

**Team Vet: VetMed - 3D printed, patient specific incline plane for management of class 2 malocclusion – Improvement in design and workflow**

**Product Design Specifications**

**Team:**

**Ethan Frohna - BSAC**

**Parker Callender - Team Leader**

**Sanam Jhaveri - Communicator**

**Amy Cao - Co-BPAG**

**Sammie Gilarde - Co-BPAG**

**Justin Grudem - BWIG**

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**Function:**

Veterinary canine patients often experience Class II Malocclusions; A movement of the upper jaw that causes the bottom canine teeth to puncture and injure the roof of the mouth. The goal of this project is develop a smooth workflow through software that will assist with the creation of a lower jaw device to move the lower canines into a suitable position within the lower jaw.

**Client requirements (itemize what you have learned from the client about his / her needs):**

- Workflow must be simplified using software
- CT Scan must be configured into an stl file
- Device outcome should fit CT Scan
- Device needs to be moldable to other canine jaws based on CT Scan
- Device must be 3D printed
- Device must be held within canine jaw for 6-8 weeks
- Device must move canines lateral to upper jaw

**Design requirements:** This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

**1. Physical and Operational Characteristics**

**a. Performance requirements:** The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.

**The device will be placed on the maxillary palate of a dog with Class II Malocclusion with a goal to, over-time, guide the mandibular canines into their correct positions within the diastema of the 3rd maxillary incisor and maxillary canine. The device will be designed to fit the canine's mouth through use of DICOM files, stl files, and 3D Software. The device**

**will be used for 3-8 weeks on a 24/7 basis as it is secured to the canine's palate with 'dental glue'.**

b. Safety: Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.

**Material used should be nontoxic to dogs. The device should not break in the dog's mouth or cause breakage of the teeth. It should not move teeth that are in proper positions, or apply too much force to the moving teeth.**

c. Accuracy and Reliability: Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.

**The device will need to be an exact fit for the patient's mouth. This will require a CT scan to get an accurate image of the jaw structure. In addition, the software will need to be able to create a model of the device that will fit perfectly around the patient's teeth.**

d. Life in Service: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)

**The device will be attached to the patient's mouth for up to several weeks, as long as the treatment needs, which depends on the age of the dog, how far the maloccluded teeth need to be moved, etc.**

e. Shelf Life: Establish environmental conditions while in storage, shelf-life of components such as batteries, etc.

**The device will need to last 6-8 weeks while attached to the patient's mouth, but once removed the device will not need to be used again.**

f. Operating Environment: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.

**Incline Plane: The device will be attached to the patient's (dog) mouth 24 hours a day- 7 days a week so its operating environment involves the conditions of a normal day-to-day environment. The device should be able to withstand temperatures ranging from -20°F to 120°F to account for any extreme conditions the patient may experience. The average force of a bite from a dog is approximately 320 pounds so the device should be able to withstand forces ranging up to 400 pounds without fracturing, loosening from mouth, or cracking. The device should also not interfere with food consumption nor should it be affected by it. Food should easily pass by the device and not stick nor peel the device's material.**

**Interface: The software should be able to be utilized by a veterinary orthodontist. The interface should be compatible for most computers and easy to follow.**

g. Ergonomics: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc..

**The inclined plane of the device should be applied to the maxillary teeth. The device will come into contact with the mandibular canines when the mouth closes and apply passive force to direct the teeth away from the palate. The device should avoid contact with the mucosa. The slope of the incline plane will be 45-60 degrees.**

h. Size: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.

**The size of the product will be dependent on each patient and their mouth size and unique Class II Malocclusion. Maintenance could be a factor depending on the integrity of the incline plane. Removal of the incline plane may need to take place but cannot be out for more than 72 hours to avoid any reversal of tooth movement.**

i. Weight: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.

**The device should weigh no more than a few ounces to ensure it sits comfortably within the mouth and the canine has little awareness of its presence.**

j. Materials: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI machines).

**The device will be planted in a canine's mouth so the material used should not be toxic to the animal. The material also should erode or deteriorate over time due to water and food being passed by it.**

k. Aesthetics, Appearance, and Finish: Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).

**Aesthetics will not be considered, but the incline plane of the device should be smooth enough to not apply excessive friction to the tooth. Rough edges should be taken away.**

## 2. Production Characteristics

a. Quantity: number of units needed

**Production will be on a customer-need basis. 1 device per patient with condition.**

b. Target Product Cost: manufacturing costs; costs as compared to existing or like products

**The device will be 3D printed and the cost of printing will be dependent on the chosen material and each particular design.**

## 3. Miscellaneous

a. Standards and Specifications: international and /or national standards, etc. (e.g., Is FDA approval required?)

**An orthodontic brace that has the ability to reposition teeth is known as a Class I device, meaning it has low to moderate risk of injury.**

b. Customer: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.

**The client wants the device to be able to fit to any size canine who has a Class II malocclusion. The team should be using software to adjust a specific model of an incline plane to fit any sized lower jaw.**

c. Patient-related concerns: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be sterilized between uses?; Is there any storage of patient data which must be safeguarded for confidentiality?

**A new device will be created for each dog through a software developed by the team so sterilization will not be necessary. The patient (owner of the dog) should be given a rundown of what the device is and how it operates before being inserted into the mouth of the dog.**

d. Competition: Are there similar items which exist

**There exists a metal incline plane called a Mann incline plane.1,5. However, this method/device is very costly to the patient and intra treatment adjustments cannot be made to the device.**