VetMed: 3D Printed, Patient Specific Incline Plane For Management of Class II Malocclusion

Preliminary Report

BME 200/300

Team Members:

Benjamin Smith, *Team Leader*

Lily Gallagher, *BWIG*

Giovanni Militello, *BSAC*

Daniel Konon, *BPAG*

Tony Pribnow, *Communicator*

Owen Kolnik, *Co-BWIG*

Client:
Dr. Graham Thatcher
Advisor:
Dr. John Puccinelli

October 18th, 2021

Abstract

A class II malocclusion is diagnosed when the mandibular (lower) jaw is shorter in length than the maxillary (upper) jaw. This is also often classified as an overbite. Class II malocclusions involve the maxillary canine, a maxillary incisor, and the mandibular canine in spatial misalignment[1]. Class II malocclusions are common in many breeds of dogs, overall 10% of purebreds are diagnosed with this condition[1]. This can be treated by removing or cutting the tooth, however, this leaves a worse quality of life for the animal. The incline plane treatment can effectively and safely correct Class II Malocclusion and save the patient's functionality of the tooth. Current incline plane devices are often constructed using acrylic composite[2]. However when these devices break the reapplication process is tedious and expensive. 3D printable inclined planes offer a solution to the reapplication process as they are easier to replicate and reinstall. However, current 3D printed incline planes require a long fabrication time along with high cost for software design. The design the team came up with seeks to avoid the software design cost and reduce the time to fabricate. This design minimizes the variables that complicate the software design process, which will in turn reduce the fabrication time and overall cost. This workflow optimization makes the inclined plane treatment more affordable and feasible for patients. Doing this can improve the quality of life for many patients by creating greater availability for this treatment.

I. Introduction

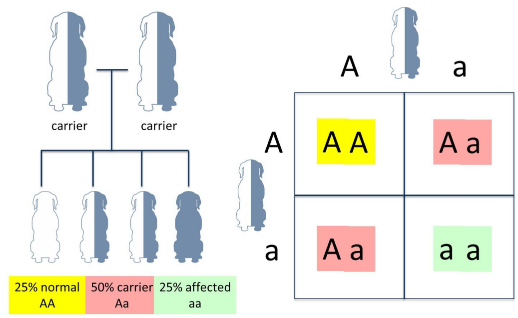
a. Impact

The goal of veterinary orthodontic procedures of companion animals is to provide pets with a healthy and functional occlusion [3]. Occlusion refers to the dental interlock between the maxillary (upper) and mandibular (lower) canines. A normal, functional occlusion occurs when the mandibular canine fits between the upper third incisor and the maxillary canine. Where the crown of the lower canine points outward allowing for the jaw to close. Abnormal alignment between one or many teeth is described as a malocclusion.

Class II malocclusion is a common genetic skeletal deformity where the canine's lower jaw is shorter than the upper jaw. A study found that this condition affects 10% of purebreds[4]. It is overrepresented in golden retriever, Labrador retriever, standard poodle, bull terrier, and German shepherd [4]. With this relatively short jaw, the mandibular canines cause damage to the palate and gum tissue of the upper jaw. In addition to pain, this can inhibit survival instincts, such as eating and defense.

Malocclusion is an inherited condition that is an autosomal recessive mutation[5]. Meaning, both parents may look normal, but they can carry recessive genes for the condition. In a litter from two recessive parents as shown in figure 1, 25% of the puppies will have the malocclusion and pass the mutated information on, if bred. 50% of the litter will carry one abnormal gene from one parent and a normal gene from the other, making them carriers. This means that they will look normal, but have the chance of passing on malocclusion if bred with another carrier. The other 25% will be unaffected and will not pass the trait onto future generations [5]. Due to this uncertainty, the Principles of Veterinary Medical Ethics of the AVMA states, “Performance of surgical or other procedures in all species for the purpose of concealing genetic defects in animals to be shown, raced, bred, or sold, as breeding animals is unethical. However, should the health of the patient require correction of such genetic defects, it is recommended that the patient be rendered incapable of reproduction.”[3]

Even if the breeding of visibly affected dogs is stopped, this does not stop the carrier puppies from mating with another carrier puppy and passing the condition onto their offspring. There needs to be a accessible treatment that can help the affected dogs diagnosed with malocclusion.



Figure[1]: references the genetic mechanism of malocclusions[6]

b. Existing Treatments

The existing treatments of malocclusions are interceptive orthodontics, crown amputation, and partial coronal pulpectomy, and tipping orthodontics.

Interceptive Orthodontics

Figure[2]: Demonstrates crowded nature of puppy teeth[7]

This treatment can be used as a temporary fix to alleviate pain in young puppies. When malocclusions are found between primary (baby) teeth present as in figure 2, interceptive orthodontics can be performed. This treatment involves the extraction of primary teeth to create more space for growth. However, it is not guaranteed to fix the malocclusion, when adult teeth are in place further treatment might be needed. This treatment would carry the least financial burden to the pet owner because the procedure is completed in a single anesthetic episode.[7] It is not recommended this treatment be used on adult canines, maxillary or mandibular because extraction of these teeth can cause loss of mandibular function, risk of iatrogenic mandibular fracture, and postoperative tongue protrusion.[7]

Crown Reduction and Partial Coronal Pulpectomy

Figure[3]- Crown Reduction and Vital Pulp Treatment [8]

Another treatment is crown reduction with vital pulp therapy. The overall goal of this treatment is to reduce the sharp tip on the canine tooth, so there is no longer painful contact [8]. The process begins with the crown reduction which reduces the crown on the tooth. Followed by sterile partial pulpectomy, which preserves and maintains the tooth structure. This treatment requires one anesthetic procedure followed by a radiographic evaluation to determine success or failure. Vital pulp therapy has been shown to have a success rate above 90% when the appropriate techniques and materials are applied [8].

Tipping orthodontics

Figure[4]**-** Incline plane[8]

Incline Plane

This incline plane uses tipping orthodontics to gradually move the canines into place overtime. Incline plane is the mandibular canines of the patient. When the patient closes their mouth, the force from the mandibular canines will be applied to the incline plane. This force causes the crown and the root to move in opposite directions about a fulcrum [8]. Over time, this repeating motion combined with the angle of the incline 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 [8]. The angle of the incline plane will be patient-specific; it will be determined by the degree of dissolution, size of teeth, and time needed for correction.

Crown Extension

Figure[5]- Crown extension composite in a dog[8]

Another form of an inclined plane that exerts tipping forces on the mandibular canine teeth. This is typically reserved for mild to moderate malocclusion and involves core build-up and shaping the mandibular canine teeth such that the incisive tip no longer impacts tissue. As the patient closes its mouth, forces are acted upon the teeth thereby causing them to tip into an atraumatic position. The success of this modality depends on a strong bond between the composite crown extension and the enamel of the tooth. When the crown extensions are applied and the patient's mouth is held in occlusion, the incisive tips of the extensions should be visible and not impact tissue. Initially, the patient will not be able to fully close the mouth.[8]

c. Problem Statement

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 canines. This current process of creating a 3D-printed incline plane begins by taking a CT scan of the canines' jaw. The data from the DICOM file is then used to produce the printable incline plane which would be placed and tested on a model of the canines' jaw. Further adjustments for the next prototype are made with the help of a software engineer. This process is time-consuming and complex. This process does not allow for flexibility between patients, nor take into account the growth of the canine, leading to patient discomfort or breakage. Dr. Graham Thatcher has asked the team to optimize the previous 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.

II. Background

a. Research

Biology and Physiology

Normal Occlusion

Figure[6]- Normal occlusion in a dog

Occlusion in dentistry refers to the proper spatial alignment of the teeth, or in other words, the teeth properly occlude. This can only occur when the maxillary and mandibular jaws are aligned properly preventing the teeth from being situated under or above oral tissue[8]. In addition, the teeth must be at a proper angle with respect to the jaw so as to not tilt inwards and cause trauma. With a proper occlusion, patients can enjoy higher quality of life.

Class II Malocclusion

Figure[7]- Class 2 Malocclusion in a dog

A malocclusion refers to a misalignment of the teeth. This can be caused by discrepancies in the length of the mandibular or maxillary jaw with respect to normal jaw lengths. In addition, malocclusions can be caused by teeth varying from their standard position. This design will specifically be considering the treatment of Class II malocclusions in veterinary patients. A class II malocclusion is diagnosed when the mandibular (lower) jaw is shorter in length than the maxillary (upper) jaw. This is also often classified as an overbite. Class II malocclusions involve the maxillary canine, a maxillary incisor, and the mandibular canine in spatial misalignment[3]. This discrepancy in the jaw results in an abnormal alignment of the teeth, as the maxillary jaw is forward with relation to the mandibular jaw. This specific malocclusion allows for the roof of the mouth to be directly situated above the mandibular canine which can lead to palatal trauma when the mandibular jaw is closed. This often leads to poor quality of life for patients.

Materials

Dental LT Resin (V2)

Dental LT Resin is a biocompatible photopolymer compatible as a 3D printer filament used in splints and occlusal guards. This filament has a flexural modulus of 350 ksi [4]. This material is available via formlabs for $350 a liter for the Form 3B printer.

Polymethyl methacrylate (PMMA)

This material is often used in orthodontics to create fake teeth and is therefore biocompatible. PMMA has a flexural modulus of roughly 350-500 ksi. The price is roughly $49/kg at laminated plastics and works with the Form Labs Form 3B.

b. Client Information

Dr. Graham Thatcher is a Veterinary Orthodontist and an Assistant Professor of Dentistry and Oral Surgery at the University of Wisconsin-School of Veterinary Medicine. Dr. Graham has been working with tipping orthodontics.

c. Design Specifications

Incline Plane and material

The client, Dr. Thatcher, requires that the team use an intraoral incline plane to treat class II malocclusions in veterinary medicine[8]. Therefore, the incline plane must consist of material safe for intraoral application. Similarly, the device's material must be able to last intraorally for roughly 6 weeks. Since the incline plane provides a force to the canine causing palatal trauma, the incline plane must also be able to withstand the force of the patient's bite force. In dogs, the incline plane must withstand a potential maximum force of 1400 N, therefore material and incline plane design must be able to withstand this force[6]. The incline plane must also be likely to survive external forces being applied. These include food, toys, and accidental mandibular trauma. Lastly, it is a client requirement that the incline plane is created via CAD software and 3D printed, hence, the material must be available as a filament for a 3D printer.

Software/workflow

Dr. Thatcher has also requested that the workflow regarding the 3D-printed incline plane be optimized. The client's current process involves using a CT scan to replicate the skeletal structure and creating a mold based on this skeletal structure. The mold is then sent to a software engineer for the creation of the inclined plane in the 3D printing software. This process can roughly take 1 week to design and print, therefore negating the need for a software engineer can reduce the fabrication process. This can be done by simplifying the variables that change for each individual inclined plane. This will allow the CAD design to be easily replicable and universal for many patients. As for cost, CT scans are between $100 and $500. Similarly, intubation anesthesia will cost between $90 and $200. Simplifying variables may reduce the need to take a CT scan if the patient has similar features to a previous patient. On the same note, the need to intubate the patient in the case of replacing the inclined plane will be reduced when variables are reduced. The client requested that the CT scan Dicom file be transformed into an STL file capable of being 3D printed.

III. Preliminary Designs

Design 1: Ring Design

The team’s first design is inspired by an expired patent, US5151027A [9]. The design features two rings that will be secured to the upper maxillary canines of the patient. Attached to these two rings will be an incline plane which will be used to tilt the lower mandibular canines into place. Supporting the pressure experienced by the upper maxillary canines from the contact with the lower maxillary canines will be a supporting bridge running along the roof of the patient's mouth, connecting the upper canines. The goal of this design is to offer the most optimized design while also simplifying the workflow. There are three main variables in this design, being the width of the rings, the length of the supporting bridge, and the angle of tilt of the incline planes. These variables are all patient-specific, and therefore will need to be measured and altered for each patient. Because of the simplification in design, the team hopes the design will eliminate the need for costly CT scans and allow the client to simply take measurements in the patient’s mouth, alter a base 3D model of the design, and print the device.

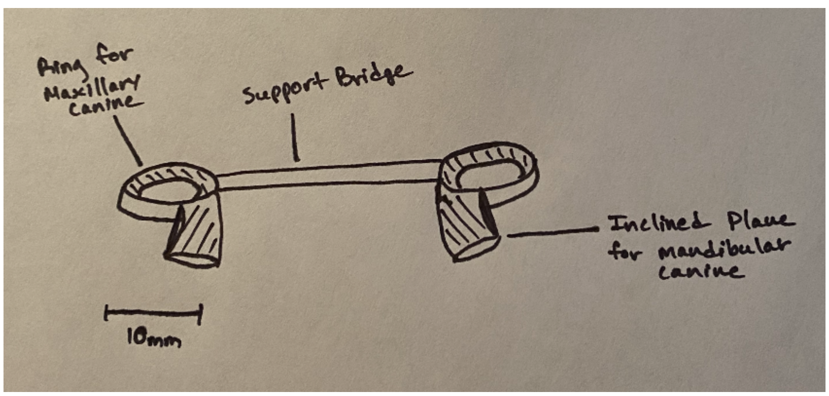


Figure [8]: *Ring design inspired by an expired patent*

Design 2: Separate Incline Plane

The second design comes from the previous group that worked on this project. This design excludes the supporting characteristics of design 1 by utilizing two separate pieces to be attached on either side of the patient's mouth. Eliminating the bridge component decreases the possibility of irritation on the upper palate of the patient’s mouth and thus mitigates risks of discomfort. To offset the pressure from the tilting of the mandibular canines, this design will be attached to the maxillary canine, maxillary molar, and 3rd incisor.

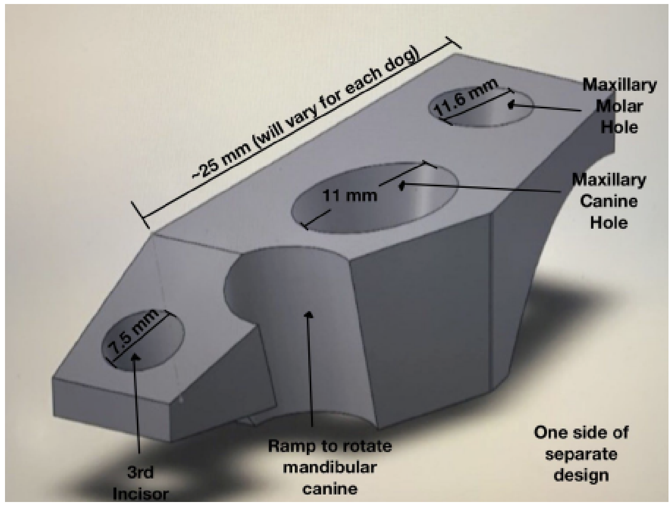


Figure [9]: *Separate incline plane design from the previous group[10]*

Design 3: Dental Retainer

The third design the team proposed was a dental retainer mold mimicking the process used in human orthodontics. The goal of this design is to eliminate the need for CT scans of the patient, ultimately shortening the manufacturing time of the device. The process to create the mold is to put the patient under anesthesia, take a vinyl polysiloxane (VPS) dental impression of the upper palate and teeth of the patient, and vacuum thermoform a sheet of thermoplastic over the impression to create the dental retainer that would have incline planes built-in [11]. This process can be done quickly and would save the client the time it would take to typically take a CT scan and then communicate with a software engineer to create a device.

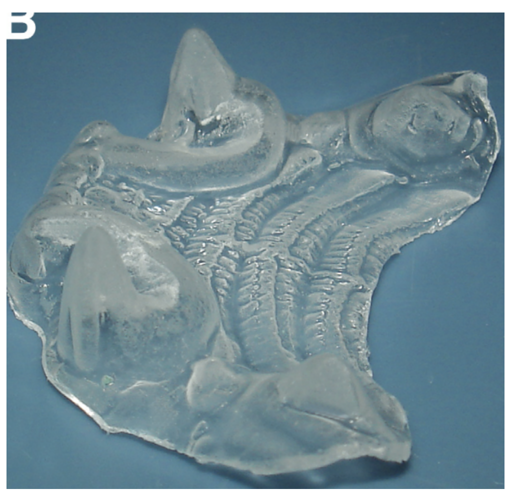


Figure [10]: *Example retainer to fix class II malocclusions*

IV. Preliminary Design Evaluation

a. Design Matrix

Incline Planes

The team used six different criteria when grading each of the three designs. These are listed in order of weight in the design matrix (figure X). Effectiveness and durability are the ability of the design to correct Class 2 Malocclusions and the ability to withstand forces that are generated from a canine, such as biting forces, respectively. This is the reason why effectiveness and durability were ranked the highest, given a score of 30, as it is an important factor that the design completes its function and does not break during usage. Designs 1 and 3 received the highest score in this criteria, as both designs 1 and 3 are single pieces with multiple support points which allows for better durability which leads to better effectiveness. The reason design 2 did not receive a similar score to design 1 and 3 is that design 2 broke upon usage during one of the client's treatments of a patient. The ease of manufacturing is the next biggest priority with the team, given a score of 20. The ability to easily 3D print the design allows for the client to have the incline plane sooner and start his treatment process right away. Design 1 scored the highest in this criteria as this design is the simplest out of all three designs and would be able to be 3D printed the fastest. Additionally, design 1 would also be able to be modified for each specific patient as this is a request from the client. The costs of the design are equally important as the team would like to produce a product that is low cost so that the client can distribute and use the product in their treatment at a relatively low cost. Designs 1 and 2 ranked the highest in this criteria as both of these designs are small and would not cost as much to 3D print compared to design 3. Safety of the patient while using the incline plane for treatment is the next priority, with the given score of 15. Because all three designs do not concern the safety of the canine, all three designs received the same score. Compatibility is the ability of the design to work with the client's process to treat Class 2 Malocclusions, given a score of 10. Design 1 received the highest score in this criteria as it is the simplest design which allows for it to be easily modified for each patient and be 3D printed, which are specific requirements from the client. Finally, treatment time is the amount of time it would take for each design to correct Class 2 Malocclusions. Because all three designs are incline planes, the treatment time is the same for all three, therefore the team ranked each design based on how much time it takes to create each design. Design 1 was ranked the highest in this criteria as it would be able to be 3D printed and modified the quickest for the client. Of the team's three designs, design 1 (Ring Design) ranked the highest compared to the other two designs with a score of 93/100 points.

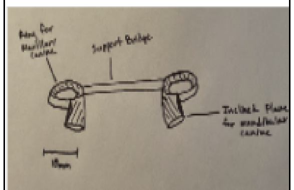
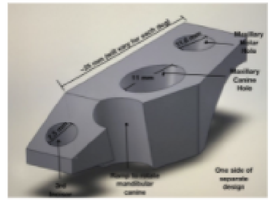
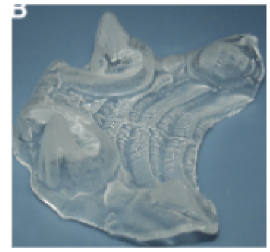
Criteria	Design 1 - Ring Design 	Design 2 - Separate Incline 	Design 3 - Dental retainer 
Effectiveness / Durability (30)	4/5 (24)	3/5 (18)	4/5 (24)
Ease of Manufacturing (20)	5/5 (20)	4/5 (16)	3/5 (12)
Cost (20)	5/5 (20)	5/5 (20)	4/5 (16)
Safety (15)	5/5 (15)	5/5 (15)	5/5 (15)
Compatibility (10)	5/5 (10)	3/5 (6)	1/5 (2)
Treatment time (5)	4/5 (4)	3/5 (3)	1/5 (1)
Total (100)	93	78	70

Table 1: *Design matrix detailing the scores of each three designs received. Individual criteria were graded on a scale of 1(Low) - 5(High), these scores were then multiplied by the predetermined weight of the criteria to calculate the weighted score. The highest scores for criteria are highlighted in blue and total scores are out of 100.*

Materials

The team used 6 different criteria when grading each of the three materials. These are listed in order of weight in the design matrix, similarly as in the Incline Planes matrix. Durability (biofunction) is the most important criterion, given a score of 30, as the material needs mechanical and physical properties that enable the implanted device to perform its function under the stresses imposed in the oral cavity. Designs 2 and 3 are ranked the highest in this criteria as both materials have mechanical and physical properties to withstand forces from a canine. Safety (biocompatibility) is the next biggest priority for the team, given a score of 25, as interactions between materials and the recipient tissues of the body are an important factor when selecting a material. Although there are no FDA safety regulations for canines, the team would like to take the same approach with canines as with humans. Given that all three materials are biocompatible with humans, the team ranked them all the same score as these materials are safe for human use. The cost of the material is equally important as the team would like to produce a product that is low cost so that the client can distribute and use the product in their treatment at a relatively low cost. Design 2 ranked the highest in this criteria as polymethyl methacrylate is lower cost compared to the other two materials looked at. Ease of fabrication in the next criteria, given a score of 10. This looks at the availability of the material for use during 3D printing. Both designs 1 and 2 are ranked the highest in this criteria as there are accessible 3D printers on campus that can print using dental LT resin V2 and PMMA. The last two criteria are weight and comfort, both given a score of 5. The team wants a material that is light in weight so it would not cause damage to the canine's mouth and therefore not cause discomfort in the canine. Designs 1 and 2 ranked the highest in both criteria as dental LT resin V2 and PMMA are lighter compared to the 3D printable titanium, as titanium is metal, and therefore would be more comfortable in the patient's mouth. Of the team's three materials, design 2 (PMMA) ranked the highest compared to the other two materials with a score of 92/100 points.

			
Criteria	Design 1 - Dental LT Resin (V2)	Design 2 - Polymethyl Methacrylate (PMMA)	Design 3 - 3D Printable Titanium
Durability (biofunction) (30)	4/5 (24)	5/5 (30)	5/5 (30)
Safety (biocompatibility) (25)	5/5 (25)	5/5 (25)	5/5 (25)
Cost (25)	3/5 (15)	4/5 (20)	1/5 (5)
Ease of Fabrication (availability) (10)	4/5 (8)	4/5 (8)	2/5 (4)
Weight (5)	4/5 (4)	4/5 (4)	2/5 (2)
Comfort (5)	5/5 (5)	5/5 (5)	3/5 (3)
Total Score (100)	80	92	69

Table 2: *Design matrix detailing the scores of each three materials received. Individual criteria were graded on a scale of 1(Low) - 5(High), these scores were then multiplied by the predetermined weight of the criteria to calculate the weighted score. The highest scores for criteria are highlighted in blue and total scores are out of 100.*

Proposed Final Design

After evaluating the three designs in the design matrix, the team decided to move forward with the Ring Design (design 1). This design scored highest in all categories of the Incline Plane Design Matrix as it most efficiently optimizes the design specifications given by the client. The Ring Design will be made out of polymethyl methacrylate (PMMA), as chosen by the Materials Design Matrix. This material is stronger than the other materials evaluated and will also satisfy the design specifications from the client.

V. Fabrication/Development Process

a. Materials

The material that the client Dr. Thatcher uses to make his incline plane is bis acryl composite which consists of bi-functional substrates to provide cross-linkage with one another and form monomer chain cross-linkage leading to an increase in impact strength and toughness. They also contain inorganic fillers to increase their abrasion resistance. Bis-acryl composite resins have low polymerization shrinkage, low exothermic reaction, reduced tissue toxicity, good wear resistance, and strength[12]. One of the materials that were considered was Dental LT Resin(V2). The previous group used this material because Dr. Thatcher used it initially for a design. It is a biocompatible dental material that is used for dental splints and guards, and it is also FDA-approved. The next material that the team looked at was polymethyl methacrylate (PMMA). This material is what the group decided to go with because it was more durable and cost less than Dental LT Resin(V2). The flexural modulus of Dental LT Resin (V2) is 350 ksi [13], whereas the flexural modulus of PMMA is 350-500 ksi, and the flexural strength of Dental LT Resin (V2) is 12.1 ksi compared to 12-17 ksi for PMMA[14]. The durability of the material is important because the team does not want the patient to break the incline plane. The final material that the team considered and ended up not moving forward with was 3D-printable titanium. The titanium was not chosen because of how expensive it is and how heavy it would be in the mouth of the patient. The PMMA was the best in the team's design matrix and will be used for the teams final design.

b. Methods

The team currently has no exact method for creating the prototype, but the basic method the team is going for is using SolidWorks to create the design and used for testing before using a 3D printer to print the prototype with the material the team decided on. The team hopes to use all available 3D printing spaces that are offered. Before the team can print and make the design, getting used to SolidWorks will be the first focus. Afterward the team will design the prototype and make adjustments to the design as it is tested so the final prototype can be produced.

c. Final Prototype

Team VetMed currently does not have a final prototype. The details of the final design are currently getting refined to be able to print out the final prototype. The design that the team chose will have two rings on the upper maxillary canines which will have a support bridge attaching them and next to the rings will be the incline plane that will be used to tilt the lower mandibular canines. The picture of the design is the first one in the preliminary design. The design will be made in SolidWorks. Creating an efficient and easy process to manufacture is the goal so that the client, Dr. Thatcher can create the incline plane without the unnecessary steps.

d. Testing

No tests have been performed yet because the prototype has yet to be made and printed. Before the prototype will be printed the team will use SolidWorks to mechanically test the prototype and fix any problems that may arise and this will help with limiting the number of prototypes needed until the team has its final prototype. So the team is currently unaware of how the design will do under stress analysis. The results of the testing will help the team determine if this design is able to tilt the mandibular canines back to the normal position.

VI. Results

Since no testing has been done, there are no results to be talked about at the moment. However, the team will use mechanical testing to revise the design to make sure the incline plane does tilt the mandibular canines back to the normal position, with that information it will help the team adjust the device to prevent problems from occurring during physical testing.

VII. Discussion

The goal of this project is to help the client optimize the workflow for the treatment of class II malocclusions. The team is confident in the proposed final design and has a plan to move forward with the fabrication and testing of this design. With these next steps in mind, it is important to consider morals and ethics in the design and testing process. While there are no published safety standards or guidelines to follow for animals in this field, the team will not consider any practice that will negatively impact or cause harm to the patient. The team will treat the patients as if they are human, using non-toxic materials and ethical test standards. In the team’s current stage, there is no testing data to be discussed as no prototype has been created.

VIII. Conclusions

The goal of the client, Dr. Thatcher, is to create a streamlined, efficient process for correcting class II malocclusions in dogs, in a safe and harmless manner. Class II malocclusions stem from the misalignment of the mandibular, or the lower canine tooth, causing puncture wounds and issues in the upper gums of the patient. Currently, the process for fixing the malocclusion with an incline plane is crude and inefficient. Some other processes that are currently used include removal or destruction of the mandibular canine, however, these can lead to future conflict in the patient. The design and process created last year also fell short in efficiency and durability. This year, the goal is to redesign the product in a way that significantly simplifies both the process and the design and in turn makes it cheaper and more efficient.

The final design the team has developed involves a ring around each of the maxillary or upper canines. The rings are connected by a support bridge that offsets the force of the incline plane in order to avoid displacement of the maxillary canines. Connected to each of the rings, on the bottom side, is an incline plane used to gradually reposition the mandibular canines. Due to the fact that the design is more simplified than in the past, a stronger 3D printable material, polymethyl methacrylate, is necessary in order to avoid breakage throughout treatment. The simplicity of the design also means that a CT scan is not necessary in order to control the variables of the ring design [15]. Instead, because the design is simplified to three variables: the circumference of the maxillary canines, the distance between these canines, and the degree of tilt of the incline plane, a caliper could instead be used to measure the variables. In the end, this saves a significant amount of money and makes the process more efficient. The team's final design significantly outperformed the other two initial designs in every category of the design matrix. The other two designs fell short in efficiency, compatibility, and cost and therefore will not achieve the goal of the product.

Testing has yet to be conducted for the product, so the team is currently unaware of how the design will perform under a stress analysis test. However, in terms of designing the product, simplifying the product worked extremely well in creating an efficient, streamlined workflow. By simplifying the design, the team was able to remove a couple of the most time and resource-consuming steps. In terms of design, one thing that did not work was using a more complicated, software and scan-reliant design. When these designs were further considered, they were much less efficient and much more resource-heavy, going against the goal of the project. The CT scan and software method would be more precise for creating the prototypes, however, with the simplistic ring design, precision is not as important as it significantly decreases the number of measurable variables within the design and the use of dental glue can fix any small errors around the circumference of the canines.

In the upcoming weeks, the team plans on starting the initial testing of the product. In order to do so, the team will create a SolidWorks model of the final design. Once completed, the design will be 3D printed and a 3D stress analysis test will be conducted. This stress test will use the maximum forces present within a dog's mouth to determine if the model is durable enough to withstand the forces. If the product is able to withstand the 3D stress test, the team will continue on to print prototypes of the product for the client. Throughout this process, the team will streamline and develop a specific process for converting the relevant measured variables into SolidWorks measurements in order to create patient-specific prototypes. These prototypes will then be tested on actual patients to determine whether the product is efficient, durable, and effective in treating the class II malocclusions. However, if the product fails during either the stress test or the patient test, the team will return to our original design, reevaluate, and manipulate it to better distribute the forces.

IX. References

[1] J. E. R. Naomi K. Hoyer, “Prevalence of malocclusion of deciduous dentition in dogs: An evaluation of 297 puppies - Naomi K. Hoyer, Jennifer E. Rawlinson, 2019,” *SAGE Journals*.
[2]R. Furman and B. Niemiec, “Variation in acrylic inclined plane application,” *Journal of Veterinary Dentistry*, vol. 30, no. 3, pp. 161–166, 2013.
[3] U. F. O. Themes, “Occlusion and Orthodontics,” Veterian Key, Aug. 15, 2020. https://veteriankey.com/occlusion-and-orthodontics/).
[4] “Malocclusion in dogs and cats,” The Veterinary Nurse. https://www.theveterinarynurse.com/review/article/malocclusion-in-dogs-and-cats.
[5] “Lingually displaced canines,” *www.dentalvets.co.uk*.
[6]“Who To Test? - Canine Autosomal Recessive Genetic Diseases.” https://www.pawprintgenetics.com/blog/2018/11/13/who-test-autosomal-recessive-genetic-diseases/ (accessed Oct. 19, 2021).
[7]M. Angel, “Maxillary Canine Tooth Extraction for Class 2 Malocclusion in a Dog,” J Vet Dent, vol. 33, no. 2, pp. 112–116, Jun. 2016, doi: 10.1177/0898756416657231.
[8] G. Thatcher, “Diagnosis and management of Class II malocclusion,” Can Vet J, vol. 60, no. 7, pp. 791–795, Jul. 2019.
[9] Orthodontic device for small animals, by Lloyd J. Mann. (1992, Sept. 29).US5151027A. Accessed on: Sept. 24, 2021.
[10] Parker Callender et. al, “VETMED: 3D Printed, Patient Specific Incline Plane for Management of Class 2 Malocclusion - Improvement in Design and Workflow Final Report,” unpublished.
[11] S. W. Blazejewski, “Thermoplastic Inclined Plane Aligner for Correction of Bilateral Mandibular Canine Tooth Distoclusion in a Cat,” J Vet Dent, vol. 30, no. 4, pp. 236–247, Dec. 2013, doi: 10.1177/089875641303000405.
[12] S. Garg and A. Singh, "Comparative Evaluation of Flexural Strength of Provisional Crown and Bridge Materials-An Invitro Study," Journal of Clinical and Diagnostic Research, vol. 10, no. 8, pp. ZC72 - ZC77, Aug. 2016, doi:10.7860/JCDR/2016/19582.8291.
[13] “Dental lt clear resin 1 L,” Formlabs.

[14] “Alphabetical list of plastic material: Laminated Plastics,” *Alphabetical List of Plastic Material | Laminated Plastics*.
[15] “3D dental scan - what is Cone Beam CT?,” Richmond Dental & Medical, 23-Oct-2019. X. Appendix

X. Appendix

a. PDS

VetMed: 3D Printed, Patient Specific Incline Plane

PRELIMINARY PRODUCT DESIGN SPECIFICATIONS

BME 200/300

Team Members:

Benjamin Smith, *Team Leader*

Lily Gallagher, *BWIG*

Giovanni Militello, *BSAC*

Daniel Konon, *BPAG*

Tony Pribnow, *Communicator*

Owen Kolnik, *Co-BWIG*

Client:
Dr. Graham Thatcher
Advisor:
Dr. John Puccinelli

September 22nd, 2021

Function:

Class II malocclusion is a common genetic skeletal deformity among a variety of animal breeds [1]. Specifically in canines, this type of mandibular distoclusion 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, by creating a design that is easier to manufacture and is more adaptable for each specific patient. In addition, to design a more efficient workflow by understanding how to more effectively flow through converting a DICOM file from a CT scan to a 3D printable .STL file, or ultimately, eliminating the need for these steps.

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
- Withstand 6-8 weeks of use
- Reduce the 1 week fabrication timeline (using a software engineer)
- Eliminate the need to intubate in the case of the device breaking (cost $90 to $200)
- Reduce the need to take CT Scans ($100-$500) for each patient.

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 using dental glue on the maxillary palate (upper jaw) in the canine's mouth. 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. In human orthodontics dimensional errors for the incline plane must be under 300-500 micrometers to be considered acceptable for treatment use[3].

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 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 and it is then removed and disposed of.

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, which is a moist environment and so the device needs to withstand the bacteria that is present in the mouth. For temperatures the device will need to be able to withstand a range of -32℃ to 50℃ 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 is not 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 distoclusion, size of teeth, and time needed for correction, which typically falls into a range of 45-60 degrees..

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. Typical canine width to consider in the design is a 11 mm width of crown as percentage compared with widest crown [9].

I. *Weight:*

The inclined plane should weigh 170 grams 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 85-113 grams, depending on the size of the patient.

J. *Material:*

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 biocompatible filament.

K. *Aesthetics:*

Color is relatively unimportant for the functionality of the inclined plane, and therefore this aspect of aesthetics is not the focus of the design. The shape of the inclined plane will be that of the maxillary arches of the patient [2]. The devices will have 3 slots for the upper maxillary, upper canine, and upper incisor. 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, which is around $10-15 [9], 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 [9].

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. Furthermore, the owner of the patient will be explained how the incline plane should be monitored when the patient eats or plays as if the incline breaks, the owner of the patient needs to return to get another incline plane implanted.

F. *Competition:*

There exists a patent for an orthodontic fixture intended for use with animals to correct lingually displaced canine teeth [9]. This device uses non-toxic metal which can be costly and difficult to manufacture. This product can be improved by adding support, such as a thicker bridge and thicker crowns, to prevent this design from breaking upon usage.

References:

[1] G. Thatcher, “Diagnosis and management of Class II malocclusion,” Can Vet J, vol. 60, no. 7, pp. 791–795, Jul. 2019. [Online] Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6563895/

[2] S. E. Kim, B. Arzi, T. C. Garcia, and F. J. M. Verstraete, “Bite Forces and Their Measurement in Dogs and Cats,” Front Vet Sci, vol. 5, p. 76, Apr. 2018, doi: 10.3389/fvets.2018.00076.

[3]“ISO 13504:2012(en), Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment.” https://www.iso.org/obp/ui/#iso:std:iso:13504:ed-1:v1:en (accessed Sep. 24, 2021)

[4] “AAHA-AVMA canine preventive healthcare guidelines,” American Veterinary Medical Association. https://www.avma.org/resources-tools/avma-policies/aaha-avma-canine-preventive-healthcare-guidelines (accessed Sep. 24, 2021).

[5]Chakroun, F., Colombo, V., Lie Sam Foek, D., Gallo, L., Feilzer, A. and Özcan, M., 2021. Displacement of teeth without and with bonded fixed orthodontic retainers: 3D analysis using triangular target frames and optoelectronic motion tracking device. [Online] Available: https://pubmed.ncbi.nlm.nih.gov/30935614/

[6]C. E. Harvey, “Shape and Size of Teeth of Dogs and Cats - Relevance to Studies of Plaque and Calculus Accumulation,”

[7]“Dental lt clear resin 1 L,” *Formlabs*. [Online]. Available: https://formlabs.com/store/dental-lt-clear-resin/. [Accessed: 15-Oct-2021].

[8] “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].

[9] Orthodontic device for small animals, by Lloyd J. Mann. (1992, Sept. 29).*US5151027A.* Accessed on: Sept. 24, 2021. [Online]. Available: https://patents.google.com/patent/US5151027A/en?q=dog+orthodontics&oq=dog+orthodontics