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# VetMed: Design and Mechanical Analysis of Patient-Specific Mandibular Reconstruction Implants

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## Abstract

Mandibulectomy, the process of removing a portion of the mandible, is a procedure done to assist canine veterinary patients suffering from acute localized trauma or osseous tumor. Currently, titanium alloy bridging plates and meshes are used to allow the canine patient to regenerate bone mass within the mandible while withstanding the normal forces of the jaw’s function. Treatments using these titanium alloy bridging plates have been proven to be incredibly successful [1]. Despite the implants’ high rate of success, there are still issues with the current implementations. These implants often use non-patient-specific implants which waste material and make use of non-ideal screw placement to lock the set of implants in place. Additionally, veterinary professionals often struggle to maintain proper alignment of teeth during resection. In order to counter the problems with this procedure, the team began to develop a stream-lined computational package that optimizes a standard set of mandibular implants for an individual patient to be 3D printed out of titanium alloy. This package will be made accessible to a wide range of veterinary professionals by using open source software. These implant sets were virtually stress tested throughout the optimization process using a biological stress testing package, FEBio, then validated by additional stress testing in SolidWorks using the method of Finite Element Analysis (FEA). The results of these tests were compared to FEBio to determine if the analysis was accurate in representing the biology of a canine mandible. With results from stress testing, problem areas in the jaw can be found and an optimized titanium implant can be made specific to the patient’s jaw. After determining that stress testing is accurate enough to create an implant, our team will make a process for veterinarians to upload their patient’s mandible CT scans, and output an optimized, patient specific, implant with very little manual computational time by the user.

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# Introduction

## Motivation

Mandibulectomies in dogs are semi frequent and common procedures, in which a veterinarian will resect a tumorous or traumatized portion of the canine's mandible. It is not common to replace the portion of the bone that is taken out, commonly resulting in impaired dental occlusion and weaker jaw function [1]. A few companies and groups, like those who are a part of VetMed, have developed initial implants to maintain more normal jaw function, but these devices still need improvements to ease patient stress as well as proper dental occlusion and usage. The team's role is to optimize veterinarians' time by minimizing the labor of the process of making an individualized implant. The team is also aiming to save resources by using exactly the correct amount of materials, reducing the amount of titanium and number of screws. Most importantly, the team is to determine how to reduce stress on the patient's jaw with optimal screw placement and implant size.

## Existing Devices and Current Methods

The team's clients, Dr. Graham Thatcher and Dr. Jason Bleedorn, currently design three parts when creating an implant set for a canine patient who will undergo mandibular reconstruction. These include a titanium bridging plate, which is secured to the bone with screws, a cut guide with the same dimensions as the bridging plate to aid the removal of a predetermined segment of the jaw during surgery, and a titanium mesh that is attached to the jaw to promote osteogenesis.

There are currently several different designs for mandibular implants, many of which are similar to the design that Dr. Thatcher uses. A design for a woven mesh called the Prosthesis-to-Bone Interface System was patented in 1977 [2]. This mesh is placed over an implant and filled with bone cement. The purpose of this piece is to redistribute forces on the bone so as not to cause any further damage to the affected area. A more recent design was patented in 2005, called the Modular Prosthesis for Mandibular Reconstruction [3]. This design includes two separate prosthetic pieces, the first of which extends across the mandible to replace the affected segment of the jaw. One end of the second prosthetic module attaches to the first, and the other end is secured to the mandibular bone. These two parts allow for an implant that can bend and conform to the anatomy of the patient's jaw, and are designed to be implemented in specific areas of the mandible.

## Problem Statement

Dogs that develop tumors or experience trauma in the mandibular region undergo surgery to resect the problem area. The removal of bone decreases structural support, which could cause mandibular drift or other health complications. Implanted bridging plates are used to remedy these conditions during the recovery period. The design of these bridging plates, though simple in appearance, is complicated due to the need to provide certain mechanical properties and avoid tooth structures and mandibular vasculature, all of which can vary patient to patient. Currently, there does not exist a streamlined or time and material effective process for generating these patient-specific bridging plates. The goal of this project is to create a computationally aided process that optimizes the dimensions of a set of implants used in mandibular reconstruction while avoiding problem areas such as tooth structure and mandibular vasculature on a patient-by-patient basis.

# Background

## Relevant Biology and Physiology

The motion of a canine's mandible is mostly in the sagittal plane with very little lateral movement [4]. Movement of the jaw is achieved through the temporomandibular joint (TMJ) which is a synovial condylar joint that connects the lower mandible to the skull [4]. Acting around the temporomandibular joint as seen in Figure I, the jaw adductor muscles are responsible for the majority of bite force generation. These jaw adductor muscles are comprised of the masseter, pterygoid, and temporal muscles [4]. The muscles only need to generate movement in the sagittal plane given the canine and feline animals have molar and premolar teeth that participate in a scissor-like action [4]. As stated earlier, motion of the jaw is achieved by jaw adductors and abductors. The bite force, which determines the stress on the mandible and our implant, comes from the already discussed jaw adductor muscles. These muscles' actions are as follows: the temporal muscles adduct the mandible and is opposed by the maester muscle, the digastric muscles move the jaw posteriorly and also partake in abduction, the pterygoid muscles move the jaw anteriorly.

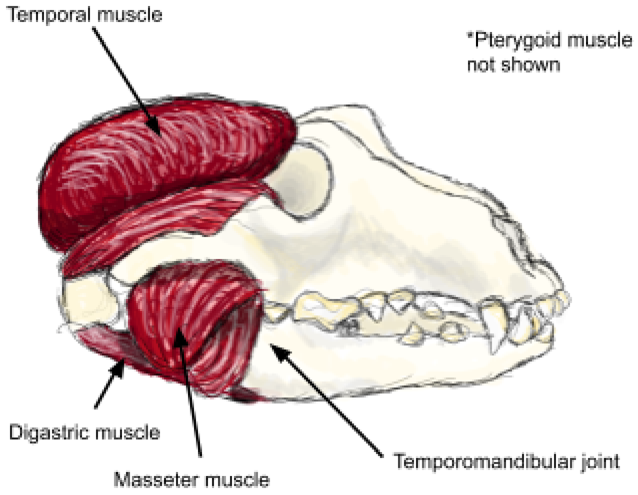

**Figure 1:** This figure demonstrates the basic musculature of a canine skull in reference to the mandible. Pterygoid muscles not show, but located between the roof of the canine's mouth and the posterior-medial edge of the mandible. *Figure illustrated by team*

The size, location, and thus the strength of all these muscles is dependent on the individual size and breed of a specific canine patient. Canine skeletal structure of the skull varies widely species to species and even individual to individual [4]. This difference in structure leads to variations in insertions and originations of the many muscles in the jaw, confounding an already complex system. These confounding variables lead to a wide range of possible bite forces across canines, seen in Table 1. This indicates that a large factor of safety is needed to guarantee that the implant will not fail under the wide range of potential forces.

**Table 1:** This table demonstrates the wide range of possible force experienced within a given canine's mandible. Forces varied largely depending on the location of force testing within the canine's jaw and equations used to determine these forces [4].

| **Measured/Estimated Location** | **Bite Force (N)** | **Measurement/Estimation Method** |
|---|---|---|
| Not specified | 13–1,394 | Measured by chewing transducer rolled with the rawhide |
| Canine teeth<br>Molar teeth | 147–926<br>574–3,417 | Maximum bite force measurement by electronic stimulations |
| Canine teeth | 300*<br>340*<br>571*<br>588* | Bite force estimation using equations of<br>Kiltie<br>Thomason<br>Kiltie (adjusted)<br>Thomason (adjusted) |
| Molar teeth | 755*<br>849*<br>1,949*<br>2,036* | Kiltie<br>Thomason<br>Kiltie (adjusted)<br>Thomason(adjusted) |
| Canine teeth<br>Carnassial teeth | 351.5*<br>549.8* | Bite force estimation using Thomason's equation |
| Canine teeth<br>Carnassial teeth | 231.99–511.80<br>620.33–1,091.1 | Bite force estimation using finite element analysis |

In addition to the complex force distributions caused by the distribution of musculature in the jaw, the material properties of bone further compound upon the complexity of the system as a whole. As a biological material bone is non-LEHI or nonlinear, non-isotropic, non-homogenous, and viscoelastic. This means that factors like the water content, the angle of application of a load, and the rate at which a load is applied can affect the response of the bone. However, bone is often assumed to be LEHI in order to simplify the calculations for modeling the system. A modulus of elasticity 1.7 GPa to 7.5 GPa and Poisson ratios of 0.39 to 0.4 are typically used to model this tissue [4].

## Background on Titanium Implants

Titanium is used for all parts of the implant as it is the most biocompatible and corrosion resistant metal. Pure titanium has an elastic modulus of 112 GPa and a Poisson ratio of 0.3 while titanium alloy, Ti6Al4V a common 3D printable alloy, has an elastic modulus of 112 GPa and a poisson ratio of 0.3 [4]. Though the core properties of these materials are very similar, the ability to 3D print the titanium alloy through a laser sintering process gives this material a significant advantage over the pure titanium. This alloy is able to match the physical properties of bone enough while remaining free of toxins to the body, which makes it extremely functional and safe for the patient [5]. Monocortical screws are used to attach the implant to the patient's jaw. These screws are durable and reduce stress on the patient's jaw compared to other surgical screws. Plastic or carbon fiber will be used if a 3D printed prototype of the implant design is needed. Plastic is a good material to use for a prototype as it holds its form well and is a cheap way to accurately model the design. 3D printing from the makerspace is valued from $0.1725-$0.3450 per mL based on the type of plastic we choose [6, 7, 8].

## Development and Process Flow

The general process of designing an implant, seen in Figure II, begins with gathering patient information in the form of a DICOM file from a CT or MRI scan. These files are imported into Materialize Mimics to convert them to 3-D image files, and the jaw is isolated from the rest of the skull. Isolating the jaw is important in order to better visualize the affected area, as well as its surroundings that need to be taken into account. The 3-D image files can be imported into the team's software and further analyzed and processed. In this software, the user is able to select the region of the mandible that will be resected during mandibular reconstruction. The user can accomplish this using a graphical user interface (GUI) or through numerical input. This allows the user to inform the software of the section of the jaw to be removed, and the software designs the implant based off this input.

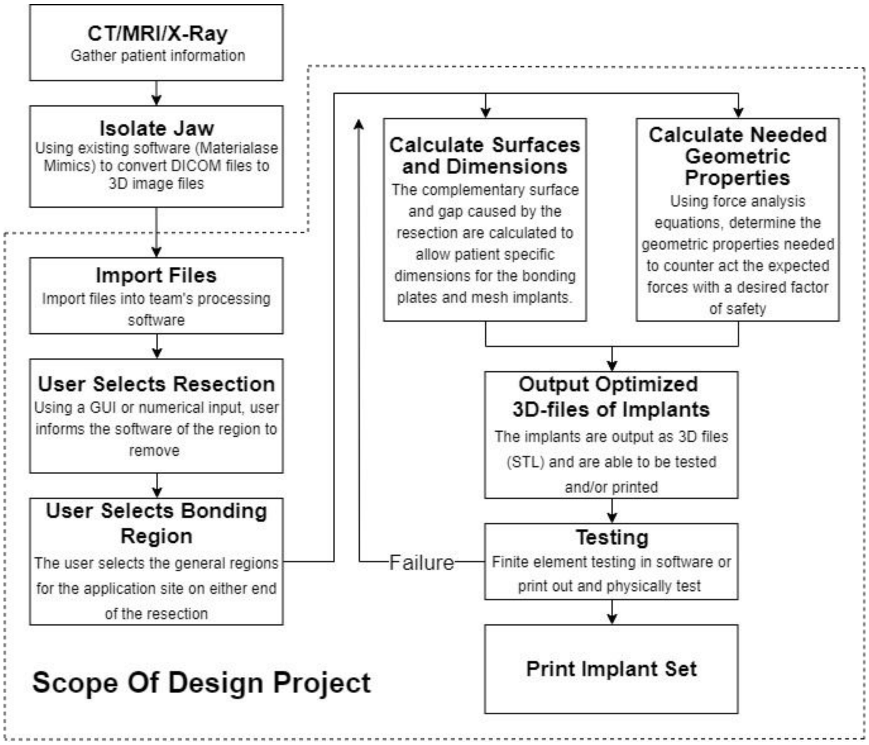

**Figure 2:** This figure demonstrates the general algorithm for this project.

The user then uses a GUI to select the general region on either side of the resection that will represent the bonding site of the implant and the mandible. These regions are the application sites during surgery. After assigning these regions in the software, the program will calculate the surfaces and dimensions of the implant. Accounting for the anatomy of the patient’s jaw, the program will design bonding plates and mesh implants that are patient-specific. The program will also use force analysis equations to calculate the geometric properties necessary in counteracting typical forces. This will include a factor of safety that will ensure the effectiveness of the implant despite the simplifications of force analysis equations.

After calculating the dimensions and properties of the implant, the program will output a design of the prototype. This prototype will be a 3-D file that will then be tested using finite element testing, a part of the software that will be programmed to test and analyze the forces on the implant. If these tests fail, the program will recalculate the design of the implant and perform stress tests again. If the prototype results in the intended success during testing, it will be 3-D printed and tested physically using machines. Once all testing has been completed, the final set of implants can be printed out.

See additional design elements in Appendix B.

## About the Client

This project was proposed to the BME department by Dr. Graham Thatcher and Dr. Jason Bleedorn. Dr. Graham Thatcher and Dr. Jason Bleedorn both currently work in the Department of Surgical Sciences within the School of Veterinary Medicine at the University of Wisconsin Madison. Dr. Graham Thatcher is currently a Clinical Assistant Professor for Dentistry and Oral Surgery, and manages dentoalveolar and orofacial related conditions. Dr. Jason Bleedorn is involved in the Comparative Orthopaedic Research Laboratory, and investigates biomechanics, augmentation of fracture healing, characterization of bone deformities, and mechanisms of cruciate ligament disease in dogs.

## Design Specifications

The developed program must create a more efficient process for designing mandibular implants by optimizing the dimensions and placement of cortical screws while avoiding tooth structure and mandibular vasculature. The program must be able to output a patient-specific design that can be 3-D printed out of a biocompatible titanium alloy. The resulting implant must withstand typical forces exerted on a canine mandible. The bridging plate used during surgery will match the screw holes of the incision, and will have dimensions that are appropriate for the patient. The process of implementing the design will maintain appropriate dental occlusion in the patient and not cause any further damage.

The program should design an implant that conforms to the anatomy of the patient such that the dimensions and the placement of screws are accurate and reliable. The process for placing these screws should demonstrate precision and be repeatable for patients with different anatomies and mandibular gap defect sizes. The implant, which should be durable and withstand numerous daily forces, will be secured permanently to the jaw of the patient. This should stay secure in the mandible while promoting new bone growth. Any implant that will be used on an actual patient must be 3-D printed with titanium, however any prototypes that are made may be printed in plastic.

The final software that is created should be easy to use for veterinarians. It should accurately represent the anatomy of the patient in order to fit specialized bone plates that restore the normal structure and appearance of the canine's mandible. One generic computation process will be applied for each patient's case that will result in a set of implants specific to that patient’s mandibular fracture or amputation. The budget for the project was $500, which was applied to creating physical models of the implants we were testing in SolidWorks and FEBio. More specific design requirements can be found in the full product design specifications in Appendix A.

## Preliminary Designs

The purpose of this design project is to develop a process to optimize a well-defined set of titanium implants on a patient by patient basis. As stated in the design specifications, every approach should make use of the general algorithm seen in Figure II. Each design is a specific approach to completing this algorithm.

### The Tiered

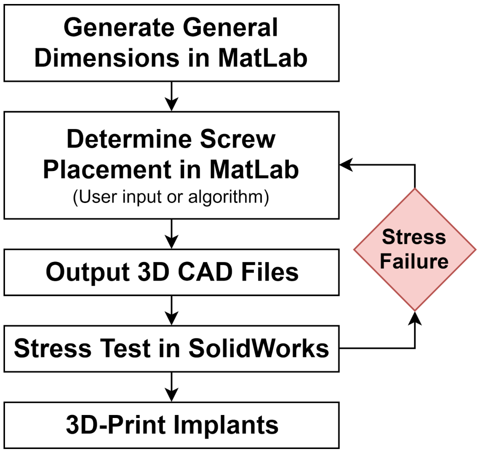

**Figure 3:** This figure demonstrates the Tiered approach. A modular approach, this design splits needed functions between MatLab and SolidWorks. Dimensions and screw placements would be calculated by MatLab and stress testing (finite element) would be done within MatLab.

The team's first design, the Tiered, used a modular approach to meet the client's requirements. As seen in Figure III, the dimensions of the portion of the bridging plate spanning the resection would be calculated in MatLab. The dimensions of this portion of the plate would only depend on easily calculable dimensions, such as length of resection, size of the individual patient's mandible, and the typical bite forces associated with a canine of the same breed as a patient. The screw placements would be selected manually or with a simple algorithm.

Once the preliminary dimensions are calculated, the bridging implants would be tested in SolidWorks using the built-in finite element testing software. If stress failure occurred due to misplaced screws, the screw placement would have been adjusted in MatLab and once again tested in Solidworks until testing success. The resulting implants would then be 3D printed.

## The Monolithic

The team's second design, the Monolithic, makes use of the ImageJ platform. ImageJ is an open source platform, meaning it is free for anyone to use and to modify. Existing plug-ins and libraries, like the 3D viewer and Import DICOM Sequence, would allow the team to get a jump start on the development of this plug in [9, 10].

As seen in Figure IV, the user would load an STL file of the patient's affected mandible into the software after activating the plug-in. The user would then make use of the plug-in's GUI to select the region to be resected. After selecting the region to be resected, the software would automatically generate the general dimensions and screw placements for the implants. Once these calculations are completed, the resulting implants would be 3D printed.

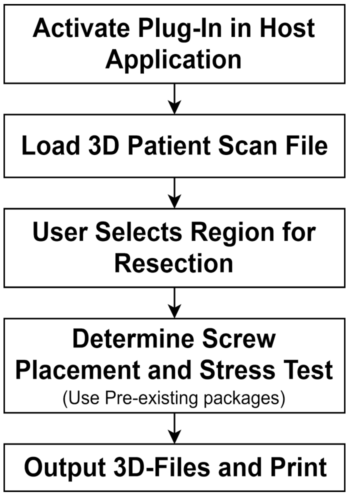

**Figure 4:** This figure demonstrates the Monolithic approach. This design is a plug in for the common and open-source image analysis platform, ImageJ. Viewing, editing, and testing of implants would be done by ImageJ libraries.

## The Iterator

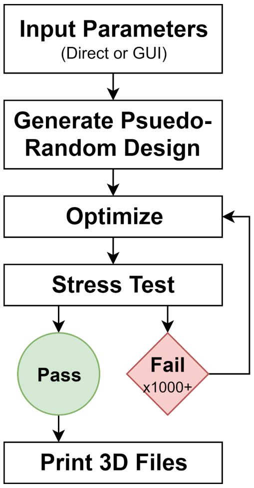

**Figure 5:** This figure represents the Iterator approach. This approach makes use of machine learning and generative design services to optimize the implants

The team's third design, the Iterator, makes use of generative design. As seen in Figure V, the user would input the parameters specific to the patient to an interface for a generative design service. This service would initially design a pseudorandom design that would be stress tested and optimized. This cycle of stress testing and optimization would be done thousands of times to guarantee a high level of patient-specific optimization. Once this optimization and testing cycle completed the resulting implants would be printed.

## The Square One

The team's fourth and final design, the Square One, would be a custom built application. As seen in Figure VI, after opening the application, the user would load the 3D image of the patient's jaw. Similar to the Monolithic, the user would select the region for resection which would lead to the program automatically calculating the dimensions and screw placement. The implant would also be stress tested with a simplified stress analysis algorithm as the stress analysis software would need to be written from scratch. Once the analysis and screw placement finish, the files would be printed.

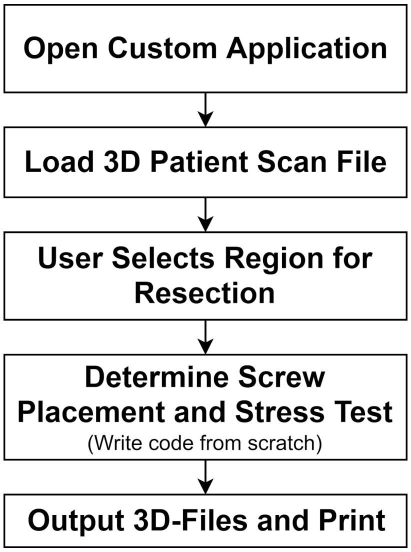

**Figure 6:** This figure represents the Square One approach. This design involves developing a custom application from scratch in Java.

## Preliminary Design Evaluation

### Design Matrix

**Table 2.** Design Matrix. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 10.
*Displayed as: score out of ten | weighted score

| | | The Tiered | | The Monolithic | | The Iterator | | The Square One | |
|---|---|---|---|---|---|---|---|---|---|
| | | Matlab / SolidWorks | | Plug-In to Image-J (Java) | | Generative Design | | Independent Application | |
| Cost | 20 | 2 | 4 | 10 | 20 | 3 | 6 | 10 | 20 |
| Accessibility / Compatibility | 20 | 4 | 8 | 10 | 20 | 10 | 20 | 10 | 20 |
| Convenience / Ease of Use | 15 | 6 | 9 | 8 | 12 | 10 | 15 | 8 | 12 |
| Computational / User Time | 15 | 7 | 11 | 8 | 12 | 1 | 2 | 5 | 8 |
| Ease of Programming | 15 | 8 | 12 | 9 | 14 | 7 | 11 | 2 | 3 |
| Resolution of Implant | 10 | 7 | 7 | 7 | 7 | 10 | 10 | 7 | 7 |
| Safety | 5 | 10 | 5 | 10 | 5 | 10 | 5 | 10 | 5 |
| **Sum** | **100** | **Sum** | **56** | **Sum** | **90** | **Sum** | **68** | **Sum** | **75** |

### Summary of Design Matrix

The four proposed design ideas were pit against each other along 7 criteria as seen in Table II.

The category weighted the highest for this matrix was cost. Different software and licensing subscriptions can vary from zero to thousands of dollars. The final product could potentially be distributed among the veterinary and surgical community, thus the cost of the final design must be accomodating for any individual to access. For the criteria of cost, both the Monolithic and Square One scored full points. The Monolithic uses ImageJ and Java, both free software available online. The Square One would be a program developed entirely from scratch, and thus could be redistributed as a standalone for free. Both the Tiered and Iterator designs require expensive licenses for the software they utilize, docking their scores heavily [1, 5].

The accessibility and compatibility of software used within each design process was ranked the next highest. Each design must be written on a readily available software, and should be compatible with the input file type that Mimics will create from CT scans of patient mandibles. Another concern with compatibility is the ability for each design to generate an output that can be utilized by a 3D printing software, or have an available method for file conversion. The Tiered was the only design that didn't score full points for accessibility and compatibility, as .stl files are difficult to import into solidworks for finite element testing.

Next was the convenience and ease of use of each design. Veterinarians and surgeons with differing levels of programming experience should be able to use the process with little to no complications. For convenience and ease of use, The Iterator scored highest. A user would simply have to input their file and select desired criteria, and the program would handle the rest of the heavy lifting. The other designs would all require extra thought and labor. Computational and user time varied greatly between designs. The Iterator would generate thousands of different possible implants, stress testing each one. This would by far take the greatest amount of time. The square one would also make use of code written by undergraduate students, so the process may not be entirely efficient or bug free.

After this was the computational and user time of each design. The computational time references the length each process would take to analyze the given input and produce an optimized implant. User time describes the amount of time a surgeon would spend providing data and transferring files to produce a final implant. The Tiered scored relatively high due to the optimized mathematical environment in MatLab. The Monolithic design scored well given it was developed on top of an existing, optimized image analysis platform. The Iterator would take hours to days to optimize, and thus scored low. The Square One would take longer to run calculations as it would be built from scratch on an unoptimized platform. The Tiered scored lower because it requires the user to manipulate data between two different programs, while the Monolithic completes the process in a single step.

Ease of programming was the fifth ranked category. This measures the feasibility of writing the program for each design within a reasonable amount of time. Difficulty of the language and computer science knowledge necessary were taken into consideration when ranking the designs. The Monolithic scored high because Java is a widely known language with many resources for guidance. The Tiered also scored high because MatLab and Solidworks are both utilized by engineering students, and resources are available to learn the necessary skills for each. The Iterator would use a third-party software, so no code would be written, but the input would have to be modified to fit the specific parameters for the proprietary format. The Square One scored low because it would take lots of time and effort to develop and entire executable from scratch. This includes the user interface, stress calculation package, and a viewing platform with limited resources and experience.

Following this was the resolution of the implant. This category entails the details and type, ie polynomial or vector, of each process. Higher resolution is desired for the implants, as this indicates a higher degree of accuracy for each patient's anatomy. The Iterator would manually revise each design and determine the optimal location for the placement of screws after each iteration. The other designs would all have simplified and manually manipulated methods for determining dimensions and screw placement, giving them equal scores.

Safety had the lowest priority against all the different categories, as each design is merely a process that will be run on a computing device. The generated implant itself must be safe, but each proposed idea has been developed with this consideration in mind.

## Proposed Final Design

Based on the results of the matrix, the Monolithic is the leading design choice to solve the problem proposed by Dr. Graham Thatcher and Dr. Jason Bleedorn. It utilizes free software found readily online, and is written in a widely used and supported language. The Monolithic also would be relatively easy for surgeons to operate as it is built on a common platform and would require a modest amount of time and attention to output a complete implant. Ultimately,the Monolithic was chosen as the final design because of its efficacy. It is cost effective, widely available, relatively easy to produce and use, and is capable of generating a patient specific implant.

After some discussion with Dr. Christa Wille, a professor of biomechanics, it was decided that it was outside of the team's abilities to develop finite element analysis algorithms from scratch. Thus, the final design needed to be modified. Dr. Christa Wille suggested using FEBio, an open source software that utilizes finite element analysis to analyse biological systems.

FEBio was chosen as a host software for the plug in over Image-J for one main reason. Like Image-J, FEBio is free and open sourced. This means it is able to be used by veterinarians for free and that the base code is publicly available which allows for easier development of a plug-in for the software. The biggest factor for using FEBio instead of previously stated designs, is the elimination of creating a code that would do finite element analysis and instead use an already developed software.

## Materials

The team used the Java programming language to develop the algorithms needed for the proposed final design. The team used the Eclipse Java IDE to develop their code, and GitHub to synchronize and store their code. The Eclipse Java IDE is a user friendly development environment that contains many features that make writing and debugging code easier, which will benefit members of the team who are new to coding [11]. GitHub is an easily accessible and clean code storage environment that not only keeps the entire project as up to date as possible but also stores older versions of code which can be beneficial for debugging and general product development [12]. Once these algorithms are developed in a familiar language, they can be translated to C++, the language FEBio is written in.

The team made use of multiple other programs throughout the file modification and stress testing processes. The programs used the file modification process included 3DSlicer[13], MeshMixer [14], and blender [15]. The programs used during the stress testing process include SolidWorks and FEBio.

## Methods

The patient's bone structure gathered during a CT scan of the patient was converted to an STL file using 3DSlicer. An STL file represents a 3D geometry by representing surfaces with numerous triangles. There is a direct relationship between the number of triangles and the complexity of the STL file and any associated analysis. The STL file obtained from 3DSlicer contained millions of triangles, was highly ribbed, and contained other artifacts and noise generated during the conversion process. To remove these artifacts within the file, the STL was loaded into blender where it was smoothed and noise was deleted. Finally, the STL was loaded into MeshMixer where the jaw was isolated from the rest of the skeletal structure.

The team then began to develop algorithms for the simplification of this still complex STL file. While these algorithms, making use of the equations in Figure 7, were being developed MeshMixer was used to reduce the triangle count of already existing files of implants and as seen in Figure 8 and the geometries of the jaw as seen in Figure 9. These simplified implants and jaws were then loaded into SolidWorks and FEBio. An attempt was made to convert both files into the meshes needed for finite element analysis. However, the geometries of the implants and jaws were still too complicated for either program to convert to a mesh for FEA.

$$\vec{A}_{\mathrm{Total\ Area}} = \sum_{n=1}^{N} a_i \hat{n}_i$$

$$\vec{r}_{\mathrm{Centroid}} = \sum_{n=1}^{N} \frac{\vec{x}_i}{N}$$

***Figure 7:*** *Equations used in STL file simplification*

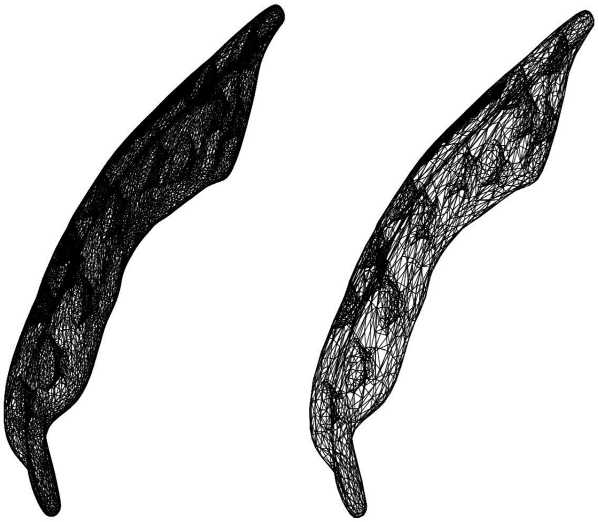

***Figure 8:*** *Demonstration of simplification of an implant using MeshMixer*

Given direct, algorithmic simplification did not result in a simplified enough model that was able to be used in FEA, Solidworks was used to create simplified models of the jaw and implant by hand. The dimensions of the original models were determined using SolidWorks, and were then used to create a simplified models that had similar dimensions and shape, seen in Figure 9.

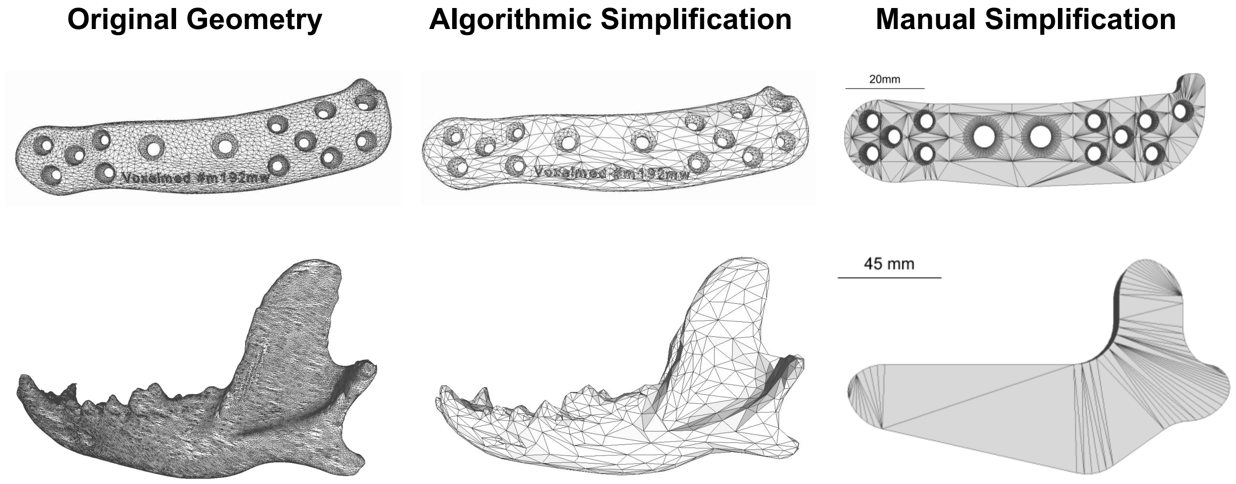

***Figure 9:*** *Simplified models of titanium implant and a canine mandible. Most detailed on the left to the most simplified model on the right. Dimensions are consistent across each geometry being modeled.*

Once the general dimensions and shape of the jaw and implant were known, 3 separate models were created for each structure. The most simple model consisted of creating the shape with straight lines. These block structures were meant to represent the jaw and implant in the most simple way while still maintaining the general shape. A true jaw or implant would not contain 90 degree angles for several reasons. From a mechanical perspective, a 90 degree angle concentrates the stress into corners. Anatomically, 90 degree angles are not found in the jaw. The implant is also not likely to contain a 90 degree angle and would be filleted to minimize injury. However, while these models don’t visually represent what a true jaw or implant would look like, the model will be used to determine the significance of simplifications. The moderately simplified model used a filleting technique to round the sharp corners of the block models. These models are better representative of a true jaw and implant. The least simplified model added topography to the moderately simplified. A true jaw will not have flat surfaces and the implants are meant to be patient specific and match the topography of the dog’s jaw. These features were added to the least simplified model.

## Final Prototype

The final implants output by the coding process will vary set-to-set as each will be optimized to an individual patient which may be tested with varying resection sizes. These implants will then be 3D printed in titanium alloy for testing and surgical purposes.

While the code is under development, the prototypes tested were simplified models for the jaw and implant. There were three prototypes created for the implant which would be tested in solidworks to determine whether the veternariance could use simplified models to currently improve their process while a code is being developed. The jaw was also simplified to determine whether the jaw could be simplified for stress analysis and to test the accuracy of FEBio and determine whether the software is a viable solution.

The simplified implant would allow veterinarians to test desired dimensions and determine if there is a likelihood of failure. This would reduce the guesswork involved in the current process and allow the veterinarian to reduce the risk of injury and failure. The simplified models are easy to make and take very little time to develop and test. The simplified models will allow the veterinarians to get a general idea of the dimensions needed to reduce waste and health risks.

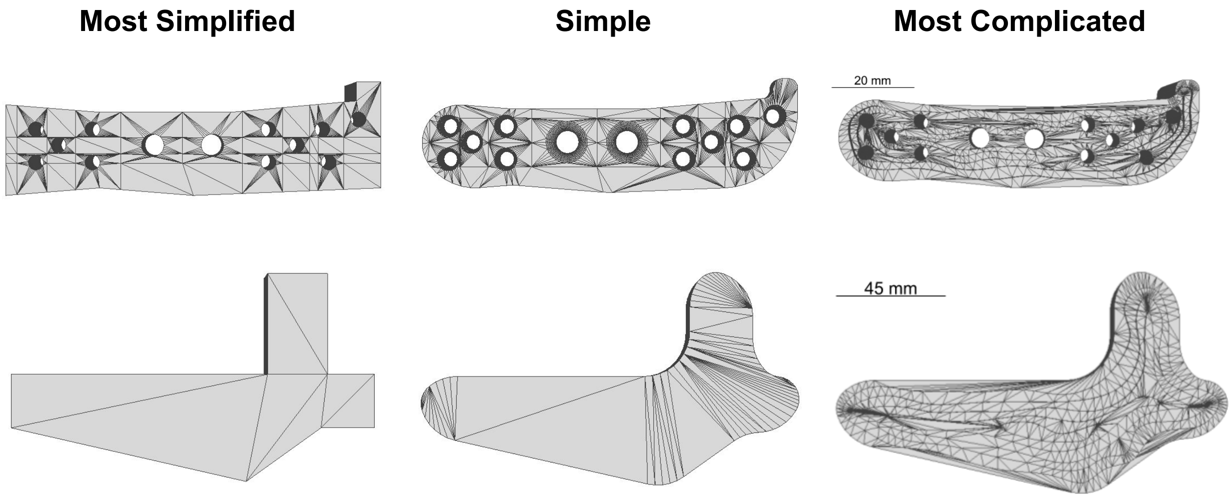

**Figure 10:** Models of bridging plate implant and jaw ranging from simple to complex. Dimensions are consistent across complexity.

## Testing

To test the final prototype the simplified models were analyzed using the finite element analysis wizard in SolidWorks. The least simplified, moderately simplified, and most simplified models were all fixed in the same location and then placed under a 1 N compressive load. The results were then compared and analyzed. To quantify the stress analysis, each magnitude of stress was ranked differently. The highest stress (red) was given a rank of 4. Orange was associated with 3, yellow with 2, and green with 1. The blues were considered non-stressed areas and were given a rank of 0. Each model was visually analyzed to determine the sum of stress ranks.

Once each model had a stress rank the average was calculated. The difference between the individual ranks and the average was calculated and used to perform a one sample t test. An alpha value of 0.03 was chosen due to the approximation process of collecting data and taking the dog's health into consideration.

The models were then tested in FEBio and compared to the results in solidworks to determine whether the open source software could be used when implementing the code in development.

For finite element testing, solidworks has a collection of materials that can be chosen when doing the testing. The materials chosen for the models and their corresponding Elastic Modulus and Poisson's ratio are shown in Table 3. These values were used for both finite element analysis in SolidWorks and FEBio.

**Table 3:** Material Properties of Models [16]

| | Implant Model | Jaw Model |
|---|---|---|
| Material Chosen | Titanium | Nylon 6/10 |
| Elastic Modulus (GPa) | 104.8 | 8.3 |
| Poisson's Ratio | 0.31 | 0.28 |

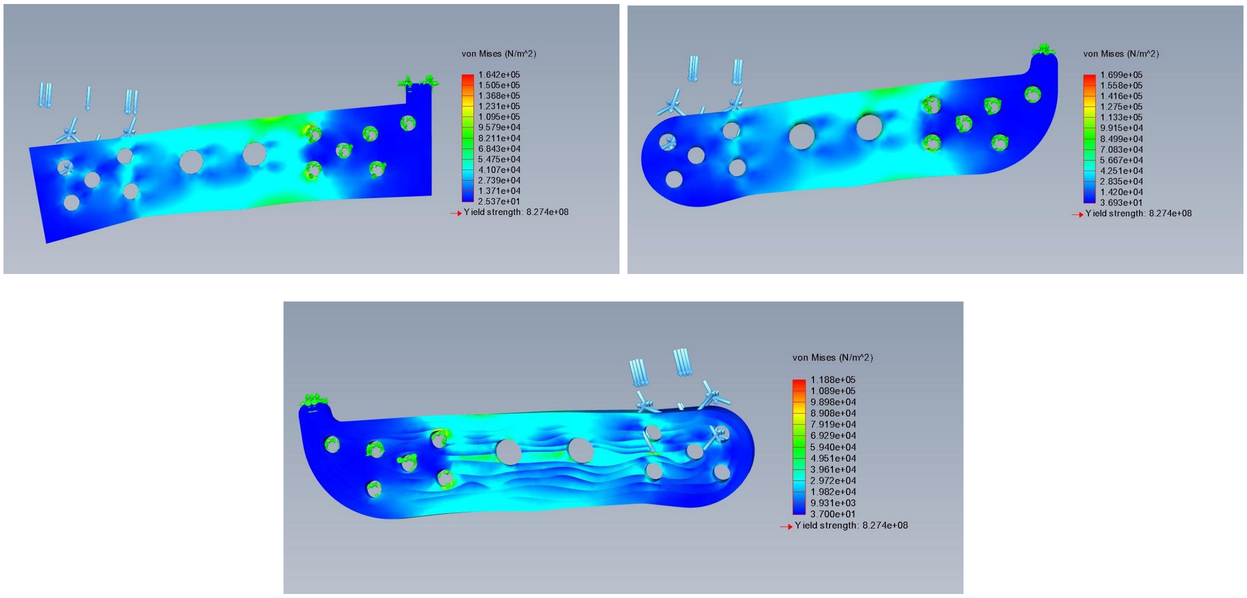

**Figure 11:** *Finite element analysis in solidworks on implants with various complexity*

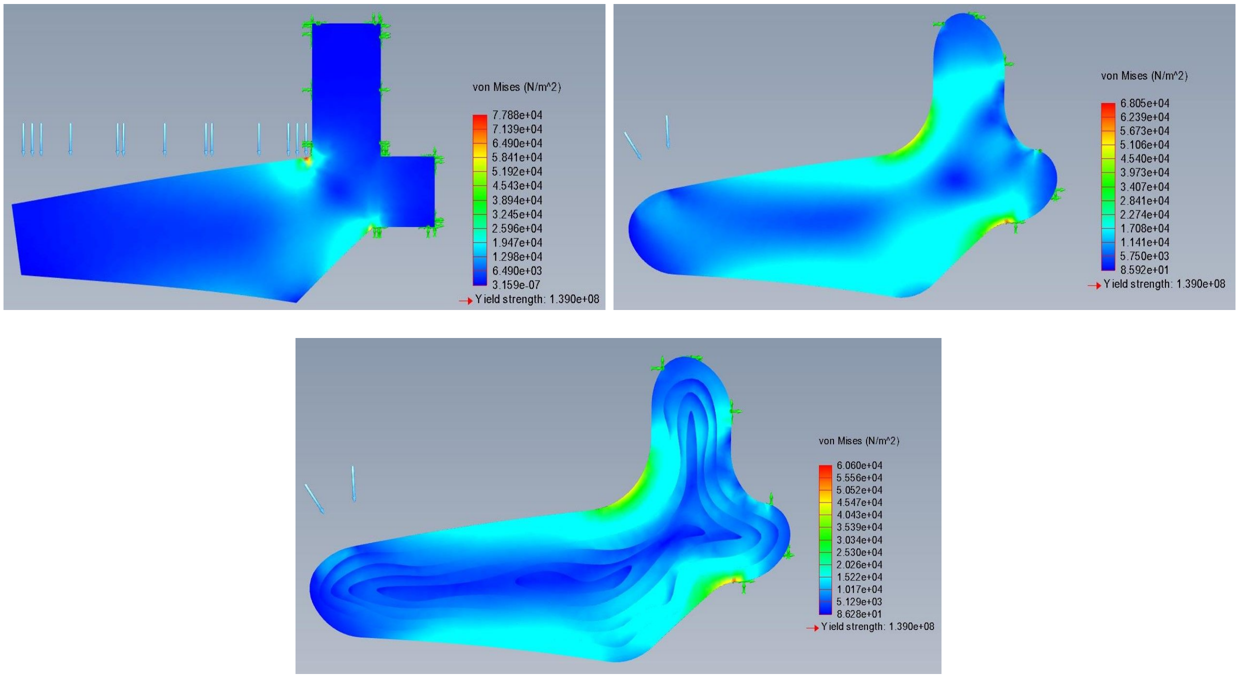

**Figure 12:** *Finite element analysis in solidworks on jaws with various complexity*

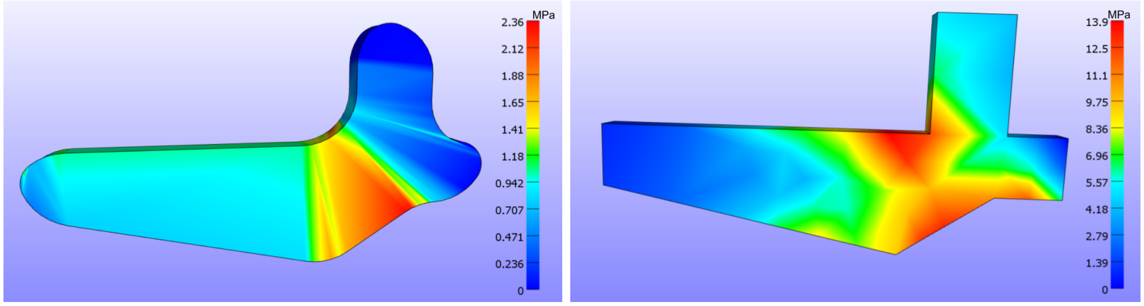

***Figure 13:*** *Finite element analysis of simplified  mandibles models in FEBio*

## Results

The expectation is that the optimization will reduce waste while maintaining function. If the ImageJ plug-in can be developed so that it outputs 3D image files that reduce waste while maintaining the required strength to withstand the proper forces, the results of this project will be considered successful.

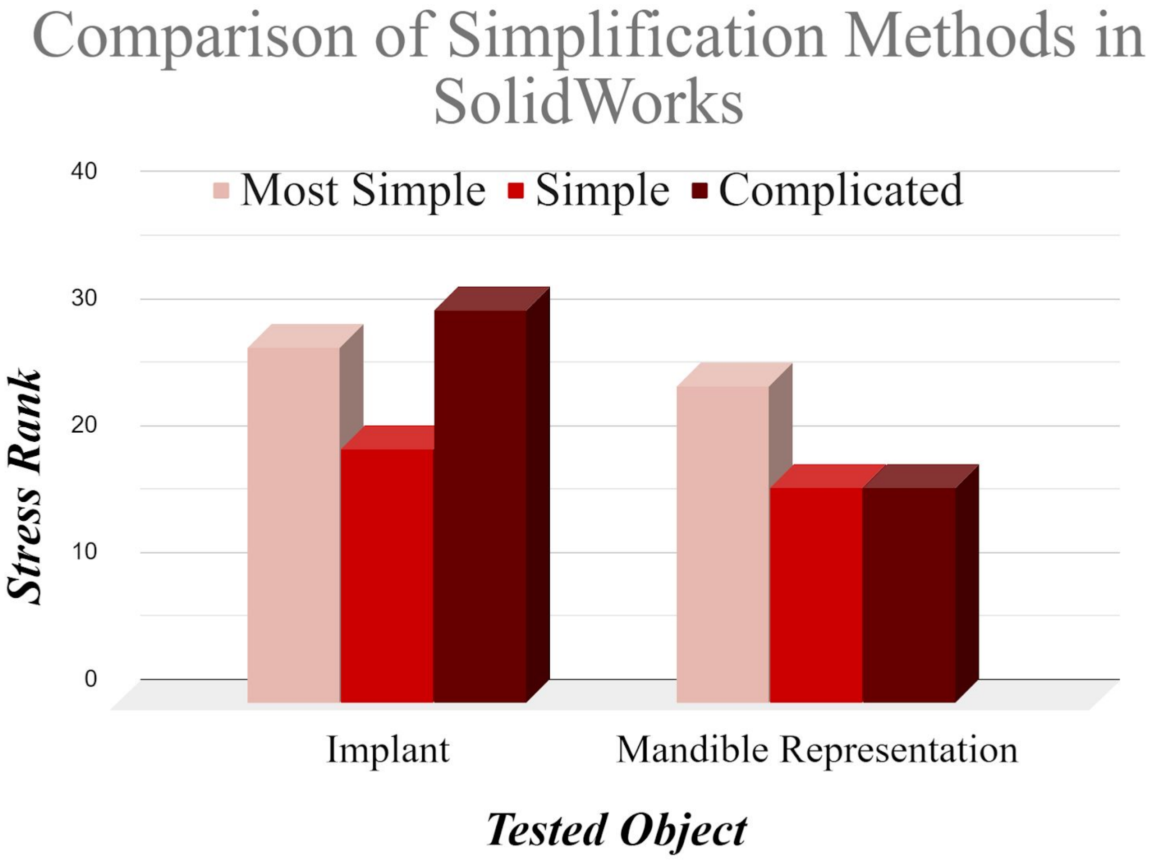

**Figure 14:** Bar graph comparing simplified models and their number of stress points

Different simplifications methods show that the titanium implant has no considerable difference when tested by a simplified model. Since a fairly simplified model will yield statistically similar results, our design can use the smallest file size to yield computationally fast results for veterinarians as well as make file exporting and sharing easier.

T-tests show that different simplification methods of the mandible do not yield statistically similar results, which can be explained by the complexity of biological systems. A summary of the statistical analysis is shown in Table 4. An alpha value of 0.03 was chosen. A typical alpha value is 0.05. However, since the models are simplified, a higher confidence level is desired to reduce the risk of injury to the dog.

**Table 4:** One Sample T test analyzing homogeneity

| | Avg Rank of Stress | P-Value |
|---|---|---|
| Implant | 26.33 | 0.045 |
| Mandible | 19.67 | 0.029 |

Since the p-value of the one sample T test analyzing the implants is 0.045 which is greater than 0.03, the implant can be simplified without substantially changing the stress distribution of the model. However, since the p-value of the one sample T test is 0.029 which is less than 0.029 which is less than 0.03, the jaw cannot be simplified while maintaining the stress distribution of the model.

The FEBio results and solidworks results were first visually compared. The stress concentrations varied however the areas in which the stresses developed were consistent. This was originally attributed to the different in mesh size. The solidworks meshing would have created smaller triangles that would allow the finite element analysis to be extremely area specific whereas FEBio uses the very simplified mesh which could cause the stress to spread out while still maintaining the general trend. While this could contribute to the differences seen between FEBio and SolidWorks, it is more likely due to FEBio's dimensioning convention. It was discovered that FEBio uses ratios instead of units. This means that since the models were created using mm and the SolidWorks testing was done in N/m, there are discrepancies in the units used. This explains the variation of the spread of stress.

The magnitude of the stress calculated was also compared. The focus was on the trend of the stress due to the general unit confusion in FEBio and SolidWorks both showed the more simplified model of the jaw had a higher stress magnitude. In general, the trends of the finite element analysis testing of SolidWorks matched those in FEBio.

## Discussion

The program created should be accessible to veterinarians and easy to use with little to no programming experience. In order to create a program that is accessible to veterinarians, an open source program was chosen as the primary platform for this project. The group decided that FEBio was the best program as it open sourced and has built in equation for finite element analysis. As a temporary solution while a comprehensive program is being written, FEBio and simplified models of the implant can be used to test estimated dimensions and use the finite element analysis to adjust the dimensions and optimize the implant manually.

Some current designs use a process of segmentation to optimize the dimensions of the implant. The Articular Bone Reconstruction Bar [17] and the Modular Mandibular prosthesis use connections to determine the length of the implant. However, the Modular Mandibular [3] uses swivel coupling to allow for three dimensional movements. An alternative to a segmentation approach, there exists designs that function more as a kit than a single implant. The Mandibular Prosthetic Apparatus is a kit that comes with a variety of materials that are used to assemble specific members for multiple areas of the mandible. While segmentation and the usage of kit is a unique way of minimizing waste, these don't provide adequate specificity [18]. The implants themselves are not contoured to the specific shape of the dog's jaw. Instead of mechanical optimization the optimization will occur on a strictly software level. There are design optimization programs , such as the simulations founded by the MSC Software Corporation [19]. Software such as this would be able to give the veterinarians a full report of the mechanics and optimization of any implant they wish to utilize. However, using a company such as this one would quickly become expensive and include corporate complications.

Due to the uniqueness of the implant provided and the expensiveness of existing optimization software, the group decided on an original open source program which utilizes simplified finite element and stress/strain analysis. A large factor of safety will ensure that the simplifications and assumptions made will not risk damaging the dog's jaw due to failure. ImageJ was chosen as the primary software due to its extensive libraries. The original code will be written in C++ so that it is compatible with FEBio.

To minimize effort on the user's part, the program will be one step. The parameters will be able to be entered along with a selection of the part of the jaw that the veterinarian wishes to remove and selections of the parts of the jaw that the veterinarian wishes to avoid when considering screw placement. Once the information has been entered, the program will run through a series of computations in which the optimal dimensions are outputted along with suggested placement of screws and a three dimensional image of the implant.

## Conclusion

A program that would create a one-step process is still in development. To improve on the current process, the testing done proves the veterinarians could use a simplified model for stress analysis. This would allow the veterinarians to quickly draw up a model with dimensions they've estimated, test it, and adjust the model accordingly. A model that has little to no stress corresponds to waste of material and a model with highly concentrated stress and a large amount of high stress corresponds to an implant that is likely to break. Using these generalizations, the veterinarians would be able to create an implant the reduces waste and reduces the risk of injury to the dog. In the future, the team would develop a cohesive program. This program will use FEBio to create optimized implants from a selected section of bone. The veterinarian will be able to indicate the desired area of removal and indicate important anatomical areas. Using these indications as guidelines, the program will generate a satisfactory implant. The output will consist of a 3D image and file of the proposed design. The program will also summarize key aspects of the finite element testing along with numerically indicating the dimensions of the proposed implant and coordinates of the screw placement. The output and final design of the optimized prototype should be easily transferable to the 3D software used for titanium printing.

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# Appendix

## Appendix A - PDS

### Function

Implanted bridging plates are used to supply structural support during the recovery period after treating mandibular fracture in canine patients. The design of these bridging plates, though simple in appearance, is complicated due to the need to provide certain mechanical properties and avoid tooth structures and mandibular vasculature, all of which can vary patient to patient. Currently, there does not exist a streamlined or time and material effective process for generating these patient-specific bridging plates. The goal of this project is to create a computationally aided process that optimizes the dimensions of a set of implants used in mandibular reconstruction while avoiding problem areas such as tooth structure and mandibular vasculature on a patient-by-patient basis.

### Client Requirements:

- Development of program to determine ideal dimensions for a set of implants
- Generates dimensions for a sets of implant based on existing plate and screw design to be 3-D printed with a biocompatible titanium alloy
- Dimensions and shape of implant tailored to specific patients
- Structural and mechanical analysis of implant through design software
- Physical testing of implant to verify its structural integrity and functionality

### Design Requirements:

1. Physical and Operational Characteristics
    a. Performance requirements:
        i. The titanium bridging plate implant will support forces exerted on a typical canine mandible from the moment of implantation.

    ii. The titanium implant will induce minimal damage to the patient; this will be done with careful placement of the cortical screws.
    iii. The titanium lattice will help supplement and support bone growth as well as provide an adaptable attachment to any titanium implant if the implant needs to be replaced for any reason before complete bone regeneration.
    iv. The bridging plate used during the operation on the patient will match the screw holes in the implant to <5mm.
    v. These screw holes will avoid any tooth roots.
    vi. The bridging plate will be the accurate length and width of the needed incision on the patient.
    vii. Overall, the entire process of implementing the design will maintain appropriate dental occlusion for the patient.

b. Safety:
    i. Tooth roots and mandibular musculature will be undisturbed during surgery and placement of the implant.
    ii. Jaw alignment will be maintained during surgery by interconnecting the teeth if necessary.
    iii. Implant will have no sharp edges. Titanium 3-D implants will be finished and scrutinized for sharp surfaces and corners.
    iv. Material will safe for biological conditions and encourage bone growth in case implant should need to be removed. [20]
    v. Risks of the device include loosening, mechanical failure and wear, infection, or user error.
    vi. Implant should be biocompatible and sterile. [21]

c. Accuracy and Reliability:
    i. The bone plate needs to be secured with three to four screws on each end that must have accurate placement so as not to disrupt the roots of the remaining teeth, gums, or the mucosa gland [22].
    ii. The process of determining where these screws are placed, potentially through software that can take a scan of a specific patient's anatomy and personalize the plate to the patient, should present accurate placement of screws such that the plate can be held firmly in place under different types of forces and not cause any further damage to the oral cavity.

    iii. The process for placing these screws should demonstrate precision and be repeatable for patients with different anatomies and mandibular gap defect sizes.

d. Life in Service:
    i. The titanium mesh implant will be secured to the mandible permanently.
    ii. The Titanium lattice itself should encourage bone growth. Ideally, bone growth will have occurred to a sufficient degree that when the bridging plate implant is removed, the permanent new bone remains.
    iii. The bridging plate implant will be secured to the mandible permanently barring any post-operational complications.
    iv. Typically, the bridging plate implant will last 6-9 months before post-operational complications occur. [23]
    v. It must endure daily compressive forces from the chewing motion of the jaw.
    vi. The exposure to these forces will vary between patients and their distinct behavior.
e. Operating Environment:
    i. The set of implants will be exposed to the oral cavity of the patient during implantation.
    ii. The bridging plate and mesh implants will be exposed to internal canine physiological conditions for extended periods of time (an average of 6 to 9 months, up to the lifespan of the patient)
    iii. The device will be exposed to typical forces on a canine mandible as soon as the patient wakes up from surgery. This includes biting and resting forces.
f. Ergonomics:
    i. The barred plate, the bridging plate, and the mesh should bridge the gap of surgically removed bone.
    ii. The bridging plate should be able to withstand the compressive forces of the jaw. Compressive forces are variable depending on dog breed and location but can reach up to 5000 N. [24]
    iii. Screw axial pull out load, screw insertion torque, screw torsional yield strength, bone plate bending strength, bone plate bending stiffness,

fatigue testing, moment diagram, and corrosion testing should all meet performance specifications. [21].

g. Size:
    i. The bridging plate implant should be designed to bridge the resected portion of the mandible.
    ii. Maximum size of the set of implants will change on a case to case basis, but the dimensions of the bridging plates and mesh must be chosen to closely resemble the actual shape of the specific mandible.[23]
    iii. The size of the bridging plate and intermandibular mesh must not be inhibitive to the patient’s normal function.
h. Weight:
    i. The plate designs will vary in weight given the differences in size and density required to handle the variability between the potential patients in species, overall size, bite force, and size of mandibular fracture.
    ii. The weight of any implants in the set need not be inhibitive to their usage during surgery and the patient’s daily function.
i. Materials:
    i. Titanium is used for 3D printing finalized implants. Other materials such as plastic or carbon fiber will be used in place of titanium in the instance of printing prototypes. Titanium is a useful material that can be used in surgery, but cheap plastics that may be used as models will not be used in actual surgeries [25].
    ii. Different types of computer software will be used, including MRI scanning software to depict the anatomy of the canine, Solidworks to create a three-dimensional representation of the bone plate that can be processed and 3D printed, and Matlab to create a program that could optimize the process of placing the screws.
j. Aesthetics, Appearance, and Finish:
    i. The final software will be easy to use for doctors and veterinarians and will be able to design a plate that is functional and provides an aesthetic outcome for the patient. This means it will be able to accurately represent the anatomy of the patient in order to fit specialized bone plates that restore the normal structure and appearance of the canine’s mandible.

        - ii. The final bone plate that results from the more efficiently designed process will give the patient a correctly aligned and aesthetically pleasing jaw [26].

2. Production Characteristics
    - a. Quantity:
        - i. There will be one generic computation process that will be applied for each patient's case that will result in a set of implants specific to that patient's mandibular fracture or amputation.
        - ii. For each patient, there will be three 3D designs generated to print in titanium:
            1. One barred bridging plate will be used during the procedure to remove the compromised region of the mandible.
            2. One bridging plate will be used to maintain structural integrity during the patient's recovery time.
            3. One mesh will be used to support an autograph composite to stimulate regrowth of the mandible.
    - b. Target Product Cost:
        - i. Pure titanium is valued at $30/lb
        - ii. Our main costs will be subscriptions to software, which we as students have but our client and future users may not
            1. A Standard subscription to SOLIDWORKS costs $3,995 but a premium subscription can be up to $7,995
            2. MATLAB license cost between $50-$150
    - c. Standards and Specifications:
        - i. All experimentation for veterinary purposes must comply with federal regulations such as the Animal Welfare Act, the Laboratory Animal Welfare Act and must be overseen by organizations like the Animal and Plant Health Inspections Services and the Institutional Animal Care and use Committee [22]
        - ii. These guidelines and enforcing agencies are less strict than their medical research counterparts.

    iii. This experiment does not intentionally cause harm for research purposes and is a modification of a well-known and tried technique and thus requires almost no oversight from the previously mentioned boards.
    iv. In order to comply with the FDA's Compliance Policy Guide (CPG Sec. 607.100), the product (computational process or implant) would have to be clearly designated for animal use only.
    v. The product, be it the computational process or the implant, will be properly designated and labeled so as to comply with CPG 607.100.
    vi. The product will not be not radiation emitting and thus does not need to comply with 21 CFR 1000-1050
    vii. The product will not be classified as a drug and thus does not require premarket approval.

d. Customer:
    i. Surgeons who perform mandibular reconstruction and want an efficient and user friendly system to optimize implants.
    ii. Veterinary hospitals who want to reduce waste.
    iii. Dogs with tumors in their jaws that need to be removed.
    iv. Dogs with mandibular deformities that decrease functionality.
    v. Eventually, humans with jaw defects.

e. Patient-related concerns:
    i. Each printed implant will be sterilized by autoclaving before surgery. Any resulting infection should be treated with antimicrobials or surgical removal of the bridging plate.
    ii. The barred bridging plate will be used during the first portion of the surgery and then disposed of.
    iii. The bridging plate will be inserted during the last half of the surgery and may remain indefinitely barring infection or further trauma.
    iv. The titanium mesh will remain indefinitely, integrated into the newly grown bone.

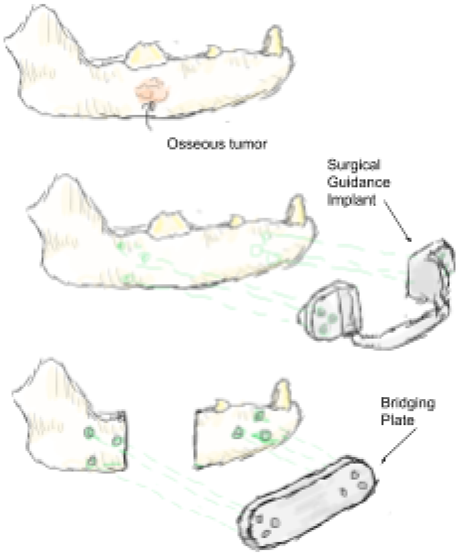
f. Competition:
    i. Implantable material and appliances and method of stabilizing body implants: porous structure made from carbon or graphite fibers. [2]

ii. Articulated bone reconstruction bar: implant that varies in size by varying the number of segments. It is used to fill a gap in the bone and is designed to fit the bone. Use fixable axles to make connections and then having mounting screws to attach. Segments are removable so that only damaged pieces are replaced without disassembling the entire bar. [17]

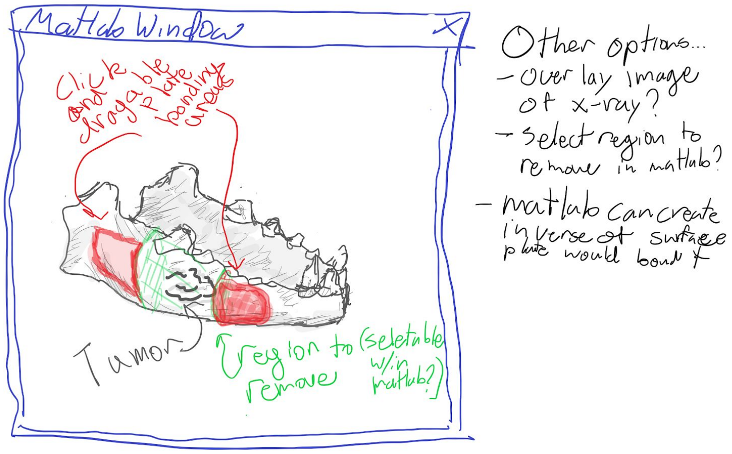
iii. Modular mandibular prosthesis: uses a pair of anchor plates and one or more connector members to bridge the gap of a bone. Each connection has swivel coupling which allows the prosthetic to have three dimensional movement. [3]

iv. Mandibular prosthetic apparatus: kit that includes prefabricated members, stainless steel mesh, mating inner and outer tubular sleeve portion (for assembling members), and screws used to attach the members to the bone. [18]

## Appendix B - Additional Figures



**Appendix B.01:** This figure roughly illustrates two of the three implants typically used by the clients. Titanium mesh not shown.



Other options...
- over lay image of x-ray?
- select region to remove in matlab?
- matlab can create inverse of surface plate would bond to

**Appendix B.02:** This figure roughly illustrates what a graphic user interface for this design could entain.