Spring 2020

A Novel Approach to Mid-foot Reconstruction Surgery in Patients with Charcot Arthropathy

Jessi Martin
jkm71@zips.uakron.edu

Deborah Falokun
The University of Akron, dof1@zips.uakron.edu

A Novel Approach to the Correction of Charcot Fracture in the Midfoot

Team Charcot

Members:

Jessi Martin

Deborah Falokun

Michala Dauterman

Jelena Bundalo

BME Design 1 (4800:491 - 001) and BME Design 2 (4800:492- 001)

Date Prepared: 04/10/2020

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Abstract

This honors project details the design and development of an internal orthopedic implant that surgically corrects the midfoot fracture and subsequent arch collapse in patients with Charcot arthropathy. The client of the project is Dr. David Kay, an orthopedic surgeon with the Crystal Clinic in Akron, Ohio. He presented a problem surrounding surgical implants meant to repair Charcot arthropathy. Implants that repair the midfoot fracture failed at a rate of about 60%. A team of senior biomedical engineering students attending the University of Akron developed a goal to design a new surgical implant that would reduce the failure rate of reconstruction of the midfoot in patients with Charcot Fracture. To meet this goal, the team implemented a methodical design approach consisting of 5 stages. Each stage had specific objectives or outputs that were evaluated for successful completion in relation to the scope of the project. The result of this project is an implant design and alpha prototype that meets customer requirements, engineering requirements, and solves the clinical problem initially presented by Dr. Kay. In addition, a Design History File was developed that documents the entire design process.

Background

Charcot arthropathy is a condition first described by French neurologist, Jean-Martin Charcot, in 1860. [1] Dr. Mahir Jani, an orthopedic surgeon affiliated with Frederick Regional Hospital in Frederick, Maryland and Dr. Jeffery Johnson, an associate professor and chief of the Foot & Ankle Service, Department of Orthopaedic Surgery at Barnes-Jewish Hospital at Washington University School of Medicine in St. Louis, Missouri, explains Charcot arthropathy as:

> *"... a progressive destruction of bone and joints, which is usually caused by unrecognized injury and occurs in people who have peripheral neuropathy." [1]*

Peripheral neuropathy is a condition resulting from damage to the peripheral nerves and is classified into three types: sensory, autonomic, and motor. Muscle weakness, numbness, lack of coordination, and pain are some of the clinical symptoms that can occur with Charcot arthropathy. [2] Within the foot, high-pressure concentrations can occur due to abnormal loading via the change in gate and protrusions from misaligned bones. If left untreated, these pressure concentrations can result in ulcerations, infections, and subsequent loss of the limb. [3] [4]

There are four main types of products that provide a solution to Charcot fracture currently. One of the solutions is called the Ilizarov method. The Taylor Spatial Frame, produced by Smith and Nephew, is a good example of this method. [5] The Taylor Spatial frame uses an external metal frame with rings and telescopic struts that can be independently lengthened or shortened to correct foot deformities. The second solution is external fixation. The Salvation 2 system, produced by Wright Medical, is a limb salvage system that utilizes a system of plates, external fixation, fusion bolts and beams, and mid-foot nails. [6] This system was of particular interest due to the interchangeability of the components based on surgeon preference. For example, if a surgeon preferred not to use external fixation in the system, they didn't have to. The third solution consists of a truss system that fixates in sturdier bone and aids in the distribution of weight from the patient on the injured area. Web4Medical, produces the Osteotomy Truss System. [7] The osteotomy truss system is a 3-D printed implant that is used as a wedge replacement for the small piece of bone in the correction surgery. This implant is of particular interest to the team because it can be customized to the patient. Web4Medical receives scans of the patient and then prints the implant that can implant for that specific patient. The fourth solution is an

intramedullary rod that runs through the foot and holds the shape of the reformed arch in place so that the bone can heal around it. Orthofix produces the G-Beam, an intramedullary rod that runs through the first metatarsal in the Charcot fracture. [8]

Project Scope

In specialized foot clinics, the prevalence of Charcot arthropathy in patients can vary between 0.1% to 13% [9]. Of these cases, Dr. Kay noted a 60% failure rate of the current surgical implants used to correct the midfoot arch fracture in patients with Charcot arthropathy. He indicated that implants fail due to either the implant breaking, wearing through the bone, or dislodging from the original placement. Dr. Kay presented to our team of four biomedical engineering undergraduates a need for a new implant that would reduce or eliminate the occurrence of failure due to the above three causative factors.

Methodology

To accomplish the objectives of this project, the team utilized a methodology that followed guidelines set forth by the Food and Drug Administration (FDA) for the design and development of medical devices. This process (Figure 1) is a waterfall-like diagram that details each step to be taken in the design and development of a medical device.
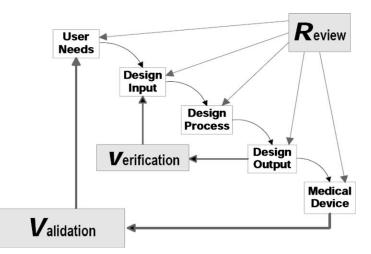

Figure 1: FDA Waterfall Diagram of Design Controls for Medical Devices [10]

The purpose of the user needs stage was to define and understand the clinical problem in addition to understanding customers' requirements. Preliminary research into Charcot fracture, its causes, severity, and different types allowed the team members to build background in the topic. This research created a basis on which fruitful, intelligent discussion was facilitated more smoothly with experts in the field. From this point, surveys and interviews were conducted with our client and other medical professionals such as Dr. Brodsky, Dr. Richter, a professor at Case Western Reserve University, and 7 other podiatrist and orthopedic surgeons that work at the University of California-San Francisco. The surveys asked for opinions on current surgical methods, details on the surgical process, including less obvious body parts involved in the surgery, and healing

time/experience of patients' post-surgery. Based on the information collected during this process the team was able to formulate a set of customer requirements that further refined the scope of the project.

Once the customer requirements were established and approved by the teams' sponsor and project readers, the project moved into the next stage, the *Design Inputs*. During this stage, the team generated a Quality Function Deployment (QFD) that produced correlated ratings between engineering and customer requirements. In addition, a concept Failure Mode and Effects Analysis (FMEA) document was generated by evaluating the common failure modes of the most common products on the market. This evaluation gave a basis for future concepts to be evaluated against.

Next, during the *Design Process* stage, we brainstormed design concepts and shared ideas for the implant. Each individual concept was broken down into components, and the components were evaluated and compared against the engineering requirements previously made. Selection charts aided in this evaluation process, and components that met requirements were incorporated into the finalized design. The material selection for the plates, rods, and screws was based on the ultimate tensile strength of the material compared to the applied load and ultimate tensile strength of bone. The goal was to choose a material that has an ultimate tensile strength higher than the expected load but lower than the ultimate tensile strength of bone, allowing the implant to withstand the applied load and not fracture, but not be so strong as to wear through the bone. These designs were modeled in Solidworks and evaluated with a QFD and FMEA similar to the evaluation of the competitor products in the previous stage gait.

When moving into the *Design Output* stage, the team's design went through a few more design iterations. Communication with the sponsor ensured that the design was in line with his expectations. The QFD, FMEA, and Solidworks documents were updated to follow the finalized design. After this, preparations for a prototype were made. An alpha prototype was 3D printed in polylactic acid filament to verify the shape and size of the prototype (Appendix A). In addition, a design package including specifications, drawings, vendors, and assemblies was constructed. At this point, the project scope changed greatly due to the COVID-19 pandemic and subsequent quarantine. The team was no longer able to meet physically but we were able to complete an FEA analysis of the implant. Further validation and verification testing was not completed.

Project Requirements

Customer Requirements

To understand the scope of the project, our team consulted with Dr. Kay to formulate his expectations and solidify them into a list. The following user needs were identified by combining the aforementioned list with the data from the survey:

1. A smaller surgical incision is necessary to reduce the risk of infection.
2. To accommodate the varying surgical techniques and preferences, an easily repeatable procedure is essential for the product to be successful.
3. In line with reducing the risk of infections, a 100% Internal Device is a necessity.
4. The product must be able to withstand cyclic loading that it will experience in the neuropathic foot for it to be a successful solution.

5. The goal of the product is to stabilize the midfoot arch
6. An FEA model that displays the ability of the product is necessary to ensure that it's capable of repairing Charcot fractures and withstanding the experienced loads.
7. A new product, unlike the options available, is beneficial since the current designs are not working.
8. Having a device that can fit multiple body types and bone structures will allow for the treatment of extreme cases.
9. The device must be biocompatible such that it does not induce a negative immune response.

Objectives

To align with the scope of the project, the team generated requirements to follow the expectations of our sponsor. To achieve the scope of the project, our team designed and developed a novel surgical implant that will correct the fracture of the midfoot arch utilizing the following objectives:

1. Implement a system that utilizes a methodical and systematic implant design approach.
2. Understand the pathophysiology, current treatments, and methods of Charcot arthropathy midfoot fracture reconstruction.
3. Identify customer requirements and develop a clinical needs statement for the development of a new implant that reduces the failure rate.
4. Develop a set of design specifications based on customer requirements, industry standards, and risk assessment results.
5. Generate and select an initial implant design concept based on customer requirements and design specifications.
6. Develop initial and subsequent prototypes of the implant design concepts utilizing 3D modeling software
7. Conduct testing and risk assessment to ensure the selected design satisfies both the design specifications and customer requirements and adjust the design accordingly.

Engineering Requirements

There were six engineering requirements identified through the customer requirements established by our sponsor. These requirements were used for the verification of the implant design.

1. The implant must withstand 10^7 cycles of fatigue testing
2. The implant must weigh less than 2 lbs
3. The implant material must be durable and non-corrosive in the human body
4. The implant must be biocompatible and not cause any adverse effects to the patient
5. The implant must be able to withstand an applied force of about 1.2 * bodyweight
6. The implant must have an ultimate tensile stress no more than about 150 MPa

Results

Design Concepts

Initial Concepts

All of the images, generated by team members, were based on different aspects of the load-sharing system and Charcot fracture fixation. Important aspects that came from these initial ideas that were incorporated in the concept creation process were: an under-arch support to prevent the medial arch from re-collapsing, a triangular load-bearing system to better transverse loads, adjustable pieces on the implant, and materials that were more "springy" to help transverse loads better and withstand cyclic loading.
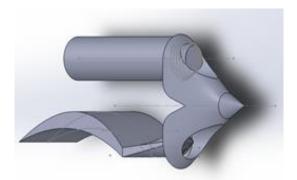
Concepts A and B

Figure 2: *3D Model of Concept A*

Concept A (Figure 2) consisted of a plate-rod system that utilized a top rod and a bottom plate. The bottom plate would be located under the arch, and the rod would run through the first metatarsal. The plate-system would be connected with a y-joint. The connection point would utilize o-ring bushings to better transverse loads. This system was meant to be able to transverse loads and withstand cyclic loading much more effectively than previous implants. As an alternative to the y-joint, Concept B (Figure 3) used screws with o-ring bushings to anchor each piece in place.
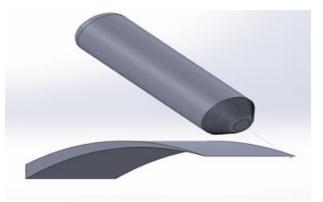

Figure 3: *3D Model of Concept B*

Risk Assessment

The first set of risk assessment was conducted on four existing products, Salvation 2, G-Beam, Osteotomy Truss System, and the Taylor Spatial Frame. The most common failures identified from the FMEA across all four products were that (a) the screws backed out; (b) the beams fractured; (c) the rods burrow through the bone; (d) the plates dislodged; (e) bacterial infections occur from external implant. We identified design considerations to mitigate these risks including (a) better thread design; (b) better anchoring of the entire implant, (c) utilizing an internal device to minimize infection; (d) ensuring use of a biocompatible material that does not cause adverse reactions for the patient
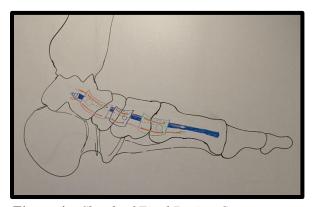
A second risk assessment was conducted to determine the superior design concept in terms of patient risk. After analyzing the results of the FMEA risk assessment, high-risk features were identified in both Concept A and Concept B. For Concept A, the Top Rod, Y-Joint, and Toe Rod contained high-level risks. All three features contained the high-level risks of (a) wearing through the bone; (b) fracturing, (c) dislodging. The Y-Joint had an additional risk of difficulty mating with other implant components due to its complex design. Both Concepts A and B utilized the same mitigation strategies to minimize the identified risks. These mitigations include: (a) design changes and (b) ensuring correct material selection. These mitigations could be verified by: (a) mechanical testing; (b) engineering calculations; (c) FEA analysis

After the complete assessment, Concept B contained fewer high-risk components and high-level risks. Ergo, in terms of patient risk, Concept B is the superior concept. Although Concept B satisfied more engineering and customer requirements, three areas for potential improvement were identified for future design iterations. These improvements included: durability of bushings made of PEEK (ensure they are non-corrosive), no protrusions from the plate-rod system that could cause rubbing on the bone, and the ability to anchor plate-rod system to the bone that would withstand the forces experienced in a neuropathic gait (up to 1.2*bodyweight).

A final risk assessment was conducted for an iterated design in the form of an FMEA. No high-level risks were detected. Moderate level risks included: (a) components fracturing and (b) components backing out. Lower-level risks were identified, but these low-level risks were deemed acceptable to move forward. Suggested mitigations to minimize the moderate risks identified in this design include: (a) FEA analysis; (b) engineering calculations; (c) mechanical testing. Compared to all other concepts presented in this project, this current design is the superior design in terms of patient risk.

Final Design: Concept C

Our final concept, Concept C, utilized the idea of a suspension bridge. Concept C comprised a plate system and rod. This plate system has a series of 3 plates attached with sutures. The three plates would cover the first metatarsal, the talus, and the calcaneus and attach to each bone through two screws and a PEEK o-ring. The purpose of the screws is to fix the plates to the bone to restrict the plates from moving. The plates are anchored to the bone in areas of better bone quality, such as the calcaneus and the talus, through suture anchors. A hollow threaded rod would be inserted into the first metatarsal and anchor into the talus. Since this component is 3D printed, the angulation of the rod would be created utilizing the patient's anatomy. Figures 4a, and 4b illustrate this new design concept. A major advantage of this new design is that because the implant is 3D printed, it can be customized to the individual patient. Currently, the implants used in the surgery to correct Charcot fracture don't have the customizable option to surgeons to have implants made for each patient.
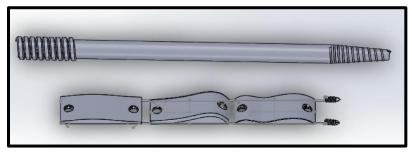
Figure 4b: 3D Model of the Final Design Concept

Figure 4a: Sketch of Final Design Concept on the Foot

Material Selection

To calculate the experienced stress, the team derived a mathematical model to determine the load experienced on each implant component. The actual implant was to be placed at a 60-degree angle from the vertical axis, toward the medial side of the foot. Because a force value loaded in a uniaxial direction is larger than a force value loaded in an angular direction, the team determined the worst-case load to be the force loaded in the vertical uniaxial direction. Figure 5 illustrates this description.
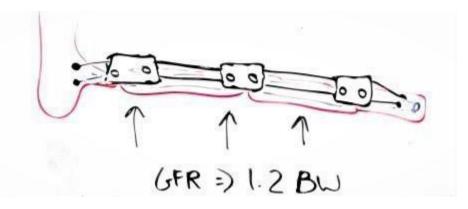

*Figure 5: Illustration of the load experienced on the Implant System (1.2 * Body Weight)*

There were two assumptions made to derive this math model:

1. The implant system (rod and plates) experienced the load equally.
2. The 3-plate system experienced the load equally.

The first assumption allowed the team to state that the load experienced on the rod was half of the applied force, and the load experienced on the 3-plate system was half the applied load. The second assumption allowed the team to state that the load experienced on each plate was ⅓ of the load experienced by the 3-plate system (which is ½ of the total load). The applied load is based on the value described by Davis et al. that states that the ground reactive force experienced in a neuropathic patient is about 1.2 * bodyweight. [11] The body

weight value was chosen from our client Dr. David Kay, based on the typical patient weight he experienced in his clinic. The weight was chosen at 400 lbs.

The following equations were used to calculate the applied force experienced by each component:

$$F_{total} = F_{Plate} + F_{Rod} = 2F \qquad (1)$$

From equation 1 and assumption 1, it was shown that the rod and plate-system experience 240 lbs of force.

$$F_{Plate} = F_{M-Plate} + F_{C-Plate} + F_{T-Plate} = 3F \qquad (2)$$

From equation 2 and assumption 2, it was found that each plate experiences 80 lbs of force.

The team then used these values to calculate the ultimate stress each component will experience. The calculation of the ultimate stress for the plates was done at worst case, which would be the smallest cross-sectional area of the plate to the applied force. The smallest cross-sectional area of the three plates was located in the T-plate. Figure 6 illustrates the T-Plate cross-sectional area with dimensions: 0.05 in x 0.13 in.
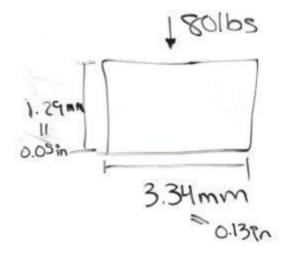

Figure 6: Cross-Sectional Area of the T-Plate with Dimensions

The experienced ultimate strength was calculated by dividing the applied load by the cross-sectional area:

$$A = length(width) \qquad (3)$$

$$\tau = \frac{F}{A} \qquad (4)$$

From equation 2,1, the cross-sectional area is $6.5 \times 10^{-3} \ in^2$. Utilizing equations 3 and 4, the ultimate stress that the plates experience is 12 kilo pounds per square inch (ksi). A carbon fiber-PEEK composite material has an ultimate strength of 15.23 ksi, which is greater than the ultimate strength of human bone (21 ksi). Ergo, a carbon fiber - PEEK composite was chosen for the material of our plates. Additionally, utilizing carbon fiber-PEEK composite will transverse loads through the implant more effectively than traditional metal

such as Ti-6Al-4V. Similar calculations were conducted for the rod. Since there is only one rod in this system, the calculations were conducted using dimensions of the rod. The rod had a radius of 0.29 in.

The experienced ultimate strength was calculated by dividing the applied load by the cross-sectional area, utilizing the equations shown below.

$$A = \pi r^2 \qquad (5)$$

$$\tau = \frac{F}{A} \qquad (6)$$

From equation 5, the cross-sectional area is $0.26\ in^2$. Utilizing equations 5 and 6, the experienced ultimate stress of the rod was 0.91 ksi.

Similar derivations used for the rod and plate-system were used for the screws. However, instead of a uniaxial force that the rod and plate-system experience, the screws experience a torsional force. That torsional force (τ) was used to calculate the experienced torsional strength. This calculation required the applied torque (T) (assumed to be 6lb$_f$ from industry standard), the distance from the center to the stressed surface (r_0) (the outer diameter of the screw threads), and the second moment of inertia (I). The second moment of inertia was used since that is a measure of resistance to torque.

The outer diameter of the screws is 4.05 mm, with an outer radius of 2.05 mm or 7.97x10^{-2} in. The inner diameter is 3.10 mm, with an inner radius is 1.55 mm. The length of the screw is 24.81 mm or 0.977 in. The equations used to calculate the applied torsional stress are as follows:

$$I = \frac{\pi}{2}(r_0{}^4 - r_i{}^4) \qquad (7)$$

$$\tau = \frac{Tr_0}{I} \qquad (8)$$

From equations 7 and 8, the torsional strength experienced by the screws is 194 ksi. The material strength of 316 S12 stainless steel has a material strength of 15.28 ksi and thus was chosen as the material for our implant screws.

FEA Analysis

The analysis illustrations are contained in Appendix B. For the rod portion of the implant system, an applied load of 240 pounds of force or 1067 N was tested. It was found that the maximum deformation the rod experienced was 3.5 mm in the center of the rod.

For the 3-plate system, each plate was tested individually. Each plate had an angularly applied force of 80 pounds of force or 355 N. This replicates the angular placement of the plate on the foot in vitro. The C-Plate experienced a maximum deformation of 0.000809 mm at the top portion of the plate. The M-Plate experienced a maximum deformation of 0.000879 mm at the top portion of the plate. The T-Plate experienced a maximum deformation of 2.529 x 10-5 mm.

The plate system essentially had a deformation of about 0 mm. This indicates that the material distributes the load evenly enough to withstand the applied load experienced in a neuropathic gait and not fail.

However, because the rod displaced at a maximum of 3.5 mm and without further testing, our team cannot definitively state that the rod will not fail

Conclusions and Future Work

From the results of the FEA analysis, we believe our plate system will satisfy our user and engineering design requirements and prove successful in correcting Charcot fracture. However, we believe that further testing and design iterations should be completed for the rod before moving forward with this design concept. We initially made the rod hollow because of the documented failures of rods that are solid wearing through the bone and fracturing. Yet, we think that the hollowness of the rod contributed to its extreme deformation.

Additionally, the material may not be as strong as we calculated it to be. We utilized a 20/80 composite of carbon fiber - PEEK. Future design changes could include utilizing a different composite ratio such as 40/60 of carbon fiber - PEEK, a different material, or even a solid rod might improve the performance of this implant component upon further testing.Additional testing also needs to be conducted to ensure this product will withstand the expected life cycle of the implant. Furthermore, tasks such as manufacturing processes still need to be developed, and a 510K needs to be submitted to the FDA to be able to put our implant into the market.

Our client showed in interest in allowing the rod and contour of the plate system to be created based on the patient's own anatomy since the implant will be 3D printed. This idea should be investigated further as this would allow our implant system to further differentiate ourselves from the competitors. Having an implant that is designed to the patient adds more customization options for the surgeon and better outcomes for the implant and patient. In order to provide a patient-fit implant, additional software would need to be created or purchased that could analyze the contours of patient scans and relate them to the implant. This model of providing on a case-by-case basis would cause the product to have a significantly higher price than competitor products on the market. A cost-benefit analysis should be completed to analyze the benefits and drawbacks of a case-by-case production model in comparison to mass production.

Lessons Learned

The team worked together with experts in the field to understand Charcot fracture and how it affected patients and medical personnel. The team learned the importance of initial research and how it enhances the conversation and level of understanding. The team also learned about the process of creating a new product and the importance of translating customer requirements into engineering requirements properly. The ability to discuss with other engineers technically while understanding the medical terminology of those personnel aided in the process of creating the implant. Additionally, communication under tight schedules and unforeseen events was a key factor in bringing the product to a conclusion that suits everyone's needs.

Acknowledgments

The team would like to thank our sponsor Dr. David Kay as well as Dr. Brodsky, for providing background knowledge and their personal experience in repairing the Charcot fracture. The team would also like to thank Gary Doll for his consultation on materials and his recommendations for our product. We appreciate and thank The University of Akron for providing resources to construct and store our prototypes.

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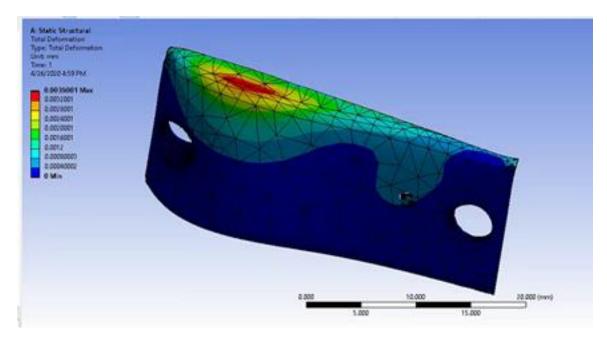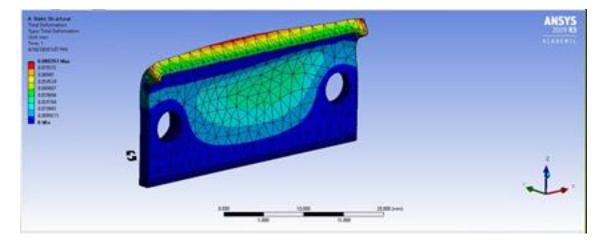
Appendices
Appendix A: Alpha Prototype

Appendix B: FEA Analysis Total Deformation

C-Plate

M-Plate

T-Plate