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VETMED: 3D PRINTED, PATIENT SPECIFIC INCLINE PLANE FOR MANAGEMENT OF CLASS 2 MALOCCLUSION – IMPROVEMENT IN DESIGN AND WORKFLOW

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Abstract

Class II malocclusions in dogs are often treated with orthodontic brace devices, called incline planes. incline planes move teeth through passive force using a slope, and can be created through several different methods. A common way of producing incline planes is to directly apply composite resin to the dog's maxillae and drill the slope into the material. Another design is made of cast metal and has a telescoping bridge to allow for growth of the patient's jaw. The method that the client, Dr. Graham Thatcher, used is a 3D printable incline plane that is constructed using scans of the patient's jaw. Problems exist with the current design and workflow of the 3D printed incline plane. The process requires many prototypes and the help of a software engineer to produce a device that will be used on the patient. The client has also requested a more adjustable, flexible design that can fit patients of different sizes and allow for growth over time. To improve the design of the incline plane, the team devised three potential alternative designs and evaluated them. The chosen design consists of two 3D printed pieces on each side of the mouth, allowing for growth of the maxillae, and decreasing risk of palatitis from the bridge piece. The team also evaluated different softwares that can be used to produce the 3D printable model of the incline plane. The Geomagic program was chosen for its compatibility with SolidWorks and ability to manipulate the model and convert different file types.

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I. Introduction

Problem Statement

In order to correct Class II Malocclusions in canine patients, client Dr. Graham Thatcher has produced a 3D printed patient-specific incline plane brace to be used on patients. The current process of creating a 3D printed incline plane starts with taking a CT scan of the patient's jaw. The data from the DICOM file is then used to produce the printable incline plane with the aid of a software engineer. The prototype incline plane would be placed and tested on a model of the patient's jaw then adjusted for the next prototype with the software engineer's help. This process is time-consuming and complex. In addition, the design of the current 3D printed incline plane does not allow for flexibility between different patients, being designed for the individual dog only.

Dr Graham Thatcher has asked the team to design a software workflow that will save time and eliminate complications in the current workflow, as well as improve on the current design so that it may be more adjustable and versatile for a wider range of patients.

Current Methods & Devices

Several other methods for creating incline planes exist. One method is to apply self-curing bis acryl composite material directly to the teeth in the dog's mouth, then shaped with filing tools to form the hole by which the tooth will be guided by [4]. This method may lead to some complications; if the material is applied and contacts the mucosa, inflammation can occur [12]. If the orthodontic appliances are not handled properly, the material used for the incline plane can generate too much heat and burn the dog's mouth [13].

Another design is the Mann incline plane, which is a fixed incline plane made of cast metal [10]. The Mann design is telescoping so that the size of the incline plane changes with growth of the patient's maxillae. Another advantage to cast metal incline planes is that they contact only with hard tissue, thus avoiding inflammation of soft tissue [11]. However, construction of this kind of incline plane requires models of the patient's teeth to be made. This increases costs and complicates the process. Due to the metal material, it is not easy to make adjustments as well. The fixed metal device is difficult to remove from the mouth.

Yet another method involves the use of telescoping metal rods combined with composite resin [14]. This device is built intraorally during one anesthesia procedure. The design allows for growth of the maxillae due to the telescoping aspect, but can also result in gingivitis and other complications associated with direct composite resin incline planes.

Motivation

Malocclusions are heritable traits that can cause issues for dogs and cats if not treated. The treatment process for malocclusions with incline planes involves visits for adjustments in addition to applying and removing the orthodontic treatment device, and these procedures require anesthesia. The creation process of the 3D printed incline planes is also inefficient. Treatment using inclined planes involves many possible complications, as adjustments may be needed throughout the process, and gingivitis is a very common side effect to treatment. This project's goals are to not only improve treatment for the patients but streamline the process for veterinarians and veterinary orthodontists alike.

II. Background

A. Physiology and Biology

Class II Malocclusion

Just like humans, many canines have orthodontic problems that affect their ability to live and especially eat. Types of these orthodontic problems range similarly to those of humans. There is one specific orthodontic issue called Class II Malocclusion that is directly specific to the misalignment of three teeth within a canine's mouth. These three teeth involve the maxillary canine, the maxillary 3rd incisor, and the mandibular canine. In normal occlusion of the upper and lower jaws, the mandibular (lower) canine sits within a diastema between the upper canine and the upper third incisor, as shown in *Figure 1*. However, in Class II Malocclusion, the occlusion of the dog's jaws is distorted with an emphasis on the location of the lower canine. As shown in *Figure 2*, the lower canine will sit more distal (towards the middle of the mouth) rather than the normal position up against the diastema [1].

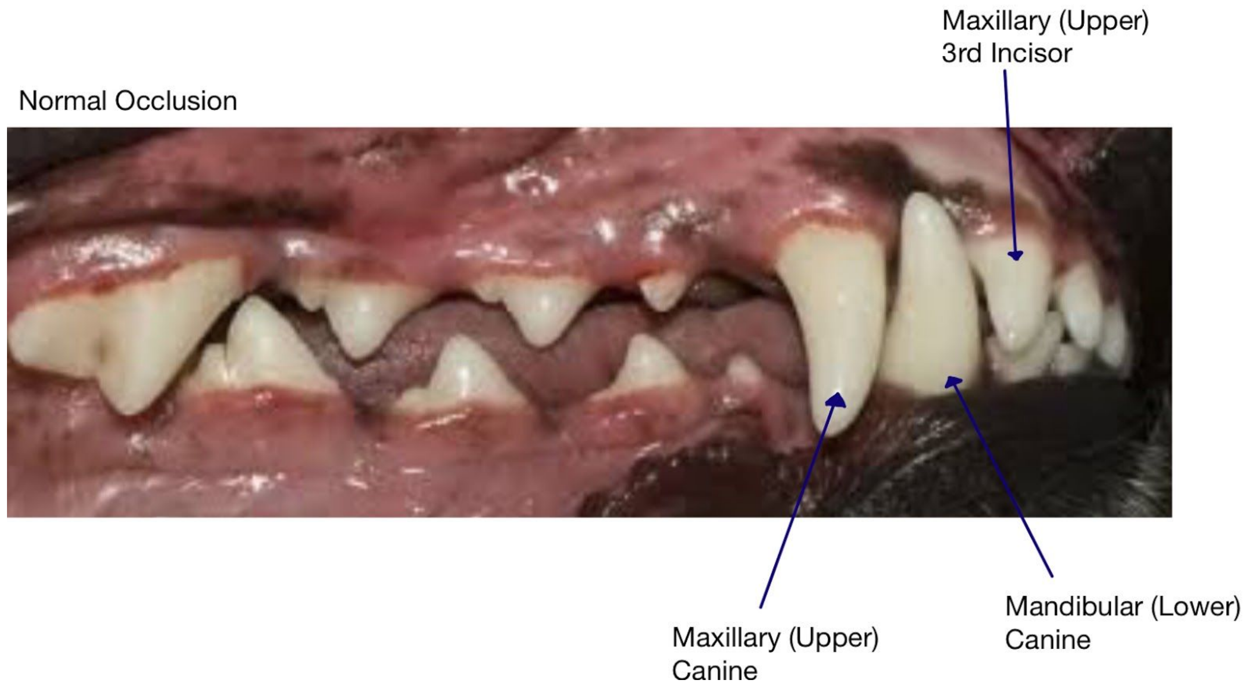


Figure 1: Normal Occlusion in a Canine. This figure shows a side view of a canine mouth with normal occlusion between the maxillary and mandibular jaws. The mandibular canine sits within the diastema (gap) between the maxillary canine and maxillary third incisor.

Class II Malocclusion is generally defined as "mandibular distoclusion" which is commonly referred to as an overbite [1]. The lower jaw sits entirely too far distal in the mouth causing the mandibular canines to not sit correctly in relation to the upper teeth. The reason this type of alignment is problematic for canines is due to the damage it can cause. A misaligned canine can cause irritation and damage to surrounding tissue and teeth. In addition, the misalignment can cause conditions such as dental attrition, periodontal diseases, and oronasal fistula [4]. As well, dogs use their canines to both puncture, tear, and hold items so they are a crucial part of their lives and daily tasks [2]. Thus, there is a high importance to ensuring they are in the correct position and alignment.

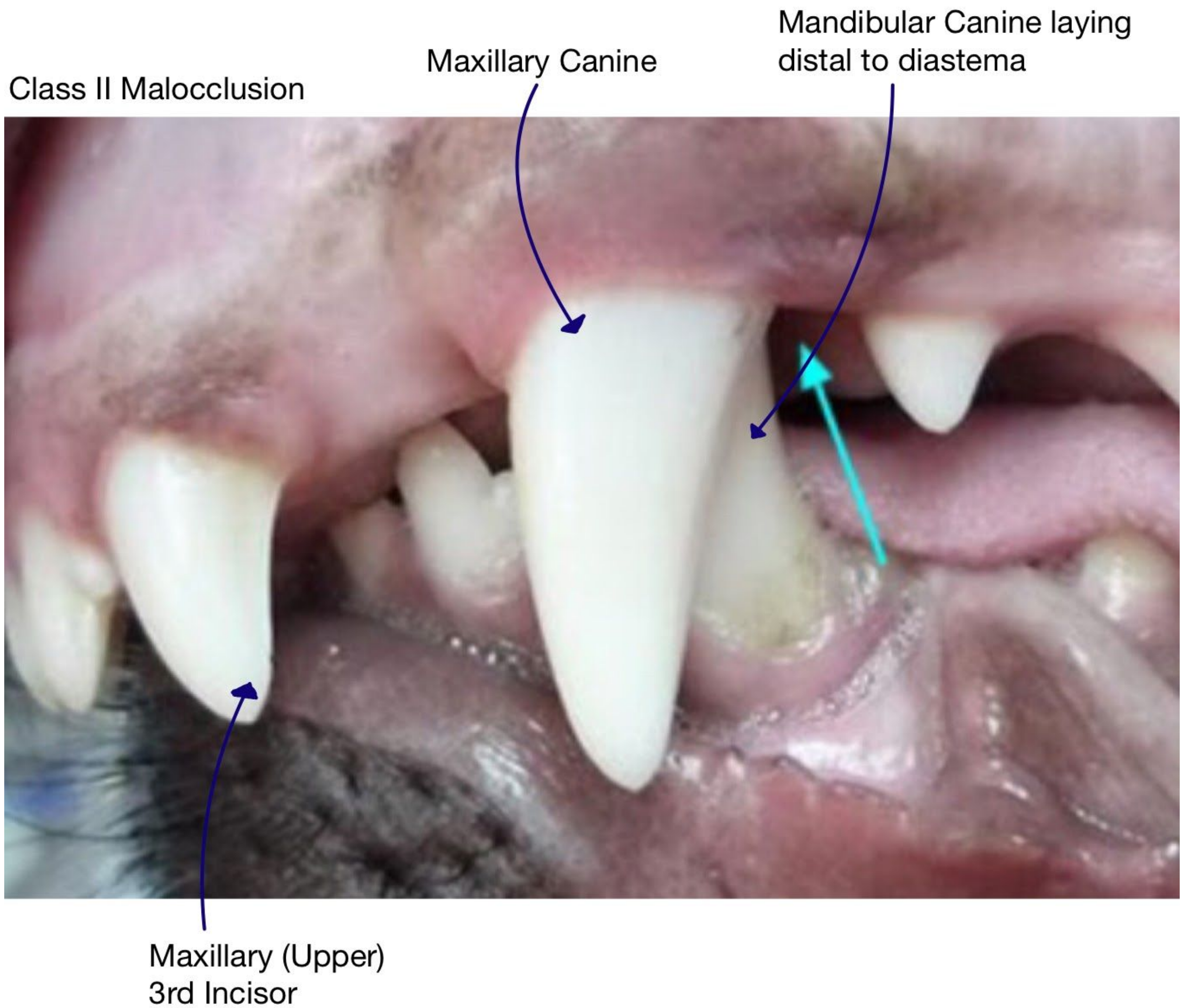


Figure 2: Class II Malocclusion. This figure shows a side view of a canine mouth with class II malocclusion. The mandibular canine sits distal to its normal position within the diastema.

B. <u>Existing Treatments/Device</u>

Extraction:

One treatment type is to simply remove the misaligned canine. This may get rid of the misalignment, but, removing the teeth will bring up more lifestyle problems for the dog. This is due to the fact that dogs need their canines to eat food and hold things in their mouth. Thus, this is not a preferred method.

Shortening

Another treatment type is to shorten the tooth so the canine does not cause irritation to the palette. While this will cause some temporary relief, again, the canine is distorted and not being able to function normally for the dog.

Incline Plane

The last type of treatment was designed by client Dr. Graham Thatcher and involves dental orthodistry treatment for the dog. The incline plane is a 3D printed device made of FDA approved dental material. The device acts as a retainer for the dog and is attached to the mandibular jaw through hole attachments. As shown in Figure 3, the incline plane attaches to the mandibular jaw through holes that are placed on the mandibular canines and molars.

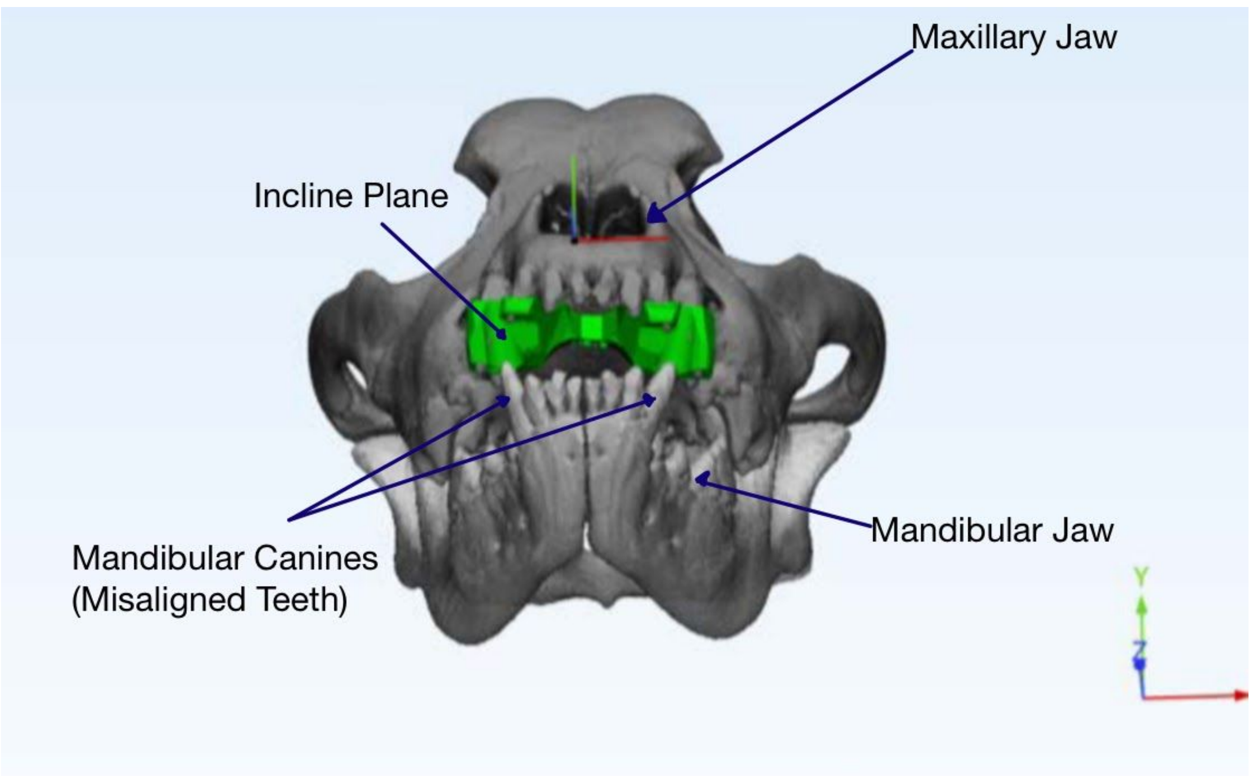
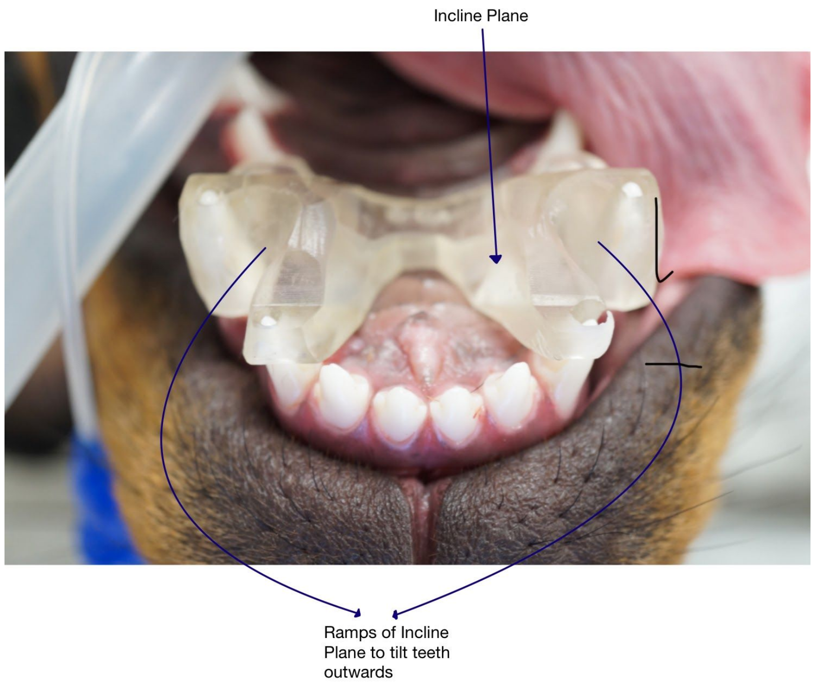
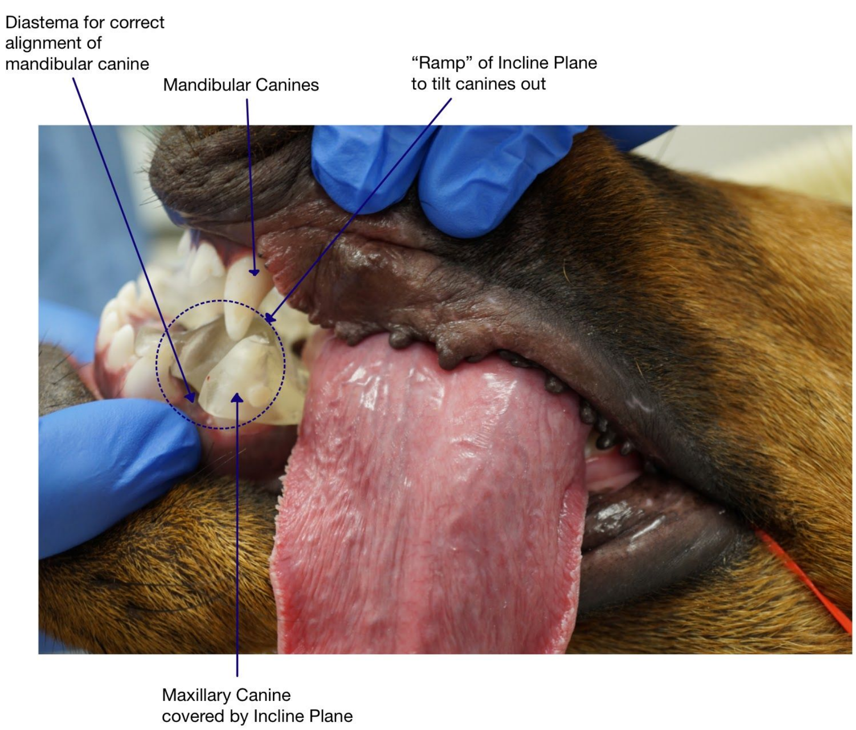


Figure 3 Incline Plane in stl file. This figure shows a CT scan of the dog's skull with the green portion indicating the incline plane device used to tilt the mandibular canines out.

The plane is essentially a combination of two ramps that are aligned to direct the mandibular canines into the correct position. Canine teeth, in dogs, are easily tilted without the need of major pressure so the use of the ramps within the inclined plane work effectively. As shown in Figures 4 and 5, the inclined plane is designed so that the mandibular canines, when the dog closes their mouth, tilt outwards towards the correct position in the diastema.





Figures 4 (Top) and 5 (Bottom) Client 1. These figures show the incline plane attached to Dr. Thatcher’s first client and how the ramps work to push the teeth outward.

Over time, the incline plane will shift the permanent position of the mandibular canines so they are set into their correct alignment. In addition, the placement of the canine in it's correct position acts as a permanent retainer for the dog due to it resting along the diastema along the gumline so no further treatment is necessary. Although the incline plane designed by Dr. Thatcher was successful in the first client, it poses many inefficiencies that are associated with negative consequences of the plane as well as the development of the plane itself.

C. Existing Development Process of Incline Plane.

While Dr. Thatcher has succeeded in creating an incline plane, his process for doing so is very inefficient and complicated. His process involves first taking a CT scan of a dog's mouth. He then 3D prints the skull of the mouth and uses a dental material to arbitrarily mold a potential design for the plane onto the skull model. Once he is satisfied with the design, he sends the CT scan (DICOM files) and the model to a software engineer who takes all the information and builds an stl file of the incline plane in an engineering software. Dr. Thatcher and the engineer then work back and forth to perfect the design through adjustments, printing prototype designs, and trials. Ultimately, this process isn't efficient nor timely. Resultantly, the second half of the team's project involves the development of an interface and software program that expedites and simplifies the process of designing the incline plane.

D. Client Information

Dr. Graham Thatcher is a veterinary dental surgeon working at the University of Wisconsin-Madison Veterinary Hospital and the School of Veterinary Medicine. He is responsible for the management of dentoalveolar and orofacial diseases and trauma as well as is an educator to current veterinary students [5]. Dr. Thatcher is currently working on this project and has solicited this team's help to refine and better his current designs.

E. Design Specifications

Incline Plane:

The new incline plane has several specifications that must be met to satisfy both Dr. Thatcher's requests as well as improve the product in general. Firstly, the product must be able to withstand constant pressure of up to 400 lbs over the course of 3-8 weeks of treatment due to the dog's natural eating and lifestyle habits. In addition, the incline plane must be able to adjust the angle of the mandibular canines by about 30 degrees of tilt. This angle will vary by each dog's unique anatomy.

Software/Interface:

When designing the software program, many specifications must be considered when choosing the right pathway. For one, the process must be simple enough where a veterinary orthodontist can easily utilize the software without the help from a software engineer. The software must also be compatible with common computers found in veterinary hospitals and offices. Lastly, the main specification is that the software must be able to manipulate multiple cross sections of a DICOM file so the veterinary orthodontist can move the mandibular canines to the right position within the program.

Preliminary Designs

I. Incline Plane:

Design 1: Adjustable Bridge

The team's first design consists of manipulating the portion of the original prototype that connects the ramps on the incline plane of both sides of the mouth. In the original prototype, this "bridge" was made of the same dental material as the ramps and created one continuous device. That continuity resulted in palatitis in the dog's mouth due to the dental material causing irritation. It also resulted in a lack of adaptability and adjustability for the incline plane to be used for other dogs and for intra-treatment changes. In this design, the team seeks to solve both these solutions by replacing the bridge with a metal adjustable bridge. They took inspiration from a human orthodontic expander [6]. The metal bridge would consist of a centric mechanical element that can be used to adjust the width of the incline plane. Just as an expander is adjusted to widen, and to thus widen the maxillary jaw, the same would apply here but with a purpose to help the incline plane be adaptable to other dogs. The rest of the design would be similar to that of the original prototype with the ramps serving the same function and being made of the same material.

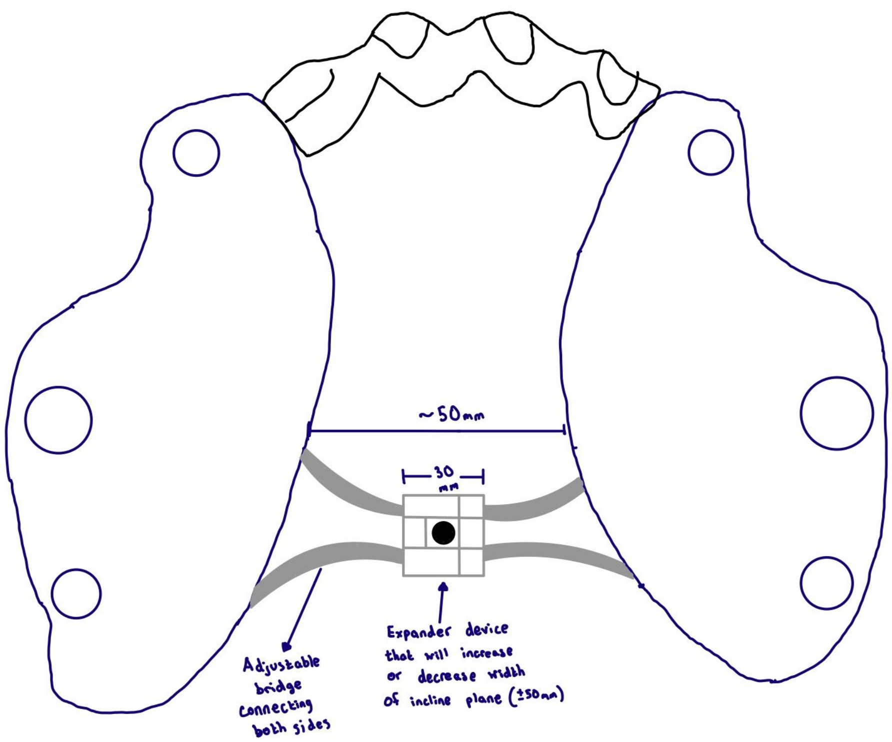


Figure 6 Adjustable Bridge. As seen in the figure above, the design consists of an expander device that can shorten or lengthen the width of the entire incline plane. This helps increase adaptability and adjustability.

Design 2: Separate

The second design also is aimed to address the issue of palatitis and adaptability by separating the incline plane into two pieces. This eliminates the bridge component which eliminates the possibility of irritation on the palette due to a lack of any material being in contact with the top of the mouth. The separate design consists of two pieces for the correction of each mandibular canine individually. The design aims to separate the malocclusion of each canine into its own unique situation to create a specially designed ramp for each canine on both sides of the mouth. The diameters of the respective holes for the mandibular teeth are shown in *Figure 7.* Again, while separate, the ramps will be of the same dental material and have the same task to tilt the lower canines outwards.

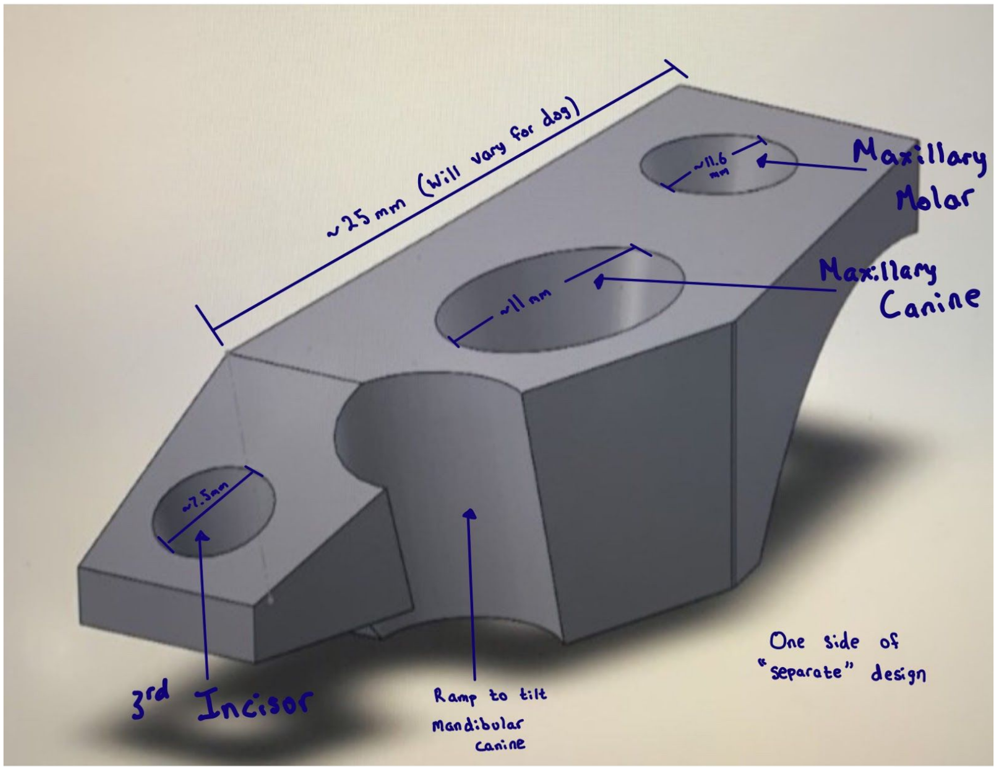


Figure 7 Separate Design. Here shows one side of the separate design. The holes are the locations for the respective maxillary teeth and each of their approximate diameters are shown. The ramp is used as normal to tilt the mandibular canines outwards.

Design 3: Rubber incline Plane

The third and final incline plane design is a model that is very similar in size and shape to Dr. Thatcher's incline plane, but instead of being made of plastic, it will be made of a rubber material. This material will allow the device to be stretched and manipulated to various different orientations, which in turn will be able to fit a variety of dog mouths'. The main goal of this design is to increase the adaptability of the device, and overall decluster the current process of generating and creating the incline plane. This design will also provide the dog with a more comfortable fit due to the softer rubber material.

II. Software

Design 1: 3D Slicer

The first design interface to help with the process of designing the incline plane is the program called 3D slicer. This program has functions that work best with processing and viewing DICOM files from CT Scans. It is based on the purpose to easily view medical images and be able to draw conclusions and conduct research from those images. It allows the user to isolate different levels of tissue from a CT scan and to also see individual frames of it as seen in *Figure 8*. However, it lacks the feasibility and ease of manipulating cross-sections of images and overall is a very complicated software.

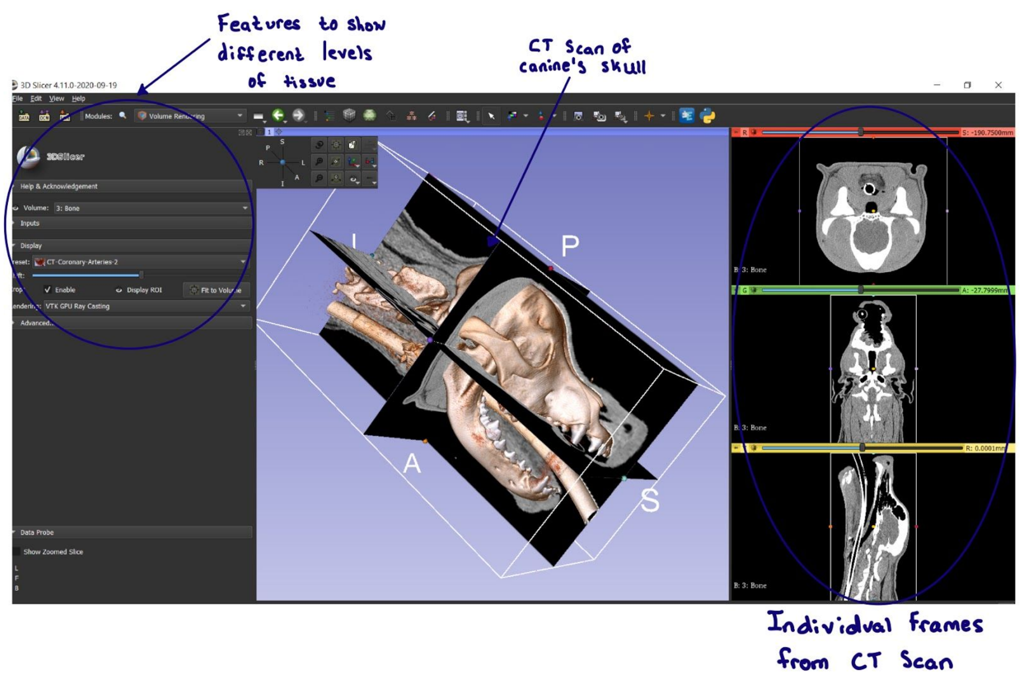


Figure 9 3D Slicer: The 3D Slicer interface shows it's ability to better view CT scans and to see cross-sections of tissue levels.

Design 2: Osiris X

Osiris X was the next software the team sought to utilize to help with the production process. This is a very mathematical based software that works with vectors and directions. It is helpful in manipulating cross sections and is specific to being able to view DICOM files well. The software was designed for medical imaging so it is very useful in simply analyzing scans.

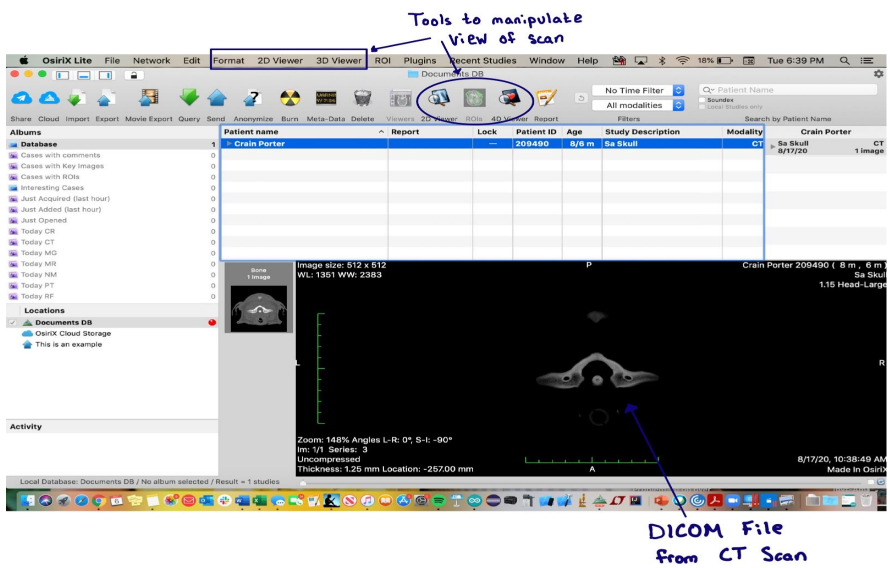


Figure 10 OsirisX. There are many tools within this program to better view and understand the CT scan

Design 3: GeoMagic

Lastly, GeoMagic is a software that works within SolidWorks which is a CAD software used by engineers to create 3D products. GeoMagic is able to process large data sets including DICOM files and can be used to generate stl files for 3D printing as well. Due to this program being embedded into CAD software, the feasibility of use is greatly simplified and allows for matriculate adjustments.

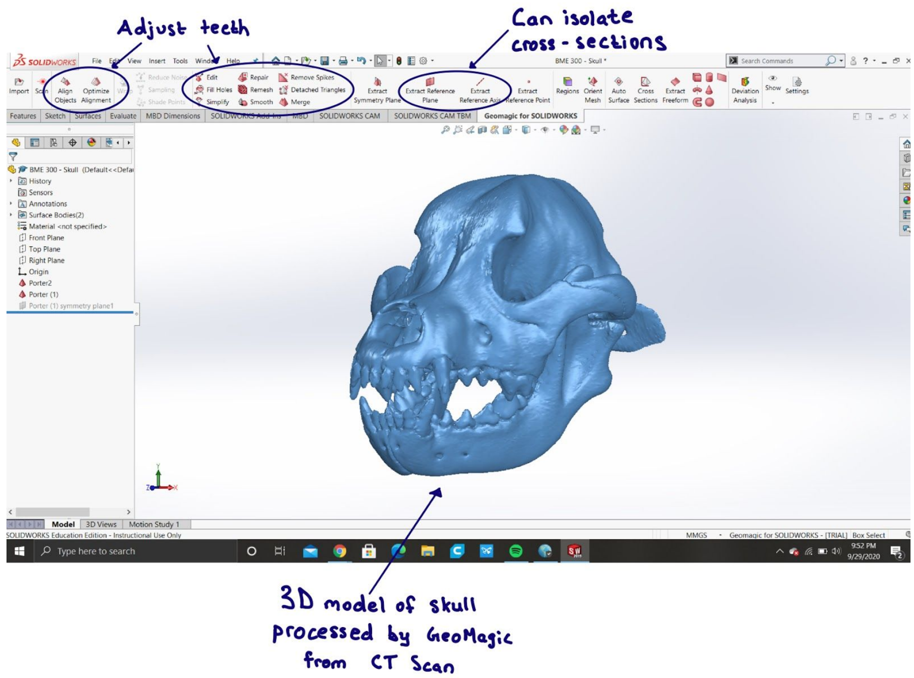


Figure 11 GeoMagic within SolidWorks. This interface demonstrates an ability for the program to manipulate teeth, process CT scans, and create additional devices and parts with the model.

Protocol for Geomagic software- Repeated in Appendix A

Below is the list of processes that will be used to design and edit the stl files:

1. Open Geomagic for Solidworks
2. Load in DICOM file in the Solidworks interface
3. Remesh structure to 15 mm for accurate dimensions
4. Use window feature to window out upper jaw
5. Load in stl file of brace design
6. Using assembly, mate the brace to the upper canines
7. Make any design adjustments necessary for fit
8. Using the simulation feature on Solidworks, change the material to match dental LT resin
9. Perform mechanical testing on brace
10. Change any aspects of design based on fit and testing

Preliminary Design Evaluation

Design Matrix: Incline Planes

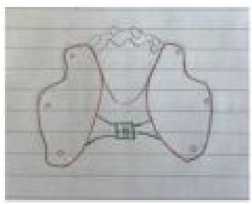
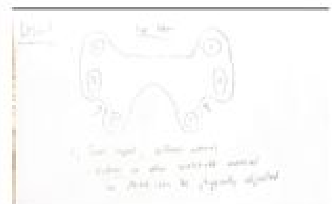
Design Criteria	Design One: Adjustable Bridge 	Design Two: Separate 	Design Three: Rubber Inclined Plane 
Effectiveness (30)	25	20	25
Adaptability (20)	15	20	15
Ease of Manufacturing (15)	5	15	10
Durability (15)	10	15	5
Safety (10)	5	5	10
Cost (10)	10	10	10
Total(100)	70	85	75

Figure 12 incline Plane Design Matrix.

As far as choosing the criteria went, the team chose what were believed to be the 6 most important aspects that applied to all 3 incline plane designs. The team ranked these criteria based on importance to this specific project, assigning each of the 3 designs with a score based on how accurately they represent each criteria. Effectiveness was defined as how well the design functions, and was ranked the highest, at 30. This is because effectiveness is the main priority of the project; if the device doesn't execute its job properly, it is a failed project. Designs 1 and 3 received the highest score in this criteria, just because they are both single-piece devices that model Dr. Thatcher's successful incline plane, meaning that the worry of how a dog will react to multiple pieces in its mouth is nonexistent. After effectiveness is adaptability, which the team defined to be how easily the device can be adjusted to different dogs. The team ranked this aspect at 20, simply because adaptability was one of the main reasons this project was assigned, and the goal is to improve the overall process of creating the incline plane for different dogs. They then gave design 2 the highest score in this category because it eliminates the problem of differing sizes of the dog's palate. Next is ease of manufacturing, which the team ranked at 15 and defined as how long it takes to create each of the designs. This criteria is ranked where it is because not only will ease of manufacturing make the overall process much more efficient, but it will also allow veterinarians to produce and print these designs without the help of an engineer. The team ranked design 2 the highest in this criteria because Dr. Thatcher has already proven that printing the incline plane with this material is possible, and in fact, relatively easy. Following ease of manufacturing is durability, which is defined as how long the device will last. Then, the team decided to also rank this criteria at 15 because in order for the device to properly adjust the dog's teeth, it must be able to last the correct amount of time in the mouth of the dog. Design 2 received the highest score in this criteria, again due to the fact that this material has been proven to last for the specified amount of time in the dog's mouth. Next is safety, which the team defined as how user friendly the device is to the veterinarian, the owner, and the dog. The rubber incline plane was ranked safety as 10 because although safety is a very important aspect of all designs, the team believes that none of the 3 incline plane designs pose a significant safety threat to the dog. The team gave design 3 the highest score in this category because it is made out of rubber, which is a much more giving material than hard plastic. The final criteria for the incline plane designs is cost, which is a self-explanatory criteria, and is ranked at 10. The team ranked all the designs the same for this criteria because it anticipated all 3 designs to cost roughly the same, with all of the costs being within the specified budget. After careful consideration and construction of the design matrix, the team has decided that design 2 will be the proposed incline plane design, receiving an overall score of 85 out of 100.

Design Matrix: Software

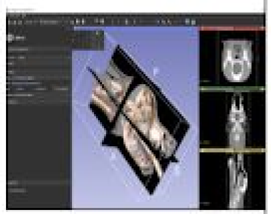
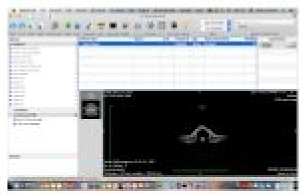
Design Criteria	Design One: 3D Slicer 	Design Two: Osirix 	Design Three: Geomagic 
Effectiveness (30)	15	20	25
Adaptability (20)	0	10	18
Ease of Use (15)	15	10	10
Cost (10)	0	0	5
Total(75)	30	40	58

Figure 13 Software Design Matrix.

The Team chose the criteria for the software design matrix in a similar fashion to the incline plane design matrix, choosing what the team thought were the most important aspects of the software programs. However, the team excluded ease of manufacturing from this design matrix because the 3 software programs that the team chose do not require any manufacturing in terms of coding the program. The team also did not include safety, because this does not apply to online softwares. Effectiveness was once again ranked highest at 30, for the same reason as above; a design that is ineffective is considered a failure. However, with the software in mind, the team defined effectiveness as how efficiently the software functions. Design 3, Geomagic, received the highest score in this category because after playing around in the software, the team determined that Geomagic was able to process a CT scan and convert it into an stl file, of which can be manipulated within SolidWorks. The next criteria is adaptability which the team ranked at 15, and defined as how well each of the software programs can convert between different types of files. This criteria received the ranking that it did because being able to convert various types of files into an stl file is crucial in this project, because it removes the step of having to send the CT scan to a software engineer. Once again, Geomagic received the highest score in this criteria because it is the most versatile software. The third criteria, ease of use, was defined as how user-friendly the software is. Ease of use is an important criteria, especially in software programs, simply because the more easily the software is used, the more likely that the user will be able to generate what they are looking for. Design 1, Slicer, received the highest score in this criteria because it allows the user to view CT scans in a variety of ways, giving them different viewpoints and overall a better understanding of the scan. The final criteria is cost, and Geomagic received the highest score in this aspect simply because it is a free program to use. With this being said, the team has decided for the proposed final software design to be Geomagic, due to the fact that it is most representative of what the team is trying to accomplish with this project and received the highest score on the design matrix, being a 58 out of 75.

Fabrication/Development Process

Materials

Once an stl file of the final design has been created, the team may use the 3D printers located in the UW Veterinary School to print off the desired pieces. The braces should stay uniform in terms of their material properties to limit the amount of variables that different materials will give the team. Dental LT was used as the material in Dr. Thatcher's initial brace design. It is a clear resin used mainly for FormLabs 3D printers for biocompatible dental splints and guards. It is also FDA approved and is known to be resistant to the mechanical and chemical stresses that occur within the mouth of both humans and canines. Nylon and polycarbonate are also ideal candidates for the brace material as each has an extremely high abrasion and temperature resistance; Perfect for long term orthodontic use.

Methods

As of the submission of this report, a final fabrication method has not been deduced. The COVID-19 Pandemic has impeded on many facilities that are used by engineering students to work on projects, however, Team VetMed hopes to use some of the 3D printing facilities that are available through the client Dr. Thatcher. Moving forward, the team needs to become familiar with the software Geomagic for Solidworks as it will be imperative to the mating and creation of the first brace prototype. Using this software, the team will create a design that can be easily mated to the CT file of the upper jaw. Further design changes can/will be made so the design fits to the upper canines. The team then hopes to learn how to use a 3D printer so the first prototype can be made and tested. See Appendix [] for Solidworks pictures.

Final Prototype

Team VetMed is currently working on refining the design for the final prototype. The final design will incorporate two separate brace pieces that are similar to Dr. Thatcher's original design, but there is no bridge connecting the two to each other. For pictures of this design, see the preliminary design section. In addition, the final software will be based in GeoMagic in SolidWorks. Creating a step-by-step process to design an inclined plane with this software will be the main focus of this project.

Testing

No testing has yet to be done upon the submission of this report. However, mechanical testing will be done through SolidWorks on the design. By giving the design similar properties to the 3D printable material, the team can gather mechanical data that would rather be acquired in a lab setting.

Results

Since there has been no testing at this point, there are no results to discuss. However the team plans to take the results of the mechanical testing done in SolidWorks and determine how effective the device is in tilting the mandibular teeth. The team will be able to adjust the device if necessary based on the outcome of this testing.

Discussion

The device will need to be effective in turning the patient's teeth in order to fix a class II malocclusion. However the team will also need to consider other factors when determining the effectiveness of the device. This includes the comfort of the patient while wearing the device. In order to make an ethical design the team must ensure the safety and comfort of the dog as well.

Conclusion

The team's client is Dr. Graham Thatcher, an orthodontist that specializes in veterinary services at UW-Madison Hospital. The client's goal is to streamline the workflow of repairing malocclusions in the mouth, specifically distal misalignment of the mandibular (lower) with the maxillary (upper) jaw. There is currently no other process on the market that does this work in a streamlined manner. Thus, this is the primary goal of the team's project. The team will need to work in parallel with the software system, Geomagic, and the mechanical system, the implant, to allow the orthodontist to be able to make adjustments to the implant (specific to the dog) on his own without the use of a software engineer.

The design that the team is currently developing is using Geomagic to splice specific pieces of the mouth, particularly the teeth in question. Once the team has effectively found a way to choose the tooth and alter the dimensions, or angle of the tooth, the orthodontist will be able to effectively test the mechanical implant against the stl file of the mouth. This process will minimize steps of prototyping, as the veterinary orthodontist will be able to make adjustments before printing, instead of having to make adjustments after each print of the implant. As expected, the team also has the goal of making "spacing gaps" in the dimensions to ensure that the implant fits correctly in the mouth and still allows room for breathing and/or air flow.

In the upcoming weeks, the team plans on learning more about the use of Geomagic in order to make these altercations of specific implants of a specific stl file, pertaining to the patient. Additionally, the team plans on printing these pieces to see where the software process runs into issues (i.e. does not allow space for enough airflow, does not fit around the teeth effectively, does not stay placed effectively, not uphold mechanical loading necessary to not break etc.). Potential issues that may arise stem from the inability to work with a direct patient at the beginning; in other words, most of the testing will be done on a model, not a real dog. Additionally, issues may arise from the difficulty of use of Geomagic (i.e. trying to alter dimensions and splice desired anatomy).

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Appendices

Appendix [A] - Protocol for Geomagic software

Below is the list of processes that will be used to design and edit the stl files:

1. Open Geomagic for Solidworks
2. Load in DICOM file in the Solidworks interface
3. Remesh structure to 15 mm for accurate dimensions
4. Use window feature to window out upper jaw
5. Load in stl file of brace design
6. Using assembly, mate the brace to the upper canines
7. Make any design adjustments necessary for fit
8. Using the simulation feature on Solidworks, change the material to match dental LT resin
9. Perform mechanical testing on brace
10. Change any aspects of design based on fit and testing

Appendix [B] - Product Design Specifications

Edited: 10/05/20

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. Specifically, the team wants to utilize the software program Osirix to be able to view the DICOM file in 3D, section off pieces of the file/image, and alter the pieces in order to effectively streamline the process for the orthodontist.

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 a 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 mechanical aspect of 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.

1. **The device will be designed to fit the canine's mouth through editing the DICOM file/stl file using 3D imaging and reduring tools (Geomagic)**
2. **The mechanical piece 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 piece should effectively lock onto upper canine teeth in order to create the right forces to wing/push misaligned teeth outward. It should not move teeth that are in proper positions, or apply too much force to the moving teeth. The device should not break in the dog's mouth or cause breakage of the 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. Specifically, the range over the true values are approximately 1cm, rather than a smaller value because the main goal is to correctly align teeth and not interrupt breath flow through the roof of the mouth tissue. In other words, the accuracy of dimensions pertaining to the exact DICOM file is less important than having the correct fit. As of now, the system is trial and error and the team hopes to limit the steps of trial and error through precision more than accuracy.

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. The interval of weeks depends on the following:

a. **As long as the treatment needs; this is a new procedure, meaning trial and error**
b. **The age of the dog**
c. **How far the maloccluded teeth need to be moved outward (typically this value is ~30˚ but can be more or less pertaining to the patient**

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

The device will need to last at least 6-8 weeks while attached to the patient's mouth, but once removed the device will not need to be used again and will be discarded to ensure sanitation.

f. <u>Operating Environment</u>: 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.

Mechanical piece places to correct misalignment in teeth:
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 used for streamlining software engineering:
The software should be able to be utilized by a veterinary orthodontist. The interface should be compatible for most computers and easy to follow. The software should include 3D imaging of the DICOM file to give access to all images as well as the ability to convert to an stl file. Once the image is converted into an stl file, the user (without software engineering prior knowledge) should be able to section off desired piece of image and alter to the users discretion, knowing that these edits will be visible on the mechanical piece once printed.

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

The ramping grooves (used for correcting the canines alignment during continuous bitting) 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.

A torque needs to be applied from the brace to create an axial moment. This type of shear moment causes a sagittal rotation of the tooth that leads to a normal occlusion. [15]

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 place. 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 correctly in the mouth and does not become misaligned due to weight adjusting the fit over time.

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 in imaging to ensure that the 3D piece is high quality and fits/operates correctly.

2. Production Characteristics

a. Quantity: number of units needed

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

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

Currently the client has offered the team to use their 3D printer that prints with a specific material used for safety during orthodontic procedures. Therefore the team has not made purchases on materials. However, the team expects to use most of its budget towards software development tools, such as advanced Geomagic.

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 software interface to be able to create a mechanical tool that works for any canine with these Class II malocclusions. The team should be using software to adjust a specific model of the ramping grooves 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. In other words, there are seemingly no competitors in this exact field, as it is a new procedure that the team gets the chance to help streamline.

Table of Expenditures and Budgeting:

Material Name	Part Numbers	Place Purchased	Cost	Quantity	Budget Left
					500