Joint unloading ankle brace to aid cartilage regeneration

J. Natenstedt, Prof. Dr. J. Dankelman, Dr. ir. Gabrielle JM Tuijthof
## Contents

Abstract .......................................................................................................................... 1

1. Introduction .................................................................................................................. 1

2. Methods ....................................................................................................................... 2
   2.1 Set of requirements ................................................................................................. 2
   2.2 Load case of the ankle joint .................................................................................... 3
   2.3 The level of unloading to stimulate healing ........................................................... 4
      2.3.1 Unloading goal ................................................................................................. 4

3. Conceptual design ....................................................................................................... 5
   3.1 Design choices ......................................................................................................... 5
      3.1.1 Acting in the joint ......................................................................................... 5
      3.1.2 Acting on the foot ......................................................................................... 6
      3.1.3 Acting on gait ............................................................................................... 7
   3.2 Concept selection .................................................................................................... 8

4. Dimensional design .................................................................................................... 8
   4.1 Preliminary design .................................................................................................. 8
      4.1.1 Position mechanical stop ................................................................................ 9
   4.2 Deriving parameters for the unloading mechanism .................................................. 9
      4.2.1 Relationship between the GRF and the unloading force .................................... 9
   4.3 Parameter optimization .......................................................................................... 10
      4.3.1 Mathematical descriptive model of the stance phase ....................................... 11
      4.3.2 Optimization results ....................................................................................... 12
   4.4 Selection of parameters .......................................................................................... 13
      4.4.1 Varying Lever shape ..................................................................................... 14
      4.4.2 Mechanical stop ........................................................................................... 14
   4.5 Constructive interpretation of the final design......................................................... 15
   4.6 Construction of the prototype ............................................................................... 15

5. Evaluation .................................................................................................................... 15

6. Results .......................................................................................................................... 17

7. Discussion ..................................................................................................................... 17
   7.1 Method ...................................................................................................................... 18
   7.2 Prototype ................................................................................................................ 19
   7.3 Evaluation ............................................................................................................... 20
   7.4 Future direction ...................................................................................................... 20
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Conclusion</td>
<td>20</td>
</tr>
<tr>
<td>References</td>
<td>20</td>
</tr>
<tr>
<td>Appendix A Talar dome contact surface area</td>
<td>24</td>
</tr>
<tr>
<td>Appendix B Concepts lowering force by acting on foot</td>
<td>27</td>
</tr>
<tr>
<td>Appendix C Matlab code</td>
<td>29</td>
</tr>
<tr>
<td>Appendix D Drawings of parts and complete list of parts</td>
<td>33</td>
</tr>
</tbody>
</table>
Joint unloading ankle brace to aid cartilage regeneration

J. Natenstedt¹, Prof. Dr. J. Dankelman¹, Dr. ir. Gabrielle JM Tuijthof¹

Abstract

Ankle injuries are one of the most common sports injuries that often lead to further complications such as cartilage defects. Recovery from these injuries can take a long time and a solution that could aid in the rehabilitation of these injuries is beneficial to the young and active patient group. The goal of this study is to design a device that can unload the patient’s ankle to such an extent that recovery is promoted. Using human motion analysis and a mathematical descriptive model, an unloading mechanism is designed that modifies the forces on the ankle joint. The resulting device consists of an attachment to the lower leg onto which a mechanism is attached that transfers a part of the load of the foot to the lower leg. The device is tested using a force plate set-up. The results are that the device can provide an unloading force throughout the stance phase of gait, reducing the maximum load on the ankle from 1.2 BW to 0.94 ± 0.04 BW. The proposed design is a wearable device that could be used during the rehabilitation of a patient’s ankle. The manner in which this device should be attached to the user’s leg needs further research; when these limitations are solved further testing can be initiated.

1. Introduction

Ankle injuries are one of the most common sports injuries. They are more common in sports that involve running and jumping like football, basketball, soccer, and volleyball (Nelson et al. 2007). Ankle injuries can lead to osteochondral defects or lesions (van Dijk et al. 2010b). Osteochondral lesions of the ankle are being recognized as an increasingly common injury, particularly in association with sports injuries (O’Loughlin et al. 2010). These patients are often young and athletic, and mostly male in the third decade of their life (van Bergen et al. 2009). Currently, most symptomatic osteochondral ankle defects require a surgical treatment (Zengerink et al. 2010). However, rehabilitation of surgery can take up to one year before clinical improvement of symptoms is obtained. A faster recovery time could considerably improve the quality of life of these patients (van Bergen et al. 2009).

During physical therapy, the forces on a joint are adjusted to aid recovery, adapting the mechanical environment of the ankle joint can improve recovery (Buckwalter 1998; Reinold et al. 2006; Schmitt et al. 2014). Joint distraction is a treatment that adapts the mechanical environment of the joint (Figure 1). Joint distraction is used in cases of severe ankle osteoarthritis: it can postpone or prevent the need for joint fusion or joint replacement. During an ankle joint distraction a mechanical external fixator is placed on the ankle, modifying the mechanical environment of the ankle while intermittent fluid pressure - presumably - transports nutrients to the regenerating cartilage (Wiegant et al. 2013; Marijnissen et al. 2014). Ankle distractions require several pins of approximately 1.5mm to be drilled through soft tissue and bone (van Valburg et al. 1995; Giannini et al. 2007). For the patient group recovering from surgery this would be far from ideal. However, if a non-invasive
approach can be used to adjust the mechanical environment of the recovering ankle, much in the same way a joint distraction does, we hypothesize that this will shorten the recovery time of the target patient group. Therefore, the goal of this study is to design a device that modifies the mechanical environment of the ankle during activities of daily life, such as walking, to stimulate cartilage regeneration.

2. Methods
In this section, a set of requirements for this device is presented. To do so, the load case of a healthy ankle will be studied as well as several other important factors that are user dependent (such as level of comfort).

2.1 Set of requirements
To start the design process, a set of requirements is formulated:

1. **Non-invasive device**
   The device should be non-invasive. Invasive devices will most likely not be accepted by patients recovering from minor surgery.

2. **Adaptable level of unloading**
   The device should be able to unload the traumatic/pathologic ankle during walking to such an extent that the level of loading on the osteochondral defect site stimulates healing (Buckwalter 1998; Reinold et al. 2006; Schmitt et al. 2014). In order to identify the required level of unloading the load case on a healthy ankle should be investigated, as well as the ideal load case to promote recovery. The level of unloading that stimulates healing will be discussed in section 2.3.

3. **Enable daily activities**
   The device should allow the user to perform daily activities such as walking and climbing staircases without compromising the user’s gait.

4. **Provide user comfort**
   The device should be wearable for the user without causing skin problems, and it should be lightweight (under 1200 grams, akin to a foot prosthesis Endolite UK).

5. **Minimize influence on gait**
   The device should aim to be minimally intrusive in walking, this way the user will feel comfortable using the device.
2.2 Load case of the ankle joint

The most common daily activity for the ankle joint is regular walking, which is chosen as the load case upon which the design is based. The load on the ankle joint is dependent on the user’s gait, bodyweight, and muscle activity.

Human walking has been thoroughly investigated; the pattern of walking is described in the ‘gait cycle’, which is further divided into a ‘stance phase’ and a ‘swing’ (Perry 1974). For this study, the ‘stance phase’ of walking is the phase of interest, because the ankle is loaded the most. The stance phase of gait is the period in which the leg is weight bearing and it is divided into 4 segments: Heel strike, Mid-stance, Heel off, and Toe off. The load on the foot can be measured using ground reaction forces, or GRFs (Sharkey and Hamel 1998; Beyaert et al. 2004). These GRFs are forces measured using a force platform. To obtain the loads inside the ankle joint, the tibial shaft force (force on the cartilage surfaces of the ankle joint) needs to be derived using the GRFs.

A typical pattern of GRFs is between 0 and 1.2 times the subject’s body weight (BW) (Figure 2, (Sharkey and Hamel 1998)).

The GRF and muscle activity lead to the tibial shaft force (TSF), the actual load on the ankle joint. The TSF is the result of the equilibrium in forces on the foot, where both the muscle force and the GRF create a moment around the ankle (Figure 3, (van Dijk et al. 2010b)).

![Figure 2: ground reaction forces (GRF) expressed in bodyweight during the stance phase of walking](image)

![Figure 3: moment arms in the foot during toe off. Here Fm is the muscle force, and a and b denote the moment arms](image)

The TSF is a measure for the load that is placed on the ankle joint, it has been a subject of several studies. These forces can be expressed in terms of bodyweight (Figure 4, (Stauffer et al. 1977; Sharkey and Hamel 1998)).

A different method uses a force plate combined with ‘foot switches’ and other markers. The muscle activity was based on electromyographic studies (Stauffer et al. 1977).

Another study uses cadaver feet with actuator-driven muscles to simulate human gait, implanted sensor and a force platform can give the GRFs and TSFs (Sharkey and Hamel 1998).

Lastly, other studies propose a complex model of the human foot, using a 3D analysis of the ankle joint (Procter and Paul 1982). The combination of muscle activity and the GRF cause the TSF to reach 4.1-4.7 times the user’s bodyweight during toe off. The differences in method probably explain the variance in the graphs.
2.3 The level of unloading to stimulate healing

Unloading the ankle joint during walking has been shown to improve cartilage regeneration in arthritic patients. Using joint distraction the mechanical contact is eliminated and intermittent synovial fluid pressure is maintained which presumably helps cartilage regeneration (Wiegant et al. 2013; Marijnissen et al. 2014). In vitro studies corroborate this statement, as dynamic (hydrostatic) pressure has been shown to increase cartilage production (Darling and Athanasiou 2003; Schulz and Bader 2007; Elder and Athanasiou 2009). The magnitude of these hydrostatic pressures vary from 3-10MPa at around 1Hz. Such loads are comparable to normal physiological levels of loading (Waters et al. 1988; Giddings et al. 2000; Brand 2005; Doke et al. 2005; van Dijk et al. 2010a).

For the design of the joint unloading device a guideline for the unloading behavior has to be found. Either one value or a certain range for the load that is to be exerted on the ankle, in order to stimulate healing. However, it is difficult to derive a guideline for the healing of damaged cartilage in vivo from in vitro studies (Natenstedt et al. 2015). This is because damaged cartilage has a vulnerable spot around the defect site (Khan et al. 2008), which likely cannot withstand the load (Guettler et al. 2004; van Dijk et al. 2010b, a; Spiller et al. 2011; Hunt et al. 2012). It is therefore difficult to set a fixed quantitative guideline for the regeneration of cartilage in the ankle.

During physical therapy, the forces on a recovering joint are adjusted to stimulate healing of the joint (Buckwalter 1998; Reinold et al. 2006; Schmitt et al. 2014). Guidelines used in physical therapy could be interpreted as a guideline for the level of unloading for the joint unloading device.

One such study proposed a loadbearing gradient (Table 1, [Ebert et al. 2012]). It should be noted this schedule is proposed for patients recovering from autologous chondrocyte implantation on the knee.

Table 1: example of the progression of joint loading during physical therapy

<table>
<thead>
<tr>
<th>Weeks after surgery</th>
<th>Weightbearing (% BW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>3</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>4</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>5</td>
<td>20%</td>
</tr>
<tr>
<td>6</td>
<td>50%</td>
</tr>
<tr>
<td>7</td>
<td>60%</td>
</tr>
<tr>
<td>8</td>
<td>70%</td>
</tr>
<tr>
<td>9</td>
<td>80%</td>
</tr>
<tr>
<td>10</td>
<td>90%</td>
</tr>
<tr>
<td>11</td>
<td>100%</td>
</tr>
</tbody>
</table>

These numbers are not a set guideline and a large scale review of weight bearing shows there is no consensus on the exact level of unloading (Schmitt et al. 2014).

Therefore this study proposes that the level of unloading the joint unloading device should be able to accommodate needs to be flexible between <20% and a 100% of weight bearing on the foot. This will allow the physician and physical therapist to determine a patient specific recovery plan.

2.3.1 Unloading goal

From the previous section the load case on the ankle joint has been investigated and an adaptable level of unloading has been chosen, however one basic consideration remains:
should the (to be designed) device aim to unload the GRF or TSF. From previous sections it is known that the TSF is the actual load on the ankle joint. Internally, the GRF force is counteracted by muscles in the lower leg, this equilibrium of moments results in the TSF (Section 2.2, (van Dijk et al. 2010b)). However, the unloading mechanism exerts an external force on the lower leg, the way this (external) force influences the (internal) muscle activity and the (internal) TSF is currently unknown and subject for further investigation.

This study operates under the assumption that the muscle forces are a consequence of the GRF, this implies that if the GRF are lowered the muscles will contract at a reduced force as well. Then the TSF simply follows from the equilibrium with the reduced GRF and $F_m$:

$$GRF = TSF - F_m$$

Eq. 1

And in the case of the unloaded GRF, named $GRF^*$:

$$GRF^* = TSF^* - F_m^*$$

Eq. 2

Therefore, the end result is that the ratio by which the GRF is reduced will affect the TSF with the same ratio (Eq. 2). This means that, using these assumptions, the device that is to be designed can either aim to reduce the TSF directly or do so indirectly by reducing the GRF.

3. Conceptual design

In this section the conceptual design choices are presented as well as the selection of the most promising concept. The working principle of the concept is explicated.

3.1 Design choices

The joint unloading device could accomplish ankle unloading at one of three levels (Figure 5): (1) by modifying the loading conditions within the ankle joint (internally), (2) by modifying the loading pattern of the foot (externally), (3) or by modifying the user’s gait. Each of these levels has different methods to achieve unloading: modifying the forces, moment arms, or surface area. The forces (GRF and muscle forces) together with their respective moment arms are factors in the load on the ankle (Section 2.2), this load on the ankle is spread over the surface of the joint. Therefore the joint surface area, the forces, and the moment arms are identified as main contributors to the load on the ankle. Unloading could be achieved by modifying any of these parameters.

![Figure 5: decision tree to select the direction of the design](image)

3.1.1 Acting in the joint

A joint unloading device that acts inside the joint (1, Figure 5) can only do so by modifying the surface area in the joint. Modifying the surface area inside the joint can unload the defective area of the ankle joint. If the location of the defect is identified, a strategy can be developed to rotate the ankle in such a fashion that the undamaged side is loaded (Figure 6).
Figure 6: superior view of the Talar dome, the region of interest for cartilage damage in the ankle. In red the defect site, in green the loaded area.

An example of such a joint unloading device is to use a valgus/varus brace, which is currently used as a treatment for cartilage damage in the knee (Larsen et al. 2013; Moyer et al. 2015). By applying a stress on the outside of the ankle, it could be possible to transfer a part of the load on the ankle joint to the undamaged side (Figure 7).

Figure 7: anterior view of a possible concept to unload the within the joint. In light blue the foot and lower leg, in dark blue the unloading mechanism.

The unloading factor that could be realized using this method is complex to calculate. Studies that used instrumented prosthesis found that for a knee valgus brace an unloading level of 24-30% can be reached (Zhao et al. 2007; Kutzner et al. 2011). These numbers are found in the knee, which is an incongruent joint with relatively thick cartilage, whereas the ankle joint is much more congruent and has thinner cartilage (van Dijk et al. 2010b). If unloading levels in the knee, using varus/valgus bracing, cannot exceed 24-30% it is not likely that this type of unloading device will be able to reach the required levels of unloading in the congruent ankle joint.

The surface area of the Talar dome that is compressed during walking is further investigated in Appendix A.

3.1.2 Acting on the foot

Unloading the ankle by acting on the foot (2, Figure 5) can be accomplished either by lowering the forces on the ankle, or reducing the moment arms or both.

Modifying the moment arms could be done using a rocker bottom shoe for example; however this solution would still require the user to place its full bodyweight on the foot with the device. Therefore the maximum load on the ankle joint can never be below 1 BW. In terms of adjustability (loading between 20-100% of bodyweight) this type of solution could also be complex to realize.

The joint unloading device could also lower the forces on the foot. By fixating the device onto the lower leg a portion of the load on the foot, caused by the GRF, can be exerted on the lower leg, thereby unloading the ankle joint (Figure 8).

Figure 8: illustration of partial joint unloading by transferring a portion of the load caused by the GRF to the lower leg.

The two main concerns for these devices are the mechanism to exert the unloading force and the attachment to the lower leg. For the unloading mechanism a spring is the simplest choice: in a worst case scenario of
100kg individual a maximum force of 980N should be exerted by the device, allowing for 10mm of space to compress, this means the spring has to have a stiffness $k$ according to Eq. 3:

$$k = \frac{F}{d}$$

Eq. 3

Which means $k$ should have a value of 98 N/mm. For commercially available springs this seems feasible (spring with wire diameters of 3-5mm from the spring catalog of Tevema, The Netherlands).

The second concern is the attachment to the lower leg, which has to exert the force onto the lower leg. The main problem in transferring load to flesh is irritation caused by skin ischemia, the external pressure causes blood vessel to collapse and stop circulation (Bennett 1975).

Shear stress and normal pressure are related to blood flow as can been seen in Figure 9.

Assuming the attachment to the leg is 200mm high and the leg has a circumference of 300mm, the surface area on the attachment is 60 000mm$^2$. Using a worst case scenario of 980N loaded in shear the shear stress on the user’s leg follows from:

$$\tau = \frac{F}{A}$$

Eq. 4

Which leads to $\tau=16$ kPa, this implies that on average the device will restrict blood flow by approximately 10-15%.

This restriction in blood flow will only occur intermittently (during walking) and is in the same order of magnitude as stresses on the stump of amputees who walk with a prosthesis (Bennett 1975).

3.1.3 Acting on gait

Joint unloading devices that act on the gait (3, Figure 5) can work in a similar fashion as the devices that act on the foot. For example the force of the unaffected leg can be used to unload the leg with the damaged ankle or the entire lower leg can be replaced with a peg leg, using a separate mechanism to load the ankle (Figure 10).

While both options have merit, the chances of them affecting the gait of the user are quite high and the risk of patients not excepting the device is higher with these larger devices. If the patient is unwilling to use the device, it will not be succesful.
3.2 Concept selection

From all options mentioned in the previous section the options to modify the forces on the foot using a device that acts on the foot is selected as the most promising to fulfill all requirements. The device needs to have a passive mechanism in order for the user to be free to walk without the need for an external power source. Springs are the most promising passive mechanism, as they are wear resistant and speed independent (unlike damper systems). Different types of springs can be installed to provide different levels of unloading.

4. Dimensional design

First the preliminary design is presented, followed by the derivation of the most important dimensions and the required stiffness and length of the spring.

4.1 Preliminary design

In order to unload the ankle using a passive spring mechanism that lowers the force on the foot, several functional interpretations can be developed (Figure 11). These concepts are further explicated in Appendix B, but they all revolve around the same principle: use a spring to exert a force next to the foot in order to unload the ankle. This can be done by having one compression spring on a rotating point (Figure 11 left), or multiple compression springs at various angles (Figure 11 second left), or perhaps a compression spring fixed onto a lever (Figure 11 second right), lastly a tension spring can also be used with a lever system (Figure 11 right).

From a structural perspective, using a tension spring is preferred over compression springs. To eliminate the risk of springs buckling or lateral deflection using a tension spring is selected as the most promising structural interpretation of the concept (Chironis 1961; Wahl 1963). Using a tension spring also implies a mechanism is needed to convert the tension in the spring to a downward force, for which a system of levers is the simplest option to construct.

The final design aims to use a tension spring to deliver an upward force next to the foot. The design consists of two parts: ‘unloading mechanism’ and ‘fixation to lower leg’. The latter part of the design connects to the lower leg in order to ‘bypass’ the recovering ankle.

For this part, already suitable options are available on the market such as the Össur air walker or the DJO global Aircast pneumatic walker (Mason and Dodds 2010). That is why this study focuses on the design of the former part, which is the new functionality that will be added.

Although more complicated designs are possible, a device attached to the lower leg with a tension spring on the posterior side connected to a lever mechanism that exerts a force on the ground on the anterior side of the foot is chosen as a preliminary design (Figure 12). With only one rotation point and few moving parts it is the simplest way to test the concept of exerting a force next to the foot in order to unload the ankle.

![Figure 11: multiple functional interpretations of the concept to unload the ankle by exerting a force next to the foot using a spring](image)
Figure 12: list of components in the preliminary design, including a guideline for minimal ground clearance

Figure 12 shows a preliminary design solution that uses a curved plate called ‘Lever’ to generate a counter moment. In dark gray the ‘side plate’ is the component of the joint unloading mechanism that will eventually attach to the ‘fixation to the lower leg’ mechanism. The mechanical stop in light gray attaches to the side plate. The tension spring in light blue exerts an upwards force on the posterior part of the Lever. The anterior part of the Lever in turn exerts a force on the ground, which unloads the ankle.

4.1.1 Position mechanical stop
The spring at the posterior part of the Lever will pull the anterior part downwards. A mechanical stop is needed to prevent the lever-spring mechanism from causing a tripping hazard. To determine the position of the mechanical stop the minimal foot clearance during the swing phase of walking found to be 10mm for the entire motion (Begg et al. 2007). The red dashed line in Figure 12 represents a 10mm clearance below the foot (The 3D foot model is lifted 10mm from the ground). If the Lever does not make contact with the floor when the foot is elevated over 10mm it will probably not be a tripping hazard. The mechanical stop offers a second functionality: preloading of the spring.

4.2 Deriving parameters for the unloading mechanism
In order to derive the required dimensions of the joint unloading mechanism a relationship between the GRF and the force exerted by the device has to be derived. After this relationship is determined a mathematical descriptive model of walking with the joint unloading device can be created to analyze the parameters of the device.

4.2.1 Relationship between the GRF and the unloading force
In order to relate the force exerted by the joint unloading device to the GRF of the user Free Body Diagrams (FBDs) have to be derived. In order to do so the following assumptions are made:

- A polynomial of the GRF is created to describe the magnitude of the forces on the foot; the swing phase of walking is neglected.
- The GRF $F_R$ (Figure 13) is assumed to be a vertical force throughout the stance phase.
- The unloading mechanism will most likely impart a vertical and a horizontal force on the lower leg. It is assumed that the vertical force will unload the user’s ankle, while the horizontal force will be experienced as a normal load on the user’s leg.
- If the device unloads the lower leg with a force larger than the GRF, the mathematical model might predict a “negative force” on the ankle of the user. At this moment, it is unclear how the user of the device will experience a “negative GRF”, for further analysis, these values are set to zero.
Figure 13 shows the three FBDs that were derived for the Lever, Side Plate, and lower leg. The resulting force $F_R$ that the Lever exerts on the Side plate follows from Eq.5:

$$F_R = \left( \cos(\beta) + \frac{A}{B} \right) F_{spring}$$

Eq. 5

The ratio between distances A and B will be determined in the mathematical model of walking. The force $F_R$ and the spring force are in equilibrium with two resulting forces on the Side plate (these resulting forces act on the lower leg) $F_{brace-x}$ and $F_{brace-y}$ (Eq.6).

$$F_{brace-y} = F_R - \cos(\beta) F_{spring}$$
$$F_{brace-x} = \left( \frac{A}{B} \right) F_{spring}$$

Eq. 6

The horizontal brace force $F_{brace-x}$ does not contribute to the unloading behavior, however it does give an estimate of the forces that act on the leg. The resulting forces that act on the lower leg lower the GRF, this reduced GRF is $GRF^*$ and it follows directly from Eq.7:

$$BW = GRF$$

$$GRF^* = GRF - \left( \frac{A}{B} \right) k (L - L_0)$$

Eq. 7

Where $GRF^*$ is the unloaded GRF, $GRF$ is the regular GRF, A and B are the moment arms of the spring force and the force on the tip of the Lever, $\beta$ is the angle between the spring and the Side plate and $k$, $L$ and $L_0$ are spring parameters. Angle $\alpha$ varies between 80 and 100° during gait, this can be neglected as the error is less than 2%.

4.3 Parameter optimization

The relationship between the unloaded GRF and the unloading force of the joint unloading device has been derived according to Section 4.2.1. In order to dimension the joint unloading device, the design parameters are identified and optimized in a mathematical model. The variables A and B are dependent on the design parameters of the joint unloading device, these design parameters are illustrated in Figure 15. The parameters are the length of the posterior

---

Figure 13: (Left) FBD of the lever with rotation point $R$, the force $F_R$ is the resulting force to balance the spring force and the tip force. (Middle) FBD of the side plate with the spring force and resulting force of the lever. Angle $\beta$ for the spring force is also illustrated. (Right) FBD of the lower leg pictured during heel off under the angle $\alpha$, with the resulting force $GRF^*$
part of the Lever $L_1$, the length of the anterior part $L_2$, the angle between these parts $\theta$, the location of the rotation point of the Lever $B_2$ (in both x and y coordinates), and the location of the upper spring attachment point $B_1$ (in x and y coordinates), the points where the Lever connects to the ground and spring are denoted as $B_0$ and $B_3$ respectively.

4.3.1 Mathematical descriptive model of the stance phase

To analyze the behavior of the joint unloading device a mathematical model of the stance phase is derived from literature. Using this model the influence of the design parameters of the joint unloading device can be derived. The GRF of the stance phase is reproduced using an 8th degree polynomial (Appendix C) and angles of the foot and lower leg are derived from literature (Perry 1974). Foot measurements from a large EU46 size foot are used as these are presumably a worst-case scenario. The progression of the stance phase can be seen in Figure 14.

Using this model the parameters of the device can be optimized, the Matlab code for this optimization procedure can be found in Appendix C.

The mathematical model solves Eq. 7 for each percentage point of the stance phase of gait (Eq. 8):

$$\sum_{n=1}^{100} \text{GRF}^*(n) = \text{GRF}(n) - \left( \frac{A(n)}{B(n)} \right) k (L(n) - L_0)$$

Eq. 8

Where ratios $A$ and $B$ follow from Eq. 9:

$$A(n) = L_1 \sin(\gamma)$$
$$B(n) = B_{0x} - B_{2x}$$

Eq. 9

The angle $\gamma$ can be seen in Figure 13, the parameters $B_{0x}$ and $B_{2x}$ are depicted in Figure 15. While $B_{2x}$ follows from the dimensions of the foot, $B_{0x}$ is derived in Eq. 10:

$$B_{0x} = L_2 \cos(\phi) + B_{2x}$$
$$\phi = \arcsin \left( \frac{B_{2y}}{L_2} \right)$$

Eq. 10

The spring length $L$ follows from the coordinates of $B_1$ and $B_3$ (Eq. 11):

![Figure 14: progression of the stance phase of walking from left to right, using a simplified foot and lower leg](image)

![Figure 15: (left) dimensions for the design of the unloading mechanism. (Right) model description of the device with the foot in blue and the Lever in green. This design with $\theta=80$ and $L_2=150$mm shows interference between the posterior Lever and the ground](image)
\[
L(n) = \sqrt{(B_{3y} - B_{3y})^2 + (B_{3x} - B_{3x})^2}
\]

\textbf{Eq. 11}

Here the coordinates for \(B_1\) follow from foot dimensions, and the coordinates for \(B_3\) follow from Eq. 12:
\[
B_{3x} = B_{2x} + L_1 \cos(\theta - \varphi)
\]
\[
B_{3y} = B_{2y} - L_1 \sin(\theta - \varphi)
\]

\textbf{Eq. 12}

The goal of the optimization is to find a set of parameters that unload the ankle maximally. To do so one set of parameter values is selected and varied across a range (Table 2). The values for \(\theta\) and \(L_1\) are chosen to ensure the anterior Lever connects with the ground on the anterior side of the rotation point \(B_2\). The spring attachment point \(B_{1x}\) is varied between 60 and 120mm from the centerline of the lower leg, values less than 60 are neglected because they are likely to interfere with the users’ leg. The rotation point of the Lever \((B_{2x} \text{ and } B_{2y})\) is selected to be at the rotation point of the ankle and is varied downwards and posteriorly by a maximum of 40mm.

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|}
\hline
Parameter & Starting parameters & Range \\
\hline
\(\theta(\degree)\) angle between Levers & 150 & [100; 160] \\
\hline
\(L_1\) (mm) Lever length & 165 & [150; 180] \\
\hline
\(B_{1x}\) (mm) upper spring attachment point (horizontal) & 65 & [60; 120] \\
\hline
\(B_{2x}\) (mm) Lever rotation point (horizontal) & 0 & [0; -40] \\
\hline
\(B_{2y}\) (mm) Lever rotation point (vertical) & 0 & [0; -40] \\
\hline
\end{tabular}
\caption{parameters in the mathematical model that are varied}
\end{table}

The parameters \(k\) and \(L_0\) of the spring are not varied, as their influence on the unloading device follow from Hooke’s law (Eq. 13):
\[
F = k(L - L_0)
\]

\textbf{Eq. 13}

Therefore varying either the initial length of the spring or its stiffness will result in a different unloading behavior, therefore interchanging the tension spring is selected to be the manner in which the joint unloading device can accommodate different levels of unloading (as per the requirements). The tension spring is the easiest to interchange with versions of different stiffness which makes the design modular and adaptable to different unloading settings which can be adjusted by a user at home. Parameters \(L_1\) and \(B_{1y}\) are selected as fixed. Changing \(L_1\) has the same effect on the ratio \(A/B\) as changing \(L_2\) (Eq. 5). Therefore selecting \(L_1\) to be 100mm ensures the spring is not likely to interfere with the users’ foot. Changing \(B_{2y}\) has the same effect as changing the initial length of the spring \(L_0\). Therefore it is chosen to be 150mm above the rotation point of the Lever.

\subsection{4.3.2 Optimization results}

The model was run varying the parameters in Table 2 one at a time. The results were that varying the rotation point of the Lever showed minimal influence (Figure 16 and 17).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure16}
\caption{the resulting force on the foot when varying the vertical position of the Lever rotation point shows moderate influence. In red a 10mm displacement, yellow 20mm, green 30mm, blue 40mm}
\end{figure}
Changing the vertical position does not change the shape of the curve, it can be assumed that the difference in the level of unloading can be attributed to a longer spring length (and therefore a higher spring force). Changing the horizontal position does not seem to make a significant difference.

Varying the lever length L2 yields minimal difference in the unloading behavior of the joint unloading device (Figure 18):

Except that the shortest L2 provides the most unloading during the last section of the stance phase.

Varying the angle θ shows that the sharpest angles provide the highest unloading (Figure 19).

Lastly, varying the horizontal position of spring attachment point B1 yielded no significant difference in the unloading behavior of the device.

4.4 Selection of parameters

After varying all the parameters a selection can be made in order to design the joint unloading device.

Concerning the rotation point of the Lever, selecting a point at a certain distance from the ankle rotation point does not seem to influence the unloading behavior. Therefore rotation point B2 is selected at the rotation point of the ankle.

The upper spring attachment B1 is selected at 70mm to ensure it does not interfere with the users’ leg. Selecting a higher value might lead to additional effects on the lower leg not described in the model (such as additional moments or transverse forces).

Lastly, the dimensions for the Lever θ and L2 can be derived. The shortest possible anterior Lever combined with the sharpest angle θ should produce the highest unloading force. However this configuration could lead to the posterior Lever interfering with the ground (Figure 15).

An interference check in the model shows an angle θ of 100° does not interfere with the ground.

Therefore, as a final design, a Lever with $\theta=100^\circ$ and $L_2=150\text{mm}$ is selected as the best outcome of these calculations.
4.4.1 Varying Lever shape

In the previous section one set of values for $\theta$ and $L_2$ are selected as optimal for maximal unloading. This design uses one contact point for the Lever. Alternatively, the joint unloading device could use a Lever with multiple contact points that would roll along with the motion of the foot (Figure 20).

Two of these adapted Levers were tested in the mathematical model and the results show that using the original Lever yields the highest unloading (Figure 21).

![Figure 20](image1.png)

Figure 20: the resulting force on the foot using differently shaped Levers. In red the top original Lever from Figure 20, in green the middle adapted Lever from Figure 20, in blue the right adapted Lever from Figure 20.

However, using the ‘original Lever’ might lead to a different practical issue: the Lever is shorter than the distance between the ankle and the ball of the foot, during the final stages of gait this means the Lever will move backwards (Figure 22).

![Figure 22](image2.png)

Figure 22: (left) solidworks model of the original Lever. (Middle) Adapted Lever using a 35° curve. (Right) Adapted Lever using a 50° curve. The corresponding unloading behavior of all three Levers is plotted in Figure 21.

In the model this does not lead to complications, but in reality it might lose contact with the ground and therefore cease to exert an unloading force on the ground. Therefore a second prototype ought to be tested with an adapted Lever that ensures contact with the ground. To ensure contact with the ground but keeping the dimensions equal ($\theta=100^\circ$ and $L_2=150\text{mm}$) the Lever can be curved at $35^\circ$ at the tip and then lengthened by 30mm (Figure 20). The angle of $35^\circ$ is chosen because this is the angle to foot contacts the ground in the mathematical model, the Lever should therefore behave the same as the regular Lever for the first stages of gait, but ensure contact with the ground during toe off.

4.4.2 Mechanical stop

The mechanical stop is placed in such a manner that during the swing phase of walking the Levers do not touch the ground, a 10mm clearance in selected and an interference check in the model shows it can be incorporated with the proposed Lever.
without problems.

4.5 Constructive interpretation of the final design

Using the parameters selected in Section 4.4 a 3D model of the proposed joint unloading device is made in Solidworks (Dassault Systèmes SOLIDWORKS Corp., USA). The design offers six holes to attach the unloading mechanism to the second part of the joint unloading device: the attachment to the leg. The mechanical stop is made with a small strip of steel and all edges are curved to prevent harm to the user (Figure 23).

![Figure 23: Solidworks model of the unloading mechanism of the joint unloading device](image)

Detailed drawings of the Solidworks model can be found in Appendix D.

4.6 Construction of the prototype

The Solidworks model was used to create a prototype, for which the steel parts were laser cut from 1.5mm stainless steel (Prins Staal BV, The Netherlands), two springs were used for testing with parameters $k=0.6N/mm$, $L_0=100mm$ (Tevema, The Netherlands), an Iglidur bearing is used for the rotation point (Igus, Germany). The complete list of parts is found in Appendix D.

The springs selected should unload the foot by approximately 30%. The Lever adaptation proposed in Section 4.4.1 was fabricated from 3mm thick aluminium (Figure 24). To attach the unloading mechanism to the lower leg a custom fitted plastic shell was created using thermoform plastic (Blrtronics, United Kingdom), fitted with padding and a Velcro white strap obtained from an off-the-shelf ankle brace (Active Ankle T2, Cramer products, USA). To ensure the unloading mechanism can be tested optimally the attachment to the leg should have minimal play; if the attachment to the leg moves a lot the unloading mechanism cannot be tested optimally. To minimize play a gray Velcro strap is ran underneath the foot, securing the attachment to the leg. After a first test rubber was added to the tip of the Lever to ensure it did not slip on the ground. An aluminium band was fastened around the brace to limit bending and unwanted movement in the Lever (Figure 24).

5. Evaluation

The prototype is evaluated in two conditions, with the standard Lever and with the adapted Lever. The goal is to measure the residual force on the foot with the device and compare this to the normal gait of the user. The difference in GRF will be the unloading force of the device.

To evaluate the prototype the RS scan force platform (RS, 2m Hi-end footscan system, RS scan International, Beringen, Belgium) was used in the Erasmus MC (Rotterdam, The Netherlands). The RS scan plate is covered with rubber, after a first test it was decided to remove the rubber from the prototype and cover the Lever end with a smoother surface (cloth) in order to prevent damage to the RS scan.
The measurement protocol was as follows. First, the test subject’s normal gait was measured, analyzed and compared to data from literature, 5 trials were averaged for the right foot. Then the device with normal and adapted Lever was tested in 5 trials and the results were averaged.

The output of the RS scan is a surface plot that yields a force per sensor (Figure 25). The location of the Lever and foot on this surface have to be selected manually in order to identify which part of the load exerted on the device and which part on the foot.

Figure 25: (left) example of the RS scan output for normal walking, (right) example of the RS scan output for walking with the device

Figure 24: construction of the prototype, with left the original Lever and right the adapted Lever. (Right) black shrink tubing on the anterior end of the lever serves as a rubber coating
6. Results
The results of the measurements can be plotted against the theoretical values predicted by the mathematical model. The GRF of the test subject matched the shape of the theoretical GRF quite well, however this subject appears to have a relatively low magnitude during the mid stance phase: a local minimum of $0.75 \pm 0.02$ BW was found, compared to 0.9 BW from theory (Perry 1974). The theoretical unloading behavior describes a peak value during heel strike of 0.9 BW and a peak value during toe off of also 0.9 BW. Both devices did not register a peak value during the first stages of the stance phase, during toe off the peak value for the standard device was $0.94 \pm 0.04$ BW and $0.88 \pm 0.02$ BW for the adapted device. Measurements of both devices show a high standard deviation in the first half of the stance phase compared to the second half. For the standard device the standard deviation is 0.09 in the first half while it is 0.04 in the second. For the adapted device the deviations are 0.10 and 0.05 respectively. The unloading curves and standard deviations of both the standard Lever and the adapted Lever are plotted against the measured GRF of the test subject without the device. This measured GRF is used as the input for the mathematical model, instead of the polynomial obtained from literature (Figure 26).

7. Discussion
In this study a solution is presented for a patient group recovering from a cartilage defect in the ankle joint. A device was

![Figure 26: comparing the unloading curve obtained from the model (black) to the unloading curves of the joint unloading device with original Lever (red) and adapted Lever (blue), showing the measured GRF as a reference (magenta). In dashed lines the standard deviations are shown](image-url)
developed that unloads the user’s foot and ankle during regular walking. This joint unloading device accomplishes this task by exerting a force next to the foot using a Lever and tension spring.

7.1 Method
The method used in this study investigated the main requirement of the device (finding the appropriate load to stimulate healing) and focused on that requirement. Three levels of unloading were identified and the option to unload by acting on the foot was selected. The results have shown that the selected approach can unload the user’s foot, however this does not mean that the other types of unloading cannot accomplish this as well. The choice to select a Lever with a tension spring as the final concept appears to be a good choice, the tension spring avoided problems of buckling and off-axis loading that could have happened with a compression spring. The use of a simple Lever design used only one joint. This joint did have some problems in the prototype; it allowed for some sideways movement and caused slight friction when moving. However other designs more complex like four-bar-mechanics would require more joints, which would aggravate these problems. The method of designing the Lever was to find optimal unloading with the Lever parameters, of which the length of the anterior part of the Lever and the angle \( \theta \) were varied. The results of the mathematical model showed a short length and sharp angle produced the highest unloading force. However both parameters caused problems during the evaluation of the prototype. The short length of the anterior part \( (L_2=150\, \text{mm}) \) caused the Lever to lose contact with the ground during toe off; the user of the device during testing reported that the Levers of the (original) device left the ground before his foot did. The adapted Lever did not show this problem. The sharp angle of \( \theta \) did increase the unloading force of the device, however it also limits the options of adapting the Lever because of the risk of interference with the ground of the posterior part (Figure 14). Perhaps selecting a sharp angle \( \theta \) is a good choice for maximum unloading, but it might have been a better choice to select larger angle and compensate with stiffer (or shorter) springs. The mathematical descriptive model relied on the assumption that the unloading force of the Lever was always vertical in direction. However during testing of the prototype the user reported feeling resistance with the first contact when using the device, the initial set-up with a rubber coating on the anterior part of the Lever even showed signs of ploughing in the rubber mat of the RS Scan. Therefore some transverse forces will have had to be present during testing. Correcting the model, using the assumption that the unloading force is always perpendicular to the Lever shows a different unloading pattern. The FBD of the Lever changes (Figure 27).

![Figure 27: Adapted FBD of the Lever using a force \( F_{\text{tip}} \) perpendicular to the Lever](image)
GRF* = GRF − \left( \cos(\phi) \frac{A}{B} \right) k \left( L - L_0 \right)

Eq. 14

Where length B is equal to the length L_1 of the anterior Lever and the angle \( \phi \) is dependent on the angle the Lever makes with the ground. The resulting unloading behavior still does not match the heel strike phase and predicts an unloading force during mid-stance which is lower than was measured. However the height of the peaks during heel strike and toe off correspond quite well with the height of the measured unloading curves (Figure 28).

7.2 Prototype

Construction of the unloading mechanism went well, attaching the tension spring turned out to be easy; which is advantageous to future users as this means selecting different springs for different unloading behavior. However in attaching the unloading mechanism to the leg some challenges need to be overcome. This study used a custom fitted plastic device; while it fit the user well a high force was felt on top of the tibia where the device ended, until sufficient padding was added the device was not usable. For new editions of the attachment to the lower leg a very long device is recommended in order to keep these forces low. During walking the Levers of the device had a tendency to move transversely which resulted in an increase in play in the rotational joint. The Levers also did not function simultaneously; it could be observed that during most of the trials one Lever left the ground before the other.

Figure 28: comparing the unloading curve obtained from the adjusted model (black) to the unloading curves of the joint unloading device with original Lever (red) and adapted Lever (blue), showing the measured GRF as a reference (magenta). In dashed lines the standard deviations are show
For future editions of the unloading device it is recommended to fixate the two Levers mechanically, perhaps by linking them either around the foot or perhaps underneath the foot.

7.3 Evaluation
Evaluating the prototype was done in a dynamic test, while all calculations on the device where done quasi-statically, this might explain some differences between theoretical and actual values.

Another explanation for the difference in the shape of the unloading curve is the time it took for one step. The average step time with the device was 30% longer than the step time without device. A longer step time makes it more difficult to directly compare the unloading curves of the device to the behavior described by the model. However, more important than the shape of the curve or the time it takes for a step, is the magnitude of the forces on the foot, as these forces are the design goal of the device.

Testing different Levers did not show dramatic changes in the unloading curve, however user testing reported the device with the adjusted Lever could not ‘cheat’ the unloading behavior. The original Levers allowed the user to walk on his toes and negate the device; the adjusted Lever could not be cheated.

Without a real change in unloading behavior, the adapted Lever ensured unloading throughout the stance phase and therefore it is recommended to use this Lever for future studies.

7.4 Future direction
This study ends with the conclusion that a device using a tension spring on a Lever can unload the GRF on the foot. However the force that is exerted on the (damaged) ankle is the TSF (Section 2.2), this force is dependent on the muscle activity and GRF.

This study assumed that a reduction in GRF also leads to a reduction in muscle activity and that this reduction should in turn reduce the TSF. A study on leg muscle activity during walking on crutches seems to support this assumption: reducing the load on a leg reduces the EMG activity of the muscles in this leg (Clark et al. 2004). However future studies should show the relation between reduced GRF and reduced muscle activity and how the TSF is affected by the joint unloading device, for example this could be done using a cadaver study when an artificial load is placed on the leg. Studies using a similar experimental set-up have already been done (Sharkey and Hamel 1998; van Bergen et al. 2010).

To improve the joint unloading device itself a new method to fixate the device to the lower leg will be needed. This study proposes pneumatic casting as a solution (Mason and Dodds 2010). This is a readily available technique used to fully fixate the lower leg and foot. A similar device will need to be adapted that places the entire load of the device onto the lower leg, without exerting a force on the foot, as this would load the damaged ankle.

The device itself is not very complex, and the modular design of the Lever and springs should allow for adaptation to different body weights, foot sizes and levels of unloading. A solution that adapts to different ground surfaces could also be beneficial to the use of the device, as a large contrast between walking on a regular stone floor and the surface of the RS scan was observed during testing.

8. Conclusion
The proposed device has been designed to aid the rehabilitation of ankle injuries; it does so while allowing the patients to keep on walking without the need for crutches. The prototype created showed unloading behavior that could achieve these goals.

References


Mason LW, Dodds A (2010) A prospective study comparing attempted weight bearing in fiberglass below-knee casts


Appendix A

Talar dome contact surface area

While this study continued with developing a joint unloading device that acts on the foot by modifying the forces on the foot, significant works was done to investigate the contact surface area of the Talar dome. Future studies that follow this approach could benefit from investigating the contact surface area of the Talar dome during walking.

Healthy persons have a range of motion in their ankle joint of $\pm 41$ degrees Plantar flexion and $\pm 16$ degrees dorsiflexion (Anderson 2006). However, during walking maximum plantar flexion and dorsiflexion are both $\pm 10$ degrees (Figure 1, (Perry 1974; Stauffer et al. 1977; Beyaert et al. 2004)).

The relative position of the talus to the tibia changes with the dorsi-plantarflexion angle and as a consequence changes the contact surface area of these two bones during walking. For the four phases of the stance phase, the following angles are selected for further calculations (Table 1).

<table>
<thead>
<tr>
<th>Phase</th>
<th>% in stance phase</th>
<th>GRF (BW)</th>
<th>TSF (BW)</th>
<th>Angle(°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HS</td>
<td>5</td>
<td>0.4</td>
<td>1.0</td>
<td>10 PF</td>
</tr>
<tr>
<td>MS</td>
<td>25</td>
<td>1.2</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td>HO</td>
<td>60</td>
<td>1.0</td>
<td>3.0</td>
<td>10 DF</td>
</tr>
<tr>
<td>TO</td>
<td>75</td>
<td>1.2</td>
<td>4.1</td>
<td>10 PF</td>
</tr>
</tbody>
</table>

Table 3: Tibial shaft forces and the angle of the ankle during 4 phases of gait

Two studies are used to determine the contact surface area of the Talar dome. These two studies use a different approach, one study uses a load of 1000N at 20deg PF and 20deg DF (Millington et al. 2007).

The other uses smaller loads to force the joint into its maximal PF or DF (Zengerink et al. 2015).

As human gait limits the ankle joint to $\pm 10$ degrees of motion in PF and DF, the values from both studies cannot be used directly. Therefore an approximation is used for this study. At plantar flexion,
the posterior side of the Talar dome is loaded and illustrations from both studies imply that this contact area is smaller than the other contact areas. Therefore 5 cm\(^2\) is used. For neutral and dorsiflexion positions the values for both studies are closer together, conservative values of 7.5 and 7cm\(^2\) are selected.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PF (10deg)</td>
<td>5 cm(^2)</td>
<td></td>
</tr>
<tr>
<td>N (0deg)</td>
<td>7.5 cm(^2)</td>
<td></td>
</tr>
<tr>
<td>DF (10deg)</td>
<td>7 cm(^2)</td>
<td></td>
</tr>
</tbody>
</table>

*Table 5: chosen values for contact surface area for this study*

Using illustrations of both studies, a rough approximation of the location of the contact surface is made (Figure 2). In this figure the superior view of the Talar dome is shown, the medial side to the left and lateral side to the right, in green the contact area of each phase during walking is shown.

![Figure 2: Contact surface area during walking](image)

Using illustrations of both studies, a rough approximation of the location of the contact surface is made (Figure 2). In this figure the superior view of the Talar dome is shown, the medial side to the left and lateral side to the right, in green the contact area of each phase during walking is shown.

![Figure 3: Contact surface area during walking](image)

The contact area is essential for the design of the device, as it is know that osteochondral defects of the Talar dome are most common on the anteromedial and posterolateral shoulders of the talus. Approximately two thirds of these lesions occur medially, while one third is laterally (Choi et al. 2013).

Using the locations marked in red (Figure 3) (van Dijk et al. 2010b), it is clear that for an anteromedial defect the ankle should be unloaded during Heel strike, Mid-stance, and Toe off. For a posterolateral
defect the ankle should be unloaded during Mid-stance and Heel off.

Figure 31: superior view of the Talar dome showing the most common locations of defects, contrasted with contact area during motion. (Left) in green the approximated contact area during heel strike and toe off, in blue the approximated contact area during mid-stance, in red the anteromedial defect. (Right) in green the approximated contact area during heel off, in blue the approximated contact area during mid-stance, in red the posterolateral defect.
Appendix B
Concepts lowering force by acting on foot

Several constructive interpretations of the concept that acts on the foot by modifying the forces are proposed. All of which rely on the use of a fixation to the lower leg and a spring (Figure 4).

The first concept relies on one compression spring that rotates with the foot to exert a force on the ground (Figure 5).

This approach was abandoned because the angle $\psi$ will likely cause lateral deflection of the compression spring.

The second concept sought to use 3 or more compression springs, one for each of the four stages of the stance phase. This approach was also abandoned for the same reason as the first concept.

The third and fourth concept work in similar fashion, using a Lever and a spring a force is exerted on the ground (Figure 6).
Figure 34: the third and fourth concept depicted during four stages of the stance phase. Both methods use a Lever combined with spring (compression spring for the third concept, tension spring for the fourth).
Appendix C
Matlab code

The Matlab code used to model walking obtains the polynomial for the GRF from:

```matlab
% GRPf= [1.79487821997531e-13 -7.2088315414301547e-11 1.2081085947729e-08 -1.09135004350436e-06 
6.44464769802105e-05 -0.00163259018120178 0.0218415785088015 -0.04000016068739376 0.02037486562393195];
g=[1:100];, aphanex
GRF=polyval(GRPf,g);
GRF(GRF<0)=0;
```

And the angle of the foot Q is obtained from literature and described as a polynomial (Perry 1974):

```matlab
X0=[1 5 10 20 25 35 40 50 60 65 75 80 90 95 100];
Y0=[20 16 10 5 2 0 1 0 1 4 20 28.5 29 29.5 30 30];
Op1=polyfit(X0,Y0,4);
OP=polyval(Op1,p);
OP(OP<0)=-OP;
```

Plotting the motion of the foot:

```matlab
%% Walking Design
F1=160; % Length of Anterior foot to ankle
F2=75; % Length of posterior foot to ankle
F3=85; % Ankle height in mm
F= F1+F2; % total foot length
O=OP;
Aly=zeros(1,100);
Alx=zeros(1,100);
for i=1:60:100
    Aly(i)=sind(O(i))*F;
    Alx(i)=F*cosd(O(i))*F;
end
Aly=zeros(1,100);
Aly=zeros(1,100);
for i=1:120
    Aly(i)=sind(180)*F;
    Alx(i)=cosd(Q(i))*F;
end
for i=1:20:180
    Aly(i)=sind(Q(i))*(F+30);
    Alx(i)=cosd(Q(i))*(F+30);
end
for i=1:20:30
    Aly(i)=0;
    Alx(i)=(F+30);
end
```
% plot XY for A0 (ankle joint)
A0y=zeros(1,100);
A0x=zeros(1,100);
W=sqrt(F2^2+F3^2); % line between heel and ankle
Wa=atan2(F3/F2); % angle of said line
E=sqrt(F1^2+F3^2); % line between toe and ankle
Ea=atan2(F3/F1); % angle of said line

for i=1:25
    A0y(i)=W*sin(Q(i)+Wa);
    A0x(i)=W*cos(Q(i)+Wa);
end

for i=26:59
    A0y(i)=85;
    A0x(i)=75;
end

for i=60:100
    A0y(i)=E*sin(Q(i)+Ea);
    A0x(i)=E*cos(Q(i)+Ea);
end

J=3p;
Tx=zeros(1,100);
Ty=zeros(1,100);
R=sqrt(F2^2+(F3+200)^2); % line between heel and top of tibia
Ra=atan2(F3+200/F2); % angle of line
Y=sqrt(F1^2+(F3+200)^2); % line between toe and top tibia
Ya=atan2(F3+200/F1); % angle of said line

for i=1:40
    Ty(i)=A0y(i)+((cosd(J(i)-Q(i))^400);
    Tx(i)=A0x(i)+((sind(J(i)-Q(i))^400);
end

for i=41:81
    Ty(i)=A0y(i)+((cosd(J(i)-Q(i))^400);
    Tx(i)=A0x(i)+((sind(J(i)-Q(i))^400);
end

for i=81:100
    Ty(i)=Ty(81);
    Tx(i)=Tx(81);
end
Plotting the Lever arms and spring

```matlab
%% %%% BRACE
 Lever
\(Bx = A0x - 0\); \footnote{\textcolor{red}{rotation point}}
\(By = A0y - 0\);
\footnote{point for spring attachment sideplate}
\(Bly = zeros(1,100); \footnote{attachment at lower leg}
\(Blx = zeros(1,100); \footnote{attachment at lower leg}
\(Ox = 70; \footnote{distance between brace-attachment and rotation point}
\(Oy = 150;
\(T2 = sqrt((Ox)^2 + (Oy)^2); \footnote{distance between rotation point lever and spring attachment lower leg}
\(T2 = atan2(Ox/Oy); \footnote{angle of line T2 to T}

for i=1:40
\(Bly(i) = B2y(i) + T2*cos(T2x-J(1) - Q(i));
\(Blx(i) = B2x(i) - T2*sin(T2x-J(1) - Q(i));
end

for i=41:100
\(Bly(i) = B2y(i) + T2*cos(T2x-J(1) - Q(i));
\(Blx(i) = B2x(i) - T2*sin(T2x-J(1) - Q(i));
end

plot lines
\(x1 = [A1x; A3x]; \footnote{line for foot}
\(y1 = [A1y; A3y];
\(x2 = [A1x; A0x]; \footnote{line for heel to ankle}
\(y2 = [A1y; A0y];
\(x3 = [A0x; A3x]; \footnote{line for toe to ankle}
\(y3 = [A0y; A3y];
\(x3 = [A4x; A3x]; \footnote{line for toe to toe tip}
\(y3 = [A4y; A3y];
\(x4 = [A0x; T2]; \footnote{line for toe to tibia}
\(y4 = [A0y; TY];
\(plot foot + 2 known brace points
BLA = zeros(1,100); \footnote{Distance B2 and B1}

% Plot motion
hFig = figure(1);
set(hFig, 'Position', [x y 900 900])
```

And simulating gait

```matlab

for i=1:100 \footnote{percentage of phase, normal is 100. Toe off is at 75}
\(BLx(i) = sqrt((BLx(i)-Tx(i))^2 + (Bly(i)-Ty(i))^2);
\footnote{plot foot}
plot(x1(i),y1(i),'b',x2(i),y2(i),'b',x3(i),y3(i),'b', 'LineWidth',3);
plot(x4(i),y4(i),'b',x3(i),y3(i),'b', 'LineWidth',3); \footnote{hold on}
\footnote{plot points}
% scatter(B2x(i),B2y(i),'k','LineWidth',3); \footnote{rotation point lever}
% scatter(B1x(i),B1y(i),'k','LineWidth',3); \footnote{hold off % spring attachment at lower leg}
axis square;
\footnote{axis([-200 400 -20 600])}
```

pause (1/16)
\footnote{pause 1/16, with 80 frames: Saco runtime}
end

31
Defining variables for the model

```matlab
for i=1:1100
% plot Lever
Fx(i)=150; % selected value for L2. VARY THIS ONE
Py(i)=100; %theta
PxA=cosd(180-Py(i))*Fx(i); % X location lever end
PyA=-sind(180-Py(i))*Fx(i); % Y location lever end
Lx1=[PxA;0]; %line for posterior lever
Ly1=[PyA;0];
Lx2=[-100;0]; %line for posterior lever
Ly2=[0;0]; %Rotation point is 0,0
subplot(2,1,1)
% plot([Lx1,Ly1,'g',Lx2,Ly2,'g'],'Linewidth',2); hold on
% % axis([-150 200 -170 3])
% title('lever design')

%Find GRF with Lever input
phi1(i)=acosd(B2y(i).*Fx(i))/Fx(i); %phi1 is the angle between ground and anterior lever
B0x(i)=cosd(phi1(i)).*Fx(i)+B2x(i); %B0x(0) is contact point anterior lever, B0y=0
phi2(i)=acosd(B0y(i)); %angle between posterior lever and horizontal
B3x(i)=cosd(phi2(i)).*x+B2x(i); %length anterior lever 100mm. 100x100 matrix
B3y(i)=sind(phi2(i)).*x+B2y(i); %B3 is the location of the spring attachment on the posterior lever
L1(i)=sqrt((B1y(i)-B3y(i)).^2+(B1x(i)-B3x(i)).^2); %spring length
%lever
Bz(i)=B0x(i)-B2x(i); %moment arm B
%cosine rule to find A
L2(i)=sqrt((B2y(i)-B1y(i)).^2+(B2x(i)-B1x(i)).^2); %distance between rotation point and spring attachment
phi3(i)=acosd((L1(i).^2+100.^2-L2(i).^2))/(L1(i)*2*100); %cosine rule for the angle between Lever and Spring
A(i)=sind(phi3(i)).*100; %moment arm A
phi4(i)=asin((B3y(i)-B0y(i))/L1(i)); %angle Beta between spring and horizontal
Fv(i)=A(i)/B2y(i).*L1(i).*sqrt(B3x(i)-B1x(i))^2; %resulting force from the brace
% Fhor(i)=cosd(phi4(i)).*k*Lx(i)-L2(i);
% Fhor(i)=Fhor/(9.81*BW);
GRF0(i)=(GRF(i)+9.81*BW)-Fv(i(i))/(9.81*BW); % force on the unloaded ankle in N
GRF0=GRF; %set negative GRFs to 0
end
```

Finally, simulating gait and brace for each 1% of the stance phase and plotting results:
Appendix D
Drawings of parts and complete list of parts

The side plate:
The original Lever:

The adapted Lever:
The pin used in the rotation point:
Other parts used:

- Deltafix velcro band (20mm wide)
- 2x T4194F tension springs, Tevema Netherlands
- 2x A181FM-0608-06 iglidur, Igus Germany
- Padding and velcro strap from the Active Ankle T2, Cramer products, United states of America
- Thermoform plastic Blrtronics, United Kingdom