CZECH TECNICAL UNIVERSITY IN PRAGUE

FACULTY OF BIOMEDICAL ENGINEERING

Department of Biomedical Technology

Design and Development of a Foot Unloading Orthosis for Patients with Charcot Foot

Master thesis

Study programme: Biomedical and Clinical Technology
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Abstract:

Patients who suffer from Charcot foot should not load the effected foot for approximately 8-12 weeks. The current orthosis at Dr. Soetomo Hospital does not provide efficient unloading of the foot, thus, the aim of the project is to design a solution that efficiently unloads the foot of their Charcot foot patients. This project yields a final solution that uses hydrostatic compression and the conical shape of the leg to bear the weight of the user. Calculations are conducted to assess the validity of the design. For users between 50 – 250kg the compressive stress required to brace the leg without slippage is calculated to be 34.1 – 117.1kPa. The shear stress between the leg and the corset is calculated to be 6.2 – 51.5kPa. These stresses are below the values measured on trans-tibial prosthetic socket users. A visual prototype is created and tested on two users to observe their response to donning and doffing. Each user showed a capability of donning and doffing the brace by themselves, and the corset accounted for the volume difference between the legs of the two users. The final design weighs 0.64kg and can be manufactured for an estimated 166.21euro. The final product theoretically achieves the aims of the project, however, a functional prototype is recommended in order to test its validity.

Key Words: *Orthosis, Charcot foot, Neuropathic arthropathy, brace, ankle foot orthosis, unloading, equipment design*

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List of Abbreviations:

CN – Charcot neuropathic osteoarthropathy
PTB – patellar tendon bearing
CROW – Charcot restraint orthotic walker
TCC – total contact casting
TAG – total anti gravity
GP – ground plate
GRF – ground reaction force
PE – polyethylene
PP – polypropylene
PP-H – polypropylene homopolymer
PP-C – polypropylene copolymer
PE-HD – high-density polyethylene
PE-LD – low-density polyethylene
AOD – advanced orthopedic designs
EVA – ethylene vinyl acetate
HS – heel strike
TO – toe off
BW – body weight
IDR – Indonesian rupee
EC – European commission
EU – European union
EFTA – European free trade association
MDD – Medical device directive
ISO – International Organization for Standardization

1. Analysis

1.1 Background

Charcot neuropathic osteoarthropathy (CN), or Charcot foot, is a potentially limb-threatening inflammatory syndrome that occurs intermittently in patients with Diabetes Mellitus.[1] The pathology of the disease begins with increased inflammation in the affected foot, which causes a loss of sensory recognition (neuropathy). An increase of blood flow combined with repeated trauma to the area causes the bones and joints to fragment. This results in a deformation of the foot.[1,2] Deformation may occur at various areas of the foot, which makes it difficult to provide a one-size-fits-all treatment option. A common deformation associated with CN is rocker bottom (figure 1.1):

Figure 1.1: Rocker-bottom Charcot deformity [Roger, et al. 2011]

Figure 1.1 shows severe inflammation and joint dislocation at the tarsometatarsal region, which results in the rocker bottom deformation. Treatment options may vary on a case-by-case basis, however, the accepted standard is to immobilize and unload the foot as soon as possible to prevent further damage. Patients with Charcot foot should not bear any weight on the affected foot for approximately 8-12weeks.[3] Thus, to maintain mobility, an orthosis is required that will allow the patient to stand, balance, and walk without loading the foot. Insofar, the aim of this project is to develop a foot-unloading orthosis for adult diabetic patients with CN at Dr. Soetomo Hospital in Surabaya Indonesia. All design considerations will be implemented with this target group in mind.

1.2 Problem Definition

The Dr. Soetomo hospital currently uses a patellar tendon bearing (PTB) orthosis to unload the foot of Charcot foot patients. This design utilizes a protrusion at the patellar tendon and compression around the lower leg to bear the weight of the body. The problem with the current orthosis is that, in some patients, it does not fully unload the foot. The reason for this is twofold: firstly, the orthosis may not fit optimally for all patients. Thus, some patients will experience slipping, which will cause the foot to bear weight. Secondly, the current brace does not sufficiently account for leg volume and circumference change over time. In patients with Charcot foot, edema and inflammation contribute to a change in leg volume over time. A change in volume may also lead to slipping of the leg from the brace and cause the foot to bear weight.

1.2.1 Cause & Effect

To better understand the problem with the current orthosis, a cause and effect diagram is created (figure 1.2).

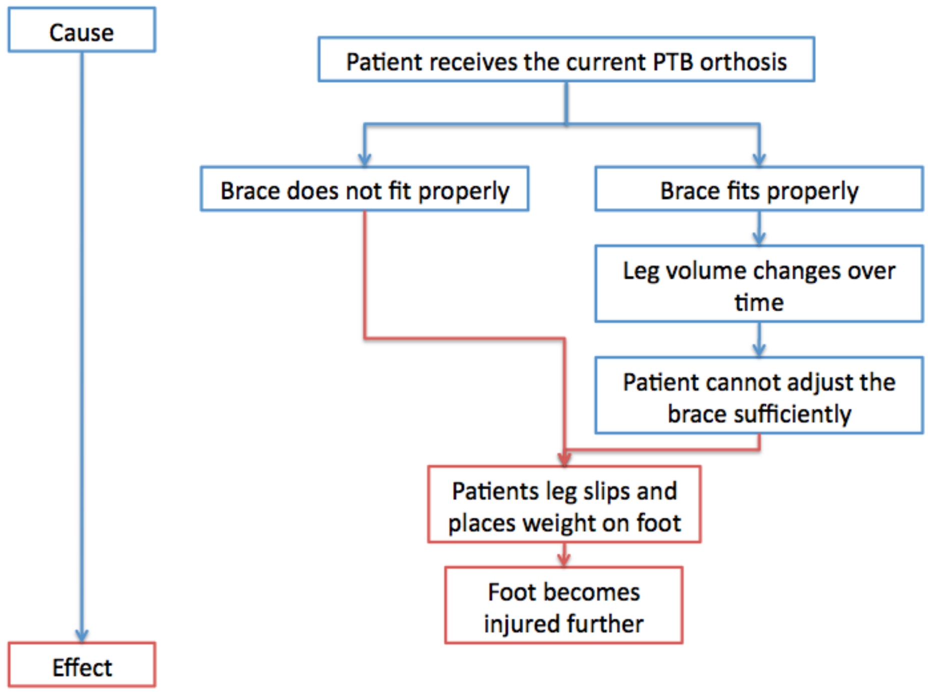

Figure 1.2: Cause and effect diagram

Figure 1.2 shows two main problems with the current orthosis. Firstly, the orthosis is difficult to fabricate and ensure a secure fitting. This can be attributed to variable shrinkage following thermosetting of the shells. Secondly, even if the brace fits properly upon initial fabrication, it cannot accommodate for a change in volume of the leg. Both of these problems result in the patient bearing weight on the leg and render the orthosis ineffective.

1.3 Stakeholders

Table 1 below shows the stakeholders that will be involved, or affected by, the orthosis. The stakeholders have been segmented into groups, and their roles, expectations, and potentials are identified.

Table 1.1: Stakeholders involved in the orthosis

Group	Characteristics	Expectations	Potentials & Deficiencies	Project Implications

Patient	Has Charcot foot and requires foot immobilization	The orthosis will unload the foot, be easy to don and doff, and be comfortable and inexpensive	Possible candidates for clinical trials	The foot will have time to heal and the patient will become healthy
Clinician/ Orthotist	Guides patient in proper use of orthosis	The orthosis will efficiently unload the foot	Clinicians can provide information about needs of patient	Clinicians may provide better aid for patients
Designer	Establishes needs of the patient and translates them to the orthosis	The patient uses the design as intended	May provide information about the design and fix problems	Can bring new contributions to field of orthotics, notoriety
Hospital	Provides rehabilitation sessions	The orthosis will prevent patient from further injuring foot	Provides rehabilitation space	May provide better treatment
Family	Concern and distress over problems with loved one	The orthosis will help loved one heal	Provides moral support and may assist the patient	Increased quality of life, happier
Workshop/ Manufacturing	Constructs and assembles orthosis	The orthosis will be capable of production using available materials/ machinery	Could provide relevant information, may be able to provide prototypes	Could profit from the design, provides new insights to manufacturing
Biomedical Engineer	Evaluates product and provides insights	Orthosis will meet design requirements	Could contribute to design and evaluate product	Can add new knowledge of medical devices
Researchers	Analyze the functionality and implications of the orthosis	The design brings new contributions/ solutions to the field of orthotics	May evaluate functionality and assess large scale implications	Could add knowledge to field, provide new insights
Society	Demands a low cost Patient number is steadily increasing	Orthosis provides a solution for immobilizing Charcot foot	Evaluates use of design, provides patients for clinical trials	A healthier and happier populous

1.4 Goals

The aim of this orthosis is to efficiently unload the foot of a diabetic adult patient. Furthermore, the bracing should be sufficiently adjustable to account for volume change in the leg of the patient.

1.5 Design Assignment

The design assignment includes the design strategy and project demarcations, and final product.

1.5.1 Design Strategy

To reach the goals that have been identified for this product it is necessary to define a general solution to the problem.

- The solution to the problem is an orthosis that provides optimal fitting and can be adjusted for leg volume change while fully unloading the foot.

1.5.2 Project Demarcations

Demarcations are set to ensure the product will meet the goals identified in section 1.4 and meet the needs of Dr. Soetomo Hospital. These demarcations include identification of the target group and design-specific demarcation:

Target Group

This design is intended for adult diabetic patients between 45-70 years of age who have Charcot foot and are treated at the Department of Rehabilitation at Dr. Soetomo Hospital in Surabaya, Indonesia.

Design Demarcations

The product must fully unload the foot and be capable of production within the workshop of Dr. Soetomo hospital in Surabaya.

1.5.3 Final Product

The conclusion of this project will yield a theoretical design that meets of the goals of project. A prototype is created that provides a visual representation of the design. A description of the manufacturing process and the details of the final design will be sent to Dr. Soetomo Hospital.

1.6 Requirements and Wishes

The orthosis must comply with the following requirements and should also comply with the following wishes.

1.6.1 Requirements:

Effectiveness

- The device must fully unload the foot
- The device must secure the patient's leg such that no slippage occurs between the leg and the device
- The device must be adjustable as leg volume changes over time

Usability

- The device must allow the user to be mobile (standing, walking)
- The device must be capable of being used on a daily basis
- The device must be capable of being donned and doffed by the user without additional help from another individual
- The device must not exceed 2kg

Cost

- The device must cost less than 175euro to manufacture

Durability

- The device must be capable of withstanding a weight of 250kg
- The device must last for up to a year
- The device must withstand temperatures up to 50°C

Safety

- The device must not have sharp edges that could harm the user or others
- The device must provide stability while standing
- The device must provide ground friction such that no slippage occurs

Time

- The device must capable of being donned and doffed in under 4min by an able user

Manufacturing:

- The device must be capable of being manufactured at the Dr. Soetomo Hospital workshop
- The device must be capable of being manufactured using a detailed description of the manufacturing process
- The device must be capable of being manufactured using locally available materials

1.6.2 Wishes:

- The device should be capable of adjustment by the user given a set of instructions
- The device should have a rocker profile that is specific to each user
- The device should be donned and doffed in under 2 minutes by an able user

1.7. Function Analysis

A function analysis is implemented to identify essential functions of the product (table 1.2).

Table 1.2: Main Functions of the Orthosis

Main Functions	**Description** (Potential options to achieve function)
Energy Transportation	Objects that provide a mechanism for unloading the foot
Material Storage	Objects that brace the leg and secure it tightly
Material Transportation	Objects that can be adjusted to account for leg volume change

Aside from the primary functions of the orthosis, there are also sub functions that are included to provide a holistic analysis of the product functionality (table 1.3).

Table 1.3: Sub Functions of the Orthosis

Sub Functions	**Description** (Potential options to achieve function)
Material connection	The assembly of all parts and components of the orthosis
Energy Transformation	All transformations of the energy transportation
Information Transportation	Necessary to start and stop movement of the material

1.8. Available & State of the Art Solutions

To treat patients with Charcot foot orthotists will recommend various orthoses that immobilize and unload the foot. The main goal of unloading the foot is to redistribute plantar pressures to the limb while minimizing the shear and normal stresses on the limb. The following orthoses show the various types of unloading possibilities and how they meet this goal.

1.8.1 Patellar Tendon Bearing Braces

One bracing mechanism for unloading the foot is the PTB brace that utilizes the patellar tendon to bear the weight of the user. The current orthosis being used at the Dr. Soetomo Hospital is a PTB orthosis, which is shown in figure 1.3:

Figure 1.3: Patellar tendon bearing brace at Dr Soetomo Hospital

This orthosis is made of two interlocking thermoplastic shells that come together to compress the leg. Two unloading bars (one medial and one lateral) redistribute the force from the ground to the shells. A protrusion on the anterior shell (located at the patellar tendon) allows the brace to press the tendon and bear weight. This design also utilizes the conical shape of the leg and applies hydrostatic compression on the leg to further bear weight. Other PTB braces on the market utilize the same concepts as this brace to unload the foot.

1.8.2 Total Contact Bracing

Total contact braces differ from other solutions in that they allow loading on the foot. They aim to redistribute the pressure evenly over the foot and leg so that the pressure in not built in one area. These braces focus more on foot immobilization to prevent the joints from further subluxation or dislocation, which would progress the deformity. A common recommendation by orthotists in this category is the Charcot restraint orthotic walker (CROW), which is a custom bi-valved total contact ankle foot orthosis (figure 1.4).

Figure 1.4: CROW brace for patients with CN [4]

The aim of the CROW brace is to distribute the pressures evenly over the foot so that the joints and skin will be protected.[5] The foam liner and thermoplastic shells reduce the shock and allow pressure to be distributed both in the foot and on the leg. Bivalve shells lock together so that the limb is compressed and bears about 30-40% of the weight, which can be adjusted by the patient.[6] The rest of the weight is distributed along the plantar surface.

Other total contact solutions include total contact casting (TCC) and aircast pneumatic walkers. Both of these solutions distribute pressure in a similar way, but vary in material selection, volume control, and donning and doffing capability.

1.8.3 Hydrostatic Compression Bracing

Hydrostatic compression bracing, or what many market solutions are referring to as 'anti gravity bracing,' utilizes the compressive force over the contact area between the brace and the leg to distribute pressure. The key is to maximize the contact area between the brace and the leg to keep pressure low while efficiently utilizing the conical shape of the leg to additionally bear weight. Figure 1.5 below shows a two of these braces.

Figure 1.5: hydrostatic compression bracing (left: Zero G AFO [7], center: TAG brace [8], right: Loadshifter AFO [9])

These braces all feature anterior and posterior shells that have an inner foam liner and close together with adjustable Velcro straps. Each of the braces claim to completely unload the foot, which has been verified in video of users ambulating in the brace.[10][11][12] However, supporting literature of the braces is required.

1.9 Evaluation of Current Solutions:

The positive aspect of the current PTB brace orthosis is the price. It can be manufactured for 175euro, which is advantageous since the user has to pay for the orthosis out of pocket. The drawbacks of the device have been described in section 1.2.

The CROW brace and total contact casting methods allow for good ambulatory motion and have had positive user feedback as well. However, a disadvantage of the CROW and aircast pneumatic walkers is the high cost of fabrication and maintenance. The CROW walker is listed at 500euro.[13] Furthermore, total enclosure casing would be too warm for users in Indonesia and thus this would not be an appropriate solution for the Dr. Soetomo Hospital patients. The total contact casting method must be changed every two weeks, which is not advantageous for patients travelling far distances.

The hydrostatic compression braces on the market fully unload the foot and also account for volume change via the adjustable Velcro closure system. They also appear easy to don and doff. However, the cost of the TAG brace alone is 800euro, which is well above the price the user is expected to pay.[14]

1.10 Summary

In summary, the Dr. Seotomo Hospital has an orthosis that does not efficiently unload the foot of their Charcot foot patients. There are two principle reasons for the brace's lack of unloading efficiently. The first is that the initial fitting may be improper, because patella tendon bearing braces are difficult to manufacture. Secondly, the brace cannot be sufficiently adjusted to adapt for a change in the patients leg volume. The goal of this project is to design a solution that efficiently unloads the foot of adult diabetic patients with Charcot foot at the Dr. Soetomo Hospital and that accounts for leg volume change as well. Requirements and wishes that the solution must meet have been noted as well as currently existing solutions that unload the foot.

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2. Synthesis I

2.1 Introduction:

In synthesis I ideas are generated to solve the problem(s) that was identified with the current orthosis at Dr. Soetomo hospital. Group brainstorming sessions are held to conceptualize many possible methods of solving the problem, and the resulting ideas are documented. From the brainstorming sessions, twelve ideas are selected to advance to the pre-concept phase. These ideas are put into sketches, described, and then graded. The grading system isolates the designs that best fit the requirements and wishes of the project. The top three designs are selected for continuation.

2.2 Morphological Map

The following morphological map identifies devices and concepts that can be used to perform the functions that were described in the function analysis in section 1.6 (table 2.1).

Table 2.1: Morphological Map

Energy Transportation	Medial/Lateral Unloading Bars	Circular offloading bars	Wheelchair	Hydraulic Attachment	Foot Sling
	Springs	Crutches	Knee Walker		
Material Storage	Cast	PTB Corset	Hydrostatic Compression	AFO	KAFO
Material Transportation	Straps	Bindings	Laces	Gears	Replaceable Padding with Varied Thickness
	Pneumatic Pressure	Diet & Exercise	Blood Pressure Medication	Gel/Fluid	
Material Connection	Velcro	Straps	Nuts/Bolts	Welding	Glue/Epoxy
	Knot/Thread	Weld/Solder	Screw	Zipper	Leather
Energy Transformation	Potential Energy	Muscle	Spring	Damper	Counter-weight
Information Transportation	Weight Detection	Pressure Gauge	Heat Sensor	Muscle	Circumference Monitor

The morphological map may be used by selecting one device from each category and linking them together to for a pre-concept. This will be used to aid in brainstorming ideas and identifying new ways to meet the goals of the project.

2.3 Brainstorming:

Group sessions were held with the intent of generating as many ideas as possible. The ideas are separated into three categories: the corset, the connection to ground, and general concepts for offloading the foot. The corset is defined as the mechanism that braces the leg and redistributes pressure from the unloading attachment onto the body. The unloading attachment is the mechanism that distributes the force from the ground to the corset.

2.3.1 Corset Ideas

- Hydrostatic compression leg sleeve with pressure gauge and Velcro liner that attaches to a two-piece corset to provide friction
- Two-piece patellar tendon bearing corset with ski straps*
- Two plastic rings around the leg (one proximal, one distal) with a thin posterior connection along the calf [minimalist design]
- Leather corset (plastically reinforced) with lacing on back of the calf that can wrap around the leg
- Air pumped corset liner to provide compression*
- Hydrostatic compression corset with gel padding that could be injected/removed to adjust fitting
- Bamboo PTB corset with adjustable straps
- Bivalve socket with overlap adjustable connector
- Plastic one-piece PTB corset with hinge to close*
- Cast with an attachable offloading frame
- Modular padding design with replaceable foam liner (varied thickness)
- Hydrostatic compression on the lower calf*
- Compression on the lower leg and pressure on the ischial tuberosity*

2.3.2 Unloading Attachment Ideas:

- Two bars (medial and lateral) that connect a distal foot plate to a corset*
- Metal attachment on the posterior calf. The attachment goes behind and then underneath the foot for stability*
- Two height adjustable medial and lateral bars that connect to the corset and a distal foot plate (elongated) and have a spring loaded footplate to allow prevent the foot from plantar flexion
- Bars that connect the corset to wheels on either side of the foot
- Bow-style circular connection to the posterior and anterior corset running underneath the foot.
- Spring system connected to metal bars to facilitate low impact walking*
- Unloading attachment connected to the anterior corset to provide a moment on the patellar tendon*
- Footplate with hydraulic cylinders to dampen impact during gait*
- Medial and lateral bars that connect triangularly to the anterior and posterior sections of a distal footplate.

2.3.2 General Solutions

- Wheelchair
- Knee walker*
- Crutches + Foot sling (around waist or shoulder)

*indicates that the idea was selected to advance to the pre-concept phase

2.4 Pre-Concept Sketches

Ideas in this section have been selected from the brainstorming sessions in section 2.3. These ideas are separated into three categories: the corset, the unloading attachment, and a combination of both the corset and the unloading attachment. The category for the combination of corset and unloading attachment simply means that the design is not modular and must have both.

Note: At this stage of the design the material is not yet selected. The sketches are meant to represent possible solutions for bracing the leg and unloading the foot.

2.4.1 Corset Design

The following sketches are ideas for the corset design and are accompanied by descriptions of the idea. All unloading corset designs should maximize surface area contact to allow for lower pressures when weighted. All relevant forces and moments will be shown in the sagittal plane.

Design 1

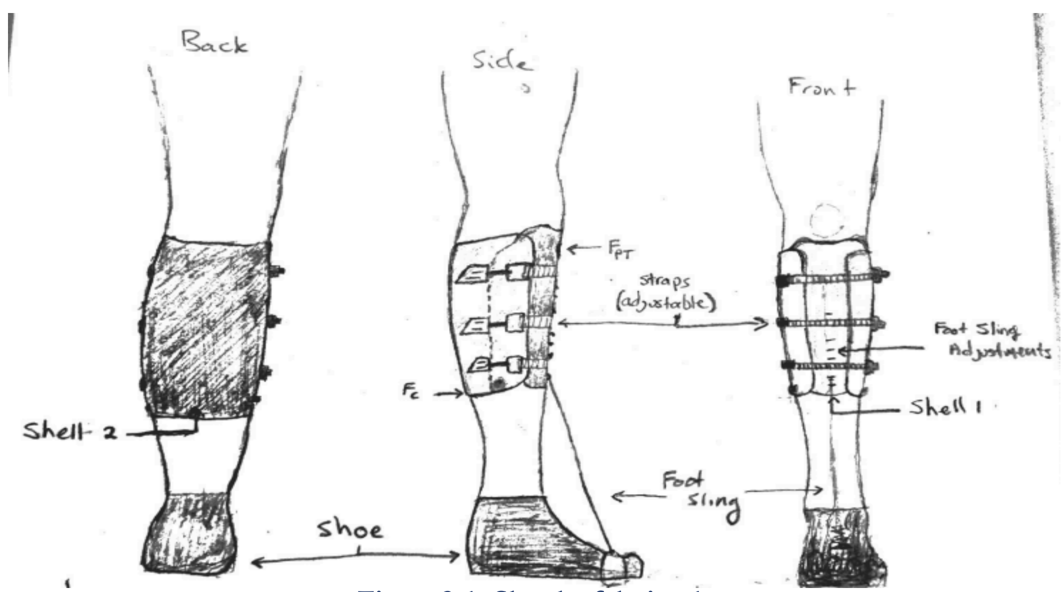


Figure 2.1: Sketch of design 1

Figure 2.1 shows the sketch of design 1 where F_{PT} is the force at the patellar tendon and F_C is the force at the distal calf.

Description:

- This design is a patellar tendon bearing corset with two shells that wrap around the trunk of the leg to secure it together
- Shell 1 has an extrusion at the proximal face that allows the shell to apply pressure on the patellar tendon. The shell wraps around the frontal leg and goes underneath shell 2.
- Shell 2 overlaps around shell 1. It has adjustable straps to secure socket 1 in place and keep constant pressure and bear weight via shear and normal stress.
- Shell 2 must be flexible enough about the sagittal plane so that it can bend around the leg. This will help the brace adjust for volume as it is tightened.
- An optional foot sling is shown in figure 2.1, which connects shell 1 to the shoe of the user in order to prevent plantar flexion and to keep the foot from hitting the ground and bearing weight. The sling may be clipped to various heights along shell 1 to adjust the amount of flexion (useful for inclines and declines)

Design 2

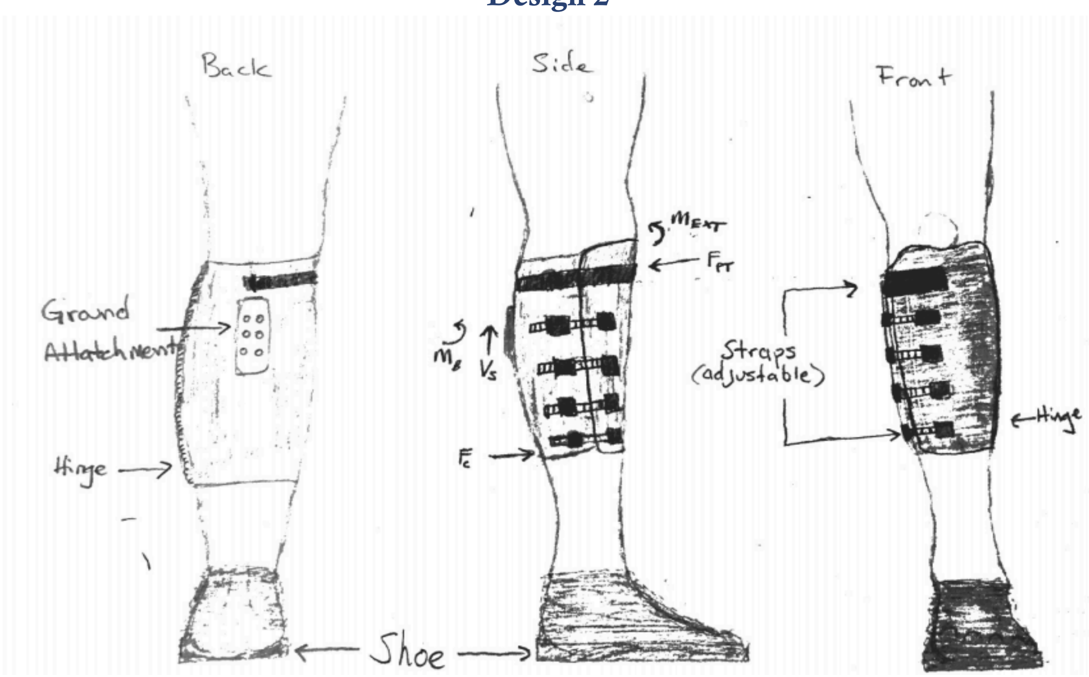


Figure 2.2: Sketch of design 2

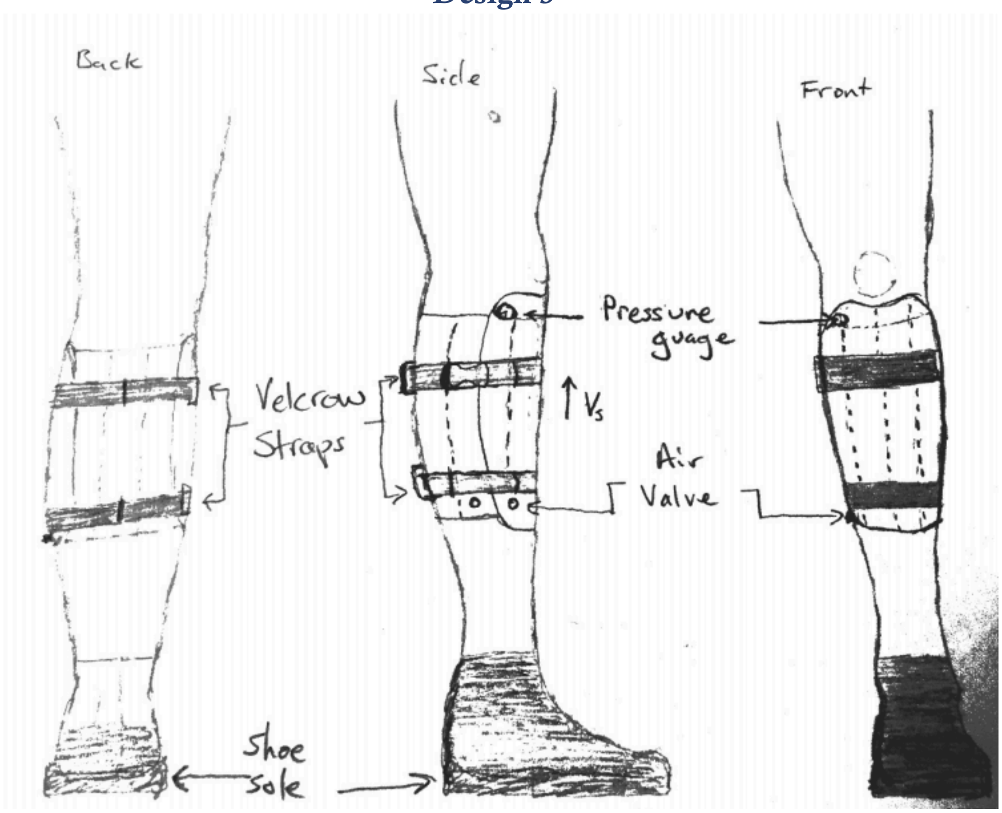
F_{PT} = force at patellar tendon, F_C = force at distal calf, V_S = shear force, M_B = bending moment at the ground attachment, M_{EXT} = extension moment at the knee. Note: All forces and moments are in the sagittal plane

Description:

- This is also a patellar tendon-bearing corset. The posterior shell is connected to the anterior shell by a hinge at the medial face (right leg). The anterior shell overlaps onto the lateral posterior shell and is connected by adjustable straps. The shells may be tightened/loosened laterally to secure the brace and compensate for volume change.

- Additional padding on the proximal anterior shell allows pressure to be applied at the patellar tendon. A proximal Velcro strap is placed to tighten the corset around the patellar tendon. Extra padding is also placed within the posterior shell to apply pressure at the bony prominences of the leg.

Design 3



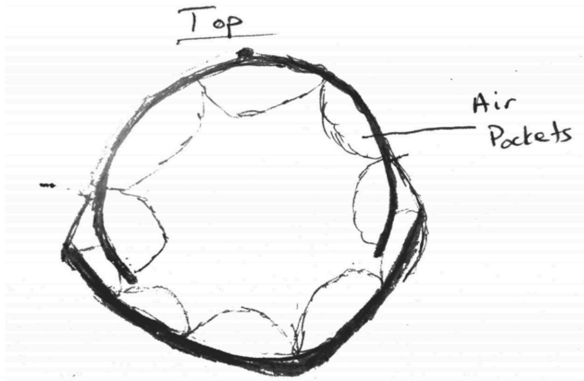


Figure 2.3: Sketch of design 3

V_S = shear force

Description:

- This design is a hydrostatic compression only design using pneumatic control to adjust for volume

- The design consists of a posterior and anterior shell that lock together medially and laterally. The interior of each shell is lined with vertical pockets that run the length of their respective shell (denoted by dotted lines in figure 2.3). The user dons the corset by placing the calf in the posterior shell. Then the anterior shell is placed such that the anterior tibial protrusion fits between the pockets of the shell. The corset is secured by two straps that have slide-release buckles.

- Each shell may be inflated individually by a hand pump (or bike pump). A pressure gauge ensures the appropriate amount of pressure needed (amount not yet determined). The design uses the air pressure to apply compressive force on the surface of the lower leg in order to bear weight.

Design 4

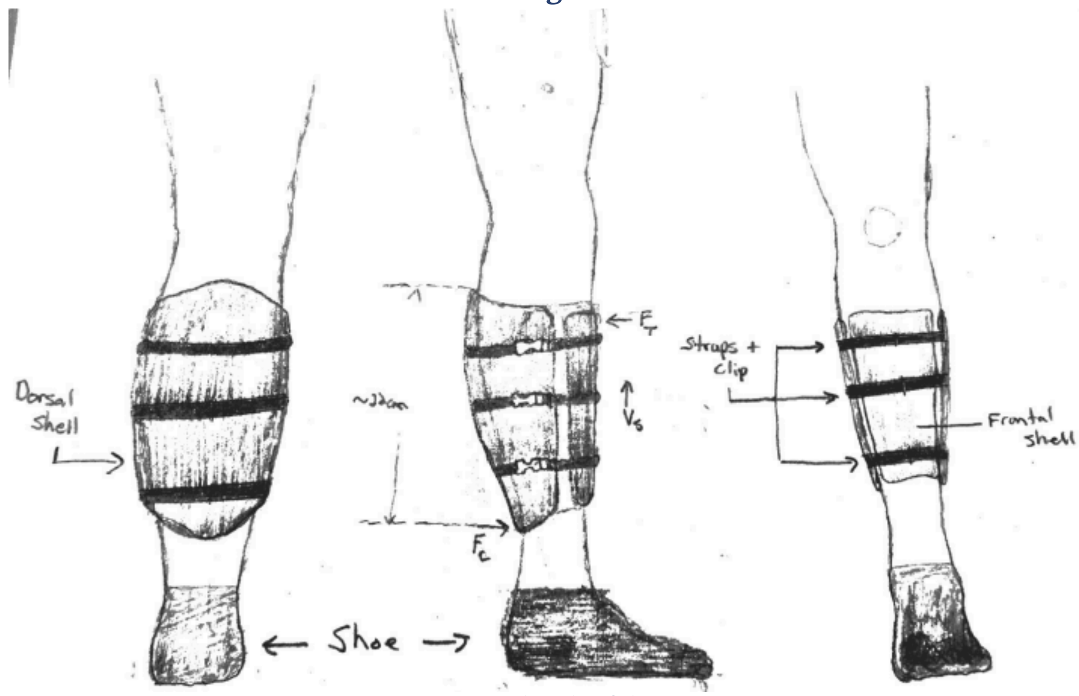


Figure 2.4: Sketch of design 4

F_{PT} = force at patellar tendon, F_C = force at distal calf, V_S = shear force

Description:

- This design also uses hydrostatic compression to bear weight.

- The calf shell has a large surface area to decrease the amount of shear force that is necessary for weight bearing. The calf shell utilizes a modular padding system with varied thicknesses. The padding can be interchanged to account for volume change of the leg. More padding is placed in the distally so the conical shape of the leg is taken advantage of. Both posterior and anterior shells will be rigid.

- An overlapping foam liner runs from the calf shell across the anterior surface of the leg. The anterior shell is then placed over the foam liner and is strapped to the calf shell. The padding in the anterior shell distributes pressure away from the tibial tuberosity and onto the medial and lateral surfaces of the leg.

Design 5

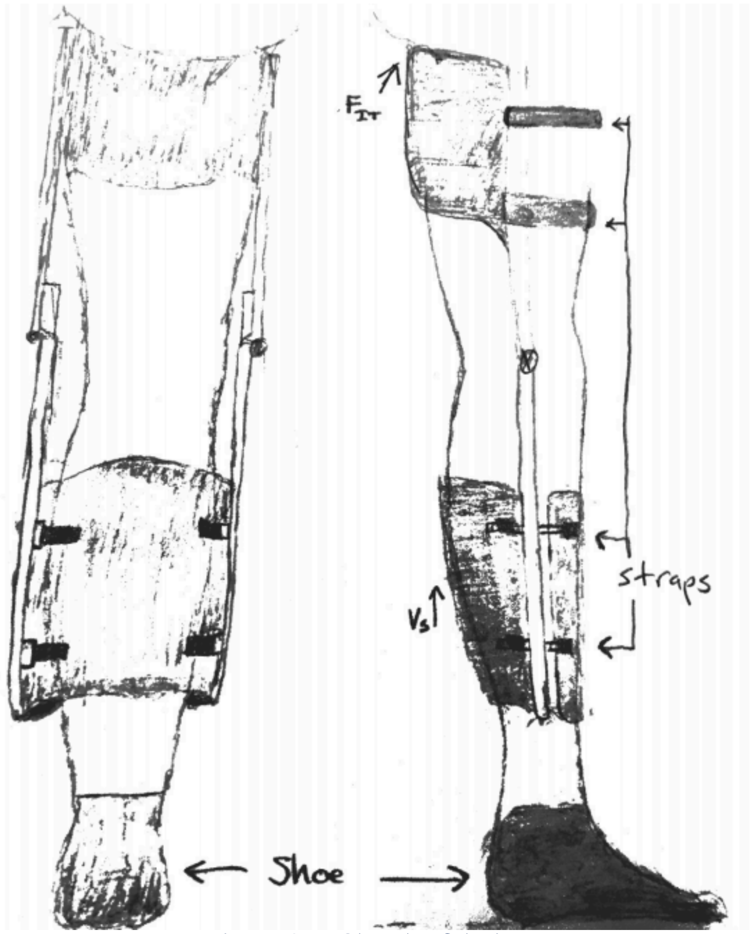


Figure 2.5: Sketch of design 5

F_{IT} = Force on ischial tuberosity, V_S = shear force at lower leg corset

Description:

- This design uses hydrostatic compression on the lower leg and pressure at the ischial tuberosity to release weight.

- Two metal bars (medial and lateral) run vertically to connect the two corsets (one distal and one proximal). The distal bars connect to the proximal bars at a hinge at the knee joint. The hinge at the knee will only allow for limited flexion and extension of the knee so that the pressure remains on the ischial tuberosity, which is applied at the posterior shell of the proximal corset.

- For the distal corset the calf shell is permanently attached to the frame. The anterior shell may be opened to don the brace and then tightened by the adjustable straps. This calf corset is similar to design 4, but has the frame to the outside surface for additional unloading.

2.4.2 Unloading Attachment Design

Designs 6-9 below show sketches of the ideas for the unloading attachment design and are accompanied by descriptions of the idea. All relevant forces and moments occur in the saggital plane. The footplate length in each design will be chosen by the orthotist based on the rocker profile needs of the user.

Design 6

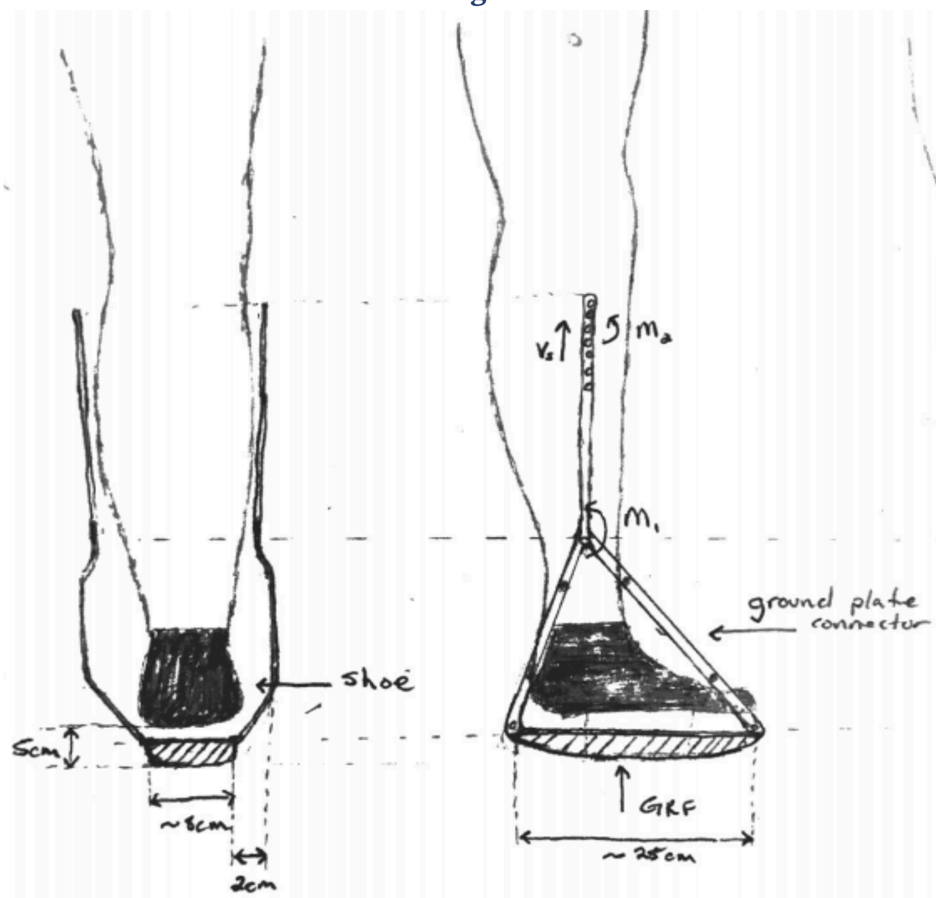


Figure 2.6: Sketch of design 6

M_2 = moment at the attachment of the unloading system to the corset, V_S = Shear force at the attachment, M_1 = moment at triangular connection point, GRF = ground reaction force at mid-stance

Description:

- This design uses a triangular system to connect the posterior and anterior sections of the ground plate (GP) to vertical bars that connect to the corset. The GP runs approximately the length of the foot, which allows for stability during stance and gait.

- The anterior and posterior connectors on the GP help to stabilize the moment between the GP and the corset connection. The GP connectors widen medially and laterally at the ankle to allow for donning and doffing. Yet, they should not be too wide so that they do not come in contact with the opposite leg during gait.

- An energy absorbent material (rubber, etc.) is on the distal GP to reduce impact on the corset during gait. This rubber material can be carved by the orthotist to provide a rocker profile that fits the need of the patient.

- The medial and lateral attachments at the corset run vertically to distribute the load across the corset and to reduce the force at each individual connection point.

Design 7

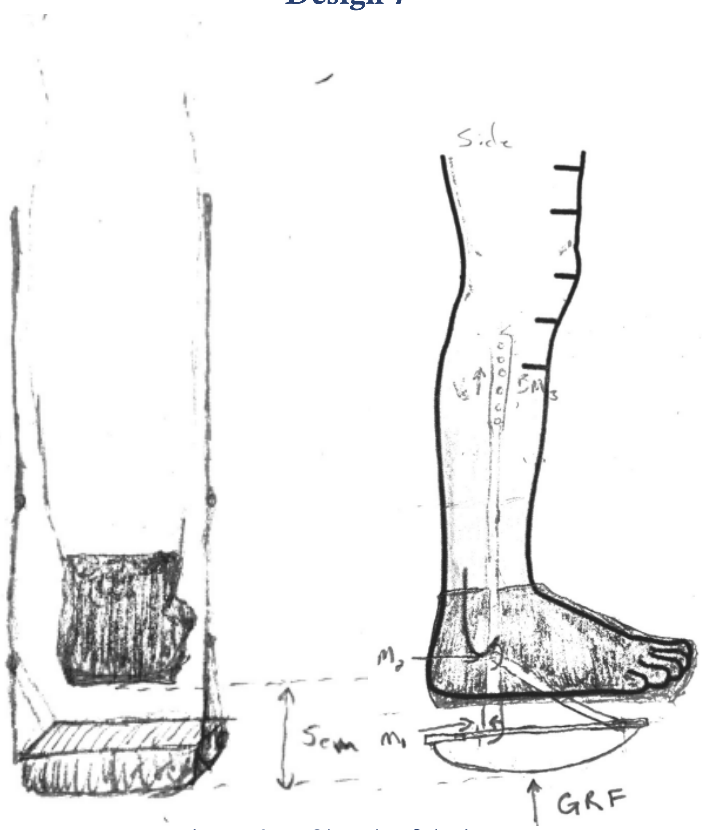


Figure 2.7: Sketch of design 7

M_1 = moment at connection to the base plate, M_2 = moment at the proximal connection to the base plate, M_3 = moment at the connection to the corset, GRF = ground reaction force at mid-stance

Description:

- This design similar to design 6 in that they both have medial and lateral unloading bars and a footplate that runs the length of the foot. However, it differs in the way the bars connect to the footplate and in the dimension of the footplate as well.

- Instead of a triangular connection between the unloading bars and the footplate the unloading bars come straight down to connect more towards the middle of the footplate. Two frontal support bars connect between the anterior footplate and the unloading bars. The purpose of the support bars is to reduce the moment at M_1

caused by the ground reaction force (GRF). The support bars will redirect the vertical GRF component into the attachment bars instead of the connection point (M_1).

- The footplate is also wider to help with balance and overall stability

Design 8

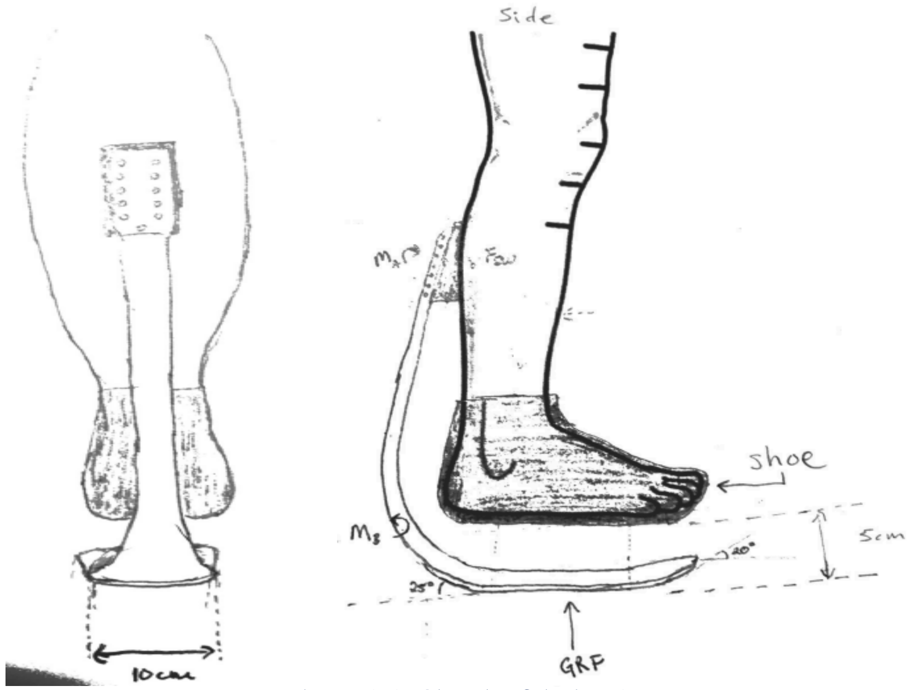


Figure 2.8: Sketch of design 8

M_A = moment at connection to the corset, M_B = moment at the bend in the unloader, GRF = ground reaction force at mid-stance

<u>Description</u>:

- This design is intended to attach to the posterior of a corset shell. By increasing the surface area at the corset attachment, the pressure and associated moment at the connection (M_A) may be distributed more uniformly along the corset.

- The unloader runs distally from the posterior attachment and curves underneath the foot, then runs approximately the length of the foot. This is to provide stability while standing and walking. Since the unloader should be rigid, the curvature is intended to help induce normal gait. The manufacturer could vary the curvature to fit the rocker profile needs of the user. The unloader will distribute the force from the ground onto the posterior of the corset.

Design 9

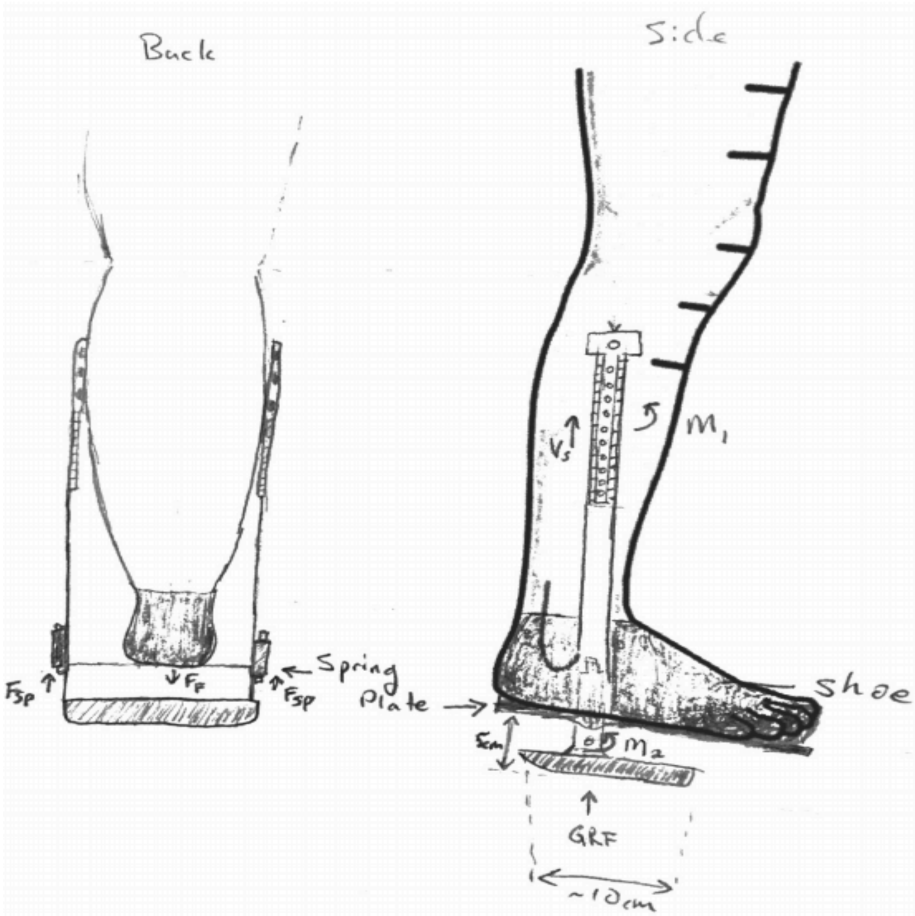


Figure 2.9: Sketch of design 9

Description:

- This unloading attachment also features two medial and lateral bars that connect the corset to the base plate.

- The base plate is shorter in this design to reduce the moment around the attachment at the medial and lateral bars.

- A spring plate is added that is connected to the medial and lateral bars. The purpose of the spring plate is to assist in bearing weight (thus this is a non-completely unloading design). The dampening affect of the spring will negate any impact force on the foot. This is a secondary measure (safety net) in case corset slippage should occur.

- A further reason for the spring plate is to prevent the foot from plantar flexion to the ground and/or footplate.

- The medial and lateral bars have multiple proximal connection ports so that the connection to the corset may be height adjustable. The advantage of user controlled height adjustability is that if the user chooses not to wear a shoe on the affected foot, the height can be reduced so that the height differential between the non-affected limb and the affected will be the same. The user will wear a shoe lift on the non-affected foot, but the shoe lift is a fixed thickness. Thus, the user can control the height difference to make sure both feet are level in the coronal plane, which will help with stability during gait.

2.4.3 Combination: Corset + Unloading Attachment Designs:

Designs 10-12 show sketches of the ideas for the non-modular designs (i.e. designs that include both corset and unloading attachment). Each sketch is accompanied by a description. All relevant forces and moments occur in the sagittal plane. Again, all corsets should maximize surface area contact to allow for lower pressures when weighted. Also, the footplate length in each design will be chosen by the orthotist based on the rocker profile needs of the user.

Design 10

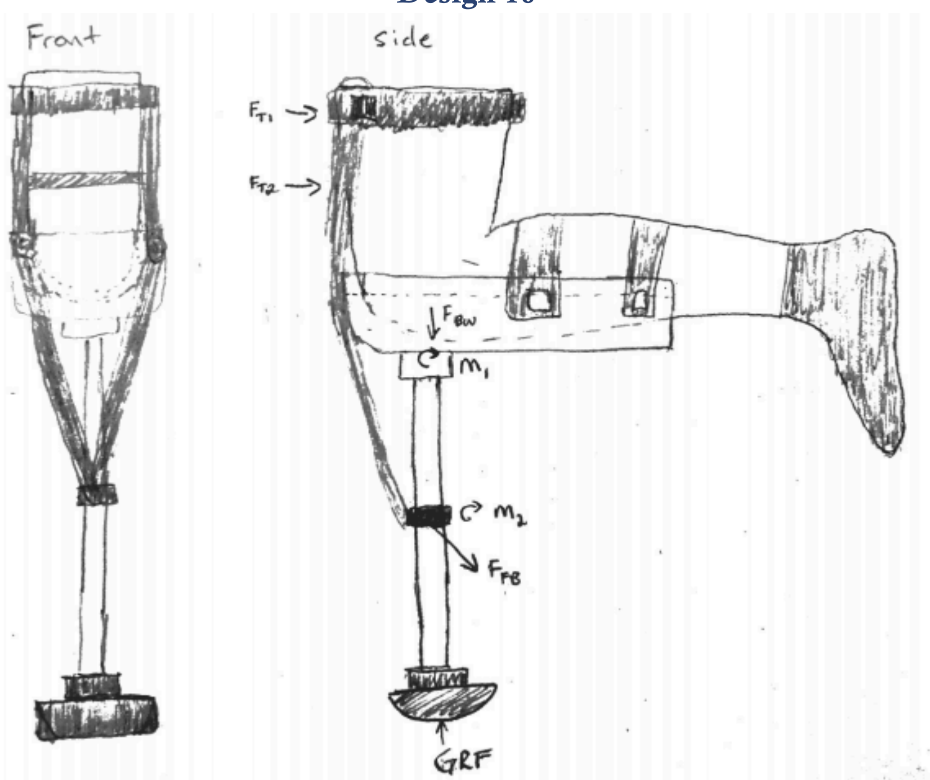


Figure 2.10: Sketch of design 10

F_{T1} & F_{T2} = force of the thigh on the frontal guard, F_{BW} = force of the body weight on the knee socket (spread across the knee socket), M_1 = moment at connection between the knee socket and the ground connection bar, M_2 = moment on the ground connection bar from the frontal bars, F_{FB} = force of the frontal bars on the ground connection bar, GRF = ground reaction force at mid-stance

Description:

- This knee walker ensures total offloading of the foot. The user places the lower leg into the knee socket, which distributes the weight from the knee to the mid-tibia.

- A rigid frontal guard is placed on the thigh to allow the user to manipulate the motion of the walker.

- Two straps connect the lower leg to the knee socket and one strap secures the thigh to the frontal guard. This also allows the user to further manipulate the walker

- Pressures will be felt on from the knee to the mid tibia where the leg is resting in the corset. Foam liner will be provided to reduce impact pressures and the surface area should be such that pressures are reduced

- The drawback of this design is that gait will be short, and potentially unstable. Also, the brace must be doffed before sitting.

Design 11

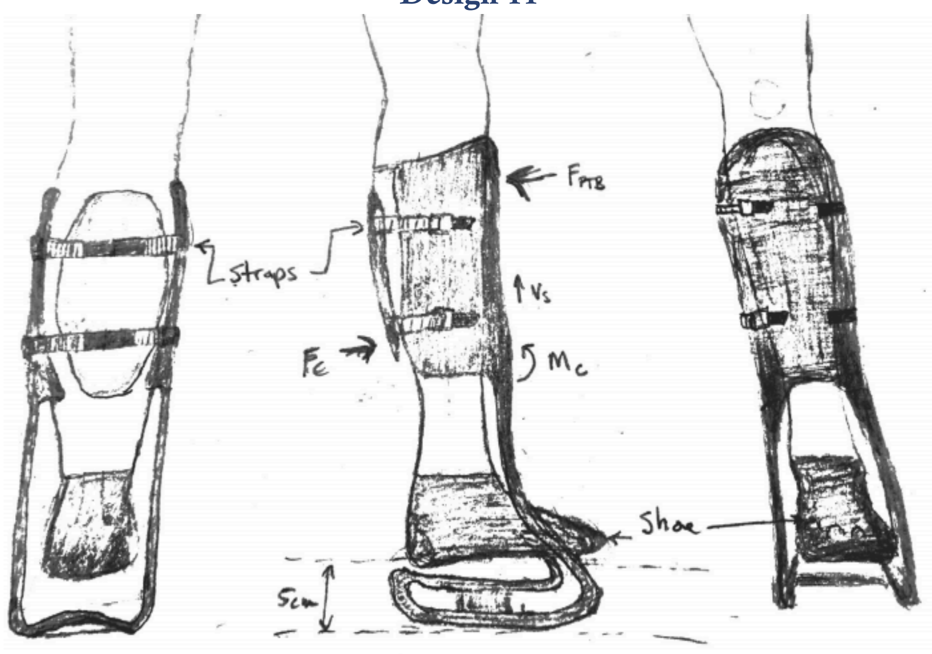


Figure 2.11: Sketch of design 11

F_{PT} = force at patellar tendon, F_C = force at distal calf, V_S = shear force, M_C = moment at connection between the corset and the unloading attachment

Description:

- This is a patella tendon-bearing corset with an anterior unloading bar attachment. The anterior placement of the unloading bars is so that when the patient bears weight a moment will be generated in the sagittal plane. This happens because the downward force from the weight of the user will not be aligned with the bars, but be a fixed radius away. This will result in a sagittal pressure at the patellar tendon. Extruded padding in the liner of the anterior shell aids in applying pressure to the patellar tendon and condyles allowing the shell to bear weight.

- A calf shell is attached to apply hydrostatic compression of the leg. The distal calf shell should be very tight to accommodate for slipping and combat the moment of the unloading bars on the corset. The calf shell can be adjusted to accommodate for volume change.

- The unloading bars extend 5cm below the patient's shoe (shoe lift needed). The bars are rigid with a lift at the heel and toe to stimulate natural gait.

Design 12

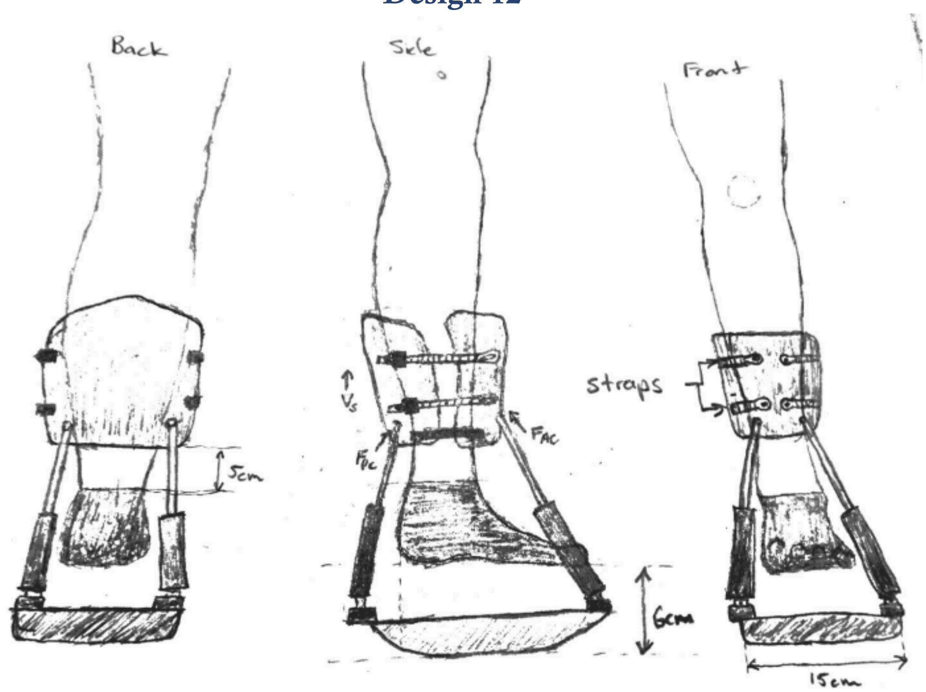


Figure 2.12: Sketch of design 12

V_S = shear force, F_{AC} = force on the anterior shell from cylinder, F_{PC} = force on the poster shell from cylinder

<u>Description</u>:

- This design uses hydrostatic compression around the leg and the conical shape of the lower leg to bear weight.

- The corset is comprised of a calf shell and a frontal shell that may be connected by three straps on both medial and lateral sides. The corset is placed roughly 5-6cm above the ankle and reaches until the mid-gastrocnemius.

- Each shell is connected to two hydraulic cylinders that provide a small damping force to reduce impact during gait. The cylinders may be tightened or loosened at the base plate to move the shells apart or closer together for donning and doffing.

2.5 Grading

Each pre-concept is graded on its effectiveness at meeting the design requirements seen in section 1.6. However, the list of requirements has been refined since some of the requirements are not possible to grade at this stage of the design process. The categories for grading include: effectiveness, usability, cost, durability, and safety. The categories that are being graded are not of equal weight. Thus, a system is set up so that the scores can be adjusted to account for the weight of the individual categories (table 2.2).

Table 2.2: Weight factor

	Raw Weight	Standardized Weight
Effectiveness	15	0.28
Usability	11	0.20
Cost	13	0.24
Durability	7	0.13
Safety	8	0.15

The raw weight is a value that is meant to separate the categories based on how essential that category is to the success of the design. Table 2.2 shows that effectiveness is chosen as the most influential and essential category and thus it is given the highest raw weight factor, whereas durability ranked as the least influential category. The standardized weight column shows the raw weight value normalized with respect to the weight of the other categories. To apply the weight factor to the grading system the standardized weight value for each category will be multiplied by the sum of the score in that respective category. Then, the weighted sum of each category will be summed to get the final score.

2.5.1 Corset Grading

Two graders have scored the designs in each category ranking them from 1-10, where 1 is poor and 10 is excellent (table 2.3 and 2.4).

Table 2.3: Corset designs graded by grader 1

	Requirements \ Design	1	2	3	4	5	10	11	12
Effectiveness	Secures the leg such that no slipping occurs	8	7	6	8	7	10	8	7
	Accounts for leg volume change over time	8	8	9	8	7	9	8	8
	Adjustable by the user	9	8	8	9	7	7	8	7
	Capable of attaching to an unloading device	8	8	8	8	8	9	9	9

Usability	Mobility (standing, walking, sitting)	8	8	8	8	5	4	8	5
	Can be used daily	8	8	8	8	8	7	8	7
	Weight	7	7	8	8	6	7	8	6
	Can don & doff by the user	7	8	8	8	6	7	8	6
	Can be used by users of various height and weight	7	7	8	7	7	8	7	8
Cost	Below 100 euro to manufacture	7	6	6	7	6	6	7	3
	Can be built using local materials	7	7	7	7	7	7	7	6
	Ease of manufacturing	8	6	6	7	7	7	6	6
Durability	Can last for up to a year	7	6	6	7	7	8	7	6
	Weatherproof (won't rust, overheat, etc)	7	7	7	7	7	7	7	7
Safety	No sharp edges	8	8	8	8	7	8	8	7
	Distributes pressure in such a way that does not harm user	8	8	8	8	7	8	8	7
Total		**122**	**117**	**119**	**123**	**109**	**119**	**122**	**105**
Total Weighted		**25.8**	**24.7**	**25.2**	**26.0**	**22.9**	**25.1**	**25.8**	**22.1**

Table 2.3 shows that corset designs 1, 4 and 11 scored the highest for grader 1 with respect to the weighted system. Next, table 2.4 is shown for grader two scoring.

Table 2.4: Corset designs graded by grader 2

	Requirements / Design	**1**	**2**	**3**	**4**	**5**	**10**	**11**	**12**
Effectiveness	Secures the leg such that no slipping occurs	6	5	6	6	7	8	8	4
	Accounts for leg volume change over time	8	7	8	7	7	8	7	7
	Adjustable by the user	8	8	6	6	6	7	7	7
	Capable of attaching to an unloading device	8	8	8	8	8	8	9	5
Usability	Mobility (standing, walking, sitting)	8	8	8	7	5	5	6	7
	Can be used daily	8	8	8	8	6	6	7	7
	Weight	8	8	8	8	6	7	7	7
	Can don & doff by the user	8	8	6	7	6	7	8	7
	Can be used by users of various height and	8	8	8	8	7	6	7	7

	weight								
Cost	Below 100 euro to manufacture	8	8	7	8	6	7	7	6
	Can be built using local materials	8	8	8	8	8	8	8	7
	Ease of manufacturing	8	8	7	8	7	8	8	7
Durability	Can last for up to a year	8	8	7	7	7	8	8	7
	Weatherproof (won't rust, overheat, etc)	8	8	8	8	8	8	8	6
Safety	No sharp edges	8	8	8	8	8	8	8	7
	Distributes pressure in such a way that does not harm user	6	5	7	6	7	10	7	8
Total		**124**	**121**	**118**	**118**	**109**	**119**	**120**	**106**
Total Weighted		**26.4**	**25.7**	**25.0**	**25.0**	**23.1**	**25.2**	**25.6**	**22.2**

Table 2.3 shows that designs 1, 2, and 11 scored the highest with respect to the weighted score. By combining the scores of the two graders the total weighted score of the designs is obtained (table 2.5).

Table 2.5: Combined scores for the corset designs

	Corset Grades							
Design Number	**1**	**2**	**3**	**4**	**5**	**10**	**11**	**12**
Total Score	246	238	237	241	218	238	242	211
Weighted Score	52.6	50.7	50.4	51.4	46.4	50.8	51.7	44.7

Table 2.5 shows that designs 1, 4, and 11 scored the best with respect to the requirements and wishes of the project.

Both graders also scored the unloading attachment designs. The grades are scored against the requirements that best fit the needs of the unloading attachment (tables 2.6 and 2.7).

Table 2.6: Grader 1 - Unloading attachment design scores

	Design / Requirements	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Effectiveness	Fully unloads the foot during gait	8	8	8	6	10	9	8
	Capable of attaching to the corset	8	8	5	6	9	9	5
Usability	Mobility (standing, walking, sitting)	8	7	6	6	4	6	7
	Weight	7	8	8	8	4	7	7
	Can be reused by users of various height and weight	1	1	1	1	1	1	1

Cost	Cost to manufacture	7	8	8	8	6	7	6
	Can be built using local materials	7	8	8	8	8	8	7
	Ease of manufacturing	8	8	7	6	7	7	7
Durability	Can last for up to a year	8	8	6	6	7	8	7
	Weatherproof (won't rust, overheat, etc)	8	8	8	8	8	8	7
Safety	No sharp edges	8	8	8	8	8	8	7
	Provides stability while standing	5	6	5	6	7	7	7
	Won't slip when in contact with the ground	6	7	5	7	9	7	4
Total		**89**	**93**	**83**	**84**	**88**	**92**	**80**
Total Weighted		**17.9**	**18.7**	**16.7**	**16.6**	**17.7**	**18.5**	**16.0**

Table 2.6 shows designs 7 and 11 scored highest for the unloading attachment with respect to the requirements and wishes. These scores may be compared grader 2 in table 2.7.

Table 2.7: Grader 2 – Unloading attachment design scores

	Design / Requirements	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Effectiveness	Fully unloads the foot during gait	8	8	8	7	10	8	7
	Capable of attaching to the corset	8	8	7	8	8	8	7
Usability	Mobility (standing, walking, sitting)	7	7	8	7	4	7	6
	Weight	7	7	7	6	6	8	6
	Can be reused by users of various height and weight	7	7	7	8	8	7	7
Cost	Cost to manufacture	7	7	7	6	7	6	5
	Can be built using local materials	7	7	7	7	7	7	7
	Ease of manufacturing	8	7	7	7	7	7	6
Durability	Can last for up to a year	7	7	7	7	7	7	6
	Weatherproof (won't rust, overheat, etc)	8	7	7	8	8	8	7
Safety	No sharp edges	7	7	8	7	8	8	7
	Provides stability while standing	8	7	8	8	8	8	8
	Won't slip when in contact with the ground	8	8	8	8	8	8	8
Total		**97**	**94**	**96**	**94**	**96**	**97**	**87**
Total Weighted		**19.4**	**18.9**	**19.1**	**18.6**	**19.2**	**19.2**	**17.2**

Table 2.7 shows designs 7, 10, and 11 scored the highest with respect to the requirements and wishes. The results from tables 2.6 and are combined to provide a total overall score for the unloading attachment grades (table 2.8).

Table 2.8: Combined scores for the unloading attachment designs

	Unloading Attachment Grades						
Design Number	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Total Score	186	187	179	178	184	189	167
Weighted Score	37.3	37.5	35.8	35.2	36.9	37.7	33.1

Table 2.8 shows that designs 7 and 11 scored had the highest combined score. To refresh, designs 1, 4, and 11 scored highest from the corset design. Design 11 scored highest in both categories and is selection for continuation onto synthesis III. Since design 11 is a combination of both corset and unloading attachment, it is determined that one additional corset design and one additional unloading attachment will selected for continuation. Table 2.5 shows that design 1 scored the highest with respect to the requirements and wishes of the corset and is selected for continuation to synthesis II. Table 2.8 shows that design 7 scored the highest with respect to the requirements and wishes of the unloading attachment and is selected for continuation to synthesis II. In summary, designs 1, 7, and 11 are selected for continuation.

2.6 Summary:

In synthesis II a morphological map is created to show possible ways of achieving the desired functions of the product. The morphological map is used to help generate ideas during brainstorming sessions. The ideas that are created during the brainstorming sessions are documented and modulated into three categories: corset designs, unloading attachment designs, and combination designs. The 5 best corset designs, 4 best unloading attachment designs, and 3 best combination designs from the brainstorming session are selected for continuation. These 12 designs are sketched and described with respect to how they brace the leg or achieve their purpose. These designs are then graded by two graders with respect the requirements and wishes of the project. The combined grades show that design 1 is scored the highest in the corset category. Design 11 scored highest in the unloading attachment category, and since design 11 is a combination of both corset and unloading attachment another unloading attachment is selected for continuation. Design 7 scored the second highest in the unloading attachment designs and is selected for continuation onto synthesis II.

3. Synthesis II

3.1 Introduction:

In synthesis II the designs that were selected for continuation in synthesis I are modified, modeled and detailed. The materials for each design are selected and calculations are conducted to better realize the efficacy of the design. All designs are dimensioned to fit a male of 72kg and 175cm. These dimensions will be altered in scale to fit the needs of each patient. Upon conclusion of synthesis II the designs are a graded and a single design is selected for continuation.

3.2 Corset Design 1:

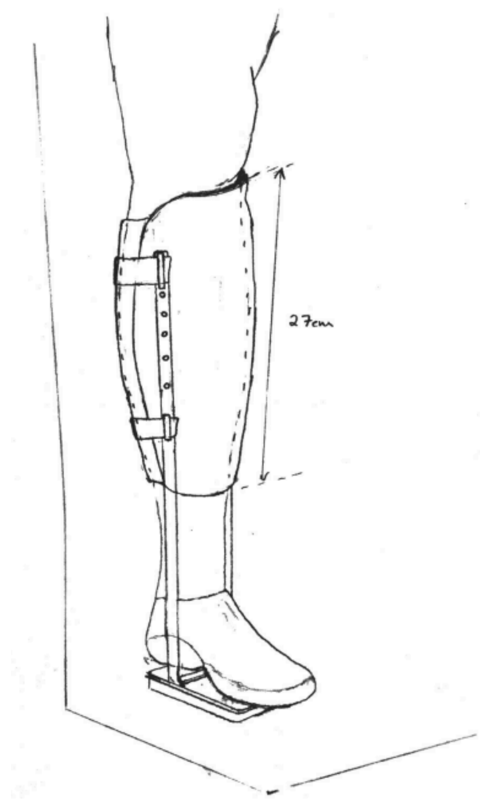


Figure 3.2.1: Isometric view of design 1

Figure 3.2.1 shows the corset attached to its corresponding unloading attachment. In previous designs the corsets and unloading attachments were designed separately, however, these attachments have been designed to fit the their respective corsets, and thus will be shown together. Of note, the footplate in this design is merely a representation of a possible length choice by the orthotist. The length and rocker profile of the footplate may be adapted by the orthotist to fit the needs of the individual patients.

3.2.1 Model of Design 1

This design is a patella tendon-bearing corset. The brace is composed of a variety of parts, which include a frontal shell, a 3mm foam liner, a calf shell, a 6mm foam liner, two nylon Velcro straps, and 4 metal attachments. A visual representation of each part has been created.

3.2.1.1 Frontal Shell

The sketches below show the frontal shell and denote essential pressure points to be relieved within the shell.

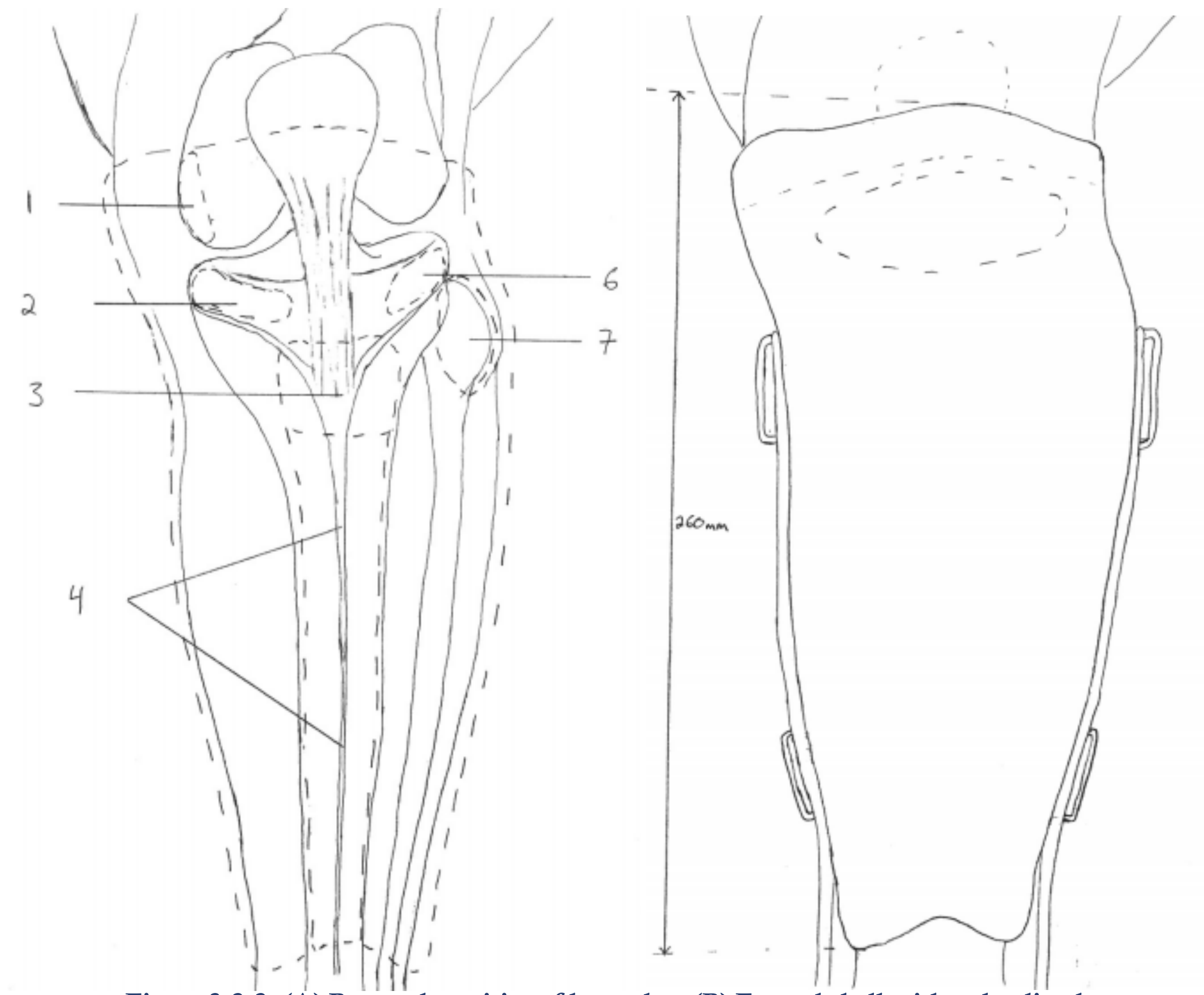


Figure 3.2.2: (A) Bony tuberosities of lower leg. (B) Frontal shell with unloading bars

Figure 3.2.2(A) shows the bony tuberosities of the leg. During the manufacturing process, extra material will be added to a positive mold of the users leg in order to relieve the pressure at the desired areas. The areas that may be relieved will be specific to each patient. Not every patient will have prominent tuberosities at each location. Thus, it will be up to the orthotist to establish which prominences will be necessary for the patient being fitted with the orthosis. The medial femoral condyle (1) and the medial head of the tibia (2) are examples of tuberosities that may not be prominent in each patient.[1] The tibial tuberosity

(3), the anterior protrusion of the tibia (4), the lateral tuberosity at the tibial head (5), and the head of the fibula (6) should all be relieved as well.

Figure 3.1.2(B) shows a frontal view of the anterior shell placement on the leg with the unloading bars and 4 attachments. The dotted line around the patellar tendon indicates the region that will region that will be protruded towards the leg to apply a force on the tendon. The length of the shell will be dependent on the user. The above shell length of 260mm corresponds to a user of 175cm, which is the average worldly human height according to Ganong's Review of Medical Physiology (23rd Ed.). [2]

The following figure (3.2.3) shows a cross section of the corset design. The anterior shell (1) with 6mm foam liner (2) cover the frontal section of the leg. The user can don the brace by undoing the straps (5) and opening the posterior section. This section is comprised of the calf shell (6) and 3mm foam liner (7), and a 3mm liner (4) to cover the back of the leg. Once the leg is in place the liner and shell may be placed over the calf and secured using the Velcro straps.

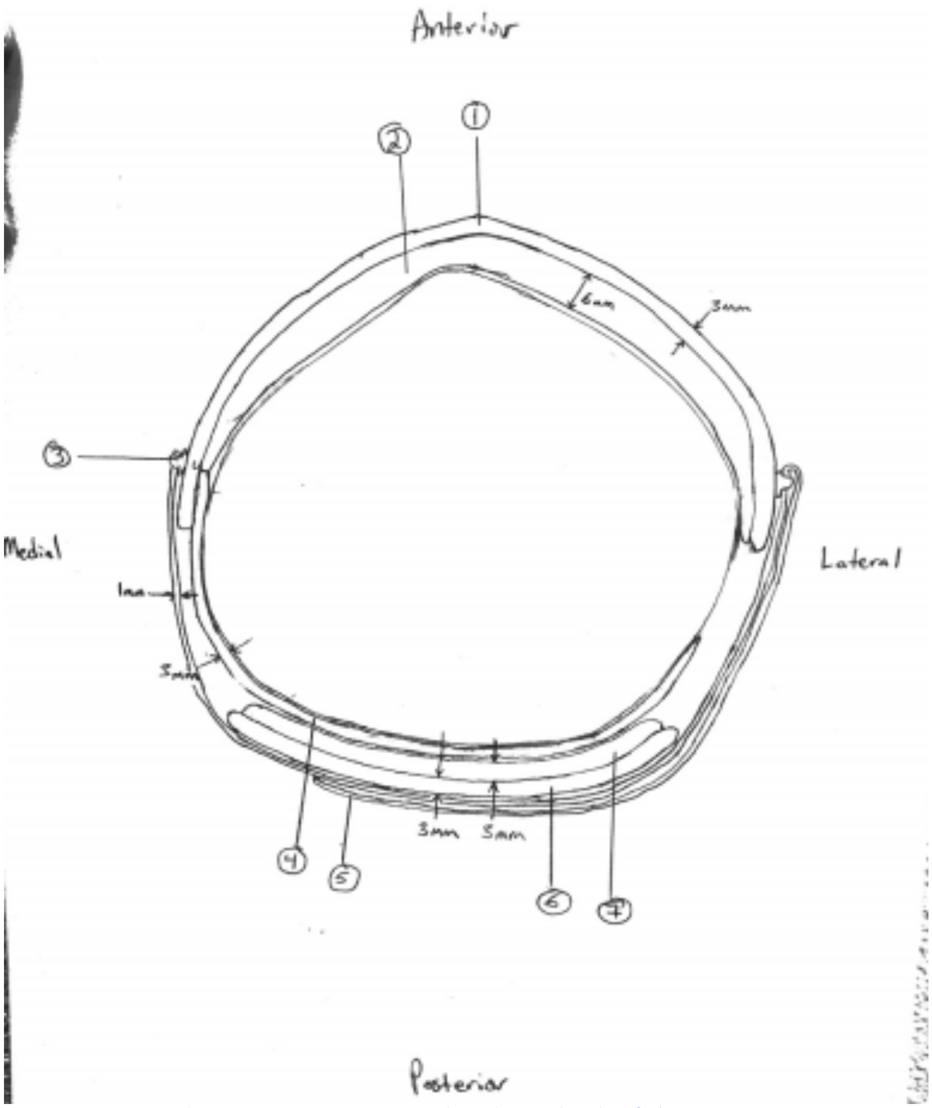


Figure 3.2.3: Cross section (top view) of the corset

To accommodate for volume change the calf shell (6,7) is not fixed to the anterior corset. As the leg increases or decreases in volume the user may tighten or loosen the calf shell as necessary. Furthermore, the calf shell may slide along the straps so that it remains centered on the calf. Additionally, the volume change of the leg may is also accounted for by changing the thickness of the padding. This can be done by providing the user with a 3-ply and 5-ply prosthetic sock. The sock may be cut at the distal end and slid over the leg to increase the leg volume and maintain a tight fitting. An advantage of the prosthetic sock is that the user will be capable of adjusting the fitting themselves and will not need to return to the clinic. A disadvantage is that it will slightly increase the cost of the brace (approx. 10eu per sock). Also, the sock will contribute to the warmth of the leg, which is of particular importance when considering warm climates such as that of Indonesia. However, a proper fitting is essential and thus these negative attributes must be accounted for in order to ensure a functional, yet affordable and comfortable brace. For example, by poking holes in the sock the leg may be able to breathe and the temperature of the leg in the brace will decrease. Also, through material selection and design adjustments the cost can be lowered to factor in the price of a sock without drastically changing the cost of the brace. The cost analysis for the corset can be seen in the material section 3.2.2.

3.2.1.2 Calf Shell

Figure 2.4 below shows the posterior view of the calf shell. The straps will connect to the metal attachments to adjust the tightness. The shell will be molded to fit the shape of the users calf. The shell will be placed over a foam liner to reduce the pressure at the edges of the shell and provide additional comfort when tightened.

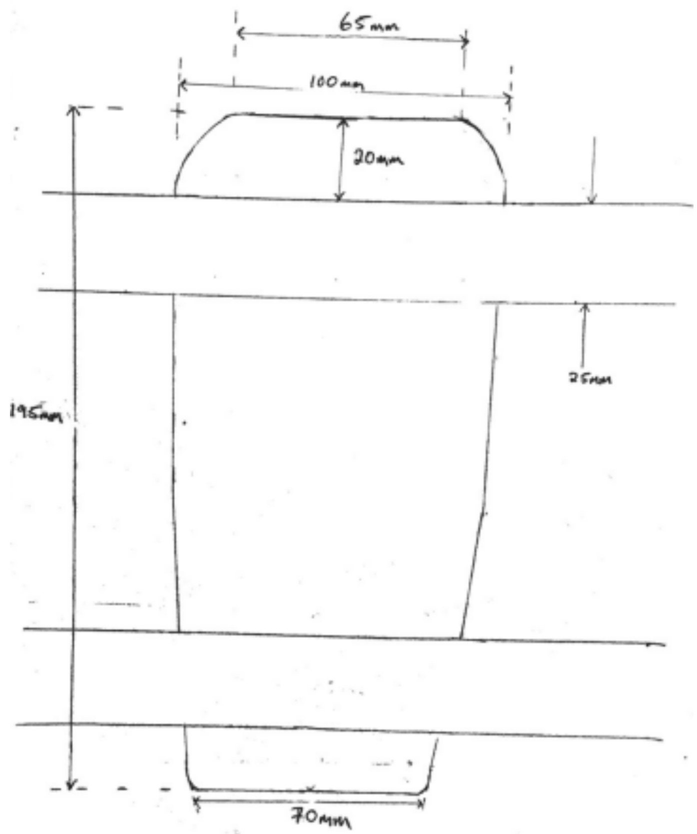


Figure 3.2.4: Calf shell dimensions

Figure 3.2.4 shows dimensions that are intended to provide a general reference of the shell size for an average user of 175cm. These dimensions are not the same for every user, will be changed by the orthotist based on the size of the user. For a look at the composition and material selection for the calf shell see section 3.2.2.

An additional design consideration for the corset is temperature control. Indonesia typically averages between 25-27C, however, it is common for the weather to be in the mid 30's.[3] Having a corset that is breathable will be an advantage in terms of comfort for the user. To achieve this, holes may be drilled into the shells of the corset and to allow for breathability. Also, the liner material should allow for air to flow to the leg.

3.2.1.3 Calculations:

In terms of biomechanics, three principles govern the quality and success of an orthosis. Those principles are: pressure, equilibrium, and the lever arm.[4] The principle of pressure applies foremost to the corset design. Pressure, by definition, is force that is distributed over an area. In the corset, this will be a force that is distributed over the shells in order to brace the leg. In this case, pressure may be described in terms of shear and normal stresses between the corset and the leg. These stresses must sufficiently withstand the weight of the user while keeping the leg from slipping in the brace. Furthermore, the stress should not be too great to cause ischemia, ulcerations, or general discomfort to the user.

The shear stress is calculated as force over area, where the area is the surface of the leg that is in contact with the corset and the force is the weight of the user (parallel to the contact surface). By maximizing the area of the corset the pressure on the leg can be reduced and still hold the same amount of force. Conversely, an increase in area means an increase in the weight of the brace. It is essential to find the balance between the two.

The area of contact is approximated using the lateral surface area of a truncated cone subtracted by the area where the posterior shell will not be in contact with the leg. This equation is shown below:

$$SA = \pi(r_1 + r_2)\sqrt{(r_1 - r_2)^2 + h} - 2(h)(a)$$

In this calculation r_1 and r_2 represent the proximal and distal radius of the leg, respectively, h represents the length of the corset and a represents the space between the calf shell and the frontal shell. Table 3.2.1 shows a range of surface areas that result from changing the length of the design. The range of the length is based on population-based statistics gathered from DINED anthropologic database on Southeast Asian men and women.[5] Within this population the height of people in 95^{th} percentile (tallest people) is 1.78 while the 5^{th} percentile (shortest people) is 1.41m, meaning that there is a 5% chance that the height of an individual from this population is outside of this range. For a user of height 1.75m the corset is chosen to be .26m, as seen in figure 3.2.2. Thus, the corset is 14.8% of the total body length. By applying this percentage to the upper and lower regions of the height statistics a corset range from 0.2 – 0.26m is obtained. Because these values are based on a chosen corset length, the range is extended by .02 on both sides to fully encompass all possible lengths. The diameters are kept constant since the relationship between length change and diameter is unknown.

Table 3.2.1: Contact area change with varied length

Proximal diameter (m)	Distal diameter (m)	Length (m)	Surface area (m^2)
0.11	0.085	0.18	0.12
		0.19	0.12
		0.20	0.12
		0.21	0.12
		0.22	0.13
		0.23	**0.13**
		0.24	0.13
		0.25	0.13
		0.26	0.14
		0.27	0.14
		0.28	0.14

Table 3.2.1 shows how the length of the corset impacts the surface area. The median length of the corset is 0.23m and the corresponding surface area is 0.13m^2. This value will later be used in calculation of the stresses on the corset. Of note, the approximation of a truncated cone may prove to be an overestimate of the surface area since the circumference of the human leg is not perfectly circular.

To determine the shear stress (τ_S), the force that is parallel to the surface must be known. This force is simply the axial force (F_s) exerted by the weight of the user. For example, a user of 72 kg will exert an axial force of 706N (weight of the user multiplied by the acceleration of gravity). The shear stress represents the amount of axial force being exerted on a user over the area of contact between the corset and the leg (SA_{tot}). The maximum shear stress ($\tau_{s,max}$) is calculated using the maximum axial force. The maximum axial force is determined from the maximum ground reaction force (GRF) during ambulation. During walking in healthy adults, the maximal GRF is typically 120% of the body weight. However, while running or exercising the GRF can be from 2-5 times the users bodyweight.[6] A user of the orthosis is not expected or advised to run on the orthosis, however, the orthosis should still be capable of undertaking up to three times the bodyweight of the user without causing harm or discomfort. Thus, to calculate for maximum shear stress the regular shear stress value will be multiplied by three. The equations to calculate the shear stress and maximum shear stress calculation are shown below. Table 3.2.2 shows the range of shear stress values for a range of users from 30-250kg.

$$\tau_1 = \frac{F_s}{SA}$$

$$\tau_{1,\max} = \frac{3 * F_s}{SA}$$

Table 3.2.2: Shear stress range in relation to axial force

Weight of User (kg)	Axial Force (N)	Shear stress (kPa)	Max. shear stress (kPa)
50	491	3.9	11.6
70	687	5.4	16.3
90	883	7.0	20.9
110	1079	8.5	25.6
130	1275	10.1	30.3
150	1472	11.6	34.9
170	1668	13.2	39.6
190	1864	14.7	44.2
210	2060	16.3	48.9
230	2256	17.8	53.5
250	2453	19.4	**58.2**

Table 3.2.2 shows that the maximum shear stress on the user ranges between 11.6 – 58.2kPa. The stresses have been calculated using a corset length of 0.23m (mean value) so that the affect on the change in force can be noted. The weight range is taken from the same population data of South East Asian people, which is 52 – 101kg. However, the upper weight range is extended to 250kg since to meet the requirements for the design. Because this design is intended for diabetic patients this requirement includes a heavier population that may be associated with diabetes.

In a study on transtibial amputees, the resultant shear stresses on the user in a PTB socket ranged from 1.9kPA to 61kPa.[7] The maximum value (61kPa) occurred on the medial tibial area during walking. The study did not indicate any harm or discomfort from the user, and thus this range is determined to be suitable for the user. Table 3.2.2 shows that the calculated stress values are below 61kPa for users up to 250kg, and thus it is determined that this design is safe for the user with respect to shear stress.

The normal stress, or pressure, on the user from the corset is calculated by normal force over the area of contact. The normal force represents the amount of force necessary to keep the leg from slipping in the brace, and is orthogonal to the surface of the leg. The following equation shows the relationship between normal force (F_N) and the force of friction (F_f).

$$F_f \leq \mu F_N$$

Here, μ is the coefficient of friction. M. Zhang & A.F.T. Mac determined the coefficient of friction between Pelite foam, which is commonly used as a prosthetic socket liner, and the skin of the leg to be 0.43.[8] This value will provide an estimate for the coefficient of friction between the leg and the foam liner in this model. In order for the corset to secure the leg in static equilibrium (no slippage/movement) the force of friction between the leg and the foam liner must be equal to or greater than the axial force. Thus, the frictional force values will be the same as the axial force values that are shown in table 3.2.2. Again, the length is selected to 0.22m so that the change in normal stress can be observed as the normal force changes. The following equations show the normal force and normal stress calculations and their maximum values, which again are multiplied by three to account for the ground reaction force during ambulation.

$$F_N = \frac{F_f}{\mu}$$

$$F_{N,\max} = \frac{3 * F_f}{\mu}$$

The normal stress is calculating using the following equation: can now be calculated to be:

$$\sigma_1 = \frac{F_N}{SA_1}$$

$$\sigma_{1,\max} = \frac{3 * F_N}{SA_1}$$

Table 3.2.3 shows the normal force, normal stress, and maximum normal stress change with respect to the weight of the user.

Table 3.2.3: Normal force and stress in relation to weight change

Weight of User (kg)	Frictional Force (N)	Normal Force (N)	Normal stress (kPa)	Max. Normal stress (kPa)
50	491	1141	9.0	27.1
70	687	1597	12.6	37.9
90	883	2053	16.2	48.7
110	1079	2510	19.8	59.5
130	1275	2966	23.5	70.4
150	1472	3422	27.1	81.2
170	1668	3878	30.7	92.0
190	1864	4335	34.3	102.8
210	2060	4791	37.9	113.6
230	2256	5247	41.5	124.5
250	2453	5703	45.1	**135.3**

Table 3.2.3 shows that the maximum normal stress ranges from 27.1 – 135.3kPa. Zhang et al. 1998 measured the maximum normal stress in transtibial amputees using a PTB socket to be 320kPa, while Convery and Buis 1999 measured a maximum average pressure in the socket to be 244kPa and saw a recording of 417kPa for the maximum of an individual sensor.[8][9] In these studies sensors were placed in multiple locations and the

measurements were taken during ambulation. Zhang noted that the normal stress nearly doubled during ambulation compared to standing. No discomfort or harm to the participants was indicated in the study. The maximum stress values in table 3.2.3 are well below the range measured by Zhang. One reason for this could be that the calculation of stress in table 3.2.3 assumes that the stress will be evenly distributed across the surface area of the corset. In reality, the stresses will be higher in certain regions such as the sagittal surface of the corset. A further analysis on specific pressure areas would be useful, yet for a feasibility analysis this shows that the corset should be capable of securing the leg within a viable margin for normal and shear stresses on the leg.

In regards to the stress calculations a few assumptions are made. As noted previously, the force vectors for the shear and normal stress are assumed to be uniform and thus the stress acts equally over the contact surface. In reality the curvature of the corset will create non-uniform stress distribution. However, the calculation of stress is primarily required to provide a proof of concept and thus an approximation will suffice. Secondly, the patellar tendon will bear some of the force within the corset. This force will be opposite to the direction of the shear force. Thus, the approximation shown above will be an overestimation of the shear stress. Thirdly, the calculations represent a two-dimensional, static situation. The leg is assumed to be in equilibrium and no additional acceleration of motion is considered. Lastly, the surface area approximation uses the lateral surface area of a truncated cone, which will differ from the natural geometry of the leg. An analysis of equilibrium, including the sagittal forces and moments on the leg from the corset is seen in section (3.3.2).

3.2.2 Corset Materials

The materials that are selected for the corset are not only refined by their physical properties, but also by cost and availability as well. Using materials that are already available at the workshop in the Dr. Soetomo Hospital will both help reduce cost and allow the technicians to construct the brace using familiar manufacturing techniques. Changing the material will be considered if the change improves the design and maintains or reduces the cost.

3.2.2.1 Shell

The material for the shell should be lightweight, rigid, and capable of molding to the shape of the user. Thermoplastics fit all three of these characteristics and are available in the workshop in Surabaya as well. The figure below identifies types of thermoplastics that are used in manufacturing by Ottobock. The types of thermoplastics that are available at the Dr. Soetomo Hospital are polyethylene (PE) and polypropylene (PP). Both PP and PE are commonly used in the production of orthotics due to their elasticity and processing characteristics. Thus, the material selection will be restricted to various grades of PP and PE.

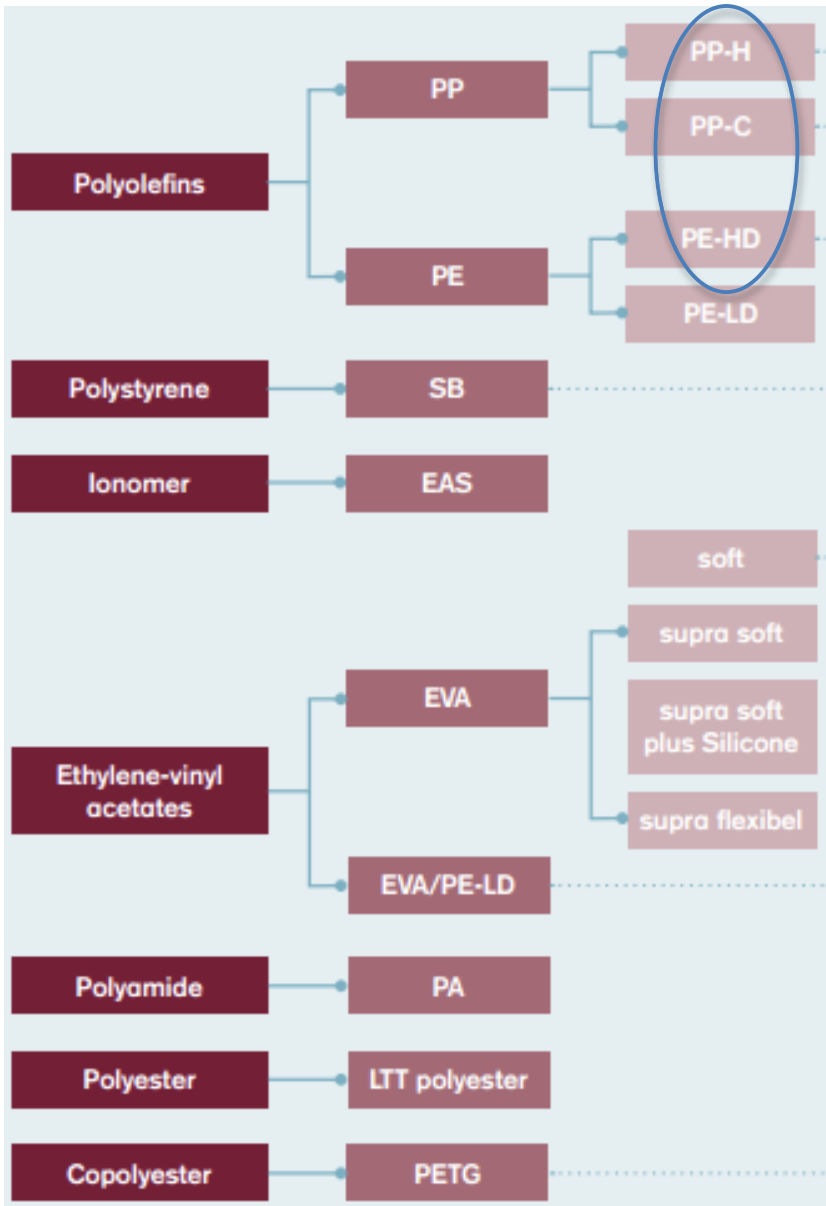


Figure 3.2.5: Thermoplastics used in production by Ottobock [10]

The diagram above shows that the selected materials are limited to the plyolefins, which are most commonly used by orthopedic technicians.[10] Specifically, polypropylene homopolymer (PP-H), polypropylene copolymer (PP-C), and high-density polyethylene (PE-HD) are selected. Low-density polyethylene (PE-LD) and the other thermoplastics are excluded due low elasticity.

Table 3.2.4 compares various types of PP-H, PP-C, and PE-HD. ThermoLyn is suggested for use by Ottobock, however, other potentially cheaper PP and PE variations exist that have similar properties and are therefore included in the chart as well.

Table 3.2.4: Material Properties and Cost for Corset

Material	Density (kg/m^3)	Weight (kg)	Modulus of Elasticity (MPa)	Cost ($euro/m^2$)
ThermoLyn PP-H	910	0.122	1200	x
Vinplast PP-H	910	0.122	1150	34.70
ATP - PP	900	0.121	1400	0.79
Moplen HP525J (PP)	900	0.121	1450	x
30% Carbon PP	1070	0.143	12750	x
ATP - HDPE	950	0.127	1300	0.90
Orhtoform HDPE	x	x	1380	40.10

ThermoLyn, Vinplast, and Orthoform are used in the production of ankle foot orthoses. However, they tend to be expensive, as seen in the table. Other forms of PP and PE show similar characteristics to these brands, yet may be purchased for significantly cheaper. ATP-PP has a high modulus of elasticity, which means that it will be even more rigid than the Thermolyn and Orthoform. Its yield strength (not shown) is 28MPa, which is comparable to the 30MPa displayed by ThermoLyn. More importantly, it may be purchased in China for 0.79 euro per m^2, and thus will be advantageous to reducing the cost the orthosis. Each brand of plyolefin is comparable in weight, which is calculated as the product of the density and the volume of the corset shells (assumes a thickness of 3mm). ATP-PP is selected for use in the corset.

3.2.2.2 Liner

The liner of the corset should be soft, dampen the contact between the leg and the rigid corset, not irritate the skin, and be cost effective. In orthoses, foams are commonly used. Durometer, a measure of the Shore hardness of a material, is used to determine the appropriate foam for the liner. Foams should not be too soft such that the rigid shell applies direct pressure to the leg, yet it should not be too hard as to be uncomfortable for the user. The Shore A scale is used for foams in companies such as Ottobock and Advanced Orthopedic Designs (AOD), and both companies suggest a Shore A 35 durometer foam for fabricating soft sockets for orthopedic leg bracing.[10] Pedilin SilverShield is selected for the foam since it has a shore of 35 and can be purchased for 5.3euro per sheet.[11],[12] This liner has antibacterial and antimicrobial treatment and is formable at 130°C.[11]

Emrich & Slater, 1998 noted that the properties to determine desirable characteristics of transtibial prosthetic liners include resistance to thickness change upon compression, shear stress abrasion resistance, and coefficient of friction[13]. In the study Pedilin was tested for each of the characteristics and was note to have good resistance to shear stress abrasion (230 ± 7.4 cycles to failure) when tested with a Stoll Flex Abrasion Tester. This indicates that the material is durable, which can save time and money in the manufacturing process. Furthermore, its static coefficient of friction was determined to be 0.785 ± 0.95%. However, the Pedilin was not tested against skin, like Pelite from the Zhang study, and thus the comparison is not possible.

3.2.2.3 Straps

Pasow 300x25mm adjustable nylon Velro straps
Price: 0.28 euro per strap [14]

3.2.2.4 Weight & Cost

From the selected materials it is essential to determine the weight and cost with respect to the corset. The weight is calculated by multiplying the density times the volume of material. The material costs are calculated based on the amount of material necessary to make each component of the design. For example, the cost of the shell is estimated by the price of the polypropylene sheet that will be necessary to make the shell. Table 3.2.5 below shows a cost estimation for the corset materials and well as the density for each material, calculated volume, and the weight of the material.

Table 3.2.5: Corset material weight and cost

	Material	density (kg/m^3)	volume (m^3)	weight(kg)	cost (euro)
Shell	ATP - PP	900	1.34E-4	0.1207	0.75
Foam	Pedilin SilverShore	140	1.341E-4	0.0188	5.3
straps	Pasow Velro	x	x	0.0204	1.12
Total:				0.1599	7.17

In total the corset will weight 0.159kg and the material cost will be 7.17euro. This value does not include the screws, bolts, adhesive and other connective material that will be required to put it together.

3.3 Unloading Attachment Design 1:

3.3.1 Model

This unloading attachment is designed for the corset shown in section 3.2. It has medial and lateral unloading bars that will attach to the corset, two reinforcement bars, and the footplate is comprised of a metal plate and a EVA/rubber sole. The components and their respective dimensions are shown in figures 3.3.1 and 3.3.2:

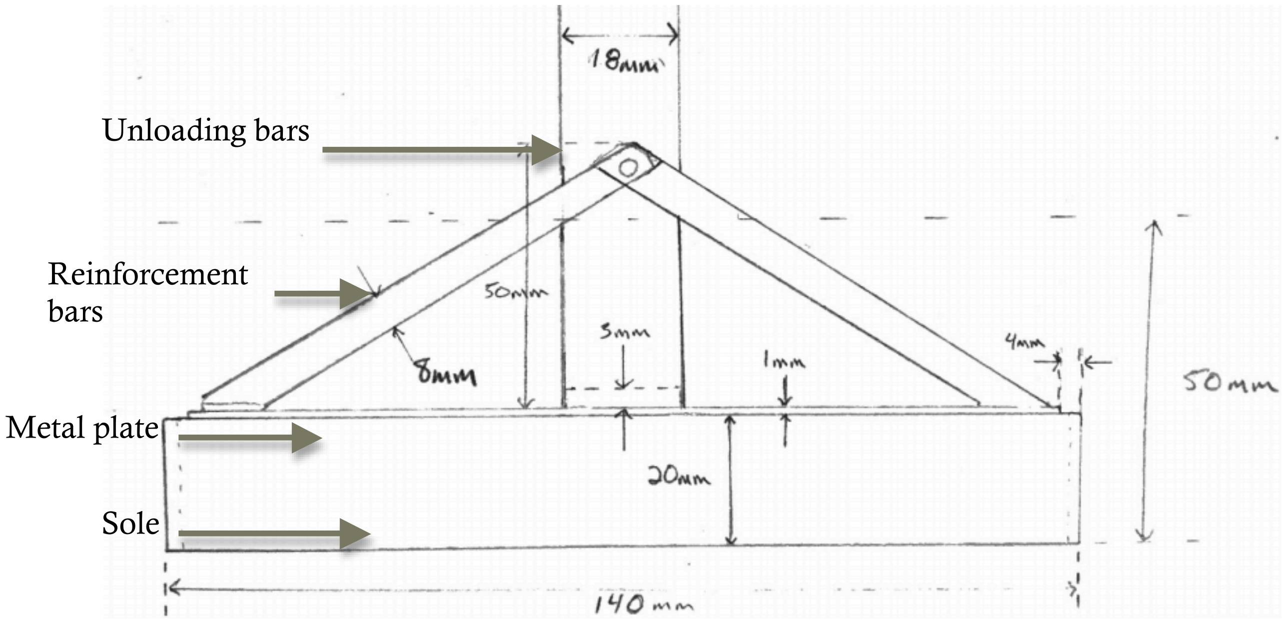


Figure 3.3.1: Sagittal view schematic for distal unloading attachment

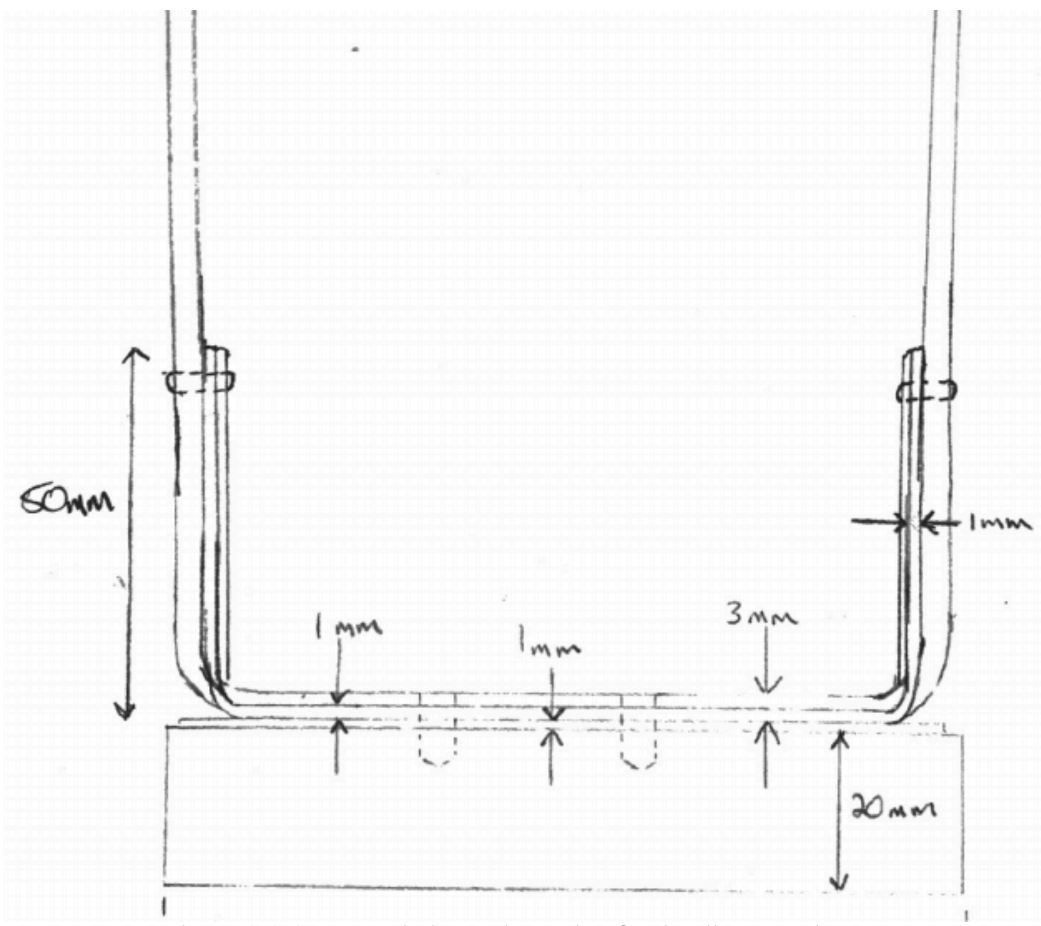


Figure 3.3.2: Frontal view schematic of unloading attachment

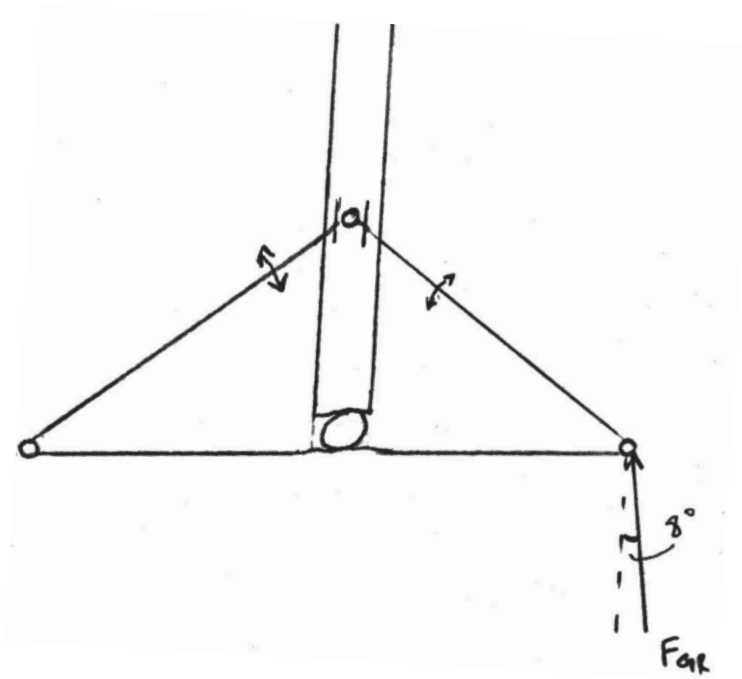
The model is designed for simplicity in manufacturing and stability during gait. The footplate width will vary based on the size of the user. The user must don the brace by placing the anterior of the leg in the corset that is attached to the unloading bars. Thus, the user must fit their shoe between the unloading bars. Henceforth, the width of the unloading bars must be at least as great as the widest section of the shoe, which is the ball width of the shoe. Population statistics of Southeast Asian men and women taken from DINED anthropometric database show the ball width of the sample population has a 95% expectancy to be between 85 – 109mm.[5] This ball width range corresponds to a orthopedic shoe size of 4-13 (U.S shoe size), and thus is the expected shoe size range that the width must accommodate for.[15] By adding 15mm to the shoe width at the ball width of the shoe the width may be determined. To provide an example, the median ball width size of a user is 97mm, which corresponds to a orthopedic shoe size of 8.5. Using an 8.5 orthopedic shoe the width about the malleolus measures to be 101mm. Thus, a footplate width of 116mm is chosen. Another important consideration is that the width will not be too wide as to come into contact with the opposite leg during gait. However, in the case of the median user the footplate width was not greater than the ball width and thus there should be no anticipated contact with the healthy leg.

The footplate length should be chosen by the orthotist based on the gait of the user. For shorter gait a shorter footplate length should be selected. At minimum, the footplate length should be at least the with of the unloading bars (18mm). To simulate normal gait, the footplate should be the length of the shoe. The foot length range of the expected population is between 210 – 246mm with a 5% expectancy that the user will be outside this range.[5] Taking a median range between the maximum length of the foot and the minimum length of the footplate a footplate length of 140cm is determined. This length gives and average expected value for the footplate length and will be used for calculations below.

Calculations:

For the unloading attachment to be in static equilibrium it must be capable of withstanding the moments and forces that are exerted on it by the user. Furthermore, the components of the forces must sum to zero, and the moments must sum to zero. An equilibrium analysis is conducted on the footplate and the forces are analyzed to see if the material can handle them.

During gait, the maximum GRF peaks twice: once after heel strike (HS) and again before toe off (TO), and the force at terminal stance just before TO is approximately 120% of the bodyweight.[16] This same force will be applied to the frontal region of the unloading attachment, and will create a moment about the unloading bars. The reinforcement bars will direct the force at toe off into the unloading bars to reduce the moment. A typical angle of the GRF at this moment is 28° (anterior) between the metatarsal heads and the coronal plane, and angle between the foot and the ground is approximately 20°[17]. Assuming that a user will have normal gait these angles may be applied to the orthosis, and the resultant GRF will be 8° between the footplate and the coronal plane. Using this knowledge a simplified model of the footplate is constructed.



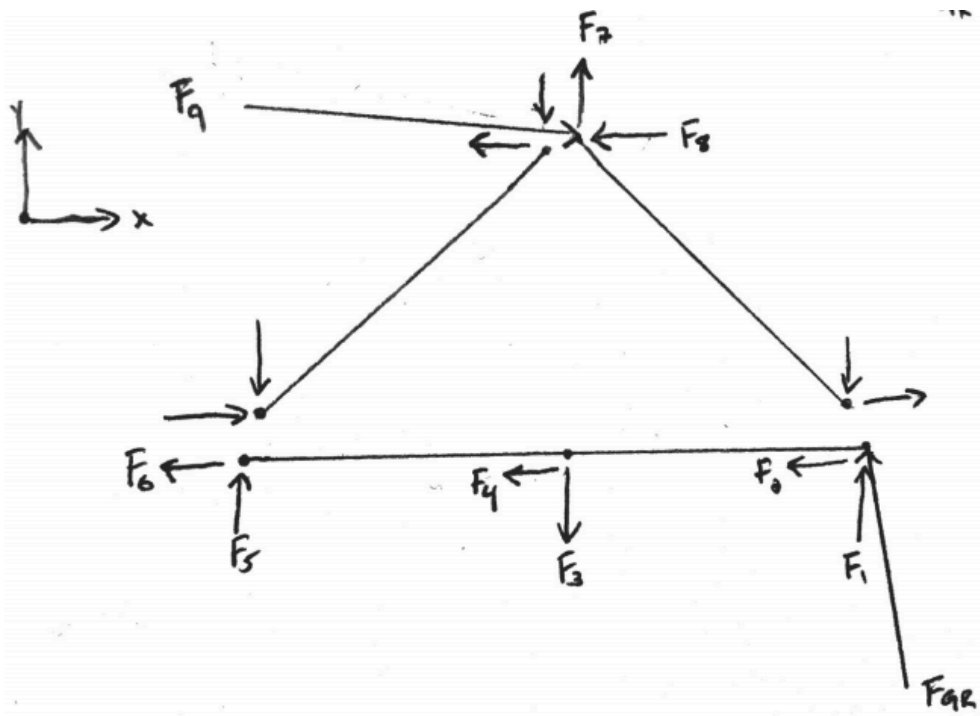
The ground reaction force (F_{GR}) at toe off is shown acting against the footplate. The connections between bars are assumed to be hinges for simplicity in calculation. In reality, these connections will be fixed. To determine equilibrium the following equations are applied:

$$\sum F_X = 0$$

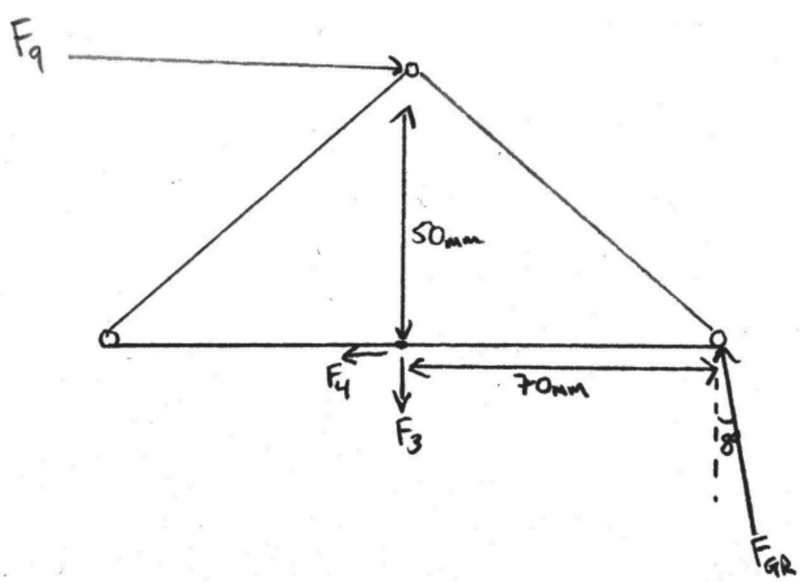
$$\sum F_Y = 0$$

$$\sum M_Z = 0$$

Where F_X represents the force components in the x-direction, F_Y are the force components in the y-direction, and M_Z are the moments in about z. To apply the theory of equilibrium to our model the components are separated to observe all forces and corresponding reactionary forces. This is shown in the figure below:



Here, F_9 is the force acting between the hinge and the unloading bars, F_4 and F_5 are the force components of the unloading attachment bars on the footplate, and the remaining forces are the result of the attachment to the other bars. To begin calculation the equilibrium equations are applied to the connected model to determine the force at F_9. The diagram below shows the forces that are at play.



$$\sum F_Y : F_{GR}\cos(8°) - F_3 = 0$$

$$F_3 = 2914N$$

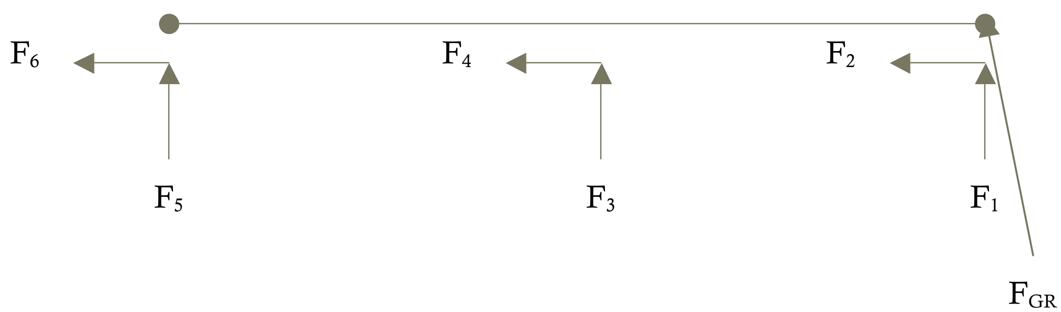
$$\sum F_X : -F_{GR}\sin(8°) - F_4 + F_9 = 0$$
$$F_4 = F_9 - 410N$$

$$\sum M_{Z(3,4)} : F_{GR}\cos(8°)(.07m) - F_9 * (0.05m) = 0$$
$$F_9 = 4080N$$
$$F_4 = 3670N$$

Here, the moment $M_{3,4}$ is the moment about the connection point between the footplate and the unloading bars. The equations show both F_9 and F_4 to be greater than the ground reaction force. This is in part due to the shape of the design. By increasing the length of the reinforcement bars, and thus the distance between the footplate an the top hinge, the moment about $M_{3,4}$ will be reduced and thus the forces F_9 and F_4 will be reduced. This is shown below:

$$\sum M_{3,4} : F_{GR}\cos(8°)(.07m) - F_9(.07m) = 0$$
$$F_9 = 2914N$$
$$F_4 = 2504N$$

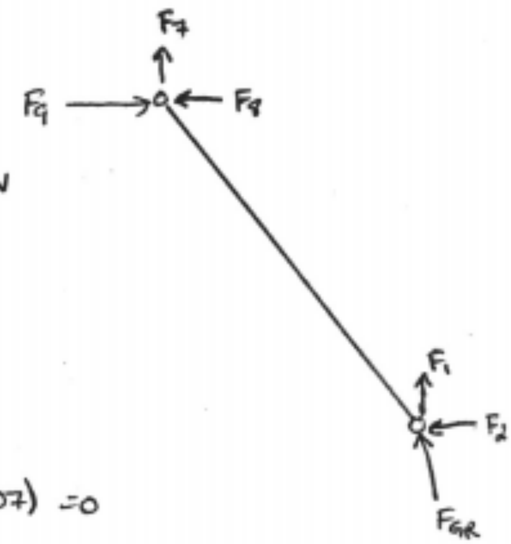
As a result of this equation the decision is made to change the distance from the footplate to the top hinge to 70mm. To calculate the remaining forces the model is split into segments. The force analysis on the bottom component is shown below:



$$\sum M_{1,2} = 0$$
$$F_3(.07m) - F_5(0.14m) = 0$$
$$F_3 = 1457N$$

$$\sum F_Y = 0$$
$$F_5 - F_3 + F_1 + F_{GR}\cos(8°) = 0$$
$$F_1 = -1457N$$

The forces in the x-direction are still unknown. Thus, the right reinforcement bar is analyzed to compute additional force components.



$$\sum F_y = 0: \quad F_{GR}\cos(8) - F_1 + F_7 = 0$$

$$2914 - 1457 + F_7 = 0$$

$$F_7 = -1457\,N$$

$$\sum F_x = 0: \quad -F_{GR}\sin(8) + F_2 - F_8 + F_9 = 0$$

$$F_2 - F_8 = -2504\,N$$

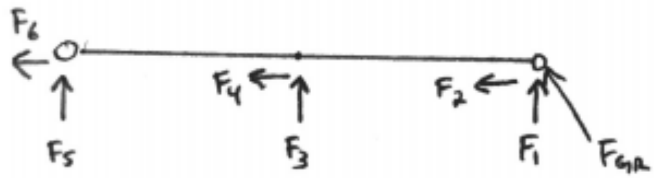
$$\sum M_{1,2} = 0: \quad -F_9(.07) + F_8(.07) - F_7(.07) = 0$$

$$F_8 = 1457\,N$$

$$F_2 - 1457 = -2504$$

$$F_2 = 1047\,N$$

Only F_6 remains and may be calculated by returning to the bottom segment and summing the forces in the x-direction. This is shown below:



$$\sum F_x = 0: \quad -F_{GR}\sin(8) - F_2 - F_4 - F_6 = 0$$

$$-410\,N - 1047 - 2504\,N - F_6 = 0$$

$$F_6 = 3961\,N$$

All the force components on the footplate are now accounted for. To determine weather the design can withstand these forces without plastically deforming information on the material is required. The calculation may be referred to in the material section (3.3.2).

Unloading Attachment & Corset:

Aside from the forces within footplate the unloading attachment also induces sagittal forces on the anterior and posterior shells of the corset during gait. These forces occur at the proximal and distal regions of the anterior and posterior shells, and will induce pressure on the leg of the user. The forces are maximized just after heel strike and just before toe off. Figure 3.3.3 shows a sagittal view of the corset and unloading attachment with the corresponding forces drawn in.

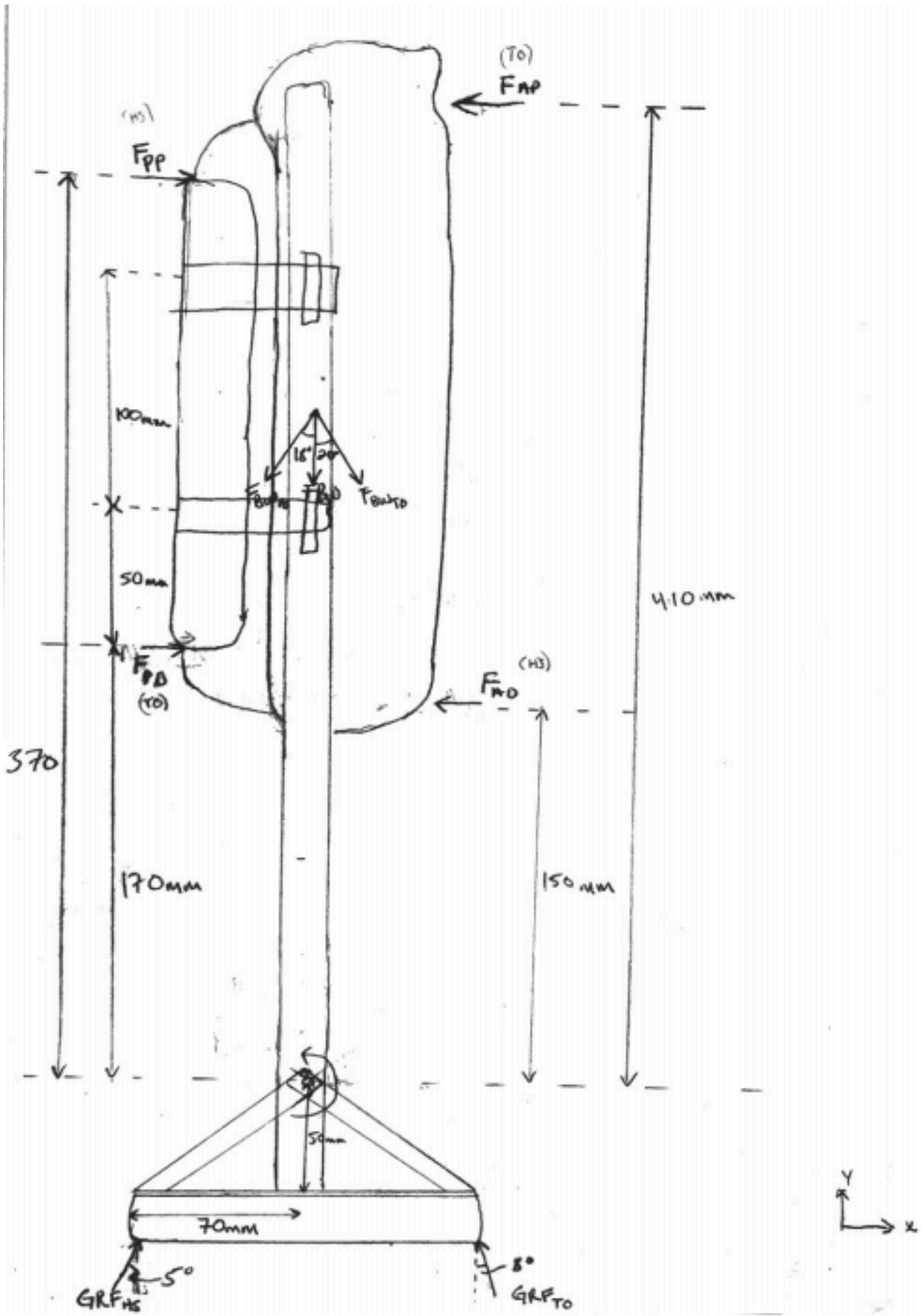
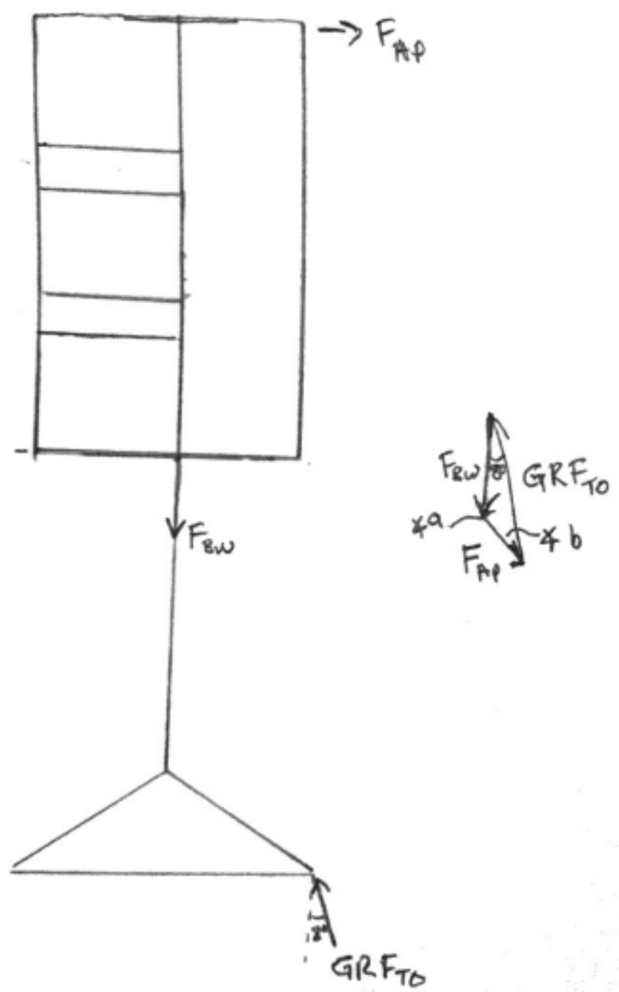


Figure 3.3.3: Forces on the corset from sagittal ground reaction force components

Where F_{AP} is the force on the anterior proximal shell, F_{AD} is the force on the anterior distal shell F_{PP} is the force on the posterior proximal shell, F_{PD} is the force on the posterior distal shell, F_{BW} is the body weight, and GRF_{HS} and GRF_{TO} are the ground reaction forces at heel strike (HS) and toe off (TO) respectively.

To determine the magnitude of these forces, and observe when they occur, the events of heel strike and toe off are analyzed. Firstly, toe-off is observed. A simplified model in the sagittal plane is generated to show the forces at play. At this moment in time the orthosis is assumed to be in static equilibrium.



In order to be in static equilibrium the force vectors must form a triangle. This shows that the combination of magnitudes and directions start and end at the same point, and indicates that the sum of the force components balance to zero. In the diagram, the GRF_{TO} and F_{BW} are both known. Furthermore, the angle between them is also known to be 8°. Using the Law of Cosines the magnitude the reactionary force on the leg (F_{AP}) induced the by the anterior corset may be calculated:

$$F_{AP}^{\ 2} = GRF_{TO}^{\ 2} + F_{BW}^{\ 2} - 2(GRF_{TO})(F_{BW})\cos(8°)$$
$$F_{AP} = 618N$$

The force induced on the leg by the anterior corset is 618N. In reality, this will not be felt as a point force, but as a pressure that will be divided along part of the area of the shell. Assuming that the pressure is distributed evenly, the top half of the posterior shell will induce a positive pressure on the leg, while the bottom half will induce a negative pressure due to the rotation of the corset. This will be the opposite for the anterior shell. Thus, by dividing the force among the area that is applying positive pressure to the leg the reactionary pressures. Firstly, the normal force of component of F_{AP} must be calculated.

$$\frac{\sin(8°)}{618N} = \frac{\sin(b)}{2452N}$$

$$b = 33.5°$$
$$a = 138.5°$$

Using the law of cosines the angles of the force triangle are found. This gives the direction of F_{AP} , which may now be used to calculate its horizontal component.

$$F_{APx} = \sin(41.5°) * F_{AP}$$
$$F_{APx} = 409.5N$$

Now, the pressure on the anterior shell may be calculated:

$$P_{AS} = \frac{F_{APx}}{0.5 * SA_{FS}}$$
$$P_{AS} = 55.3kPa$$

where P_{AS} is the pressure on the top half of the anterior shell. This pressure represents the additional pressure no the anterior socket that is generated during toe-off. This pressure is combined with the normal stress values from table 3.3.1 to obtain the total amount of compressive pressure on the leg during toe off.

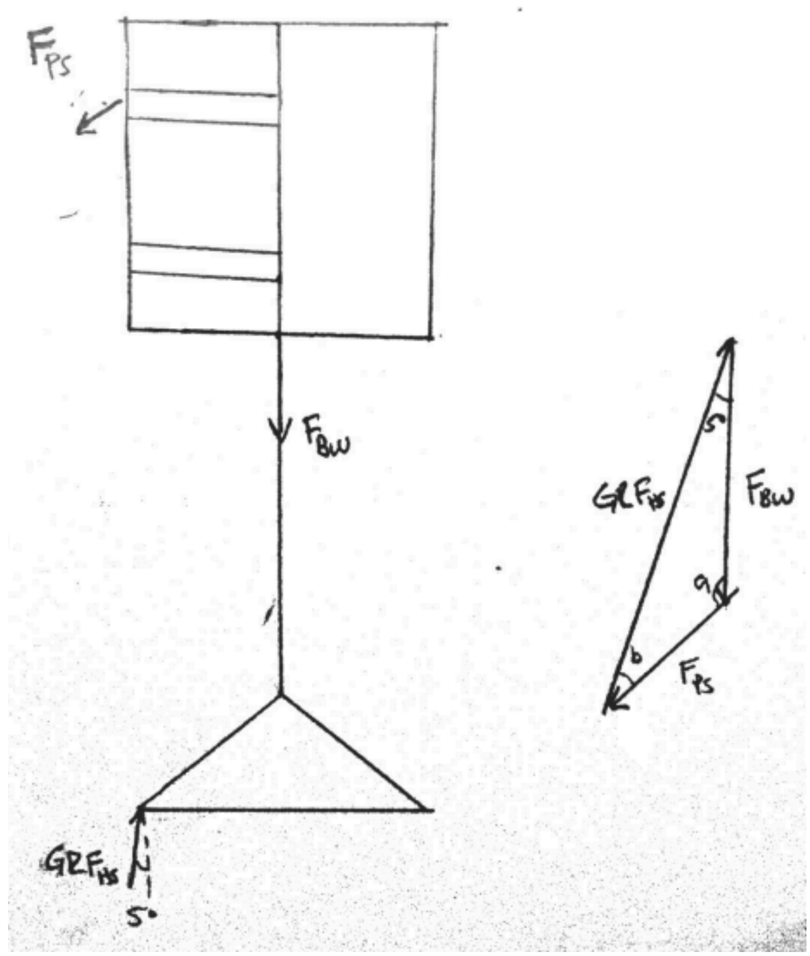
$$P_{TO} = P_{AS} + \sigma_{\max}$$

Table 3.3.1: Pressure at Toe Off

Weight of User (kg)	Max. Normal stress (kPa)	Pressure at Toe Off (kPa)
30	16.2	71.5
50	27.1	82.4
70	37.9	93.2
90	48.7	104.0
110	59.5	114.8
130	70.4	125.7
150	81.2	136.5
170	92.0	147.3
190	102.8	158.1
210	113.6	168.9
230	124.5	179.8
250	135.3	**190.6**

Table 3.3.1 shows that the pressures at toe off are less than 417kPa from the Zhang study, and thus it is deduced that the design will not cause the user harm or discomfort. The maximum pressure at toe off is 190.6kPa for a maximum user weight of 250kg and median corset size of 0.23m. This value may be compared to the pressure at toe off in design to see which design has lower pressures.

The forces at the posterior shell are calculated below. As shown in the figure, the ground reaction force that will cause these reactionary forces will occur at heel strike. Just after heel strike the GRF can peak between 115 - 125% body weight [18]. 120%BW is chosen for the GRF (F_{HS}). Furthermore, the GRF angle is approximately 5° from the coronal plane.[17]



Using the triangle of forces method the magnitude and direction of the force on the leg by the posterior shell is calculated.

$$F_{PS}^2 = GRF_{HS}^2 + F_{BW}^2 - 2(GRF_{HS})(F_{BW})\cos(5°)$$

$$F_{PS} = 544N$$

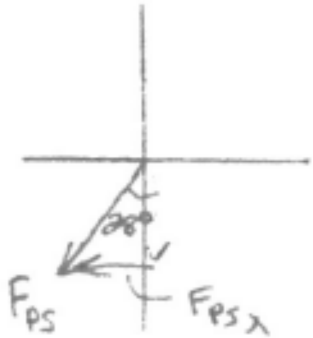
$$\frac{\sin(5°)}{F_{PS}} = \frac{\sin(b)}{F_{BW}} = \frac{\sin(a)}{GRF_{HS}}$$

$$\sin(b) = \frac{F_{BW}}{F_{PS}}\sin(5°)$$

$$b = 23°$$

$$a = 152°$$

Now that the magnitude and direction of F_{PS} is known the normal force component may be calculated and the pressure on the corset determined:



$$F_{PSx} = F_{PS}\sin(28°)$$
$$F_{PSx} = 255N$$

$$P_{PS} = \frac{F_{PSx}}{0.5 * SA_{CS}}$$
$$P_{PS} = 28.7kPa$$

P_{PS} represents the pressure on the posterior shell as a result of heel strike. This may be added to the maximum normal stress values to obtain the total pressure on the leg following heel strike (P_{HS}).

$$P_{HS} = P_{PS} + \sigma_{\max}$$

Table 3.3.2: Pressure at heel strike

Weight of User (kg)	Max. Normal stress (kPa)	Pressure at Heel Strike (kPa)
30	16.2	44.9
50	27.1	55.8
70	37.9	66.6
90	48.7	77.4
110	59.5	88.2
130	70.4	99.1
150	81.2	109.9
170	92.0	120.7
190	102.8	131.5
210	113.6	142.3
230	124.5	153.2
250	135.3	**164.0**

Table 3.3.2 shows the pressure is below 417kPa. Thus, at this pressure the corset would be considered safe and would not cause harm to the user. Furthermore, the maximum pressure at heel strike is 164kPa at a maximum weight of 250kg and a median corset size of .23m. This value may be compared to design two to show the differences between the two designs.

However, a few assumptions affect the pressure calculations and should be noted. Firstly, it was assumed that the pressure was distributed evenly within the shell. However, the pressure may be higher or lower in certain areas of the shell. Localizing the pressure to certain areas indicates that the force would be occurring over a smaller surface area rather than the over the whole region. If the force remains the constant and the surface area decreases, then the pressure on the corset will increase. This is likely what is happening in a real situation. Secondly, more forces may be involved than the simplified model allowed for. A three dimensional analysis of the forces at play and the corresponding pressure may be valuable to provide validation for the calculation.

3.3.2 Materials

Unloading Bars

The unloading bars require a sturdy yet lightweight material. Dr. Soetomo Hospital currently uses an aluminum alloy for the unloading bars. Aluminum alloy is recommended by orthotists for its high yield point and low cost when compared to titanium or stainless steel.[19] 2024 Aluminum is selected for the bars.

<u>2024 Aluminum</u>
Density: 2800kg/m^3
Yield strength: 280MPa
Weight: 0.14kg
Cost: 1.15euro
*Cost calculation: The price is listed at 1.27eu/kg and is sold in 3meter bars. One 3 meter bar is 0.45kg. Cost = price per kg*weight of one bar. Thus, the cost is referenced per bar.[20]

As noted previously, the maximum GRF during ambulation can be up to 3 times the bodyweight of the patient. Thus, the unloading bars must be capable of withstanding this force. In reality, this force will be divided among two bars, one medial and one lateral. Using the cross sectional area (A) of the unloading bars the stress may be calculated:

$$\sigma_B = \frac{3F_{BW}}{2A} = 70.6MPa$$

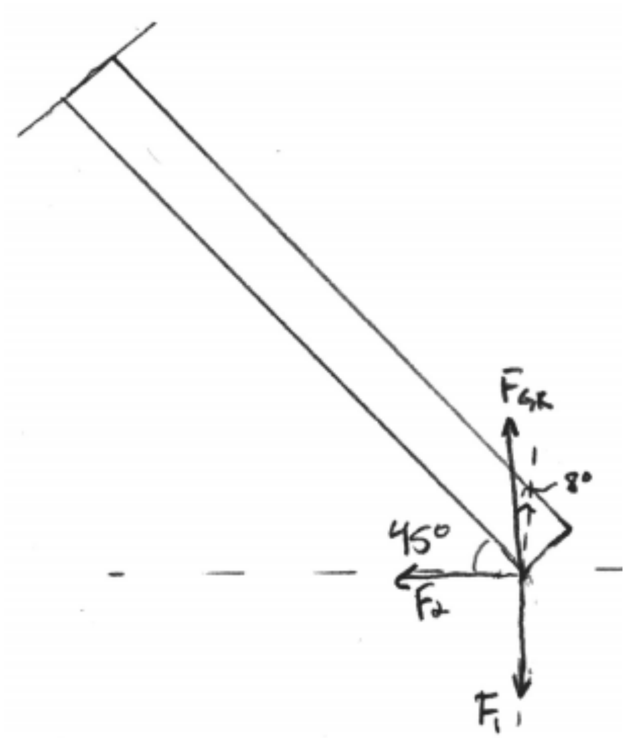
The load bearing yield strength of 2024 Aluminum is 280MPa, which is above the stress being induced by the user. This indicates that the bars will not plastically deform during use by the user.

Reinforcement Bars

<u>Aluminum Flat Bar [21]</u>
Density: 2700kg/m^3

Weight: 0.018kg
Cost: 4.26 euro
Yield Strength: 240 MPa
*Cost is for 4 reinforcement bars of 120mm each.

This material must withstand the forces that are being applied by the user during gait. To determine this, we must analyze the amount of stress these forces induce on the beam. Firstly, the resultant force on the beam is calculated using a free body diagram of the forces on the beam:



$$R = F_{GR}\cos(37°) + F_2\cos(45°) - F_1\cos(45°)$$
$$R = 2060N$$

where R is the resultant force along the beam at 45°. The beam is assumed to be fixed at the end opposite the free body diagram. Stress is then calculated by diving the force by the cross sectional area of the beam:

$$\sigma = \frac{R}{A} = \frac{2060N}{(.002m * .015m)} = 68.7MPa$$

The bar plastically deforms at 240MPa, and thus it will be capable of withstanding this stress. Furthermore, the design of the footplate has two reinforcement bars (one medial and one lateral) that will take the ground reaction force. Thus, the calculated stress is double what is expected on the reinforcement bars.

Footplate Sheet

Aluminum 5052-H32. [22]
Density: 2680kg/m^3
Weight: 0.038kg
Cost: 3.36 euro

Sole

Rubber/ Neoprene
Shore A 70 durometer [23]
Density: 1200kg/m^3
Weight: 0.336kg
Cost: 35.5euro

*Weights are calculated based on the volume of each material being used in the design multiplied by the density of the material. The costs shown are the prices for the material required to make the part and includes extra material overlap.

Table 3.3.3 shows the weight and cost for both the unloading attachment and then the total combined weight and cost for the orthosis.

Table 3.3.3: Weight and cost of unloading attachment and orthosis

	Weight (kg)	Cost
Unloading Attachment	0.532	44.27
Total	**0.691**	**47.28**

The total weight of the orthosis is 0.69kg, which meets the requirement of the design weighing less than 2kg. The cost for the material components alone is 47.28euro. This number does not account for shipping costs or manufacturing costs. The minimum wage in Surabaya is 3.3 million per month IDR.[24] Assuming that: a manufacture pays the laborer 1.5 times the minimum wage, the worker works 22 days a month, and it takes 2 days to make a the orthosis, then the labor costs are 450,000 IDR which is 30.05euro. Adding on an additional 30 euro for estimated shipping brings the total cost to 107.33euro for the brace.

3.4 Corset Design 2:

This design uses hydrostatic compression and the conical shape of the leg to bear the weight of the patient. It is comprised of an anterior shell, a 5mm foam liner, a calf shell, 4 Velcro straps and two ski boot straps. The design is shown in figure 3.4.1:

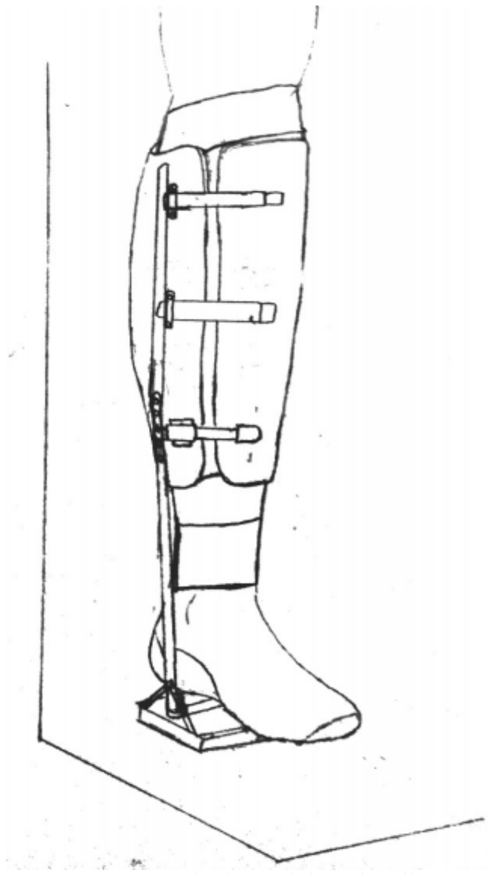


Figure 3.4.1: Corset design with unloading attachment

3.4.1 Model

In this design the calf shell that is connected to the unloading attachment bars. The corset may be donned by placing the calf in the calf shell, wrapping the frontal foam liner around the anterior face of the leg, and then securing the anterior shell over the foam liner and fastening it tightly to the posterior shell. For a top view of the corset see figure 3.4.2:

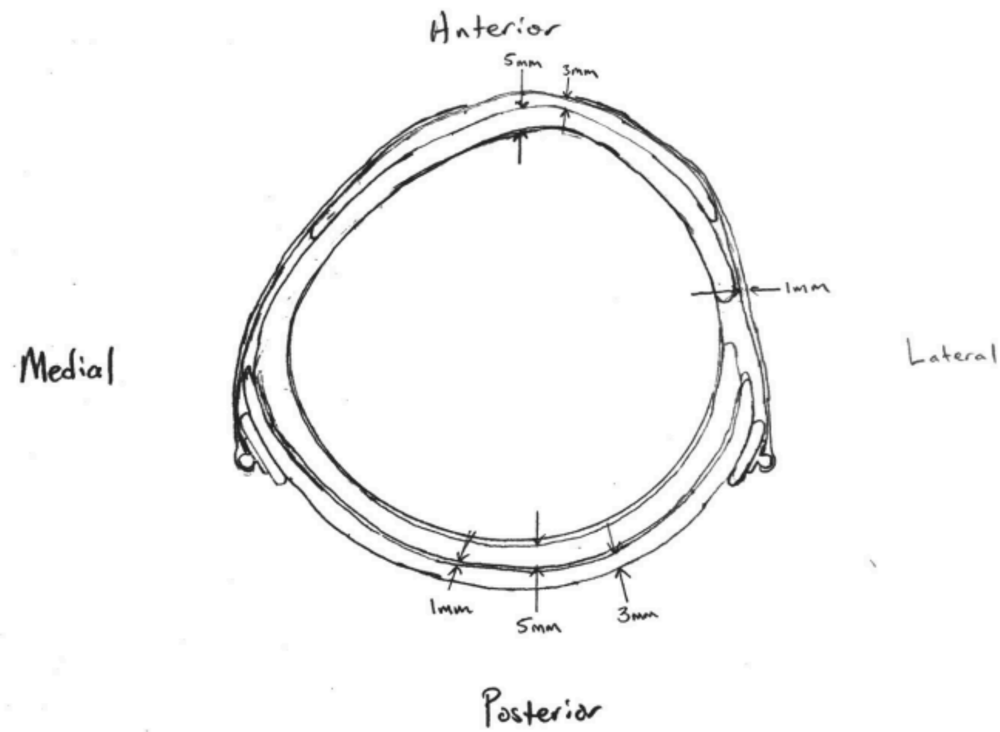


Figure 3.4.2: Top view of the corset

The foam liner is permanently connected to the posterior shell. The liner may be wrapped around the anterior leg and the anterior shell is placed on top and fastened. Straps on both sides allow the position of the anterior shell to be adjusted about the center of the leg in order so that the user can correct the alignment.

The dimensions of the calf shell are shown in figure 3.4.3. These dimensions are intended for a median population size (as referenced in section 3.2.1).

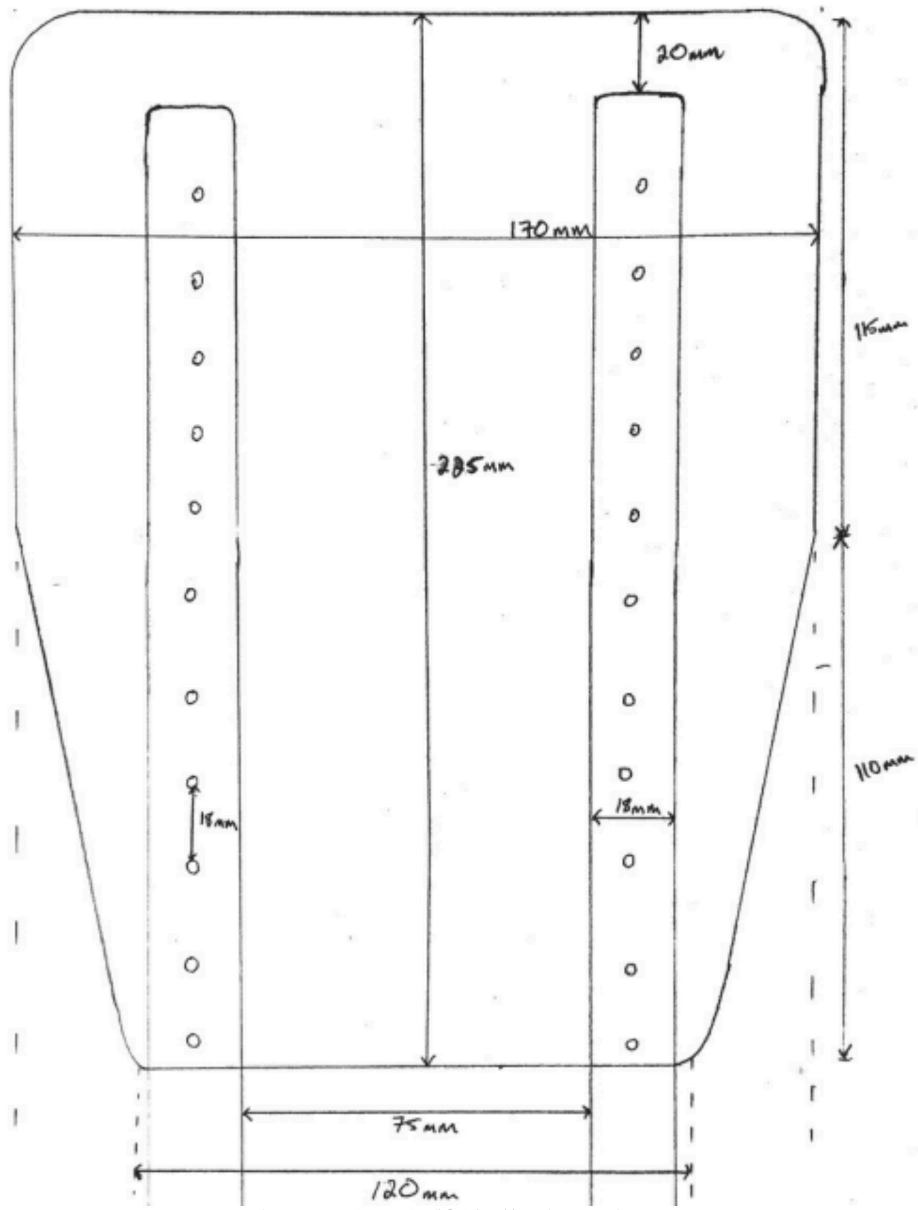


Figure 3.4.3: Calf Shell Dimensions

The dimensions should allow for the medial and lateral edges of the shell to touch the coronal plane. Specifications will vary per user. The unloading bars run the length of the shell to provide rigidity and support.

The anterior shell of the corset is shown in figure 3.4.4 below.

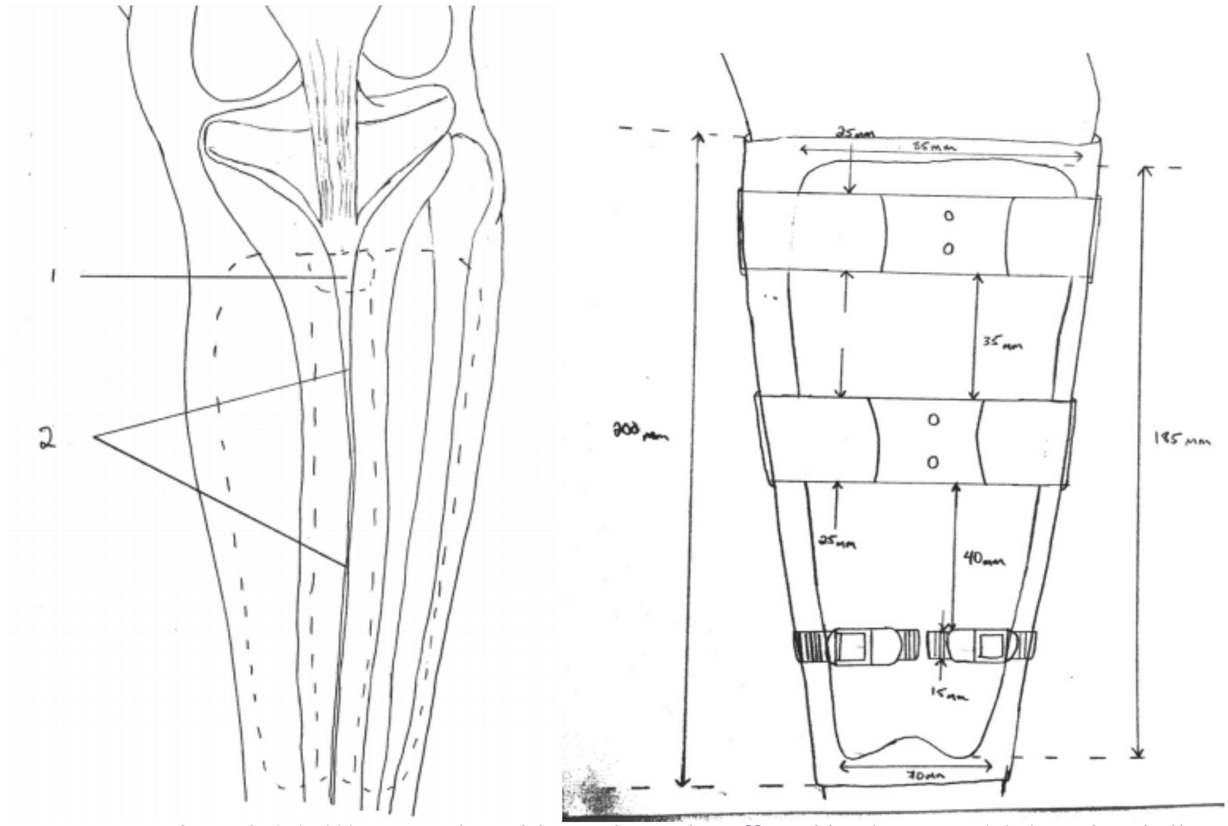


Figure 3.4.4: (A) Bony tuberosities on lower leg affected by the corset (B) Anterior shell dimensions

Since the design is non-PTB, the corset may be placed lower on the leg and avoid bony tuberosities. The two that remain include the tibial tuberosity (1) and the anterior tibial protrusion (2), as shown in figure 3.3.4(A). In comparison with corset design 1, this design bypasses many pressure points and at risk areas for discomfort.

Hydrostatic compression of the corset is achieved by fastening a series of straps: two Velcro straps (proximal and middle) and two ski-boot style straps at the distal end. The ski-boot straps can be fastened easier and it is important to have a tight fit on the distal corset to fully utilize the conical shape of the leg. To determine if the hydrostatic compression will be either sufficient, or potentially harmful to the user, shear and normal stresses must be calculated.

Calculations:

To calculate the surface area the same truncated cone approximation is used as previously seen in section 3.2.1. However, the shells in this design cover a larger portion of the leg. Thus, the variable, a, is changed in the truncated cone equation to .02m to account for the increase in area. The corset size range is the same as in section 3.2.1. Table 3.4.1 shows the relationship between corset size and surface area.

Table 3.4.1: Corset length effect on surface area

Proximal diameter (m)	Distal diameter (m)	Length (m)	Surface area (m^2)
0.11	0.09	0.18	0.13
		0.19	0.13
		0.20	0.14
		0.21	0.14
		0.22	0.14
		0.23	**0.15**
		0.24	0.15
		0.25	0.15
		0.26	0.16
		0.27	0.16
		0.28	0.16

The range for corset lengths is the same, thus, the median corset length is still 0.23m. The corresponding surface area is 0.15m^2, as seen in table 3.3.1. This surface area will be used to calculate the shear and normal stresses between in the corset and the leg. Both shear and normal stresses are calculated using the same equations as seen in section 3.2.1. Table 3.4.2 shows the shear stress and maximum shear stress for design 2.

Table 3.4.2: Range of shear stress and maximum shear stress

Weight of User (kg)	Axial Force (N)	Shear stress (kPa)	Max. shear stress (kPa)
30	294	2.1	6.2
50	491	3.4	10.3
70	687	4.8	14.4
90	883	6.2	18.5
110	1079	7.5	22.6
130	1275	8.9	26.8
150	1472	10.3	30.9
170	1668	11.7	35.0
190	1864	13.0	39.1
210	2060	14.4	43.2
230	2256	15.8	47.3
250	2453	17.2	**51.5**

Table 3.4.2 shows that the maximum shear stress on the leg ranges from 6.2 – 51.5 kPa. These values are below 61.9kPa (the measured maximum shear stress measured in transtibial amputees during ambulation). Furthermore, the maximum shear stress that corresponds with the maximum weight at the median corset length is 51.5kPa. This is compared to the maximum shear stress in design one under the same conditions, which is 58.2kPa. Thus it is seen that this design yields lower shear stress values.

Normal stress is computed using the normal stress equations from section 3.2.1. The median surface area from table 3.4.1 is used for the calculation. Table 3.4.3 shows the normal stress and maximum normal stress over the established weight range.

Table 3.4.3: Normal stress and maximum normal stress of design 2

Weight of User (kg)	Frictional Force (N)	Normal Force (N)	Normal stress (kPa)	Max. Normal stress (kPa)
30	294	684	4.7	14.1
50	491	1141	7.8	23.4
70	687	1597	10.9	32.8
90	883	2053	14.1	42.2
110	1079	2510	17.2	51.5
130	1275	2966	20.3	60.9
150	1472	3422	23.4	70.3
170	1668	3878	26.5	79.6
190	1864	4335	29.7	89.0
210	2060	4791	32.8	98.4
230	2256	5247	35.9	107.7
250	2453	5703	39.0	**117.1**

Table 3.4.3 shows the maximum normal stress ranges from 14.1 – 117.1kPa. These values are below 417kPa, which was the maximum normal stress measured in ambulating trans-tibial amputees in the Zhang study. The maximum normal stress in table 3.3.3 that corresponds to the maximum weight and median corset length is 117.1kPa. This value is less than, yet comparable to, the values found in design 1. These calculations have the same assumptions as section 3.2.1. For a further analysis of the forces acting on the corset, see section 3.5.1.

3.4.2 Materials

The materials for this corset design are chosen in the same method as seen in section 3.2.2. The materials of the corset shells, lining, and Velcro straps remain the same. Two ladder straps with push release buckles are added to the design. These straps enhance the fixation at the distal corset, which allows the corset to better utilize the conical shape of the leg. The weight and cost of the materials for this design are calculated using the dimensions

Table 3.4.4: Corset 2 Weight and Cost

	Material	Quantity	Density (kg/m^3)	Volume (m^3)	Weight (kg)	Cost (euro)
Shell	ATP – PP	2	900	0.000134	0.1207	0.75
Foam	Pedilin SilverShore	1	140	0.000134	0.0188	5.30
Straps	Pasow Velcro	2	x	x	0.0204	1.12
	Ladder strap w/ push release	2	920	8.9E-6	0.0164	13.45
Total					**0.194**	**20.92**

In table 3.4.4 the weight is calculated from the material density multiplied by the volume of material. The cost is estimated based on the amount of material needed make one corset, and includes extra material that will be cut away. The total material weight is 0194kg and the cost is 20.92 euro. Not included in the weight and cost are the screws, glue and other attachment components required to piece the materials together. These will be accounted for in the final design.

3.5 Unloading Attachment Design 2

3.5.1 Model

This unloading attachment is designed to attach to corset design 2 (3.2). It is comprised of two metal attachment bars that attach to a footplate distal to the shoe of the user. It will attach to the calf shell of corset design 2. Figures 3.5.1 and 3.5.2 show the schematics for the footplate.

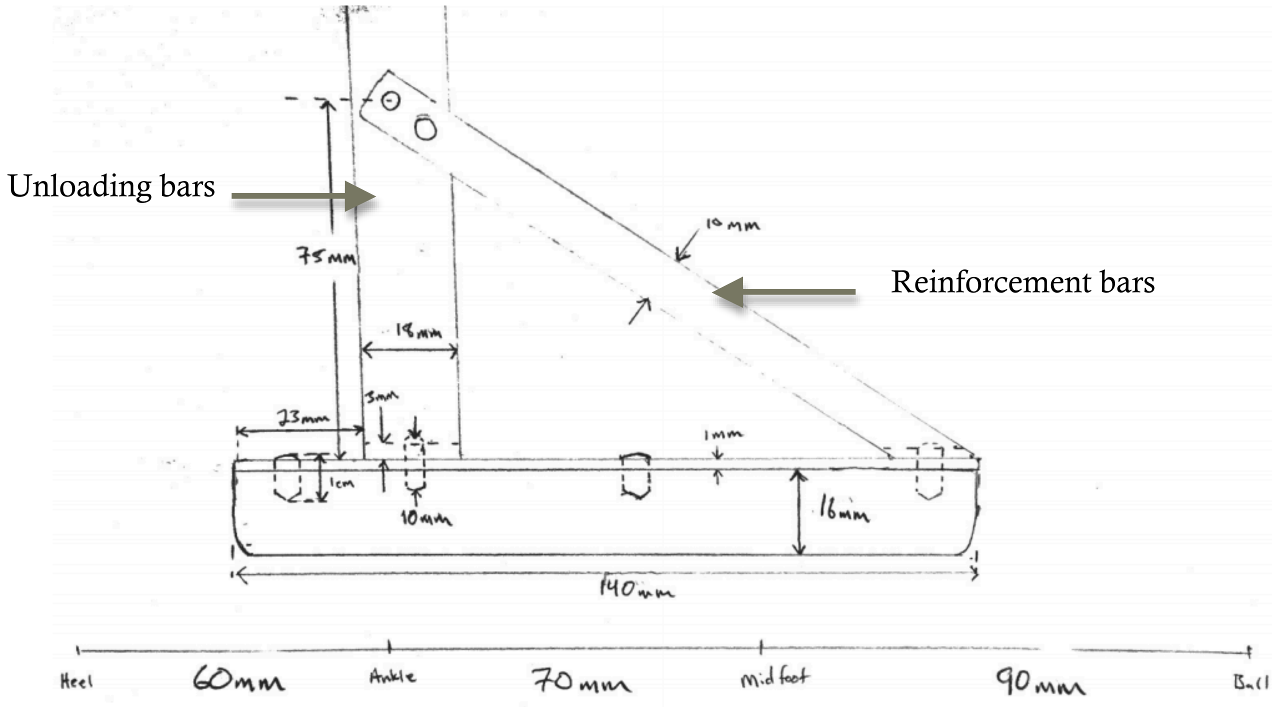


Figure 3.5.1: Footplate Schematic - Side View

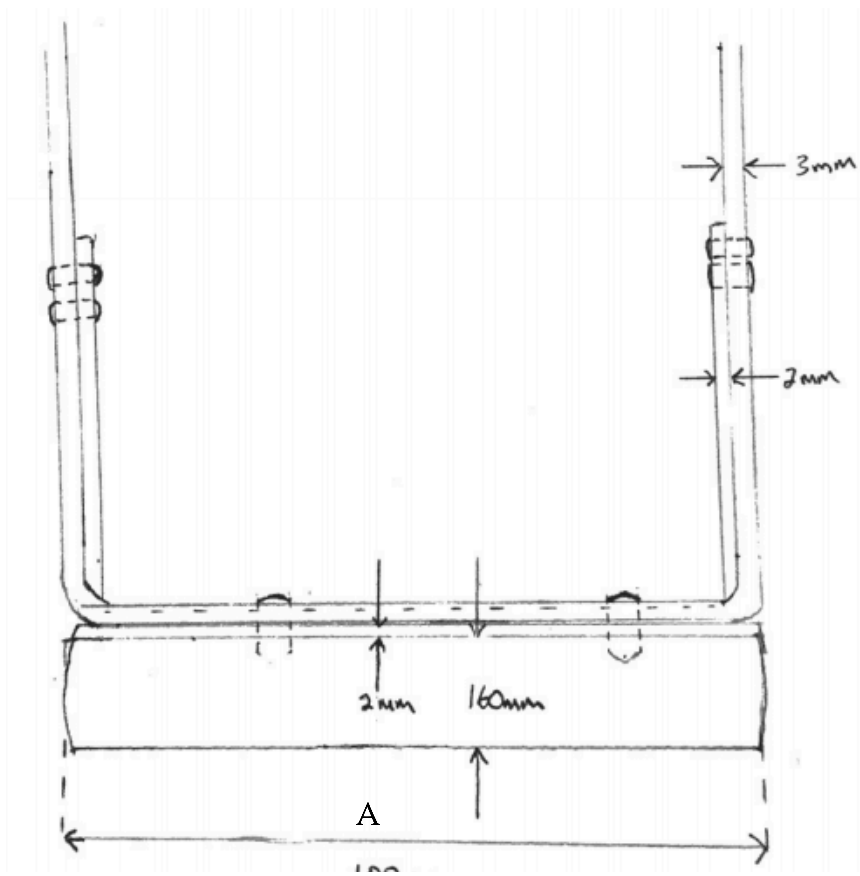
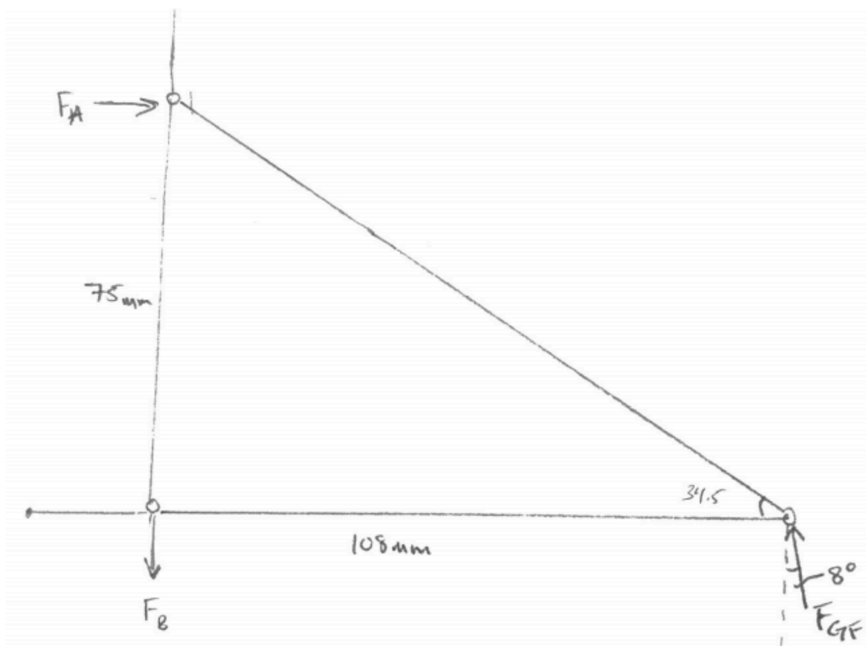


Figure 3.5.2: Footplate Schematic - Back View

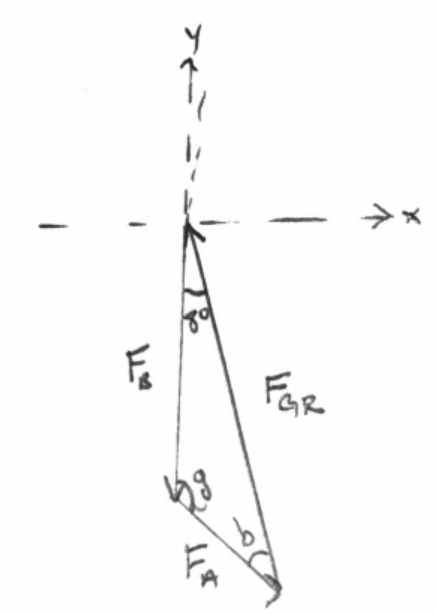
The width of the brace (A) varies based on the size of the user. This width in figure 3.5.2 differs from the design in 3.3.2 in that the user can don the brace posteriorly. This allows the width to be narrower since the front of the shoe will not have to slide through. Furthermore, the posterior donning method gives the user the option to put on their orthotic shoe before donning the brace, which will allow for easier donning of the brace. Here, the width will be selected by measuring the width of the users shoe at the region of the malleolus. Then, 20mm will be added to this length. For example, for a median user of 97mm the width and the malleolar region a corresponding size 8.5 shoe measured 75mm. Thus, the footplate width was selected to be 95mm.

The length of the orthosis will be chosen in the same manner as in section 3.5.2. The median length will be chosen for calulations.

Calculations:
The unloading attachment assembly must be designed to withstand the forces from the weight of the user and corresponding GRFs, while remaining in static equilibrium. A simplified model of the footplate is created to show the forces that are acting on the design.



Here, F_A is the force between the unloading bars and the reinforcement bars, and F_B is the force of the users bodyweight being pushed down into the footplate. In order for the footplate to truly be in equilibrium the forces must obey the rule of triangles. That is, that the vector diagram of the forces must produce a closed triangle. The direction of F_A is unknown, however, the direction of F_B will along the unloading bar and the magnitude may be assumed to be equal to the weight of the user. With this information, the vector diagram may be constructed.



Using the Law of Cosines the magnitude of F_A is calculated:

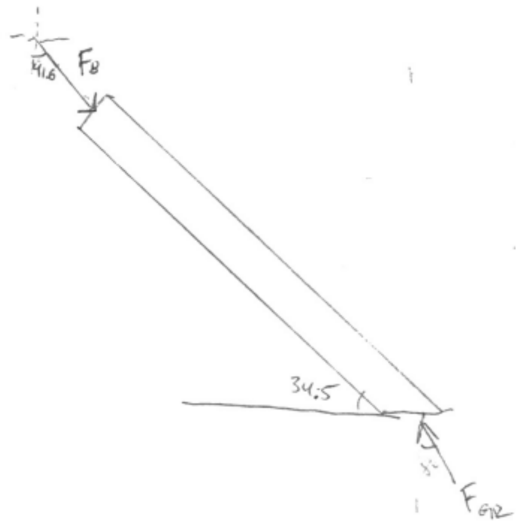
$$F_A^2 = F_{GR}^2 + F_B^2 - 2F_{GR}F_B\cos(8°)$$
$$F_A = 617N$$

Where F_{GR} is 2943N and F_B is 2452N corresponding to the maximum range values. Once the magnitude is determined the angles may be calculated using the Law of Sines to find the position of the vectors:

$$\frac{\sin(8°)}{F_A} = \frac{\sin(b)}{F_B} = \frac{\sin(g)}{F_{GR}}$$

$$b = 33.6°$$
$$g = 138.4°$$

Now that the magnitudes and directions of the force vectors are known the force vectors may be used to see their impact on the individual beams. For the reinforcement beams the force vectors in the direction of the beam are calculated.



Where F_R is the sum of the forces acting in the direction of the reinforcement beam. The forces are compressing the beam and thus they are added together to determine the total compressive force. This is compressive force is calculated to be 2587N. In reality, this force will be distributed to two beams, one on the medial and lateral side of the footplate. Thus, by halving the resultant vector and dividing it by the cross sectional area (A) the stress on the beam may be determined:

$$F_R = F_{GR}\cos(47.5°) + F_B\cos(13.9°)$$
$$F_R = 2587N$$

Thus, the stress on the beam is 43.1MPa. The value of this stress is analyzed in the section (3.5.2) to determine if the selected material is capable of withstanding this stress.

For the compressive force on the unloading bars it is most useful to calculate while the GRF is vertical, and not at toe off. This calculation is the done using three times the body weight of the user, and is the same as in section 3.3.2. The compressive stress on the unloading bars is 70.6MPa, which is within the yield strength range of the selected material, 2024 Aluminum, indicating that it will not plastically deform.

Sagittal Forces on Corset

The unloading attachment design will induce sagittal forces on the corset at the anterior and posterior shells. As seen in section 3.3.2 these forces are the result of the GRF. The summation of the forces occurring on this design will be the same as in design one. The horizontal force induced on the anterior shell was calculated to be 409.5N, and pushes on the proximal half of the shell. Dividing this force by the surface area of the proximal half of the anterior shell the resulting pressure on the leg is determined. This pressure is calculated to be 52kPa. This value represents the additional pressure on the corset at toe off. Thus, the total pressure on the corset at toe off will be the normal stress plus the additional pressure. This yields a total pressure range of 66.1kPa – 169.1kPa, which is below 417kPa and thus determined to be safe for the user. The horizontal force component on the calf shell was found to be 255N, which yields a pressure of 17kPa. Combined with the normal stress on the corset this gives a total pressure range on the leg from 31.1kPa – 134.1kPa at heel strike. These values are below 417kPa and thus are determined to be safe for the user. A comparative analysis of these values is seen in the section 3.6.

3.5.2 Materials

The materials for this design are the same as for the unloading attachment design 1 (3.3.2). The consistency between materials allows for an analysis of how the design changes affect weight, cost, and capability of handling forces. Calculations are run to determine the weight and cost of the material based on the dimensions of the new design.

Table 3.5.1: Weight and Cost of Unloading Attachment 2

	Material	Density (kg/m^3)	Volume (m^3)	Weight (kg)	Cost (euro)
Unloading Bars	2024 Aluminum	2800	5.08E-5	0.1421	1.15
Reinforcement Bars	Al Flat Bar	2700	7.31E-6	0.0197	3.61
Footplate Sheet	Al 5052-H32	2860	1.40E-5	0.0400	3.36
Sole	Rubber/ Neoprene	1200	2.24E-4	0.2688	35.5
Total:				**0.4706**	**43.62**

The weights are calculated based on the volume of each material being used in the design multiplied by the density of the material. The costs shown are the prices for the material required to make the part and includes extra material overlap. The material for the unloading attachment will weigh 0.47kg and cost 43.62euro. This is 0.062kg lighter and 0.65 euro cheaper than the unloading attachment in section 2.2. Thus, it is determined that the two designs are both cost and weight comparable.

The cross sectional area of the unloading bars is the same as design 1. Thus, the unloading bars must be able to withstand a stress of 70.6MPa, which is below the yield strength of 2024 Aluminum (280MPa) and thus is determined that the material is feasible. In section 2.4.1, the stress on the reinforcement bars was calculated to be 43.1 MPa. The bar plastically deforms at 240MPa, and thus it will be capable of withstanding this stress.

Table 3.5.3 shows the weight and cost for both the unloading attachment and then the total combined weight and cost for the orthosis.

Table 3.5.2: Weight and cost of the orthosis

	Weight (kg)	Cost
Unloading Attachment	0.47	43.62
Corset	0.19	20.54
Total	**0.66**	**64.54**

The total weight of the orthosis is 0.66kg, which meets the requirement of the design weighing less than 2kg. The cost for the material components alone is 64.54euro, which is more expensive than the 47.28euro cost of design one. This may be attributed to the addition of the ladder straps. With the addition of a prosthetic sock the price will raise to approximately 74.54euro. The cost estimate does not account for shipping or manufacturing costs. Factoring in a labor cost of 30.05euro and an additional 30euro for estimated shipping brings the total cost to 134.59euro for the brace. This number is below 175euro and thus meets the requirements of the design.

3.6 Summary

3.6.1 Design 1:

Corset 1:

The corset is a two-shelled patella bearing design. The median surface area of the design is $0.13m^2$. The maximum shear stress between the corset and the leg was calculated to be 11.6kPa – 58.2kPa for a range of expected users. This range is below the maximum shear experienced by in transtibial socket users (61.9kPa). The maximum normal stress required to brace the corset without slipping is 27.1kPa – 135kPa, for a range of expected users. This range is below the maximum normal stress experienced by transtibial socket users during ambulation (417kPa). An additional pressure on the anterior corset occurs at toe off, and is calculated to be 55.3kPa. This yields a total value pressure range of 71.5kPa – 190.6kPa at toe off. The loading response following heel strike induces a pressure of 28.7kPa, which yields a total pressure range on the corset of 44.9kPa – 164.0kPa following heel strike.

The material weight and cost of the corset is shown in table 3.6.1:

Table 3.6.1: Weight and Cost of Corset 1

	Material	Weight (kg)	Cost (euro)
Shell	ATP - PP	0.121	0.749
Foam	Pedilin SilverShore	0.0188	5.3
Straps	Pasow Velro	0.0204	1.12
Total:		**0.160**	**7.17**

Table 3.6.1 shows that the material cost for the corset, not including attachment materials, is 7.17euro. This cost estimate does not include shipping of the materials or work hours required to put the material together. However, the material cost provides a number that may be compared with the material cost of design 2 to observe the differences between the two designs. The weight for the corset is calculated to be 0.160kg.

Unloading Attachment 1:

The unloading attachment bars must withstand a stress of 70.6MPa induced by the weight of the user during ambulation. The aluminum bars can withstand a compressive yield strength up to 280N, and thus the bar will not plastically deform during ambulation. The reinforcement bars must withstand a stress of 68.7MPa, induced just before toe off. This value represents the maximum stress that will be induced on the bars. The yield strength of the reinforcement bars is 240MPa, and thus the reinforcement bars will not plastically deform during ambulation. The material cost and weight for the unloading attachment is shown below:

Table 3.6.2: Unloading Attachment Weight and Cost

	Material	Weight (kg)	Cost (euro)
Unloading Bars	2024 Aluminum	0.1421	1.15
Reinforcement Bars	Al Flat Bar	0.0197	4.26
Footplate Sheet	Al 5052-H32	0.0400	3.36
Sole	Rubber/ Neoprene	0.2688	35.5
Total:		**0.4706**	**44.27**

This shows that the total weight of the unloading attachment is 0.47kg. The material cost will be 44.27euro, excluding shipping and additional attachment materials.

Combined Design 1:

The total combined weight of the design is 0.63kg, which is below the maximum weight requirement of 2kg. The total cost of the materials is 51.44euro. The user is recommended to wear a prosthetic sock if slipping begins to occur, which raises the cost to 61.44euro. Factoring in shipping and work hours the total of the orthosis is estimated to be 117.33euro.

3.6.2 Design 2:

Corset 2:

This design relies solely on hydtrostatic compression of the leg. The median surface is $0.15m^2$. The maximum shear stress, τ_{max}, is calculated to be 6.2kPa – 51.5kPa for a range of expected users. The maximum normal stress on the user during ambulation, σ_{max}, is calculated to be 14.1kPa – 117.1kPa. Both of these values are below the maximum values experienced by transtibial socket wearers during ambulation and thus are determined to be safe for the user. An additional pressure on the anterior shell occurs during toe off. This pressure is calculated to be 52kPa, which creates a total pressure on the socket of 66.1kPa – 169.1kPa just before toe off for an expected range of users. Following heel strike there will be an additional pressure of 17kPa on the posterior shell. This creates a total pressure of 31.1kPa – 134.1kPa during heel strike for an expected range of users.

The material cost and weight of the corset is shown below:

Table 3.6.3: Weight and Cost of Corset 2

	Material	Weight (kg)	Cost (euro)
Shell	ATP – PP	0.1207	0.75
Foam	Pedilin SilverShore[24]	0.0188	5.30
Straps	Pasow Velcro[]	0.0204	1.12
	Ladder strap w/ push release[25]	0.0164	13.45
Total		**0.194**	**20.92**

The total material cost of the corset is 20.92 euro. However, in this design additional straps were added ensure a good distal fitting. By omitting these straps and keeping consistent with design 1, the total cost would be 7.17euro.

<u>Unloading Attachment 2:</u>
The unloading bars must withstand a calculated stress of 70.6kPa. This is the same value as in design one, since the cross sectional area of the bars and the force of the user remains unchanged between the two designs. This value is below the yield strength of 2024 Aluminum (280MPa) and thus the bars will not plastically deform under the stress of the user.

The reinforcement bars undergo a maximum calculated stress of 43.1MPa just before toe off. This represents the maximum stress the bars will undergo during gait, and is below the yield stress for the aluminum material (240MPa). Thus, the bars will not deform during gait. The material weight and cost is shown in table 3.6.4:

Table 3.6.4: Weight and Cost of Unloading Attachment

	Material	Weight (kg)	Cost (euro)
Unloading Bars	2024 Aluminum	0.1421	1.15
Reinforcement Bars	Al Flat Bar[26]	0.0197	3.61
Footplate Sheet	Al 5052-H32	0.0400	3.36
Sole	Rubber/ Neoprene	0.2688	35.5
Total:		**0.4706**	**43.62**

Table 3.6.4 show the total weight of the unloading attachment is 0.47kg and the total material cost is 43.62euro.

<u>Combined Design 2:</u>
In total, the weight of the orthosis will be 0.66kg. The total material cost is 64.54 with the additional ladder straps, and 51.09 without. Including the estimated costs of shipping, work hours and the addition of the prosthetic sock the total cost of the design is 134.49 euro.

Comparison:
Table shows a comparison between design 1 and design 2:

Table 3.6.5 Comparison between design 1 and 2

	Design 1	Design 2
Bony Tuberosities to be un-weighted	7	2
Contact Area (m^2)	0.13	0.15
Max. Shear Stress (kPa)	58.2	6.2 – 51.5
Max. Normal Stress (kPa)	135.5	117.1
Pressure at TO (kPa)	190.6	169.1
Pressure at HS (kPa)	164.0	134.1
Stress on Unloading Bars (kPa)	70.6	70.6
Stress on Reinforcement Bars (kPa)	68.7	43.1
Weight (kg)	0.63	0.62
Cost (euro)	117.33	121.04

The weight and cost of design 2 are without the additional ladder straps to maintain a consistency between the designs. It may be observed that the pressures and stresses experienced in design 2 are consistently lower than in design 1. This may be attributed to the slightly larger contact area of design 2, and the shape of the design as well. The weight and cost is comparable between the two. To further distinguish between these designs each is graded with respect to the requirements and wishes.

3.7 Grading

Corset designs 1 and 2 are graded against each other, and unloading attachment 1 and 2 should be graded against each other. These designs are graded with respect to the requirements and wishes set in the analysis phase. Below is a the grading system for the corset designs:

Corset Grading System

Table 3.7.1 is a grading system for the corset designs. For each box a grade between 1 and 10 is given (1 = poor 10 = excellent)

Table 3.7.1: Corset Design Grading

	Design / Requirements	1	2
Effectiveness	Secures the leg such that no slipping occurs	8	9
	Accounts for leg volume change over time	8	8
	Adjustable by the user	8	8
	Capable of attaching to an unloading device	9	9
Usability	Mobility (standing, walking, sitting)	7	7
	Can be used daily	7	7
	Weight	8	9
	Can don & doff by the user	6	8
	Can be used by users of various height and weight	6	6
Cost	Below 100 euro to manufacture	3	3
	Can be built using local materials	6	6
	Ease of manufacturing	7	7
Durability	Can last for up to a year	7	8
	Weatherproof (won't rust, overheat, etc)	6	6
Safety	No sharp edges	7	7
	Distributes pressure in such a way that does not harm user	8	8
Total		**111**	**116**

For the corset, design two scored higher. The grading system from the unloading attachment is shown below:

Unloading Attachment Grading System

Table 3.7.2 is a grading system for the unloading attachments. For each box a grade between 1 and 10 should be given (1 = poor 10 = excellent).

Table 3.7.2: Unloading Design Grading

	Design / Requirements	1	2
Effectiveness	Does not come into contact with foot/shoe	7	7
	Capable of attaching to the corset	8	8
Usability	Mobility (standing, walking,	8	8

	sitting)		
	Weight	8	8
	Can be made for users of various heights and weights	5	5
Cost	Cost to manufacture	7	7
	Can be built using locally available materials	7	7
	Ease of manufacturing	7	8
Durability	Can last for up to a year	6	6
	Weatherproof (materials won't rust, overheat, etc)	5	5
Safety	No sharp edges	8	8
	Provides stability while standing	8	8
	Won't slip when in contact with the ground	7	7
Total		91	91

The unloading attachments did not differ in grading with respect to the grading system. Design 2 showed fewer bony tuberosities, lower shear and normal stress and lower stress on the corset and reinforcement bars. The corset for design two also scored higher than design 1 with respect to the requirements and wishes for the design. From this, it is determined that design two is better fit for the needs of patients at Dr. Soetomo hospital and is selected for continuation to synthesis III.

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4 Synthesis III

4.1 Introduction:

In synthesis III the final concept that was selected in synthesis II is prototyped. The prototype is analyzed and alterations are made. The final design is detailed, technical drawings are generated, the manufacturing process is described, and a risk analysis of the final product is created.

4.2 Initial Prototype:

The final design from synthesis II is prototyped to observe its dimensions with respect to the user and further verify is efficacy. The prototype is constructed of wood, cardboard, fabric liner, two Velcro straps, and two push-release straps. Its chief purpose is to provide a visual representation of the orthosis, not a functional one.

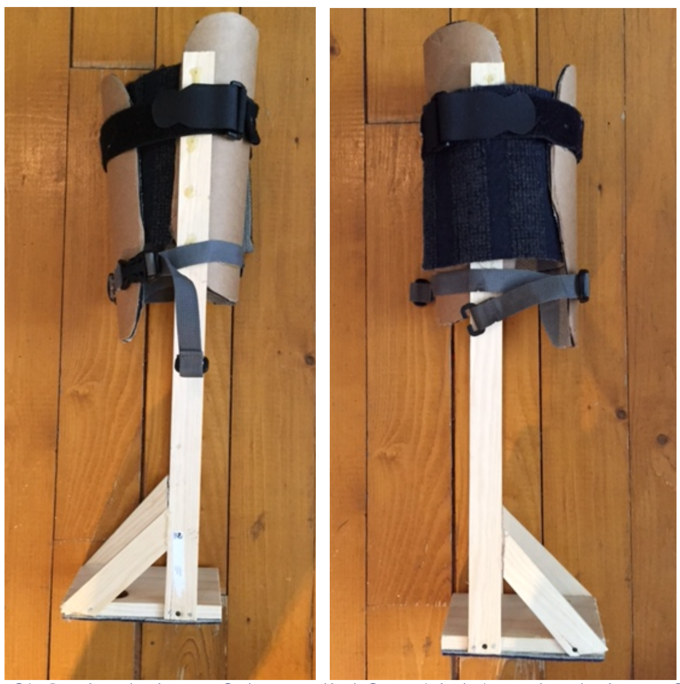


Figure 4.2.1: (left) Sagittal view of the medial face (right) sagittal view of the lateral face

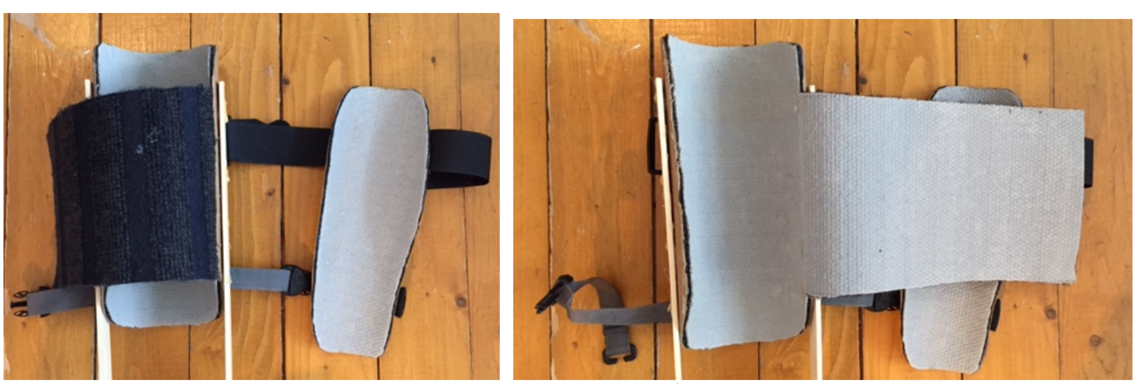


Figure 4.2.2: Frontal view of the corset

Figure 4.2.3: Top view

4.2.1 Donning and Doffing

Although the prototype as a whole is not intended to be functional, tests may be conducted to determine its feasibility such as donning and doffing the corset. These purpose of these tests are to:

(1) Observe the users response to donning the brace
(2) Determine problematic areas that may arise for the user.
(3) Determine the corsets capability to adjust for changing leg volume between users.
(4) Determine if the prototype meets the requirement of donning the brace in under two minutes

The orthosis was donned and doffed by two able-bodied users. User 1 is: 92kg, 181cm and 23yrs, and the user 2 is 84kg, 176kg, and 27yrs. Each user had no previous experience with the brace. Each user donned and doffed the brace three times from a seated position. When the user is given the brace the frontal shell is already strapped at the medial side. The task given to each user to don the brace is as follows:

- Place their right leg into the corset
- Overlay the frontal liner
- Overlay the frontal shell
- Secure the shell (first laterally then medially) so that the shell is aligned symmetrically about the tibia
- Verbally indicate when all straps are tightened

The task for doffing the brace is as follows:

- Un-strap the frontal shell
- Remove the leg from the brace

Donning time is measured from the moment the user grabs the brace to the moment it was secured and tightened on the leg, which is verbalized by the user and afterwards checked by a supervisor. The doffing time is measured from the moment the user began to un-strap the corset to the moment the leg is completely out of the brace. Comments from the users are noted regarding what they found easy and difficult.

4.2.2 Results

Each user was capable of donning and doffing the prototype without additional help. After two practice trials it was determined that the user was familiar enough with the brace and time was measured for the third trial. Table 4.2.1 shows donning and doffing time after the third trial.

Table 4.2.1: Donning and doffing time

	User 1	User 2
Donning Time (s)	74	91
Doffing Time (s)	8	10
Total:	82	101

Table 4.2.1 shows that the total time to don the brace was 82 seconds for user 1 and 101 seconds to for user 2. Both of these times are below the requirement of 5 minutes and within the wishes of 2 minutes as seen in section 1.6.

4.2.3 Analysis

The users showed that they were capable of adjusting the prototype and securing it to their leg by themselves. Furthermore, they showed that they were capable of donning the brace within the time requirement of two minutes. The dimensions of the prototype were not specific to the user; however, each user secured the corset tightly to their leg indicating that the corset could adjust to the variation in volume change. During the donning and doffing process no discomfort was noted from the users.

Observations were noted during the testing process. From these observations a few problems with the prototype were detected.

<u>Problem 1:</u>
The most time consuming part of the donning process was securing the frontal shell. Each user experienced difficulty holding the frontal liner down while strapping the frontal shell in place. Both users noted this difficulty in their comments.

<u>Solution 1:</u>
This problem is accounted for by including Velcro to the frontal liner and the lateral face of the unloading attachment bars. This will allow the user to secure the frontal liner in place before securing the frontal shell. The additional Velcro will be on the face on the liner that

comes in contact with the brace. The Velcro will extend the length of the liner and have a width of 5cm and will cost 9.66 euro for a 5-meter role (1.07euro/brace).[1]

Problem 2:
For user 1 the frontal liner nearly extended past the posterior loops that the Velcro straps are intended to pass through (seen in figure 4.2.1). This issue made strapping the brace on the lateral side more difficult for user 1.

Solution 2:
The orthotist will trim the liner to the dimensions of each patient. However, in the case of a significant volume decrease this issue may arise again. Placing the posterior loops more central on the posterior corset will increase the distance between the loops and the frontal liner so that the liner should not come in contact with the loops.

Problem 3:
Each user noted that the distal buckle straps were harder to tighten than the Velcro straps. The reasoning for this is twofold: Firstly, the user had to pull the straps in the distal posterior direction, which was found to be awkward for the user. Secondly, the internal bar within the buckle makes it difficult for the strap to slide past. This bar is designed to restrict the backward motion of the strap so the unit may remain tight, however, it also seems to restrict forward motion as well.

Solution 3:
These straps are intended to be Velcro (same as the proximal straps). However, due to an insufficient quantity of Velcro straps buckle straps were placed on the prototype. Thus, this problem should not exist in terms of the intended design. However, to further increase the efficiency and ease-of-use of these straps the Velcro could be replaced by ladder straps with a ratchet buckle. This would increase the tensile strength of the straps and allow for a more fine-tuned tightness by the user. This would also increase the cost of brace. The inclusion of the ladder straps is further explored in section 4.3.2.

To provide a further analysis of the efficacy and functionality of the orthosis a functional prototype must be constructed.

4.3 Prototype Additions

The design and its initial prototype represent the most basic form of the orthosis that will efficiently brace the leg and account for volume change. This is done to reduce cost while still meeting the requirements and wishes for the product. However, additional upgrades and design considerations are possible. This section focuses on design considerations that may improve the quality of the orthosis while remaining within the 55euro that leftover in the project budget from synthesis II.

4.3.1 Thermal Regulation

In Surabaya the high temperatures may cause discomfort to the user if no airflow can reach the leg. The current prototype does not allow for any form of airflow, thus, perforations to the shell and foam liner are included and evaluated to see their effect on the design. Ideally, the perforations would be at the medial and lateral faces on the corset since less pressure will be experienced at these regions during gait. However, due to the placement of the unloading bars this region is not possible to perforate. Thus, holes are placed on the anterior and posterior faces instead, and an inner liner is introduced to reduce the effect of edema and extra pressure from the holes on the leg. Figure 4.3.1 below represents a few considerations for the size, spacing, and alignment of the perforations in the posterior shell. Of note, the anterior shell will have no perforations along the tibia so that pressure does not increase at that area.

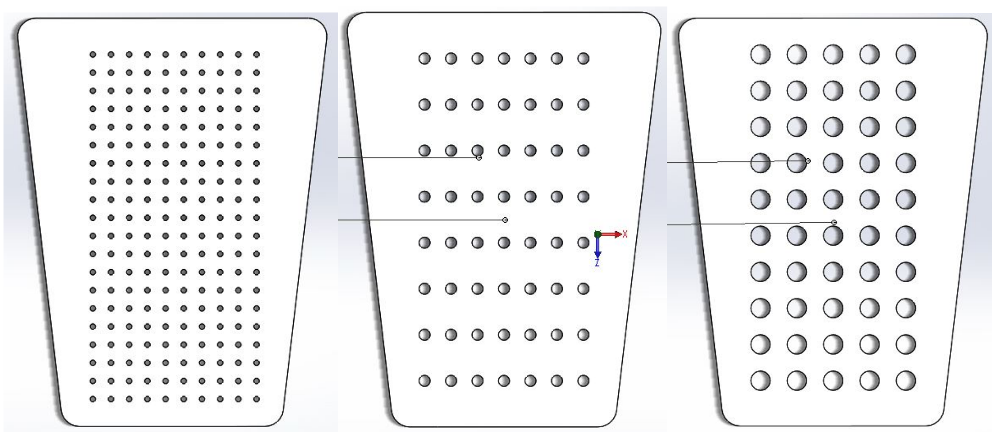


Figure 4.3.1: variation in hole diameter and distribution on the posterior shell (left: 3mm, center: 6mm, right: 10mm)

Figure 4.3.1 shows the size distribution of the holes while keeping the area of the spread constant. The left shell has hole diameters of 3mm, the center shell is 6mm, and the right shell is 10mm. With smaller holes the surface area and structural rigidity are preserved. However, small holes may require a drill press or an automated drilling machine. If this is not available in Surabaya, the workshop can heat a drill bit and make the perforations by hand.

The inclusion of perforations to the design requires an analysis of its effect on the surface area of the shell. The surface area of the corset should be maximized in order to reduce the shear and normal stress on the leg of the user. Yet, the perforations should be widely distributed to provide airflow to as much of the leg as possible. Thus, a balance must be met. The table below shows the original surface area as well as the surface area of the perforated shells.

Table 4.3.1: Effect of perforation diameter on surface area

	No perforation	3mm	6mm	10mm
Number of holes	0	200	56	45
Surface area (mm^2)	32814	30929	31758	31400
% Decrease		5.7	3.2	4.3

Table 4.3.1 shows that the 3mm diameter would require 200 perforations to be done by hand if a drill press is not available. This would be quite cumbersome for the orthotist. Thus, the 3mm diameter is ruled out. The reduction in surface area ranges form 3.2% to 5.7%. Since the goal is to maximize surface area, and the 6mm hole distribution shows the least impact to the surface area, it is ranked as the best choice in this category. Insofar, the 6mm diameter and distribution is selected for the shell.

Inherently, the inclusion of holes in the shell and liner will cause an elevated pressure at the region with of the hole, especially if edema is present in the user. This happens because the skin will push out into the empty space as a result of compression. To alleviate this pressure another liner is introduced between the skin and the foam liner. This liner must be breathable, or else the effect of the holes would be useless. This liner will be the prosthetic sock that was introduced in synthesis II to aid in volume control. For a further look at the prosthetic sock see section 4.3.5.

For the liner, Pedilin Silvershield comes in pre-perforated form. However, for the cooling effect to be maximized the holes of the liner would have to match the holes of the corset, which may be difficult to do. Thus, drilling holes in both the liner and shell guarantees hole alignment and ensures airflow.

The inclusion of perforations to the shell also has an effect on the sanitation of the device. By allowing holes in the shell dirt and non-sanitary buildup can accumulate within these areas. Thus, it is recommended that the user clean the brace once a week using an anti-bacterial agent (wipes, spray, etc.).

4.3.2 Material Upgrades

Ladder Straps & Ratchet Buckles

Velcro straps are commonly used in leg orthoses. However, many designs upgrade to ladder straps and ratchet buckles to increase the tensile strength of the binding, make the tightness more easily adjustable for the user, and reduce the variation in tightness. By reducing the amount of variance at the distal end of the corset the orthosis will better utilize the conical shape of the leg and reduce the potential for slipping. Thus, the two distal

Velcro straps are replaced with ladder straps. The company m2, inc. offers thermoplastic buckles (6.75euro) and straps (3euro) that are designed specifically for orthopedic use and fit within the leftover budget established in synthesis II. Figures 4.3.2 and 4.3.3 show the strap and buckle design.

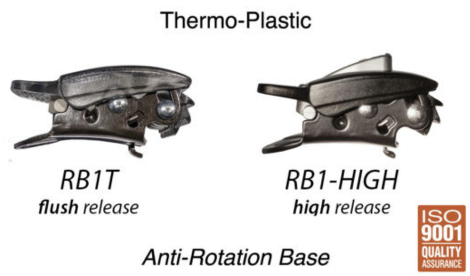


Figure 4.3.2: m2, inc. Ratchet Buckle Design

Specifications:

- Height: 22mm
- Length: 56mm
- Width: 36mm
- Weight: 36g
- Maximum Load: 230kg

Figure 4.3.3: m2, inc. Ladder Strap Design

Specifications:

- Length: 178mm
- Width: 25mm
- Material: Dupont Zytel® ST801

[m2, inc. Ratcheting buckles and Ladder straps. Accessed: June 16, 2017
https://www.ratchetingbuckles.com/ratchet-buckles-ladder-straps/]

4.3.3 Foot Sling (Optional)

Some users may experience a tendency to plantar flex their foot while using the brace. This may cause the foot of the user to hit the footplate or ground and apply pressure on the frontal region of the foot. If this occurs, a foot sling may be introduced to the design. The foot sling would connect the shoe of the user to the anterior shell of the corset. Thermoplastic bars can be drilled to the anterior shell so that the foot sling can be easily clipped.

4.3.4 Shoe Lift

The orthosis is designed to extend 4cm distal to the shoe. The footplate breadth is 2cm and the shoe should hover about 1-2cm above the footplate to prevent it from hitting the footplate. Thus, a 3-4cm shoe lift is needed on the shoe opposite the affected foot to prevent lop-sided gait. The shoe lift can either replace the sole of the shoe or be added to the sole of the existing shoe. The type of shoe lift should be recommended by the orthotist.

4.3.5 Prosthetic Sock

As noted in synthesis II, the inclusion of a prosthetic sock will be pivotal to accounting for volume change of the leg. Due to the inclusion of the perforations in the shell, the prosthetic sock will also act as a barrier between the leg and the corset and reduce the pressure from the holes. A 1-ply or 3-ply CoolMax Soft-Sock is introduced, which is knit polyester and lycra and allows for breathability as well as reduction in hole pressure.[2] Furthermore, the prosthetic socks come in various thicknesses. If the leg decreases significantly in volume a thicker sock may be used instead of having to reconstruct a whole new brace. See appendix A for size and dimensions of the sock, and section 4.6 for a cost analysis.

4.4 Finalized Detailing

The detailing for the final design of the orthosis is shown in sections 4.5 – 4.7. In these sections all parts required for assembly are identified, the material is specified, the configuration of the parts is shown, and manufacturing instructions are given.

4.5 Technical Drawings

The dimensions of the orthosis will be specific to each user. Thus, the intention of the following drawings is to show how the orthosis should fit on the leg and provide a reference for the location of the individual parts and full assembly. This is done to provide the orthotist with sufficient information to fabricate the orthosis. All variable dimensions will be identified by a letter.

4.5.1 Corset:

Figures 4.5.1 – 4.5.5 show the dimension of the corset

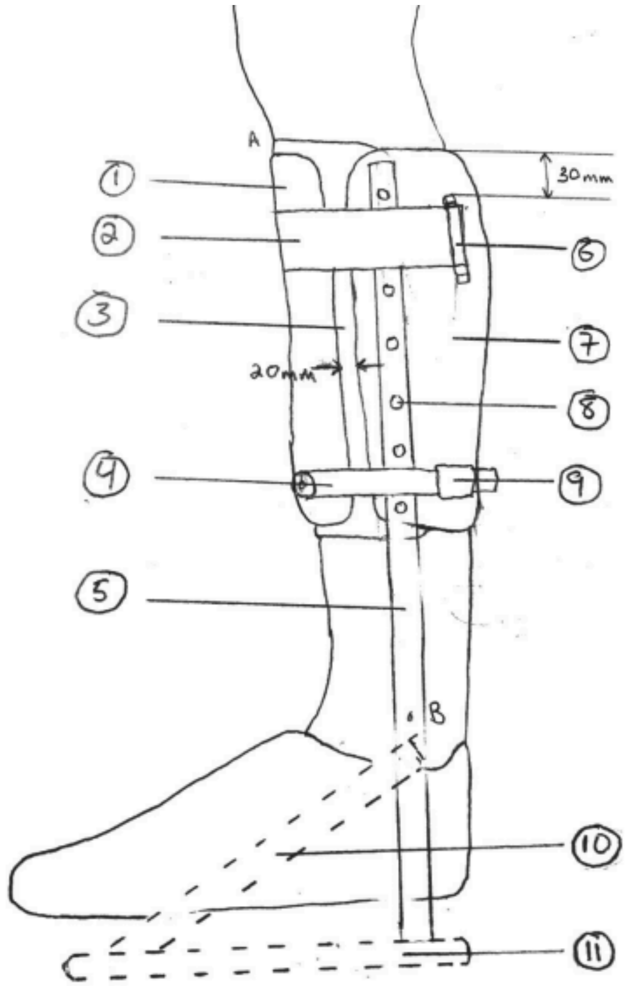


Figure 4.5.1: Components of the orthosis

- 1 – anterior shell
- 2 – Velcro strap
- 3 – frontal liner
- 4 – ladder strap
- 5 – unloading bars
- 6 – binding D ring
- 7 – posterior shell
- 8 – hole + screw
- 9 – ratchet buckle
- 10 – reinforcement bar
- 11 – footplate
- A – tibial tuberosity
- B – malleolus

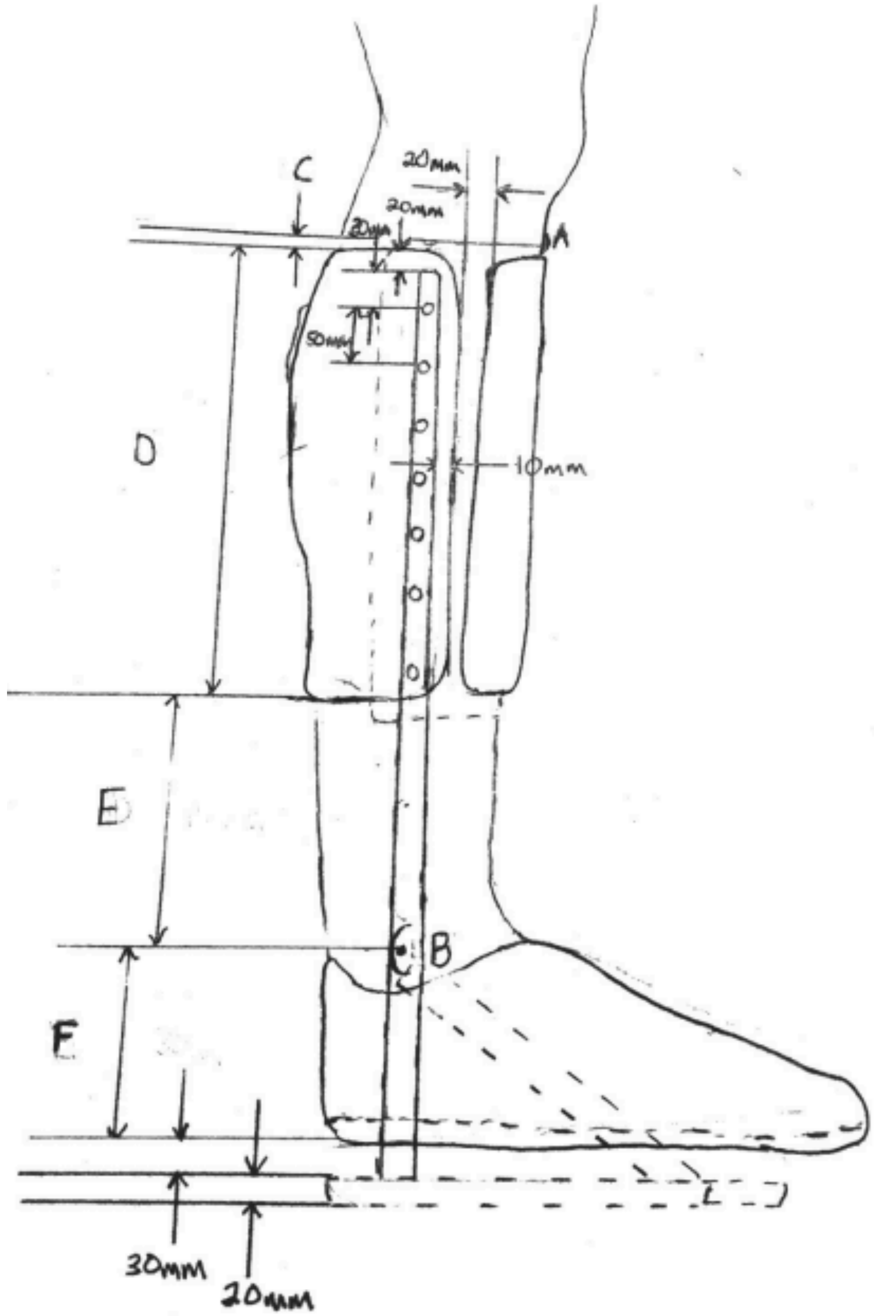


Figure 4.5.2: Dimensions of assembly

Figure 4.5.2 shows the dimensions with respect to the placement on the leg. The proximal end of the corset should be just distal to the tibial tuberosity. This will allow the user to sit and flex the knee without the brace coming in contact with the biceps femoris. The distal end of the corset should be proximal to the malleolus. The surface area of the corset should be maximized in order to keep pressure on the leg low. To provide a reference: In this case of a user of 175cm the proximal end of the corset was placed 10mm below the tibial tuberosity and the distal eng of the corset was placed 110cm proximal to the malleolus. The variable dimensions and their respective descriptions are listed as follows:

C – Distance from the tibial tuberosity to the proximal corset
D – length of the posterior shell (will be same as anterior shell, as shown in figure 4.5.3)
E – Distance from the malleolus to the distal corset
F – length from B to the bottom of the shoe

The length F will be dependent on the size/type of the shoe the user wears. The orthosis is designed so that the user may wear the shoe while using the brace. It is recommended that the same shoe should be worn each time. As was mentioned in section 4.3.4 a shoe lift should be placed on the shoe at the healthy foot. The shoe lift should be fit so elevates the healthy leg to a length equal to the distance between the bottom of the shoe to the bottom of the orthosis on the affected limb. This is to ensure that both feet are on the same transverse plane, which will help with balance and gait. If a user decides not to wear the shoe on the affected foot, the user will have to place a taller insert on top of the footplate when donning the orthosis to account to the change in length. Two inserts should be given to the user to account for both situations. For proper donning methods that account for these situations see section 4.8.

Figure 4.5.3 shows the placement of the straps with respect to the corset, as well as the placement of the anterior shell on the frontal liner.

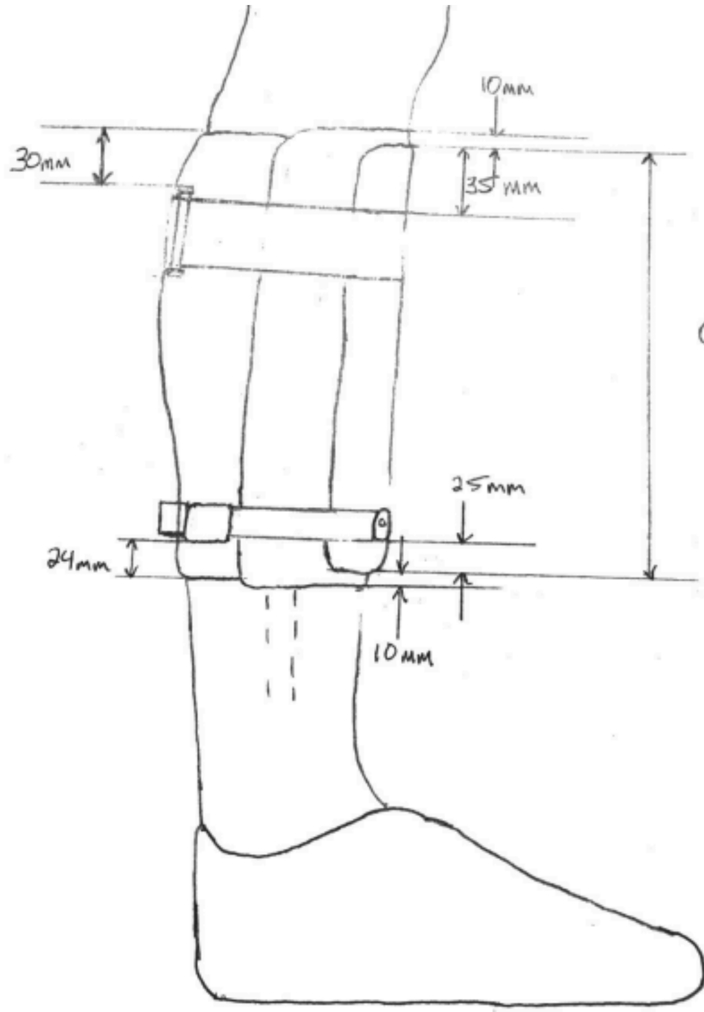
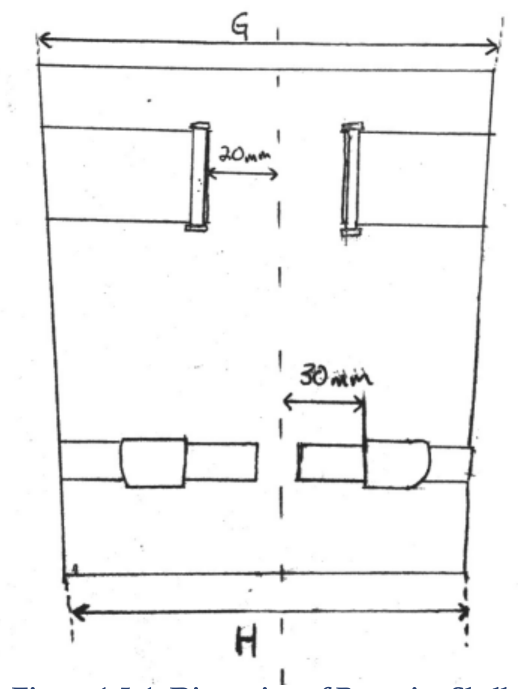


Figure 4.5.3: Dimensions of Strap and Liner Placement

Figures 4.5.4 shows the back view of the posterior shell, and figure 4.5.5 shows the front view of the anterior shell. Both views show the placement of the strap, buckle, and D loop attachments with respect to the center of the leg.



- G – Diameter of the leg measured just distal to the tibial tuberosity
- H – Diameter of the leg measured proximally to the malleolus

Figure 4.5.4: Dimension of Posterior Shell

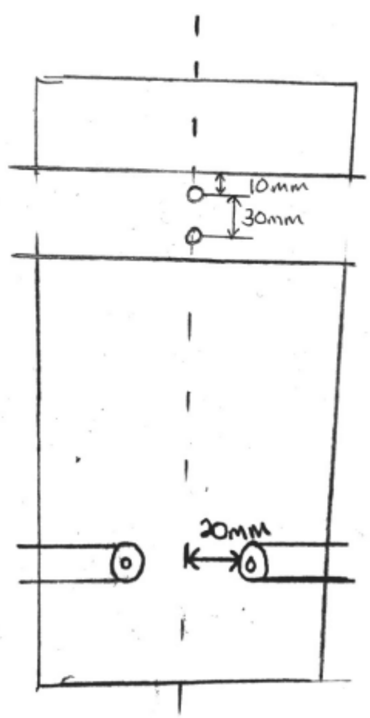


Figure 4.5.5: Anterior Shell

4.5.2 Unloading Attachment

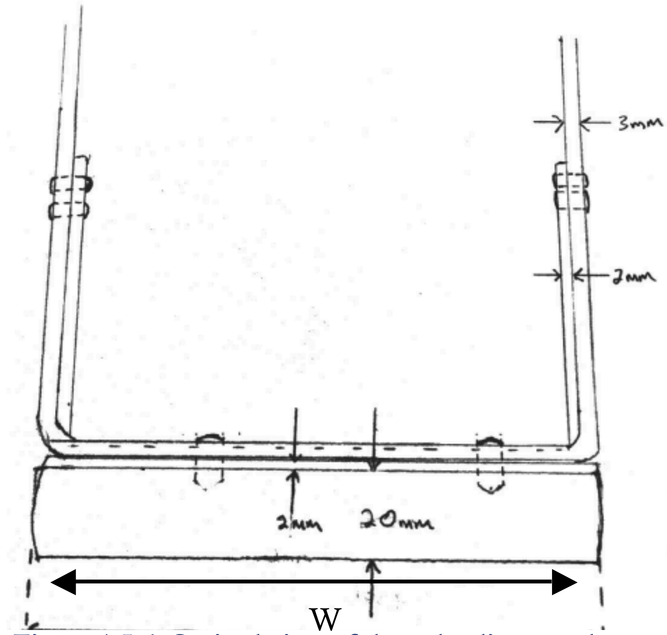


Figure 4.5.6: Sagittal view of the unloading attachment

Figure 4.5.6 shows the sagittal view of the footplate. The proximal material is a 70 durometer rubber pad described previously in synthesis II. This pad is 20mm and may be carved by the orthotist to fit the rocker profile needs of the user. The width of W is based on the size of the user. This width range is explained in section 3.5.2. The aluminum unloading bars are a fixed 3mm and the reinforcement bars are 1mm. Figure 4.5.7 shows the top view of the unloading attachment.

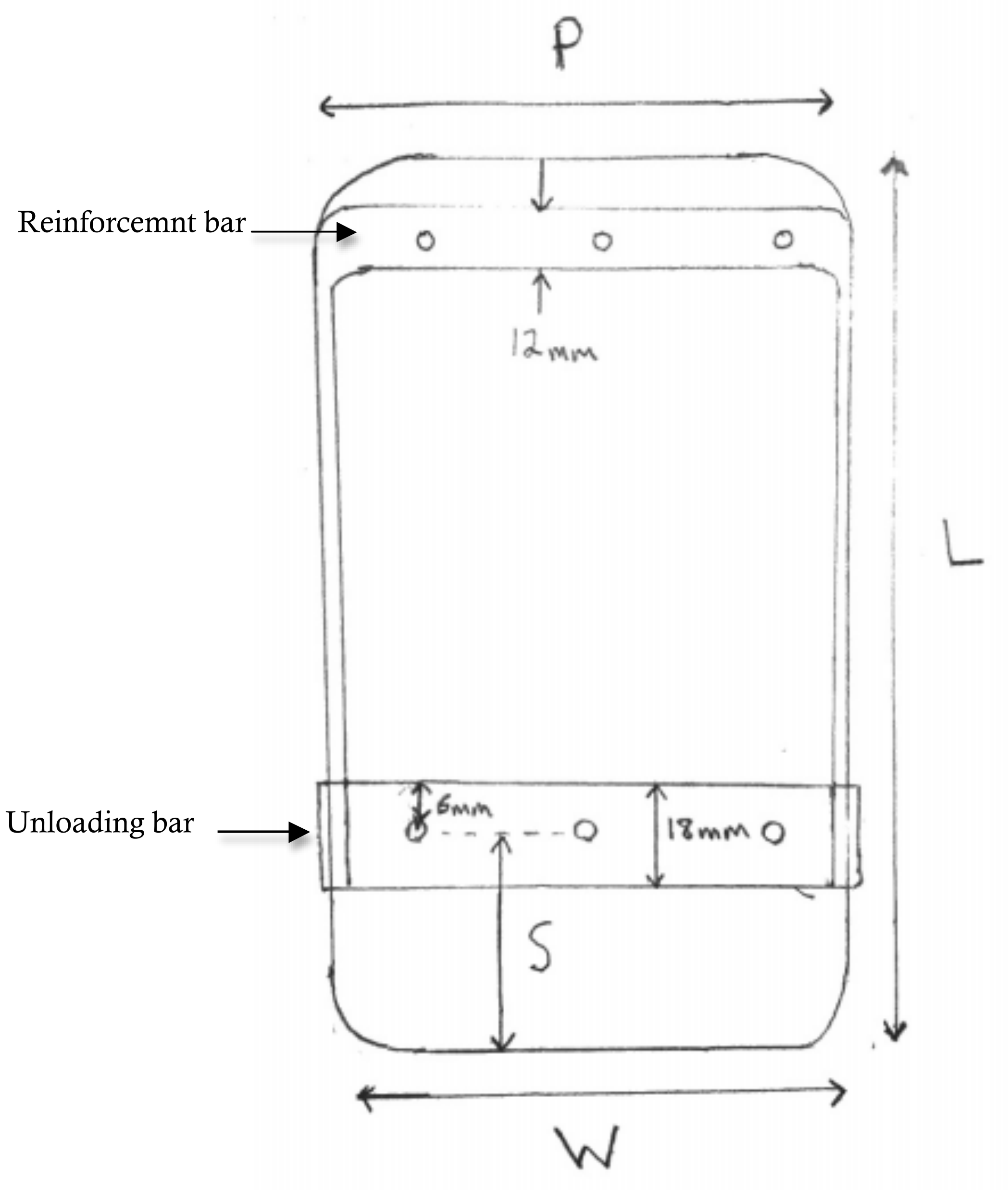


Figure 4.5.7: Top view of footplate

Figure 4.5.7 shows the dimensions for the footplate. The variable lengths are as follows:

W – proximal width of the footplate
L – length of the footplate
S – Distance between the malleolus and the posterior calcaneus
P – anterior width of the footplate

The length (L) changes based on the recommendations of the orthotist corresponding to the gait of the user (shorter stride → shorter length of footplate). The anterior width of the footplate (P) must be greater than the ball width of the shoe. Thus, the ball width should be measured and 10mm added to this length. As noted in synthesis II, the expected ball width ranges from 85 – 109mm. This measurement is only necessary if the length of the shoe extends past the ball of the foot. If not, the length of P should equal the length of W.

For a detailed analysis of the how to assemble the parts and make the orthosis see sections 4.7. The cost and list of all materials necessary for fabrication are shown below in section 4.6.

4.6 Bill of Materials & Cost Analysis

A bill of materials is provided to show the components that are necessary for manufacturing the orthosis.

Bill of Materials

Assembly Name :	VAFOO
Assembly Number :	Custom
Assembly Revision :	1
Approval Date :	
Part Count :	14
Total Cost :	€ 72.67

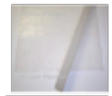
Part #	Part Name	Description	Qty	Units	Picture	Unit Cost	Cost
501	PP Sheet (610mmX610mm)	Polypropylene Copolymer Sheet for Corset Shell	1	each		€ 16.36	€ 16.36
502	Foam (5mm)	Pedilin Silvershield 35 Durometer Foam Liner	1	each		€ 5.30	€ 5.30
503	Rubber Sheet (0.8mm)	Silicone rubber liner for anterior shell	1	each		€ 1.25	€ 1.25
504	Cinch Straps (450X50mm)	Proximal Velcro Straps	2	each		€ 1.40	€ 2.80
505	Ladder Straps (25mm)	25mm polyurethane ladder strap	2	each		€ 3.06	€ 6.12
506	Buckle (25mm)	25mm thermoplastic ratchet buckle w/anti rotation base	2	each		€ 6.35	€ 12.70
507	2024 Al Flat Bar (3X18X6000mm)	Aluminum unloading bar	1	each		€ 1.15	€ 1.15
508	2024 Al Flat Bar (2X15X200mm)	Aluminum reinforcement bar	2	each		€ 0.44	€ 0.88
509	5052-H32 Al Sheet (305X305mm)	Aluminum footplate sheet	1	each		€ 3.36	€ 3.36
510	Rubber Pad (20mm)	Footplate Sole (Shore A 70 durometer)	1	each		€ 17.75	€ 17.75
511	MISC	Rivets, Screws, Adhesive, etc.	N/A	N/A		€ 5.00	€ 5.00
	Total		14			€ 61.42	€ 72.67

Table 4.6.1: Total Production Cost

Production Cost	
Description	Total Cost (€)
Raw Material	72.65
Prosthetic Sock[8]	20.00
Shoe Lift	10.00
Shipping	20.00
Labor	43.58
	166.21

According to the workshop in Surabaya the cost of labor for their current orthosis is 40% of the material costs. Thus, the labor is calculated as 40% of the material cost from the bill of materials. The total cost to make the brace is 166.21€.

4.6.1 Material References:

[501] Polypropylene Sheet Copolymer. http://k-mac-plastics.com/polypropylene-copolymer-sheet.htm Accessed June 16, 2017

[502] Pedilin SilverShield Tan. https://professionals.ottobockus.com/Prosthetics/Materials-Equipment/Padding-Materials/Pedilin-SilverShield-Tan/p/617S203 Accessed June 16, 2017

[503] Silicone Rubber Sheet http://www.ebay.com/itm/Silicone-Rubber-Sheet-High-Temperature-1-32-Thick-x-12-wide-x-24-/272484438565 Accessed June 16, 2017

[504] Velcro Cinch Straps https://www.amazon.com/1805-OW-PB-B-5-Nylon-Onewrap-Length/dp/B00I0TTU1S/ref=sr_1_11?s=industrial&ie=UTF8&qid=1498941819&sr=1-11&keywords=velcro+straps+heavy+duty Accessed June 16, 2017

[505] Ladder Straps https://www.ratchetingbuckles.com/ratchet-buckles-ladder-straps/1-ladder-straps-ls1/ Accessed June 17, 2017

[506] Themoplastic Ratcheting Buckle. https://www.ratchetingbuckles.com/ratchet-buckles-ladder-straps/1-ratcheting-buckle-wanti-rotation-tab-blacktanwhite/ Accessed June 17, 2017

[507] Alibaba – Aluminum alloy bars/duralumin alloy bars in China https://www.alibaba.com/product-detail/Aluminum-alloy-bars-duralumin-alloy-bars_60411789916.html Accessed June 3, 2017

[508] GAH. Alberts Clakke Strip 15x2 mm Aluminium zilver. http://www.hornbach.nl/shop/GAH-ALBERTS-Vlakke-strip-15x2-mm-aluminium-zilver-2-m/736390/artikel.html?varCat=S4788&WT.mc_id=nl14a999&origin={adtype}&WT.srch=1##v736390 Accessed June 3, 2017

[509] Aluminum Bare Sheet 5052 H32 https://www.onlinemetals.com/merchant.cfm?pid=7126&step=4&showunits=inches&id=240&top_cat=0 Accessed June 3, 2017

[510] Rubber Sheet, Neoprene Spring, Plain Backing Type. https://www.grainger.com/product/E-JAMES-Rubber-Sheet-WP165753/_/N-188k?breadcrumbCatId=16279&s_pp=false&picUrl=//static.grainger.com/rp/s/is/image/Grainger/1MTU1_AS01?$smthumb$webparentimage$ Accessed June 3, 2017
[8] Prosthetic Sock. https://www.amazon.com/gp/offer-listing/B00ZJT0J1M/ref=dp_olp_new_mbc?ie=UTF8&condition=new Accessed June 17, 2017

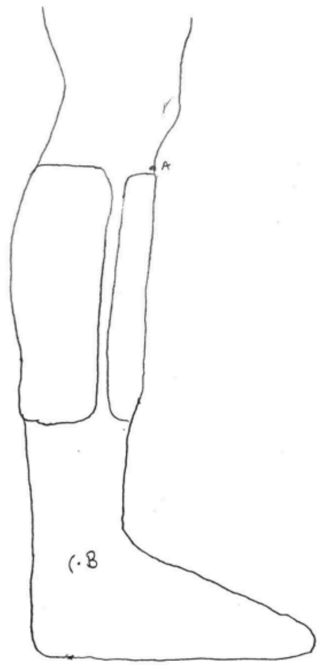
4.7 Description of Manufacturing Process

Below is a recommended process for fabricating the orthosis. The materials and required components for fabrication are listed in section 4.6. The process is a combination of recommendations from OIM Orthopedie, Ottobock, and the International Committee of the Red Cross. [3][4]

4.7.1 The plaster mold

- Create a plaster mold of the users leg
- Have the leg be 90degrees to the floor
- Mark the bony tuberosities and add plaster to those areas

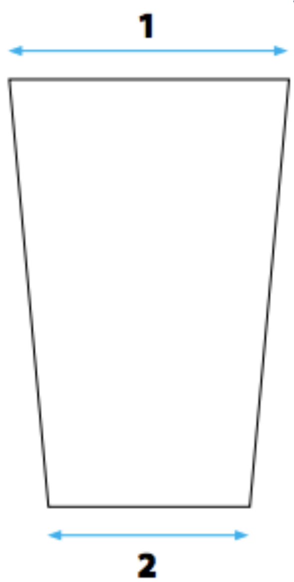
4.7.2 Orthosis Trim Line



Mark the orthosis trim line in marker on the positive mold

- Leave 2cm between the anterior shell and the posterior shell
- Mark the distal shell proximal to the malleolus (B)
- Mark the proximal corset distal to the tibial tuberosity (A)

4.7.3 Vacuum Forming



Polypropylene sheet (PP-C) size:
*Add 10cm to each dimension

- 1 – leg circumference just below the tibial tuberositu
- 2 – leg circumference proximal to the malleolus
- The length is determined by the distance between the two circumference measurements

[4]

- Set the oven to 155ºC (may be altered between 150-165C depending on the efficiency of the oven)
- Heat the PP-C sheet for 20-25min
- Wrap the PP-C sheet around the mold and stick it together on the anterior side (try to close the gap between the 2cm space in between the anterior and posterior shell)
- Tighten the PP-C sheet around the suction cone and fasten using a rope or elastic band, etc.
- Remove the excess PP-C with scissors
- Keep suction applied until PP-C is cool

4.7.4 Placing the Bars

[3]

- First, measure the distance from the bottom of the shoe just below the tibial tuberosity
- Then, add 4.5cm to this distance and the height will be known
- Measure the width between the bars by measuring the width of the shoe at the malleolus. Add 20mm to this width

4.7.5 Attaching the Footplate:

- Cut the rubber sole (510) to the desired size
- Mark aluminum sheet (509), cut, and screw on top of rubber sole
- Bore holes in distal unloading bars
- Screw bars to footplate
- Measure reinforcement bars, bore holes, and screw to footplate
- Bend bars and screw them into the unloading bars

[3]

- Draw the trim line on PP-C as done in section 4.7.2
- Shape the unloading bars to the mold
- Mark the holes that need drilling
- Bore the holes and screw the bars in place

4.7.6 Shaping the Shells


[3]

- Using an oscillating saw, cut around the trim line
- Remove the cut material
- Grind the PP-C edges to smooth them out
- Smooth all edges so that no sharp or harmful areas appear

4.7.7 Straps & Liner

- Attach the straps in accordance with figures 4.5.1 – 4.5.5
- Put in the liner
- Drill 6mm diameter holes in shell (see figure 4.3.1 center)
    - Avoid the straps

4.7.8 Finishing Touches

- Place a sticker, or similar, on the proximal anterior shell to indicate where the user should align the shell on the leg.
- Fit the opposite shoe with a shoe lift.
- Check the alignment on patient.

4.8 Donning Instructions:

<u>Standard Instructions (with original shoe):</u>

- Step 1: Place a ~2.5cm wedge on the top of the footplate
- Step 2: Step on the wedge and secure the calf in the posterior shell of the corset
- Step 3: Wrap the frontal liner over the front of the leg and secure it tightly with the Velcro
- Step 4: Place the anterior shell onto the frontal liner and align the sticker with the tibia to ensure proper fitting
- Step 5: Secure the straps of the shell (easiest when the two medial straps are already connected)
- Step 6: Fasten the straps so that the sticker on the anterior shell is aligned at the tibial protrusion.
- Step 7: Remove the wedge from under the shoe
- Step 8: Slowly begin to stand and gradually place weight on the affected limb
- Step 9: If no slippage occurs then the process is done. If the brace is not tight enough repeat the process from step 1.

<u>No shoe on insured foot:</u>

- Place a ~4.5cm wedge on top of the footplate (dependent on the thickness of the shoe sole)
    - Alternatively, the user could be given a 20mm shorter shoe lift to account to the height/fit difference
- Follow the standard instructions from step 2.

In both cases, the standard case and the no shoe case, a shoe with a shoe lift should be worn on the healthy leg.

4.9 Testing Phase: Classification & Quality Standards

<u>Classification:</u>

According to the European Commission (EC) it is the responsibility of the manufacturer to provide the classification of the medical device.[5] In this case the manufacturer is non-European Union and may set the classification based on the rules on regulations of their country. However, to insure that a safe product is developed the designer will also classify the device. is classified according to the European Union (EU) and European Free Trade Association (EFTA).

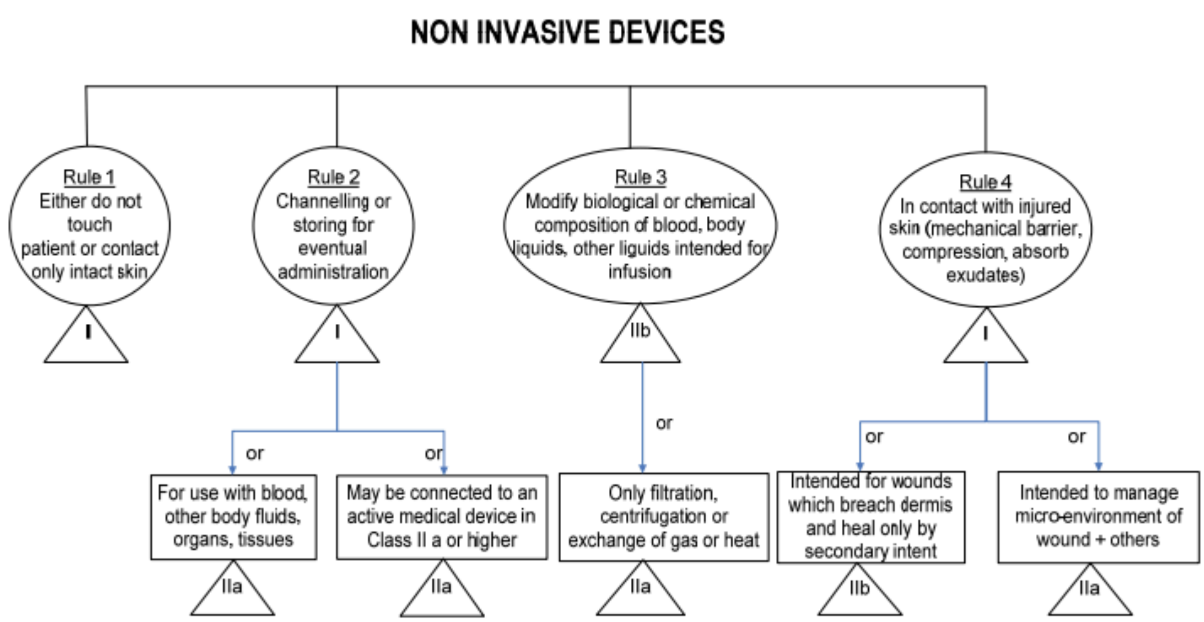


Figure 4.9.1: Rules for determining the classification of a medical device [EU]

The applicable rule(s) according to Figure 4.9.1 is rule 1, which states that the device either does not touch or is only in contact with intact skin, and potentially rule 4, which applies to devices that are in contact with injured skin. Due to edema and ischemia the skin may be damaged. However, this device should not be used if the skin is open (ulceration, miscellanioius open wound, etc.) and thus the device will fall under Class I. Furthermore, according to Annex IX of the medical device directive (MDD) all non invasive devices are categorized as class I, unless affected by rules 2-18 of the doctrine.[6] After reviewing the rules of the doctrine it is determined that the product is indeed a class I device. Because the product is categorized as a class I medical device it does not require a CE marking.[6].

The following quality standards are applicable to the orthosis:

General:

- ISO 13285: Medical Devices

Material in contact with the skin (Foam)

- EN ISO 10993: Biological Compatibility [3]
  - Part 5 (Cytotoxicity)
  - Part 10 (Irritation and Sensation)

Material Property Testing:

- ISO 1183: Density
- ISO 868: Shore Hardness
- ISO 178: Flexural Modulus
- ISO R527: Yield Strength (Tensile)
- ISO 527: Tensile Modulus

Device Labels:

- ISO 15223: Symbols and labeling information

4.10 Failure Mode and Effect Analysis

A failure mode and effect analysis provides a detailed description of possible risks or failures within the design. The risks are ranked and assigned a priority level in based on a combination of the likelihood of occurrence and the impact the failure will have. Then, risk prevention steps are identified to ensure that the failure does not occur. Of note, the risk is defined as: any circumstance that will negatively impact use of the foot unloading orthosis. Table 4.10.1 shows the list of possible risks

Table 4.10.1: List of Risks

Category	Description	Number
Requirement(s)	The requirement(s) are unclear	1.1
	The product does not meet the requirement(s)	1.2
	There are missing requirement(s)	1.3
Manufacturing	The product cannot be manufactured	2.1
	There is not enough information for assembly	2.2
	The parts do not fit together	2.3
	Some individual parts cannot be constructed	2.4
	The manufacturer does not have to tools to produce the product	2.5
	The product cannot be made to fit every type of leg	2.6
Functionality	The weight is not being unloaded from the foot	3.1
	The product cannot be adjusted for volume change	3.2
	The corset cannot be easily tightened or loosened	3.3
	The corset cannot be tightened enough	3.4
Time	Donning and doffing takes more than 5 minutes	4.1
Design	The materials are not strong enough to bear a patients weight	5.1
	The materials harmfully interact with the patients skin	5.2
	The device is too bulky for users to walk	5.3
	The product is too heavy for users to walk	5.4
Safety	The pressure on the leg is too great	
	The product has sharp edges that can harm the user	6.1
	This product can become too hot and burn the user	6.2
Cost	This product is greater than 175euro	7.1

Once the risks are identified the likelihood of occurrence is established. Table 4.10.2 shows the evaluation system for likelihood along with its corresponding score.

Table 4.10.2: Likelihood of risk

Likelihood	Description	Score
Very low	There is a very small chance this occurs during use	20
Low	This is a small chance of occurrence	40
Medium	There is a likely change of occurrence	60
High	There is a good chance this occurs	80
Very high	This is almost guaranteed to happen	100

Table 4.10.3 shows the categorization system for evaluating the impact each risk will have on the design.

Table 4.10.3: Impact of risk

Impact	Description	Score
Very low	Measurement of impact is too small to measure	20
Low	Low impact, Ex: <5% deviation of a specific calculated or measured value	40
Medium	Medium impact, Ex: 5-10% deviation of a calculated or measured value	60
High	High impact, 10-25% deviation of a calculated or measured value	80
Very high	Very high impact, Ex: >25% deviation of a calculated for measured value	100

Next, a priority level for the risks must be established. Table 4.10.4 shows the priory ranking, which is based on the average score between the impact and likelihood of occurrence.

Table 4.10.4: Risk priority level

Priority Level	Color	Score
Very low		0-20
Low		20-40
Medium		40-60
High		60-80
Very high		80-100

Table 4.10.5 shows each risk scored based on impact and likelihood, along with the associated priority level.

Table 4.10.5: Priority level based on risks

Number	Impact	Liklihood	Priority Level	Rating
1.1	40	60	50	Medium
1.2	80	60	70	High
1.3	60	60	60	Medium
2.1	40	40	40	Low
2.2	40	60	50	Medium
2.3	40	40	40	Low
2.4	40	60	50	Medium
2.5	40	40	40	Low
2.6	60	40	50	Medium
3.1	100	40	70	High
3.2	80	40	60	Medium
3.3	60	40	50	Medium
3.4	80	60	70	High
4.1	40	60	50	Medium
5.1	100	40	70	High
5.2	80	40	60	Medium
5.3	80	40	60	Medium
5.4	80	60	70	High
5.5	80	60	70	High
6.1	80	20	50	Medium
6.2	80	40	60	Medium
7.1	60	60	60	Medium

Table 4.10.6 shows the risks in order of rating and identifies risk prevention strategies for each associated risk.

Table 4.10.6: Risk prevention strategies

Rating	Number	Risk Prevention
High	1.2	The product must meet the requirement(s)
High	3.1	Efficiently secure the leg so that no slipping occurs
High	3.4	Ensure straps can be easily tightened
High	5.1	Use materials that can withstand the forces of the user
High	5.4	Use light materials (weight of orthosis < 2kg)
High	5.5	Increase the surface area to reduce pressure
Medium	1.1	Define the requirements clearly
Medium	1.3	Include all necessary requirements
Medium	2.2	Provide a fully detailed description of the assembly
Medium	2.4	Choose parts that can be fabricated or purchased
Medium	2.6	Include sizing ranges that encompass the target group
Medium	3.2	Design an volume adjustable corset
Medium	3.3	Choose straps that may be manipulated easily by the user
Medium	4.1	Simplify the donning process
Medium	5.2	Choose materials that do not harmfully interact with skin
Medium	5.3	Choose a width and length that is specific to each patient
Medium	6.1	Ensure no sharp edges are in the design
Medium	6.2	Select proper material and provide thermal regulation
Medium	7.1	Select inexpensive material and simple assembly processing
Low	2.1	The product must be designed to be built using the tools available at Dr. Soetomo Hospital workshop
Low	2.3	Select parts that can fit together
Low	2.5	Design the product using the tools that are available in Surabaya

By implementing the risk prevention strategies identified in table 4.10.7 the risk may be effectively managed.

4.11 Summary

A prototype of the final design from synthesis II is constructed and tested on two able bodied users to observe their response to donning and doffing the brace. Users noted issues they experience while performing the tasks, and solutions to the noted issues are provided. Both users were capable of donning and doffing the brace by themselves and the adjustable anterior strap proved to accommodate for a change in volume between the legs users. Technical drawings are shown, a bill of materials and cost analysis is conducted, and a description of the manufacturing process is included along with a description of intended donning and doffing methods. This material is included so the manufacturer can produce the orthosis, if necessary. Furthermore, the product is classified as a class I medical device and does not require a CE mark. Also, a failure mode and effect analysis shows the potential risks involved with using the orthosis and gives solutions to reduce or eliminate those risks.

4.12 References

[1] Velcro Liner. https://www.amazon.com/VELCRO-Brand-Industrial-Strength-Black/dp/B00006RSP1/ref=pd_bxgy_229_2?_encoding=UTF8&pd_rd_i=B00006RSP1&pd_rd_r=V8KXS9A227J8M9EZ1HY8&pd_rd_w=e5bRQ&pd_rd_wg=eT8fi&psc=1&refRID=V8KXS9A227J8M9EZ1HY8 Accessed June 18, 2017

[2] Knit rite Prosthetic Sock. http://www.knitrite.com/images/catalog20/Interior-CAT20-final-pages-2017_KR-Catalog_Page6.pdf Accessed June 17, 2017

[3] Fabrication of a Complete Leg Orthosis using Thermplastic Technology. (Ottobock) https://professionals.ottobockus.com/media/pdf/646T5_4.6-EN-02-1204w.pdf Accessed June 26, 2017.

[4] Manufacturing Guidelines – Ankle-Foot Orthosis (International Committee of the Red Cross). https://www.icrc.org/eng/assets/files/other/eng-afo-2010.pdf Accessed June 26, 2017

[5] http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf Accessed July 3, 2017.

[6] Design Reader Interdisciplinary Project. H4.3 Test Procedures

5. Discussion:

The goal of this project was to design an orthosis that efficiently un-weights the foot of an adult diabetic patient with Charcot foot at Dr. Soetomo Hospital in Surabaya, Indonesia. The term 'efficiently' is defined as providing 100% unloading of the foot. Furthermore, the orthosis must account for leg volume change over time. These goals are imbedded into the requirements and wishes for the orthosis. To determine if the final product that is described in synthesis III has met these goals it is necessary compare the product to the requirements and wishes.

In terms of effectiveness the requirements are as follows:

- The device must fully unload the foot
- The device must secure the patient's leg such that no slipping occurs between the leg and the device
- The device must be adjustable as leg volume changes over time

Theoretically, the calculations from section 3.4 show that the compressive stress required to brace the leg without slipping is 117.1kPa for a user of 250kg with a median size corset. Thus, the design should be capable of unloading the leg. Furthermore, stress values were below values that were measured in trans-tibial socket users during ambulation. The brace did prove to be adjustable in terms of leg volume, as was shown when both users who donned the brace were able to secure it to their own legs, which varied in volume. However, since the final product did not yield a functional prototype it is not possible to test if the theoretical stresses will match practical values.

In terms of usability the requirements state:

- The device must allow the user to be mobile (standing, walking)

- The device must be capable of being used on a daily basis
- The device must be capable of being donned and doffed by the user without additional help from another individual
- The device must not exceed 2kg

This design proved capable of meeting the requirement of being donned and doffed by a user without additional help. This was shown in section 4.2. Furthermore, in section 3.6.2 the total weight of the corset was determined to be 0.64kg. Thus, the device does not exceed 2kg. In terms of mobility, the placement of the design below the tibial tuberosity should allow the user to sit and stand with the orthosis on the leg. Balance will be affected by the height elevation of 4.5cm, yet with increased usage the orthosis the user should acclimate over time. Ultimately, the mobility requirement and capability of daily use requirement cannot be tested/observed without a functional prototype.

The cost requirement is as follows:

- The device must cost less than 175euro to manufacture

The cost analysis in section 4.6 shows the calculated cost of the product is 166.21 euro, thus meeting the cost requirement.

The durability requirements are:

- The device must be capable of withstanding a weight of 250kg
- The device must last for up to a year
- This device must withstand temperatures up to 50°C

Calculations from section 3.4 and 3.5 in synthesis II show that for a user of 250kg the shear stress is 51.5kPa and the normal stress is 117.1kPa, which are below the values measured on the leg in literature (61.9kPa), and thus are determined to be safe for a user of this weight. Furthermore, for a user of 250kg the unloading bars had a stress of 70.6kPa and the reinforcement bars had a stress of 43.1kPa, both of which are below the yield strength of their respective material, aluminum 2024, which is 280MPa. Thus, it is determined that the orthosis is capable of withstanding a weight of 250kg. Furthermore, the aluminum 2024 unloading bars should not deform prior to 3million cycles.[1] Healthy older adults (50+ years old) walk between 2,000 – 9,000 steps a day.[2] The user of the orthosis is expected to walk less steps than the average adult, and thus 2,000 steps are assumed. This yields 0.73 million cycles by the end of a year, thus, the unloading attachment should withstand use for up to one year. Of note, the use of the orthosis should only be for 8-12 weeks, and thus the year long requirement is an overestimate. The requirements for the device withstanding a temperature of 50°C were not determined.

In terms of safety the following requirements are set:

- The device must not have sharp edges that could harm user or others
- The device must provide stability while standing
- The device must provide adequate friction with the ground such that no slipping occurs

In the manufacturing process described in sections 4.7, the instructions noted that all sharp edges should be smoothed or rounded. The stability while standing and friction with the ground were not determined and could not be observed/tested without a functional prototype.

The requirement for time states that:

- The device must capable of donning and doffing in under 4min by an able user

The tests conducted in section 4.2 showed that users were capable of donning and doffing the brace in less than 4 minutes.

The manufacturing requirements are as follows:

- The device must be capable of being manufactured at the Dr. Soetomo Hospital workshop
- The device must be capable of being manufactured using a detailed description of the manufacturing process
- This device must be capable of being manufactured using locally available materials

The materials that were selected in this design are either available in Surabaya or can be ordered at the workshop. The materials that were selected are similar to the materials that they are currently using, and thus, it is determined that the workshop has the tools that are necessary to manufacture the design. A detailed description of the manufacturing process is found in section 4.7

5.1 References:

[1] Groner, C., "Trends and techniques in materials, part I: O&P" Ler Magazine. 2011. http://lermagazine.com/article/trends-and-techniques-in-materials-part-i-op Accessed on June 12, 2017

[2] Tudor-Locke, C., et al. "How many steps/day are enough? For older adults and special populations." International Journal of Behavioral Nutrition and Physical Activity. 2011.

6. Conclusion

For the final design, calculations show the amount of compressive stress required to unload the leg of the user without slipping in the brace is below measured stress values found on trans-tibial patients during ambulation. This implicates two notions: firstly, the design has sufficient compressive stress to fully unload the weight of the user. Second, the user should not experience skin damage or discomfort, assuming the user has healthy skin (this may not be the case). Furthermore, the design is adjustable for leg volume, it may be used for patients up to 250kg, weighs 0.64kg, can be donned and doffed by a user in under two minutes without additional help, and costs less than 175euro. The requirements that were met in this study are theoretical and are validated through equations and literature comparisons. To further establish validation of these requirements a functional prototype should be constructed and tested. The requirements that were not met in this design were chiefly because a functional prototype was not realized. For future work, a functional prototype should be created to tests the validity of the remaining requirements. With the information provided in this project it would be possible for Dr. Soetomo Hospital to construct the design and test the remaining requirements before considering use of the brace.

7. Ethics

Before implementing, or even recommending, the use of this orthosis it is necessary to consider the ethical ramifications that this device could have on the user and on society as a whole. One ethical question that was raised by Paul Citron in his article "Ethic Considerations for Medical Devices R&D" and is a primary consideration within the scope of this design relates to the concept of 'good enough.'[1] This refers to the idea of determining a point in the timeline of the project when the device is ready to be given to a patient for use. How much testing needs to be done in order to ensure the patients safety? Is it ethical to test this product? In terms of this project, verification is done to ensure safe usage for the user such as comparing calculated values to literature, observing users response to a prototype in a controlled environment, and conducting a failure mode and effect analysis. However, much of the design work at this stage of the project is theoretical. Conceptually issues such as materials harmfully interacting with the skin or elevated stress levels due to shear or compressive force should not arise. Yet, it is necessary run tests on healthy subject using a functional prototype to ensure that these issues do not arise. Furthermore, the users of the orthosis should be made aware of any potential risks before use.

Another import ethical consideration regards product cost. Although the primary goal of this project was to design a brace that could efficiently unload the foot, a strong secondary goal was keeping the design cost below 175euro. Many decisions (especially material choices) were made on the basis of cost and trying to keep it low. On one hand there is an ethical consideration that the best possible healthcare should be provided to a patient. However, in this case it is more pertinent to provide access to affordable healthcare so that the patient may be treated and allowed to heal. Furthermore, it is the responsibility of the hospital, clinicians, and involved personnel to ensure that this product is being sold at the valued price (175euro) so the intended users will have access to the device and the hospital is not unduly profiting from the device.

Lastly, this device may be considered in terms of its impact on society and the scientific community. This project is important because it adds knowledge to the field of orthotics. It provides new methods of solving issues related to the efficiency and volume change of unloading orthoses. Furthermore, through cost reduction the brace can provide patients access to a feasible solution.

[1] Citron, P. "Ethics Considerations for Medical Devices R&D" Progress in Cardiovascular Deseases. 2012. 55(3); 307-317
[2] Human Subjects http://research-ethics.net/topics/human-subjects/#background Accessed July 20, 2017.

Appendix A:

GRF Forces During Walking and Running

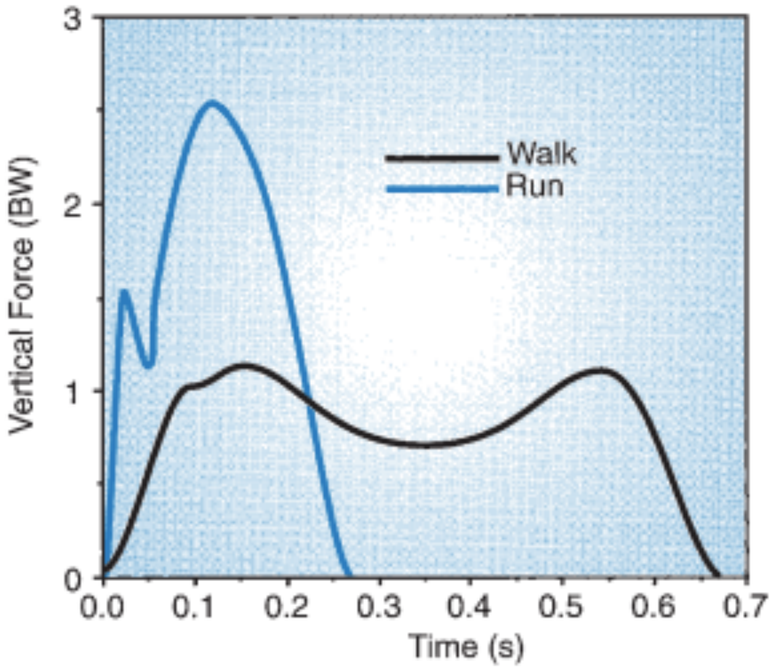


Figure 1: Vertical Ground Reaction Force as a Result of Walking and Running

http://kt.ijs.si/markodebeljak/Lectures/Seminar_MPS/2012_on/Seminars_2015_16/Miha%20Dezman/Miha_Dezman_references/%C4%8Clanki/19_Biomechanical%20Basis%20of%20Human%20Movement.pdf Accessed April 15, 2017

Pressure in PTB Socket (transtibial)

In a study in transtibial patellar tendon bearing socket users, the pressure distribution was measured during ambulation[Convery & Buis, 1998]. The regions of pressure that were measured and the resulting pressure measurement are seen below:

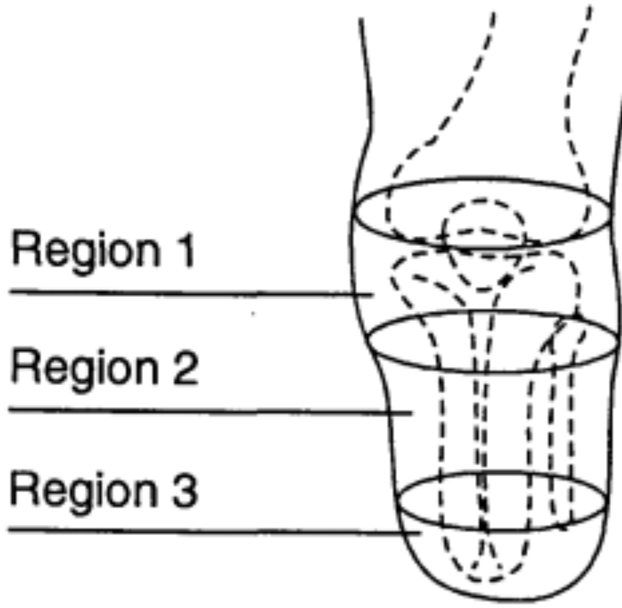


Figure 2: Regions of the PTB Transtibial Socket

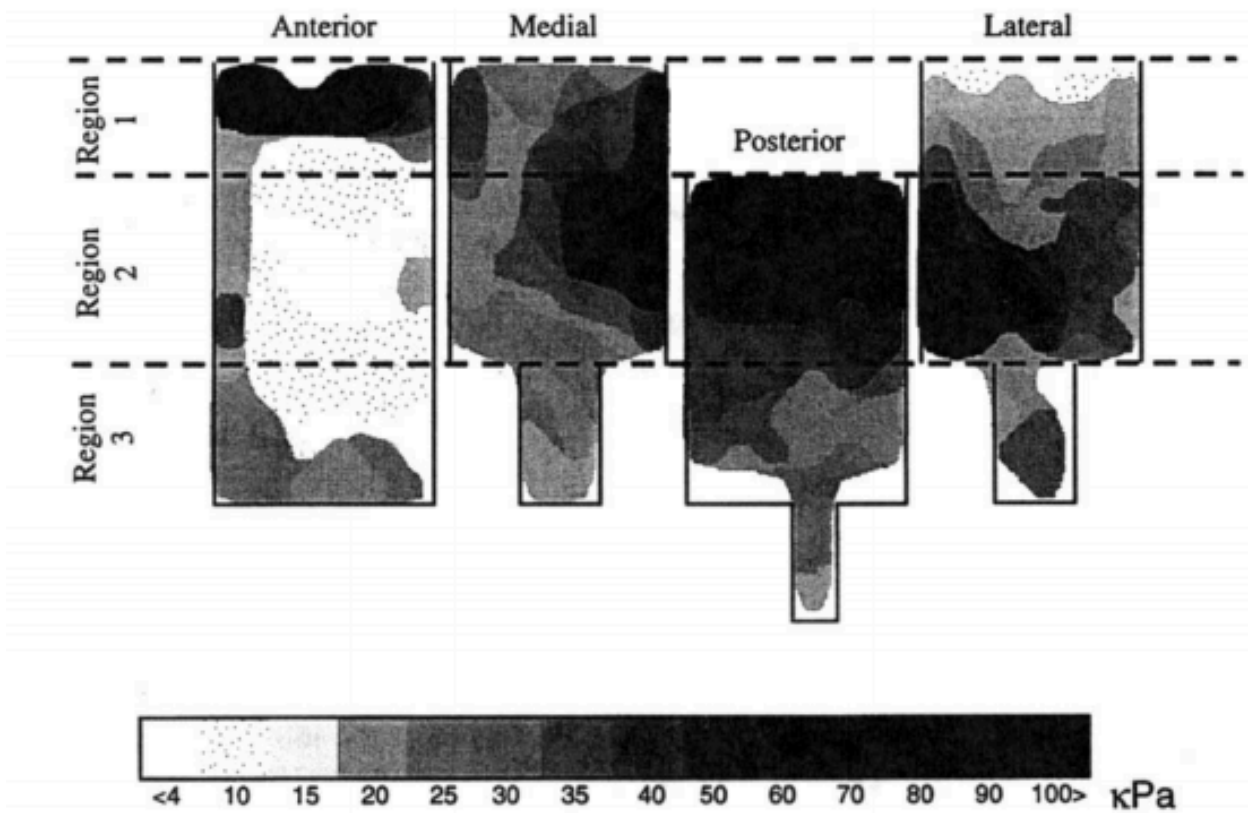


Figure 3: Pressure distribution in a PTB socket

Four regions of the socket experienced pressure greater than 100kPa. These regions were:

(i) patellar tendon bar
(ii) proximal popliteal

(iii) posterior medial flare
(iv) fibular head

These regions must are noted for consideration when calculating the forces and pressures on the corset.

Material Considerations for Foam Liner:

Foam Sheets				
Product Name	Durometer	Available Thicknesses	Sheet Size	Order No.
AliPlast™ 4E	23	1/8", 3/16", 1/4", 1/2"	24" x 36"	ALP-4E-[ ]-[ ]
AliPlast™ 6A	34	1/8", 1/4"	24" x 29"	ALP-6A-[ ]-[ ]
AliPlast™ 10	60	1/8", 1/4"	25" x 30"	ALP-10-[ ]-S
AliPlast™ XPE	68	3/16", 3/8", 9/16"	29" x 32"	ALP-XPE-[ ]S
EFM™	75	1/8", 1/4"	22" x 36"	SDUR-0004X
Durofoam		1/2", 9/16"	24" x 30"	NEP 216 [ ]
Microcell Puff® Lite	25	1/16" to 1"	44" x 40"	PUFF-00XXX
Microcell Puff®	35	1/16" to 1"	37" x 30"	PUFF-00XXX
Microcell Puff®	55	1/16" to 3/4"	34" x 34"	PUFF-00XXX
Microcell Puff®	65	1/16" to 5/8"	29" x 32"	PUFF-00XXX
Neo-Sponge™		1/8"	42" x 48"	SDUR-0020X
Neo-Sponge™ X-Static®		1/16", 1/8"	42" x 48"	XSSDUR-000XX
NickelPlast-Lite™	42	3/16", 3/8"	36" x 44"	482X
NickelPlast-S™	45	1/8", 3/16", 1/4"	39" x 43"	479X
NickelPlast X-Firm™	55	1/8", 3/16", 1/4", 3/8", 1/2"	35" x 39"	480X-AM
P-Cell™	20-25	1/16" to 1"	30" x 44"	SDUR-001XX
Pe-Lite® B-4	14	1/8", 3/16", 5/16", 3/8", 1/2"	39" x 39"	PLT-[ ]
Pe-Lite® A-8	37	1/8", 3/16", 5/16", 3/8", 1/2"	39" x 39"	PLT-[ ]
Pe-Lite® A-20	45	1/8", 3/16", 5/16", 3/8", 1/2"	39" x 39"	PLT-[ ]
Pe-Lite® A-30	54	1/8", 3/16"	39" x 39"	PLT-[ ]
Plastazote®	20	1/16", 1/8", 3/16", 1/4", 1/2", 3/4", 1"	30" x 40"	PTZ-1-[ ]-S
Plastazote®	35	1/16", 1/8", 3/16", 1/4", 1/2", 3/4", 1"	34" x 34"	PTZ-2-[ ]-S
Plastazote®	69	1/16", 1/8", 3/16", 1/4", 1/2", 3/4", 1"	25" x 35"	PTZ-3-[ ]-S
PPT®	18-20	1/16", 1/8", 1/4"	30" x 36"	PPTS-[ ]-[ ]
QuickStick™ Padding	15	3/16"	5.75" x 25'	4177
QuickStick™ Padding	15	3/16"	18" x 25'	4178
Sifoam™ Padding		3/8", 1/2"	8" x 9"	83SIA-[ ]
Slow Recovery Urethane	35	1/16", 1/8", 1/4"	36" x 44"	PORX-000XX
Soft Sponge™	6	1/8", 1/4"	18" x 24"	4445, 4446
Urethane	15	1/16", 1/8", 1/4", 3/8"	36" x 42"	PORX-000XX
Urethane	15	1/16", 1/8", 1/4", 3/8"	36" x 38"	PORX-000XX
Urethane w/Fabric Top	15	1/16", 1/8"	36" x 42"	PORS-000XX
Urethane X-Static®	15	1/16", 1/8"	27" x 36"	XSPORS-0000X

[https://www.cascade-usa.com/cascade-media/pdfs/salessheets/SSN_sheetgoods.pdf]

Appendix B

Design Meeting Notes and Agendas:

Meeting (Jan 31, 2017):

Meeting with Klaas & Bart

31/1/17

3:00-3:30pm

What has been done since last meeting (17/1/17):

- Met with Mark at OIM
  - Looked at the orthosis that they had designed
  - Made a cast of my leg up to the knee. Left the cast for Mark to poor molding into. Will return to shape the mold of my leg and use it to make a prototype
- Emailed Dr. Alit, but without response as of yet.

What needs to be done:

- Send follow up email to Dr. Alit and cc Klaas
- Conduct literature review and make a summary of current existing solutions
- Write a background for the project
- Follow steps for Analysis phase

Next Meeting:

- Held at 12:30-1:00 at UMCG (Bart and Mark)
  - Email any necessary reading material in advance
  - Meeting will be held every other week at this time

Things I learned:

- Have a meeting agenda and make meeting notes
- Stick to the design schedule

Meeting (Feb 14, 2017)

ATTENDEES

Dr. Klaas Postema (Advisor), Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

Since Last Meeting:

1. Literature Review
   a. Article summaries. Anything additional I should read?

2. State of the Art
    a. CROW, T-Brace, Toad Medical Anti-Gravity Brace, Casting (TCC & RCW), etc.
3. Background
4. Problem Definition
    a. The design is intended for patients in the Department of Rehabilitation at Dr. Soetomo Hospital in Surabaya, Indonesia. The current technology being used is a Patella Tendon Bearing (PTB)- orthosis that utilizes the patella and a conical shape around the lower leg to bear the weight of the body. However, the fitting is not optimal for all patients and thus the foot may slip onto the footplate and undertake some more of the body weight. Furthermore, patients who initially fit into the PTB-Orthosis often experience decreased volume and/or circumference in their lower leg over time, and thus the orthosis will again fail. The aim of this project is to design a cost-effective, locally produced, orthosis for daily use that will provide optimal unloading on the patient's foot while maintaining ease of mobility (standing, walking), and account for the decrease in lower-leg volume over time.

Coming Up

- Finish ‘goals’ and design assignment this week
- Next week: Requirements and Wishes & Function Analysis
- Analysis Phase should be complete before next meeting (28/2/17)
- Meeting with Mark again to work on shape leg model

MEETING NOTES

- Literature review: record specifically what you have searched
- Background: make sure I specify that the design is intended for use in Surabaya, Indonesia. Provide essential information such as: Who, what, why, where, etc
- State of the art: make sure to analyze the solutions for their efficacy in regards to our problem.
    - Are they a good fit for our design? Why? Why not? Do they meet the requirements and wishes of the project?
    - I will go back and look at them after I have defined the requirements and wishes next week.
- Problem definition: focus on the general problem first, then go deeper and deeper into the specific problems that need be fixed. Also, only include the problems. No background information or goals. Be concise and precise.
- Goals: will be opposite of the problem definition. Ex: “Problem definition states that the leg volume decreases over time. Goal states the leg volume stays the same. Etc.”

- Design Assignment: State who the design is for. Also include the final desired result. Ex: A functional prototype to be tested
- Talk to Mark van der Heide about the machinery they use to make their orthoses

Meeting (Feb 28, 2017):

ATTENDEES

Dr. Klaas Postema (Advisor), Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

Since Last Meeting

1. Literature Review, State of the Art, and Background completed
2. Revised Problem Definition
    a. Dr. Soetomo hospital currently uses a Patella Tendon Bearing (PTB)- orthosis which utilizes the patella and a conical shape around the lower leg to bear the weight of the body. The problem with the current orthosis is that it is insufficient in bracing the leg. Firstly, the orthosis may not fit optimally for all patients. Thus, some patients will experience slipping, which will cause the foot to bear weight. Secondly, the current brace does not sufficiently account for leg volume and circumference change over time. In patients with Charcot foot, swelling, edema, and inflammation may all contribute to a change in leg volume over time. A change in volume may also lead to slipping of the leg from the brace and cause the foot to undergo a load.
    b. Added Stakeholders and Cause & Effect diagram to problem definition
3. Goals
4. Design Assignment
    a. Includes: Design Strategy, Target Group, and Project Demarcations
5. Requirements & Wishes
6. Function Analysis
7. Review of Current Orthoses

Coming Up

- Begin Synthesis I
- Create Function Schemes and Morphological Map in the next few days
- Have a brainstorming session with Thijs, Roy, and Pin
- Create sketches of ideas
- Select three pre-concepts

NOTES

- Make sure to send previous work to advisors in advance

- Goals
  - Avoid pre-requisite usage. Only include the overarching goals of the project and not underlying information such as how the goals are to be met.
- Design Assignment
  - Add a description of the manufacturing process as an end result.
  - Revise project demarcations: move items such as cost, ease of donning and doffing to the requirements section. Limit the demarcations to the target group, where the device should be produced, etc
- Requirements and Wishes
  - Avoid using unquantifiable terms such as "easy" or "comfortable"
  - Change design to device (it's not the design that needs to meet all the requirements but the device itself)
  - How should the brace be adjustable (automated, user based, etc.)?
- Function Analysis
  - Things to include: material transport (movement of brace/ adjustability), energy transport to make that happen, and information transport to start and stop that movement
- Research again about CROW to see if it fully unloads the foot
- Considerations:
  - an indication system to let the patient know when the brace needs to be adjusted
  - A tutorial video for how to use the orthosis properly (or an instruction manual)
- Send meeting notes, literature review and analysis phase to advisors

Meeting (Mar 14, 2017):

ATTENDEES

Dr. Klaas Postema (Advisor), Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Revised Analysis I based on feedback
   a. Discuss feasibility of testing prototype (not with patients/ formal, but rather can it withstand 250kg, does it fully offload the foot, is it comfortable, etc.)
2. Made a mold of my leg at OIM and scanned it to have a virtual copy modeling
3. Brainstorming
   a. What level of detail is expected from these designs?
4. Morphological Map
5. Pre-concept Sketches
6. Ideas to make the design cheaper?

Due This Week

1. Add drawings of new concepts from meeting
2. Add descriptions of Sketches
3. Weight pre-concepts
4. Grade pre-concepts

5. Revise Schedule

NOTES

- For the requirement: “withstand 250kg” Discuss with mark how they test force load and moments on the orthosis and see what it should be capable of withstanding
- Testing of prototype is possible on a few healthy patients
    - Testing to see if the device fully unloads the foot and accounts for volume change (maybe by layering the leg with socks)
- Brainstorming
    - Separate the socket drawings from the ground connection drawings (modular)
    - Add information regarding force distributions/ reactionary forces and moments in each design
    - Add relevant specifications such as distance between foot and bottom of footplate
- Need to send designs to Alit + Dr. Soetomo Workshop, Klaas, Bart, Mark & OIM, etc. for grading

Meeting (Mar 28, 2017):

ATTENDEES

Dr. Klaas Postema (Advisor), Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Revised grading and concepts based on feedback
2. Received grades back from supervisors [thank you!]
    a. Alit, the Dr. Soetomo Workshop, & Mark still have yet to send the grades back
3. Grading
    a. Socket designs 1, 2, & 3 are in the lead
    b. Unloading designs 6, 8, & 9 are in the lead
4. Will continue with these designs after Wednesday
5. Midterm Review

Due This Week

1. By Wednesday evening select designs for continuation
2. Gather and submit the completed synthesis I
3. Begin modeling designs (sketches, descriptions, split-model)
    a. GRF Forces, reactionary forces

By Next Week

4. Materialization
5. Sterilization (no, since its non-critical class. Only cleaning required) FEM?
6. Technical Risk Analysis/ Theory of Inventive Problem Solving (TRIZ)

NOTES

- Biggest take-away from the meeting was that I need to better explain how my concepts function
    - Explain whether they use shear force, pressure on the tendon, or another method to unload the foot. Essentially I must state the mechanism for how it exactly unloads the foot.
- This week I will be going back over my design and readjusting them with this in mind.
- I will submit the designs again for grading
- After talking with Mark I will also be including some more “out of the box” ideas and different ways of solving the problem (applying pressure/force at different areas)

Meeting (Apr 11, 2017):

ATTENDEES

Dr. Klaas Postema (Advisor), Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Revised pre-concepts to include more information about how they function, and added new pre-concepts
2. Received grades back from Klaas (discuss over empty boxes)
    a. Alit, the Dr. Soetomo Workshop, & Mark still have yet to send the grades back. I will email them today and will wait until thursday before selecting the best designs from the grades given.
3. Created a weighting system for the grades (at the moment it does not seem to do a good job of separating the designs)
4. Revised design schedule (still appear to be on track, but it will be tight)
5. General comment: I need to focus on improving the areas that were spelled out in the midterm review. I think this starts with me sending more information and communicating more consistently so that I can have feedback on how I can improve

Due This Week

1. Finish synthesis I and send to supervisors for review
2. Begin synthesis two
    a. Modeling (discuss)

NOTES

- Continue with grading and design selection process without Mark & Alit
- The weighting system seems appropriate
    - Select two corsets and two unloading attachments for continuation
    - If the grades are close select the design that scores highest in the aspect that is most desirable (i.e. effectiveness)

- Once selected, I can/should combine elements of other designs to improve upon the designs that have been selected.
- Finish the write up for synthesis I and send it to supervisors
- Move on to modeling
    - Most important aspect of modeling is to have good, detailed, proportionate sketches that represent the idea very well
        - If this is finished maybe create a physical model if possible

Meeting (Apr 25, 2017)

ATTENDEES

Dr. Klaas Postema (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Selected designs 1, 7, 10 for continuation.
2. Began modeling/drawing the design
    a. Started with unloading attachment for design 7
    b. Taking me much longer than anticipated
3. Gathering material choices for material selection
    a. Once I choose the materials I can begin calculations like weight, stress, yield strength, etc.

Upcoming:

1. Will have finished corset model for design 7 by next week (2/5),
2. Will finish corset model for design 1 (5/5),
3. Will finish design 10 model (9/5)
4. Next meeting on 9/5

Meeting (May 9, 2017):

ATTENDEES

Dr. Bart Verkerke (Advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Meeting with Klaas on 25/4
    a. Thought design was too complex, and would be too expensive
    b. Restructured the designs to simplify them and make them more feasible

2. Modelled by drawing schematics/ pictures
3. Changed footplate designs to adapt to various rocker profiles (not just one)
4. Gathering material choices for material selection
    a. Once I choose the materials I can begin calculations like weight, stress, yield strength, etc.
    b. Trying to choose materials that are currently available at Dr. Soetomo Hospital, or ones that they can easily get
5. Discuss testing possibilities & options for quantitative analysis.

Upcoming:

1. Will have finished new design for corset 2 + attachment by Friday (12/5)
2. Will finish selecting materials by the next Thursday (18/5)
3. Will run calculations and have a grading system by next meeting (23/5)
4. Looking to begin prototype by 13/6

MEETING NOTES:

- Another possibility for the unloading attachment is to have the unloading bar centered at the footplate. Create a model for this.
- Make all drawings in mm for consistency
- The metal plate on the footplate should be scaled down to 1mm
- In socket design #2 it would be best to create a system that is always adjustable about the center point of the leg. This will allow the user to adjust the volume of the brace while keeping the padding in the right places. Otherwise the padding will rotate and you will have an issue.
- Create a grading system for the designs by next meeting so that we can move forward with the final design

Meeting (May 23, 2017):

ATTENDEES

Prof. Dr. Klaas Postema (Supervisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Have two designs for the corset (one PTB and one non PTB) and two/three designs for the unloading attachment

2. Spoke with Alit about what materials they have available
    a. They use PP and PE for the shell and duralumin and rubber for the unloading attachment
    b. Alit advised that I use a stirup to avoid fixation in my PTB orthosis
3. One of the designs is non-PTB. I've been in contact with Advanced Orthopedic Designs about the design of their LoadShifter AFO
    a. Use 35 durometer EVA liner + 3- and 5- ply prosthetic socks
        i. Found socks for 8euro online, so would not dramatically increase cost
    b. "Design is easier to make & tolerate than PTB"

Upcoming:

1. Finish write of for the designs by tomorrow (24/5)
2. Grade the designs and select a final design for continuation (29/5)
3. Looking to begin prototype by 13/6

Meeting (May 24, 2017):

ATTENDEES

Dr. Elvira Tijdens, Brady Perkins (Leader/Secretary)

Notes:

- At UMCG they typically use the CROW walker, which provides about 30-40% offloading (see literature)

Thinks it would be interesting to have a dexiscan at the beginning and end of the use of the brace (if we could make the project bigger)

Typically at risk patients are those who have previously had a transplant (liver, cardiac, etc). Higher risk of neuropathy

2 types of Charcot foot

- 1. Explosion of the joints, dislocation and sublaxation leading to rocker bottom profiles (commonly) → likely to brace in this situation
- 2. Luxation at the side bone → needs operation, more at risk for ulceration due to the area of skin that is tightened by the luxation. (bottom of the foot skin is tougher)

Meeting (June 6, 2017):

ATTENDEES

Prof. Dr. Klaas Postema (Supervisor), Prof. Dr. Bart Verkerke (advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. The materials for the designs and have been selected
    a. Still have to calculate the weight and cost of corset 2 and unloading attachment
2. A grading system will be up by tonight *(no longer important after meeting)

3. The calculations are fairly simplified (2D assumptions). If time permits for the final design, I would like to make a virtual model and run simulations in COMSOL

Upcoming:

1. Calculate weight and cost of design 2 (6/6)
2. Redo calculations on corset
3. Grade the design myself

MEETING NOTES:

- Discussed designs with Klaas
- Talked about moments on the corset that are distributed from the unloading bars (are these moments useful/accurate? Discuss with Bart)
    - Bart advises that instead of calculating the moments at the edges of the corset I should be looking at the forces (and what is really happening is the force is distributed over a small area, so maybe calculate the pressure on the patellar tendon region and distal and proximal calf areas)
        - Keep in mind that the diagram should be in equilibrium
    - The shear stress calculation has the following assumptions:
        - The shear forces are equally distributed within the corset (not true so calculation will be slightly inaccurate)
- Consider redrawing the free body diagram to incorporate angles at heel strike and toe of for a full analysis
    - No need to redraw the whole diagram. Draw the force at the appropriate angle and incorporate it into the calculations
- Talk to Bart about:
    - potentially prototyping with him (at UMCG)
        - Bart will discuss this with Klaas
    - Is formal grading a necessity or is selecting a best concept based on the calculations a better option?
        - Answer: It is acceptable to select a design for continuation based on the analysis of the calculations
        - I should still grade the designs myself and send it in to Bart and Klaas to check if it is appropriate.
    - A virtual model may take a lot of time and still not provide a useful force analysis (not necessary to do)

Meeting (July 4, 2017):

ATTENDEES

Prof. Dr. Klaas Postema (Supervisor), Prof. Dr. Bart Verkerke (advisor), Brady Perkins (Leader/Secretary)

AGENDA

1. Ask Klaas about 'share value' for corset shell material
2. Discuss prototype (positives and negatives)

3. Discuss synthesis III material
    a. Prototype additions
        i. Velcro on frontal liner
        ii. Thermal regulation (holes in shell)
        iii. Ladder straps
    b. Technical drawings (more than what was done in synthesis 2?)
    c. Description of manufacturing process
        i. Can I use suggestions & pictures from Ottobock/Internation Comittee of the Red Cross?
    d. Quality Standards

Upcoming Schedule:

1. Thursday (6th) → send first revision of synthesis III
2. Monday (10th) → send final report (first draft)
3. Tuesday/Wednesday (11th/12th) → receive synthesis III back
4. Friday (14th) → receive final report back
5. Tuesday (18th) → Submit final report and give presentation

MEETING NOTES:

- Klaas meant shore value for the liner
- Discussed with Klaas:
    - Height of the unloading bars is adjustable based on the dimensions of the patient
    - Length and rocker profile of the footplate is chosen by the orthotist (I think I may need to explain this more clearly in my report)
    - Holes in shell
        - Would be nice to place on the medial lateral faces since less pressure occurs there, but that is where the unloading bars are
        - Could/should include a thin inner liner (like cotton, etc. to reduce the edema and pressure from the holes on the leg)
            - This liner would also have to be breathable or else the inclusion would be pointless
        - Discuss the effect of the inclusion of holes on the rigidity and strength of the shell
    - Include info about the shoe lift
- Redraw technical drawings based on new inclusions
    - Unloading attachment could be drawn in Solidworks, whereas the corset should be hand drawn to show (easier to show curvature)
- Manufacturing process:
    - Don’t include info on how to make a positive mold (orthotist will already know this)

    - It's okay to include pictures of the manufacturing process from other sources (site each picture so that you're not plagiarizing)
- Quality Standards:
    - Use standards for the EU (Dr. Soetomo Hospital can implement their own standards if they decide that is necessary)