University of Manitoba

# Design of a Rapid Fabrication Custom-Fit CROW Orthosis

Final Design Report

MECH 4860: Engineering Design



*Report Prepared For:* Anderson Orthopedics

*Report Prepared By Group 16:* Avery Barsalou
Long Phan
Eric Crooks
Brenden St.George

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## Executive Summary

The Client, Anderson Orthopedics, is looking to use Additive Manufacturing to improve their manufacturing time for a support device called the Charcot Restraint Orthotic Walker (CROW). The function of a CROW Orthosis is to offload and support the patients' foot and support the existing sole geometry when the joints in the foot are weakened and cannot properly support weight. Patients that require a CROW orthosis have a high risk of lower limb amputation if they continue to load their foot without proper support. Thus, it is critical that patients receive their CROW orthosis as soon as possible. Excessively long manufacturing times delay patients from starting their treatment and increase their risk of lower limb amputation.

The objectives of this project were to design a 3D Printable CROW Orthoses that performs the same as the current design but takes less time to manufacture than the current design. The objective was to have the new manufacturing process take less than 15 hours and cost less than CAD$ 1,000. The new design must be able to use in an environment like Winnipeg, where the temperature ranges from -30 °C to 30 °C as well as prevent water from seeping in. The design must also support the weight of the patient without yielding. In addition, the design should last the treatment period, which is typically 1 year.

The final design took a modular approach to solve the Client's problems. The outer shell is composed of four MJF Nylon 12 3D printed components, which split the limb between anterior and posterior with segments for the calf, and two for the ankle-foot. Both posterior components glued to one another and further stiffened with aluminium rods. To provide user comfort, a lined PPT foam is glued into the inside of the shells. A a rocker sole designed into it to reduce the manufacturing time. Ratcheting BOA straps are used to hold the posterior and anterior shells together, as well as provide easy adjustability for the patient. Further adjustability for swelling was accommodated through a square wave pattern between the anterior and posterior shells.

The time to print and cool the parts of the design is 24 hours. The cost associated with this design was CAD$ 1,945.93. These results did not meet the objectives for the manufacturing process, but do allow for fewer technician hours at Anderson Orthopedics. For the design, the material that was identified is waterproof and functions within the specified temperature range. The FEA showed that yielding does occur during the more extreme loading cases of the walking cycle. The final design and manufacturing process did not meet all of objectives that were established, and for those that were not met, future recommendations were made for they could be met in future work.

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# 1 Introduction

Additive manufacturing (ADM) technologies have been revolutionizing the way custom support devices are manufactured. The Client, Anderson Orthopedics, is looking to incorporate ADM into their in-house manufacturing process to reduce the lead times for their support devices. The Capstone Team was tasked with designing a CROW Orthoses to be manufactured using a Selective Laser Sintering (SLS) machine. The goal of the new design was to reduce the current manufacturing process of the CROW Orthoses. The deliverables of this project were a new CROW Orthoses design and breakdown of the manufacturing process, with an estimated manufacturing time.

## 1.1 Anderson Orthopedics

Anderson Orthopedics was founded in 1946 by former Department of Veteran Affairs employee, George Anderson. George Anderson was involved in a new subbranch of Veteran Affairs, the Department of Prosthetics. The purpose of the Department of Prosthetics was to assist World War 2 veterans in gaining access to prosthetics to replace limbs lost in the war. Ordinary civilians were not eligible to be treated by this department. George Anderson began treating patients that were not able to get treated through the department of prosthetics from his house. George then went on to found Anderson's House of Orthopedics, which later got renamed to Anderson Orthopedics [1].

**Anderson Orthopedics Mission Statement:**

Provide superior quality of treatment that patients prefer, rehabilitation professionals recommend, and employees are proud of.

Anderson Orthopedics goal is to provide the following:

- A treatment plan to help the patients attain their goals and achieve their maximum potential.
- Prosthetics or Orthotics that are fabricated and assessed using state of the art practices, quality components and suitable designs.

## 1.2 CROW Orthosis

A CROW orthosis, seen in Figure 1 [2], is a system that supports and protects the lower extremity below the knee, including the ankle and the foot. This allows patients with severe foot deformities and pressure ulcers to have some freedom of movement without worsening their condition. The CROW Orthosis was developed to treat neuropathic arthropathy, a disease common in people with diabetes, and has been in use since 1980's. Neuropathic arthropathy is a condition that causes a loss of sensation in the patient's lower extremities (starting in the foot), leading to the weakening of joints and eventual changes in the foot's geometry. The changing foot geometry alters the pressure distribution on the sole of the foot causing softer tissue to bear stress, leading to

the development of ulcers. The CROW orthosis supports the shape of the patients foot, preventing any further deformation and progression of ulcers and offloads the patients weight onto the calf during the walking motion [3].

Figure 1: CROW with Mechanical Hinge

Prior to the CROW Orthosis, patients would get their afflicted limb put in a plaster cast to prevent further deformation in the foot. A study conducted in 1993, tracked the treatment of 18 patients with a CROW Orthosis. Patients that took part in the study noted that their lifestyle with the CROW was significantly improved relative to the cast solution and rated their experience with the device as either good or excellent. Patients noted that they felt their freedom of movement was impacted less by the CROW Orthosis compared to the cast. The 2 custom, rigid exterior shell mate with the patients leg and offloads the foot and ankle. A rounded rocker sole allows for the patient to use both legs to walk while managing the pressure distribution in the patient's sole [3].

It is critical that patients receive their CROW boot as soon as possible. Patients who require a CROW orthosis but continue to walk without one are at a high risk of progression of ulcers and total collapse of the midfoot. Ultimately, this worsening of a patient's foot condition can lead to various levels of foot or lower limb amputation which increase in risk with prolonged time without treatment. Amputation of the leg affects the patient's quality of life, poses a new risk of surgical site infections or other surgery related complications [4].

## 1.3 Current CROW Manufacturing Process

The entire CROW orthosis and custom foot orthotic are manufactured by Anderson Orthopedics. The design of the custom foot orthotic is considered out of scope for this project. The current strategy to manufacture a CROW orthosis is to make a plaster model of the patient's leg and add foam and thermoplastic around that mold so that device properly envelopes the geometry of the patient's leg. Figure 3 shows a general work flow for the current CROW manufacturing process.

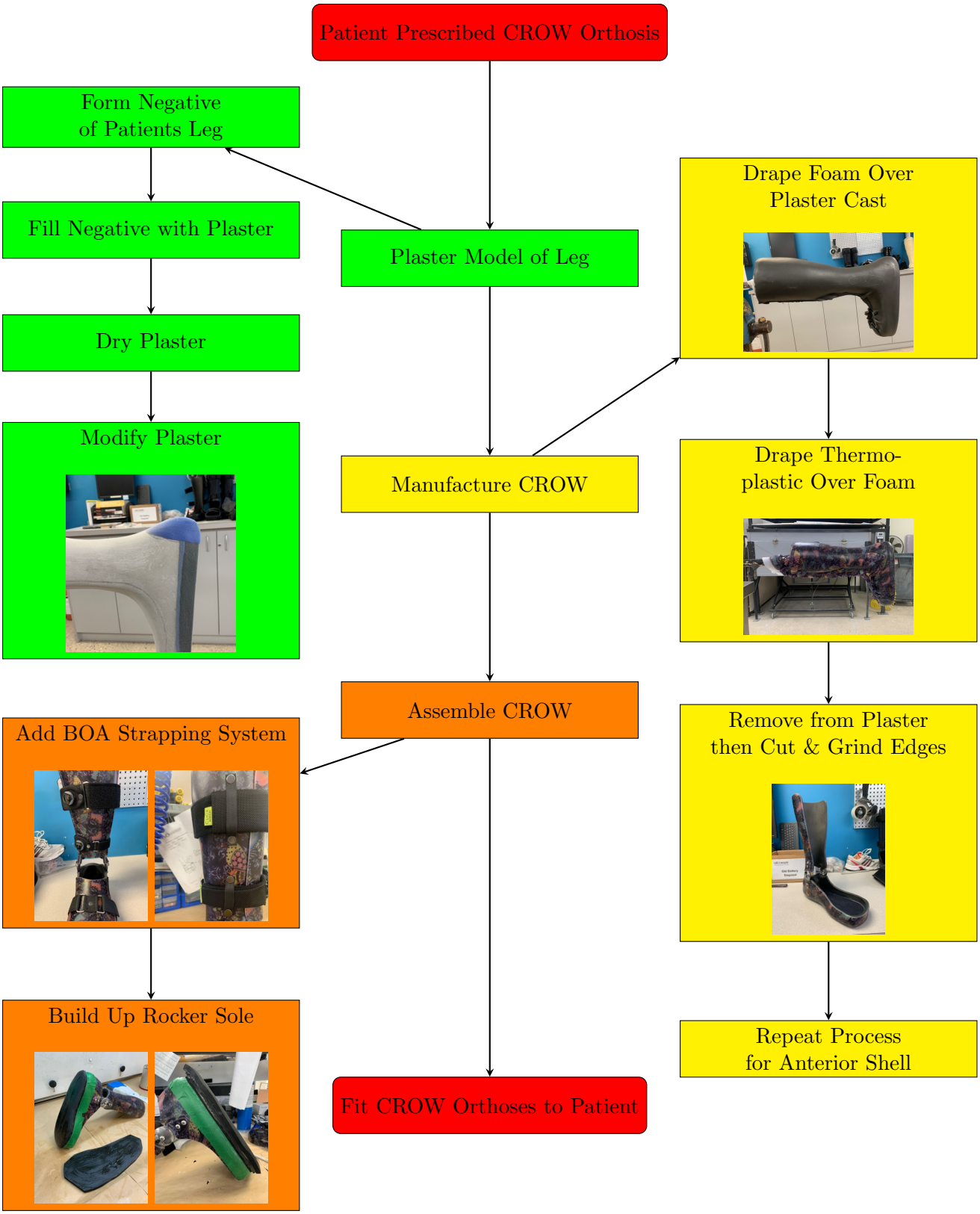



Figure 3: Current CROW Manufacturing Process

Table I shows a detailed breakdown of the time associated with each manufacturing step. This CROW model has a hinge at the ankle and has a couple of extra processes included. It is important to note that the final design of each CROW is unique.

TABLE I: Manufacturing Time Breakdown

| | Task | Time |
|---|---|---|
| 1 | Stamp & Smooth | 30 min |
| 2 | FO | 2 hours 15 min |
| 3 | Liner (Posterior) | 1 hour 30 min |
| 4 | Heel Relief | 1 hour |
| 5 | Joint Alignment | 2 hours |
| 6 | First Drape | 30 min |
| 7 | Cut, Grind, Buff Plastic (Posterior) | 1 hour 30 min |
| 8 | Install Joints | 1 hour |
| 9 | Liner (Anterior) | 1 hour 30 min |
| 10 | Second Drape | 30 min |
| 11 | Cut, Grind Buff Plastic (Anterior) | 1 hour |
| 12 | Straps | 2 hours |
| 13 | Soling | 2 hours 45 min |
| | **Total Time** | **18 Hours** |

## 1.4 Problem Definition

The Client needs a faster, more cost-effective manufacturing process for their custom fit, adjustable CROW orthosis. The need for this project stems from the current manufacturing process being long and labor-intensive which has a current lead time around 8 weeks for patients of the Client. This 8-week lead time is considered an issue to the Client due to the need for patients of Anderson Orthopedics to receive their CROW boot as soon as possible to begin rehabilitation of ulcers within universal delivery of wound healing protocol. By reducing the total cost (labor and manufacturing) of the CROW's manufacturing through alternative materials and/or labor reduction, this important rehabilitation device can be obtainable by more people and mitigate the chance a patient requires amputation.

### 1.4.1 Project Objectives

The following primary objectives were developed upon consultations with Anderson Orthopedics.

- To improve upon the Client's existing CROW orthosis design and production process.
- For the proposed improvement to meet or exceed the existing product's treatment ability.

- For the designed product to accommodate a variety of end users with varied medical conditions.
- To produce a prototype or the necessary documentation to do so, of the final solution proposed by the Capstone Team.

These objectives were used to drive the development of the customer needs, target specifications, constraints and limitations of the project.

### 1.4.2 Customer Needs and Target Specifications

The customer needs were developed utilizing the following project requirement gathering techniques: internal brainstorming with the Team, interviews with the Client, and observation of the Client's current manufacturing design process. The Team used the Numerical Assignment Technique to rank each requirement using a scale of 1 (lowest priority) to 5 (highest priority). Using feedback from the Client [4][5], the finalized design needs were prioritized in Table II below.

TABLE II: Prioritized Customer Needs

| # | Need | Importance |
|---|---|---|
| 1 | The orthosis: is safe for patient use. | 5 |
| 2 | The orthosis: immobilizes the foot. | 5 |
| 3 | The orthosis: is durable for daily use. | 5 |
| 4 | The orthosis: supports patient weight. | 5 |
| 5 | The orthosis: lasts the treatment period. | 5 |
| 6 | The orthosis: immobilizes the ankle. | 5 |
| 7 | The orthosis: accommodates inclusion of a custom foot orthosis. | 5 |
| 8 | The orthosis: is cost effective to produce. | 4 |
| 9 | The orthosis: is adjustable to fluctuations in limb volume. | 4 |
| 10 | The orthosis: is water resistant. | 4 |
| 11 | The orthosis: is quick to manufacture. | 4 |
| 12 | The orthosis: works normally in Manitoba's climate. | 4 |
| 13 | The orthosis: is a modular design. | 3 |
| 14 | The orthosis: is aesthetically pleasing. | 2 |

The needs above in Table II form the framework governing all decisions made throughout the design process.

TABLE III: Target Specifications

| Metric # | Need #'s | Metric | Units | Ideal Value |
|---|---|---|---|---|
| 1 | 11 | Manufacturing Time | hours | $< 15$ |
| 2 | 1, 4 | Minimum Weight Supported | lbs | 275 |
| 3 | 8 | Unit Manufacturing Cost | CAD$ | $< 1{,}000$ |
| 4 | 1, 2, 3, 5, 6 | Factor of Safety | N/A | 3 |
| 5 | 13, 9 | Minimum Circumferential Length Increase | cm | 4 |
| 6 | 5 | Treatment Length | year | 1 |
| 7 | 3, 10 | Minimum Water Resistance Rating | IP | 54 |
| 8 | 3, 12 | Minimum Operating Temperature | °C | -30 |
| 9 | 3, 12 | Maximum Operating Temperature | °C | 30 |
| 10 | 14 | Survey of Aesthetics | subj. | Pass |
| 11 | 7 | Inclusive of Custom Foot Orthosis | Binary | Pass |

Further description has been provided below to clarify some of the metrics stated as target specifications in Table III:

- The Minimum Weight Supported metric is defined as the minimum vertical loading weight that must be supported by the CROW orthosis to be considered successful. This vertical loading weight will be different to each patient as this value is classified as their total body weight. For the target specifications the Team targeted a minimum acceptable value of 275 lbs to design towards. The loading values based on this vertical loading weight will be determined further in the following project phase.

- The Factor of Safety metric is defined as the minimum allowable factor of safety for the overall design. This factor of safety includes cyclical loading experienced from ambulation and any plastic deformation of the CROW orthosis in use. The factor of safety value was chosen to prevent plastic deformation and fracture failure during the treatment period specified in Table III. The forces applied to the CROW orthosis while in use will be calculated in the following project phase and used as a baseline when validating the factor of safety (FOS) metric.

- The Minimum Circumferential Length Increase metric is defined as the ability for the CROW orthosis to increase in circumference at the leg region. A baseline circumference will be custom to each custom CROW orthosis. This metric will be evaluated by measuring the baseline circumferential length of the CROW orthosis and observing if the baseline circumferential length can be increased by a minimum value 4 cm.

- The Survey of Aesthetics metric will be subjectively judged a pass or fail for evaluation purposes. The judging of this metric will be conducted by Jacques Swanepoel and Dan Mazur from Anderson Orthopedics.

- The Inclusive of Custom Foot Orthosis metric will be judged a pass or fail for evaluation

purposes. The judging of this metric will be conducted by Jacques Swanepoel and Dan Mazur from Anderson Orthopedics.

### 1.4.3 Constraints and Limitations

The following project constraints were developed based on the project goals, needs and target specifications in addition to discussions with Anderson Orthopedics. These are listed in the order of importance, as identified in team discussions.

- Project must be completed by Dec. 7, 2022

Additionally, the project limitations outlined below were developed in tandem with the constraint itemized above.

- Only below-the-knee CROW devices are to be considered
- Design prototype project occurs after Dec. 8, 2022
- Only ailments which the CROW are designed to treat are to be accounted for
- Physical therapy and treatments not provided by the CROW need not be considered
- Redesign of the custom foot orthotic is out of scope

## 2 Background Information

The team followed the design methodology outlined in Figure 4 and drove the approach to the problem. [6].

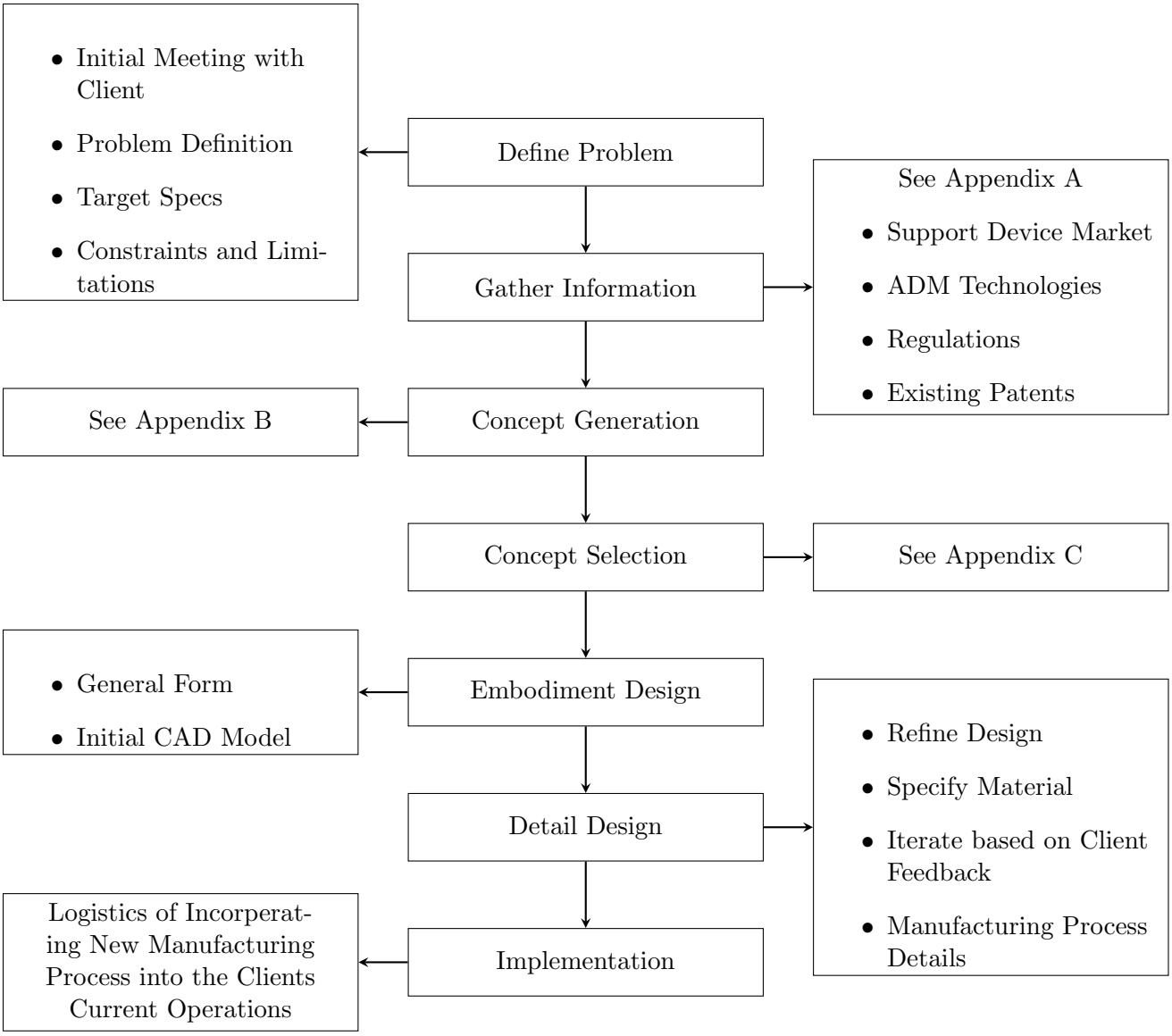



Figure 4: Overall Design Process

Relevant information gathered that influenced the project is included in Appendix A. The concept generation and selection processes were documented in detail and included in the Appendix B & C respectively. The embodiment design and detail design are discussed in Section 3.1.2. The implementation is discussed in Section 3.2.

## 2.1 Additive Manufacturing Technologies

Additive manufacturing processes are ideal for the custom CROW application, as it does not require large tooling costs that can only be offset with large scale production, as well as by reducing the wasted material. These are investigated as the CROW design is an ideal example for 3D printing, due to the one-off nature with complex natural shapes to the designs. There are a large variety of ADM processes. Listed below are some common ADM processes which will be discussed in further detail.

- Fused Deposition Modeling (FDM)
- Selective Laser Sintering (SLS)
- Stereolithography Printing (SLA)

### 2.1.1 FDM Printing

FDM remelts polymer filaments then extrudes it through a nozzle, adding on to a base plate and builds the part up layer by layer to create the final shape. This method is of relatively low cost ADM technology, which poses the greatest opportunity for cost reduction in the manufacturing of the CROW device [7]. FDM Printers are relatively limited in the geometry they can print. They typically need a flat surface on the part to mate to the bottom of the build plate. Post processing is not always required for FDM parts, however overhangs on parts may require support material. In addition, the material properties tend to exhibit anisotropic properties due to the relatively large layers and voids between them that form, thus, their structural use cases are dependant on load cases. As such, this method may be suitable for the CROW design depending what material is selected.

### 2.1.2 SLS Printing

SLS uses fine material powder, using a laser to melt patterns into the powder layer by layer, where the layer can either be metallic or polymer, although the metallic based powders have large costs compared to the polymer based powders [8]. SLS devices form the part layer by layer using a laser to fine bind together fine particles; this form of ADM results in exceptional material properties and print resolutions. First, a layer of material particles get spread over the area of the build volume. Next a laser passes over and sinters together neighbouring material particles, forming a 2D section of the part. This process gets repeated layer by layer until the full height of the part is manufactured.

The sintering process stores heat inside the build volume as each layer of material gets added; once the machine is done printing, the part must be left to cool. Once the print has cooled, the parts can be post processed. Post processing SLS parts typically entails sandblasting to remove

the material particles that were not fused into the part. An added bonus of SLS printing is that the excess powder acts as a natural support material for the sintered areas. This makes it simple for SLS printers to produce complex geometries with such good surface finish.

Covering the build area with material each layer also allows the operator to fill the build volume with parts. Figure 5 shows the build volume of a generic HP SLS printer filled with parts. This has the possibility of reducing the time for large numbers of parts to be printed, as many can be printed within the same volume without impact on printing time.

Figure 5: HP Slicer Filled With Parts

SLS printing has a narrower range of materials to print with relative to FDM, however SLS can print material certified by ISO, FDA and ASTM.

### 2.1.3 MJF Printing

Multi Jet Fusion (MJF) printing uses fine material powder in a similar manner to SLS and require comparable post processing, but differs in the fusing of the material and its associated properties. MJF uses an infra-red laser to fuse a binder compound added to the print powder in the region of the part [9]. This binder helps providing a large portion of the strength of the printed part and allows for material properties that are closer to isotropic with a higher strength than SLS equivalents, although it is more brittle [10]. This printing method has a limited range of possible materials. This could be beneficial for the CROW device due to the increased strength, and isotropic properties over the SLS method with the same material. Certain MJF print materials are certified by ISO, FDA and ASTM.

### 2.1.4 SLA Printing

SLA printing functions by focusing UV light within a resin bath to selectively cure portions, allowing the printed part to be drawn out of the bath. This method allows for very high detail, but is limited to UV curable resins whose material properties change with long term exposure to UV light. Like SLS, SLA printing requires post processing of the parts before they can be used. SLA printing requires cleaning off any uncured resin still attached to the part and finally post curing in a UV chamber [11].

As the CROW device is intended to be used for relatively long terms, as well as in situations where UV light will be present, SLA is not a suitable method for the production on the outer shell of the device as the material properties would change undesirably, becoming more brittle [7].

## 2.2 Regulations

Regulations and professional responsibilities were investigated, as these will impact who can or cannot develop the product to market, but also what regulations, guidelines or laws are in place to ensure patient safety and or professional ethics.

### 2.2.1 Orthotics Prosthetics Canada (OPC)

The assessment and fabrication of Orthotic devices in Canada is left to the discretion of Healthcare providers with special certifications and registrations designations indicating their experience and knowledge base in the field; these certifications and registrations are managed through Orthotics Prosthetics Canada (OPC). The CROW boot, as a custom foot orthotic, would fall within this jurisdiction. Below is the full list of designations managed through the OPC:

1. Certified Orthotists (CO)
2. Certified Prosthetists (CP)

3. Certified Prosthetist Orthotists (CPO)
4. Registered Orthotic Technicians (RTO)
5. Registered Prosthetic Technicians (RTP)
6. Registered Prosthetic Orthotic Technicians (RTPO)

Certifications and Registrations relating to orthotics are the most relevant to this project, however the designations relating to prosthetics were included to show the full scope of OPC. Certification through OPC takes 8 years, including 2 years of residency and maintaining the certification requires continued education [12].

The OPC's Standards of Practice outlines the expectations for healthcare providers holding a designation managed by OPC (referred to as OPC members). The expectations for product recommendation are outlined in the document as follows [13]:

*When OPC Members use, recommend, provide, or sell products integral to treatments, they must do so in a way that serves the patient's best interests and limits the potential conflict of interest associated with product use and the product recommendation*

**Indicators**

1. *OPC Members use the best/current practices available to make their recommendations and give patients complete information to make an informed choice*
2. *When providing information about products, the OPC designation is not used to endorse a product.*

### 2.2.2 Manitoba Health (MB Health)

Manitoba Health (MB Health) is a branch of the Manitoba Government responsible for resource management of the provincial health care services. Among MB Health's duties, they are responsible for the management of insured benefit claim payments for citizens of Manitoba related to the cost of medical services and devices through various programs. MB Health's Prosthetic and Orthotic Program covers the cost of Prosthetic and Orthotic devices prescribed by a medical practitioner for Manitoban citizens [14]. The Prosthetic and Orthotic Program reimburses the cost of devices and services provided by healthcare personnel certified through the Canadian Board for Certification of Prosthetists (CBCPO) and Orthotists. This has a direct impact on the possible cost for the CROW device, as it limits the total cost that the boot can be valued at due to limits on the reimbursement maximums. OPC certifications are recognized by the CBCPO [12]. This program will cover the cost of one device every two years, unless there is a medically diagnosed change in the patients condition or the device is damaged beyond repair. Claims for this program are sent to MB Health by the supplier of the support device [15].

## 2.3 Existing Patents

The Team conducted a patent search with a focus towards ankle foot orthosis and CROW orthosis devices. The search included current patents and patent-pending devices. This patent search allowed the Team to analyze independent claims made for given patents. A summarized list of the independent claims for each patent was tabulated. These claim descriptions have been simplified for simple evaluation of the final design's potential patent infringement. Detailed descriptions for each component of a patent's independent claim are provided in Appendix A.3.

Table IV below provides a summarized list of the components of the independent claim made in Patent US 10,675,168 B2: ANKLE FOOT ORTHOSIS [16].

TABLE IV: Claim Components of Patent US 10,675,168 B2 [16]

| Component | Description |
|---|---|
| 1 | foot assembly & shin assembly |
| 2 | foot assembly attached to the shin assembly with hinge |
| 3 | foot assembly having rigid heel cup |

Table V below provides a summarized list of the components of the independent claim made in Patent US 9,452,077: FOOT AND ANKLE ORTHOSES THAT ENABLE NATURAL MOVEMENT OF THE FOOT [17].

TABLE V: Claim Components of Patent US 9,452,077 [17]

| Component | Description |
|---|---|
| 1 | upper member secured to lower leg |
| 2 | lower member secured beneath foot |
| 3 | hinge connecting upper and lower member |
| 4 | tracking element & guide to stabilize ankle during movement |
| 5 | arcuate receptacle for the tracking guide |

Table VI below provides a summarized list of the components of the independent claim made in patent-pending US Patent Application Publication Number 2021-0259871 A1 [18].

TABLE VI: Claim Components of US Patent Application Number 2021-0259871 A1 [18]

| Component | Description |
|---|---|
| 1 | calf sleeve secured about leg of user |
| 2 | foot plate secured to foot of user |
| 3 | distractive force mechanism connected between calf and foot |
| 4 | rigid flange configured on the medial aspect of the foot assembly |

## 2.4 Stress Analysis

The movement of the foot during walking is called gait cycle, which consists of 2 periods: stance and swing. The stance period is the time during which the foot is in contact with the ground. The swing period follows the stance period and is the time during which the same foot is in the air. Therefore, the stance period is the load bearing period [19].

Figure 6: Overview of Gait Cycle [20]

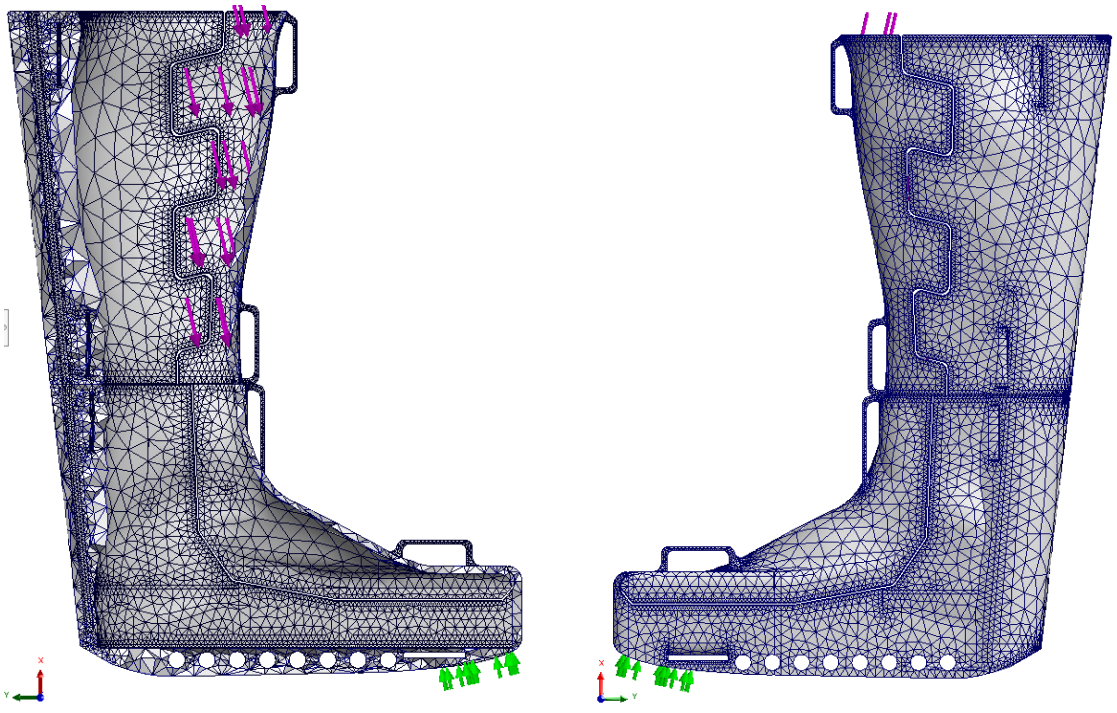
During the stance period, the extreme load cases are:

- Heel Strike: When the heel first contacts the ground, the load is distributed on both legs.
- Midstance: When the load is distributed on one leg while the other leg is swinging.
- Toe Off: When the toe last contacts the ground, the load is distributed on both legs.

To simulate the worst case scenario, and to simplify the analysis, only the heel strike and toe off position were considered, where the load was only applied to one leg. During heel strike case, the load was applied to the posterior calf section. During toe off case, the load was applied to the anterior calf section. Only these two cases were considered as they were expressed the most extreme forces [19].

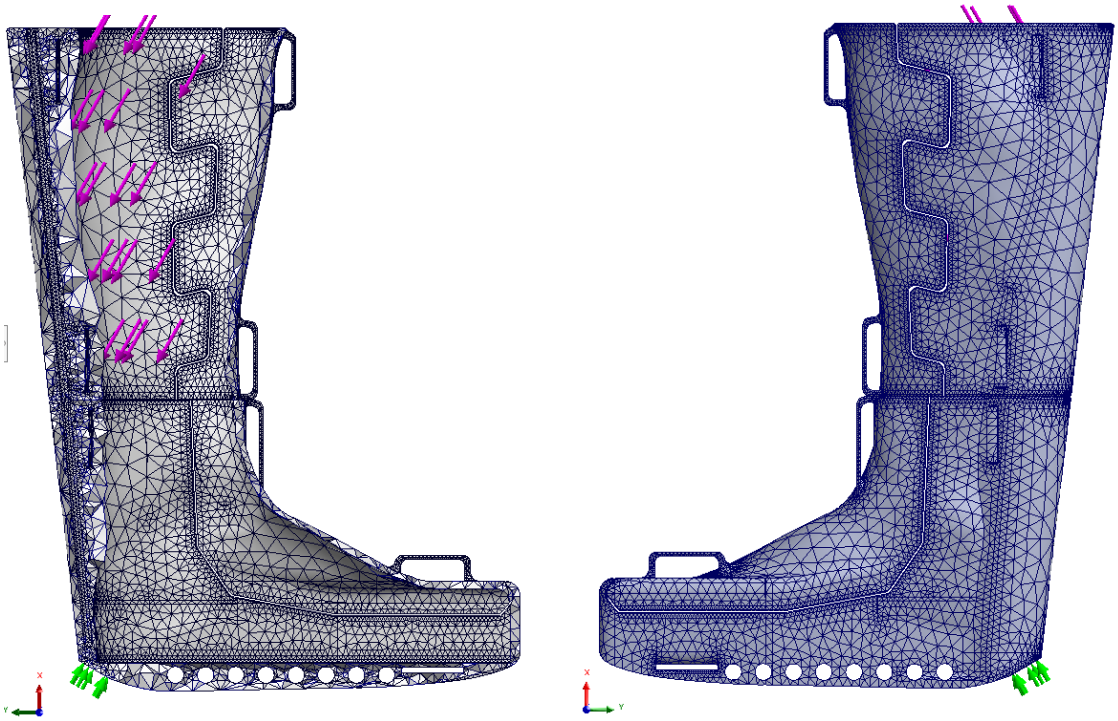
Figure 7: Three Component Resultant Ground Reaction Force Vector During the Gait Cycle in Newtons [19]

During stance period, the hip extends from 30° of flexion during heel strike to 13° of hyperextension during toe off [21]. Therefore, the simulation model was set up so that the force and fixture of heel strike acted along a 30° axis in front of the normal ground reaction axis, while the force and fixture of the toe off acted along a 13° axis behind the normal ground reaction axis. Figure 8 and 9 show how the forces and fixtures were applied on the final model, with the maximum mesh size of the model as 2 inches.



(a) Toe Off FEA Setup Inside (b) Toe Off FEA Setup Outside

Figure 8: Toe Off FEA Setup



(a) Heel Strike FEA Setup Inside (b) Heel Strike FEA Setup Outside

Figure 9: Heel Strike FEA Setup

The design was modeled to fit Eric Crooks, one of the Capstone Team members, with a weight of 170 lbs. However, the actual load in the model used was 275 lbs, which is the specified maximum load. With the factor of safety of 3, the applied force on the CROW boot became 825 lbf. Using this load, the design failed to support the patient's weight if material yielding occurred, with a yielding strength of 53 MPa [22].

# 3 Final Design

The final design of the CROW device was accomplished through a cycle consisting of design, specification verification, and Client reviews. Below, in the CROW Design subsection, the detailed design is discussed, with it, the numerical analysis that was performed, the material details, and the complete proposed process for the creation of a CROW device. A visual side by side comparison of the 3 primary revision that occurred can be seen in Figure 10, where Rev 1 is on the left, Rev 2 is in the middle, and Rev 3 is on the right. It is to be noted that these are only the outer shells of the design.

(a) Rev 1 (b) Rev 2 (c) Rev 3

Figure 10: CROW Boot Outer Shell Prototypes

## 3.1 CROW Design

### 3.1.1 Design Development

The initial design, Rev 1, was quick to model, although was the least conforming to the shape of the patient's leg. Figure 11 features the Solidworks model.

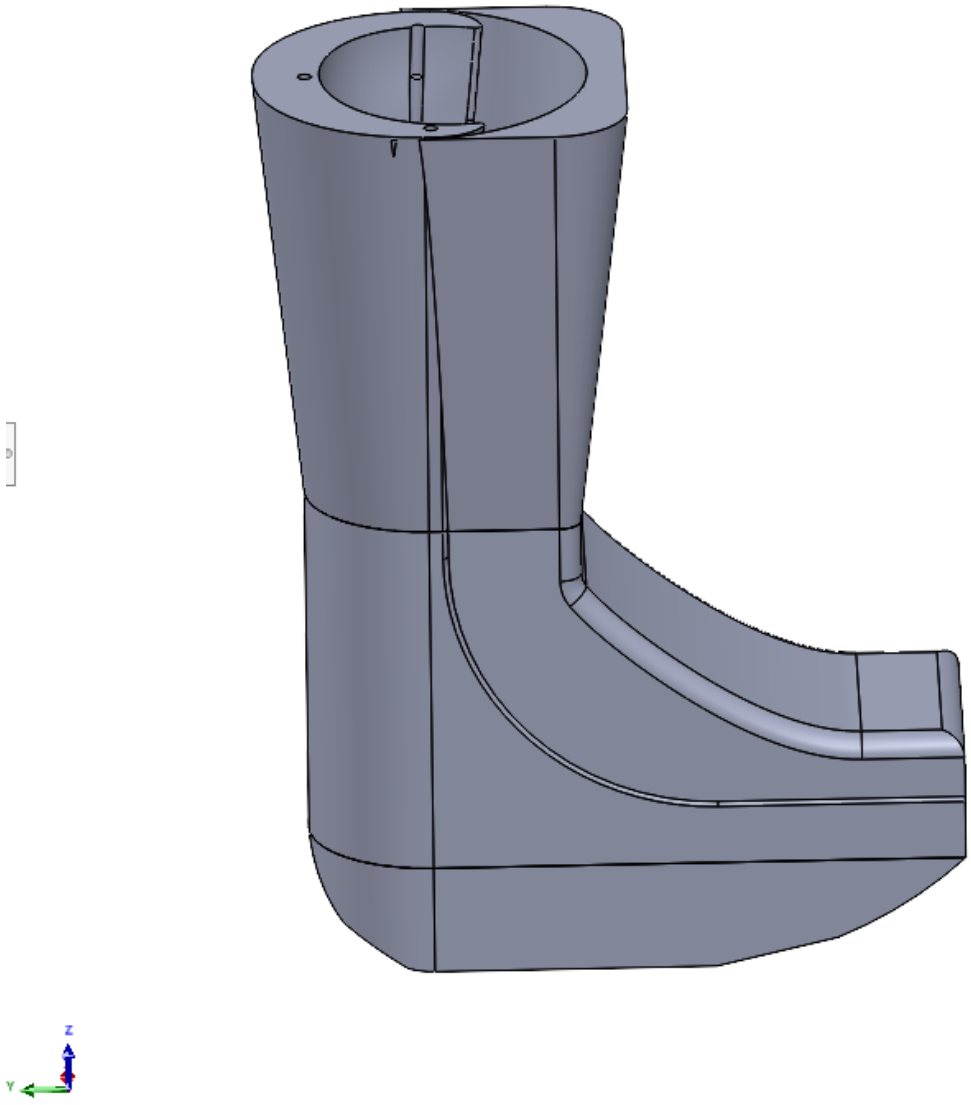


Figure 11: CROW Boot Rev 1 Render

The key features of this version are:

- Integrated rocker sole to help with the movement of the patient
- Six part design for easy manufacturing and more adjustability
- Three support rods to align the parts as well as provide stiffness
- Contoured surface for snuggle fit and provide uniform stress distribution of the foot

Using Solidworks, the Finite Element Analysis (FEA) was performed on the first iteration to verify the strength specifications. The result showed that the model was capable of supporting the weight

of the patient, given the factor of safety of 3 and bearing load of 275 lbs, bringing the load applied to the model up to 825 lbf. Following are the simulation results to the heel strike and toe-off.

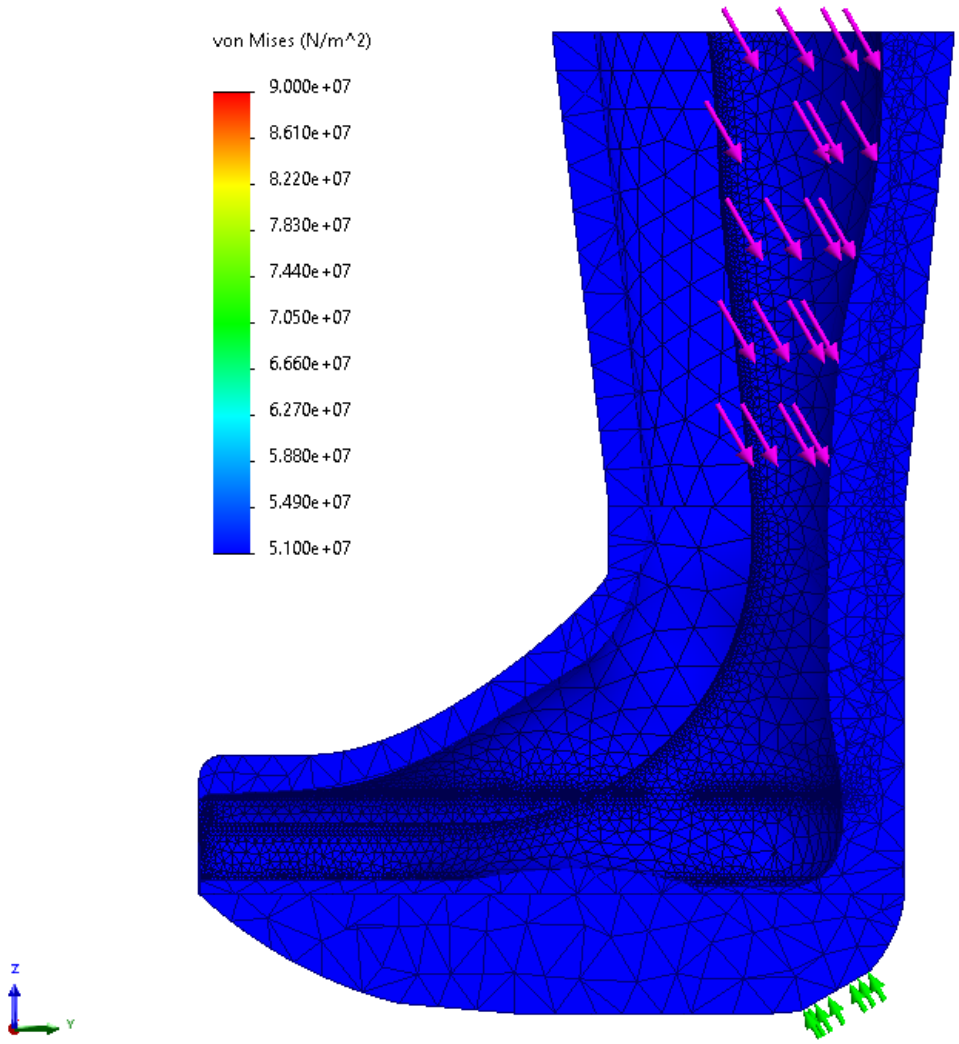



Figure 12: CROW Boot Rev 1 Heel Strike FEA Result

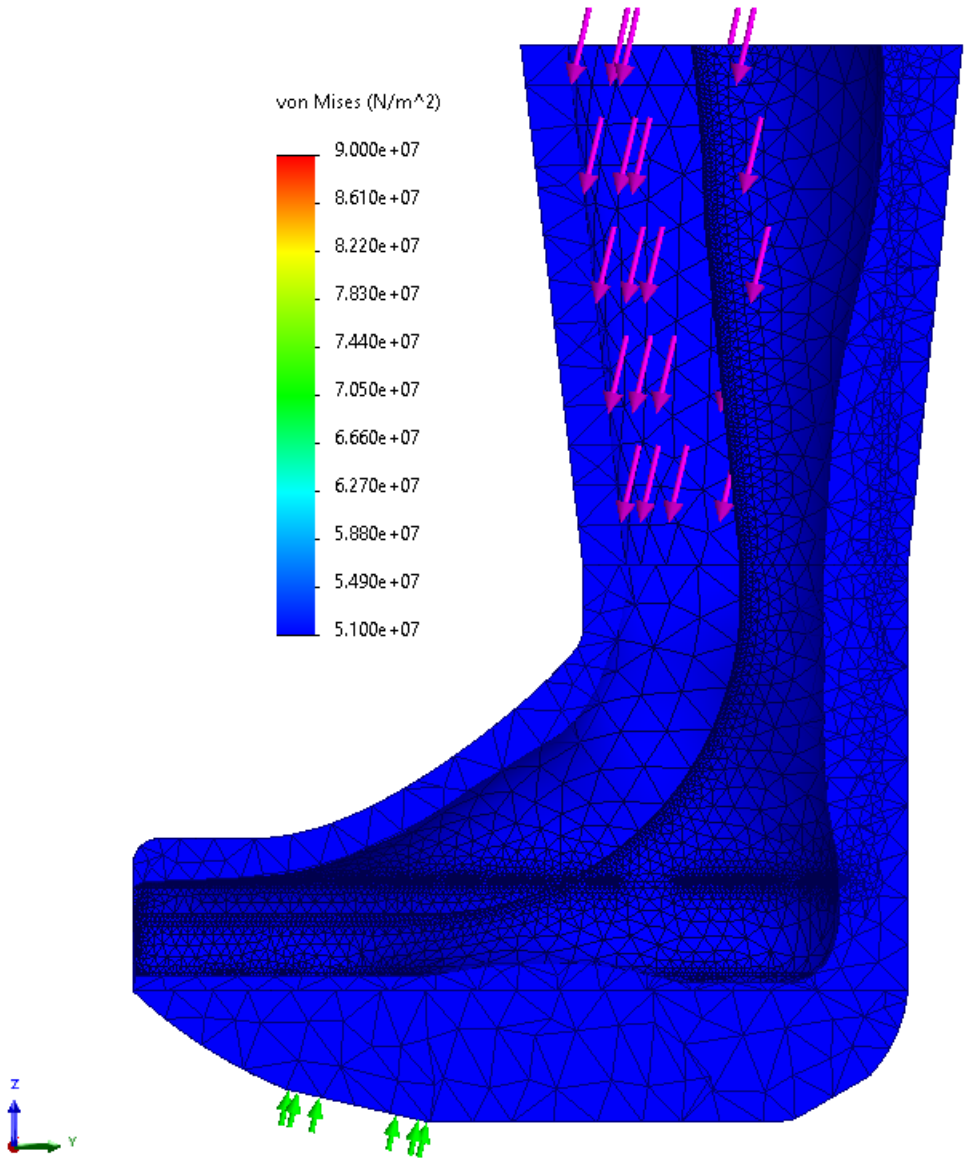



Figure 13: CROW Boot Rev 1 Toe Off FEA Result

The first design satisfied every specification related to the dynamics and strength of the design but it exceeded the cost of manufacturing. This design cost $4000 to manufacture while the Team aims for the maximum cost of $1000. Also, after revision with the Client, there was significant feedback on the design. The cost and the feedback, in addition to observations from the Team of the physical model was used in the development of the second version. The second revision, shown in Figure 14, was modeled using processes which allowed for much more organic shapes which better reflected the user's limb. This greatly increased the modeling time of the CROW boot.


Figure 14: CROW Boot Rev 2 Render

The key feature changes of the second revision are as follows:

- The support rods were moved further back to allow the sides of the calf segments to flex, increasing the circumferential length adaptability
- Interlocking pattern between anterior and posterior segments to prevent movement between them

- Integrated brackets and mounts for BOA straps to be used to tighten the device together
- Material reduction all around with a focus on a more natural shape and reduced rocker sole height
- Total segments reduced to two anterior segments and 2 posterior segments to simplify the design

The second design was also verified using the same method and setup as the previous one. The results showed that the device was still capable of supporting weight while the patient is at heel strike position but will yield at the toe off position, however the manufacturing cost was reduced to $2800. This can be seen in the Figure 15 to 18.

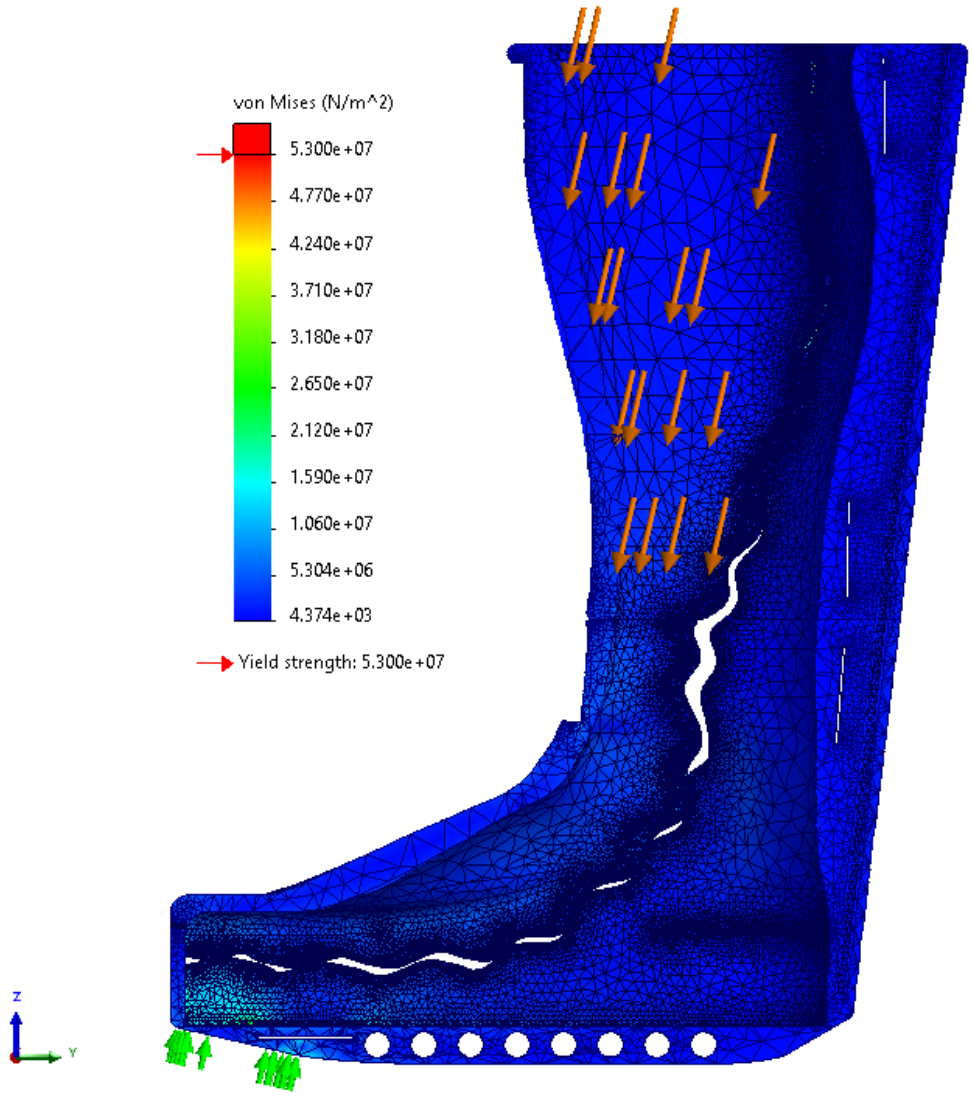



Figure 15: CROW Boot Rev 2 Toe Off FEA Result

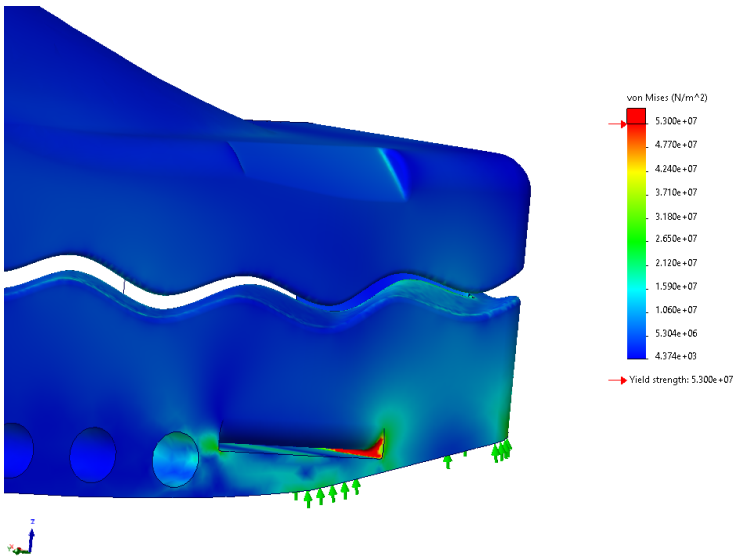



Figure 16: CROW Boot Rev 2 Toe Off Yielded Area

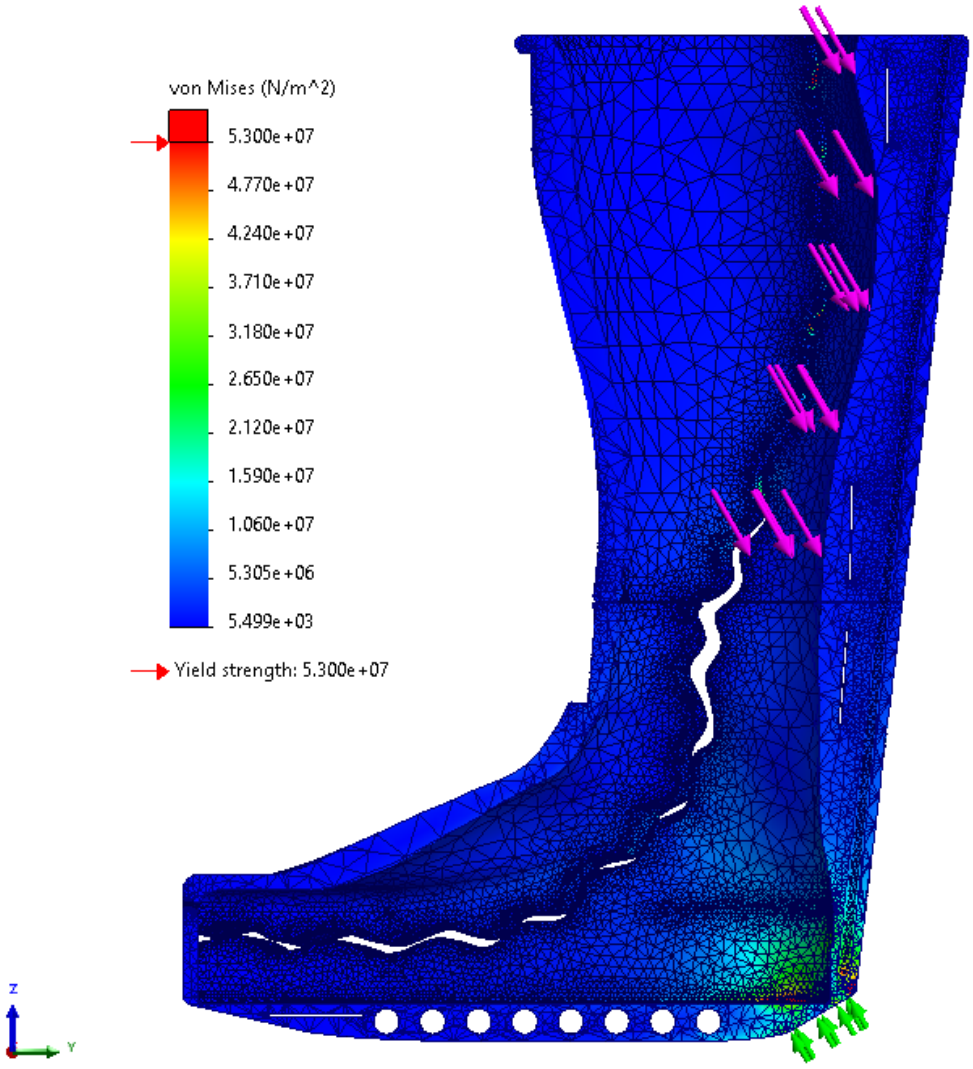



Figure 17: CROW Boot Rev 2 Heel Strike FEA Result

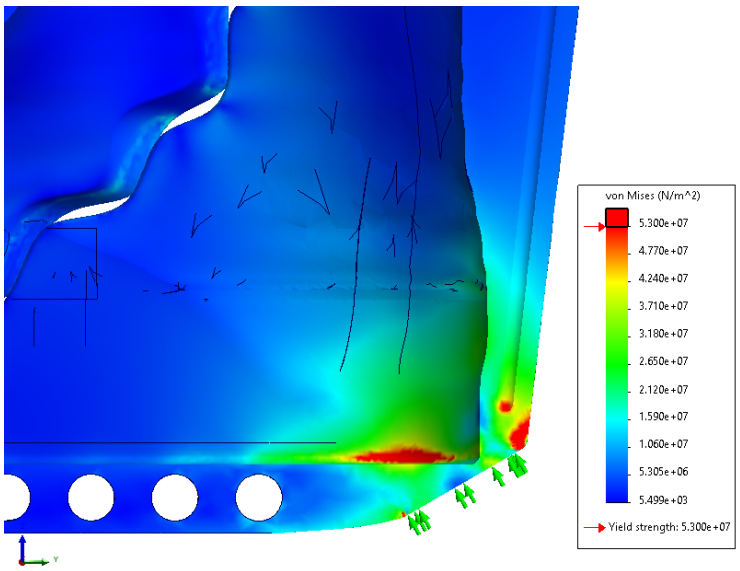



Figure 18: CROW Boot Rev 2 Heel Strike Yielded Area

The feedback received from the Client and test fits of the device by the Capstone Team revealed that the squiggle pattern used for the engagement only functioned when the shells were fully compressed to one another, and thus did not meet the circumferential specification. In addition, the heel of the boot was very narrow, which posed a possible stability risk for the patient. The use of BOA straps were deemed to be a valid method of affixing the anterior and posterior component, but required a more robust method for locating the straps on the anterior components. The reduction of number of segments was also beneficial, as the upper most portion of the initial revision did not contribute to the offloading as well as if it were merged with the remainder of the calf segments. The final design drew from the previous iterations, further consultation with the Client regarding the rocker sole, took improvements from the previous versions. The final design can be seen in Section 3.1.2. A few key changes are as follows:

- Slopped rocker sole for better articulation
- Squiggle pattern replaced with square wave pattern
- Eliminated the lock-in mechanism of the ankle foot section to eliminate stress concentration
- Reduced thickness of the posterior parts and an increase material thickness in localized regions on the anterior segments based on stress distribution

The verification of the final design is discussed in the Section 4.1.

### 3.1.2 Final Design Details

The final design was developed based on iterative design and specification verification steps, where Team and Client reviewed, is detailed in the following paragraphs. The final concept is composed of a 3D printed 4 segment outer shell with stiffening rods and ratcheting BOA straps to assemble the CROW device. To provide user comfort, a foam lining is glued to the segments, and a rubber walking sole is glued to the rocker profile integrated into the boot segments. Lastly, the selected material can be easily painted and customized. The design can be seen annotated in Figure 19 below.


Figure 19: CROW Boot outer shell render

The 4 segments are the posterior and anterior shells of the foot and calf regions. The calf segments uses a semi-square wave pattern to locate both anterior and posterior calf segments to one another. They also to allow for the locating when the "teeth" are only partially engaged due to excessive swelling of the limb. The expansion of this joint can be seen visually in Figure 20 bellow, where the yellow arrows show the direction of expansion. These "teeth" also allow for greater flexibility in the anterior and posterior shells. As the feet were found to not swell as much as the calf the material flexibility was deemed sufficient [23]. At the very tip of the toe, the posterior foot section possess a lip in which the anterior foot segment slots into and pivots about it. This allows

for some degree of adjustability in the foot region, but also acts at the primary locating feature for the anterior foot segment, which helps keep the foot segments located through ambulation.

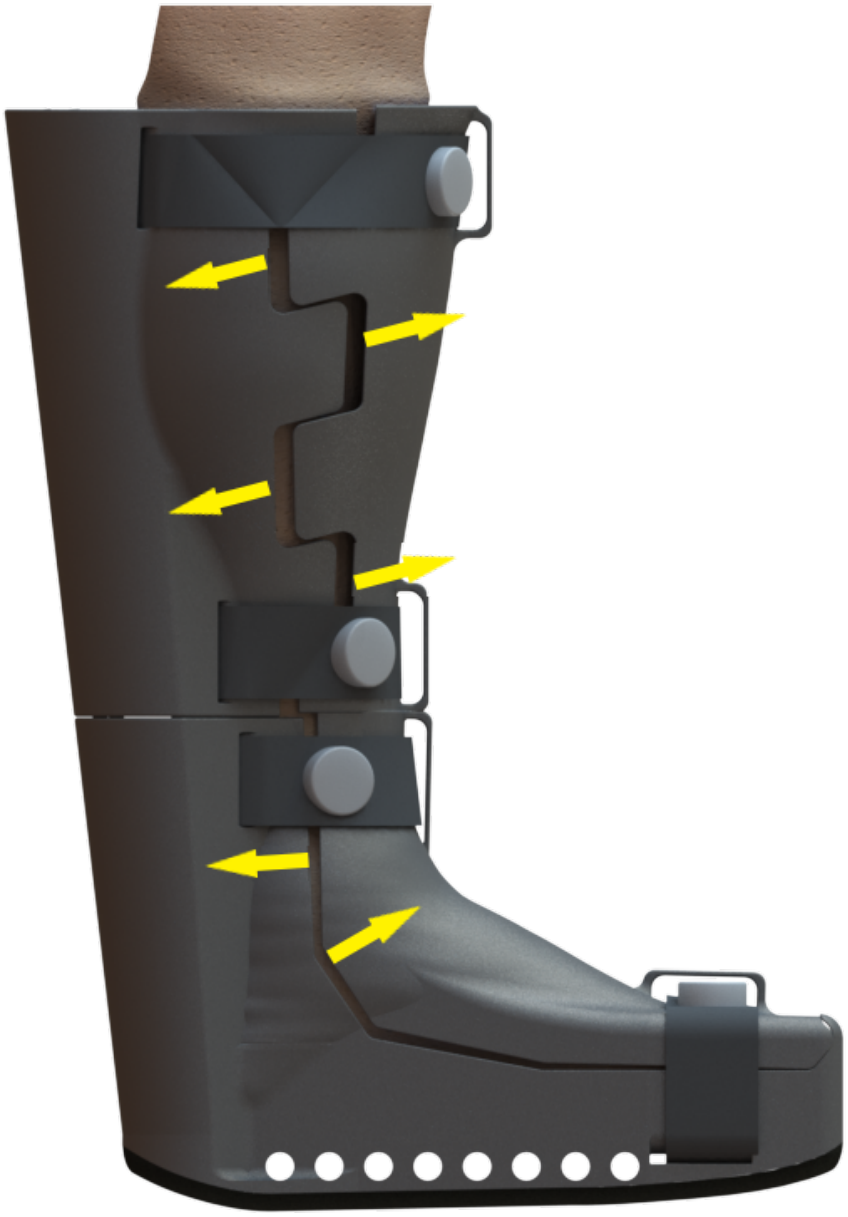


Figure 20: CROW Boot with Expansion Shown by Yellow Arrows

Ratcheting BOA straps are intended to hold anterior and posterior shells, with two straps for both the foot and calf segments respectively. The straps pass through strategic points in the boot where cut outs in the posterior segments were created to locate the straps on the boot and reduce the overall length of strap needed. On the anterior segments, the BOA straps pass through locating hoops to prevent the straps from moving undesirably during use. The BOA straps were selected

as the anterior-posterior joining method as they allow for up to 4” of circumferential adjustability, which provides sufficient versatility for the patient to both fasten their leg into the CROW and to provide the accommodation for the change in limb size while retaining sufficient pressure on the limb to provide the necessary off-loading.


Figure 21: 1.5” Width BOA Strap with Velcro

The 1.5” strap was selected as it possessed the necessary strength and distribute the load over a relatively large area. In addition, the BOA straps close the loop using hook and loop material, which allows for the anterior and posterior segments to be easily completely detached from one another, to make it easier to put the crow on and off, as well as for cleaning of the device. Lastly, the BOA tensioning is performed by turning a ratcheting knob with a 5:1 motion ratio and quick release, this allows for the Patient to easily recreate the fit prescribed by the Clinician.

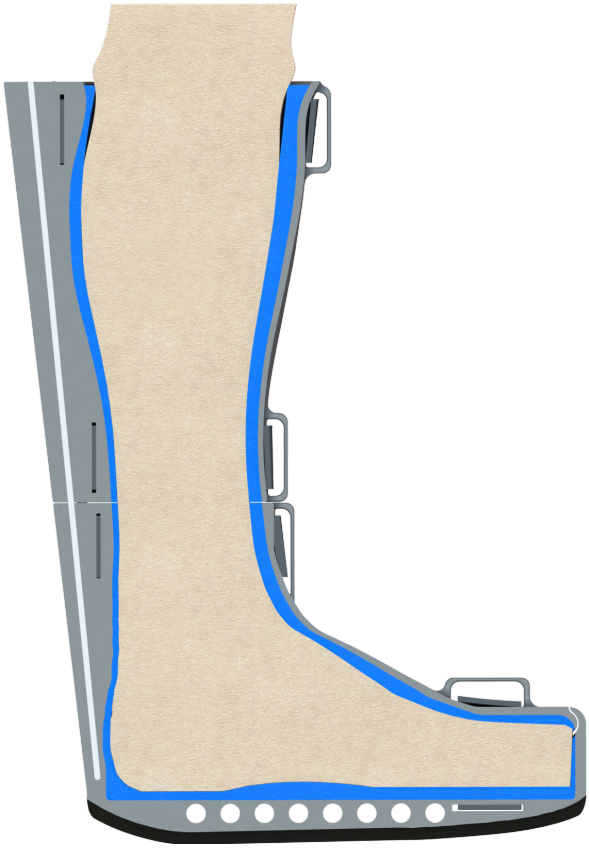


Figure 22: CROW Boot Cross-Section

When observing the profile of the boot, seen above in Figure 23 a rocker sole can be seen. The purpose of this is to allow for natural ambulations during walking since the patient's the ankle rotation is fixed. The rocker profile was designed following recommendations from the Client and external resources [24]. This design has a steeper radius on the region posterior of the ankle and a mild curvature from the mid foot forwards, where there is a 4° forwards slopped flat section to facilitate the static standing position. The profile height from the bottom of the foot was minimized to attempt to reduce the height offset between the patient's leg with and without the CROW. Voids in the form of holes are to reduce the weight of the extra volume required to form the rocker sole. A rubber walking shoe sole is glued to the bottom of the rocker to provide additional ambulation cushioning and grip to the patient.

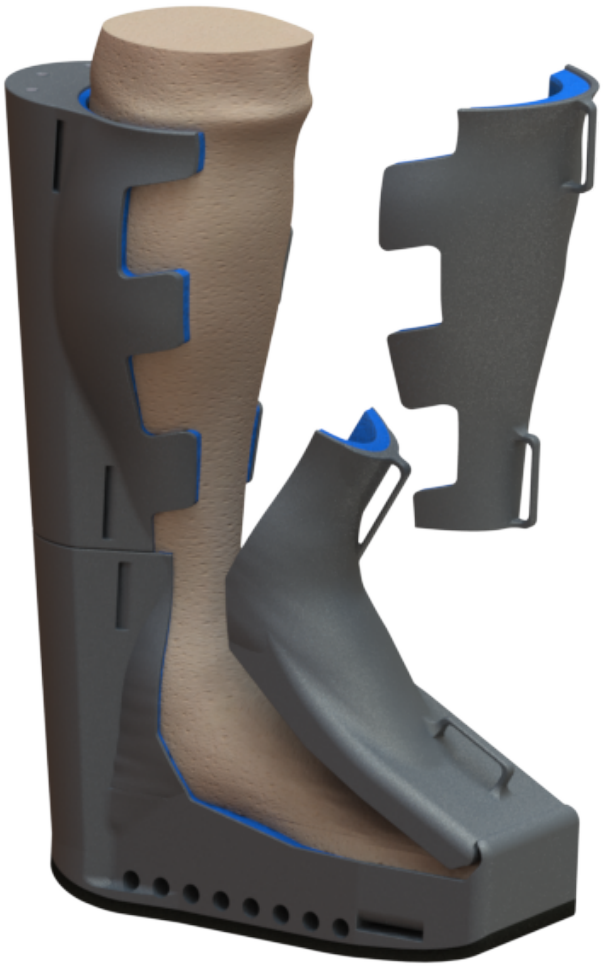


Figure 23: CROW Boot Partially Exploded View

The interior of the CROW device conforms to the scanned shape of the patient, but allows for roughly 1/4" of cushioning using closed cell lined PPT except on the sole of the foot, where sufficient space is reserved for the insertion of a custom foot orthotic. The foam lining follows the same shape of as the outer shell and is glued to the inner surface of the device.

Three 6061-T6 (SS) aluminium rods were used to provide additional stiffness to the boot, and as a method to locate the calf and foot posterior segments to one another. These rods are designed to be glued in place using minimal epoxy. The three rods are askew to one another which prevent the foot and calf segments from pulling apart without the prior removal of the rods, which reduces the epoxy's role in retaining the two posterior segments to one another, and act more as a rod retaining method.

### 3.1.3 Material Specification

For the outer shell segments of the CROW boot, Nylon 12 was selected as the material of choice as it is a commonly 3D printed material under a variety of printing methods and possess promising material properties given the CROW application [25]. In addition, many Nylon 12 materials for ADM are rated by the FDA for contact with human skin. PPT was selected as it is a closed cell foam, which would prevent the permanent ingress of bacteria, making the surface easier to clean. The integrated lining act as a more comfortable surface for the patient's limb in that is has a better friction interaction with the socks used and is less likely to cause cytotoxicity or other allergic reactions [4][5].

## 3.2 Proposed Manufacturing Process

### 3.2.1 Manufacturing Method

The MJF 3D printing process was selected because it is the ADM process best suited for Nylon 12. Due to Nylon 12's relatively low melting temperature, it is sensitive to warping. With MJF the printed part is surrounded by material, which acts as supports on all surfaces of the part, as well as reduces the cooling rate of the nylon, further reducing the risk of warped parts. In addition, the powder vat printing process allows for the nesting of parts without majorly impacting the print time, making higher production rates more economical.

Figure 24 shows the work breakdown for manufacturing the CROW Orthosis. The overall process is broken down into 3 high level parts: Developing the 3D model of the CROW, Printing the exterior shell of the CROW and Assembling the CROW.

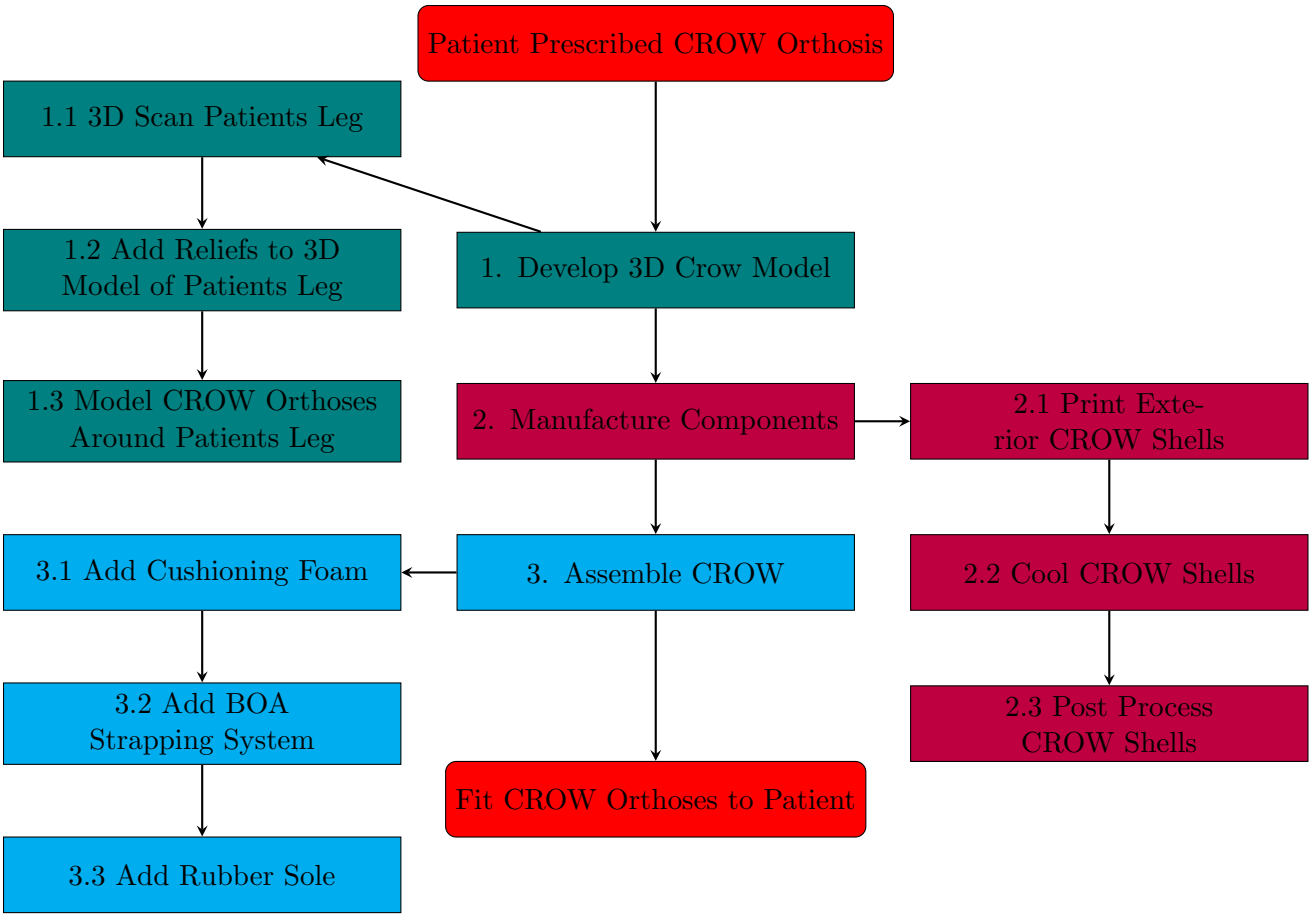



Figure 24: CROW Manufacturing Process Utilizing ADM

Steps 1 and 2 from Figure 24 replace the plaster casting and draping process of the current manufacturing process which significantly simplifies the overall manufacturing process. The plaster model also requires a significant amount of space to store and a designated area in the clinic where technicians are free to work with plaster. In the current manufacturing process, technicians require a special fixture that can support the weight of a plaster leg and a station where they can work with messy materials such as plaster. Similarly, the draping process requires a significant amount of space and time management to transfer a sheet of hot thermoplastic from an oven onto the plaster cast. The technicians have a window of approximately 20 seconds to form the material before it cools off and solidifies. It should be noted that if there is still moisture in the plaster cast when hot material is draped over it, the moisture will absorb the heat and create defects in the CROW. At any given point during the manufacturing process, a patient may come in requiring an immediate treatment. In this case, manufacturing work may need to get stopped so that the patient can get treated. The current manufacturing process has many time sensitive steps involving material drying or cooling and does not have much flexibility for immediate stopping and starting.

Moving to a digital system to model the CROW and automating the manufacturing process

of the hard exterior shells will relieve a significant labour burden on technicians and provide the clinic better flexibility to react to urgent needs. Working with digital files to add reliefs to the patients' leg and model the CROW orthosis will save space and provide technicians more flexibility on where they can work. It will also give the opportunity to store more detailed virtual records of patient cases including the CAD model of the patients' leg and their CROW orthosis. Using an MJF machine to automate the exterior CROW shell manufacturing frees up at least 2 technicians that can now work on manufacturing other devices or assembling CROW shells. In the event of an emergency that the staff must attend to, the manufacturing of the CROW shell will not get interrupted.

### 3.2.2 Manufacturing & Assembly Time Estimates

The manufacturing time shown in Table VII below is a summary of the proposed time for an external company to manufacture and post process the CROW shells. Several quotes for outsourcing the manufacture of CROW shells provide lead time estimate of 4-5 days. This lead time is the total duration between 3D file submission to delivery of the printed parts to Winnipeg, MB.

TABLE VII: CROW Shell Manufacturing Time

| | Task | Time |
|---|---|---|
| 2.1 | Print Exterior CROW Shells | 12 hours |
| 2.2 | Cool CROW Shells | 12 hours |
| 2.3 | Post Process CROW Shells | 4 hours |
| | **Total Time** | **28 Hours** |

The total time to manufacture a single unit's CROW shells is 28 hours. This total time does not include time required to ship the CROW shells.

The proposed assembly time shown in Table VIII below is a summary of the assembly time required for a technician to assemble the overall CROW design for patient use, once the CROW shells have been manufactured.

TABLE VIII: CROW Assembly Time

| | Task | Time |
|---|---|---|
| 3.1 | Add Cushioning Foam | 1.5 hours |
| 3.2 | Add BOA Strapping System | 30 min |
| 3.3 | Add Rubber Sole | 30 min |
| | **Total Time** | **2.5 Hours** |

The total time to assemble a single unit is 2.5 hours for a technician.

### 3.2.3 Unit Manufacturing Cost

The cost estimate per CROW orthosis unit was generated through consultation with vendors that specialize in HP Multi Jet Fusion (MJF) and Selective Laser Sintering (SLS) ADM services. The total cost in Canadian dollars to manufacture the CROW shells for one orthosis is shown in Table IX below. The values in Table IX were extracted from Xometry Quote Q00-8696-0081 located in Appendix D.

TABLE IX: Unit Manufacturing Cost Estimate

| Component | Name | Qty | Unit Price | Total Price |
|---|---|---|---|---|
| 1 | Posterior Calf | 1 | $560.09 | $560.09 |
| 2 | Anterior Calf | 1 | $262.93 | $262.93 |
| 3 | Anterior Foot | 1 | $264.45 | $264.45 |
| 4 | Posterior Foot | 1 | $665.30 | $665.30 |
| 5 | BOA Strap | 4 | $15.00 | $60.00 |
| 6 | Support Rod | 3 | $5.12 | $15.36 |
| 7 | Rubber Sole | 1 | $2.82 | $2.82 |
| 8 | PPT Liner | 0.5 | $29.95 | $14.98 |
| 9 | Technician Labor | 2.5 | $40.00 | $100.00 |
| | | | **Total Cost** | **$1,945.93** |

With the total material cost estimated to be $1,845.93 and 2.5 hours of technician labor estimated at $40/hour to assemble, the total cost including material and labor, to manufacture and assemble a single unit is $1,945.93.

# 4 Evaluation of Design

The final design was evaluated using the specification metrics discussed in the Introduction section to determine if it meets the needs of the Project. Below are the evaluations of the respective specifications.

## 4.1 Verification of Specifications

Verification of the target specifications was done to assess the success metrics for this project. Table X summarizes the target specifications, listed in Table II, and whether the ideal values were met or not.

TABLE X: Target Specification Verification

| Metric # | Metric | Verification Group | Units | Ideal Value | PASS/FAIL |
|---|---|---|---|---|---|
| 1 | Manufacturing Time | Manufacturing | hours | $< 15$ | FAIL |
| 2 | Minimum Weight Supported | Material Specification | lbs | 275 | FAIL |
| 3 | Unit Manufacturing Cost | Manufacturing | CAD$ | <1,000 | FAIL |
| 4 | Factor of Safety | FEA | N/A | 3 | FAIL |
| 5 | Minimum Circumferential Length Increase | Overall Design | cm | 4 | PASS |
| 6 | Treatment Length | FEA | year | 1 | FAIL |
| 7 | Minimum Water Resistance Rating | Material Specification | IP | 54 | PASS |
| 8 | Minimum Operating Temperature | Material Specification | °C | -30 | PASS |
| 9 | Maximum Operating Temperature | Material Specification | °C | 30 | PASS |
| 10 | Survey of Aesthetics | Overall Design | subj. | Pass | PASS |
| 11 | Inclusion of Custom Foot Orthosis | Overall Design | Binary | Pass | PASS |

In the following subsections, the metrics are grouped by their verification group, where the results of the final verification are discussed. This is because certain metrics overlap in their evaluation to certain extents.

### 4.1.1 Overall Design

#### 4.1.1.1 Minimum Circumferential Length Increase

The ideal minimum circumferential length increase of the final design was specified as 4 cm. The design utilizes a BOA strap which provides 4" of adjustable travel to tighten the device around a patient's leg in conjunction with a expanding CROW shell design. As seen in Figure

20, the square wave pattern between the anterior and posterior calf shells allow for up to 4.3 cm of circumferential increase while maintaining the limit to vertical movement between the shells. This was evaluate through CAD assemblies and measurements of the final 3D printed prototype. Therefore, the device meets the circumferential length increase specification.

#### 4.1.1.2 Survey of Aesthetics

The survey of aesthetics was a subjective specification that would be judged a pass or fail. A survey was distributed to the Client's champions, Dan Mazur and Jacques Swanepoel for review. The completed survey verified that the final design was considered aesthetic and successfully met target specification. This signed survey can be viewed in Appendix E.

#### 4.1.1.3 Inclusive of Custom Foot Orthosis

Inclusive of custom foot orthosis was a binary specification that would be judged a pass or fail. A survey was distributed to the Client's champions, Dan Mazur and Jacques Swanepoel for review. This completed survey verified that the final design would accommodate the insertion of a custom foot orthosis. The inserted custom foot orthosis would be located distal to the plantar position of the foot. This signed survey can be viewing in Appendix E.

### 4.1.2 Finite Elemental Analysis

The specifications that tie to FEA results are the maximum weight supported, the factor of safety and the treatment length. And to ensure the FEA results are applicable to the actual manufactured CROW boot, convergence tests were conducted to verify the FEA results.

#### 4.1.2.1 Maximum Weight Supported

The maximum weight supported by the design was set to 275 lbs. The design will be deemed succeeded if there is no yielded area under maximum load, given the yield strength of the Nylon 12 is 53 MPa [22]. The result shows that by applying the maximum load of 275 lbs and a factor of safety of 3, the design is yielded at the bottom BOA slot due to high stress concentration in toe off position.

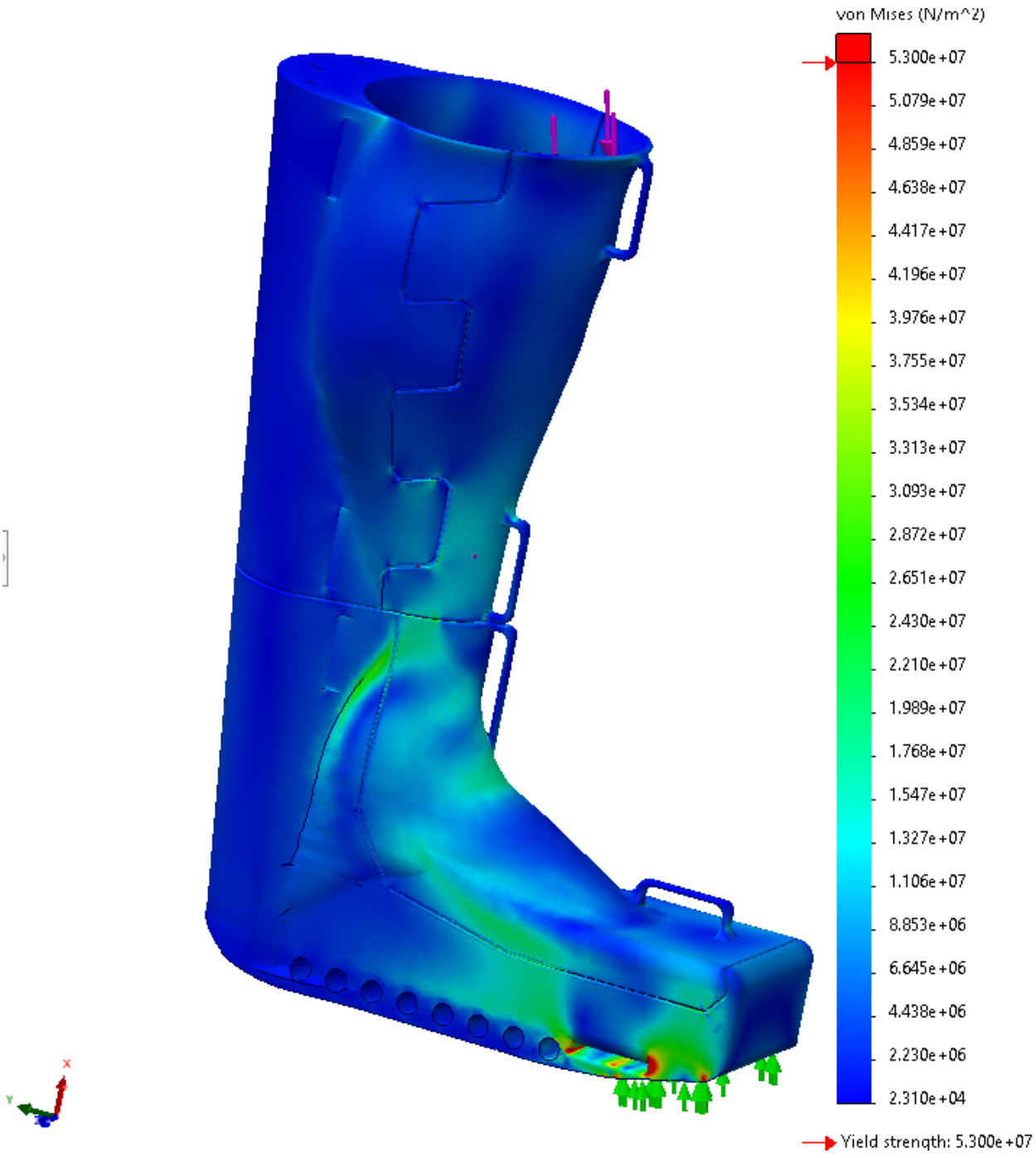



Figure 25: Stress Distribution Overall at Toe Off under Maximum Weight

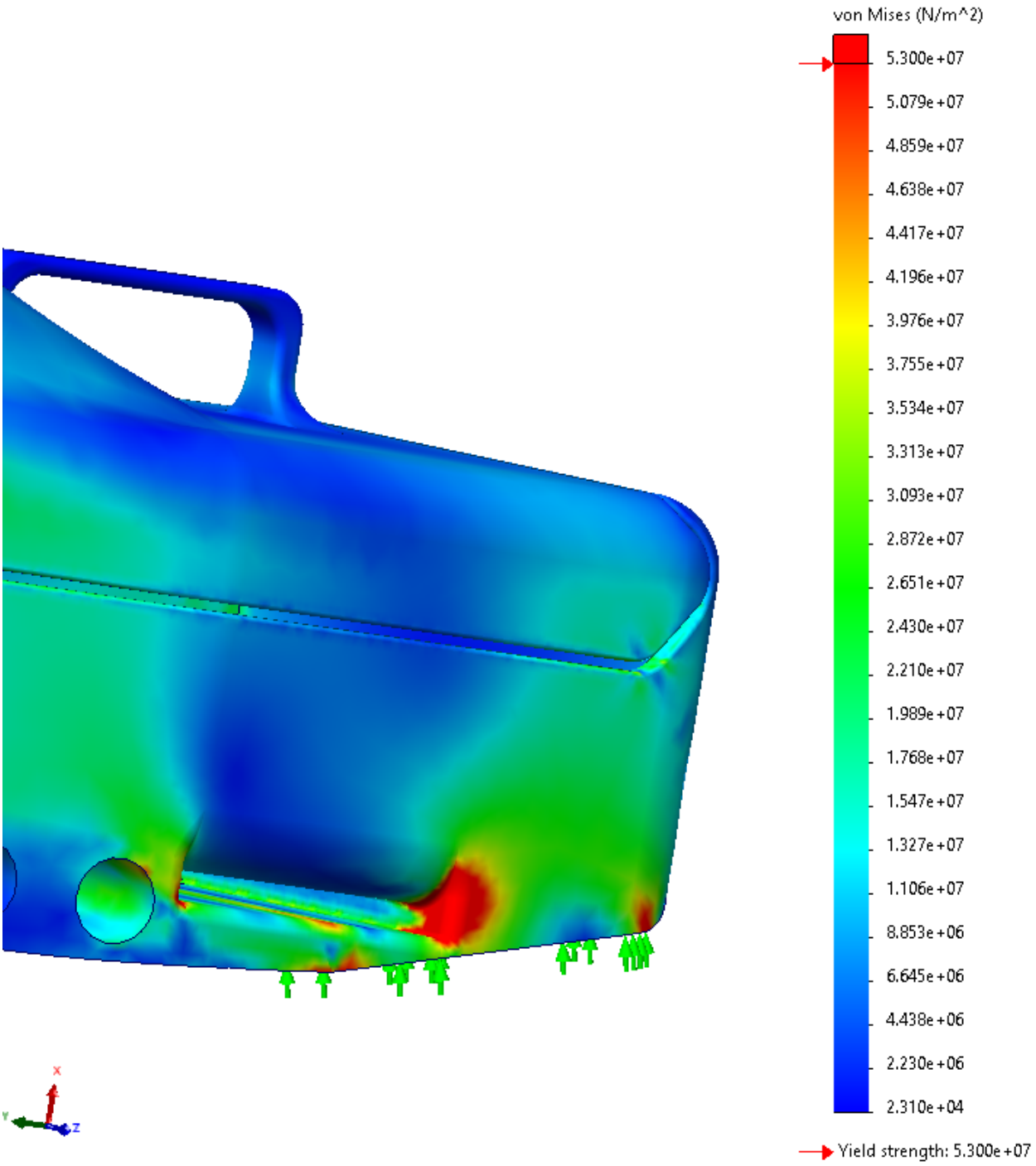



Figure 26: Yielding Area at Toe Off under Maximum Weight

However, running the simulation again with the weight of 170 lbs and a factor of safety of 3, the design is still yielded but the area of affect is much smaller.

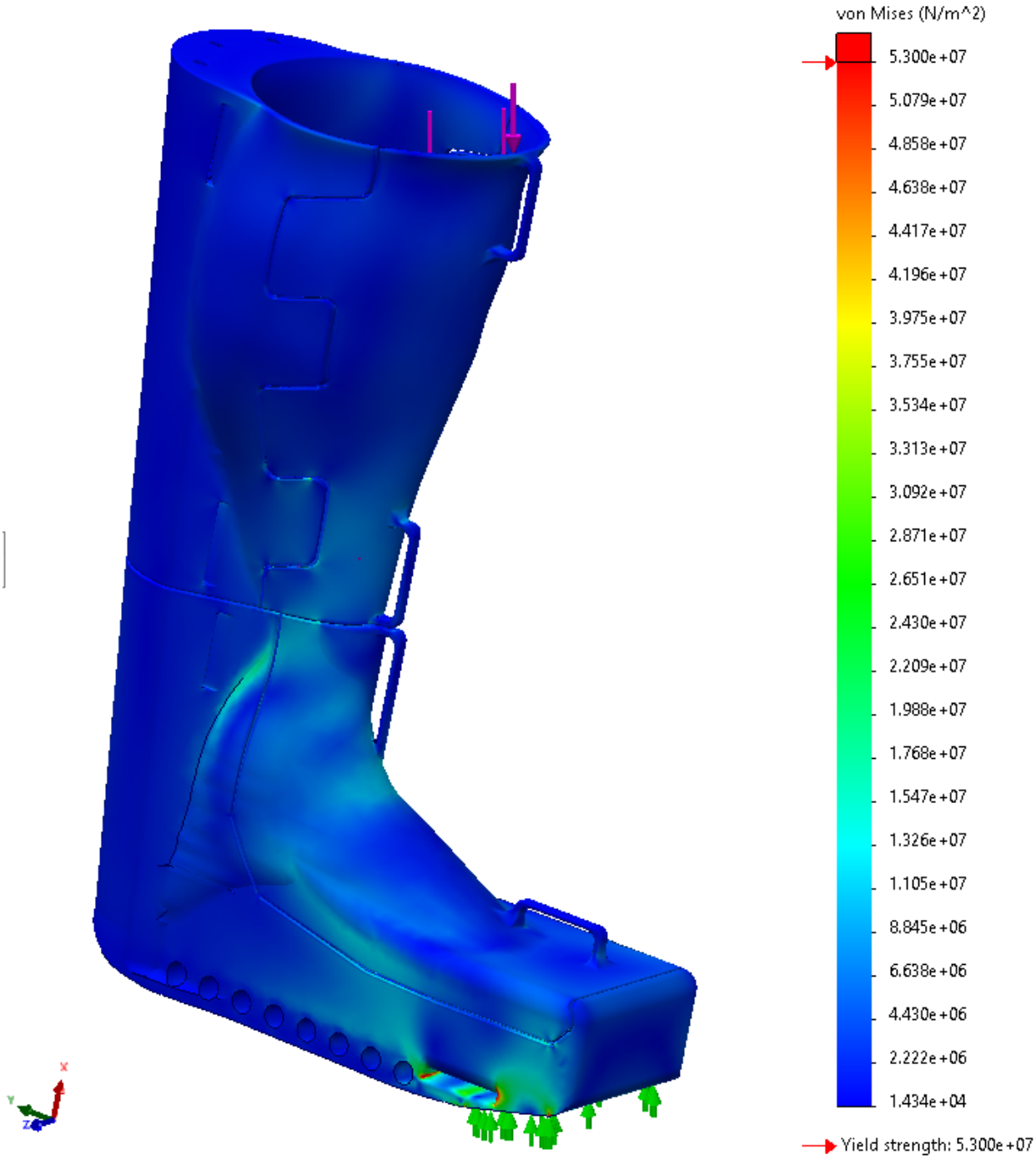



Figure 27: Stress Distribution Overall at Toe Off under Eric's Weight

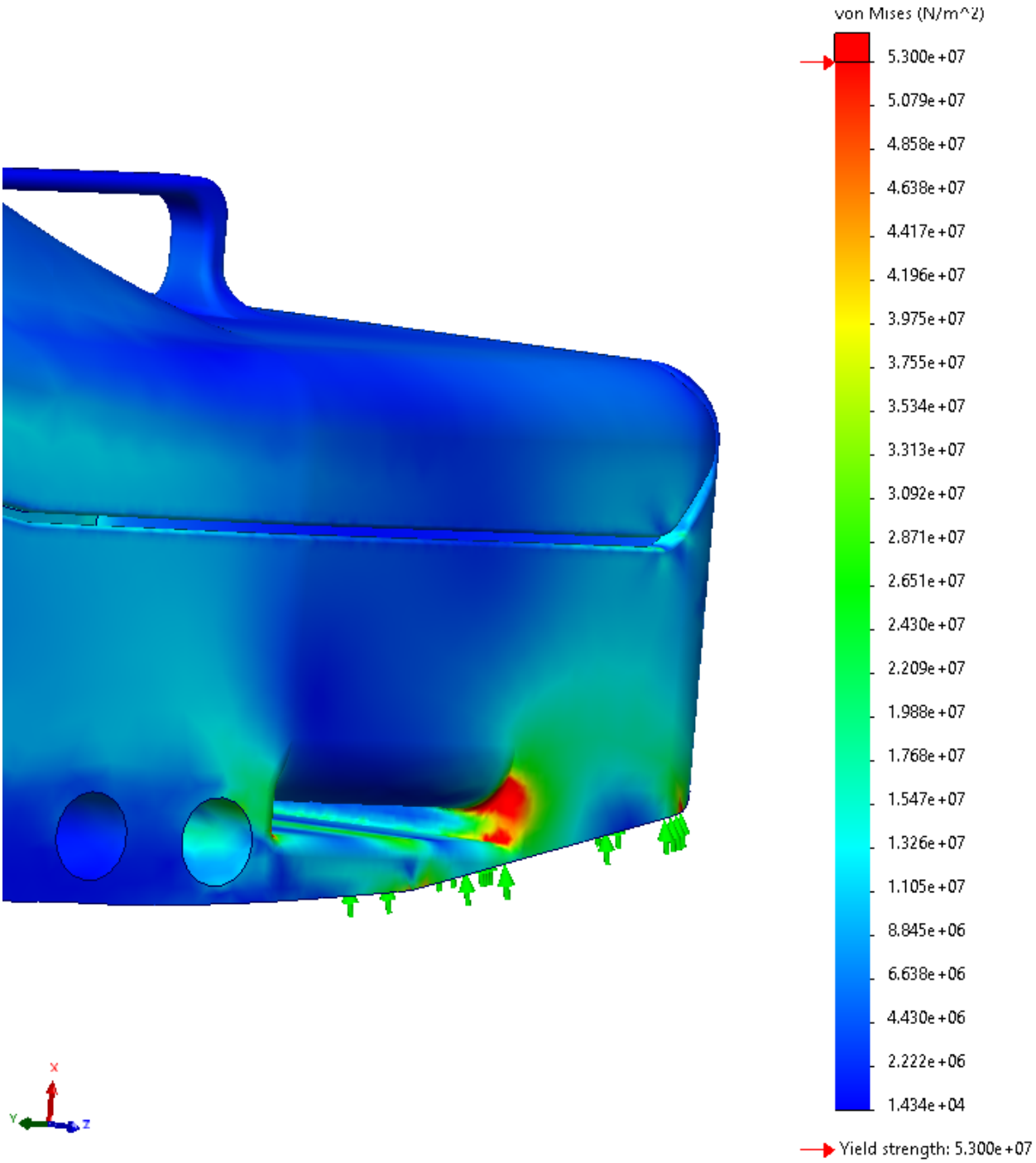



Figure 28: Yielding Area at Toe Off under Eric's Weight

Similarly, the design shows yielding while under load at heel strike position .

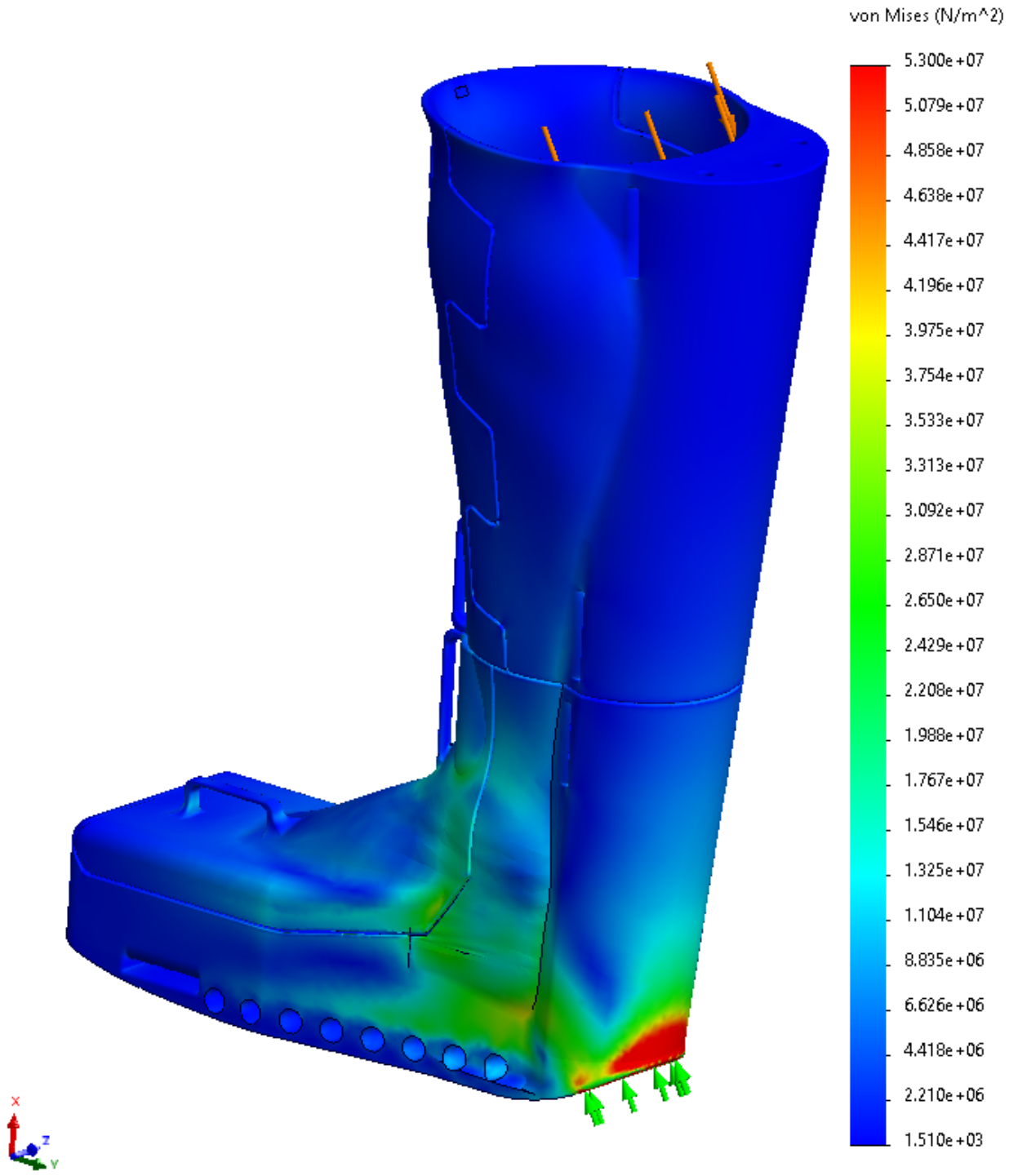



Figure 29: Stress Distribution Overall at Heel Strike under Maximum Weight

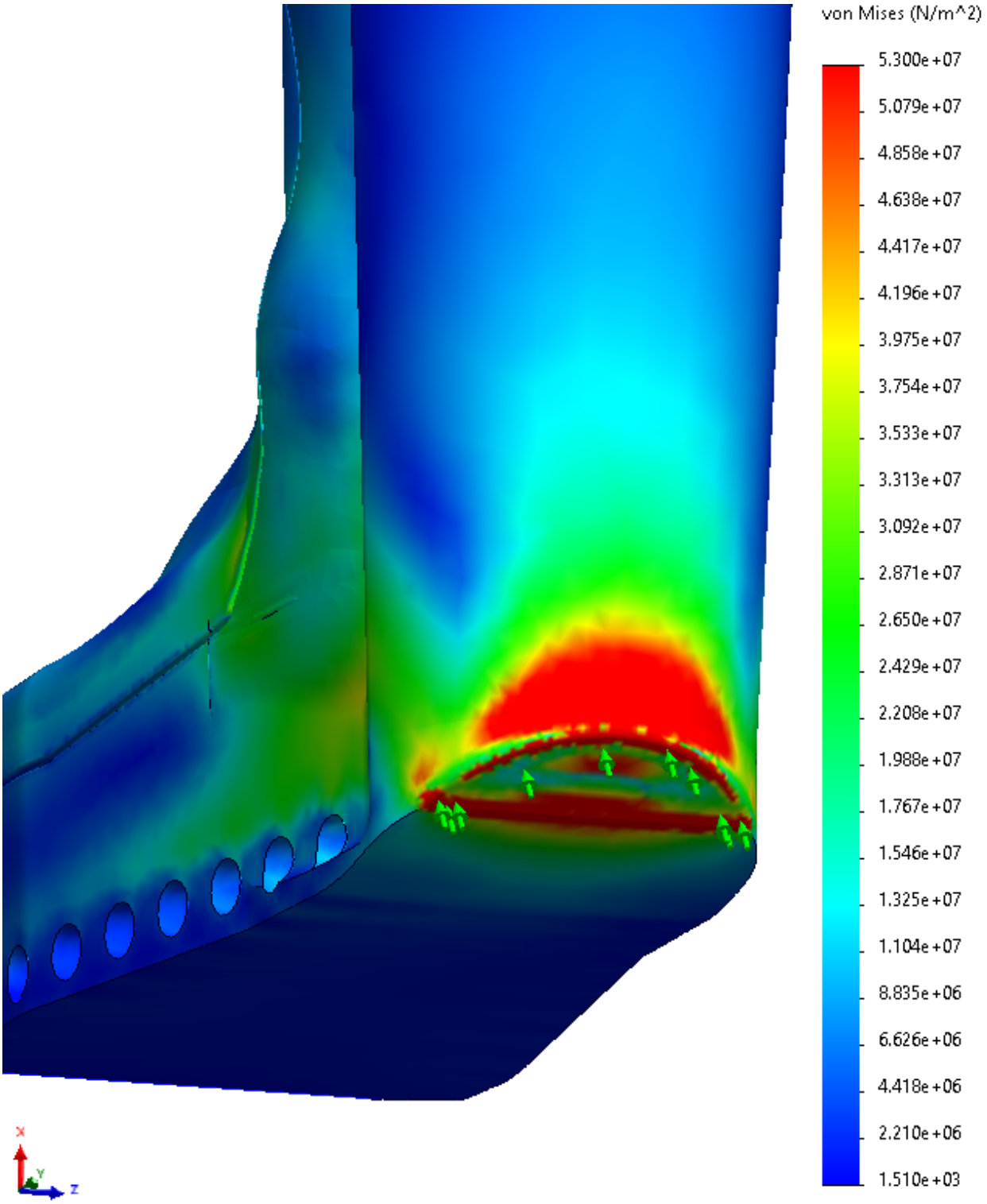



Figure 30: Yielding Area at Heel Strike under Maximum Weight

And under the loading of Eric's weight, the design is still yielding. However, the affected

area decreases.

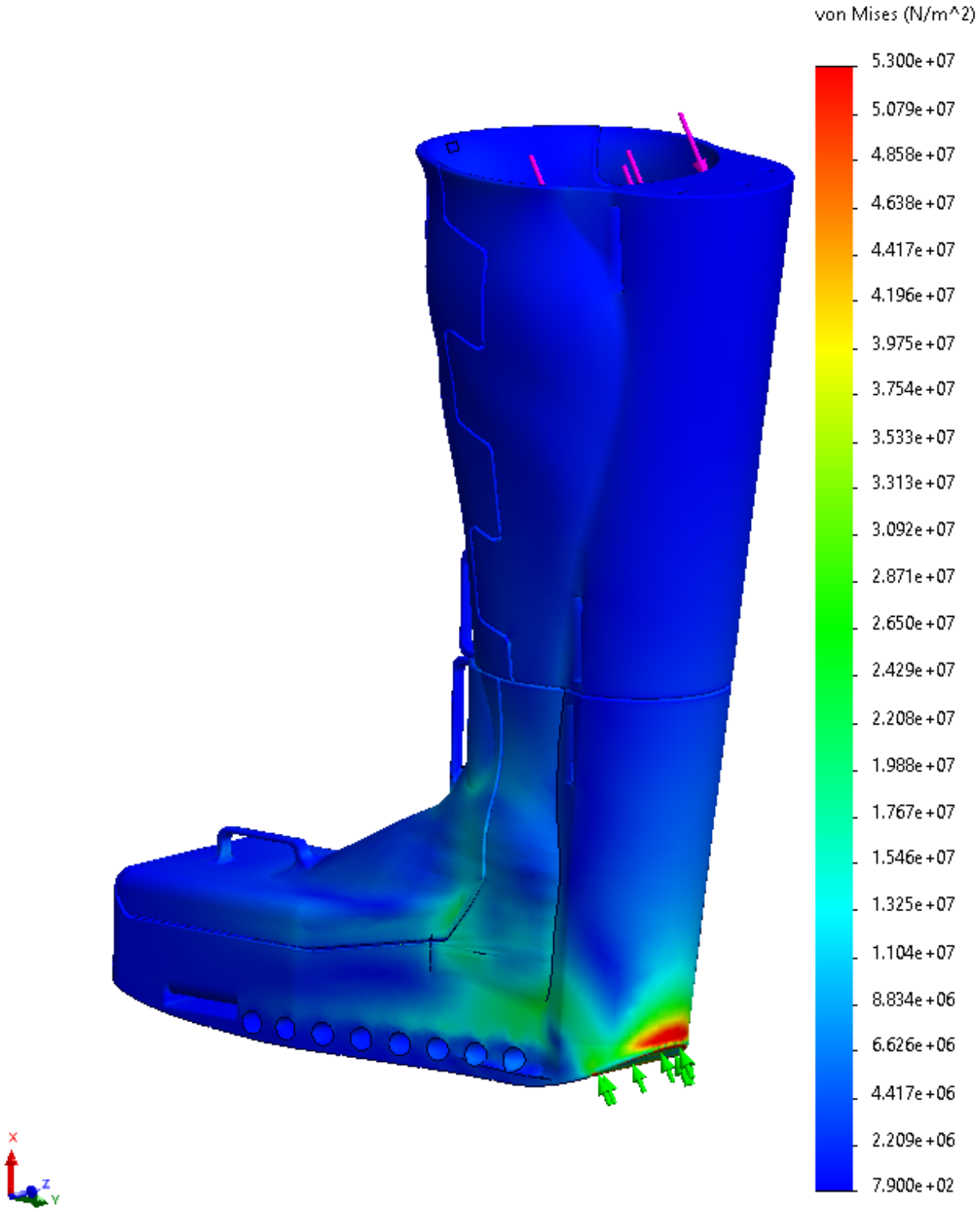



Figure 31: Stress Distribution Overall at Heel Strike under Eric's Weight

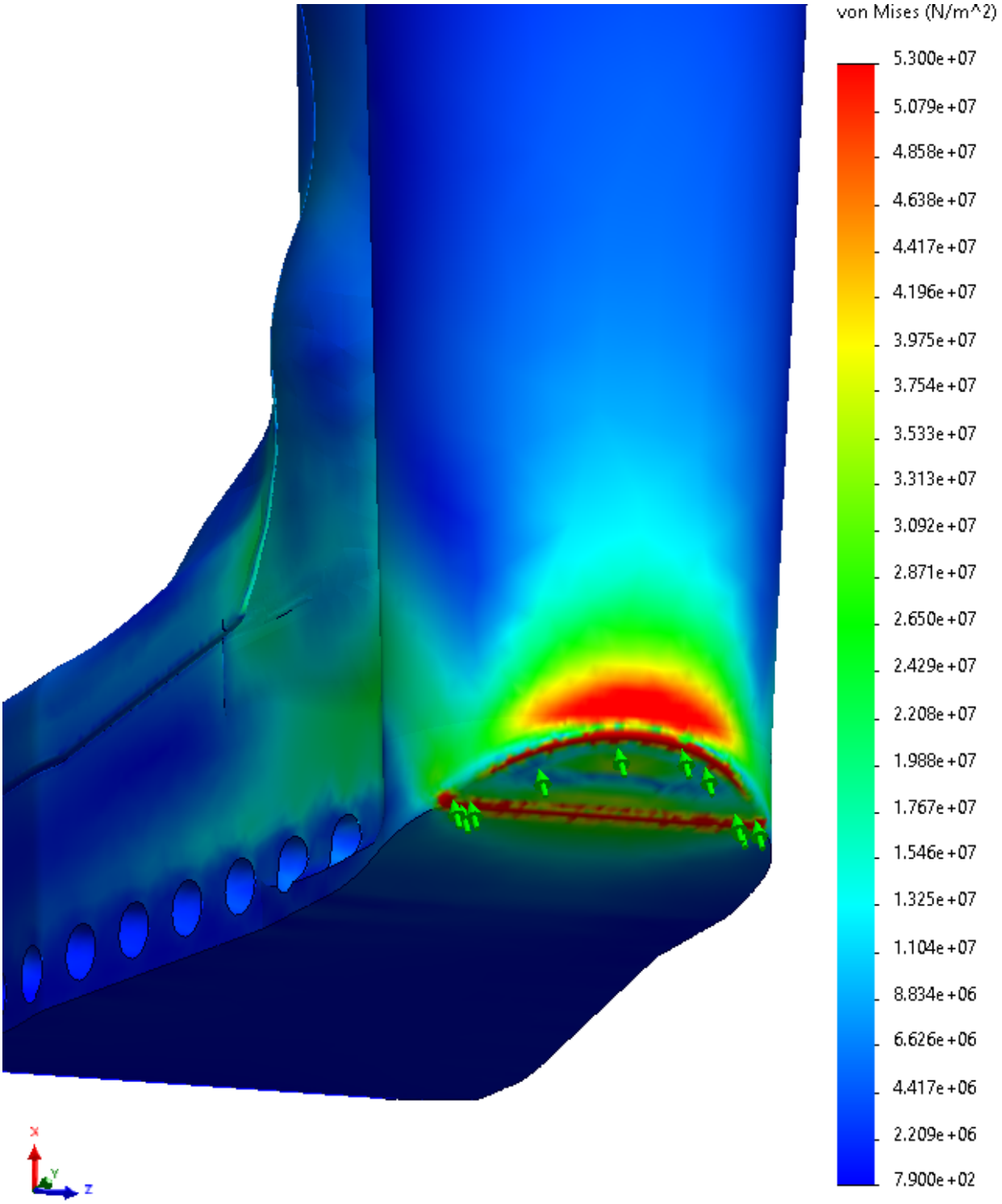



Figure 32: Yielding Area at Heel Strike under Eric's Weight

In conclusion, the model has failed to support the maximum load of 275 lbs, but was close to supporting the weight of the actual model, 170 lbs, during the toe off load case. The design

was also failed to supporting the maximum load in the heel strike load case, therefore, it can be concluded that the design failed to support the maximum weight of 275 lbs using numerical methods, but further experimental methods are needed to validate the maximum load that the design can withstand.

#### 4.1.2.2 Factor of Safety

A Factor of Safety (FoS) was applied to the FEA simulation to act as a conservative estimate of the loading, such that in the case where the loading is exceeded unpredictably or the CROW boot has some manufacturing defect, the device does not fail prematurely. For a bio-mechanical device, this FoS would need to be higher than usual to accommodate any extreme scenario that can endanger a patient's life. Therefore, the Team opted for the Factor of Safety of 3. Since the FoS related to the supported weight of the design by the total load applied to the model, a failure to support the total load in the simulation indicated a failure to comply with the FoS of 3.

#### 4.1.2.3 Treatment Length

To make sure the design can last the treatment time, an S-N curve of the selective laser sintering material was used to identify the fatigue properties of Nylon 12 under cyclic loading. The endurance limit for Nylon 12 is 18 MPa [26] and it can be expected that any part of the design that exceed this value will develop cracks and extensive yielding, follow by ductile fatigue failure. The red areas shown in Figure 33 and 34 are regions that exceed endurance limit.

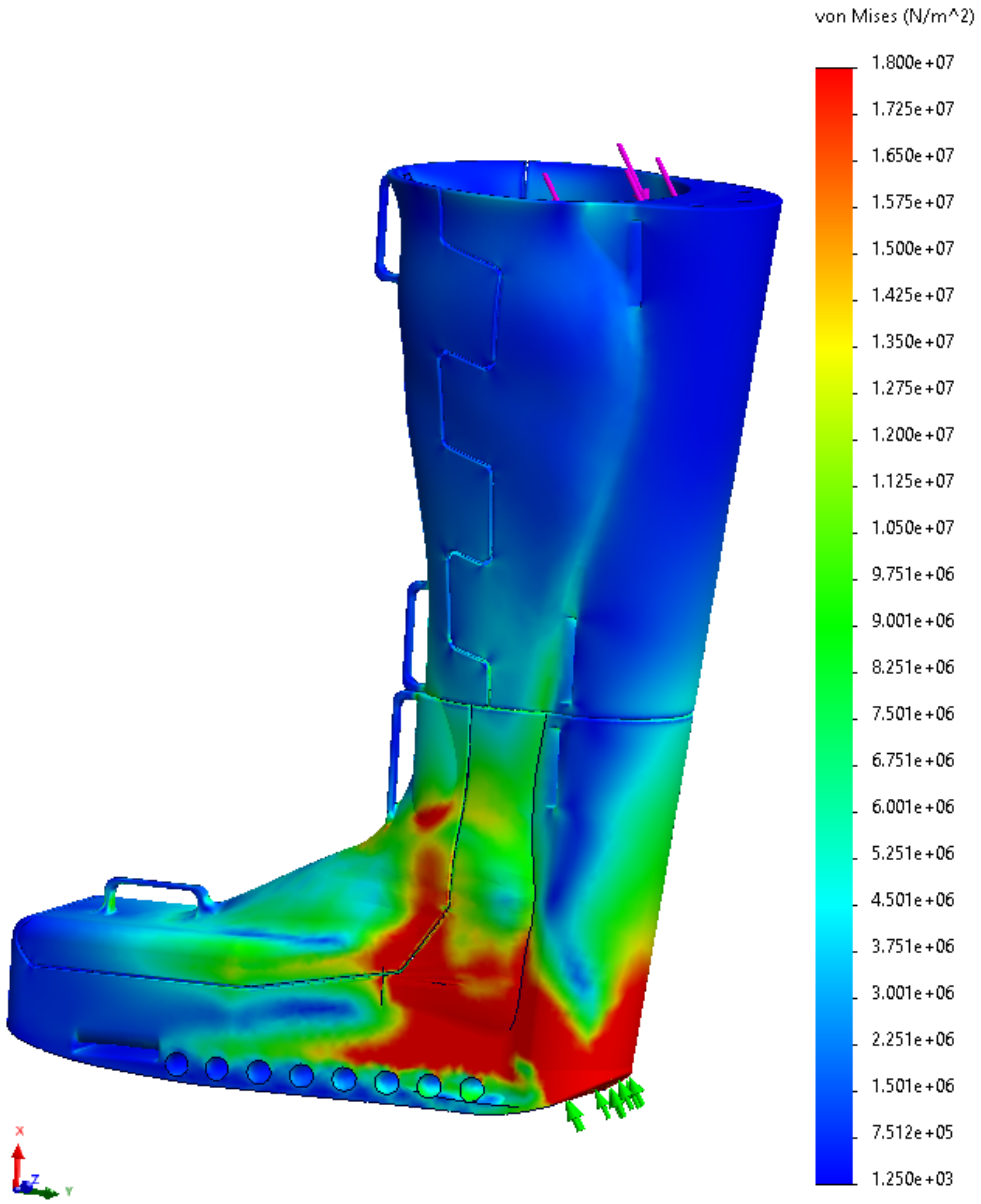



Figure 33: Stress Distribution during Heel Strike under Maximum Weight at Endurance Limit

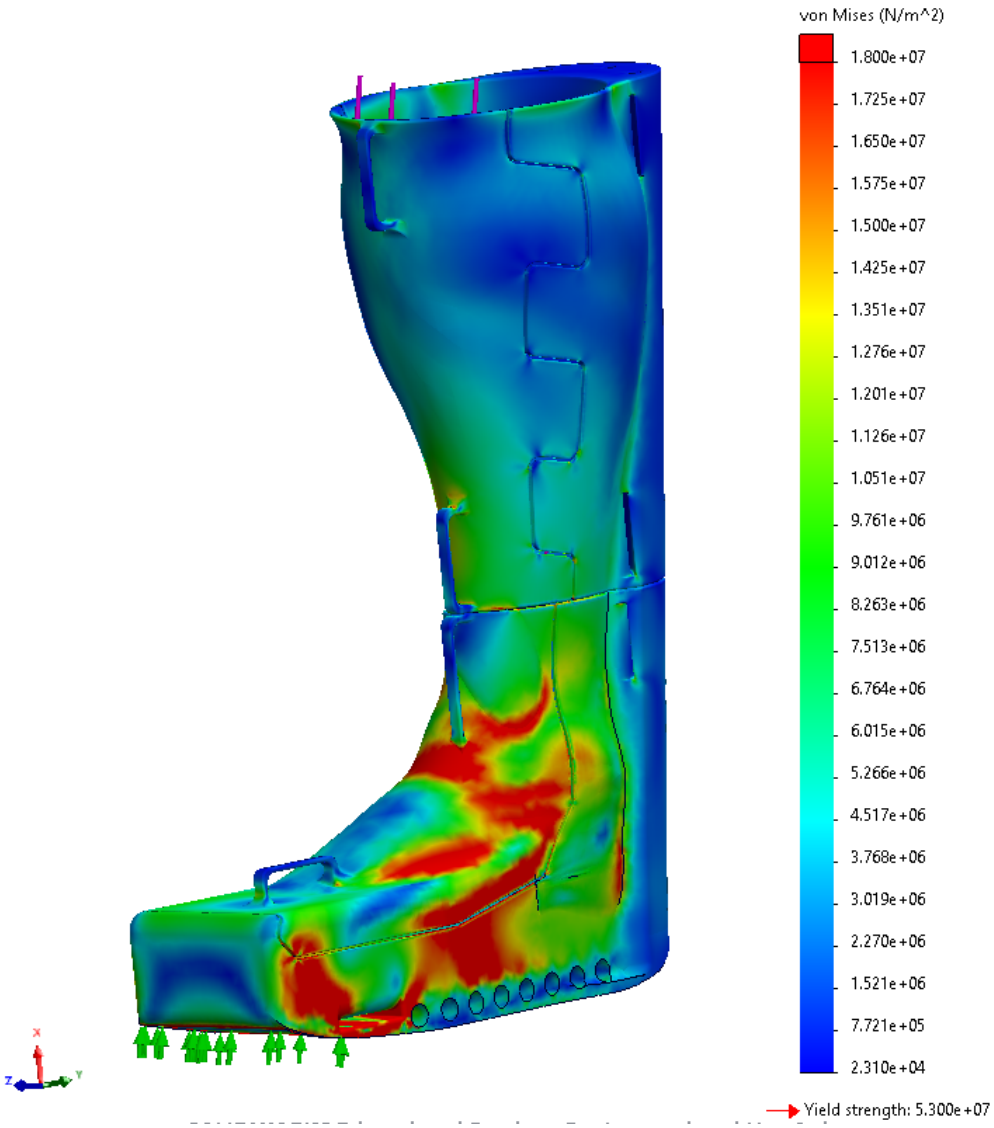



Figure 34: Stress Distribution during Toe Off under Maximum Weight at Endurance Limit

All of the FEA results show that the final design failed to withstand cyclic loading.

#### 4.1.2.4 Convergence Test

The convergence test is not one of the specifications but it is an important engineering test to verify the FEA results. A converged study ensures the FEA model capture the real life behavior, while reducing solve time. Convergence tests were performed on the two main study: maximum load at toe off and maximum load at heel strike. Due to the complex geometry of the design, the model failed to generate meshes if the maximum mesh size went under 0.8 inch. Therefore, the maximum mesh size used for the convergence test were from 2 inch to 0.8 inch. There are three sensors placed to gather the average von Mises stress value, which is shown in Figure 35.

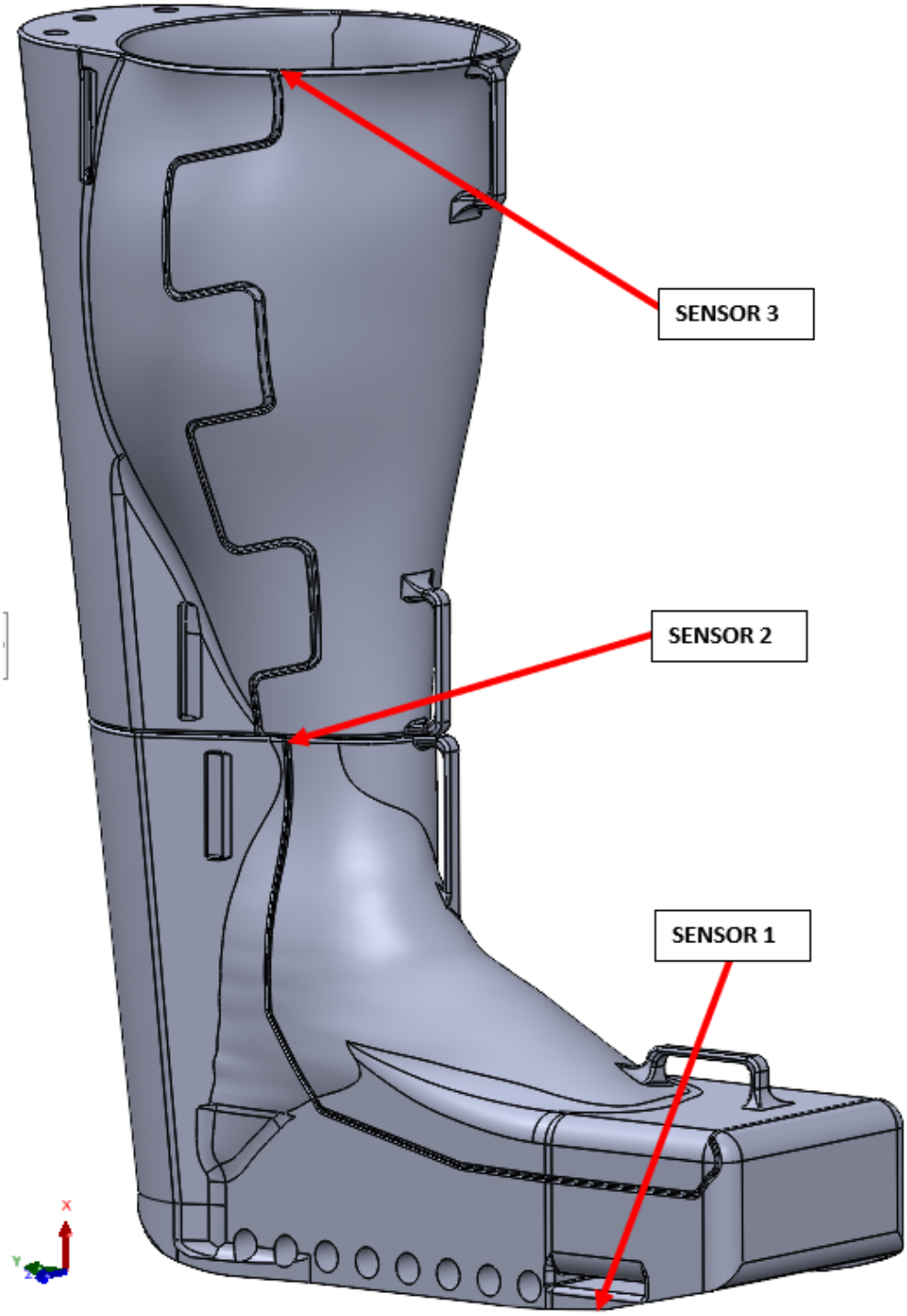



Figure 35: Sensors Location for Convergence Test Data

After 10 runs with decreasing maximum mesh size, the convergence test results are shown in Figure 36 and 37.

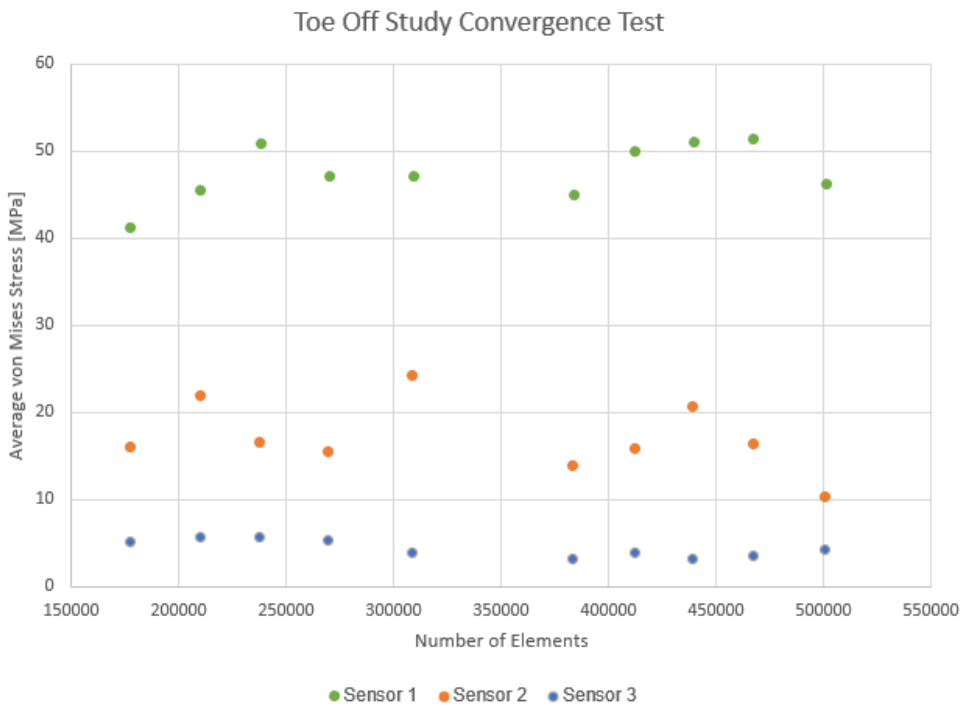



Figure 36: Toe Off Study Convergence Test

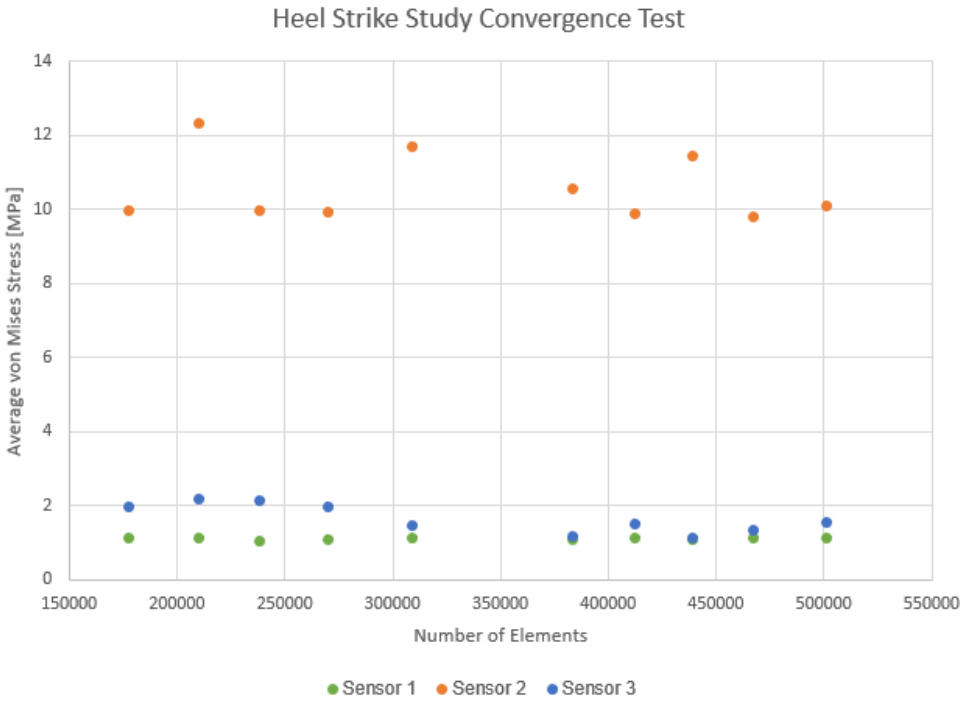



Figure 37: Heel Strike Study Convergence Test

Both of the studies show that no data point converged, given that the model could only mesh up until maximum mesh size of 0.8 inch. Therefore, the FEA results were not able to predict the exact behavior of the design under given circumstances, but rather be used as a graphical result to probe the possible failure points of the design.

### 4.1.3 Material Specification

The material that was specified for the CROW prototype was HP PA12 (Nylon 12). The melting point of HP PA12 was tested using ASTM D3418 to be 187 °C. The minimum operating temperature Nylon 6/12 is listed on McMaster Carr as -40 °C [27]. HP performed leakage tests on HP PA12 to characterize it's fluid tightness. The tests used HP PA12 samples as pressure vessels with water as the working fluid and pressurized the enclosure. Therefore, the material will not allow water to seep in. The breaks between the different shells are similar to those present on current CROW devices. With this, it can be concluded that the new CROW will be water resistant to a similar degree as the current CROW design.

HP PA12 is also FDA certified to be in contact with the skin. This was not a requirement as the PA12 will not be in contact with the patient but is a nice thing to have.

Nylon 12 was tested for it's water retaining properties. This gives us confidence that the exterior shell, made from Nylon 12, will prevent water from entering the CROW Orthotic through the shell material itself. The boundaries between each shell of the CROW boot pose a risk for water intrusion. However current CROW boots have similar separations between shells, thus, it was assumed that the water resistance will be no worse than the current solution [28].

The effects of the MJF manufacturing process on this property is not definitively known. Despite this, the McMaster Carr Nylon materials are rated to operate down to - 40°C. Both the HP PA12 and the McMaster Carr Nylon 12 exhibit similar properties in addition to both being Nylon 12, thus, it may be assumed that provided the fusing of powered material in the MJF process is of sufficient quality, the cold temperature properties may be comparable, although this hypothesis remains to be tested.

The data sheet for HP's Nylon 12 material shows that the heat deflection temperature are well above the Maximum Operating temperature that have been specified for this application [29]. As such, the impacts on material property due to reasonably temperatures is negligible.

### 4.1.4 Manufacturing

#### 4.1.4.1 Manufacturing Time

The ideal value of manufacturing time was less than 15 hours. The final design has a manufacturing time of 30.50 hours. The 30.50 hours is compromised of 2.50 hours of technician labor and 28 hours to print, cool, and post process the CROW shells.

Considering the current manufacturing process is labor intensive for Anderson Orthopedics' technicians, the reduced labor input from 15 hours to an estimated 2.5 hours is a positive improvement to the overall manufacturing process. As the difference between the actual manufacturing time and the ideal manufacturing time is 15.50 hours, the Team was unsuccessful in meeting this target specification. Future improvements to the proposed manufacturing process would include batch ordering to overlap shipping time of printed CROW shells.

#### 4.1.4.2 Unit Manufacturing Cost

The ideal unit manufacturing cost specified by the Client was a value under $1,000. The final design including both labor and material costs came out to be an estimated $1,945.93 per CROW orthosis unit.

The final cost to manufacture one unit of our final design is a large improvement over the current traditional manufacturing cost of $4,500 per CROW orthosis unit. The Team was unsuccessful in meeting the target specification for this project due to the cost difference of $945.93 between the actual final cost and ideal device cost. Future improvements that would reduce the overall cost for the design would include removing material in low stress areas through the creation of material cut-outs and batch printing the CROW shells to utilize the entire build volume when ordering printed components.

## 4.2 Patent Infringement Review

Reviewing the patent search results from earlier in the concept generation phase, the Team verified, to the best of their knowledge, that the final design does not infringe on any current patents or patent pending devices. In evaluation of patent infringement, all components of a patent's independent claim are required on a device for patent infringement to occur.

Table XI below provides a visual comparison of the final design's features to the listed components of the independent claim made in Patent US 10,675,168 B2: ANKLE FOOT ORTHOSIS [16]. The third column states if the final design includes a component or not.

TABLE XI: Evaluation Against Patent US 10,675,168 B2 [16]

| Component | Description | Final Design |
|---|---|---|
| 1 | foot assembly & shin assembly | YES |
| 2 | foot assembly attached to the shin assembly with hinge | NO |
| 3 | foot assembly having rigid heel cup | YES |

As the final design does not include a hinge, the independent claim of Patent US 10,675,168 B2 has not been infringed.

Table XII below provides a visual comparison of the final design's features to the listed components of the independent claim made in Patent US 9,452,077: FOOT AND ANKLE ORTHOSES

THAT ENABLE NATURAL MOVEMENT OF THE FOOT [17]. The third column states if the final design includes a component or not.

TABLE XII: Evaluation Against Patent US 9,452,077 [17]

| Component | Description | Final Design |
|---|---|---|
| 1 | upper member secured to lower leg | YES |
| 2 | lower member secured beneath foot | YES |
| 3 | hinge connecting upper and lower member | NO |
| 4 | tracking element & guide to stabilize ankle during movement | NO |
| 5 | arcuate receptacle for the tracking guide | NO |

As the final design does not include a hinge connecting upper and lower members or a tracking element with an arcuate receptacle for the tracking guide, the independent claim of Patent US 9,452,077 has not been infringed.

Table XIII below provides a visual comparison of the final design's features to the listed components of the independent claim made in patent-pending US Patent Application Publication Number 2021-0259871 A1 [18].The third column states if the final design includes a component or not.

TABLE XIII: Evaluation Against US Patent Application Number 2021-0259871 A1[18]

| Component | Description | Final Design |
|---|---|---|
| 1 | calf sleeve secured about leg of user | YES |
| 2 | foot plate secured to foot of user | YES |
| 3 | distractive force mechanism connected between calf and foot | NO |
| 4 | rigid flange configured on the medial aspect of the foot assembly | NO |

As the final design does not include a distractive force mechanism or rigid flange configured on the medial aspect of the foot assembly, the independent claim of US Patent Application Number 2021-0259871 has not been infringed.

# 5 Future Work

With the conclusion of the third phase of the Capstone project, multiple topics and items relevant to the Project were determined to benefit from future work on the respective topics, of which, can be split into two main categories; design improvements and process improvements.

## 5.1 Design Improvements

### 5.1.1 Design for Manufacturing

As MJF printing fills a vat of powder in the printing process, in order to create internal voids, drain holes must be incorporated. Such features could be integrated into the CROW boot design to allow for the weight saving of void, with drain holes, but can be covered during post process to preserve the moment of inertia, outer shape, and prevent debris from getting trapped in the voids. This would have the added benefit of reducing the CROW boot weight, which impact directly on ergonomics and material cost.

Alternatively, the design can have a lip or it can be designed for an overlap such that the segments are located left to right on the board a bit better, thus optimise the print volume and cut down manufacturing time.

Lastly, the posterior calf and posterior knee shell should be considered as a single component, since this may reduce weight, size and manufacturing time with fewer parts. It would additionally be easier to design and adapt to a barometrically driven model.

### 5.1.2 Design for Specifications

The final design does not meet all of the specifications, with all the failed specifications related to the rigidity and dynamics of the design. Therefore, based on FEA results, materials can be cut off on low load bearing sections, while adding material or redirect the stress flow on high load bearing sections.

Even though the design passed the water resistance rating, adding sealants or debris anti-ingress methods for the seams between the anterior and posteriors shells can improve all weather rating since repetitive exposing to extreme weather conditions may reduce the life of the device.

## 5.2 Process Improvements

### 5.2.1 Implementation of this Design Process

Currently, the Client is using a robust 3D scanning process that includes a 3D scanner and a process to add reliefs to the 3D scan so no changes to this part of the process is needed. However, the process described in Section 3.2 assumes that the Client's staff are proficient in a CAD package

to design support devices but the Client does not currently use any CAD packages to design orthotic devices. Therefore, one or more computer aided design software need to be incorporated into the design process to create a file that can be read by the MJF printer slicer. Furthermore, the process may require a software that can generate the device parametrically based on the 3D scan and specific patient criteria such as weight.

### 5.2.2 In House Fabrication versus Outsourcing Printing

There is the option to outsource the printing of the exterior CROW shells to an external fabrication hub. This is the option that was used to create our cost estimate shown in Table IX. One of the benefits of outsourcing the printing of the exterior CROW shells would be not making major purchases and becoming financially committed to shifting to this process. Be able to outsourcing also helps keep the change of staff, change of work process and work environment to a minimum comparing to in house fabrication option.

However, if the Client opted for in house printing right away, there would be an immediate challenge to build the knowledge base for designing for MJF printing as well as having staff learn CAD packages and get used to designing digitally. But as soon as the Client has the designing process sorted out, this option can benefit not only CROW boot manufacturing process but potentially also many others manufacturing processes. This option also has a lower lead time and more logistically independent comparing to outsourcing option.

# 6 Conclusion

The Team developed a finalized design and manufacturing process for a rapid fabrication, custom-fit CROW orthosis for Anderson Orthopedics. To get the finalized design, the Team utilized a design methodology that included; defining the problem, gathering information, generating concepts, selecting a concept, embodiment design, and detailed design.

The final design incorporates four nylon-12 3D printed outer shell components, three 6061-T6 aluminum stiffening rods, four BOA adjustable straps, a comfortable inner PPT foam lining, and a rubber walking sole.

The manufacturing process starts with creation of the four nylon-12 3D printed out shells. The outer shells are modeled using a 3D scan of a patient's leg and refined using a CAD program before outsourcing for MJF 3D printing company. The total print time for all outer shells is approximately 28 hours which does not include shipping time. Once the outer shell components have been printed and shipped, the device can be assembled by a technician in an estimated 2.5 hours. This assembly process includes aligning of the posterior outer shells using the 6061-T6 aluminum stiffening rods, gluing of cushioning foam to the inner part of each outer shell, and gluing a rubber sole to the bottom of the device.

With a material cost of $1,845.93 and 2.5 hours of technician labor estimated at $40/hour, the total cost to manufacture and assemble a single unit is $1,945.93.

The final design is considered aesthetic, accommodates the inclusion of custom foot orthosis, and operates in Manitoba's climate. To the Team's knowledge, the final design has not infringed any patents.

There are several features of the final design that improve upon a traditional manufactured CROW orthosis. One improvement is the accommodation for a changing limb size caused by swelling from edema, up to a circumferential length increase of 4.1 cm. Another improvement is the modular design that integrates several 3D printed components that allows for replacement of singular components if they break or the user needs modified fit.

The final design met six out of the eleven target specifications. The CROW orthosis and proposed manufacturing process succeeded in the minimal circumferential length increase, minimum and maximum operating temperatures, water resistance, aesthetics, and, sufficient space for the inclusion of a custom foot orthotic. The design failed to meet specifications related to strength and cost, these metrics were; manufacturing time, minimum supported weight, factor of safety, unit manufacturing cost, and treatment length. Despite this, potential future design and process improvements have been identified which would allow the further design and process revisions to meet the specifications. Areas for design improvements include design refinements to mitigate yielding due to fatigue and extreme load cases and reduction of material in low stress areas to reduce printing cost. A key recommended process improvement was the use of better suited design software for the modeling of the CROW device.

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# 8 Appendix

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# Appendices

# A Information Gathering

Prior to the concept generation and selection, detailed information needed to be gathered on regulations, competitor's products, materials, foot load distribution, and other possibly relevant information that will be necessary in the detailed design.

## A.1 ISO Biomaterials Verification

The International Organization for Standardization (ISO) specifies the testing procedures to ensure a material is safe to be in contact with the skin; ISO 10993 details lab conditions and testing procedures to verify a materials biocompatibility. This standard will be a major consideration for the Final Design Phase, as the CROW product may interface directly or very closely with the patient's skin for prolonged periods of use.

## A.2 Competitors' Products

The team researched various orthotic clinics around the world to see how they tackled the challenge of creating CROW devices, but also to reveal other approaches that may be used in the team's solution to Anderson Orthopedics problem.

### A.2.1 Additive Manufactured Products

Korthotics is an orthotics company based out of Sydney, Australia. Utilizing high quality nylon-11 (black) materials in combination with 3D software, Korthotics is capable of printing complex designs. The equipment they have on site includes a PROX SLS 6100 Printer which is an industrial grade SLS (Selective Laser Sintering) printer that consists of a powerful laser that selectively sinters the nylon-11 powder material. Korthotics currently manufactures an AFO that appears to have a two piece design that is assembled with a hinge at the ankle joint of the device, this is shown in Figure 1 below.

Figure 1: 3D Printed Ankle-Foot Orthosis Manufactured by Korthotics [1]

Korthotics also offers a variety of custom, single piece, 3D Printed ankle foot orthoses. Some variations are shown in Figure 2 below.

Figure 2: 3D Printed Ankle-Foot Orthosis Styles Manufactured by Korthotics [2]

Another competitor in the custom fit orthoses industry is Cascade Orthotics Ltd. Casecade Orthotics Ltd. is an orthotic company based out of Calgary, Alberta. Cascade currently offers 3D Printed orthoses include a 3D Printed AFO (Ankle Foot Orthosis) and 3D Printed Foot Insole. Cascade's 3D Printed AFO is shown below in Figure 3.

Figure 3: 3D Printed Ankle-Foot Orthosis Manufactured by Cascade Orthotics Ltd. [3]

### A.2.2 Conventionally Manufactured Products

Cascade Orthotics Ltd. also offers several different AFOs including; an Articulated Ankle Foot Orthosis (AAFO), a Rigid AFO, and a Graphite AFO. These different AFOs can been seen in Figure 4 below.

Figure 4: Ankle-Foot Orthoses Manufactured by Cascade Orthotics Ltd. [4]

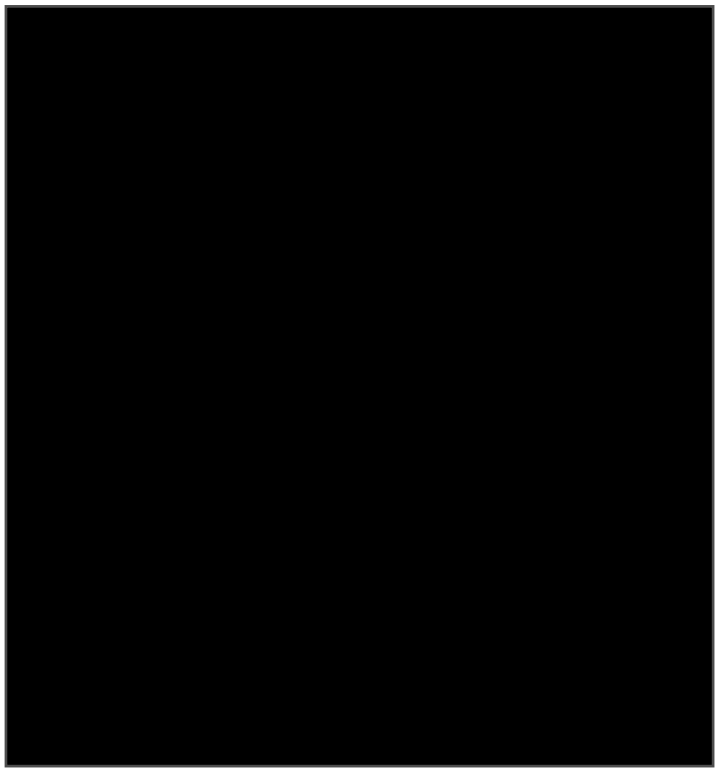
## A.3 Patent Search

The team conducted a patent search with a focus towards ankle foot orthosis and CROW orthosis devices. The search included current patents and patent-pending devices. This patent search allowed the team to analyze independent claims made for given patents.

### A.3.1 Current Patents

Overview of the independent claims for active patents was done for mitigation of potential patent infringement for future designs.

#### A.3.1.1 Patent Number US 10,675,168 B2: ANKLE FOOT ORTHOSIS



The independent claim for this patent specified a leg and foot orthosis which reduces pronation, for use inside a shoe, the leg and foot orthosis being configured to be customized for an individual user, the leg and foot orthosis comprised of the below items [5]:

1. A foot assembly and a shin assembly.
2. The foot assembly being attached to the shin assembly with a first hinge configured to attach immediately distal to an apex of the medial malleolus and a second hinge configured to cover an apex of the lateral malleolus, wherein the first and second hinge each create an axis which is horizontal and provides a single axis of movement of the shin assembly relative the foot assembly.
3. The foot assembly having a rigid heel cup which limits pronation and a sole configured to extend to a distal end about a quarter inch proximal to each metatarsal head of a user and is configured to cover the back of the heel just below the Achillies tendon of a user for whom the orthosis has been configured for.

#### A.3.1.2 Patent Number US 9,452,077 B2: FOOT AND ANKLE ORTHOSES THAT ENABLE NATURAL MOVEMENT OF THE FOOT

Figure 6: US Patent 9,452,077 Drawing [6]

The independent claim for this patent is an ankle brace, comprised of the below items [6]:

1. An upper member configured to be secured to a lower leg of an individual.
2. A lower member configured for placement beneath at least a portion of a foot of the individual.
3. A hinge connecting the upper member and the lower member, the hinge configured to be positioned at an elevation lower than a tibialtalor junction at an ankle of the individual when the upper member is secured to the lower leg of the individual.
4. A tracking element configured to stabilize the ankle during movement of a foot between full dorsiflexion and full plantarflexion, the tracking element including a protruding tracking guide.
5. An arcuate receptacle for the tracking guide, the arcuate receptacle defining a path for the protruding tracking guide, the path having a shape configured to generally follow movement of a tibia of a leg of the individual over a profile of a tibial trochlea of a talus bone of the foot of the individual, the arcuate receptacle positioned at a location of the ankle brace that will substantially align the path with the tibial trochlea when the ankle brace is positioned over the ankle, the protruding tracking guide and the arcuate receptacle together defining a range of motion for the lower member.

### A.3.2 Patent Pending

The Team noted the patent below had an application submitted in 2021 and classifies this claim as patent-pending. Review of this patent application mitigates the risk associated with designing a similar concept and a possible patent infringement if this patent application is approved in the near future [7].

#### A.3.2.1 Patent Application Publication Number US 2021-0259871 A1: DYNAMIC ANKLE ORTHOSIS DEVICES, SYSTEMS, AND METHODS

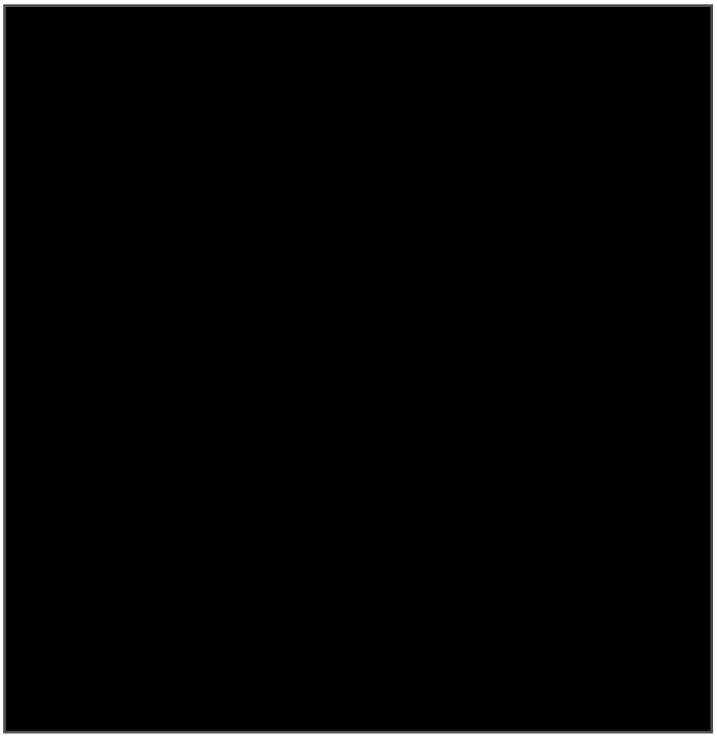


Figure 7: US Patent Application Publication Number 2021-0259871 A1 Drawing [7]

The independent claim for this patent specified a dynamic ankle orthosis system comprised of the below items [7]:

1. A calf sleeve configured to be secured about a leg of the user.
2. A foot plate configured to be secured about a foot of the user.
3. A distractive force mechanism connected between the calf sleeve and the foot plate, wherein the distractive force mechanism is configured to generate a force between the foot plate and the calf sleeve acting bidirectionally across an ankle of the user to substantially offload body weight of the user passing through the foot, ankle, and leg.

4. A rigid flange configured on the medial aspect of the foot assembly wherein the rigid flange is configured to curve over the top of the first metatarsal of the user for whom the orthosis has been configured, with upwardly extending side edges configured to partially cover and impede a medial axial rotation of a first metatarsal without creating pressure points, wherein each side edge of the rigid flange terminates upwardly at a rollover configured at the first metatarsal.

## A.4 Design Software

In researching other competitors, two software were identified which allow for the processing and modification of 3D scans of patient limbs. These are tailored specifically for the design of custom orthopedic devices such as wrist braces or orthopedic boots. The first program, MediACE3D is owned by RealDimensions Inc, and a trial licence was obtained which allows for the rectification of the 3D model, but not the export of the files due to the trial licence [8]. The second program, is in fact a suite of programs, although the most applicable to this Project is the Rodin4D NEO, owned by Lagarrigue [9]. A student or trial licence has not yet been obtained, but is currently in the works. A sample computer image of products designed in this software can be seen in the images below, for both MediACE3D and Rodin4D Neo

These programs function by importing a 3D scan of the patient's limb, and allowing the user to modify the model geometry based on the patient's needs. Then, the program will generate the orthopedic device, where any additional components, such as hinges, clips, stiffeners, etc... can be included and accounted for. These programs then output 3D model files which are used to directly print the orthopedic devices that were modeled, or to produce a CNC'd foam model of the patient's limb, which has the modifications done to the leg for draping, hinges, support, etc.... to allow for a jump to the draping process. This method does not require the use of plaster of clay modeling.

Moving forward to Final Design Phase, the Team will be using a 3D scan of a patient's limb to analyze and optimize the CROW design proposed in this phase. Figure 8 shows the modified CROW of the patient from Anderson Orthopedics.

Figure 8: Sample of a Patient Limb for a CROW [10]

## A.5 Plantar Stress Distribution Analysis

Most stress measurement devices measure the normal force and longitudinal stress, but the stress in the plantar that affects the ulcers is shear stress. However, Cornwall and McPoil were able to predict fore-aft or anterior-posterior shear force with a pressure sensor platform using a combination of peak force, time to peak pressure, and stance phase duration. To accomplish this, the authors attached a pressure sensor platform to a force platform and collected data with both systems recording simultaneously at a similar sampling frequency. The research cannot find a direct method to determine the medial-lateral shear force component using a pressure sensor platform [11]. But once the data is obtained, it can be presented in pictorial, in parametric and in graphical form. Parametric characterisations include magnitude, timing and location of peak forces and 'impulses' (the force-time integrals), parameters describing the local concentration of force and the distribution of the 'impulse' over areas of the foot sole. Pictorial displays include force-time graphs for selected areas of the foot, display of movement of the centre of pressure on specific areas

and cross-sections through the pressure distribution profile at a specified recorded instant [12]. A company called Kitronyx has successfully developed a platform to perform foot pressure mapping and gait measurement called MC1600.

## A.6 Materials & Manufacturing Methods

In addition to the existing materials used, a large assortment of materials and manufacturing methods were researched. From the multitude of possible manufacturing methods, it was found that conventional subtractive manufacturing methods were not commercially viable for the CROW, as each CROW is custom to fit the patient's needs, and not produced in large quantities. As such, additive manufacturing processes are ideal for the custom CROW application, as it does not require large tooling costs that can only be offset with large scale production, as well as by minimizing the wasted material.

There are a large variety of additive manufacturing processes, among them, Fused Deposition Modeling (FDM), powder bed fusion (PBF), and vat photopolymerization (VPP). FDM remelts polymer filaments then extrudes it through a nozzle, adding on to a base plate layer by layer to create the final shape. This method is of relatively low cost [13]. PBF uses fine material powder, using a laser to melt patterns into the powder layer by layer, where the layer can be metallic or polymer based in nature, although the metallic based powders have large costs compared to the polymer based powders [14]. This method has a smaller range of polymers which can be used than FDM, where these processes are referred to as Selective Laser Sintering (SLS) and Multi Jet Fusion (MJF), although these methods can produce much more intricate shapes than FDM. Examples of this would be the HP Fusion Jet, the Formlabs Fuse 1, and the EOS SLS System. VPP functions by focusing UV light within a resin bath to selectively cure portions, allowing the printed part to be drawn out of the bath. This method allows for very high detail, but is limited to UV curable resins, whose material properties change with long term exposure to UV light. Both the VPP and the PBF methods require post processing of the printed parts before they can be used, where for PBF they must be cleaned and smoothed with a form of sand blasting, where as the VPP require washing and post curing of the parts to achieve their final state and material properties [15].

As the CROW device is intended to be used for relatively long terms, as well as in situations where UV light will be present, VPP is not a suitable method for the production on the outer shell of the device as the material properties would change undesirably, becoming more brittle [13]. Both FDM and PBF processes could yield components with material properties which will be suitable for the CROW application due to the currently developed engineering materials.

In the Final Design Phase, based on the loadings that are calculated and the detailed design, appropriate materials and or combination of materials will be determined, where the manufacturing of the CROW device would be well suited to 3D printing.

## A.7 Search Summary

Through the process of information gathering the Team identified areas to focus for concept development. Through identifying relevant regulations, the Team gained a greater understanding of the professional responsibilities for those who manufacture orthotic devices. Through research of competitors' products, the Team identified common operating principles and manufacturing techniques used within the industry. Through a patent search, identification of existing patents was conducted to mitigate patent infringement during the production of our chosen concept.In addition, the search for patents and for competitor's products led to the discovery of 2 computer programs which allow for the modification of the 3D patient scans to allow for digital design of the orthotics. As stress distribution in the foot and CROW boot will have large impacts on the design and treatment of the device, research was performed in this topic, where it was determined that to reduce the impact on ulcers, the shear forces between the foot and the boot need to be minimized, along with design considerations for the patient specific loading and load distribution on the foot.

# B Concept Generation

To develop potential concepts, the Team held a brainstorming session to generate concepts. The concepts that were generated during this session were then screened and similar concepts were grouped together. The 7 remaining concepts that the Team identified as having potential were then developed further by specifying manufacturing methods.

## B.1 Brainstorming

The Team generated 29 concepts during brainstorming session. In order to ensure that the generated concepts explore all potential design avenues, the Team did not eliminate or scrutinize any design while brainstorming. Doing this encouraged creativity and gave group members the freedom to explore unconventional solutions. The goal of the brainstorming session was not to come up with a final design, but to ensure all potential designs were identified. It was important to develop concepts as a group as opposed to individually. Working as a group and seeing what concepts other members came up with mitigated the risk of 2 members developing the same design and ensured the Team would have a variety of different concepts. Images of the 29 concepts generated can be found in the appendix.

## B.2 Screening & Grouping

The purpose of screening and grouping the concepts developed during the brainstorming session was to eliminate non feasible concepts and combine similar concepts. Screening reduced the number of potential concepts to 10 from 29; grouping similar concepts further reduced the list of concepts to 7. Out of the batch of concepts generated during brainstorming, the concepts identified through screening and grouping represent the most likely to get successfully implemented and solve the Client's problem. Screening and grouping concepts was done as a team to ensure that each member had the opportunity to provide insight into each concept. During the screening phase, each concept is qualitatively evaluated individually and eliminated if the group felt the concept has no potential. The grouping phase looked at the concepts that remained from the screening phase categorized them based on if they shared a key characteristic.

For Screening concepts, the Team looked at each concept individually and asked the following questions about it:

1. How does this concept solve the problem?
2. Is the concept feasible?

If the Team had difficulty answering these questions in a reasonable amount of time with respect to a certain concept, the concept would be eliminated. Most of the concepts were eliminated because they either did not solve the problem or were not realistically manufacturable.

The batch of concepts that remained after screening process were then grouped together based on similar characteristics shared by more than 1 concept. The 10 concepts that came out of the screening phase were fairly unique; as such, this phase did not reduce the number of concepts by too much. The concepts that were grouped together shared modular characteristics.

## B.3 Concepts

The 7 concepts that came out of the Screening and Grouping phase were divided up amongst the Team to develop in more detail.

### B.3.1 Concept 1 - Air Boot

The design took inspiration from a sphygmomanometer also known as a blood pressure cuff. This design was tailored towards a high level of adjustment around the foot and leg. Air pressure is an effective way to maximize adjustment and create a form fitting device. A preliminary sketch of this design is shown in Figure 9 below.

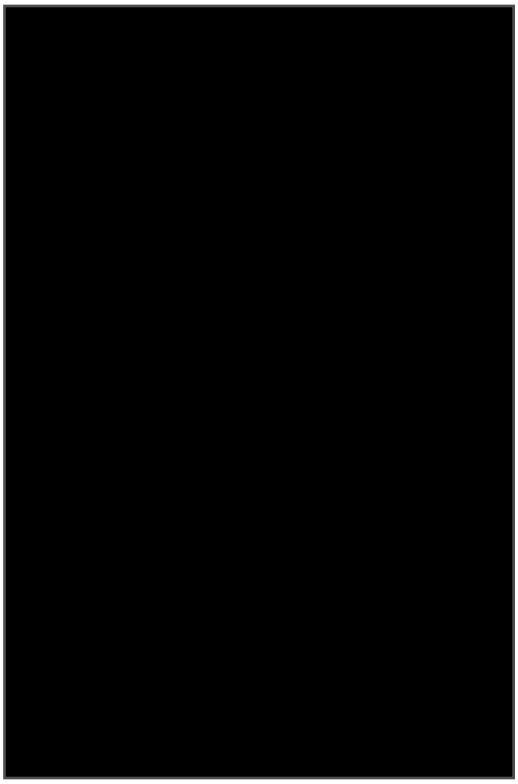


Figure 9: Air Boot [16]

The design is made from parts that can be sewn together by technicians and connected using adhesive. The rocker sole is made using current sole making manufacturing process or can be made using 3D printing. Circumference measurements would be taken on leg and foot in distinct locations such as the forefront foot, the mid-foot, the ankle, the mid-calf, and just below the knee. These measurements would be used to derive the material required to manufacture the air bladder component of the design. This air bladder would be manufactured using heavy duty nylon or polyester oxford. The inward facing side of the air bladder that contacts the patient's leg would have neoprene lining. An air pump and release valve would be sewn into the air bladder of the

boot to provide pneumatic pressure to the leg.

This design has the ability to have a custom appearance through stitching fabric to the outside of the air bladder or printing onto the air bladder material prior to stitching. The air pressure would also be distributed across the entire contact area of the design resulting in an evenly distributed contact pressure. In addition, this design can be sewn and measurements taken for typical garment production would eliminate the need to 3D scan or plaster cast a patient's leg during the manufacturing process.

However, this design is not modular as there are no components that can be interchanged once the device no longer suits the patient's physical dimensions. Also, this design is prone to failure in cold weather climates and can be popped by sharp objects.

### B.3.2 Concept 2 - Air Pump Sleeve

The design took inspiration from Concept 1, the Air Boot and Reebok 20K Pump Ice Skates. The idea was to have develop slim fitting sock-type design that features fine tuned pneumatic pressure system. A preliminary sketch of this design is shown in Figure 10 below.

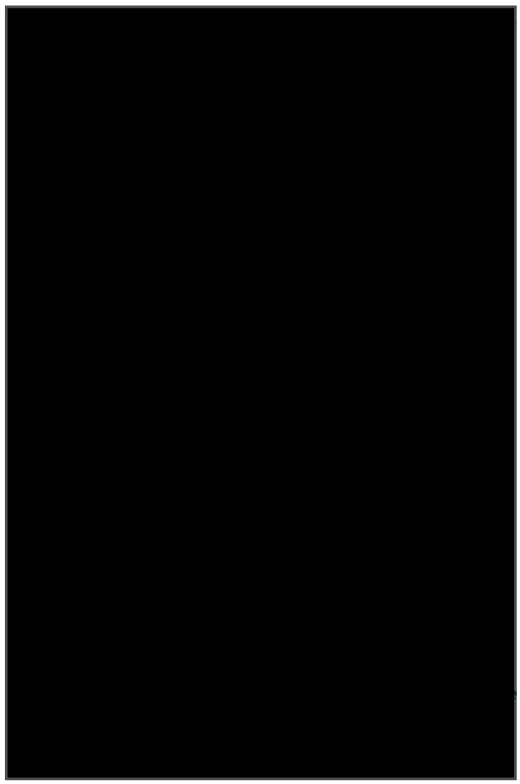


Figure 10: Air Pump Sleeve [16]

The design is made from components that can be sewn together by technicians and connected using adhesive. The rocker sole is made using current sole making manufacturing process or can be

made using 3D printing. Circumference measurements would be taken on leg and foot in distinct locations such as the forefront foot, the mid-foot, the ankle, the mid-calf, and just below the knee. These measurements would be used to derive the material required to manufacture the inner and outer neoprene sleeve. Each air bladder would be ideally purchased externally as off-the-shelf components and sewn into the neoprene sleeve in multiple locations. Similar to the use of the Reebok 20K Pump Ice Skates, each bladder would have their own independent bulb used to pump air into the bladder and a slightly smaller release valve located beside the bulb which can deflate each independent bladder every time you need to adjust or take the device off.

This design has the ability to have a custom appearance through stitching fabric to the outside of the neoprene sleeve printing directly onto the outer neoprene prior to stitching. The air pressure could also be distributed across the total contact area of the air bladders integrated into the design resulting in the potential for evenly distributed contact pressure. In addition, this design can be sewn and measurements taken for typical garment production would eliminate the need to 3D scan or plaster cast a patient's leg during the manufacturing process.

However, this design is not modular as there are no components that can be interchanged once the device no longer suits the patient's physical dimensions. Also, this design is prone to failure in cold weather climates and can be popped by sharp objects.

### B.3.3 Concept 3 - Elastic Moon-Boot

This design took inspiration from the idea to elastically offload the sole of the foot. The idea was to develop a platform that allows a free floating feeling through the use of elastics attaching said platform to a base that has metal supports that go up and attach to the leg just below the knee. A preliminary sketch of this design is shown in Figure 11 below.

Figure 11: Moon Boot [16]

The design would require a 3D scan or imprint of the patient's sole to manufacture an appropriately sized platform section. The base and platform would be 3D printed and assembled through the use of elastic bands. The metal supports would be positioned such that one runs of the medial side of the leg and one runs up the lateral side of the leg. Three bolted connections would connect the metal supports to the base of the design. A boa would then be attached to the metal rod and the boa cable would be strung through a fabric cuff for user comfort.

A large drawback of this design includes the use of many independent components, this would increase the assembly time of the device. Another potential drawback would be the reliability of using several elastic bands on a device that could be exposed to Manitoba's climate, during the winter specifically.

### B.3.4 Concept 4 - BOA Shell

The BOA Shell concept has a rigid outer shell broken up into different regions and get strung together using an adjustable BOA system. Figure 12 shows a schematic of this concepts implementation. The modular design allows the patient to easily adjust the compression of the boot, accommodating for variations in the patients limb caused by swelling. Multiple BOA systems can be utilized to allow the patient to fine tune the amount of pressure the device applies on specific regions of the leg, ankle and foot. The manufacturing process for the shell would utilize 3D printing, reducing the patient wait time for receiving the device. 3D printing also provides the ability to manufacture internal channels within the shell to run the cables of the BOA system.

Figure 12: BOA Shell [17]

This concept does have some draw backs. Lots of load will be applied through the cables of the BOA system in order to properly secure all the parts of the shell and offload the patients leg. This means that the BOA system is the most likely part of the device to fail, which would require multiple follow up visits for repairs. The patient has a lot of control over the fit of the device and my not consistently tighten it to same extent. They may feel that the fit demonstrated to them in the clinic was too tight and gradually loosen it over the treatment period.

### B.3.5 Concept 5 - Modified Shoe

The Modified Show concept would have a 3D printed support device that would attach to the patients shoe which would get modified to support the inclusion of a custom foot orthotic. This concept emphasizes customizability; patients will be able to choose their own shoe style to incorporate into the devices design. This will give the device a very casual look and incentivizes the patient to wear it while in public. Figure 13 shoes the various components of this concept and how they fit together.

Figure 13: Modified Shoe [18]

The red line outlining the mouth of the shoe indicates where the offloading device will interface with the shoe. The components labelled in Figure 13 are broken down below:

1. Offloading Device
2. Shoe
3. Custom Orthotic

The rigid offloader will be manufactured by 3D printing. The modifications of the patients shoe will be managed by the Client's shoe makers on staff. This concept is a radical departure from the Client's current design which introduces some significant risks to its functionality. The patients shoe may not do an adequate job of offloading the patients foot and protecting it from impacts.

### B.3.6 Concept 6 - Side Braces + 3D Printed Sole + BOA's

The Side Braces + 3D Printed Sole + BOA's design took inspiration from the idea to reduce the material needed while maintaining the functionality of the CROW boot. Also, to be able to 3D manufactured, the design is made from different parts that will be put together by the technician. The rocker sole is made using current sole making manufacturing process or can be made using 3D printing. The plantar is scanned and then the model is simulated to generate a compatible rocker sole design that require least material to 3D printed. The sole is then attached to 2 vertical brace that will go up until the knee of the patient. The leg is then secured by a system of straps

and BOAs that attached to the sole and the vertical braces. A preliminary sketch of this design is shown in Figure 14 below.

Figure 14: Side Braces with 3D Printed Sole Design [16]

Since the design has a rigid connection between the side braces and the sole, it will immobilize the foot and ankle as well as having a low risk of fracture, given that the connection between two parts is well implemented. In addition, the straps and BOAs system will allow modifying for changing limb volume. Also, manufacturing different parts using 3D printing will cut down the assembling time and manufacturing time.

However, the design does not allow an evenly pressure distribution on the skin, which might elongate the treatment period. Also, there is not much printable areas so it is hard to customize appearance. Lastly, the design is not fully enclosed so it is not prone to weather.

### B.3.7 Concept 7 - Multiple Segment 3D Printed CROW

This concept is very similar the existing clam shell design, although it splits the the CROW boot into 3 primary segments, each with their own anterior and posterior components. The three segments are to be braced with a carbon fiber rod to provide the main stiffness, and small fasteners or clips will keep the segments affixed to one another. Each of these can be seen components can be seen the the sketches below. In addition, the shells are to be 3D printed, along with the primary cushioning material. Unfortunately, often these materials are not rated for prolonged use with exposure to the skin, as such, lined PPT will be used for final cushioning, comfort and skin contact

compatibility.

The first segment is the Foot segment, where sufficient space would be retained to allow for the custom orthotic. The second segment is the ankle segment. This is the portion which would have the largest impact on the stabilization of the ankle. The final segment is that of the calf, where significant swelling and muscle atrophy is expected to occur, as such, this segment could be replaced to reflect significant changes in the patient across the length of the treatment, without the need to reproduce an entire boot. This method would mostly enclose the foot and leg, allowing for the boot to be more suitable for a varied climate. Division of the segments with respect to the foot, ankle, and leg, are subject to change in order to reflect changes required to support the required loads. A preliminary sketch of this design is shown in Figure 15 below.

Figure 15: Multiple Segment 3D Printed CROW [16]

The anterior and posterior shells will be tightened to one another using the BOAs cable ratcheting system coupled with the quick release clip variant, such that the foot and ankle can be easily removed form the device, but also to allow for adjust-ability to account for patient swelling. The BOAs will be connected to the boot segments using mechanical fasteners.

# C Concept Selection

From the pre-screened 7 feasible concept designs, matrices and analysis were conducted to determine the best alternative concept design to develop in the Final Design Phase based on the Project goals, needs, specifications and limitations.

## C.1 Methodology

The concept selection method chosen by the team was the weighted rating method. The decision to choose this method came from the qualitative state of the client's needs and assigning weights to chosen criteria during concept selection would lead us to the best overall concept. The Team developed a weighted decision matrix (WDM) to rank and compare the pre-screened concept designs. The weighted decision matrix was prepared by identifying customer focused selection criteria. The Team identified selection criteria by reviewing the customer needs, this criteria is defined below:

(a) *Modular design* - The design is constructed of elements that can be easily assembled and reused to develop different finished products.

(b) *Customize-able appearance* - The design's appearance can be customized through modification of the outward facing components.

(c) *Immobilizes the foot and ankle* - The design has the ability to effectively immobilize the foot and ankle.

(d) *Low risk of component failure* - The design has a low risk of component failure when used under expected conditions.

(e) *Off-loads the patient's weight* - The design off-loads the patient's weight from the sole of the patient's foot that the device is attached to.

(f) *Cost effective to produce* - The design is cost effective to manufacture; this includes labor cost, material cost, and any associated manufacturing costs.

(g) *Modifiable/adjustable for changing limb volume* - The design can be modified easily or is adjustable to accommodate a change in limb volume due to edema.

(h) *Evenly distributes pressure on skin* - The design distributes pressure in a way to minimize discomfort for end users.

(i) *Quick to assemble* - The device is quick to assemble for technicians and/or clinicians.

For the sake of concept selection, the team excluded customer need 7 shown in Table **??**; "Accommodates inclusion of a custom foot orthosis from the selection criteria'. This decision was made after discussions that the pre-screened conceptual designs were not detailed enough to differentiate a rating between concepts for this criteria. During detail design, the team will work with orthotists at Anderson Orthopedics's to involve a design that is suitable for accommodation of a custom foot orthosis in the CROW device.

The Team developed a weighting for each selection criteria through a comparison process. This comparison process compared each criteria in a one-to-one comparison where a vote between the four team members was conducted and the more significant criteria was chosen as the winner. The weighting was then calculated for each selection criteria by adding the number of "wins" by the total number of comparisons made. The total number of comparisons made was 36.

| | | **A** | **B** | **C** | **D** | **E** | **F** | **G** | **H** | **I** |
|---|---|---|---|---|---|---|---|---|---|---|
| | | ***Modular Design*** | ***Customizable Appearance*** | ***Immobilizes the foot and Ankle*** | ***Low risk for component/boot failure*** | ***Off-loads the Patients Weight*** | ***Cost effective to produce*** | ***Modifiable/adjustable for changing limb Volume*** | ***Evenly distributes pressure on skin*** | ***Quick to Assemble*** |
| **A** | ***Modular Design*** | | A | C | D | E | F | G | H | I |
| **B** | ***Customizable Appearance*** | | | C | D | E | B | G | H | B |
| **C** | ***Immobilizes the foot and Ankle*** | | | | D | E | C | C | H | C |
| **D** | ***Low risk for component/boot failure*** | | | | | D | D | D | D | D |
| **E** | ***Off-loads the Patients Weight*** | | | | | | E | E | H | E |
| **F** | ***Cost effective to produce*** | | | | | | | G | H | I |
| **G** | ***Modifiable/adjustable for changing limb Volume*** | | | | | | | | H | I |
| **H** | ***Evenly distributes pressure on skin*** | | | | | | | | | H |
| **I** | ***Quick to Assemble*** | | | | | | | | | |
| | Number of Hits | 1 | 2 | 5 | 8 | 6 | 1 | 3 | 7 | 3 |
| | Weight (%) | 3% | 6% | 14% | 22% | 17% | 3% | 8% | 19% | 0% |

TABLE I: Selection Criteria Weighting Matrix

## C.2 Weighted Decision Matrix Results

With the criteria and associated weightings established, the Team created a weighted decision matrix to rate the 7 concepts. During this process, the Team systematically went through each selection criteria and evaluated each concept and rated them with a score between 1 and 5. This rating was done a single criteria at a time to ensure comparisons between concepts were made consecutively. The Team revisited a given concept's rating for a criteria if revisions were required, based on subsequent ratings for other concepts.

The rating scores are defined following the scale shown in Table II below.

| | |
|---|---|
| Best | 1 |
| Mediocre | 3 |
| Worst | 5 |

TABLE II: Rating Legend

The Team calculated the score for each concept's selection criteria by dividing a concept's voted rating by the sum of all ratings for a given criteria. This is how the values in Table III were calculated. The criteria, labelled A through I in Table III, are described in Methodology section C.1 above.

| | Criteria | | | | | | | | | Score |
|---|---|---|---|---|---|---|---|---|---|---|
| Concept | A | B | C | D | E | F | G | H | I | Total |
| 1 | 4.8 | 7.3 | 6.3 | 4.2 | 4.0 | 16.0 | 17.0 | 18.0 | 6.5 | 8.9 |
| 2 | 12.0 | 7.3 | 6.3 | 5.3 | 6.7 | 5.3 | 8.5 | 9.0 | 4.3 | 6.9 |
| 3 | 4.8 | 4.4 | 5.0 | 4.2 | 6.7 | 5.3 | 8.5 | 4.5 | 2.6 | 5.1 |
| 4 | 8.0 | 11.0 | 8.3 | 10.5 | 10.0 | 8.0 | 8.5 | 9.0 | 4.3 | 9.0 |
| 5 | 6.0 | 11.0 | 6.3 | 10.5 | 5.0 | 8.0 | 3.4 | 6.0 | 3.3 | 6.8 |
| 6 | 8.0 | 4.4 | 8.3 | 10.5 | 10.0 | 5.3 | 8.5 | 4.5 | 4.3 | 7.7 |
| 7 | 12.0 | 11.0 | 12.5 | 21.0 | 20.0 | 8.0 | 5.7 | 9.0 | 6.5 | 13.7 |
| Weight | 3% | 6% | 14% | 22% | 17% | 3% | 8% | 19% | 8% | 100% |

TABLE III: Weighted Decision Matrix

From Table III above, the winning concept was found to be Concept 7, the Multiple Segment 3D Printed CROW design.

## C.3 Sensitivity Analysis

Three sensitivity analyses were done to understand the influence each selection criteria weighting had in identifying the top concept. The team redistributed weights between high impact criteria and evaluated the resulting total scores for the concepts. The following scenarios below were conducted.

### C.3.1 Analysis 1: Increasing Weight of Criteria F

By lowering the weight of criteria D and E, the Team redistributed this weighting to increase criteria F. This reduced the total score for Concept 7 to 12.6. Concept 7's total score was still 26% higher than the second place concept in this scenario. The decision matrix for this sensitivity analysis is shown in Table IV below.

TABLE IV: Sensitivity Analysis #1 WDM

| | Criteria | | | | | | | | | Score |
|---|---|---|---|---|---|---|---|---|---|---|
| Concept | A | B | C | D | E | F | G | H | I | Total |
| 1 | 4.8 | 7.3 | 6.3 | 4.2 | 4.0 | 16.0 | 17.0 | 18.0 | 6.5 | 10.0 |
| 2 | 12.0 | 7.3 | 6.3 | 5.3 | 6.7 | 5.3 | 8.5 | 9.0 | 4.3 | 6.8 |
| 3 | 4.8 | 4.4 | 5.0 | 4.2 | 6.7 | 5.3 | 8.5 | 4.5 | 2.6 | 5.1 |
| 4 | 8.0 | 11.0 | 8.3 | 10.5 | 10.0 | 8.0 | 8.5 | 9.0 | 4.3 | 8.9 |
| 5 | 6.0 | 11.0 | 6.3 | 10.5 | 5.0 | 8.0 | 3.4 | 6.0 | 3.3 | 6.8 |
| 6 | 8.0 | 4.4 | 8.3 | 10.5 | 10.0 | 5.3 | 8.5 | 4.5 | 4.3 | 7.3 |
| 7 | 12.0 | 11.0 | 12.5 | 21.0 | 20.0 | 8.0 | 5.7 | 9.0 | 6.5 | 12.6 |
| Weight | 3% | 6% | 14% | 17% | 13% | 12% | 8% | 19% | 8% | 100% |

### C.3.2 Analysis 2: Swapping Weight of Criteria D and E

The Team swapped the weight of criteria D and E as these are high importance selection criteria. This reduced the total score for Concept 7 to 13.6. Concept 7's total score was still 51% higher than the second place concept in this scenario. The decision matrix for this sensitivity analysis is shown in Table V below.

TABLE V: Sensitivity Analysis #2 WDM

| | Criteria | | | | | | | | | Score |
|---|---|---|---|---|---|---|---|---|---|---|
| Concept | A | B | C | D | E | F | G | H | I | Total |
| 1 | 4.8 | 7.3 | 6.3 | 4.2 | 4.0 | 16.0 | 17.0 | 18.0 | 6.5 | 8.9 |
| 2 | 12.0 | 7.3 | 6.3 | 5.3 | 6.7 | 5.3 | 8.5 | 9.0 | 4.3 | 6.9 |
| 3 | 4.8 | 4.4 | 5.0 | 4.2 | 6.7 | 5.3 | 8.5 | 4.5 | 2.6 | 5.2 |
| 4 | 8.0 | 11.0 | 8.3 | 10.5 | 10.0 | 8.0 | 8.5 | 9.0 | 4.3 | 9.0 |
| 5 | 6.0 | 11.0 | 6.3 | 10.5 | 5.0 | 8.0 | 3.4 | 6.0 | 3.3 | 6.5 |
| 6 | 8.0 | 4.4 | 8.3 | 10.5 | 10.0 | 5.3 | 8.5 | 4.5 | 4.3 | 7.7 |
| 7 | 12.0 | 11.0 | 12.5 | 21.0 | 20.0 | 8.0 | 5.7 | 9.0 | 6.5 | 13.6 |
| Weight | 3% | 6% | 14% | 17% | 22% | 3% | 8% | 19% | 8% | 100% |

### C.3.3 Analysis 3: Increasing Weight of Criteria A

By lowering the weight of criteria C,D and E, the Team redistributed this weighting to increase criteria A. This reduced the total score for Concept 7 to 13.1. Concept 7's total score was still 45% higher than the second place concept in this scenario. The decision matrix for this sensitivity analysis is shown in Table VI below.

TABLE VI: Sensitivity Analysis #3 WDM

| | Criteria | | | | | | | | | Score |
|---|---|---|---|---|---|---|---|---|---|---|
| Concept | A | B | C | D | E | F | G | H | I | Total |
| 1 | 4.8 | 7.3 | 6.3 | 4.2 | 4.0 | 16.0 | 17.0 | 18.0 | 6.5 | 9.0 |
| 2 | 12.0 | 7.3 | 6.3 | 5.3 | 6.7 | 5.3 | 8.5 | 9.0 | 4.3 | 7.5 |
| 3 | 4.8 | 4.4 | 5.0 | 4.2 | 6.7 | 5.3 | 8.5 | 4.5 | 2.6 | 5.1 |
| 4 | 8.0 | 11.0 | 8.3 | 10.5 | 10.0 | 8.0 | 8.5 | 9.0 | 4.3 | 8.9 |
| 5 | 6.0 | 11.0 | 6.3 | 10.5 | 5.0 | 8.0 | 3.4 | 6.0 | 3.3 | 6.6 |
| 6 | 8.0 | 4.4 | 8.3 | 10.5 | 10.0 | 5.3 | 8.5 | 4.5 | 4.3 | 7.6 |
| 7 | 12.0 | 11.0 | 12.5 | 21.0 | 20.0 | 8.0 | 5.7 | 9.0 | 6.5 | 13.1 |
| Weight | 12% | 6% | 12% | 17% | 15% | 3% | 8% | 19% | 8% | 100% |

## C.4 Concept Analysis

Concept 7 was selected as this concept had the best total score, 13.7, from the concept selection process. The Team compared this winning total score to the second placed concept, Concept 4, and it was noted that Concept 7 had a 52% higher total score than Concept 4. Based on this high comparative score and conducting three sensitivity analyses on the weighted decision matrix, the team was confident in pursuing this design further.

The Multiple Segment 3D Printed Crow Design has similar functioning principles to the currently tested and implemented CROW design. Maintaining the use of these functioning principles is beneficial to mitigate the risk of unforeseen complications that may arise from other functioning principles such as electrical, hydraulic, pneumatic, and chemical. This reinforced the feasibility of the design to the Team.

This design is also broken up to take advantage of streamlining the manufacturing process. Streamlining would be done through additive manufacturing of the device compared to the traditional casting and draping procedure currently used. As this design is compromised of modular components, each separate component can be manufactured with a small 3D print volume. As this design incorporates BOAs to adjust the device's accommodation for limb volume fluctuations, there will still be assembly time required integrate off the shelf components into the design. A visual of the selected concept, showing the components and segments can be seen in the sketches below.

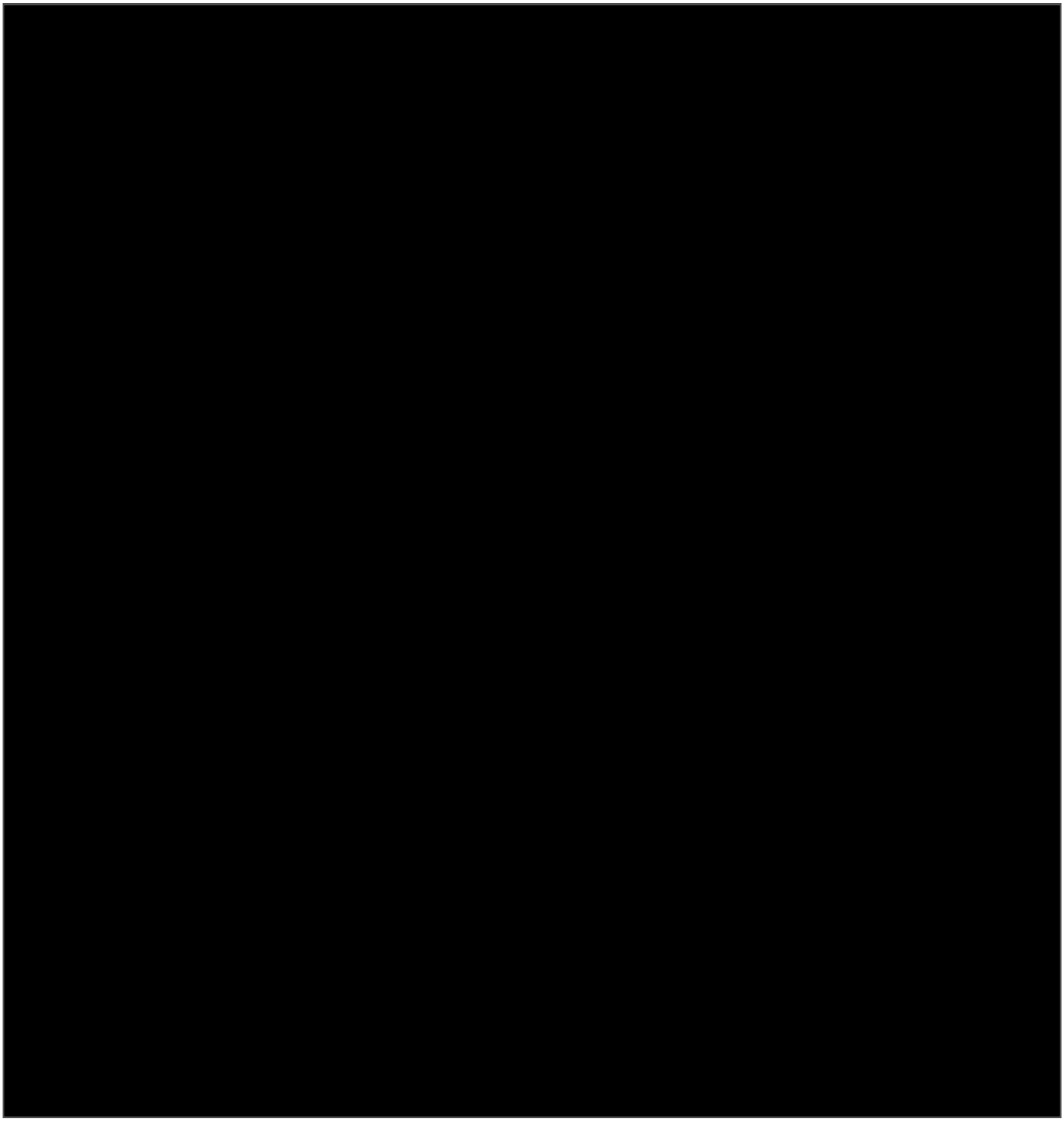
Figure 16: Multiple Segment 3D Printed CROW; Additional Sketches [16]

With this concept selected, more detail was developed, as such, the additional two sketches can be seen above, in Figure 16. On the left if a sample cross-section of the overlap of two of the segments, showing where mechanical fastening will be used to mechanically connect the segments in addition to the stiffening rod. The sketch to the right show a mid-calf cross-section of the CROW device, where the padding methods, and orientation of items are shown, as labeled. It is proposed that this concept will use additive manufactured primary cushioning, where a secondary, bio-compatible material will be used to the patient interface, as many flexible cushioning materials that are additive manufactured are not explicitly rated for prolonged skin interface. It is to be noted that the division of the segments with respect to the foot, ankle, and leg, as well as the location of the fastenings with the associated stiffening rod are subject to change in order to reflect possible changes that may be required to support the required loads during the use of the CROW device.

## C.5 Selected Concept Summary

Through the concept selection process, the team was able to compare feasible concept designs to evaluate the best alternative concept design. Comparison of each design was done by reviewing and detailing the customer needs that would be applicable in comparing conceptual designs. Concept 7, the Multiple Section 3D Printed Crow design was selected as the best alternative concept design and was developed further in the Final Design Phase of this project.

# D Xometry Quote



# E Client Survey



## UMIDEA Program – Anderson Orthopedics 2022

**Group 11 Final Design Survey (December 4, 2022)**

Thank you working with our team. Please take a moment to tell us about your experience and how well our **Rapid Fabrication Custom-Fit CROW Orthosis Design** has met the pre-determined target specifications developed in Phase 1 of this project.


Images of Final Design

1. Please tell us how you consider the **aesthetics** of our final design by choosing the relevant option below.

   ☑ The design is aesthetic and therefore **passes** the pre-determined target specification.

   ☐ The design is *not* aesthetic and therefore **fails** the pre-determined target specification.

2. Please tell us how you consider the **inclusion of a custom foot orthosis** to our final design by choosing the relevant option below.

   ☑ The design accommodates the inclusion of a custom foot orthosis and therefore **passes** the pre-determined target specification.

   ☐ The design does *not* accommodate the inclusion of a custom foot orthosis and therefore **fails** the pre-determined target specification.

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