



## VetMed: 3D Printed, Patient Specific Incline Plane

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PRELIMINARY PRODUCT DESIGN SPECIFICATIONS

*BME 200/300*

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**Client:**

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## **Function:**

Class II malocclusion is a common genetic skeletal deformity among a variety of animal breeds [1]. Specifically in canines, this type of mandibular distocclusion refers to the misalignment of the teeth; the canines lower jaw is shorter than the upper jaw[1]. This condition leads to destruction of the palate and gum tissue of the upper jaw. This negatively affects the canine's quality of life by inhibiting necessary instincts, such as eating and defense. The current design scope of our project is to further develop the current design, Dr. Thatcher's incline plane. In addition, to design a more efficient workflow, by understanding the software.

## **Client Requirements:**

- Incline plane device
- Device can be modified based on each specific patient based on their CT scan
- Device must be easy to create from CT scan using user friendly software
- Device must be placed in the patient's mouth
- Simplified Software Workflow

## **Design Requirements:**

### **Physical and Operational Characteristics:**

#### *A. Performance requirements:*

The goal of the incline plane is to slowly, over time guide the mandibular (lower) canines into the correct positioning. The incline plane will be positioned comfortably on the maxillary palate (upper jaw) in the canine's mouth for 6-8 weeks. It will need to withstand a bite force of the canine teeth ranging from 147-926 N [2]. In addition, the device will be interfaced with the chosen software and generated from patient specific DICOM and stl files.

#### *B. Safety:*

The incline plane should not impede the canine's wellbeing. The device should adjust to the mouth without causing sores and pain. The device also must be made of a non-toxic material, it must follow the standard, "ISO 13504" Dentistry requirements and related accessories used in dental implant placement and treatment[3]. The device should be strong enough to withstand the force of the dog's bite, for 6-8 weeks without breakage. The initial veterinary examination should follow the AAHA-AVMA canine preventive healthcare guidelines[4]. In addition, the following implant and implant materials should follow, "ISO 13504"

### *C. Accuracy and Reliability:*

The device will be patient specific in order to minimize error. To get an accurate, personalized fit, a CT scan is required to generate DICOM and stl files. Information from the DICOM files will be interfaced with the software to create a model that fits around the patient's teeth.

### *D. Life in Service:*

The inclined plane should last 6-8 weeks, depending on the circumstances of the malocclusion. The device will be placed on the maxillary arches, and therefore will need to last in the mouth of the patient for the stated amount of time.

### *E. Shelf Life:*

The inclined plane should be fit to last 6-8 weeks in the patient's mouth, however the plane needs to have a shelf life of up to 10 weeks to consider the time between manufacturing the device and putting the device into the mouth of the patient. After the correction cycle is complete, the device will not need to operate anymore as it is specific to one patient.

### *F. Operating Environment:*

The inclined plane will be worn 24 hours a day- 7 days a week and so the patient's day-to-day environment will be its operating conditions because the device will be attached to the patient's mouth. For temperatures the device will need to be able to withstand a range of -32°C to 50°C to accommodate extreme weather conditions the patient may encounter. The device will need to withstand bite forces of a dog bite that ranges from 147-926 N [3] so the device is not loosened from the mouth or isn't cracked or fractured. The device should not interfere with the patient's food consumption, so it should not have food stick to it or cause the device to peel off. The device should also withstand normal interactions with toys and other other objects. The software used should be accessible to the veterinary orthodontist to use. The software should also be easy to follow and can be used on most computers.

### *G. Ergonomics:*

The plane will be placed on the mandibular canines of the patient. When the patient closes their mouth, force from the mandibular canines will be applied to the inclined plane. Over time, this repeating motion combined with the angle of the inclined plane will slowly guide the canines into the desired position. The device should be non-intrusive to the rest of the patient's mouth with a height and size that is patient specific. The angle of the incline plane will be patient specific; it will be determined by the degree of distocclusion, size of teeth, and time needed for correction.

#### *H. Size:*

The size of the inclined plane will vary from patient to patient and therefore should be size adjustable to accommodate for each patient and the varying Class II Malocclusions. Maintenance should not be an issue, as the device is accurately modeled from a scan of the mouth and made to withstand forces of a canine's bite (147-926N). If breakage occurs or adjusting is necessary, the inclined plane can be removed for a maximum of 72 hours to avoid reversal of the canines.

#### *I. Weight:*

The inclined plane should weigh 6 ounces or less. This will ensure that the patient does not notice the device and is able to use it comfortably for 6-8 weeks. The optimum weight would be around 3-4 ounces, depending on the size of the patient.

#### *J. Material:*

Primarily the material used must be safe orally for the patient, while being available in 3D printing filament options. Current treatments use a self-curing temporary crown material (bisacryl composite)[2], however, the material for this treatment must be available as a 3D printer filament. Therefore, possible materials are Dental Resins equipped to be used as a filament.

#### *K. Aesthetics:*

Color is relatively unimportant for the functionality of our inclined plane, and therefore this aspect of aesthetics is not the focus of our design. The shape of the inclined plane will be that of a mold roughly the shape of the maxillary arches of the patient [2]. The devices will have 3 slots for the upper maxillary, upper canine, and upper incisor. Each inclined plate will be specified for each patient's mouth dimensions and malocclusion, and therefore will have different dimensions. As for texture the devices should be smooth to negate any lacerations and to maximize comfort for the patient.

### **Production Characteristics**

#### *A. Quantity:*

Units are designed specifically for each individual patient, so quantity depends on the number of patients with Class II Malocclusions. One device is used per patient.

#### *B. Target Product Cost:*

The cost of production will be based on the specific material used for 3D printing the incline plane as well as the size of it as each incline plane will vary from each patient.

### 3. Miscellaneous

*C. Standards and Specifications:*

The incline plane would go under the category of Orthodontic appliance and accessories, in which the device is affixed on a tooth so that pressure can be exerted on teeth for orthodontic treatment, which is a Class 1 classification. This means the incline plane is low to moderate risk of injury [5].

*D. Customer:*

The client would like an incline plane that would be able to fit on any size canine with Class 2 Malocclusion. This would be achieved by having software that can take scans of the mouth of the patient and create a specific incline plane that fits the patient.

*E. Patient-related concerns:*

For each individual patient, a scan will be taken through software, an incline plane will be created specifically for that patient, resulting in no need for sterilization between uses. Additionally, the owner of the patient will be explained how the incline plane is supposed to work to fix the Class 2 Malocclusion.

*F. Competition:*

There exists a patent for an orthodontic fixture intended for use with animals to correct lingually displaced canine teeth [6]. This device uses non-toxic metal which can be costly and difficult to manufacture. This product is also outdated and can be greatly improved.

## References:

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- [5] "CFR - code of federal Regulations Title 21," *accessdata.fda.gov*. [Online]. Available: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=872.5410>. [Accessed: 24-Sep-2021].
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