

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

Product Design Specifications

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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 1 small, 1 medium, and 1 large final design.

b. *Target Product Cost:*

- The team will have a budget of \$500 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.

References

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