin.
- The muzzle should not limit the dog's ability to breathe or lightly pant as this is how dogs circulate the necessary air throughout their bodies to cool down.
- The muzzle should be washable, so it is easy to clear away any build-up of dirt or bacteria that could lead to infection.
- The device needs to account for common complications of muzzles including moist dermatitis, aspiration of food and hyperthermia due to possible impairment of panting[4].

c. *Accuracy and Reliability:*

- In order to validate the model, the team will perform mechanical strain testing on a canine cadaver mandible. The strain readings of the jaw must be within 5% of the results of the model.

d. *Life in Service:*

- The muzzle must support the jaw without loss of strength for at least 6 weeks when the jaw is stable. Canine dental fractures are reported to have functionally healed within as little as 2-3 weeks, with average healing time of 5.5 weeks [5]. Fractures often return to 90% of their original stiffness within 6-weeks [1]. The dog is then able to resume normal activities without risking further damage to the mandible.

e. *Shelf Life:*

- The muzzle has no specific shelf-life components as it will be stored in the dry, clean environment of a veterinary clinic before use.

f. *Operating Environment:*

- The muzzle will be exposed to the forces typically experienced by a canine mandible. These include but are not limited to biting, resting, and chewing.
- The material will be exposed to the typical fluids secreting from the canine mouth area for extended periods of time (duration of recovery of about 5-6 weeks).
- The muzzle may be exposed to dirt or dust a canine may encounter during everyday activities.

g. *Ergonomics:*

- The adjustable strap should be breathable and lightweight in order for the canine to perform daily needs such as eating, drinking, and panting. The muzzle should be tight yet comfortable, providing support and range of motion.

h. *Size:*

- 3 sizes will be produced, small, medium, and large, with standard snouts analogous to a [labrador]
- The product shall not exceed 12 inches in circumference for the largest muzzle size, 8 for medium, and 4 for small
- The product will be easily portable as a result of its small size and ability to be compacted flat
- The space available is the immediate area surrounding the head of the dog, with as little being taken up as possible with most pieces flat and flush to the dog
- Access for maintenance is not a primary concern, as the muzzle can be taken off easily for repair or adjustment, with possibility for adjustment while product is still on

i. *Weight:*

- The weight of the muzzle shall not exceed 1 pound (454g), and not weigh less than 2 oz (57g)
- An optimum weight for the product relies on the most efficient sustainability with the least weight possible.

j. *Materials:*

- Non-toxic and non-abrasive materials should be used in the product for the safety of the patient
- Metals should also be avoided when possible due to their tendency to have increased weight and rigidity in comparison to other materials

k. *Aesthetics, Appearance, and Finish:*

- The final product should be neutral in color, with a cylindrical shape that can be compacted flat for packaging/storage
- The texture will be as non-abrasive as possible with key areas specified as high sensitivity locations necessitating special attention.

2. Production Characteristics

a. *Quantity:*

- The project requires 1 prototype muzzle and 1small, 1 medium, and 1 large final design.

b. *Target Product Cost:*

- The team will have a budget of 200 dollars to create an adjustable and reinforced muzzle. Though this number is subject to change. The team will also have remote access to the Makerspace, to which we will pay a $50 materials fee. Commercially available muzzles for everyday use range from $10-20, though many lack adjustability and support to cradle a mandibular fracture. The muzzle will also act as a potential alternative treatment to high-cost mandibular surgeries, such as plating, which can range from $6,000-8,000.

3. Miscellaneous

a. Standards and Specifications: For veterinary medical devices, FDA approval is not required. However, veterinary devices are required to follow the guidelines stated in the Federal Food Drug and Cosmetic Act regarding misbranding, mislabeling and adulteration [6].

b. *Customer:* Customers prefer that the muzzle be user-friendly, meaning that it can easily be taken on and off without displacing the fracture further. An inevitable consequence of long term wear of the muzzle is a build up and dirt and bacteria. Providing multiple muzzles or an easy way to clean the muzzle needs to be considered. Another customer preference would be the ability to easily provide food and water while not compromising the integrity of the muzzle.

c. *Patient-related concerns:* A main concern for this product would be patient non compliance. Comfort, sizing and placement of the device are all areas of interest that would help reduce the patient's ability to fight the device. The muzzle must also be able to provide proper stability and alignment while allowing the patient to easily drink, eat and breathe [4].

d. *Competition:* Currently the primary form of non-invasive treatment for mandibular fracture in canines is a tape muzzle. This treatment has been standardized and is taught all over the world, however there are numerous fallbacks to this method. Secondary to tape muzzles are commercial nylon muzzles. Most nylon muzzles on the market are for everyday use.

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