VetMed: Patient-specific mandibular reconstruction implants

Preliminary Product Design Specifications

Date: 09/20/2019

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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. [1]
   v. Risks of the device include loosening, mechanical failure and wear, infection, or user error.
   vi. Implant should be biocompatible and sterile. [2]

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 [3].
   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. [4]
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. [5]
   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. [2].

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.[4]
   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 [6].

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 [7].

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

3. Miscellaneous
    a. *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 [8]
        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.
    b. *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.
    c. *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.

d. Competition:

i. Implantable material and appliances and method of stabilizing body implants: porous structure made from carbon or graphite fibers. [9]
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. [10]
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. [11]
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. [12]

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