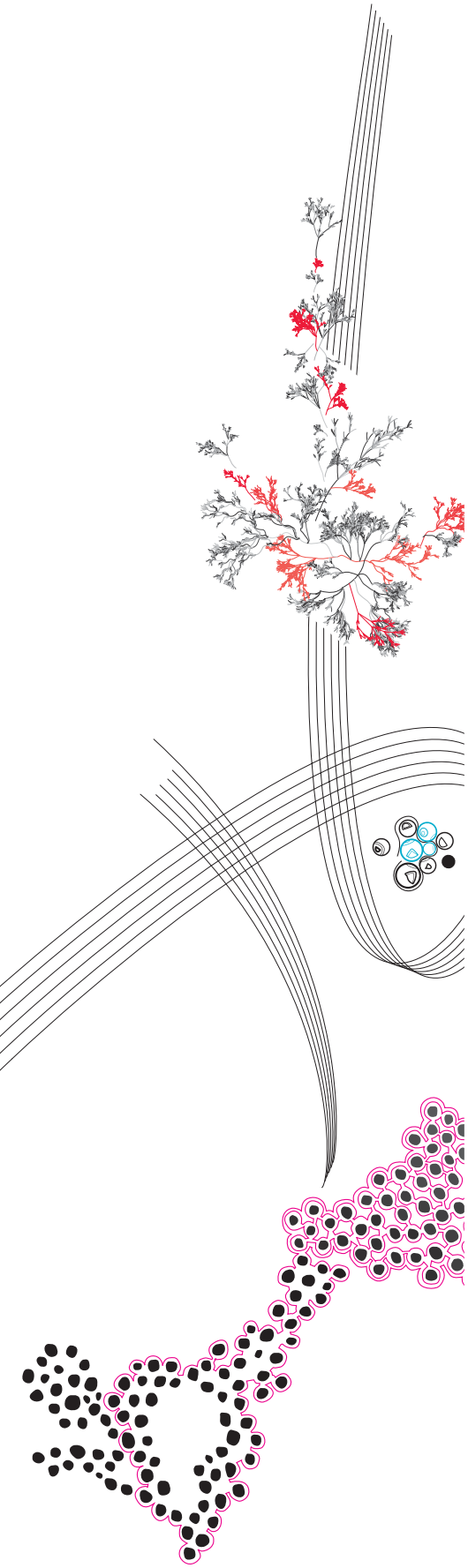

Master Thesis

The redesign and evaluation of an ankle joint offloading ankle orthosis to aid cartilage regeneration.

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Abstract

Ankle joint ankle orthoses are great assistive tools for people rehabilitating from isolated osteochondral lesions in the talus. It enables patients to control weight-bearing during the rehabilitation period after surgery. Current methods for achieving partial weight-bearing, e.g. crutches, splints, or braces, can interfere with daily activities for active and young individuals. In addition, the accurate assessment of the offloading of the affected ankle is challenging, and the rehabilitation period is 15–26 weeks. Two prototypes have been developed to reduce the rehabilitation time and to access the offloading accurately. The first prototype proved the working principle of the orthosis. The second prototype included improvements, mostly focusing on the cover of the lower leg. However, during tests with the second prototype, certain problems were found; downwards tilting, breakage of material, dysfunction of the mechanical stop, and missing a spring cover.

This study presents the redesign and evaluation of an ankle joint offloading ankle orthosis. The aim is to redesign the ankle joint offloading ankle orthosis, ensuring its compatibility for usability testing with healthy individuals. A third prototype has been designed, including three main components: (1) two shells to cover the lower leg, (2) a lever and GroundContact to transfer the forces from the ankle to the lower leg, and (3) an offloading spring mechanism for offloading the affected ankle. Component (1) was designed based on existing anti-gravity braces and should cover the entire lower leg. Component (2), lever, needed to be stiff in bending and torsion as all load transfers through this part, resulting in a hollow tube. The GroundContact was based on the design of the tip of crutches, using a larger contact area with the ground to reduce the risk of getting stuck. Component (3) was determined based on a bodyweight range of 60-90 kg, with offloading of the ankle from 25% till 75% of the bodyweight. A cover was included to ensure the patient's safety and to reduce the coils to adjust the stiffness.

The prototype was adjusted during the technical and subject validation tests. The mechanical performance of the prototype was tested with a compression/extension testing machine. The lever and GroundContact demonstrated resistance to a load of 1080N. The spring demonstrated resistance to a load of 535 N, resulting in a maximum offloading of 50% during the subject validation tests. The subject validation tests were performed using a total of 5 healthy subjects. The final test with the fourth prototype did succeed, with no breakage or bending of the device.

The fourth prototype was improved compared with the second prototype. The fourth prototype is now adjustable for different lower leg sizes, does not include pressure points, withstands mechanical forces of 1080N, includes adjustable offloading, has a larger contact area with the ground, and offloads the ankle, but till 50% of the bodyweight instead of 75%. Other improvements needed in the future are a rubber sleeve around the GroundContact, a mechanism to track the position of the offloading, a damper to reduce the sound, and holes in the frame for better compression of the Velcro bands.

In conclusion, the device proved to be a promising design step in the direction of a solution in the development of an ankle joint offloading ankle orthosis. The strength of the device was proved during functional tests, ensuring the compatibility for usability testing with healthy individuals. After some adjustments, the final subject test did succeed.

Contents

Chapter 1

Introduction

1.1 Isolated osteochondral lesion in the ankle

Osteochondral lesions of the talus (OLTs) involve damage to the articular cartilage and the underlying subchondral bone of the talus. Up to 75 % of the OLTs are caused by traumatic injuries, which include ankle sprains and fractures [1–3]. Ankle sprains account for the majority of sport-related ankle injuries, making the ankle the second most often injured body region behind the knee. In team sports and court games, the incidence was particularly high [4]. Ankle sprains can cause microfractures in the cartilage and subchondral bone plate (Figure 1.1B) as a result of the talus's contact with the distal tibial platform (Figure 1.1A) [5,6]. Osteonecrosis (Figure 1.1C) can develop when synovial fluid infiltrates these microfractures caused by elevated pressure under load-bearing circumstances [6,7].

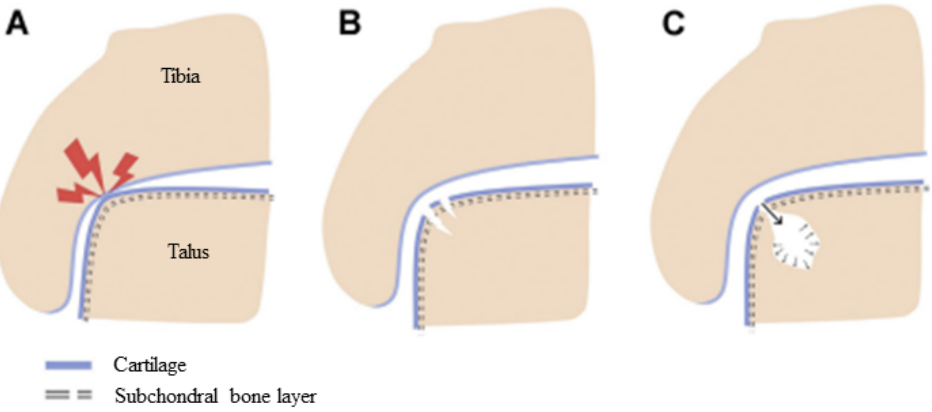


Figure 1.1: The formation of a traumatic OLT. (A) The impact of the talus on the tibia in an ankle sprain. (B) Microfractures occur in the talus. (C) Hydrostatic loading during weight-bearing forms an OLT. [8]

Patients typically manifest symptoms within 6 to 12 months following an initial trauma. This may include deep ankle pain triggered during or after load-bearing activities. Other potential symptoms may include stiffness, swelling, a locking or catching sensation, and a diminished range of motion (ROM) [9].

The treatment of isolated OLTs can be divided into conservative and surgical treatment, with conservative treatment always the primary intervention. Conservative treatment consists of a combination of interventions, including restriction of weight-bearing and physical or occupational activities, to reduce symptoms and facilitate a complete return to daily activities and sports while managing pain and avoiding high-impact sports [8]. Surgical treatment can include bone marrow stimulation [10–15], fixation techniques [8,16,17], osteochondral transplantation [10,16], and regenerative and retrograde treatments [8,14] (Appendix A). These may be considered, due to the low success rate (45 %) of conservative treatment [16,18].

This study will focus on osteochondral lesions smaller than 15 mm, probably treated with con-

servative treatment or bone marrow stimulation. Both treatments include a period of offloading the ankle. The revalidation of BMS can take up to several weeks, and partial weight-bearing is recommended immediately after the surgery [10–15, 17, 19–25]. Partial offloading reduces ankle stiffness, facilitates the healing of articular cartilage, minimizes muscle and bone atrophy, lowers the risk of complications, and contributes to early return to activities [26]. Different weight-bearing protocols were found, indicating a period of partial weight-bearing right after surgery (Figure 1.2). Wei et al. [25] mention a partial weight-bearing of 25 % of the patient's body weight by 10 minutes a day, increasing the weight with 25 % body weight and increasing the time with 10 minutes each week. Other studies suggest weight-bearing as tolerable [27–30]. The partial weight-bearing period takes on average 0 to 6 weeks, followed by full weight-bearing (Figure 1.2) [10–15, 17, 19–25, 27–34].

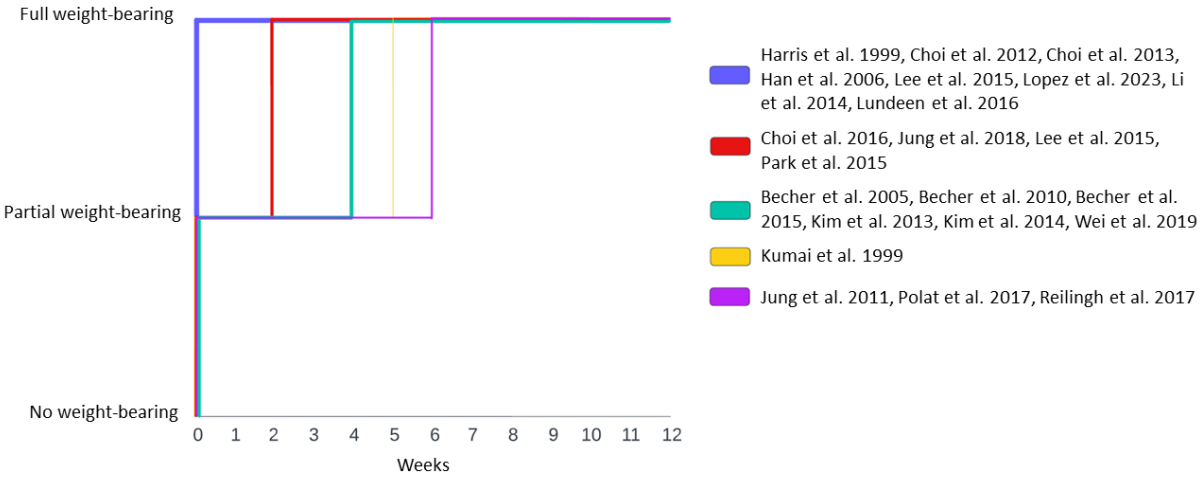


Figure 1.2: Overview of 22 studies including rehabilitation protocols after BMS treatment, starting with weight-bearing immediately after surgery [10–15, 17, 19–25, 27–34].

The rehabilitation of patients with isolated OLTs in the ankle typically includes the use of various assistive devices to fully immobilize or partially offload the affected ankle. Full ankle immobilization can be achieved with crutches, walking boots, splints, and unloading orthosis [35–39] (Appendix B). Partial offloading of the affected ankle can be achieved with crutches, walking boots, and offloading orthoses [13, 33, 37–44] (Appendix B). Wearing these devices for 15 to 26 weeks can interfere with daily activities, particularly for active and young individuals. Furthermore, accurately assessing the offloading of the ankle is challenging with these devices, making them unreliable. Therefore, an ankle joint offloading ankle orthosis is designed to support a weight-bearing recovery process for precise offloading of the ankle.

The OLTs are most commonly located on the anteromedial (marked in red) and posterolateral (marked in orange) shoulder of the talus (Figure 1.3). The load on these areas varies during the gait cycle. The dorsi-plantar flexion angle is the primary factor that influences the variation in the contact surface area of the talar dome at different stages of the gait cycle (Figure 1.3). The contact surface area varies with the angle formed by the talus and the tibia. An estimation of the contact surface area can be illustrated at four distinct gait cycle stages (Figure 1.3). The anteromedial OLTs should be offloaded at the toe-off, midstance, and heel strike phases. The posterolateral OLTs should be offloaded during midstance and heel off [45].

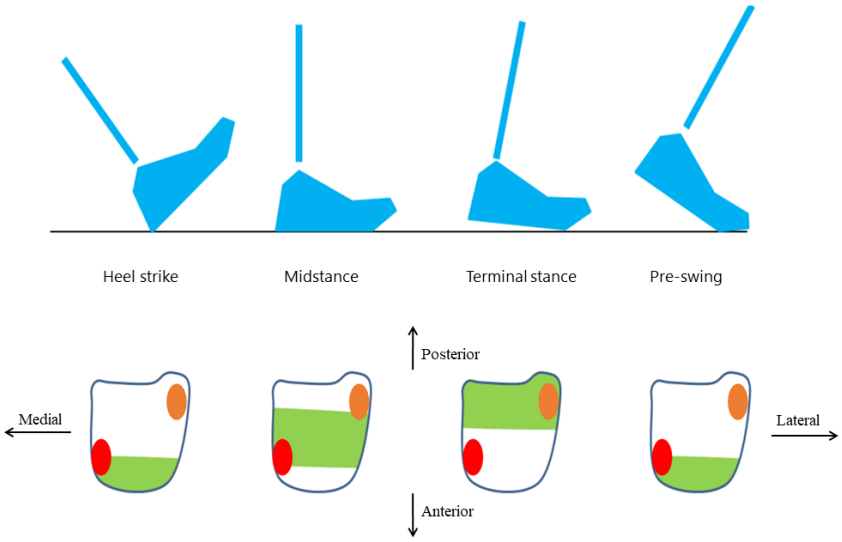


Figure 1.3: The contact surface area of the superior view of the talar dome during four different stages of the gait cycle [45]. The lateral side is on the right, the medial side on the left, the posterior side on the top, and the anterior side on the bottom.

1.2 The current design of the ankle joint offloading orthosis

An ankle joint offloading ankle orthosis was designed to decrease the rehabilitation period compared to other assistive devices and, therefore, to increase the quality of life. This is important because the target group is mostly young and active individuals. In addition, the ankle joint offloading ankle orthosis can be used to accurately access the offloading of the affected ankle for a controllable weight-bearing rehabilitation period.

The device is intended to be used for offloading of the traumatic / pathologic ankle to stimulate healing of the osteochondral defect site minimizing the influence on the gait. The two main functions are (1) connection to the lower leg and (2) unload the ankle. During this study, two assumptions have been made. The first assumption is the offloading of the ankle joint is possible using a spring. This assumption is already proven in the other first study about this design [45]. The second assumption is the adjustable parts should move analog. This assumption is made because it should be adjustable for each person.

A previous study already developed a concept (Figure 1.4.1), for an ankle joint offloading ankle orthosis and proved the working mechanism (Design 1) [45]. This concept includes two main components: the fixation part to the lower leg and the offloading mechanism. The fixation of the lower leg part consists of a custom plastic shell (Figure 1.4.1A), a side plate (Figure 1.4.1H) that connects the two main components, a Velcro band (Figure 1.4.1B) to fixate the device around the leg and an aluminium band (Figure 1.4.1I) to limit bending and unwanted movement in the levers. The offloading mechanism consists of two levers (Figure 1.4.1C), including a bending end (Figure 1.4.1D) with the anti-slip material (Figure 1.4.1E) to ensure it does not slip on the ground. During the gait cycle, the levers touch the ground before the foot, causing the spring (Figure 1.4.1F) to elongate. This results in redistributing the weight to the lower leg rather than the ankle. A mechanical stop (Figure 1.4.1G) prevents further extension of the spring so that the levers do not touch the ground during the swing phase. It will also be used for preloading the spring.

A second study continued to improve the first design (Figure 1.4.2), focusing mainly on the

fixation of the lower leg part (Design 2) [46]. In the new design, the custom plastic shell and the side plate have been combined into a single component (Figure 1.4.2AH), using an organic shape with padding inside for greater comfort. To improve overall comfort and better fixation, an additional shell was incorporated in the back of the device (Figure 1.4.2J). The aluminium band, previously situated at the bottom of the custom plastic shell (Figure **??**I), is now located at the end of the levers (Figure 1.4.2I) to avoid sliding apart on the ground. The levers were made adjustable, allowing the design to be personalized in height between the fixation of the lower leg part and the ground. Finally, the mechanical stop (Figure 1.4.2G) has been made longer to prevent the levers from falling out of this stop during ankle offloading.

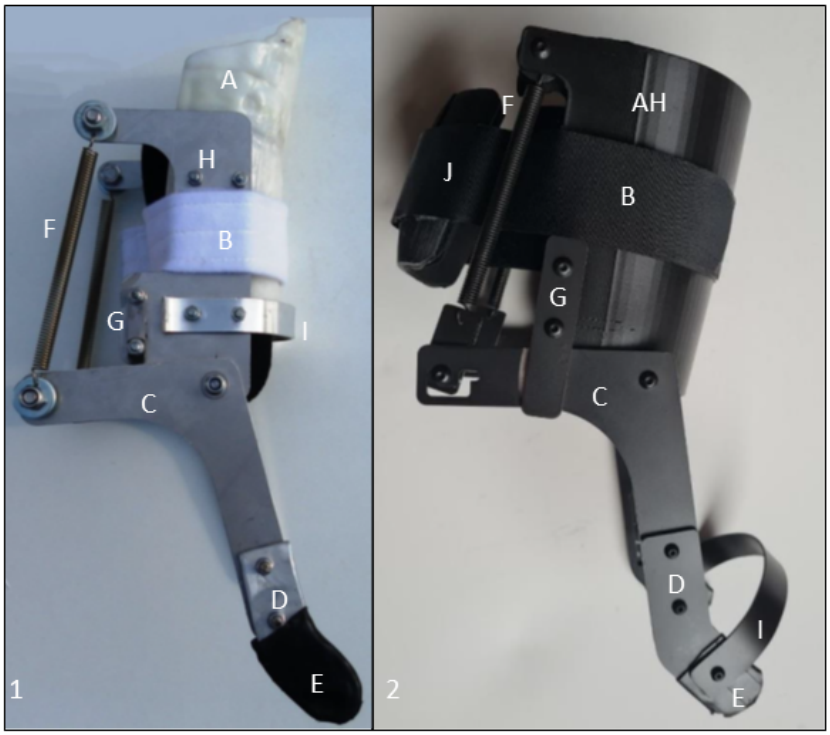


Figure 1.4: The current ankle joint offloading ankle orthosis. (Left) The design of the first study [45]. (Right) The redesign of the second study [46].

1.3 Problem analysis offloading device design 2

The first prototype did prove the working mechanism of the ankle joint offloading ankle orthosis. Tests using a force plate showed offloading of the affected ankle [45]. In the previous study, walking tests were performed and questionnaires were filled out using the second design. During these tests and after feedback of the questionnaires, certain problems were found [46].

The problems concerning the shells of the offloading device design 2 are [46]:

- Dimensions are based on the lower extremity of the researcher. Therefore, the brace cannot be used for several test subjects.
- The dimensions and shape of the front and back shell are not substantiated.
- Downwards tilting of the device resulting in the brace losing contact with the lower leg.
- The material used in the device is not strong and did already break.
- The mechanical stop, incorporated on the outside of the front shell, was too short, causing the lever to fall out. This results in insufficient offloading of the ankle.

The problems occurring to the levers of the offloading device design 2 are [46]:

- The placement of the extra band, placed in an upwards arc to avoid shearing apart of the levers, should be reconsidered to improve comfort of the device.
- A continuously adjustable mechanism should be designed instead of the track to improve the adjustability for different heights and weights.
- The footprint of the levers can become stuck on uneven terrain.

Finally, the problems concerning the spring mechanism of the offloading device design 2 are [46]:

- The Velcro band (Figure 1.4B) was frequently positioned over the spring (Figure 1.4F) during the tests because the spring was placed at the back as well as the tightening of the Velcro bands.
- The spring did not include a cover, enabling skin or material to get between the spring coils when releasing of the spring after tensioning.

1.4 Study objectives

This study aims to redesign the ankle joint offloading ankle orthosis, ensuring its compatibility for usability testing with healthy individuals. To achieve this goal, certain study objectives have to be realized.

- The usability, functionality, and adjustability of the ankle joint offloading ankle orthosis should be refined.
- The mechanical performance of the ankle joint offloading ankle orthosis should be assessed during functional tests.
- The comfortability of the ankle joint offloading ankle orthosis should be evaluated during walking tests with healthy individuals.

Chapter 2

Compliance with the Medical Device Regulation of design 2

The device will be used to ensure compliance with the Medical Device Regulations. It is important to verify that the device complies with the legal regulations. First, the general product information will be covered, including the intended use and classification of the product. The process continues by performing a risk analysis, covering the hazards, harms, and risks. During the risk analysis, the guidelines in ISO 14971:2019 (Application of risk management to medical devices) [47] are followed.

2.1 General product information

The device is classified according to its intended use. The intended use of the ankle joint offloading ankle orthosis is to offload the traumatic / pathologic ankle to stimulate healing of the osteochondral defect side, minimizing the influence on the gait. The classification is determined using a series of criteria established following Annex VIII of the MDR [48]. It is assumed that the device is used for a transient duration, intended for uninterrupted use for less than 60 minutes, or a short-term duration, intended for continuous use for more than 60 minutes and less than 30 days [49]. This is dependent on the patient because the brace can be worn or removed during sitting.

The device is not invasive because it does not penetrate the body through the surface of the body. In addition, the device is not active because it does not depend on a source of energy other than that generated by the human body or by gravity [49]. The device does transfer force from the ankle to the lower leg, but a passive mechanism (spring) is used. Therefore, the ankle joint offloading ankle orthosis can be classified as a Class 1 medical device according to Rule 1 [49].

2.2 Risk analysis

The design of Device 2 from the previous study (Figure 1.4.2) does not yet meet all requirements and should be improved in various aspects. Moreover, it was not evaluated for compliance with the MDR. The safety characteristics of Design 2 were identified using Annex A of NPR-CEN-ISO/TR 2491:2020 [50]. The goal is to identify all hazards by answering 34 questions (Appendix C). The potential hazards that accompany this type of medical device can be identified using Annex C of ISO 14971:2019 [47], which gives a complete list of possible hazards occurring in medical devices. The hazards relating to the ankle joint offloading ankle orthosis are classified into six different hazard classes: energy hazards, biological hazards, environmental hazards, hazards related to the use, hazards related to the inappropriate, inadequate, or overcomplicated user interface, man / machine communication and hazards arising from functional failure, maintenance, and ageing. These six hazard classes are used to perform the risk analysis. Improvements are needed to the device for the hazard classes posing a high risk to the user. Improvements for risks posing a medium risk should be considered, and no improvements are

needed for risks posing a low risk. Based on this analysis, it can be considered what needs to be improved in addition to the functionality.

2.2.1 Energy hazards

Four energy hazards (Table 2.1) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.1: The energy hazards identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H1.1	Mechanical forces	• Breaking of material due to shear forces at the connection points • The forces on the lower leg causing pressure points. • Irritation caused by skin ischemia	• Product failure • Harm to patient	High
H1.2	Moving parts	• Change in offloading due to screw moving out of the track • Skin between the coils of the spring	• No treatment • Harm to patient	Medium
H1.3	Unintended motion	• No offloading due to levers falling out of the mechanical stop	• No treatment	High
H1.4	Pressure	• Blood vessel to collapse and stop circulation	• Harm to patient	Low

2.2.2 Biological hazards

Two biological hazards (Table 2.2) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.2: The biological hazards identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H2.1	Exposure to bacteria	• Skin irritation • Bacterial infection	• Harm to patient	Medium
H2.2	Allergenicity	• Allergic reaction to the padding	• Harm to patient	Medium

2.2.3 Environmental hazards

Five environmental hazards (Table 2.3) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.3: The environmental hazards identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H3.1	Accidental mechanical damage	• Falling of the device • Hitting the device to an object	• Product failure • No treatment	Low
H3.2	Contamination due to waste products and/or medical device disposal	• Wrong disposal	-	Low
H3.3	Water-resistant	• Rusting of the materials	• Product failure	Low
H3.4	Inadequate performance of cleaning	• Device must be able to be cleaned after using it outside • Device must be cleaned to avoid exposure to bacteria	• Product failure • Bacterial infection	Low
H3.5	Inappropriate environmental conditions	• Materials can deteriorate when storing the device at high temperature	• Product failure	Low

2.2.4 Hazards related to the use

Four hazards related to the use of the ankle joint offloading ankle orthosis (Table 2.4) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.4: The hazards related to use identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H4.1	Inadequate operating instructions	• Incorrect placement of the orthosis • Unclear how to tighten the orthosis • Unclear how to personalize the orthosis using the adjustable part	• No treatment	Medium
H4.2	Use by unskilled patients requiring to adjust the orthosis	• Inadequate instructions • Incorrect way of handling the device • Loading of the ankle	• Product failure • No treatment • Harm to patient	Medium
H4.3	Incompatibility with consumables, accessories, and other medical devices	• Not wearable with shoes due to the distance between both levers	• Possible harm to patient	Low
H4.4	Sharp edges or points	• Pressure points • Causing wounds	• Harm to patient	Medium

2.2.5 Hazards related to user interface

Six hazards related to inappropriate, inadequate or over-complicated user interface, man/machine communication (Table 2.5) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.5: The hazards related to the user interface identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H5.1	Violation or abbreviation of instructions, procedures, etc.	• Loading of the ankle • Change of gait cycle by starting with the toes on the ground	• No treatment • Harm to patient	Low
H5.2	Lapses and cognitive errors	• Inadequate instructions • Incorrect way of handling the device • Placing the Velcro bands around the springs	• Product failure • No treatment	Medium
H5.3	Slips and blunders (mental or physical)	• Not wearing the orthosis properly. • Change of gait cycle by starting with the toes on the ground • Incorrect offloading percentage	• No / incorrect treatment • Harm to patient • Product failure	Low
H5.4	Complex or confusing control system	• Unclear how to use the device • Change of gait cycle by starting with the toes on the ground • Incorrect offloading percentage	• No / incorrect treatment • Product failure	Medium
H5.5	Mistakes and judgement errors	• Personalization using adjustable part • Incorrect offloading percentage	• Product failure • Incorrect treatment	Medium
H5.6	Ambiguous or unclear device state	• Incorrect offloading percentage	• Incorrect treatment	High

2.2.6 Hazards arising from functional failure, maintenance, and ageing

Seven hazards relating to functional failure, maintenance, and ageing (Figure 2.6) are listed, including the related hazardous situation, the harm, and the risk level (high, medium, low).

Table 2.6: The hazards related to functional failure, maintenance and ageing identified for Design 2. The risk level ranges from low to high.

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H6.1	Lack of adequate determination of the end of life of the device	• Wearing of the rubber • Performance material decreases causing bending and breakage • Performance spring decreases	• Product failure	Medium
H6.2	Re-use and/or improper re-use	• Wearing of the rubber • Performance material decreases causing bending and breakage • Performance spring decreases	• Product failure	Low
H6.3	Inadequate packaging	• Damage during transport	• Product failure	Low
H6.4	Lack of, or inadequate specification for maintenance include inadequate specification of post-maintenance functional checks	• Using the device while not functioning optimally	• Harm to patient	Low

# ID	Initiating events and circumstances / causes	Hazard situation	Harm	Risk level
H6.5	Deterioration in function as results of repeated use	• Wearing of the rubber • Performance material decreases, causing bending and breakage • Breakage of spring	• Product failure	Medium
H6.6	Insufficient control of materials	• Different properties of materials	• Product failure	Low
H6.7	Insufficient control of manufacturing process	• Different manufacturing process needed • Wrong use of materials • Wrong dimensions	• Product failure	Low

The risk analysis indicates that the product still poses risks to the patient. This can be improved by changing the design of the product to decrease the risk level (Chapter 5). Prior to implementing these design improvements, a detailed list of requirements must be presented (Chapter 3). This list is needed to address all relevant factors and constraints to ensure improved design changes.

Chapter 3

Requirements

The list of requirements has been drawn from the processes and evaluation of Design 1, Design 2, and the risk analysis (Tables 2.1-2.6). To ensure that all necessary factors and needs are considered, the requirements are divided into four categories: user requirements (Table 3.1), functional requirements (Table 3.2), performance requirements (Table 3.3), and interface requirements (Table 3.4). These categories also help during the evaluation of the prototype to separate the tests. The evaluation begins with testing the functional requirements through technical validation tests. Next, the performance requirements are assessed, starting with technical validation tests and concluding with subject validation tests. These subject tests are also used to evaluate the user requirements and user interface requirements.

3.1 User requirements

User requirements comprise a set of requirements defining users' needs and expectations of the device. The user requirements are provided in an overview (Table 3.1) including the target value. The derivations of the requirements where target values are indicated are explained below.

The second prototype already met requirements UR-01 until UR-05, UR-07, UR-10, and UR-11 (Table 3.1) [45, 46]. The target value of UR-05 was changed to $\leq$ 2 kg based on other orthoses on the market [51]. The value of UR-11 was set at 5 minutes to ensure the donning and doffing would not be a big burden throughout the day. The third prototype designed in this study should incorporate user requirements UR-06, UR-08, and UR-09 into the device (Table 3.1). The value of $\leq$ 90 kg (UR-09) is based on the upper limit of the Dutch adults between 20-60 years in 2004 [52]. The other two requirements (UR-6 and UR-09) should be true.

Table 3.1: The user requirements for the ankle joint offloading ankle orthosis, including the target value and if the requirement was already compliant within design 2.

User requirements			
# ID	**Requirement**	**Target value**	**Already compliant**
UR-01	The device shall be non-invasive [45]	True	Yes
UR-02	The device shall be minimally intrusive in walking [45]	True	Yes
UR-03	The device shall allow performing daily activities without compromising the gait [45]	True	Yes
UR-04	The device shall be wearable without causing skin problems [45]	True	Yes
UR-05	The device shall be lightweight [45]	$\leq$ 2 kg [51]	Yes
UR-06	The device shall be adjustable for different lower leg sizes	True	No
UR-07	The device shall not have sharp edges and corners	True	Yes
UR-08	The device shall not cause pressure points	True	No
UR-09	The device shall be able to be used for different body weights	$\leq$ 90 kg [52]	No

User requirements			
# ID	Requirement	Target value	Already compliant
UR-10	The device shall be comfortable [46]	$\leq$ 60 % on NASA-TLX	Yes
UR-11	The donning and doffing of the device shall not exceed 5 minutes	5 minutes	Yes

3.2 Functional requirements

Functional requirements specify the functionality of the device (Table 3.2). The second prototype already met the requirements FR-05 and FR-07 (Table 3.2). The derivations of the requirements where possible target values are indicated are explained below.

To deduct the required loading, the device should be able to resist breaking or plastic deformation. To start with the user requirement (Table 3.2, UR-09) which specifies a maximum body weight of 90 kg. From this, the maximum loading during walking can be deducted. During walking, the vertical ground reaction force increases two times above the user's body weight. During the heel strike to the first peak, the foot strikes the ground, causing the body to decelerate downward. The result is a load transfer from the back of the foot to the front of the foot during initial double support. The first peak is around 1.2 times the body weight. After the first peak, the knee extends, causing the body to decelerate upward. The result is a trough of 0.7 times the body weight. After this trough, the heel lifts, and the foot is pushed down. A second peak of 1.2 times the body weight occurs. The maximal mechanical force that the device should withstand will be the body weight times 1.2 [53]. To ensure the strength of the device in case of unexpected movement, a material safety factor of 1.5-2.0 should be applied (Table 3.2, Requirement FR-04).

FR-02 and FR-03 are important to ensure optimal offloading of the ankle joint (Table 3.2. A rehabilitation offloading protocol has been found after BMS treatment. The protocol mentions a weight-bearing time of 10 minutes every day and an initial weight of 25% of body weight. Each week, weight and duration increase by 25% body weight and 10 minutes. In the fourth week, full weight-bearing is achieved. This protocol will be used as a guideline for adjustable offloading (Table 3.2, FR-02 and FR-03) [25].

To prevent a risk of falling, a foot clearance of 10 mm should be provided to enhance efficiency and safety [54]. This requirement (Table 3.2, FR-05) is crucial to ensure that the orthosis does not drag on the ground, causing a tripping hazard of the lever-spring mechanism.

The final functional requirements with a target value are about the contact surface with the ground (GroundContact). First, the surface of the GroundContact (Table 3.2, FR-07). The GroundContact shall not get stuck between the stones when walking on the street or pavement. Elbow crutches are used as a reference because the tip of the crutches and the GroundContact of the device have the same intended use. According to ISO 11334-1:2007, the part of the tip of elbow crutches that is in contact with the walking surface shall have a minimum diameter of 35 mm [55]. The device will not be limited to a round surface, so a width of 35 mm is required. The length should still be taken into consideration in the design process, so the device does not get stuck in the vertical direction. Second, the minimum frictional force of the anti-slip material surrounding the GroundContact (Table 3.2, FR-06). According to ISO 24415-1:2010, the minimum frictional force of the GroundContact shall not be less than 25 N [56].

The remaining functional requirements include ease of cleaning, the inclusion of a user manual,

and the use of biocompatible materials. The device should have smooth surfaces and removable parts for easy cleaning to ensure safe use for a longer period. A user manual should be included with instructions for donning and doffing, usage, adjustments, maintenance, troubleshooting, and safety information. Finally, using biocompatible materials reduces the risk of allergies and skin irritation.

Table 3.2: The functional requirements for the ankle joint offloading ankle orthosis, including the target value and if the requirement was already compliant within Design 2.

Functional requirements			
# ID	**Requirement**	**Target value**	**Already compliant**
FR-01	The device shall withstand mechanical forces (vertical direction) of 1080 N	$\leq$ 1080 N	No
FR-02	The device shall be able to off-load the ankle during walking [25]	25% up to 75% of BW	No
FR-03	The offloading of the ankle should be adjustable [25]	25%, up to 75% of BW	No
FR-04	The device shall not break in case of unexpected movement	Safety factor of 1.5-2.0	No
FR-05	Minimal foot clearance of 10 mm for the entire motion [45]	10 mm	Yes
FR-06	The minimum frictional force of the anti-slip material around the GroundContact shall not be less than 25 N [56]	$\leq$ 25 N	No
FR-07	The footprint shall have a minimum width of 35 mm [55]	35 mm	No
FR-07	The device shall be designed for easy cleaning to prevent contamination	True	Yes
FR-08	The device shall be accompanied by a user manual, providing instructions for use	True	No
FR-09	The device shall be made from biocompatible materials to comply with the ISO 10993 standard [57]	True	Yes [58]

3.3 Performance requirements

Performance requirements outline how a device must function to ensure safety, efficacy, and reliability (Table 3.3), including the target value. Only requirement PR-05 was already compliant within the second prototype (Table 3.3).

The first performance requirement covers the fixation of the device on the lower leg (Table 3.3, PR-01). The second prototype showed slight downward tilting during the test. The compression mechanism should be improved to reduce sliding over the leg.

The second performance requirement addresses the degradation of the device (Table 3.3, PR-02). Wei et al. [25] mention a partial weight-bearing period of 4 weeks, with an increased load every week. Other studies suggest a partial weight-bearing for 0 to 6 weeks, followed by full weight-bearing (Figure 1.2) [10–15, 17, 19–25, 27–30]. The worst-case scenario of six weeks is taken to ensure functionality for each rehabilitation period.

The third performance requirement covers the life cycle of the device (Table 3.3, PR-03). Wei et al. [25] suggest a standard of 10 minutes of weight-bearing each day. However, in a worst-case scenario, the device can be worn for the entire day with other rehabilitation methods. Given that 10,000 steps a day is a reasonable target for healthy adults, the device must be designed for daily use [59]. PR-04 (Table 3.3) was deducted from activities for daily life (ADL), as people want to move between places outside, involving various surfaces, including pavement, gravel, and slopes.

PR-05 was derived from the need to test the device after use by a patient to ensure its functionality (Table 3.3). Testing after use is crucial to verify the performance of the device. This includes assessing the wear and tear, and mechanical failure and ensuring the functions of the components are as intended.

Table 3.3: The performance requirements for the ankle joint offloading ankle orthosis, including the target value and if the requirement was already complaint within Design 2.

Performance requirements			
# ID	**Requirement**	**Target value**	**Already compliant**
PR-01	The device shall not slide over the leg during walking	True	No
PR-02	The device shall not lose any functionality for the duration of the treatment	Life cycle of 6 weeks	No
PR-03	The device shall be able to make 10,000 gait cycles a day	10,000 cycles/day	No
PR-04	The device shall be able to be used on uneven ground	True	No
PR-05	The device shall be checked and tested after being used by a patient	True	Yes

3.4 Interface requirements

Interface requirements specify characteristics for the interaction between the device and the user and are provided in an overview (Table 3.4). IR-01 and IR-02 were already compliant in Design 2. IR-03 should be implemented in Design 3.

IR-01 and IR-02 were derived from the need to be a straightforward process and, therefore, should be completed in under 5 minutes without using specialized tools (Table 3.4). According to the rehabilitation protocol of Wei et al. [25], the offloading percentage should be adjusted weekly. Changing the springs or modifying the offloading should be an easy switch done by the patient himself, without significant time or effort. Clear indicators should be incorporated to guide the patient in adjusting to the correct offloading percentages (Table 2.5, Risks H5.4, H5.5, and H5.6). This could be markers or audible clicks to confirm successful adjustments.

To reduce the risk of user error (Table 2.5, Risks H5.2, H5.3 and H5.5), the device should be designed to be used in only one possible way (Table 3.4, IR-03). The design should include intuitive design elements that naturally guide the user in the correct direction of use. This can be achieved using ergonomic shapes or visual cues. In addition, a user manual should provide clear instructions with detailed steps for application, adjustment, and removal.
The four list of requirements (Tables 3.1, 3.2, 3.3, 3.4) are the guidance principle for the design.

Table 3.4: The interface requirements for the ankle joint offloading ankle orthosis, including the target value and if the requirement was already compliant within Design 2.

Interface requirements			
# ID	**Requirement**	**Target value**	**Already complaint**
IR-01	The spring(s) shall be able to be removed when necessary by the patient	$\leq$ 5 minutes	Yes
IR-02	The offloading percentage shall be able to be changed by the patient when necessary	$\leq$ 5 minutes	Yes
IR-03	The device shall be able to be used in one possible way	True	No

These ensure the design meets the safety and performance standards. By following these lists of requirements, the risks (Section 2.2) can be mitigated. After setting up the list of requirements, a functional analysis can be performed. This will check how the product functions against the requirements and what needs to be changed to optimize performance and safety.

Chapter 4

Functional Analysis

A functional analysis (Figure 4.1) has been carried out to understand the separate components and how those components interact to perform the intended functions. This creates a clear picture of what important functionalities the device should contain. The process starts by identifying the intended use and primary functions, followed by the sub-functions.

The device is intended to be used for offloading of the traumatic / pathologic ankle to stimulate healing of the osteochondral defect site minimizing the influence on the gait. The two main functions are (1) connection to the lower leg and (2) unload the ankle (Figure 4.1). During this analysis, two assumptions have been made. The first assumption is the offloading of the ankle joint is possible using a spring. This assumption is already proven in the other two studies about this design [45, 46]. The second assumption is the adjustable parts should move analog. This assumption is made because it should be adjustable for each person. The subfunctions are highlighted with a colour (Figure 4.1), with blue for the subfunctions used for the shells, red for the subfunctions used for the spring mechanism, and green for the subfunctions needed for the offloading mechanism.

The final sub-function covering the adjusted moment arm, including the translation in the plane and the fixation of this translation, was not continued in the design process. The moment arm only showed a difference of 1.5 % change in offloading [46]. Therefore, this sub-function is not incorporated into the design of the lever and the adjustable offloading will only be dependent on the spring stiffness.

The functions within the functional analysis (Figure 4.1) include the requirement (Table 3.1-3.4) it must meet. This process ensured that the focus was not only concentrated on the current design but that a broader perspective was taken by looking at each function the device should incorporate, before looking at the details.

The functional analysis has provided valuable insights into the important functionalities, including the corresponding requirements. This has highlighted where changes are needed to reduce the risks. Based on these findings, the design changes can be conceptualized (Chapter 5). This phase involves refining potential design solutions that address the issues and meet the requirements.

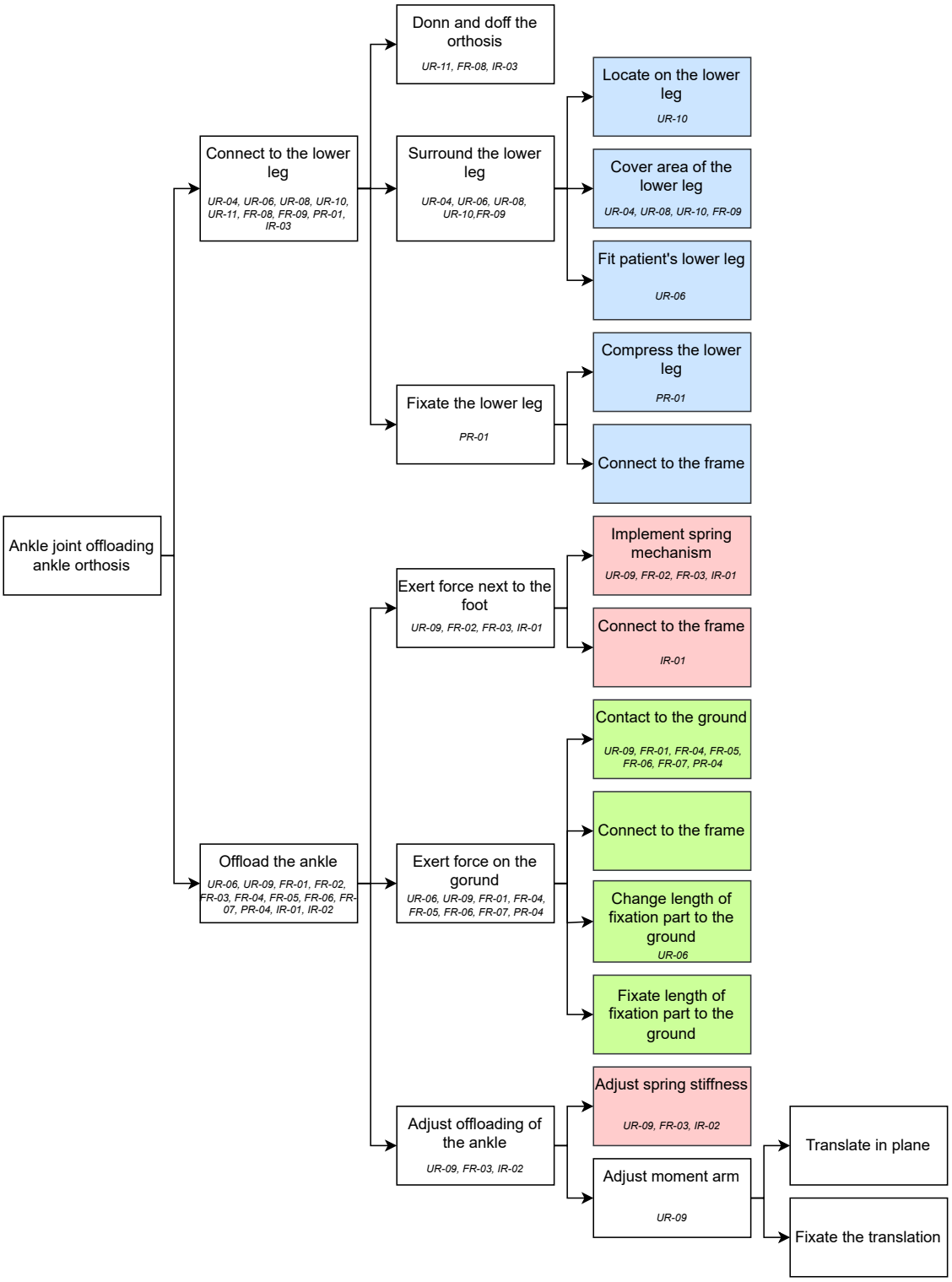


Figure 4.1: Functional analysis of the ankle joint offloading ankle orthosis. In blue the requirements and functions the shell must meet, in red the requirements and functions the spring mechanism must meet, and in green the requirements and functions the offloading mechanism must meet.

Chapter 5

Conceptualization

The functional analysis provided a good understanding of the necessary functions and requirements of the device. This understanding was the basis for generating conceptual ideas, ensuring each concept addressed the essential functions and met the specified requirements. This is discussed in this chapter, divided into three main components: (1) the shell, (2) the lever and GroundContact, and (3) the offloading spring mechanism. All associated functions of each main component are listed in a morphological chart, along with various concept ideas.

5.1 Shell

The design of the shell is dependent on five different sub-functions; (1) location on the lower leg, (2) cover area of the lower leg, (3) fit of patient's lower leg, (4) compression of lower leg, and (5) connection to the frame (Figure 4.1). Various concept ideas were generated for each sub-function (Table 5.1). These concept ideas were used for evaluating potential design solutions (Section 5.4.1).

The first sub-function is the location on the lower leg, including three concept ideas. The orthosis can extend from above the ankle up to the bottom of the knee, below the tibia tuberosity, the orthosis can extend from above the ankle till a height around the middle of the calf muscle, and the orthosis can extend till just above the ankle joint (Table 5.1).

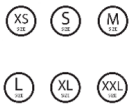
The second sub-function is the cover area of the lower leg. The orthosis can provide support in different areas, each designed to address different needs. Four different types of support were chosen as concept ideas. The orthosis can have an anterior support, posterior support, side support to support the lateral and medial sides of the lower leg, and complete support (Table 5.1).

The third sub-function is the fitting around the patient's lower leg, with two different concept ideas. The orthoses come in two different varieties: pre-fabricated orthosis and customized orthosis (Table 5.1).

The fourth sub-function is the compression of the lower leg to secure placement on the lower leg. The three concept ideas for this sub-function are: Velcro bands, air bladders, and laces (Table 5.1).

The final sub-function is the connection of the compression of the lower leg part to the frame. This subfunction was not prioritized during the beginning of the design process but was addressed in the later stages when necessary. Some options with which the chosen part of the function 'compress lower leg' can be connected to the frame are a hinge, a cut-out in the frame, glue, or nuts and bolts (Table 5.1).

Table 5.1: Morphological chart of the functions contributing to the design of the front and back shell. The functions in bold have had higher priority during the design process.

Function	**Conceptual solutions**			
	1	2	3	4
Location on lower leg	 Calf high	 Calf middle	 Calf low	
Cover area of lower leg	 Anterior support	 Posterior support	 Side support	 Complete support
Fit patient's lower leg	 Pre-fabricated	 Customized		
Compress lower leg	 Velcro	 Air bladders	 Laces	
Connect to frame	 Hinge	 Cut out	 Glue	 Nuts and bolts

5.2 Lever and GroundContact

The design of the lever and GroundContact are dependent on four different sub-functions; (1) contact with the ground, (2) connection to frame, (3) change length of fixation part to ground, and (4) fixate length of fixation part to ground (Figure 4.1). Various concept ideas were generated for each sub-function (Table 5.2). These concepts ideas were used for evaluating design solutions (Section 5.4.2).

The first sub-function is the contact to the ground, including four concept ideas. The orthosis can be in contact with the ground using a lever, an internal footplate, an external footplate, or an external boot (Table 5.2).

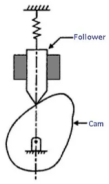
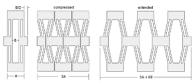
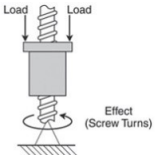
The second sub-function is the connection to the frame of the part chosen at the sub-function

'contact with the ground'. This subfunction was not prioritized during the beginning of the design process but was addressed in the later stages when necessary. The connection can be achieved using a hinge joint, a pin, and nuts and bolts or the parts could already be in one piece (Figure 5.2).

The third sub-function is the change length of the fixation part to the ground. The length has to be continuously adjustable to ensure optimal fit for each patient. This could be achieved by using a cam follower, a rail, flexure hinges, and a slot (Figure 5.2).

The fourth sub-function addresses the fixation of the length between the fixation part and the ground. This subfunction was not prioritized during the beginning of the design process but was addressed in the later stages when necessary. The length can be fixed by using a non-back drivable screw, a set screw, or nuts and bolts (Figure 5.2).

Table 5.2: Morphological chart of the functions contributing to the design of the lever and GroundContact. The functions in bold have had higher priority during the design process.

Function	**Conceptual solutions**			
	1	2	3	4
Contact with ground	 Lever	 Internal footplate	 External footplate	 External boot
Connect to frame	 Hinge joint	 One-piece	 Pin	 Nuts and bolts
Change length of fixation part to ground	 Cam follower	 Rail	 Flexure hinges	 Slot
Fixate length of fixation part to ground	 Non-back drivable	 Set screw	 Nuts and bolts	

5.3 Offloading spring mechanism

The design of the offloading spring mechanism is dependent on three different sub-functions; (1) implement spring mechanism, (2) connect to the frame, and (3) adjust spring stiffness (Figure 4.1). Various concept ideas were generated for each sub-function (Table 5.3). These concepts

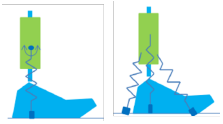
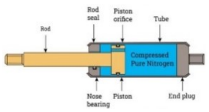
ideas were used for evaluating design solutions (Section 5.4.3).

The first sub-function is the implementation of the spring mechanism (Table 5.3). The first study introduced three different spring mechanisms: (1) the use of one or more compression springs, (2) the use of a tension spring in combination with a lever system, and (3) the use of a compression spring in combination with a lever system [45]. Another option is to use a gas spring in combination with a lever system.

The second sub-function is the connection of the part chosen for the sub-function 'implement spring mechanism' to the frame (Table 5.3). This subfunction was not prioritized during the beginning of the design process but was addressed in the later stages when necessary. These parts can be connected using a hole in the frame, a gas strut bracket, eyes, or nuts and bolts.

The final sub-function is the adjustment of the spring mechanism (Table 5.3). Three different concept ideas were generated. The adjustment of the spring stiffness can be achieved by reducing the coils of a mechanical spring, releasing gas from a gas spring, or replacing the spring.

Table 5.3: Morphological chart of the functions contributing to the design of the offloading spring mechanism. The functions in bold have had higher priority during the design process.

Function	**Conceptual solutions**			
	1	2	3	4
Implement spring mechanism	 Compression spring(s)	 Compression spring + lever	 Tension spring + lever	 Gas spring
Connect to frame	 Hole in frame	 Gas strut bracket	 Eyes	 Nuts and bolts
Adjust spring stiffness	 Reduce coils	 Release gas	 Replace spring	

5.4 Final conceptual design

The final conceptual design can be created based on the morphological charts (Tables 5.1, 5.2, and 5.3). Each choice should be reviewed if it meets the desired function (Figure 4.1) and the desired requirements (Tables 3.1, 3.2, 3.3, and 3.4). After evaluating each option of the morphological charts and performing calculations, the final concept (Design 3) can be chosen and designed using CAD drawings. Each CAD drawing includes the most important dimensions. The CAD drawings can be used for the production of the parts (Chapter 6).

5.4.1 Shell

Requirements UR-09 (3.1 and FR-02 (3.2) indicate high force transferred to the cover around the lower leg. The height and cover area (Table 5.1) of the ankle joint offloading ankle orthosis are therefore chosen to cover the complete leg, so extending from above the ankle joint up to the tibial tuberosity surrounding the entire lower leg. This will provide optimal support and ensure the most uniform distribution of forces across the lower leg. This was already proven in antigravity braces (Appendix section B.2). The cover area consists of two organic-formed shells (Figure 5.1), to simplify the donning and doffing process (Requirement UR-11 3.1). One larger back shell and a smaller front shell which slides underneath the larger shell for better compression (Figure 5.1).

A prefabricated orthosis is chosen to reduce the costs and simplify and shorten the production time. During this study, only one prototype is produced. This prototype is designed with adjustable features to ensure proper compression, which is achieved using extra padding when needed and Velcro bands.

The shells were selected based on the morphological chart. As noted, these shells need to withstand significant force, which means they must be made of a stronger material. While this stronger material might be heavier, a frame has been incorporated into the conceptual design to save weight (Requirement UR-05, Table 3.1). The frame is integrated into the shells, with the lever attached to it (in between the 10 mm). Constructed from a stronger and heavier material, the frame allows the shells to be made from a lighter material, ensuring the overall weight remains below 2 kg (Requirement UR-05, Table 3.1).

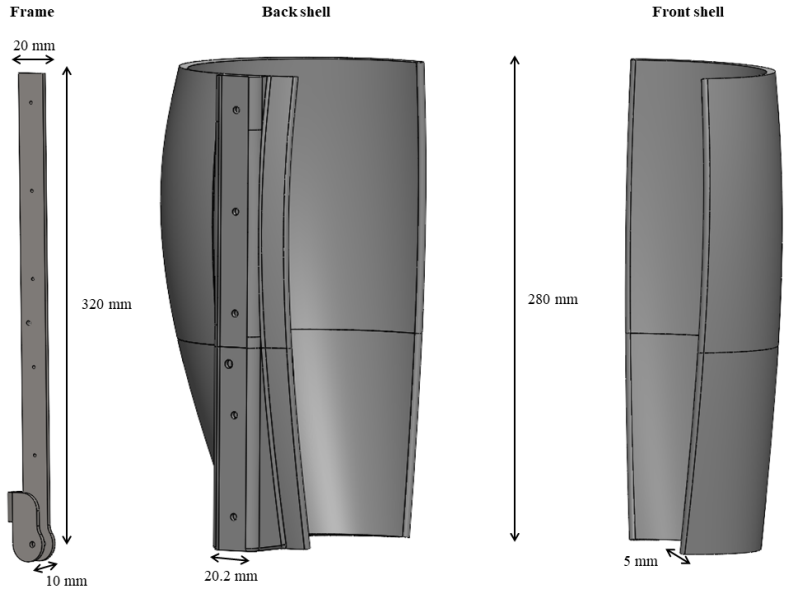


Figure 5.1: The CAD design of the frame (Right), back shell (Middle), and front shell (Left), including the main dimensions.

The shells (Figure 5.1) were designed using a lower-leg SolidWorks model to achieve an organic shape. The diameter of the shell has been made 15 mm larger to include the padding on the inside. The height of the shells is determined based on the height of the lower leg. The bottom of the orthosis starts at four centimeters above the ankle joint to allow a full range of motion and extends up to the tibia tuberosity. Both shells have a thickness of 5 mm, providing strength and support, but also flexibility to ensure proper compression.

A frame was placed on the lateral side of the shell to transfer the forces to the lower leg. The design of the shell is adjusted to incorporate the frame within the shell. This will restrict lateral movement of the frame caused by the forces generated during walking. The frame aligns with the shell but continues at the bottom until the ankle joint. This extension is necessary because the lever, attached at the end of the frame, needs to be positioned at the ankle joint. The frame has a width of 20 mm. The width was determined by the distance of the rotation point and the spring placement connection and kept as small as possible. The thickness was chosen to be the same as the lever because both experienced the same high forces (Section 5.5.2).

5.4.2 Lever and GroundContact

The lever already showed offloading in Design 1 and is therefore chosen as part to be in contact with the ground, including the end of the lever that is bent at an angle of 35° (Figures 5.2, 5.4). This angle was already proven to offload the ankle the most [45]. In the previous designs, a double lever-spring system is used on both sides of the shells [45, 46]. In this design, a lever-spring system is chosen to be at only the lateral side of the foot. This was chosen so that the lever on the medial side of the lower leg does not contact the other foot during the swing phase of the gait cycle. The lever is connected using a pin. The frame includes a U-shaped end (Figure 5.1). The lever rotates over the pin within the U-shaped end.

A slot was chosen to change the length of the fixation part to the ground (Figure 5.2). The slot is also used to connect the lever with the GroundContact. The lever and GroundContact will slide over each other, between the minimum length and maximal length set by the slot. A nut and bolt are used to set the length in the right position.

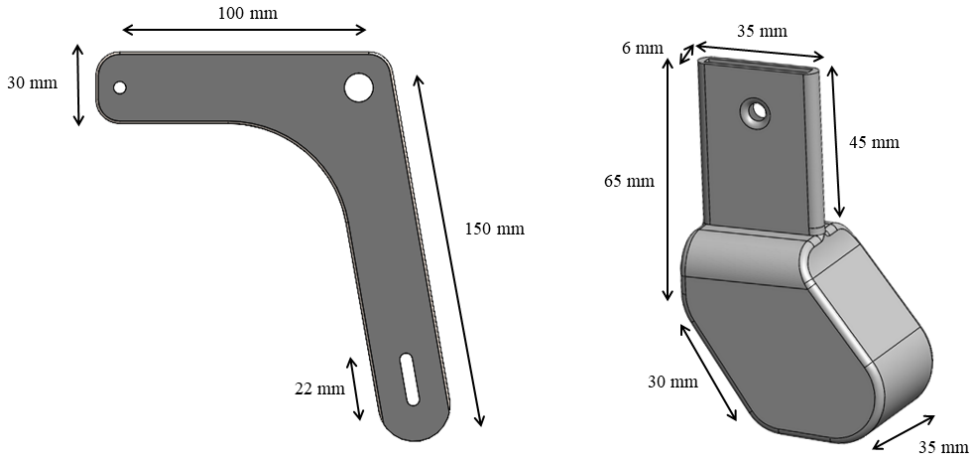


Figure 5.2: The CAD design of the lever (Left) and the GroundContact (right), including the main dimensions.

The lever design is based on the previous designs. The horizontal length is 100 mm between the connection points, and the oblique length is 150 mm between the rotation point and the end of the lever. The width of the lever has a value of 30 mm, with all connection points on the centreline of 15 mm. The thickness needs to be calculated to meet requirement FR-01 (Table 3.2), and is done in Section 5.5.2. The angle between the horizontal length and the oblique length is kept the same at 100° ensuring the highest offloading [45]. The slot at the bottom is 22 mm, with in the middle the mean ankle height of 85 mm [45].

The shape of the GroundContact is kept the same, with a height of 65 mm till the bending point. The lever extends here with a length of 30 mm. The design did change by adding a flat surface after the bending point. This was done to increase the contact surface when the Ground-

Contact is in contact with the ground. The width was also increased to 35 mm (FR-07, table 3.2) to decrease the risk of getting stuck. In addition, the lever slides into the GroundContact instead of being connected at the side of the GroundContact. This disables lateral movement which arises due to the connection with only one screw.

5.4.3 Offloading spring mechanism

A tension spring was chosen for the offloading spring mechanism to eliminate buckling of the springs [45]. To resolve the problem of the tension spring getting in the way of the donning and doffing, the adjustment of the Velcro bands should be relocated to the front of the orthosis. In addition, a spring cover was designed to ensure user safety, eliminating the risk of trapping materials or the user's fingers between the coils. The connection of the spring mechanism to the frame is incorporated within the spring cover and uses nuts and bolts. Finally, the approach of reducing the number of coils has been selected for the purpose of achieving various levels of offloading during the rehabilitation period. This concept enables the user to use only a single spring throughout the entire rehabilitation period, reducing the costs and time required to change the spring.

A spring cover (Figure 5.3) is designed to protect the user. The spring cover consists of two tubes, which can slide over each other when the spring extends. Both tubes include a long hole, which can be used as pin guidance to rotate the screw nut. The screw nut consists of an outer and inner thread. The outer thread has an opposite hollow profile and an opposite direction compared to the spring, so the spring can be rotated around this screw nut. The inner thread also has the opposite hollow profile but in the same direction as the spring. The pitch has been made 0.5 mm bigger than the wire thickness of the spring, leaving 0.5 mm between each coil connecting the pin at the outside. Within the screw nut, a rod is included, surrounded with outer thread in the same circular profile as the spring, but in the opposite direction. This rod will keep the length between the connection points the same. So, when the outer tubes are turned clockwise, the pin and screw nut will rotate in a clockwise direction as well, turning the spring off the screw nut. The screw nut will move upwards over the rod. The cols are activated and the stiffness of the spring is lowered. When the outer tubes are turned in a counter-clockwise direction, the spring turns on the screw nut, deactivating the coils. The stiffness of the spring increases.

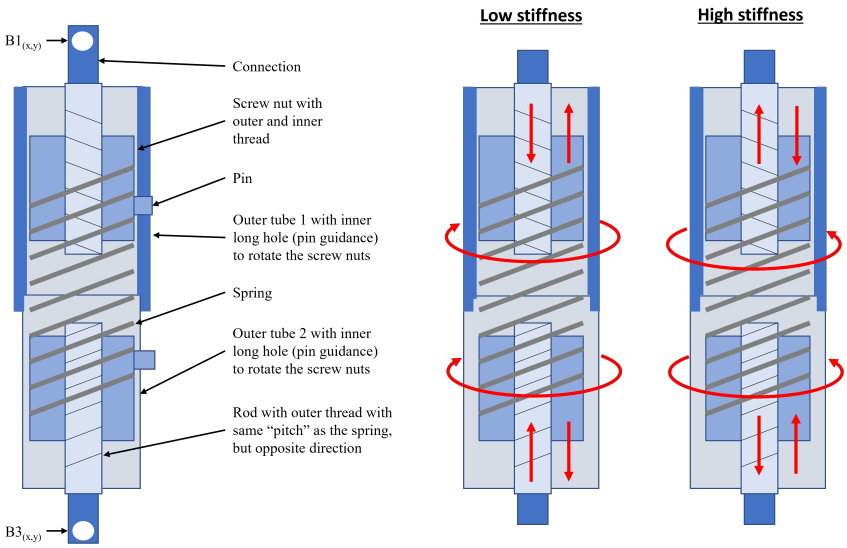


Figure 5.3: The spring cover used for stiffness regulation of the spring by deactivating and activating coils (©M. Asseln, 2024. Reprinted with permission).

The spring mechanism should be created using specific spring dimensions, especially using the wire thickness and the prestressed spring length. The prestressed spring length should correspond to the length between the two screw nuts. In addition, the value of $L3_{min}$ (Table 5.4) needs to match the length between the connection points of the spring mechanism.

5.5 Design specifications

The previous section already included the head dimensions of the parts (Section 5.4). However, the thickness of the lever needs to be calculated to ensure the strength meets requirement FR-01 (Table 3.2). In addition, a spring will be chosen to cover the entire stiffness range to meet requirement FR-03 (Table 3.2). Finally, the spring cover will be designed based on the chosen spring. This will also include the CAD drawings which can be used for the production process.

5.5.1 Design parameters

The ankle joint offloading ankle orthosis is shown with its three main components: (1) the frame included in the lower leg cover, (2) the spring, and (3) the lever in combination with the GroundContact to offload the ankle joint (Figure 5.4). The parameters and part names will be used during the design process (Table 5.4). The motivation of each parameter is included as well.

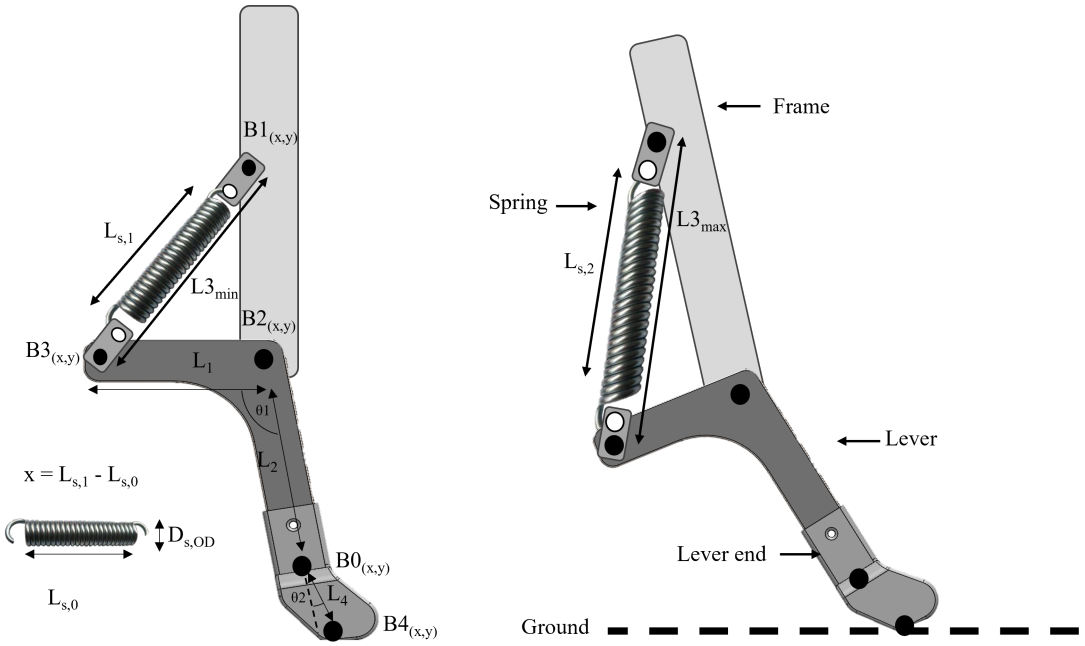


Figure 5.4: The parameters used in the design. (Left) The spring is pre-tensioned in its minimum length position. (Right) The spring is elongated by the required load to offload the ankle joint (% of the body weight (BW))

Table 5.4: The parameters including the values used in the design.

Symbol	Item	Dimension	Value	Motivation
$B0_{x,y}$	Location of the end of the lever	mm	(26,-147.7)	The location is kept the same compared to the original design including the GroundContact in an angle of 35°. [45]
$B1_{x,y}$	Location of the spring attachment point on the frame	mm	(-10,150)	The height is kept the same compared to the original design [45]. The horizontal position is 10 mm to the left, so the spring will not contact the frame.
$B2_{x,y}$	Location of the rotation point of the lever	mm	(0,0)	Is placed on the ankle joint. Placing this point on a certain distance did not seem to influence the off-loading behavior [45].
$B3_{x,y}$	Location of the spring attachment point on the lever	mm	(-100,0)	Fixed length ensuring the spring is not likely to interfere with the user's lower leg [45].
$B4_{x,y}$	Location of the tip of the GroundContact in contact with the ground	mm	(43,-172)	The tip contacts the ground before the foot does to offload the ankle joint.
L_1	The length from $B2_{x,y}$ to $B3_{x,y}$.	mm	100	The length is kept the same as in the first design [45]. An adjustable length did only show 1.5% change in offloading [46].
L_2	The length from $B2_{x,y}$ to $B0_{x,y}$.	mm	150	The length is kept the same as in the first design [45]. A slot is included to adjust the height.
$L_{3,min}$	The minimal length from $B1_{x,y}$ to $B3_{x,y}$.	mm	183.5	Received from trigonometric calculation in Matlab
$L_{3,max}$	The maximal length from $B1_{x,y}$ to $B0_{x,y}$.	mm	243	Received from trigonometric calculation in Matlab.
L_4	The length from $B4_{x,y}$ to $B0_{x,y}$.	mm	30	The length is kept the same as in the previous designs [45]. The GroundContact was extended to increase the contact points with the ground.
$\theta 1$	The angle between L_1 and L_2	°	100	Highest off-loading with no interference of the lever with the ground [45].
$\theta 2$	The angle between L_2 and L_4	°	35	The GroundContact was extended in an angle of 35° to increase the contact points with the ground [45].
$L_{s,0}$	The unstressed spring length	mm	-	-
$L_{s,1}$	The prestressed spring length	mm	-	-

Symbol	Item	Dimension	Value	Motivation
$L_{s,2}$	The loaded spring length	mm	-	-
OD_s	The outer diameter of the spring	mm	-	-
d_s	The wire thickness of the spring	mm	-	-

5.5.2 Lever thickness

The same-shaped lever is chosen to be in contact with the ground, already showing offloading of the ankle joint. The thickness of the lever can be calculated using the Column Buckling formula of Euler's (Formula 5.1), using the second moment of inertia of a rectangle.

$$P = \frac{\pi^2 EI}{(KL)^2} = \frac{\pi^2 Ebh^3}{12(KL)^2} \tag{5.1}$$

The effective length factor (K) is kept the same as the previous study [46], with a pinned connection on both sides (Figure 5.5).

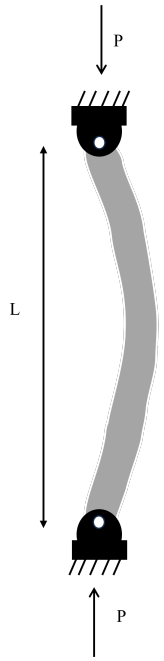


Figure 5.5: The effective length factor (K) used in the Column Buckling formula of Euler's including the load (P).

The height corresponds with the thickness of the lever. The length (L) is chosen to be from the $B2_{x,y}$ to $B0_{x,y}$ (Figure 5.4). To determine the height, already-known values are used (Table 5.5).

Table 5.5: Parameters and values to calculate the lever thickness

	Definition	**Value**	**Motivation**
BW	Body weight	90 kg	Table 3.1
SF	Safety factor	1.5	Table 3.2
P	Critical load	1620 N	Table 3.2
b	Width of rectangle	0.03 m	[45, 46]
h	Height of rectangle	-	-
I	Second moment of inertia	-	-
K	Column effective length	1.0	[46]
L	Length	0.15 m	[45, 46]
E	Young's Modulus	210000 MPa	Young's modulus of steel

This resulted in a lever thickness of 0.002 m. This value is rounded up to a value of 0.003 m and corresponds with the value used in the previous designs. The weight can be reduced when choosing a lever of 0.002 m, but the priority is handling the forces.

5.5.3 Offloading spring stiffness range

The spring will be placed using pre-tension to prevent it from accidentally deattaching when the lever is in the unloaded position. The pre-tension (F_0) should not be higher than 65.7 N, because ISO 11228-2 showed this value as maximum pulling force without backrest for females between 20-30 years [60]. For the remainder of the calculation, values of 20 N and 50 N were used.

The three off-loading percentages of the ankle and the bodyweight set for the three different cases (Table 5.4) are used to calculate the stiffness of the spring (Equation 5.2).

$$k = \frac{(F_{max} \cdot \%_{offloading}) - F_0}{x} = \frac{(1.2 \cdot BW \cdot 10 \cdot \%_{offloading}) - F_0}{x} \tag{5.2}$$

The F_{max} is the maximal load during weight acceptance and push-off and is calculated using the BW added with a safety margin of 1.2 expressed in N. For the different body weights and off-loading percentages, the spring stiffness is calculated (Table 5.6).

Table 5.6: The spring stiffness for different bodyweights, offloading percentages and pre-tension values.

Case	**Offloading %**	**F_{max}· % (N)**	**F_0 (N)**	**k (N/mm)**
Case 1: 60 kg	75 % offloading	540	20	8.74
			50	8.24
	50 % offloading	360	20	5.71
			50	5.21
	25 % offloading	180	20	2.69
			50	2.18
Case 1: 75 kg	75 % offloading	675	20	11.01
			50	10.50
	50 % offloading	450	20	7.23
			50	6.72
	25 % offloading	225	20	3.45
			50	2.94

Case	Offloading %	$\mathbf{F}_{max}$· % (N)	F_0 (N)	k (N/mm)
Case 1: 90 kg	75 % offloading	810	20	13.28
			50	12.77
	50 % offloading	540	20	8.74
			50	8.24
	25 % offloading	270	20	4.20
			50	3.70

The stiffness ranges between 2.18 N/mm and 13.28 N/mm. The two different pre-tension values only show a small difference in spring stiffness.

5.5.4 Selection of spring covering stiffness range

The range of stiffnesses is known, but other criteria must be considered when choosing a spring. Five criteria are set:

1. $F_1 = F_{max}$
2. $F_0 \leq 65.7$ N
3. $L_{S,0} < L3_{min}$
4. $L_{S,0} < L_{S,1}$
5. $OD_S <$40 mm

The stiffness of the spring is dependent on the material and dimensional parameters (Equation 5.3):

$$k = \frac{G{d_s}^4}{8ND^3} \rightarrow N = \frac{G{d_s}^4}{8RD^3} \tag{5.3}$$

with the shear modulus of the material [G] in N/m^2, the number of coils [N], and the mean diameter of the spring [D], which is the outer diameter [OD] minus the wire diameter [d]. Each of these parameters can be changed to change the stiffness. The number of coils can be changed relatively easily as some solutions are available. Therefore, changing this parameter was chosen to work out further (Table 5.3).

A spring, with the lowest calculated stiffness, of 2.18 N/mm or 2.69 N/mm (Table 5.6 should be chosen to receive an F_1 of 180 N, which is the force needed for the off-loading related to the lowest calculated spring stiffness. The number of coils must be reduced (Equation 5.3) to achieve the highest calculated stiffness of 13.18 N/mm or 12.77 N/mm (Table 5.6).

The spring T32722 is chosen to use as spring (Table 5.7). Because its stiffness falls within a range of 10% of the required lowest value (Table 5.6) and the spring met the criteria:

1. F_1 = 180 N (F_{max}) for the lowest spring stiffness (Table 5.6).
2. 36.01 N (F_0) <65.7 N (Equation 5.2)
3. 147 mm ($L_{S,0}$) <183.5 mm ($L3_{min}$)
4. 147 mm ($L_{S,0}$) <160.2 mm ($L_{S,1}$) (Equation 5.2)
5. 20 mm (OD_S) <40 mm

Table 5.7: Spring T32722 characteristics.

	T32722
Spring stiffness (k)	2.42 N/mm
Outer diameter (OD)	20 mm
Wire diameter (d)	2.8 mm
Unstressed spring length (L_S)	171 mm
Unstressed body length ($L_{S,0}$)	147 mm
Prestressed spring length ($L_{S,1}$)	160.2 N
Shear modulus (G)	81500 N/mm^2
Mass (m)	139 g

In order to reach the entire stiffness range from 2.18 N/mm to 13.28 N/mm, the chosen spring T32722 needs a reduction in the number of effective coils. The number of active coils can be calculated (Equation 5.3), using the spring parameters (Table 5.7). This results in a number of active coils of 51 coils. This calculation is repeated, using a stiffness of 13.28 N/mm, keeping the shear modulus, wire diameter, and outer diameter the same. This results in a number of active coils of 9.25 coils. So, to increase the stiffness from 2.42 N/mm (Table 5.7) to 13.28 N/mm, the number of active coils has to be reduced from 51 to 9.25 coils, deactivating the chosen spring T32722 by 35.75 coils, since this will generate the largest required stiffness.

5.5.5 Offloading spring mechanism dimensions

The spring should be connected to the screw nut before tensioning of the spring. Comparing this mechanism with other spring adjusters [61], 2–3 coils should be already turned around the screw nut at each side. The total amount of active coils is reduced from 51.5 to 45.5 active coils. Lowering the number of coils will change the stiffness of the spring (Equation 5.3) to a spring stiffness of 2.73 N/mm. The values of L_S, $L_{S,0}$, $L_{S,1}$ and F_0 will change as well (Table 5.8).

Table 5.8: The spring characteristics after removing 6 coils.

k	2.73 N/mm
L_S	154.2 mm
$L_{S,0}$	130.2 mm
$L_{S,1}$	136.6 mm
F_0	17.57 N

All these calculations result in the dimensions of the spring cover (Figure 5.6. The screw nut has a height of 15 mm and includes an inner and outer thread. One screw nut has an opposite inner and outer thread, the other screw nut has the thread both in the same direction. The pitch of the thread is 3.3 mm, leaving 0.5 mm between each coil with a wire thickness of 2.8 mm. This space is used to connect the pin. The pin has a length of 7.5 mm, extending beyond the largest tube. The width of the pin is 5 mm.

The two tubes covering the spring have a length of 114 mm. The overlap between the two tubes should be higher than the extension of the spring. The value of the overlap between the tubes is 61.4 mm, which is higher than the extension of the spring of 59.5 mm. A notch is included in the top tube, making it possible for the bottom tube to slide up and down. Within the bottom tube, a stop has been made, to block complete sliding over the top tube. The notch is important for the alignment of the tubes, making sure the slot for the pin stays in line.

Finally, the rod part including the thread with the same pitch as the screw nut. This is impor-

tant to align the movement of the spring and screw nut. The length of the rod part is 95 mm, making it possible to reduce 21 coils on both sides.

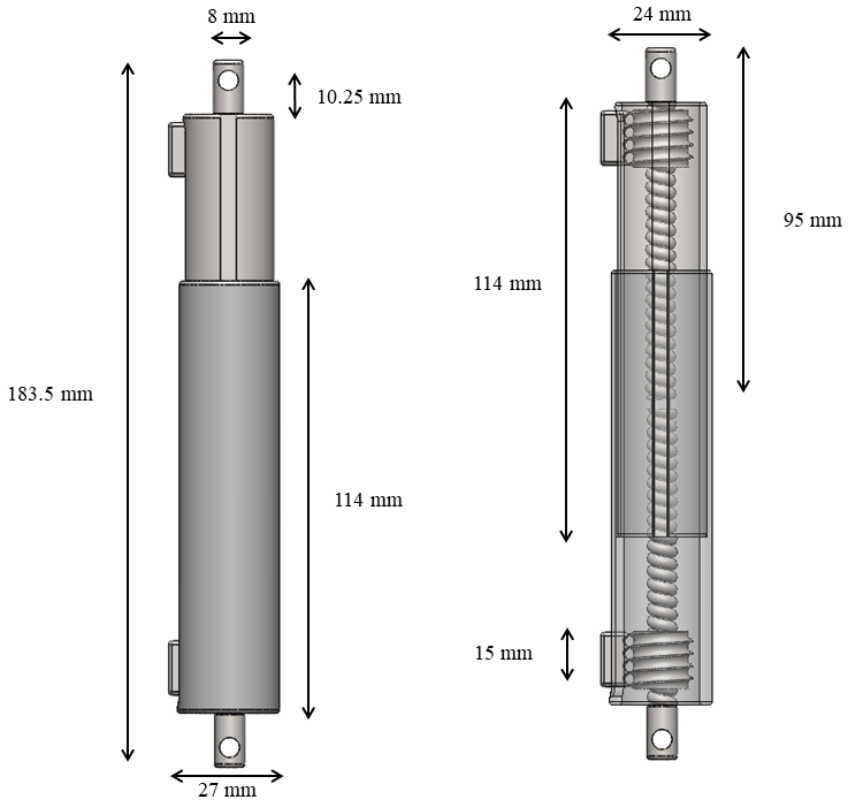


Figure 5.6: The CAD design of the spring mechanism including the main dimensions.

Chapter 6

Prototyping

A prototype of the ankle joint offloading orthosis was built (Figure 6.1). The shells, spring mechanism, lever and GroundContact, frame, and pin at the rotation point were designed and produced at the University of Twente. The spring was ordered at Tevema and the screws, Velcro bands, padding, and washers were already available at the University of Twente.

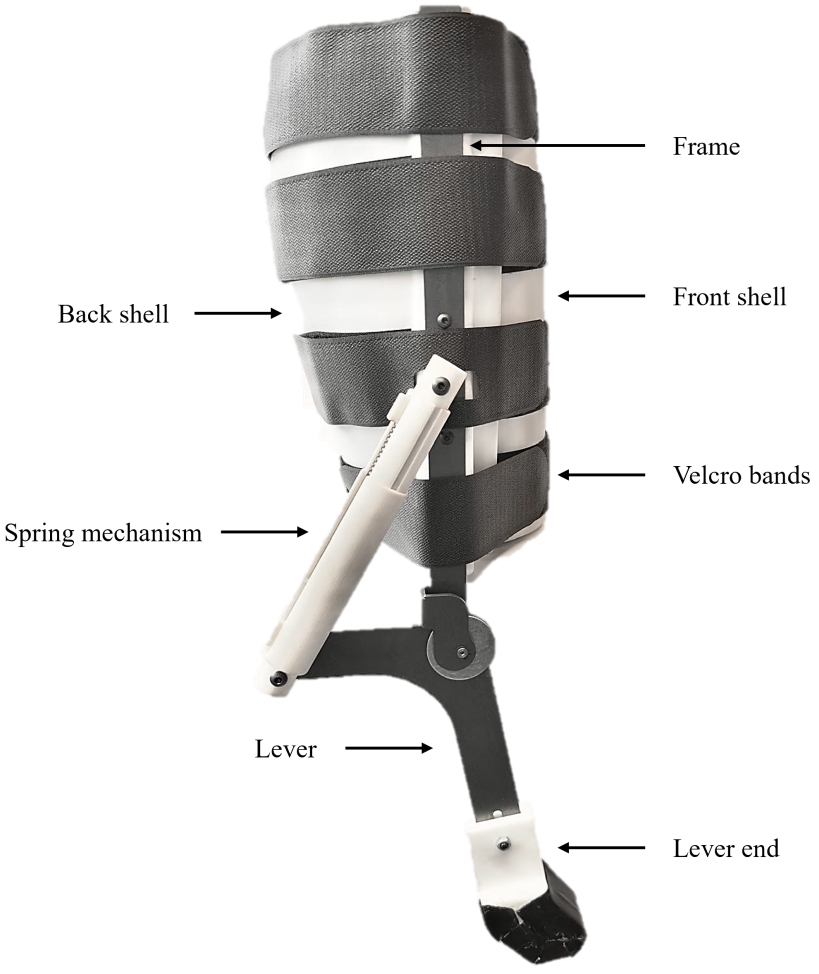


Figure 6.1: The prototype of the ankle joint offloading ankle orthosis.

The lever and frame were made of steel produced using laser cutting. These two parts experience the highest forces, therefore, a strong material was considered. The shells, the spring mechanism, and the GroundContact were printed with Selected Laser Sintering (SLS) using PA 2200. The dimensions were acceptable within the design to ensure enough strength while using SLS. All parts were produced from a CAD drawing made in SolidWorks (2023), followed by converting the CAD drawing into an STL file.

A list of materials has been drawn for the construction of the device (Table 6.1). Each part needed to build the prototype is included. The amount, the manufacturing process (if necessary), and the materials are indicated for each part as well. The prototype is assembled following the manual (Appendix F.1).

Table 6.1: Bill of materials

# ID	Description	Amount	Make / buy / Already available	Material
		Shell		
A1	Upper part back shell	1	Make (SLS)	Nylon
A2	Lower part back shell	1	Make (SLS)	Nylon
A3	Upper part front shell	1	Make (SLS)	Nylon
A4	Lower part back shell	1	Make (SLS)	Nylon
A5	Frame	1	Make (laser cut)	Steel
A6	Velcro bands hook	2000 x 50 mm	Already available	-
A7	Velcro bands loop	2000 x 50 mm	Already available	-
A8	Padding	0.2 m^2	Already available	-
A9	M4 screw	5	Already available	Steel
A10	M4 nut	5	Already available	Steel
		Lever and GroundContact		
O1	Lever	1	Make (laser cut)	Steel
O2	GroundContact	1	Make (SLS)	Nylon
O3	Pin ⌀ 6 mm	1	Make (milling)	Steel
O4	Rubber	0.05 m^2	Already available	Rubber
O5	Bearing ⌀ 6 mm	1	Already available	Steel
O6	M5 screw	1	Already available	Steel
O7	M5 nut	1	Already available	Steel
O8	Washer ⌀ 5 mm	2	Already available	Steel
		Spring mechanism		
S1	Spring T32722 Tevema	1	Buy	Steel
S2	Upper tube	1	Make (SLS)	Nylon
S3	Lower tube	1	Make (SLS)	Nylon
S4	Screw nut	2	Make (SLS)	Nylon
S5	Rod	2	Make (SLS)	Nylon
S6	M5 screw	2	Already available	Steel
S7	M5 nut	2	Already available	Steel
S8	Washer ⌀ 5 mm	10	Already available	Steel

Chapter 7

Validation

7.1 Technical validation

Technical validation is necessary before subject validation should be performed to ensure patient's safety. During the technical validation, the spring mechanism and the lever with the GroundContact were tested.

7.1.1 Materials & methods

A bench test was performed using the Zwick Z100, a testing machine with a 100 kN load capacity. This machine was chosen for its clamping capabilities, which ensure a secure and stable positioning of parts during tests. This minimizes the setup time and reduces the risk of slippage during testing. The clamps used are the grips 8506. Three different tests were performed; (1) A compression test to test the maximum force of 1080 N (Requirement FR-01, Table 3.2) on the lever and GroundContact at a -15 ° angle to observe any cracks or displacement of the screw within the slot, (2) A compression test to test the maximum force of 1080 N (FR-01, Table 3.2) on the lever and GroundContact in a 20 ° angle to observe any cracks or displacement of the screw within the slot, and (3) An extension test to test the fixation of the spring around the screw nut and the strength of the parts included in the spring mechanism.

The first test (Figure 7.1) was a compression test performed using the lever in combination with the end of the lever in the position of angle $\alpha 1$. Since no universal testing standard for ankle joint offloading ankle orthoses was available, the International Standards Organisation (ISO) for testing prosthetic devices around the ankle and foot was reviewed. During the test, the proof strength will be tested using a static proof test for verification. A maximum force of 1080 N (Requirement FR-01, Table 3.2) will be applied during the heel strike and toe-off phases of the gait cycle. The lever will be angled at -15° to replicate the heel strike position. A preload of 10 N is applied at a preload speed of 5 mm/min to ensure initial contact between the GroundContact and the platform. This preload helps to remove slack, ensuring accurate test results. When the preload is reached, the force will be increased to 1080 N with a speed of 5 mm/min. After reaching 1080 N, the setup will return to the start position. The lever will be observed for cracks in the material and shifts of the screw within the slot. The test will be repeated three times, with the setup fully disassembled and reassembled each time. When these tests succeed, an additional series of tests will be conducted with 10 repetitions at a speed of 50 mm/min to imitate the walking pattern. The lever and GroundContact were checked again for cracks in the material and shifts of the screw within the slot. All compression tests are being video recorded.

The second test (Figure 7.1) was a compression test performed using the lever in combination with the end of the lever in the position of angle $\alpha 2$. The angle $\alpha 2$ will be 20 ° to replicate the toe-off position. The compression test will be the same as in the first test. So, first, the compression test will be performed thrice using a speed of 5 mm/min, continued with a test including 10 repetitions at a speed of 50 mm/min to imitate the walking pattern. All compression tests are being video recorded.

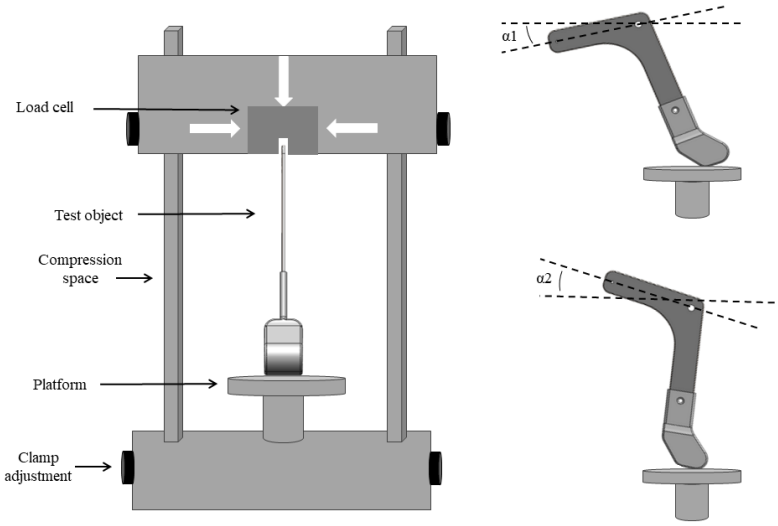


Figure 7.1: The compression bench test set-up including the position of the lever within the machine.

The third test (Figure 7.2) is an extension test performed using the spring mechanism, without the tube covers. During the test, the maximal force absorbed by the spring is chosen to be the testing force. This force is selected to offload 75% of the weight of a 90 kg individual, resulting in a force of 810 N. The spring mechanism will be clamped between the clamps using a screw. The screw is inserted through the hole in the rod, ensuring that there is no clamping force on the nylon material. An excessive clamping force could cause the nylon part to break. The extension force will be increased to 810 N with a speed of 50 mm/min. After reaching 810 N, the setup will return to the start position. The spring mechanism will be observed for cracks in the material and deforming of the spring. The test will be repeated three times, with the setup fully disassembled and reassembled each time. When these tests succeed, an additional series of tests will be conducted with 10 repetitions at a speed of 50 mm/min to imitate the walking pattern. The spring mechanism will be checked again for cracks and possible deformations of the spring. All extension tests are being video recorded.

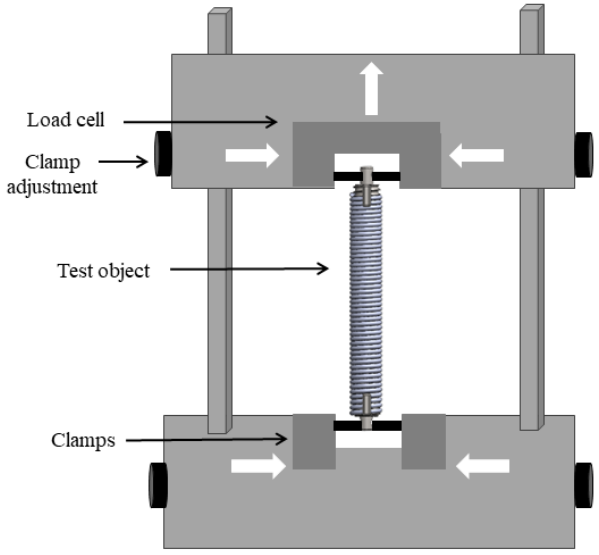


Figure 7.2: The extension bench test set-up including the connection of the spring within the machine.

7.1.2 Results

The first test was performed till a force of 620 N (Figure 7.3), at which point the GroundContact got cracks. The sides of the GroundContact, where the lever slides in, were not strong enough to withstand the forces. The test was stopped, as indicated by the descending line in the graph after a force of 620 N was reached. Therefore, the second test using the lever and GroundContact was not performed. The GroundContact does not meet the requirements and will need to be redesigned before conducting further tests.

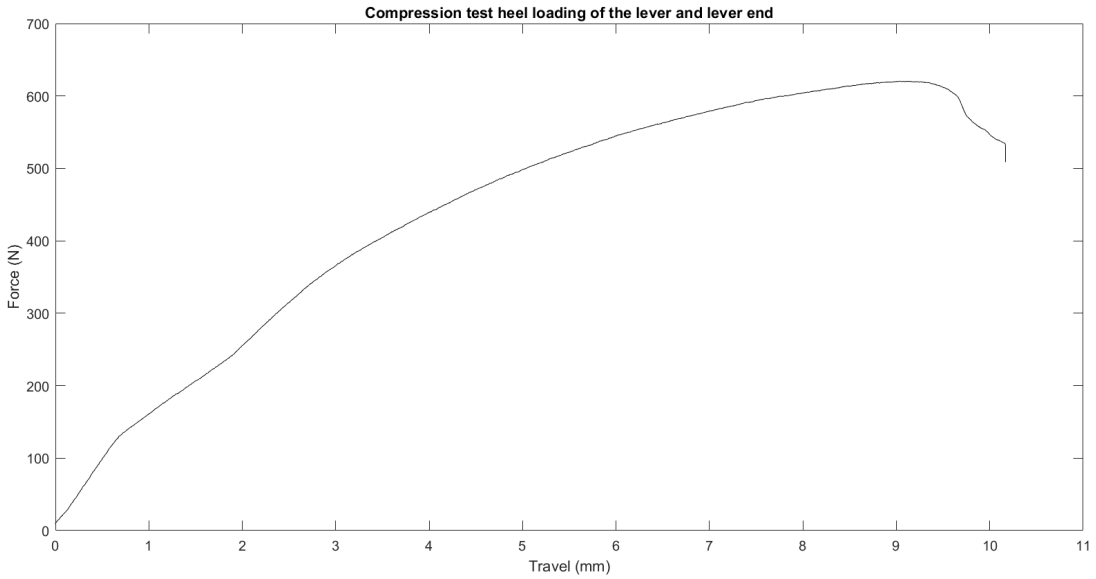


Figure 7.3: Compression test in the heel loading position of the lever, including the GroundContact.

The third test reached a value of 466 N, before the rod located at the top broke. Resulting in breakage of the rod at the bottom and both the screw nuts. The graph of the extension test (Figure 7.4) proves the linearity of the spring. It was possible to conduct a linear formula that aligns with the extension test using the spring. This resulted in a spring stiffness of 2.76 N/mm for a spring mechanism setting used for 25% offloading of an individual of 60 kg. This corresponds with the calculated value of 2.73 N/mm. The linear formula indicates that a pre-tension force of 73 N was applied before the spring exhibited linear behaviour.

The test was not repeated three times because the rod part already showed strength failure, assuming that the screw nut did break due to impact after breaking the rod part. Therefore, the rod part does not meet the requirements and will need to be redesigned before conducting further tests.

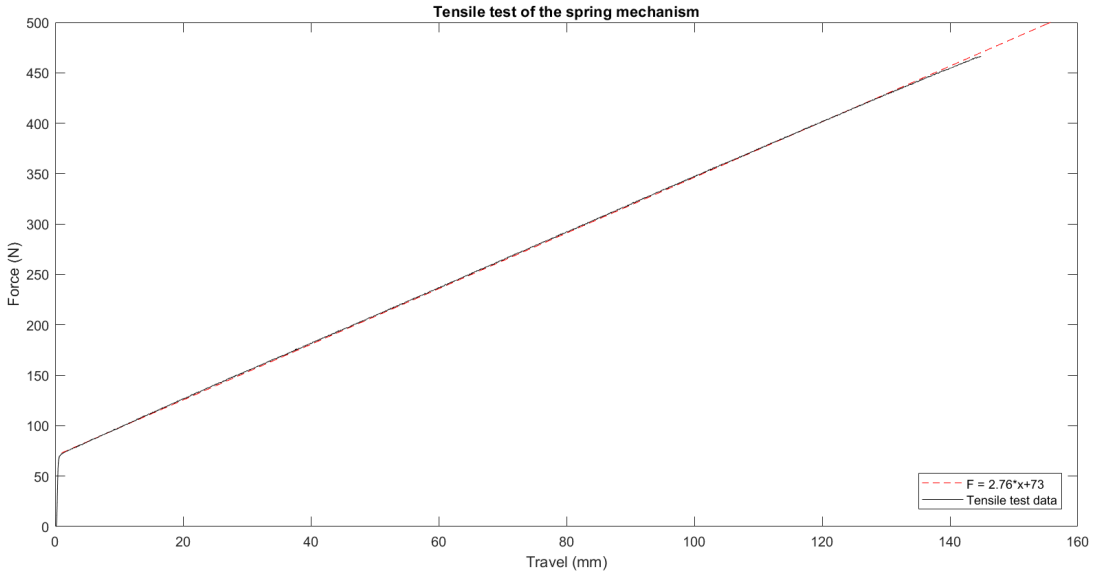


Figure 7.4: Tensile test of the spring mechanism excluding the covering tubes. A linear formula was included to show the linear behaviour of the spring and the corresponding spring stiffness.

7.1.3 Adjusted prototype based on function validation tests

The results (Section 7.1.2) showed a lack of strength of both the GroundContact part and the rod part of the spring mechanism. The thickness of the sleeve where the lever slides in is determined using a simplified calculation (Figure 7.5).

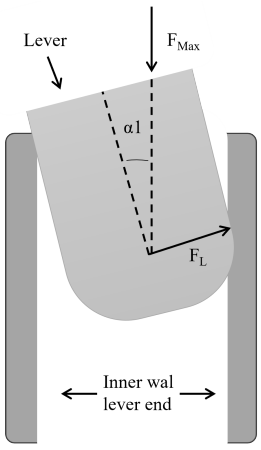


Figure 7.5: Schematic overview used for the simplified calculations

The force of the lever on the inner wall (F_L) of the GroundContact can be calculated (Formula 7.1).

$$cos(90° - \alpha 1) = \frac{F_L}{F_{max}} \tag{7.1}$$

This results in a force of 279.5 N. The deformation of the GroundContact was plastic, so the flexure formula (Formula 7.2) was used to calculate the wall thickness. The formula can be used to calculate the bending stress (σ_b) over the beam's cross-section (I_c) at a specific location using the bending moment (M_y).

$$\sigma_b = \frac{M_y}{I_c} = \frac{12FL}{4bh^3} \tag{7.2}$$

The bending moment is assumed to be in the middle of the length of the sleeve. The width and height could be varied to receive a bending stress below 75% of the yield strength to ensure no elastic deformation. The yield strength of nylon is 46 MPa [62], so the bending stress should be below 34.5 MPa. Choosing a width of 16 mm and a height of 6.9 mm, the bending stress will result in 7.2 MPa. This is a lot lower than the yield strength, but this was necessary to ensure the GroundContact could withstand the forces and because of the simplification of this calculation.

In addition to the GroundContact, the rod part also underwent some design adjustments. The diameter has been made as large as possible but still lower than the inner diameter of the covering tubes to ensure optimal movement of the spring mechanism. The space between the hole and the top has also been made larger, to ensure that the rod part will not break due to the tensile forces. Adjustments of the GroundContact and the rod part resulted in two new redesigns (Figure 7.6). Both parts should be validated using functional validation before subject validation can be performed. The test methods are kept the same.

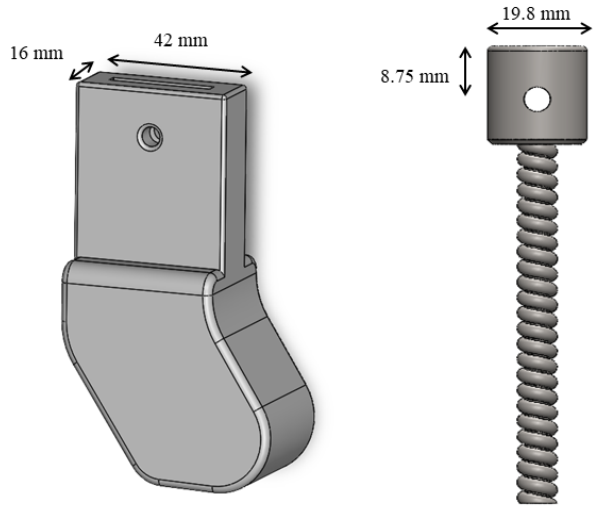


Figure 7.6: The design adjustments of the GroundContact (Left) and the rod part (Right).

7.1.4 Results adjusted prototype

The first test, a compression test, was performed using the lever and adjustable GroundContact positioned at an angle of -15° (heel loading). During the first test, the GroundContact shifted on the platform, resulting in an increased testing angle. This result is shown in the purple dotted line in the graph (Figure 7.7). At approximately 600 N, the line shows a continuous increase, indicating a secure fit of the lever in the clamps and on the platform. After the first test, the testing angle was measured at around -25°, creating a larger force on the inner wall of the GroundContact. No cracks or displacement of the screw within the slot were observed. Therefore, it was chosen to conduct the other tests at an angle of -25°, as the lever and GroundContact were not adequately secured at an angle of -15°. This may be explained by the fact that the clamps used were primarily designed for extension tests, making them less than ideal for securing a material during a compression test.

After the first test, two other tests were performed at a speed of 5 mm/min. These tests are shown in the pink and green dotted lines in the graph (Figure 7.7). After each test, no cracks or displacements were shown, so the 10 times repetition tests were continued at a speed of 50 mm/min. These tests are indicated with the straight lines in the graph (Figure 7.7).

The results of the second and third tests conducted at a speed of 5 mm/min, as well as the 10 repetition tests at 50 mm/min, display parallel lines.

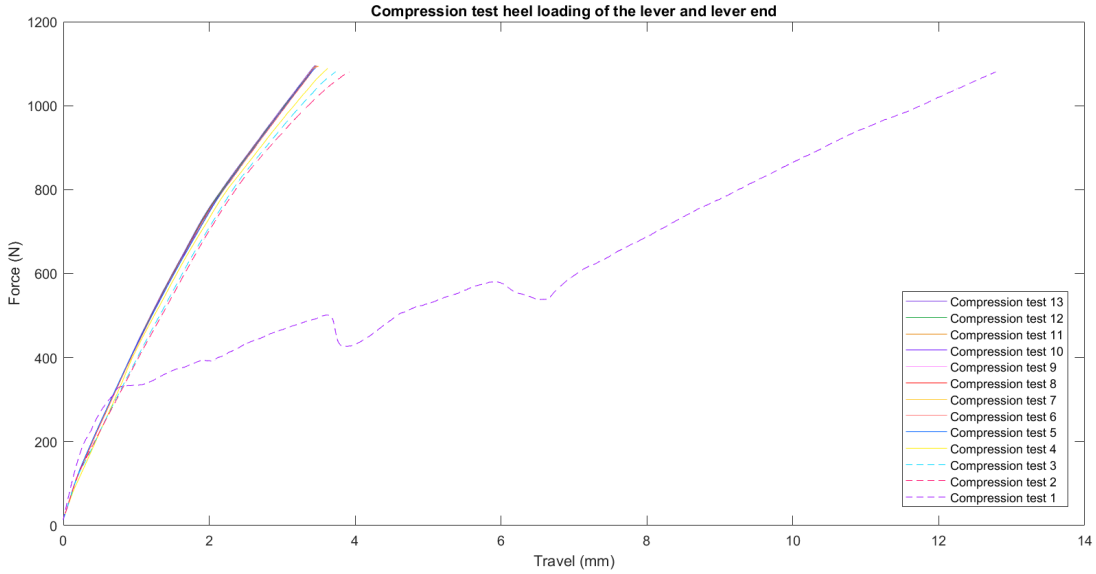


Figure 7.7: The first compression test at an angle of -15° and -25° with three repetitions at a speed of 5 mm/min (dotted lines) and 10 repetitions at a speed of 50 mm/min (straight lines).

The second test, a compression test, was performed using the lever and adjustable GroundContact at an angle of 20° to imitate toe loading. The lever and GroundContact had a secured fit during all the tests with no change in starting angle and angle at the end of the test. The first three tests are indicated with a dotted line (Figure 7.8). After each of the three tests conducted at a speed of 5 mm/min, no cracks of the GroundContact or displacement of the screw were observed. The tests then proceeded with ten repetitions at a speed of 50 mm/min, which also showed no signs of cracks or displacement. All the lines are parallel to each other, with a travel distance, the distance the testing machine's platen moves while applying the force on the lever, of less than 0.4 mm.

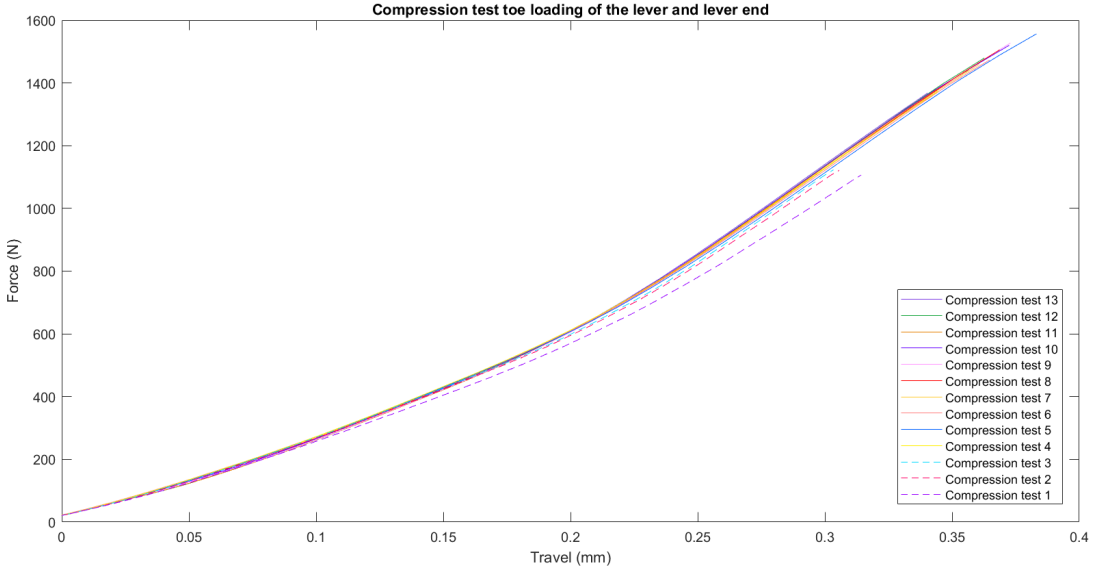


Figure 7.8: The second compression test at an angle of 20° with three repetitions at a speed of 5 mm/min (dotted lines) and 10 repetitions at a speed of 50 mm/min (straight lines).

The final test, an extension spring, was performed using the spring mechanism without the covering tubes. During the first test, without the adjusted rod part, the spring extended by 140 mm. During the final test with the adjusted rod part, the coils were reduced to decrease the extension of the spring. The coils were reduced to a level of an individual of 90 kg with an offloading of 75% of the body weight.

The spring was placed in the extension machine, which increased the force to 810 N. The graph initially shows a straight line but begins to deflect at around 535 N. The test was continued till 700 N, but the line only deflected more. At this point, the test was discontinued and the setup was reset. The spring experienced plastic deformation between the two set screws. This indicates that the spring mechanism functioned as intended, but the mechanism cannot offload more than 535 N without deforming. The second and third tests were not executed, as well as the 10 times repetition test. A linear line was generated that corresponds to the straight line in the testing data. The spring stiffness was 10.5 N/mm with a preload of 47 N.

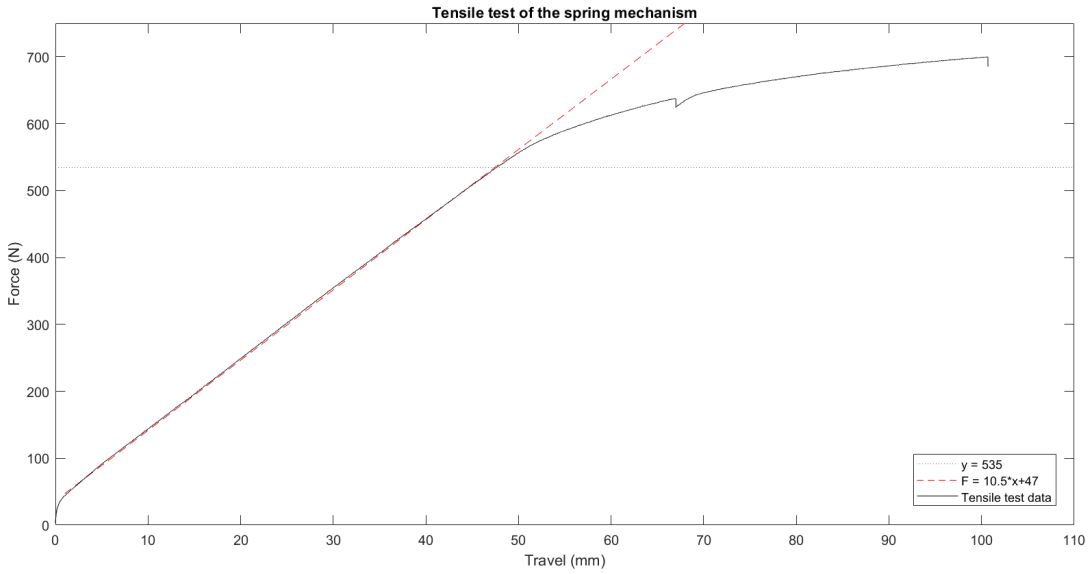


Figure 7.9: Tensile test of the adjusted spring mechanism excluding the covering tubes. A linear line is included following the tensile test data. The dotted line shows the point of deformation of the spring.

The two different compression tests both showed the lever and GroundContact were strong enough. The spring mechanism was also strong enough, but the spring deformed. The tests were continued with subject validation tests, to test user requirements UR-01, UR-06, UR-08, UR-10 and UR-11 (Table 3.1), functional requirements FR-02 and FR-06 (Table 3.2), performance requirement PR-01 (Table 3.3), and interface requirements IR-02 and IR-03 (Table 3.4). The offloading force can not exceed 535 N during these subject validation tests.

7.2 Subject validation

7.2.1 Materials & methods

The prototype is evaluated in two conditions, with the setting using 25% offloading and in the setting using 50% offloading. The goal is to measure the residual ground reaction forces (GRF) 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 force plate of AMTI's AccuGait system was used at the University of Twente. The force plate was implemented within a track (Figure 7.10), with additional plates on both sides to ensure there is no height difference before and after stepping on the force plate, thereby increasing the measurement accuracy. The subject starts walking from the side of the camera, placing the right foot on the force plate. The subject will walk in a figure-eight pattern, but on the way back, the subject will walk next to the track. This setup ensures that the camera, which is focused on one force plate, can accurately capture if only the foot, and not the GroundContact, is placed on the force plate.

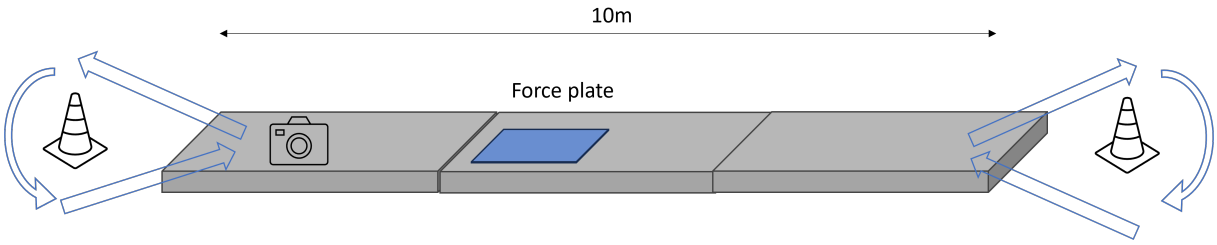


Figure 7.10: The track, including the force plate, used during the subject validation tests to evaluate the ankle joint offloading ankle orthosis.

The data will be recorded using the Qualisys software, which is connected to the AMTI force plate. The force plate is connected to the Qualisys computer via the DAQ box. A ribbon cable connects the force plate with the BNC cables, which then connects the analog outputs of the force plates to the Qualisys DAQ. The analog signals from the force plate are processed by the Qualisys software to produce ground reaction forces, moments, and centers of pressure. During the experiment, only the data of the ground reaction forces will be used. In addition, a power supply cable connects to the Junction box PJB-101, which is linked to the force plate via an RJ11 cable.

The measurement protocol was as follows. First, the researcher will check if informed consent (Appendix E.1) is signed and if the subject meets the inclusion and exclusion criteria (Appendix E.3) by asking questions and measuring the weight and the circumference of the lower leg (Appendix E.4). The subject started by filling in a pre-test survey (Appendix E.5 before the measurements started. Afterward, the subject is asked to put the brace on without instructions, followed by a NASA Task Load Index (NASA-TLX) questionnaire (Appendix E.6) to assess the workload of this task. The measurement starts with testing the subject's normal gait. The subject puts the brace on following the instructions (Appendix F.2) and was asked to walk without the device on the track (Figure 7.10), placing the right foot on the force plate. A total of 10 measurements were taken and were averaged. Video recordings will be made anonymously by only filming the lower extremities when stepping on the force plate. After testing the subject's normal gait, the subject is asked to walk with the device for two sessions of 5 minutes each to measure their gait while wearing the device. The first session will involve 25% offloading of body weight, followed by a second session with 50% offloading. All steps taken during the 25% offloading session will be averaged, as well as all steps during the 50% offloading session. After the test with the device, the subject was asked to fill out a NASA-TLX questionnaire (Appendix E.6) and a final questionnaire with specific questions regarding the device (Appendix E.7).

The outputs of the subject validation tests are the answers to the questionnaires and the data from the force plate. The data of the force plate are the GRF, which are divided into vertical GRF, anterior-posterior GRF, and medial-lateral GRF. The vertical GRF is used to analyze possible offloading while wearing the device.

7.2.2 Results

Subject validation tests were performed with a total of 5 subjects. The test with the first subject did indicate bending of the frame at the point where the shell ended. The test was stopped before the measurements even started. To continue testing with other subjects, an additional 8 mm thick steel plate was added at the point of bending (Figure 7.11). The next three subjects had an average age of 24.5 ± 2.5 years, a weight of 80.3 ± 7.6 kg, and an average height of 182.7 ± 4.0 kg.

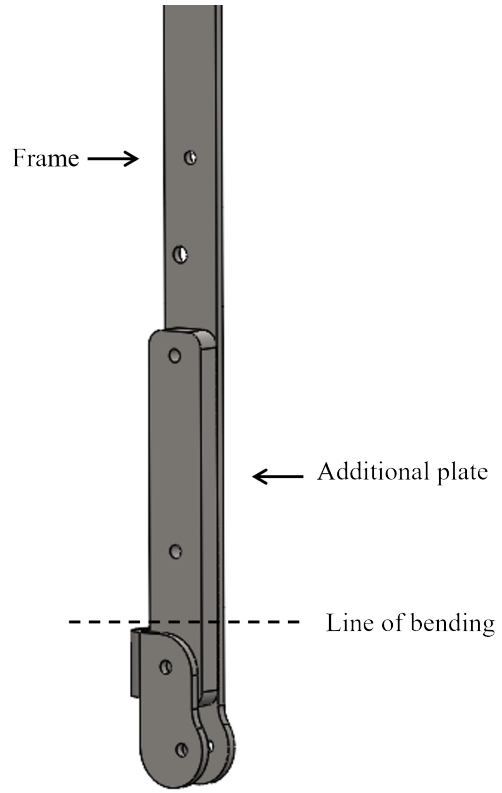


Figure 7.11: The frame with the extra added steel plate, including the line of bending during the first test.

During the second test, using a new test subject, it was possible to perform all measurements. The bending that occurred during the tests with the first test subject was not indicated during the tests with the second subject. The extra 8mm thick steel plate counteracted the bending. Another problem did occur during the analysis of the data. The video recordings made during the experiment did show incorrect offloading. During the video recording of the subject wearing the device with 25% offloading, the coils were not or with only a view reduced, where it needs to be reduced with 5.5 coils at each side (Figure 7.12). During the 50% offloading, the coils reduced at both sides were approximately 7-8 coils (Figure 7.12). For a subject of a weight of 78 kg, the coils on both sides needs to be reduced by 14. This is also shown in the graph (Figure 7.13), where the green line does not indicate an offloading of 50%. The coils were probably not reduced on each side with 5.5 or 14, but the total amount of coils were reduced by these numbers.

The video recordings did also shown rotation of the spring covers (Figure 7.12). The slot including the pin should be in line, but the bottom tube is rotated. Therefore, the offloading percentage was incorrect.

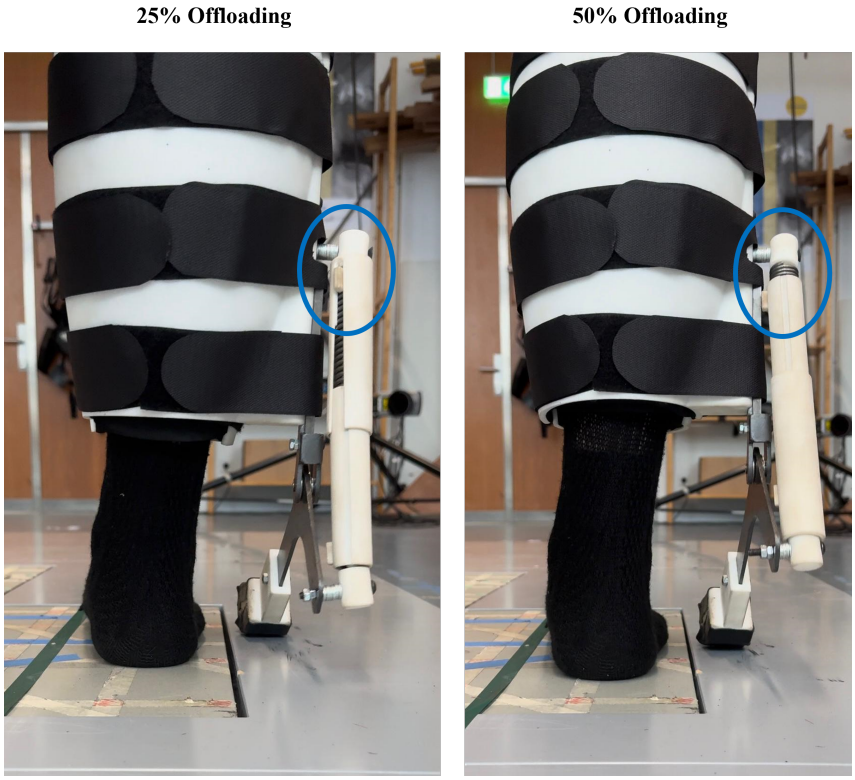


Figure 7.12: The video recordings of subject 2 showing a wrong number of reduced coils. This resulted in a wrong offloading percentage. (Left) The 25% offloading and (Right) the 50% offloading.

The tests were continued using a third test subject. The test started well, but during the measurements while wearing the orthosis with 25% offloading, the rod part broke. The tests were continued with a new rod part (Figure 7.6). At the start of the measurement with offloading 50% of the body weight, both parts of the rod broke in the first step. The spring forces became too high, resulting in the end of the measurements with the third test subject. During the analysis of the video recordings, it turned out that the leg was dragged slightly diagonally. This caused the GroundContact to be placed on only one side on the ground. The force was now absorbed on one side of the end of the lever. This caused the lever to also absorb the force under an angle, causing it to bent.

The fourth test was performed using the bent lever. The test continued to see whether this bending would have an effect. The test using the orthosis while offloading the ankle joint with 25% went well, but the rod part broke again at the end of the measurement. This was the final rod part, so the test was stopped. The video recordings did show better placement of the GroundContact on the ground compared to the placement of subject 3.

The results of the measurements with subjects 2,3 and 4 were plotted (Figure 7.13). The analysis started by taking the mean value of the different steps taken by a subject for each condition. This resulted in a mean vertical GRF of each test subject for 0%, 25%, and 50% offloading. The analysis continued by calculating the mean of all subjects for each condition. The standard deviation is taken from the mean values of each test subject. Normally, it is not allowed to calculate the standard deviation out of already mean values. However, several steps of each subject were collected due to the known variation in step size and walking speed. This is caused by normal walking behaviour, but this is not the variation to look at. Therefore, it is an exception to take the standard deviation of the mean values of each test subject.

The mean first peak value of the GRF without the device was 0.95 ± 0.07 BW, compared to 0.79 ± 0.11 BW with the device applying 25% offloading and 0.84 ± 0.07 BW with the device applying 50% offloading. Both peaks with the device were delayed compared to the vertical GRF without the brace. The mean second peak value of the GRF without the device was 1.08 ± 0.08 BW, compared to 0.9 ± 0.07 BW with the device applying 25% offloading and 0.96 ± 0.03 BW with the device applying 50% offloading. All measurements show a high standard deviation in the first half of the stance phase compared to the second half. This was also the case during the test with the first prototype [45].

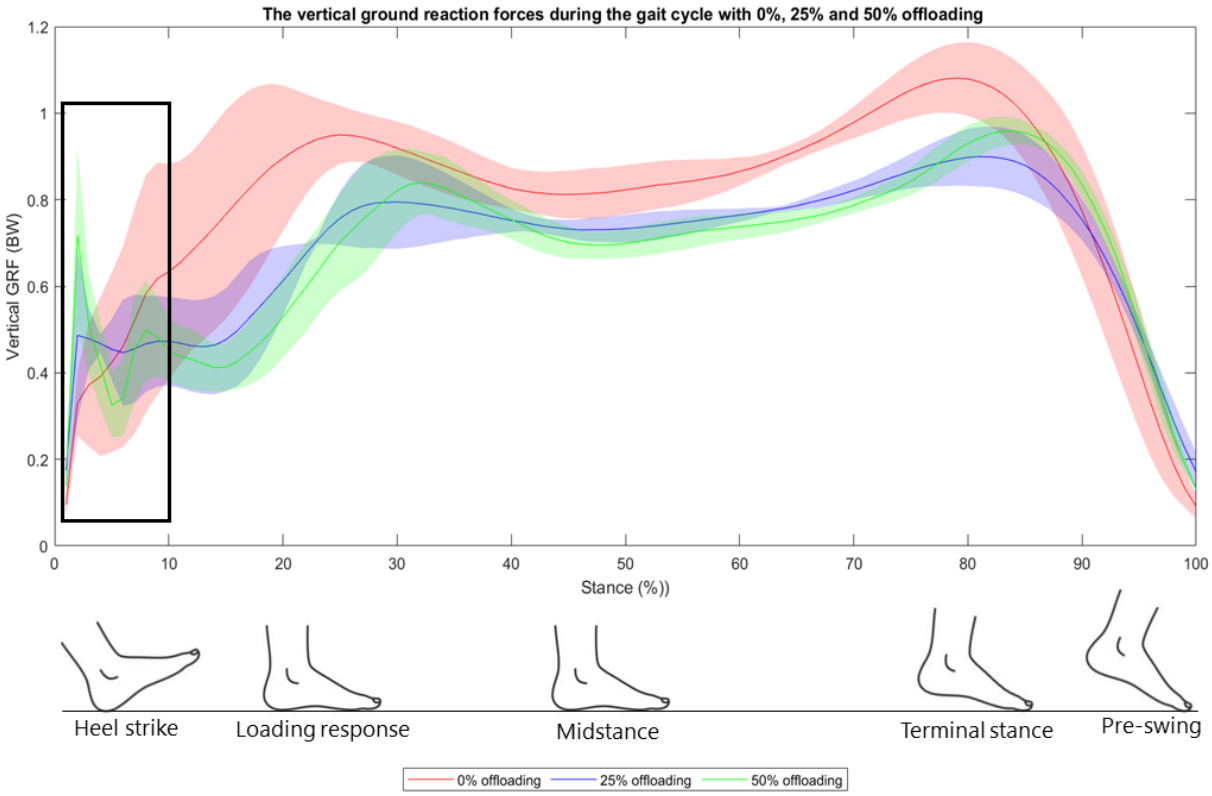


Figure 7.13: The GRF during the gait cycle with 0%, 25% and 50% of 3 different healthy subjects. The gait cycle phases are based on the 0% offloading data.

During the measurements, subjects were asked to complete different questionnaires. A pre-test was filled in before the experiment started. All three subjects were correct that the orthosis should be worn on the right lower leg. Two subjects thought the device should be put on by sliding in from the front side. The other subject did think the orthosis could be put on as a regular shoe. This was not correct, but it is possible to put it on like this. At the question to walk with it all day, two subjects did give it a 7 out of 10 to wear the brace all day, the other subject gave it a 3 out of 10. Adjusting the width of the orthosis was correctly noted, however, only one person was correct about adjusting the height.

The second questionnaire was the NASA-TLX after the task of putting on the device (Device 3 in Figure 7.14). The third questionnaire, NASA-TLX, was filled in after the measurements with the offloading ankle orthosis (Device 3 in Figure 7.14). Both include a standard deviation.

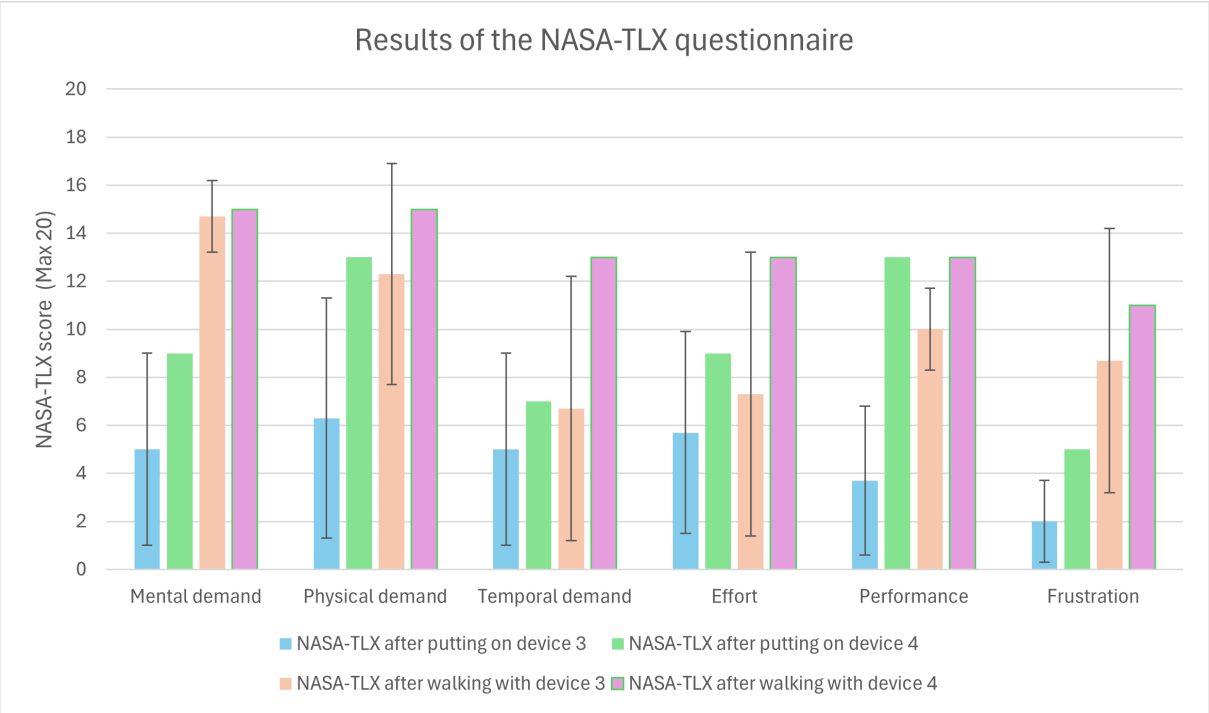


Figure 7.14: The NASA-TLX questionaire results after putting the device on and after walking with the device using device 3 and device 4.

The final questionnaire was filled in after all tests and contains questions about the device. Two of the three subjects did think the weight of the device was good, the other subject thought it was too heavy. Two of the three subjects did think the weight distribution of the device around the lower leg was good, however, the other subject mentioned the device was moving downwards. The third question was about the pressure points. Only one subject experienced pressure points in the middle of the brace.

The questions 4 until 10 were on a scale between 0-10 (Device 3, table 7.1). Question 9 was leaven out since the researcher had adjusted the offloading. This was done because the rod part was not strong enough and broke off when the tubes were rotated. One improvement the subjects mentioned was slipping of the foot, so this should be more stable. In addition, a subject did mention that the normal gait cycle felt disrupted due to the device and another subject did mention the leg should be lifted more during the step. One subject did not feel a lot of difference between walking with or without the device, one subject did feel a minimum difference and the third subject did feel the offloading.

Table 7.1: The results of the questionnaire about the device, with results between 0-10. Device 3 covers the answers of 3 healthy subjects and device 4 covers the answers of 1 healthy subject.

Question	**Device 3**	**Device 4**
Question 4	7 ± 1	6
Question 5	2.7 ± 3.1	3
Question 6	4 ± 2	7
Question 7	4.3 ± 2.3	5
Question 8	5.7 ± 1.5	6
Question 10	4.0 ± 2	6

7.3 Adjusted prototype based on subject validation tests

7.3.1 Design adjustments

An important result of the measurements was the breakage of the rod part during different experiments with different subjects. All the video recordings did show rotational forces, making the cover tubes turn during walking. Because of this, the spring stiffness was adjusted while performing the measurements. In addition, all subjects placed the GroundContact at a slide angle on the ground, increasing these rotational forces and resulting in the bending of the lever. To better compensate for these rotational forces than a flat lever, a tube could be used. This should be adjusted before other experiments are performed.

Figure 7.15: The rotational forces causing the covering tubes to turn. (Left) The first step with the pin guidance of both covering tubes in line. (Right) The three subjects, after taking several steps, causing the covering tubes to rotate.

The wall thickness of the hollow tube can be calculated using the Column Buckling formula of Euler's (Formula 5.1), but the second moment of inertia of a hollow tube is used (Equation 7.3).

$$F = \frac{\pi^3 E(D^4 - d^4)}{64(KL)^2} \tag{7.3}$$

The same values (Table 5.5) of the flat lever were used, only the safety facor and the K value did change. The safety factor was increased to a value of 2 (Table 3.1) because the experiment showed more sideways forces than expected. This results in a critical load of 2160 N. The value K was evaluated again and was chosen to be 2.0, because the GroundContact is fixed on the ground, with the brace (and the lever itself) moving around this fixed point (free end).

The outer diameter was chosen to calculate the inner diameter. The outer diameter was chosen to be 10 mm, resulting in an inner diameter of 9.5 mm. An existing tube with an outer diameter 10 mm, and a wall thickness of 1 mm is chosen. The strength of the tube decreases when a hole of 6 mm for the pin is drilled in the bending point of the tube. Therefore, an extra plate of 4 mm is welded against the tube. A plate of 4 mm is chosen to reduce the slack on the bearing. The plate includes the hole for the rotation point, and does function as the mechanical stop. The design has been made in a CAD drawing (Figure 7.16) and produced using the technical drawing.

The GroundContact must be redesigned due to changing the flat lever into a tube. Only the sleeve of the GroundContact is changed in the shape of the tube. The thickness remains unchanged compared to the previous design, because this design did already show enough strength

during the functional validation and the subject validation. The outer wall of the GroundContact has been shaped into a square to provide a flat surface for the screw to secure on when fixating the tube's position. The design has been made using a CAD drawing and is produced using SLS printing.

The rod part and the screw nut were changed as well. The designs were kept the same, only the diameter of the thread part of the rod part was increased to 9 mm to increase the strength. A chamfer of 3 mm was added as well between the thread and the top part. Therefore, the inner diameter of the screw nut did need to increase to 9.2 mm.

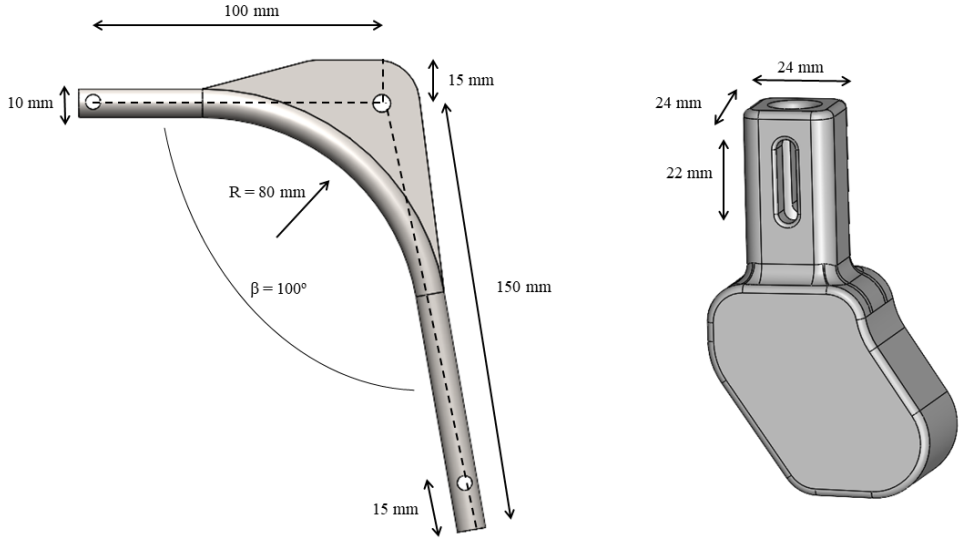


Figure 7.16: The adjusted lever (left) and GroundContact (right) after subject validation including the main dimensions.

7.3.2 Results

The new prototype (Design 4) was used in a subject test using only one subject to test if the GroundContact bent. The subject had an age of 23, a length of 1.82 m, and a weight of 73 kg. The test started with a pre-test questionnaire. The subject was correct about the side where the brace should be worn, but thought the lower leg should slide in as a regular shoe. The subject answered the question about wearing the device all day with a 7 based on the looks. The final question was answered with adjusting the height and width both with the Velcro bands. The subject continued by putting the brace on and completing the NASA-TLX questionnaire (Device 4, figure 7.14)

After completing these two questionnaires, the tests wearing the orthosis were performed. Both tests were performed successfully with no bending of the tube and no breakage of the rod parts. The results are shown in the graph (Figure 7.17). During the experiment, the rubber started to wear, causing more slipping on the smooth surface.

The mean first peak of the vertical GRF without the device was 0.97 ± 0.01 BW, compared to 0.85 ± 0.04 BW with the device applying 25% offloading and 0.84 ± 0.04 BW with the device applying 50% offloading. Both first peaks while wearing the device were delayed compared to without the device. The mean second peak value of the vertical GRF without the device was 1.12 ± 0.02 BW, compared to 0.93 ± 0.06 BW with the device applying 25% offloading and 0.92 ± 0.03 BW with the device applying 50% offloading. The measurements with the deivce show a high standard deviation in the first half of the stance phase compared to the second half.

This was also the case during the test with the first prototype [45] and the test performed with device 3.

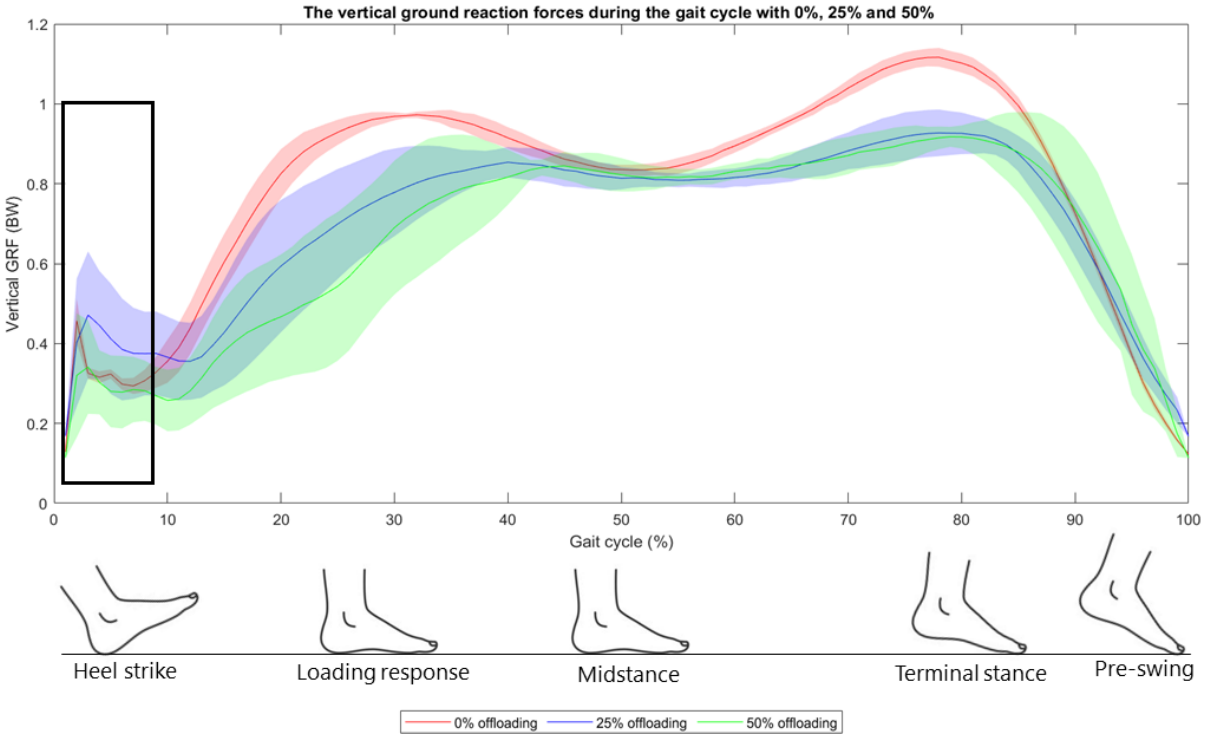


Figure 7.17: The GRF during the gait cycle with 0%, 25% and 50% offloading of one healthy test subject. The gait cycle phases are based on the 0% offloading data.

After performing the measurements while wearing the orthosis, the subject was asked to complete two questionnaires. The first questionnaire was the NASA-TLX (Device 4, figure 7.14). The second questionnaire included questions about the device. The subject thought the weight and weight distribution were good and there were no pressure points. The questions 4 until 10 were answered on a scale from 0-10 (Device 4, table 7.1). The subject did experience a difference between the off-loading and felt less pressure on the ankle. The improvement mentioned is the slipping of the GroundContact, which did increase the mental workload.

7.4 Updated risk analysis

The overall risk of the device is reduced (Figure 7.2). The energy, biological, and hazards related to use are decreased from a high or medium risk to a low risk. The hazards related to user interface includes only one hazard which stayed at medium risk. The two hazards arising from functional failure, maintenance and ageing were also not improved in the new design.

Table 7.2: The updated hazards regarding the new design, with risks ranging from low to high.

# ID	Initiating events and circumstances/causes	Previous risk	New risk	Motivation
H1.1	Mechanical forces	High	Low	The strength of the device is increased and tested with no breakage or pressure points as consequence.
H1.2	Moving parts	Medium	Low	Adjustable parts are secured proved by functional tests. A spring cover is designed for skin getting between the coils.
H1.3	Unintended motion	High	Low	No possibility of lever falling out of the mechanical stop.
H2.1	Exposure to bacteria	Medium	Low	A sock needs to be worn underneath
H2.2	Allergenicity	Medium	Low	A sock needs to be worn underneath
H4.1	Inadequate operating instructions	Medium	Low	Manual is provided
H4.4	Sharp edges or points	Medium	Low	Nuts incorporated in the frame so no sharp points
H5.2	Lapses and cognitive errors	Medium	Low	Manual is provided and no possibility of placing Velcro bands around the spring
H5.4	Complex or confusing control system	Medium	Low	Manual provided for instruction to use. The device is designed to use in one-way.
H5.5	Mistakes and judgement errors	Medium	Medium	Still possible to adjust the offloading percentage incorrect. However, a manual is provided.
H6.1	Lack of adequate determination of the end of life of the device	Medium	Medium	Still wearing of rubber
H6.5	Deterioration in function as results of repeated use	Medium	Medium	Still wearing of rubber

Chapter 8

Discussion

8.1 Requirements fulfillment

The requirements that were not already compliant were reviewed with the new device (Figure 8.1). This indicated that 12 out of the 15 previously non-compliant requirements have now been fulfilled. The final prototype (Design 4) weighs 1692 grams, which is still below requirement UR-05.

Table 8.1: The requirements for the ankle joint off-loading ankle orthosis that were not already compliant.

User requirements			
# ID	**Requirement**	**Target value**	**Compliant**
UR-06	The device shall be adjustable for different lower leg sizes	True	Yes
UR-08	The device shall not cause pressure points	True	Yes
UR-09	The device shall be able to be used for different bodyweights	$\leq 90\ kg$	Yes
FR-01	The device shall withstand mechanical forces of 1080N	$\geq$ 1080 N	Yes
FR-02	The device shall be able to off-load the ankle during walking	25% up to 75% of BW	No
FR-03	The offloading of the ankle should be adjustable	25% up to 75% of BW	Yes
FR-04	The device shall not break in case of unexpected movement	Safety factor of 1.5-2.0	Yes
FR-06	The minimum frictional force of the anti-slip material around the tip shall not be less than 25 N	$\leq 25\ N$	No
FR-07	The footprint shall have a minimum width of 35 mm	35 mm	Yes
FR-08	The device shall be accompanied by a user manual, providing instructions for use	True	Yes
PR-01	The device shall not slide over the leg during walking	True	Yes
PR-02	The device shall not lose any functionality for the duration of the treatment	Life cycle of 6 weeks	No
PR-03	The device shall be able to make 10,000 gait cycles a day	10,000 cycles/-day	Yes
PR-04	The device shall be able to be used on uneven ground	True	Yes
IR-03	The device shall be able to be used in one possible way	True	Yes

The requirement FR-01 is not fulfilled in the final prototype. During the functional validation,

the spring was not able to withstand more force than 535 N. Therefore, the offloading percentage was changed to 25% up to 50% offloading of the body weight during the subject validation tests. However, this could be solved by choosing another spring that can withstand forces up to 810 N. The second requirement that was not compliant was FR-06. The rubber used during the experiments was a thin butyl rubber layer with a thickness of 1.5 mm. To improve the design, a rubber sleeve should be designed, using the same thickness and material used for the tip of crutches. In addition, the bottom should be anti-slip to increase the grip and decrease the sliding. This resulted in not fulfilling requirement PR-02. The device looses functionality during use because of the wearing of the rubber.

8.2 Limitations

During the fabrication process, the greatest limitation was the restriction of time. To save time, manufacturing processes were chosen that were available at the University of Twente. In addition, the materials used to make the parts were also chosen from materials already available from the University of Twente.

In the case of prototype testing, the greatest limitation during functional validation was the placement of the lever and the inability to perform a dynamic test using the average walking speed. The clamping of the lever was difficult because the clamps were normally used for extension tests. The dynamic test was imitated by a faster repeat of a single test. The greatest limitation during the subject validation tests was the equipment used in the experiments. The output of the force plate was the vertical ground reaction force and not the data of each sensor within the force plate. Therefore, it was not possible to put the foot, including the end of the GroundContact, on the force plate. The subject needed to put the foot on the force plate, and placing the GroundContact next to the force plate. This did make the meeting less accurate, because occasionally the placement was not completely correct for each step.

The final limitation was the amount of test subjects using the final prototype (Design 4). The final prototype was only tested by 1 test subject. Therefore, the received data cannot be compared. To ensure that the data is correct, the tests must be repeated in the future with around 20 test subjects.

8.3 Design improvements and future steps

Section 8.1 lists the requirements, showing all improvements compared to the first redesign. Not all requirements have yet been met. Besides changing the spring and designing a GroundContact sleeve of another material including anti-slip at the bottom, there are some other improvements to be made. The first recommendation covers the compression of the lower leg. In the current design, eight Velcro bands are used to compress the lower leg. Four beneath each other, with one on each side of the connection between the back shell and front shell. The Velcro bands are short, making it harder to compress the lower leg. This could be improved by adding a cut in the frame and pulling the Velcro band through these holes. Pulling these Velcro bands backward, it is easier to compress the lower leg better. Another recommendation for the next redesign is a mechanism to track the position of the offloading within the tubes. This could done by a sound after reducing one coil, or visual lines along the slot of the tubes with a distance of 2.8 mm between them to track the reduction of coils. The third recommendation is the use of a damper within the spring mechanism. During each step, the spring makes a sound during release after extension. Using the orthosis for longer periods or in daily activities, the sounds could be irritating and will attract the attention of other individuals in public.

There were some other recommendations on subject validation tests. Multiple subjects did mention slipping of the GroundContact during walking. A reason for this was the wearing of the rubber around the GroundContact. However, the plates in the middle of the track surrounding the force plate were smooth. This resulted in more slipping, even when the rubber was not worn yet. Another recommendation during the subject test is to use the same height during walking. The track did include two other plates beside the plate including the force plate, however, the subjects did mention it was harder to make a step at the plates with an increased height.

8.4 Comparison with the current rehabilitation methods and existing devices

The current rehabilitation period of patients with OLTs include mainly the use of a walking boot or a splint when full immobilization is necessary and crutches or a walking boot when partial weight-bearing is possible. These assistive devices are unreliable for partial weight-bearing because accurately assessing the offloading of the ankle joint is challenging. The current design of the ankle joint offloading ankle orthosis makes it possible to assess and adjust the offloading accurately for individuals between 60 kg and 90 kg, increasing the reliability. In addition, the assistive device can interfere with daily activities. The current design does still need improvements, but the shorter rehabilitation period is important for young and active individuals. In addition, when using crutches, the hands are always used during walking. The ankle joint offloading ankle orthosis enables the individual the use their hands and arms.

The existing devices were Design 1 and Design 2 designed during two previous studies. Design 1 was already improved by Design 2. The final design (Design 4) did improve more compared with Design 2, by:

1. Adding a back shell for better compression.
2. Increasing the cover area around the lower leg for more even force distribution.
3. Relocating of the compression of the lower leg to the front to ensure the Velcro band was not placed over the spring.
4. Replacing the lever by a hollow tube to withstand rotational forces.
5. Placing lever only on the lateral side of the lower leg to prevent the medial lever touching the other lower leg.
6. Increasing the surface area that contacts the ground to prevent getting stuck.
7. Adding a spring cover to ensure patient's safety.
8. Adding a continuous adjustable offloading percentage.
9. Increasing the offloading percentage to 50% BW.

Chapter 9

Conclusion

Ankle joint offloading ankle orthosis is a great assistive tool for people rehabilitating from isolated osteochondral lesions in the ankle. It enables patients to control weight-bearing during the rehabilitation period after surgery. Already two other prototypes were designed, however, 15 requirements were not yet compliant.

The device created in this project proved to be a promising design step in the direction of a solution to the development of an ankle joint offloading ankle orthosis. The device has an easy manufacturing process using laser cutting and SLS printing. The other components used in the prototype can be purchased online. The assembly can be done using the manual, clearly stating the steps to assembling the devices as easy as possible.

The strength of the device was proved during functional testing, where the lever, Ground-Contact, and spring mechanism did succeed. The spring was the only failure during these tests, however, the offloading percentages could be lowered to 50%. This resulted in the use of this spring during the subject validation tests. Some design adjustments were made during the subject validation tests, resulting in a renewed prototype succeeding during all measurements without breakage or deformation of parts.

In conclusion, the aim of this thesis: "Redesign the ankle joint offloading orthosis, ensuring its compatibility for usability testing with healthy individuals" has been achieved. The design meets 12 of the 15 requirements that did not comply with the first redesign. In addition, the design was able to be used during usability testing with healthy individuals. Further improvements can be made by redesigning a rubber tip and choosing another spring. Some other recommendations were mentioned in section 8.3 which will improve the device, but are not necessary according to the requirements.

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Chapter A

Treatment of OLTs

The treatment of OLTs is a personalized approach that incorporates all patient and lesion characteristics to determine the optimal treatment. Treatment of OLTs can be divided into conservative treatment or surgical intervention, with conservative treatment always the primary intervention. Conservative treatment consists of a combination of interventions, including restriction of weight-bearing and physical or occupational activities. The aim is to reduce symptoms and facilitate a complete return to daily activities and sports while managing pain and avoiding high-impact sports [8]. Surgical intervention may be considered, due to the low success rate (45 %), when patients are restricted from participating in high-impact sports or still experience deep ankle pain three to six months after conservative treatment [16, 18]. There are four commonly used surgical treatments: bone marrow stimulation, fixation techniques, osteochondral transplantation, and regenerative and retrograde treatments.

1. **Bone Marrow Stimulation (BMS)** is the most commonly utilized treatment for primary OLTs and is recommended for small (<15 mm diameter or 150 mm^2), noncystic, nonfixable lesions [63–65]. The treatment includes arthroscopic abrasion arthroplasty, debridement and drilling, and microfracture [66]. Clinical results are successful in 82 % of the primary OLTs and the sports outcomes show a return to sport (RTS) rate at any level and a pre-injury level of 88 % and 79 % [63, 67]. The time to RTS after BMS was between 15 weeks and 26 weeks [68]. Partially weight-bearing is already implemented in postoperative treatment.

2. **Fixation techniques** are a viable option for OLTs when the fragments are fixable, both in acute primary cases and in chronic cases. The osteochondral fragment must have a diameter of at least 10 mm and a depth of 3 mm for a feasible fixation [69]. The treatment will be performed arthroscopically when the lesion can be reached, otherwise, open fixation can be considered. If both options fail, BMS can still be considered as follow-up intervention [8]. Clinical outcomes are successful, with an RTS rate at any level of 97 % [67].

3. **Autologous or allogenic osteochondral transplantation (AOT)** is a reparative method that replaces the compromised bone chondral unit while restoring the load-bearing capacities of the talus. AOT is typically used for larger lesions (>15 mm in diameter) as well as for massive cystic, primary, and secondary lesions of the talus [9, 63, 70]. The treatment includes an arthrotomy or osteotomy. Graft(s) are harvested and implanted into the debrided and excised lesion side, using the ipsilateral knee as the primary donor site [71]. The RTS rate at any level of this treatment is 90 % and the rate of RTS at the pre-injury level is 72 %. The time to RTS was between 13 and 26 weeks [67].

4. **Regenerative and retrograde treatments** are cell-based therapies such as cartilage transplantation and chondrogenesis-inducing techniques that are used for larger (>15 mm diameter), cystic, and secondary lesions. These methods involve using autologous chondrocytes sourced from non-weight-bearing areas of the ankle or blood/marrow-like products to resurface the osteochondral lesion [8]. A cartilage transplantation technique is autologous chondrocyte implantation (ACI), which has an RTS rate at any level of 87 % and an RTS rate at a pre-injury level of 69 % [67].

Chapter B

Assistive devices for rehabilitation of patients with isolated OLTs

B.1 Crutches, walking boot, and splint

Crutches belong to the category of assistive devices which are specifically designed to support a weight-bearing impairment on one leg while walking. Compared to other assistive devices, crutches enable more overall physical activity which has positive long-term health consequences. There are many different types and designs of crutches to fit the specific needs [72, 73]. Two types of crutches are the forearm crutches and the IWALKFree knee crutch [74].

Forearm crutches (Figure B.1A) have become the standard of care for patients offloading their lower extremities. However, there are several disadvantages associated with the forearm crutches. First, the gait cycle is typically slower and less energy-efficient than an actual walking pattern. Secondly, the use of crutches changes the joint kinematics and ground reaction force (GRF) patterns. The forearm crutches used for partial offloading, lack precision and control and, therefore, are an unreliable method for weight-bearing. In addition, not using the arms while using crutches can interfere with daily activities.

The iWALKFree (Figure B.1B) is a hands-free single crutch (HFSC) that offers pain-free mobility for patients with below-the-knee injuries. The L-shaped crutch is attached to the user's shank and thigh by straps. As the user walks, the leg remains flexed in a 90-degree ankle offloading the ankle and foot and engaging the same upper leg muscles as during normal walking. It is comprised of an upper leg part and a lower leg part, each independently adjustable [75]. In a previous study, the iWALKFree had higher patient preference, perceived exertion, and physiological demand, and decreased upper limb pain than the traditional axillary crutches [76]. Another study revealed minimal changes in the gait pattern analyzed in the sound leg compared to normal gait [77]. However, the iWALK-Free can interfere with daily activities, e.g. sitting with the device, walking on uneven terrain, fatigue of the upper limb muscles and limited mobility in small spaces. In addition, the iWALKFree only allows full offloading of the ankle.

Orthopedic walking boots are often used for ankle sprains, stress fractures, foot and ankle fractures, chronic tendinopathy, and recovery from surgery. The benefits of using a walking boot compared to a traditional cast include that it is less costly and easier to remove. However, the boot positions one limb higher than the other, creating a leg length discrepancy (LLD). The LLD leads to changes in the kinematics and kinetics of the gait, resulting in knee, hip or back pain. Three types of walking boots are the traditional controlled ankle motion walker boot, a hinged boot walker, and a spring-loaded boot [78].

A traditional walking boot is the Össur Formfit Walker Air (Figure B.1C). The Össur Formfit Walker Air walking boot offers stability and support for many types of lower extremity injuries. An air bladder system delivers adjustable compression and a personalized fit to increase the patient's comfort and optimal healing. A rocker sole promotes a stable and natural walking pattern [79]. However, adjustable offloading with this device is not possible. In addition, the

walking boot leads to uneven heights of the legs, no footwear choice, and the ROM is limited resulting in a reduction of activities for the user.

A hinged walking boot is the Össur Range of Motion (ROM) Walker (Air) (Figure B.1D). The Össur ROM Walker offers immobilization and support of the lower limb. The clinician can control the ROM to determine the level of ankle joint movement to promote healing and rehabilitation. This will result in a more natural gait mechanism. The boot walker, when including an air system, can be personalized using adjustable compression for increased comfort and optimal healing. The rigid frame of the boot walker encloses the foot and ankle, using adjustable straps to secure the foot in place [80, 81]. Controllable offloading of the ankle is not possible with this walking boot. The ROM can be controlled, however, the walking boot still interferes with daily activities by restricting participation during activities, and a height difference between the legs.

In the spring-loaded boot (Figure B.1E), the hinge was replaced with linear springs. A larger gap between the foot and the footbed accommodates spring compression. In a static stance, the stiffness is intended to unload approximately 50 % of the body weight. Since the foot does not make contact with the footbed upon foot strike, the initial force is transferred to the shank. The springs compress as the force increases, closing the gap between the foot and the footbed, and causing the foot to load. In the late stance phase, this process is reversed [81]. This walking boot does offload the ankle, however, no controllable offloading is possible. The walking boot does still interfere with daily activities because it leads to uneven heights of the legs, no footwear choice, and a limited ROM results in a reduction of activities for the user.

Splints are non-circumferential immobilizers that are typically only used temporarily and can accommodate swelling. Splinting is used to protect and immobilize the injured extremities, aid in healing and to reduce the pain. Prolonged immobilization resulting from the continued use of a splint may cause more serious consequences such as joint stiffness, muscular atrophy, or chronic pain. Patients are closely monitored while utilizing a splint to recover. A below-knee splint is used for the recovery of OLTs after BMS treatment [82]. An example of a posterior below-knee splint is the DARCO Posterior Splint Fix (Figure B.1F). The DARCO Posterior Splint Fix is an immobilization device for the lower extremity. It provides strong support and stability for injuries of post-surgery rehabilitation. Key features are lightweight and durable, adjustable straps for personalization and padded inside for patient comfort. Splints do not allow weight-bearing, resulting in no partial offloading. In addition, by fully immobilizing the lower leg, the user is restricted during walking, household tasks, and outdoor activities.

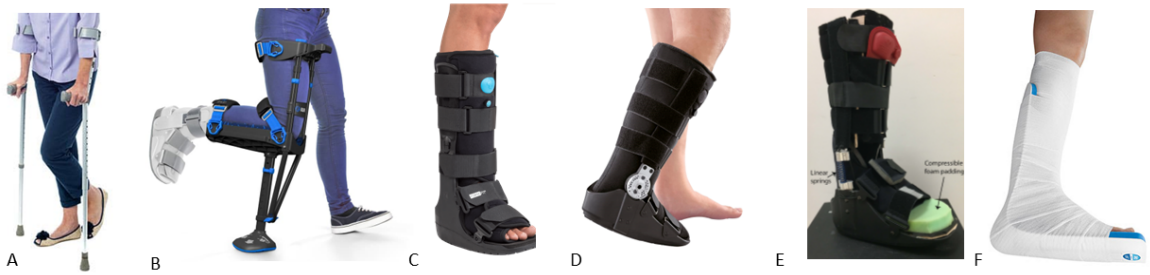


Figure B.1: Different crutches, walking boots, and splints. (A) Forearm crutches, (B) iWALK-Free, (C) Össur Formfit Walker Air, (D) Össur Range of Motion Walker, (E) Spring-loaded boot and (F) DARCO Posterior Splint Fix.

B.2 Current unloading orthoses

Unloading orthoses, also known as anti-gravity braces or hydrostatic compression bracing, work by placing compressive force across the area of contact between the brace and leg to create a uniform pressure distribution. The goal is to maximize the surface area in contact, minimizing the pressure, whilst making the conical shape of the leg do the work and support further weight. Three types of antigravity orthoses will be examined in this study, the Zero-G AFO (ZG), the TAG brace, and the LoadShifter [83].

The Zero-G is an AFO that allows the patient to completely offload the foot and ankle. The Zero-G is composed of two distinct parts: the calf lacer and the AFO base.The calf lacer consists of the lacer, straps, and SmartKnit fracture sock and remains connected to the lower leg. The parts are easily adjustable with the Velcro fasteners. The AFO base incorporates the healing shoe, foot insert, donning pad, foot cover, and bidirectional ankle joints to assist the adjustment. The donning pad is used to ensure a repeatable offloading system, and the foot cover is used to protect the foot. This part is adjustable and is universal for left and right fitting [84].

The Toad AntiGravity brace allows patients to completely unload the foot and ankle through patella tendon loading. In addition, the brace removes all pressure and shear. The weight is distributed across the remaining skeletal structure, significantly reducing muscular atrophy and thus maintaining bone density and stability [85].

The Loadshifter AFO allows the unloading of the distal tibia, talus, and calcaneus and shifts the weight to the calf muscle. The method for unloading the ankle is the donning technique. The donning technique starts with creating a mold of the patient's leg and cutting it above the ankle. The two parts are separated by 2.5 centimeters and reassembled. While donning the AFO a wedge of 2.5 centimeters must be placed in the AFO. The patient will secure the brace to the leg and remove the wedge, so the heel will barely touch the AFO. Hydrostatic compression is used, increased with friction from the overlapping liner. The brace is designed with a layer of carbon fiber on the back, and a laminated flexible material on the front, resulting in the required rigidity during loading and flexibility for variable loading [86]. All three orthoses only allow full unloading of the ankle joint. Therefore, these could not be used during the rehabilitation of OLTs where adjustable partial offloading is necessary.

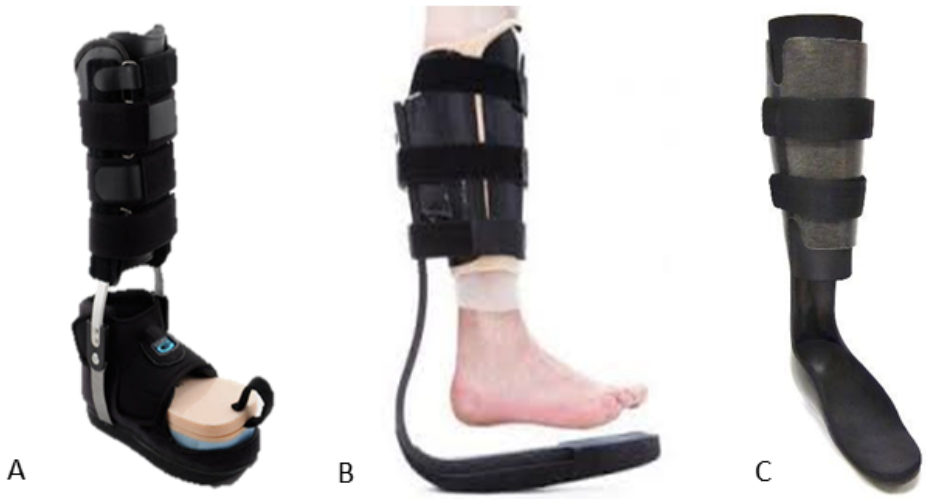


Figure B.2: Three different unloading orthosis. (A) Zero-G AFO, (B) Toad AntiGravity brace, and (C) Loadshifter AFO.

B.3 Current offloading orthoses

Unless the unloading orthoses, mentioned in section B.2, the offloading orthosis will not completely unload the foot and ankle. These orthoses do not meet the requirement: no contact of the bottom of the foot with the shoe or brace [83]. This section will discuss two different off-loading AFOs: the dynamic ankle orthosis and the momentum off-loading brace.

The Dynamic Ankle Orthosis (DAO) is an orthotic device used to offload the foot and ankle while permitting the talocrural and subtalar joints to move naturally during gait. The orthosis includes pneumatic (air) cylinders connecting the calf sleeve to the modified shoe. These cylinders apply a modulated distractive force on the ankle upon inflation. The active DAO unloads longitudinal force transmitted through the foot and ankle by 30.5% during static standing. An anatomically oriented tie rod ball joint allows functional ankle joint movement [87]. This orthosis does allow offloading, however not controlled offloading. In addition, only 30.5% offloading can be achieved, where 75% offloading needs to be achieved during the rehabilitation of OLTs. Besides, a modified shoe should be worn, which can interfere with the user's preferences.

The momentum off-loading AFO is a custom carbon fiber AFO that partially offloads the foot and ankle. It can be used to help alleviate pressure and pain following foot and ankle injuries. The AFO consists of an anterior knee clamshell, a posterior strut, and a solid ankle section. The knee clam-shell allows for partial transfer of strain away from the foot and ankle to load-tolerant areas. The posterior strut allows for energy storage through the gait cycle with subsequent rapid release during push-off. Lastly, the ankle component blocks the painful tri-planar motion during gait and increases stability [88]. This orthosis does partially offload the foot and ankle, but this offloading cannot be controlled. Therefore, it cannot be used as assistive device during the rehabilitation of OLTs.

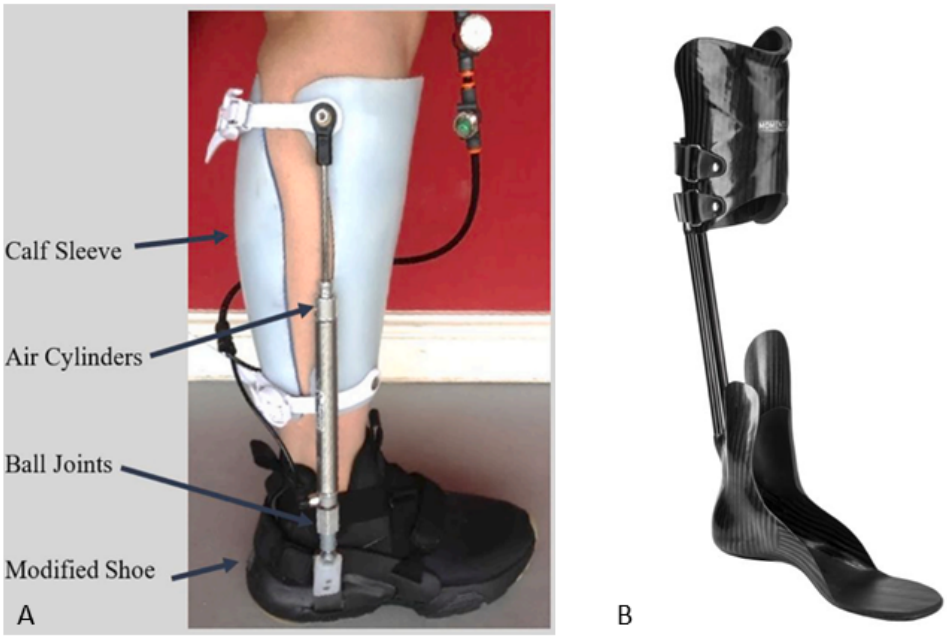


Figure B.3: Two offloading orthoses. (A) Dynamic Ankle Orthosis, and (B) Momentum offloading AFO.

Chapter C

Identification of the characteristics of the current design.

Table C.1: The 34 questions to define the characteristics to identify the hazard of the orthosis.

	Question	**Applicable (Y/N)**	**Remark**	**Hazard**
1	What is the intended use, and how is the medical device to be used?	Yes	The device is intended to be used for offloading of the traumatic / pathologic ankle to stimulate healing of the osteochondral defect site while minimizing the influence on gait.	
2	Is the medical device intended to be implanted	No		
3	Is the medical device intended to be in contact with the patient or other persons?	Yes	The lower leg of the patient is in contact with the ankle orthosis.	Bacteria and allergenicity
4	what materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Yes	Used materials are padding (foam), steel and plastic.	
5	Is energy delivered to or extracted from the patient?	No		
6	Are substances delivered to or extracted from the patient?	No		
7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No		
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No		
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No		

	Question	**Applicable (Y/N)**	**Remark**	**Hazard**
10	Is the medical device intended to modify the patient environment?	No		
11	Are measurements taken?	No		
12	Is the medical device interpretative?	No		
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No		
14	Are there unwanted outputs of energy or substances?	No		
15	Is the medical device susceptible to environmental influences?	No		
16	Does the medical device influence the environment?	No		
17	Are there essential consumables or accessories associated with the medical device?	No		
18	Is maintenance or calibration necessary?	No		
19	Does the medical device contain Software?	No		
20	Does the medical device have a restricted shelf-life?	Yes	The spring could deteriorate over time	Failure of component due to ageing, wear of fatigue
21	Are there any delayed or long-term use effects?	No		
22	To what mechanical forces will the medical device be subjected	Yes	Shear force at the connection parts	Mechanical forces
23	What determines the lifetime of the medical device?	Yes	Deterioration of the materials and spring	Failure of a component due to ageing, wear or fatigue.
24	Is the medical device intended for single use?	No		
25	Is safe decommissioning or disposal of the medical device necessary?	No		
26	Does installation or use of the medical device require special training or special skills?	No		
27	How will information for safe use be provided?	Yes		

	Question	**Applicable (Y/N)**	**Remark**	**Hazard**
28	Will new manufacturing processes need to be established or introduced?	No		
29	Is successful application of the medical device critically dependent on human factors such as the user interface?	Yes	Positioning of the length changing components	Use by unskilled or untrained personnel
29.1	Can the user interface design features contribute to use error?	Yes	Length changing components and the use of the Velcro band may be incomprehensible	Ambiguous or unclear state of medical device
29.2	Is the medical device used in an environment where distractions can cause use error?	Yes	Device may be used different from intended use by changing gait	Complex or confusing control system
29.3	Does the medical device have connecting parts or accessories?	No		
29.4	Does the medical device have a control interface?	No		
29.5	Does the medical device display information?	No		
29.6	Is the medical device controlled by a menu?	No		
29.7	Will the medical device be used by persons with special needs?	No		
29.8	Can the user interface be used to initiate user actions?	No		
30	Does the medical device use an alarm system?	No		
31	In what way(s) might the medical device be deliberately misused?	Yes	Deliberately changing the gait by touching the ground first with the toes	Violation of instructions.
32	Does the medical device hold data critical to patient care?	No		
33	Is the medical device intended to be mobile or portable?	Yes	The orthosis shall be worn by the patient	Accidental mechanical damage
34	Does the use of the medical device depend on essential performance?	Yes	The	

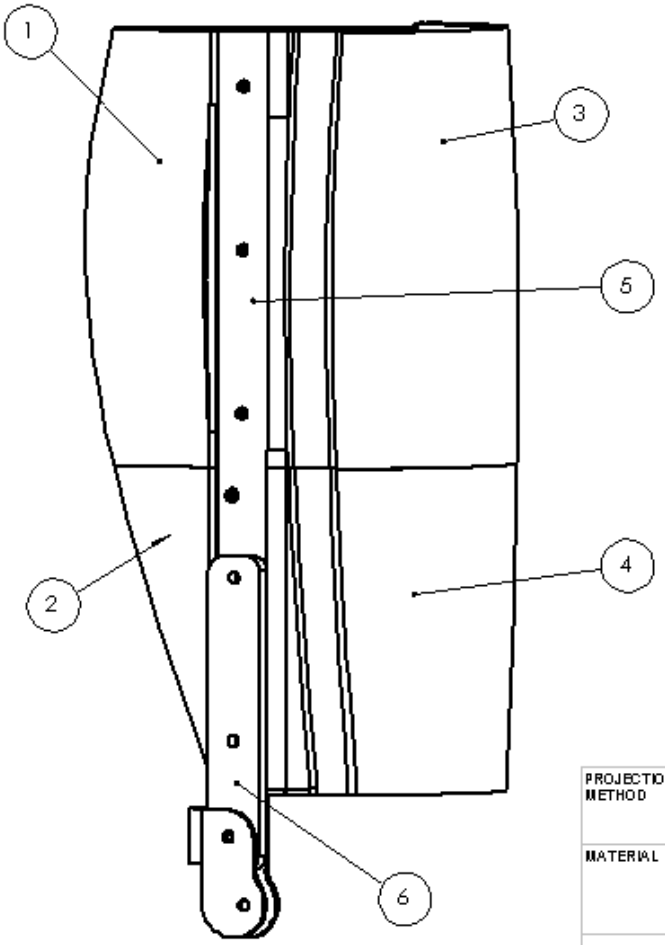
Chapter D

Technical drawings

Technical drawings are provided for the parts within the final design (Design 4) made using laser cutting or SLS printing. The parts needed are viewed in an overview (Table D.1).

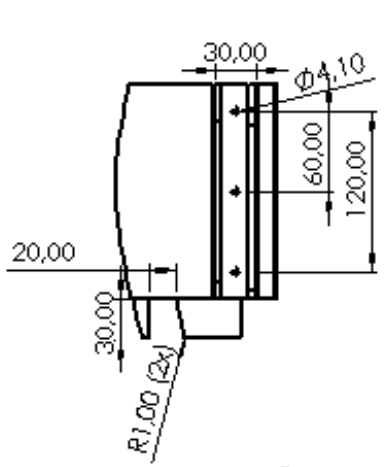
Table D.1: Parts included within design 4 used for laser cutting or SLS printing.

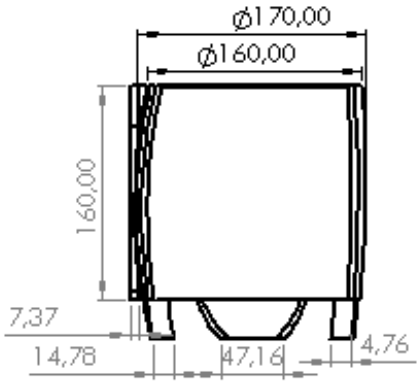
Component ID	**Component name**	**Amount**
1.0	**Shells assembly**	
1.1	Upper part back shell	1
1.2	Lower part back shell	1
1.3	Upper part front shell	1
1.4	Lower part front shell	1
1.5	Frame	1
1.6	Additional metal plate	1
2.0	**Lever and Ground-Contact assembly**	
2.1	Lever	1
2.2	GroundContact	1
2.3	Pin	1
3.0	**Offloading spring mechanism assembly**	
3.1	Upper tube	1
3.2	Lower tube	1
3.3	Screw nut 1	1
3.4	Screw nut 2	1
3.5	Rod 1	1
3.6	Rod 2	1

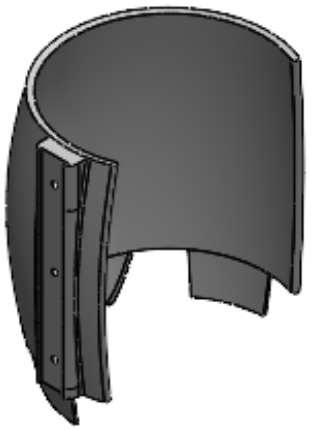


ITEM NO.	PART NUMBER	QTY.
1	Upper part back shell	1
2	Lower part back shell	1
3	Upper part front shell	1
4	Lower part front shell	1
5	Frame	1
6	Additional metal plate	1

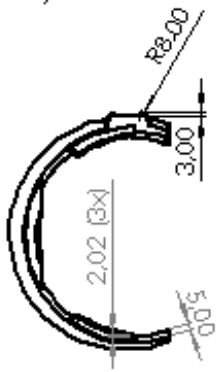
PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	M. Brughuis	DATE	4-8-2024
		CHECKED		SCALE	1:2
MATERIAL: Nylon, Steel	SURFACE TREATMENT: --	TITLE: Shells			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO.: --			A4
FACULTY OF ENGINEERING		FILE/PART NAME: Shells			
		DIMENSIONS IN MILLIMETERS			SHEET 1 OF 1

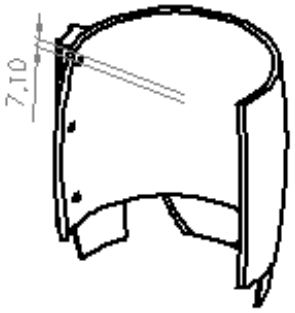




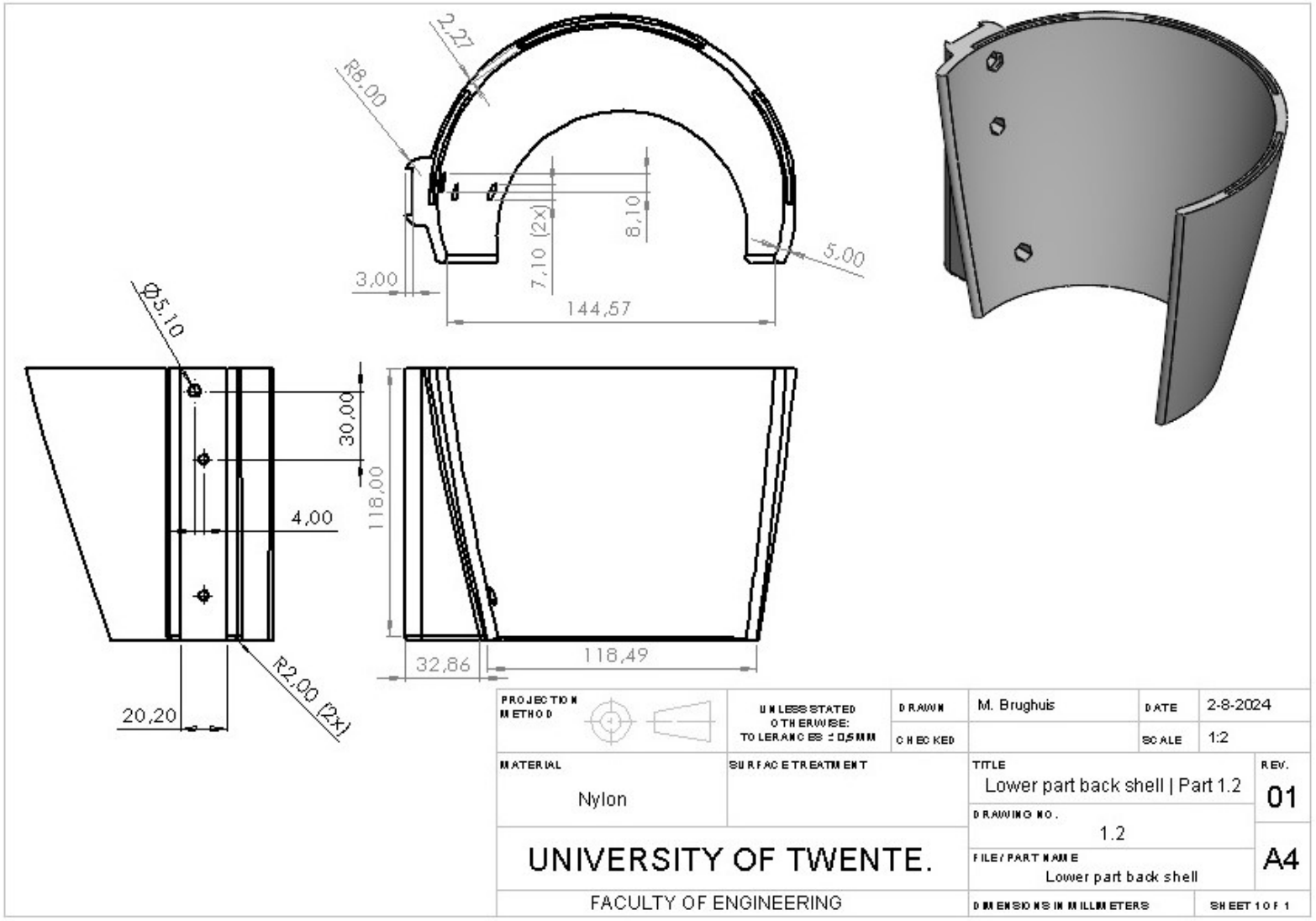


VIEW
SCALE 1 : 3





PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	M. Brigleb	DATE	4-6-2024
		CHECKED		SCALE	1:4
MATERIAL: Nylon	SURFACE TREATMENT: --	TITLE: Upper part back shell | Part 1.1			REV. 01
		DRAWING NO.: 1.1			A4
UNIVERSITY OF TWENTE.		FILE / PART NAME: Upper part back shell			
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	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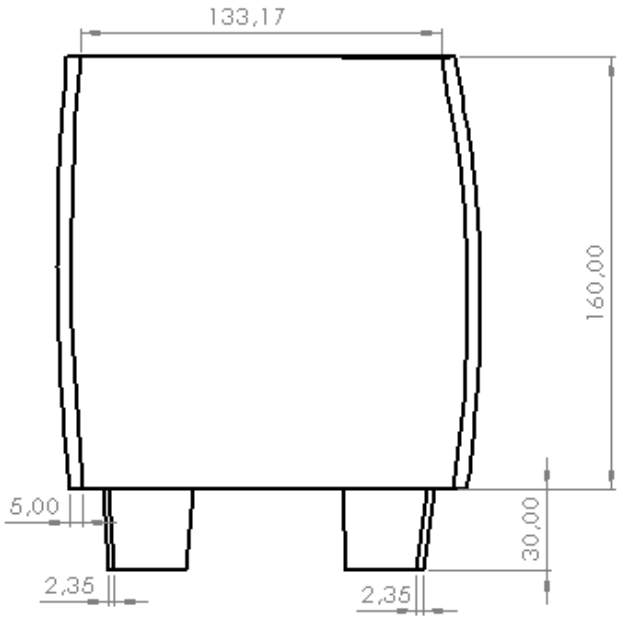
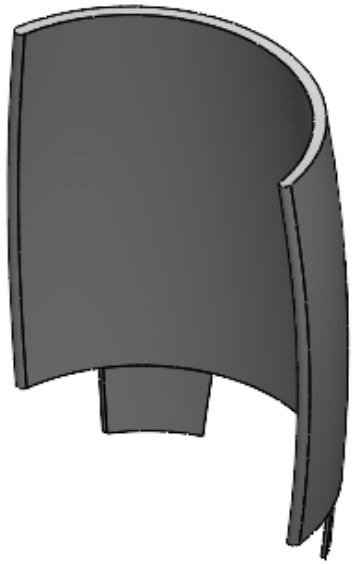
R8,00
8,10
7,10 (2x)
3,00
144,57
5,00
Ø5,10
30,00
4,00
118,00
32,86
118,49
20,20
R2,00 (2x)
PROJECTION METHOD
UNLESS STATED OTHERWISE: TOLERANCES ± 0,5MM
DRAWN
M. Brughuis
DATE
2-8-2024
CHECKED
SCALE
1:2
MATERIAL
Nylon
SURFACE TREATMENT
TITLE
Lower part back shell | Part 1.2
REV.
01
DRAWING NO.
1.2
UNIVERSITY OF TWENTE.
FILE/PART NAME
Lower part back shell
A4
FACULTY OF ENGINEERING
DIMENSIONS IN MILLIMETERS
SHEET 1 OF 1





PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ±0,5MM	DRAWN	M. Brughuis	DATE	4-8-2024
		CHECKED		SCALE	1:2
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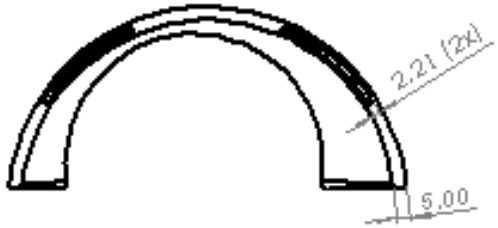
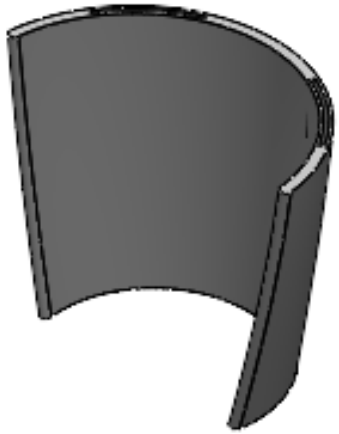
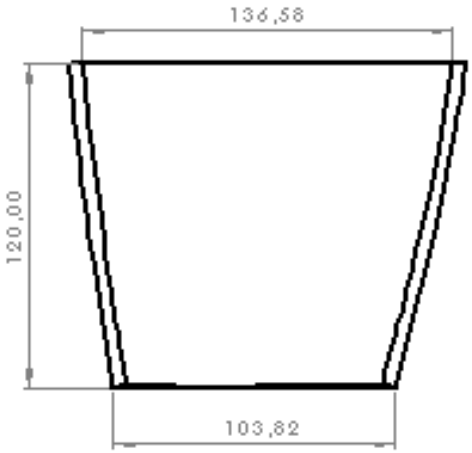
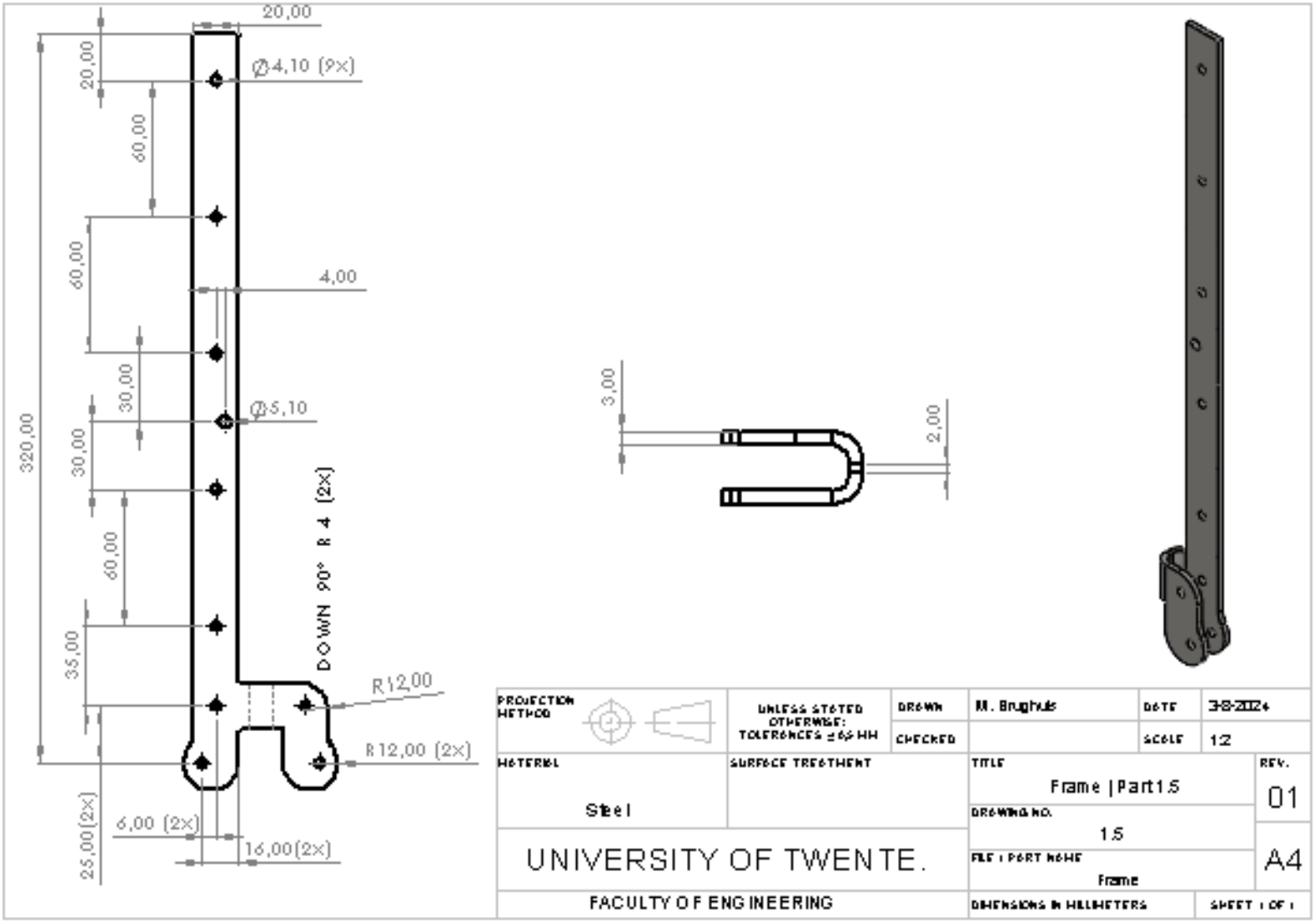
UNIVERSITY OF TWENTE.		DRAWING NO.: 1.3			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Upper part front shell			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	

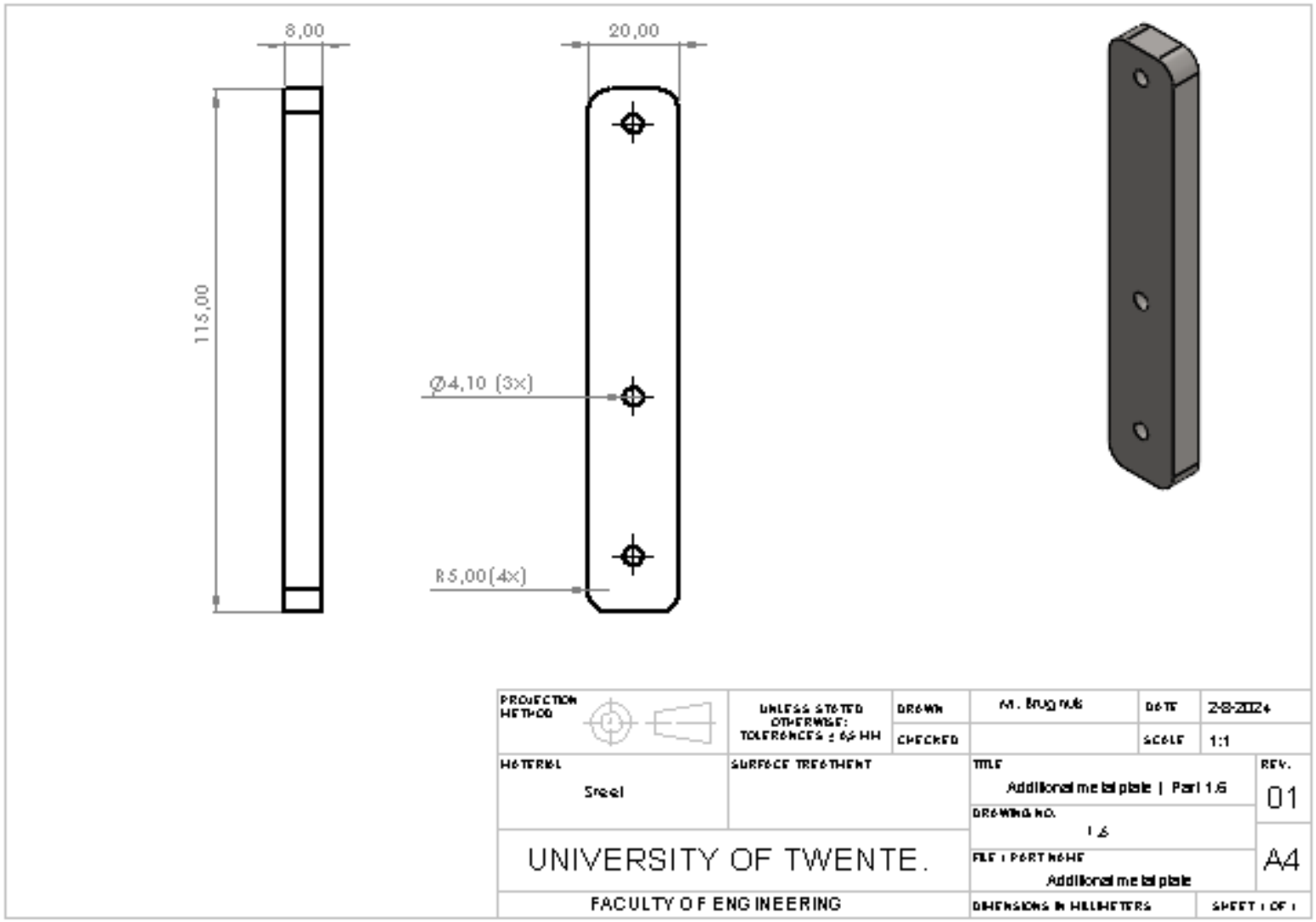




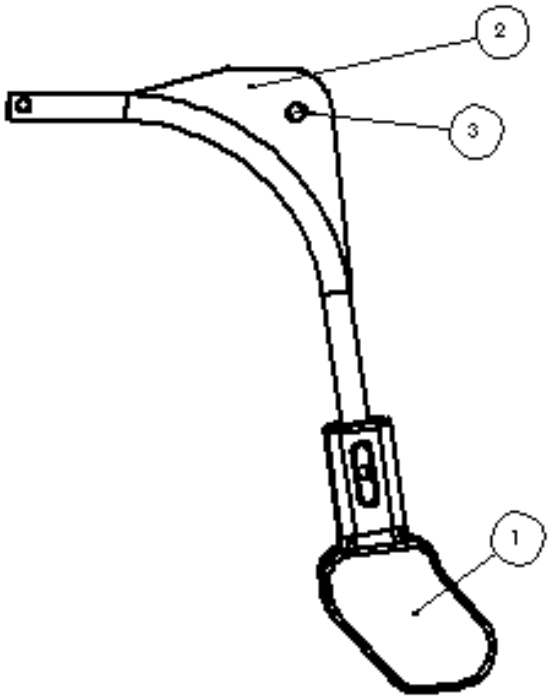


PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ±0,5 MM	DRAWN	M. Brughuis	DATE	4-3-2024
		CHECKED		SCALE	1:2
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: Lower part front shell | Part 1.4			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO. 1.4			A4
FACULTY OF ENGINEERING		FILE | PART NAME: Lower part front shell			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	


20,00
20,00
Ø4,10 (9x)
60,00
60,00
4,00
30,00
Ø5,10
30,00
320,00
60,00
35,00
DOWN 90° R 4 (2x)
R12,00
R12,00 (2x)
25,00(2x)
6,00 (2x)
16,00(2x)
3,00
2,00
PROJECTION METHOD
UNLESS STATED OTHERWISE: TOLERANCES ±0,5 MM
DRAWN
M. Brughuis
DATE
3-8-2024
CHECKED
SCALE
1:2
MATERIAL
Steel
SURFACE TREATMENT
TITLE
Frame | Part1.5
REV.
01
DRAWING NO.
1.5
A4
FILE / PART NAME
Frame
UNIVERSITY OF TWENTE.
FACULTY OF ENGINEERING
DIMENSIONS IN MILLIMETERS
SHEET 1 OF 1

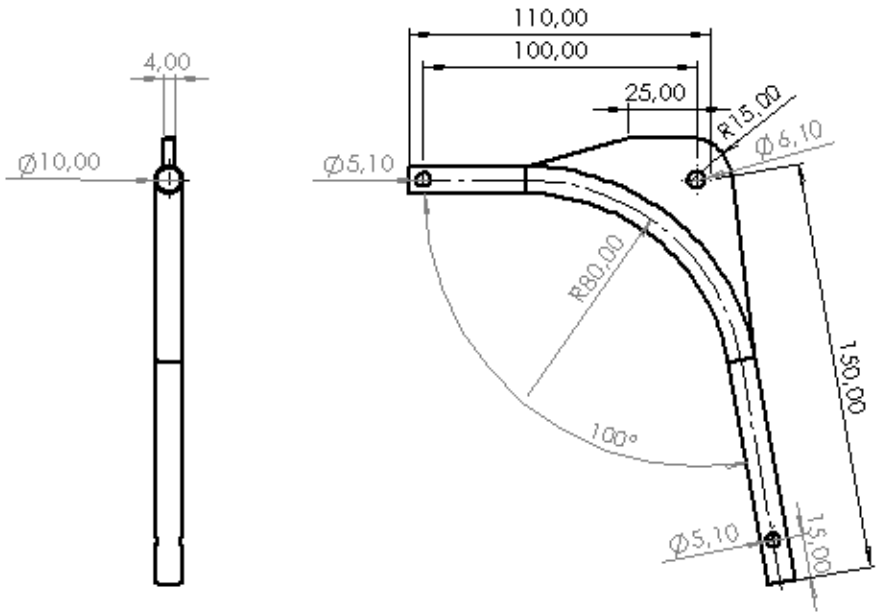


PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	M. Bruining	DATE	2-8-2024
		CHECKED		SCALE	1:1
MATERIAL: Steel	SURFACE TREATMENT	TITLE: Additional metal plate | Part 1.6			REV. 01
		DRAWING NO.: 1.6			
UNIVERSITY OF TWENTE.		FILE | PART NAME: Additional metal plate			A4
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	

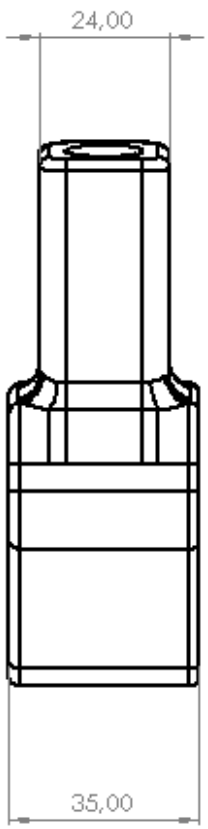


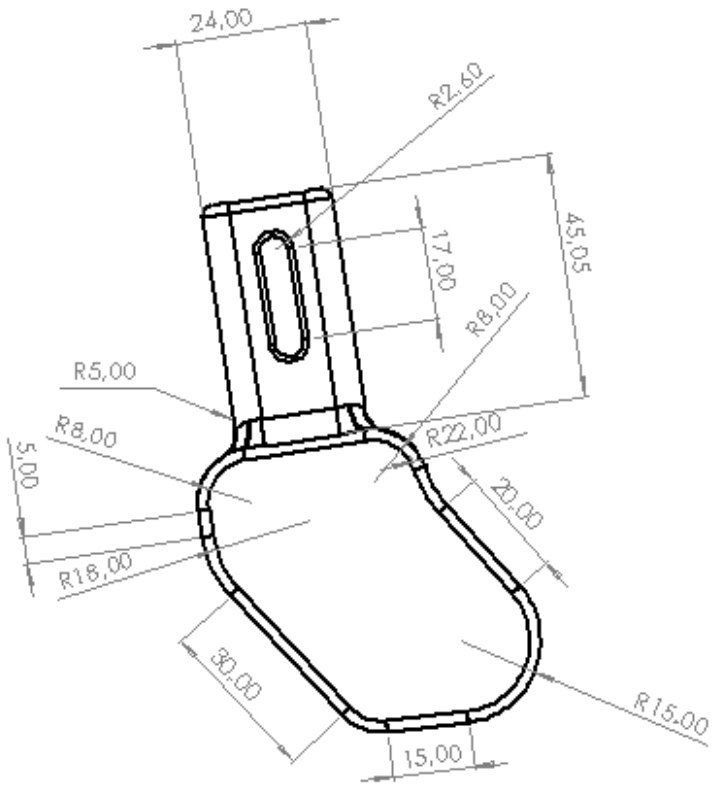
ITEM NO.	PART NUMBER	QTY.
1	Ground Contact	1
2	Lever	1
3	Pin	1

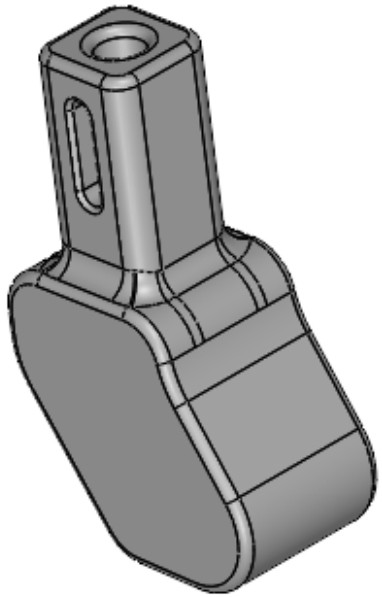
PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0.5 MM	DRAWN	M. Brughuis	DATE	4-8-2024
		CHECKED		SCALE	1:2
MATERIAL: Nylon, Steel	SURFACE TREATMENT	TITLE: Lever and Ground Contact			REV. 01
		DRAWING NO.: --			
UNIVERSITY OF TWENTE.		FILE / PART NAME: Lever and Ground Contact			A4
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS			SHEET 1 OF 1



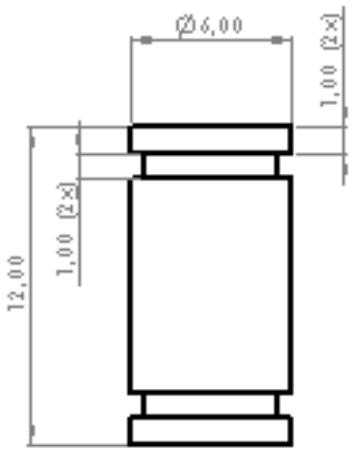
PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	M. Brughuis	DATE	3-8-2024
		CHECKED		SCALE	1:2
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: Lever | Part 2.1			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO.: 2.1			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Lever			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	



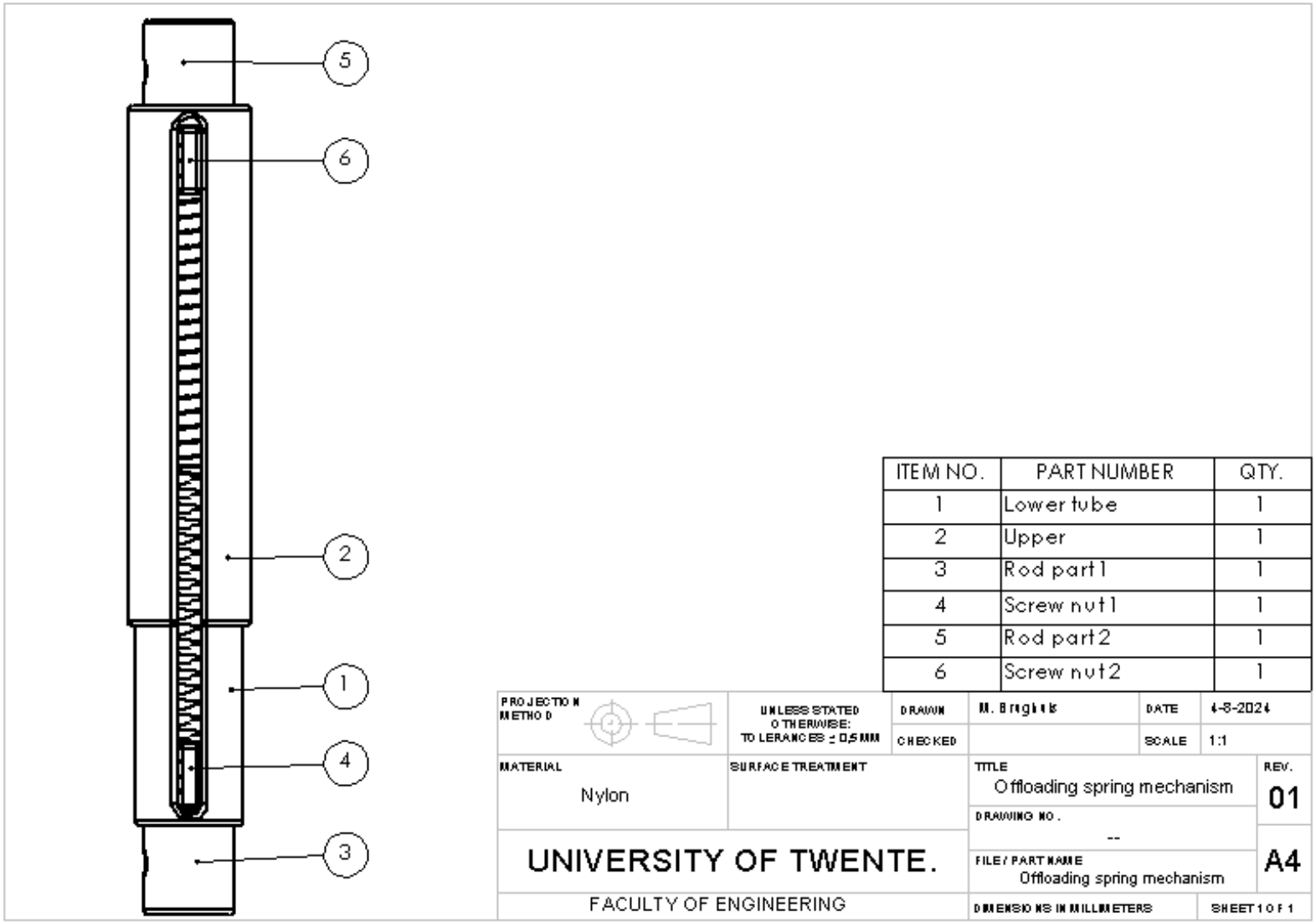




PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ±0,5 MM	DRAWN	M. Brughuis	DATE	3-8-2024
		CHECKED		SCALE	1:1
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: GroundContact | Part 2.2			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO.: 2.2			A4
FACULTY OF ENGINEERING		FILE / PART NAME: GroundContact			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	

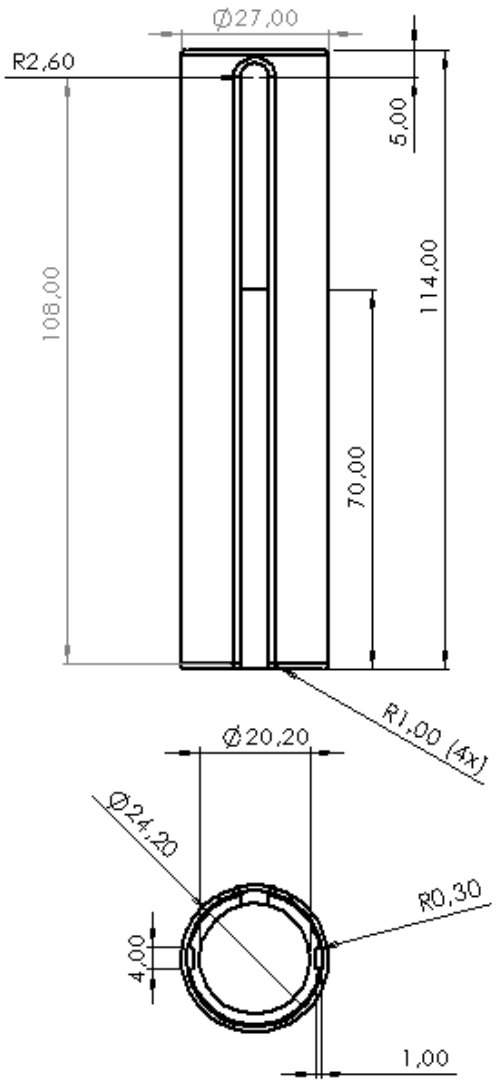


PROJECTION METHOD	UNLESS STATED OTHERWISE TOLERANCES ±0,5 MM	DRAWN	H. Bruggink	DATE	14-2-2024
		CHECKED		SCALE	5:1
MATERIAL: Steel	SURFACE TREATMENT	TITLE: Pin | Part2.3			REV. 01
		DRAWING NO. 2.3			
UNIVERSITY OF TWENTE.		NEXT ASSY NAME: Pin			A4
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	

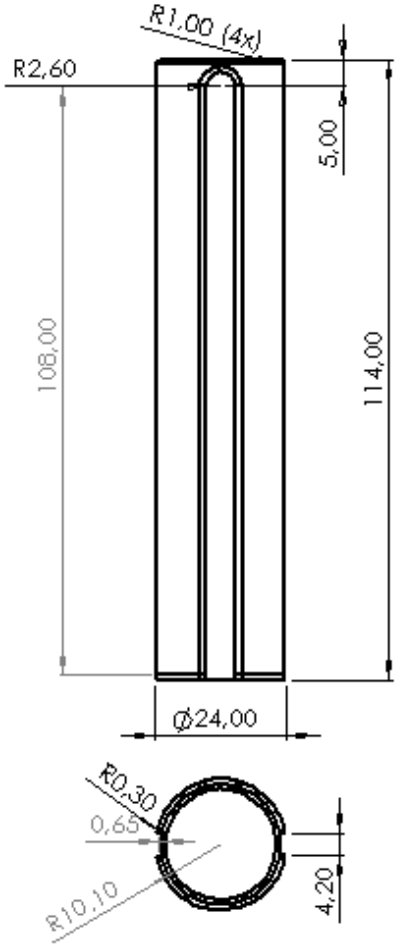


ITEM NO.	PART NUMBER	QTY.
1	Lower tube	1
2	Upper	1
3	Rod part1	1
4	Screw nut1	1
5	Rod part2	1
6	Screw nut2	1

PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	M. Brighi'ti	DATE	4-6-2024
		CHECKED		SCALE	1:1
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: Offloading spring mechanism			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO.: --			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Offloading spring mechanism			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	



PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ±0,5MM	DRAWN	M. Brughuis	DATE	3-8-2024
		CHECKED	--	SCALE	1:1
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: Upper tube | Part 3.1			REV. 01
UNIVERSITY OF TWENTE.		DRAWING NO.: 3.1			A4
FACULTY OF ENGINEERING		FILE/PART NAME: Upper tube			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	



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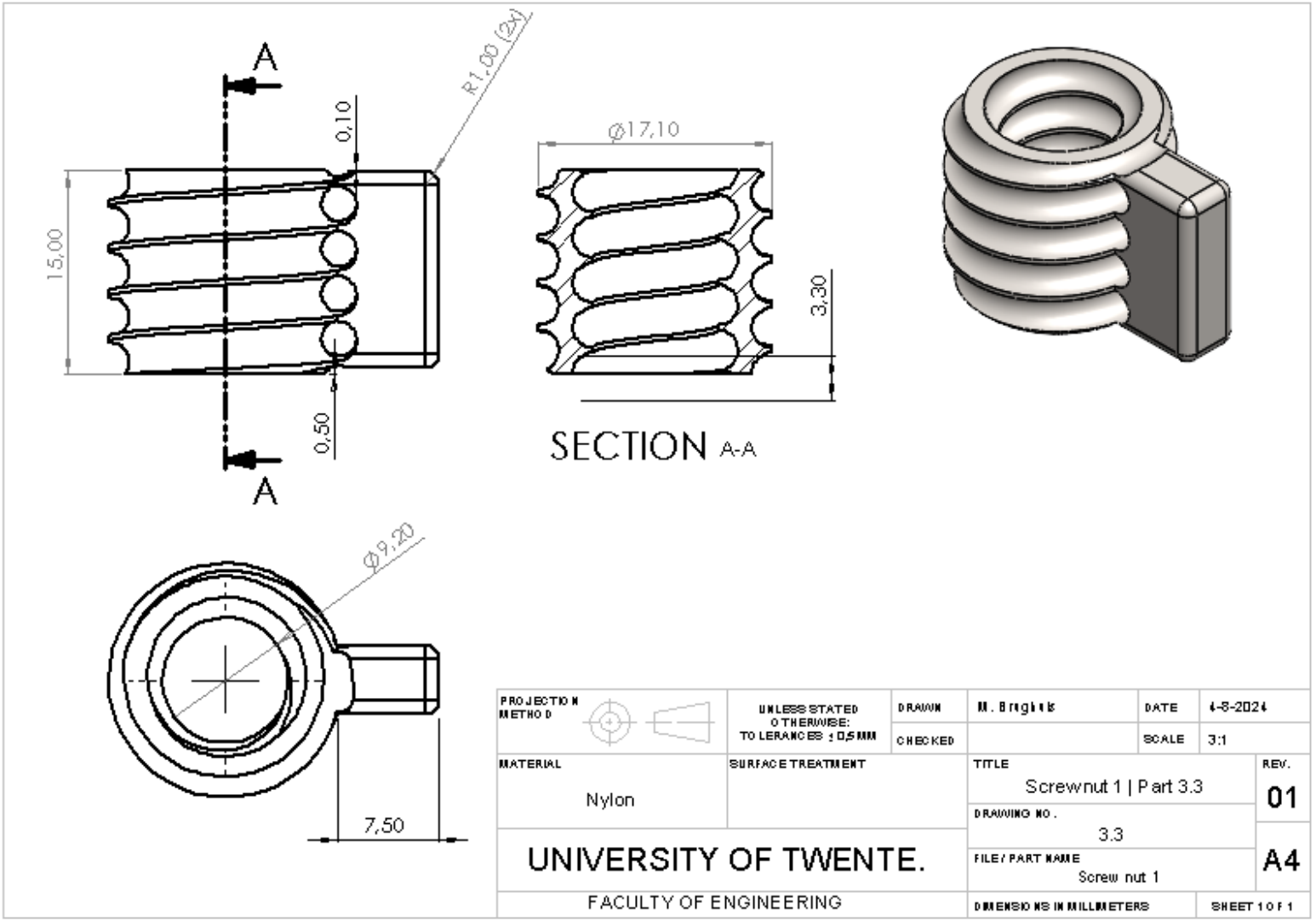
UNIVERSITY OF TWENTE.		DRAWING NO.: 3.2			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Lower tube		DIMENSIONS IN MILLIMETERS	SHEET 1 OF 1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SECTION A-A
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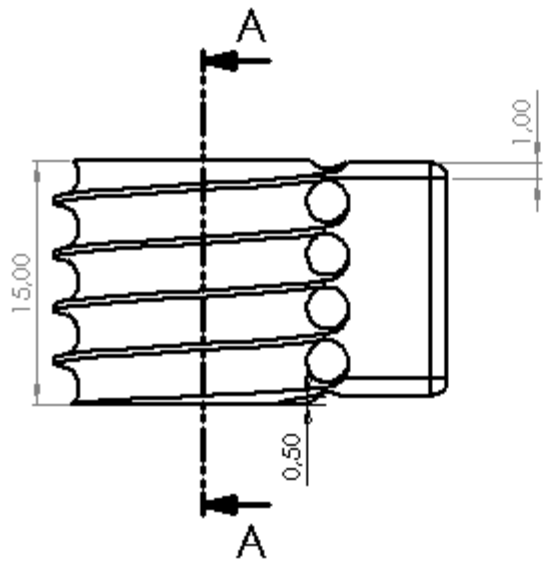
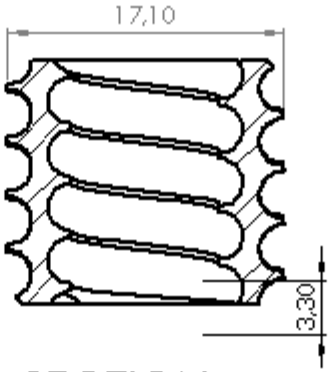
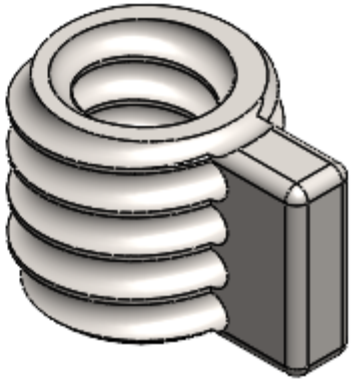
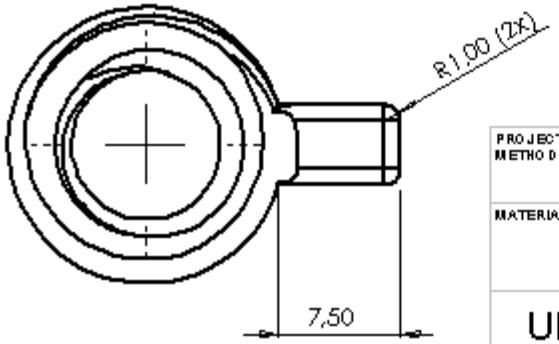
PROJECTION METHOD
UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM
DRAWN
M. Brighis
DATE
4-8-2024
CHECKED
SCALE
3:1
MATERIAL
Nylon
SURFACE TREATMENT
TITLE
Screwnut 1 | Part 3.3
REV.
01
DRAWING NO.
3.3
A4
UNIVERSITY OF TWENTE.
FILE / PART NAME
Screw nut 1
FACULTY OF ENGINEERING
DIMENSIONS IN MILLIMETERS
SHEET 1 OF 1





SECTION A-A





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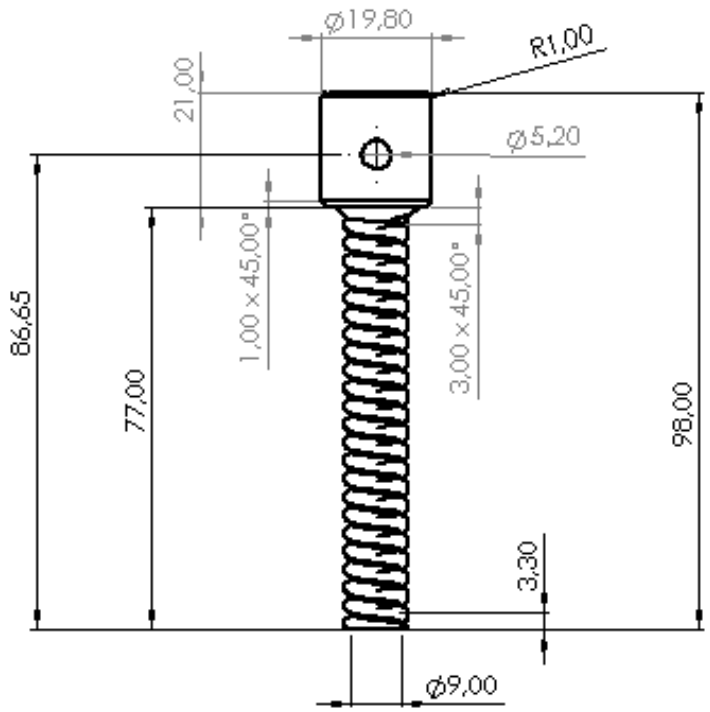
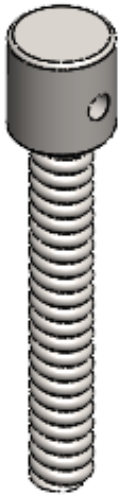
UNIVERSITY OF TWENTE.			DRAWING NO.: 3.4		A4
FACULTY OF ENGINEERING			FILE / PART NAME: Screw nut 2		
			DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1





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		CHECKED		SCALE	1:1
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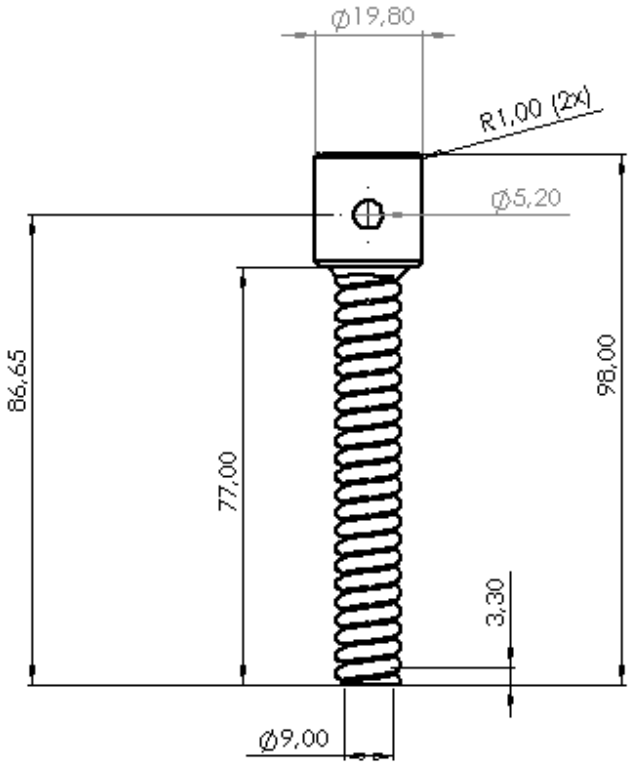
UNIVERSITY OF TWENTE.		DRAWING NO.: 3.5			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Rod 1			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	



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		CHECKED		SCALE	1:1
MATERIAL: Nylon	SURFACE TREATMENT	TITLE: Rod 2 | Part 3.6			REV.: 01
UNIVERSITY OF TWENTE.		DRAWING NO.: 3.6			A4
FACULTY OF ENGINEERING		FILE / PART NAME: Rod 2			
		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	

Chapter E

Subject Validation

E.1 Subject information

Subject information for participation in medical research

Verification of the usability of a redesigned ankle joint off-loading orthosis to aid cartilage regeneration

Official title: Een herontwerp van een enkelgewricht ontlastende orthese om de regeneratie van het kraakbeen te bevorderen.

Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a study to evaluate the usability and perceived comfort of the redesigned ankle joint off-loading ankle orthosis and confirm the level of precise off-loading. Participation is voluntary.

You can read about the study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, complete the form in Appendix A.

Ask your questions

You can take your decision based on the information in this information sheet. We also suggest that you do this:
- Put your questions to the investigator who gave you this information.
- Talk to your partner, family or friends about this study.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

1. General information

Gabriëlle Tuijthof has set up this study within the University of Twente and master's student Merel Brughuis will conduct this study. The research is being conducted at the University of Twente campus in the Horst complex on De Horst 2, 7522 LW Enschede, The Netherlands.

2. What is the purpose of the study?

Osteochondral lesions of the talus involve damage to the articular cartilage and the underlying subchondral bone of the talus. Depending on the size of the lesion, the treatment can be divided into conservative treatment or surgical intervention, both involving a period of off-loading the ankle. Partial weight-bearing is recommended immediately after surgery, reducing ankle stiffness, facilitating healing of articular cartilage, and minimizing muscle and bone atrophy, lowering the risk of complications, and contributing to an early return to activities. Current methods for achieving partial weight-bearing involve the use of crutches, splints, braces, and walking boots. Accurately assessing the level of off-loading of the ankle is challenging with these devices, which can cause a suboptimal off-loading regime. To this end, we developed an ankle joint off-loading ankle orthosis that allows precise off-loading of the ankle by the use of mechanical spring(s). A proof of concept has been demonstrated. Based on that, a redesign has been made for testing with human subjects. The redesign is shown in Figure 1. Part A will surround your leg, including extra padding on the inside. Part B is the mechanical spring covered so it will not hurt you in any way. The spring will cause the off-loading. Part C is in contact with the ground. The end has a larger footprint, so you won't be able to get stuck.

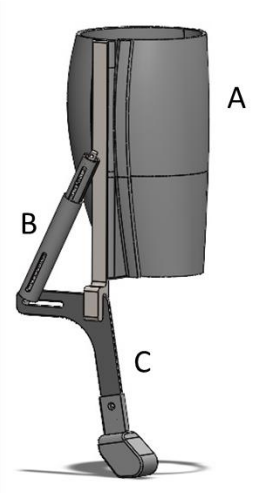


Figure 1: The redesigned ankle joint off-loading ankle orthosis.

The aim of this study is to evaluate the usability and perceived comfort of the redesigned ankle joint off-loading ankle orthosis and confirm the level of precise off-loading with twenty healthy subjects.

3. What happens during the study?

Are you taking part in the study? It will take about 45 minutes in total.

First, we want to know if you are eligible to take part. That is the reason that the investigator is doing some checks:

- Your age
- Functionality of the legs
- Known cartilage damage in the ankle
- History of lower extremity surgery or trauma

- Neurological or cardiac impairments
- Measuring the weight and the lower leg circumference at three points:
    1. Two finger widths below the patella
    2. Maximum calf circumference
    3. Four centimeters above the ankle joint

These questions and measurements will approximately take 5 minutes.

Please note: it is possible that you are not eligible for this study, even if you are healthy. The investigator will tell you more about this.

When all steps are completed and you meet all the inclusion and exclusion criteria, the experiment can start. The experiment consists of six steps:

- Step 1: You are asked to put the brace on without any instructions.
- Step 2: You are asked to fill out a NASA Task Load Index (NASA-TLX) questionnaire to assess the workload of this task.
- Step 3: You are asked to walk without the device on a track of 10 meters, involving a force plate in the middle to measure your normal walking pattern (Figure 2). You will walk 5 times up and down, with each time putting the same foot on the force plate. During stepping on the force plate, video recordings will be made anonymously by only filming the lower legs.
- Step 4: You are asked to walk with the device 3 times 5 minutes to measure your walking pattern while wearing the device, each time with another off-loading percentage set by the researcher. At 5 time point, you are asked to walk 5 times up and down over the track of 10 meters (Figure 2), with the force plate in the middle. The foot should be placed on the force plate. Between the measurements, you are free to walk somewhere else. During stepping on the force plate, video recordings will be made anonymously by only filming the lower legs.
- Step 5: You are asked to fill out a NASA-TLX questionnaire to assess the workload of this task.
- Step 6: You are asked to fill out a final questionnaire with specific questions regarding the device.

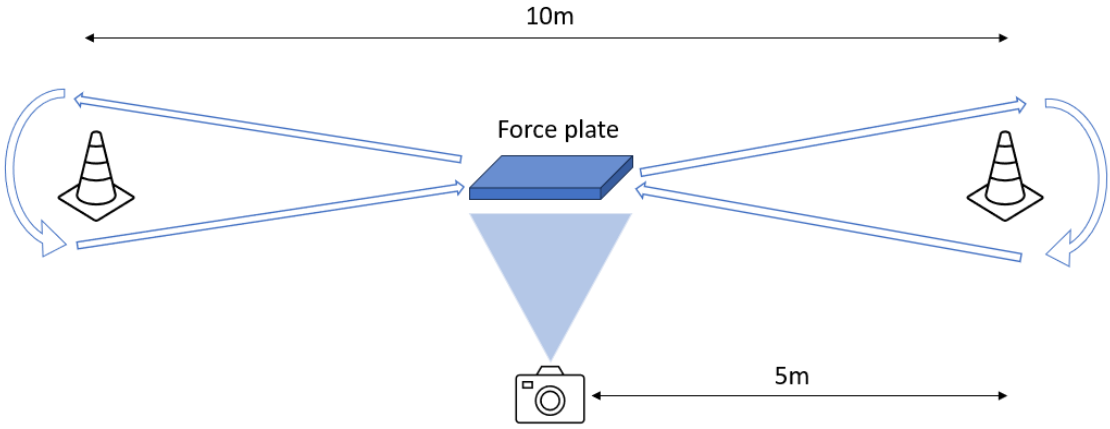


Figure 2: The track including a force plate and a camera in the middle. The arrows indicate the walking path.

The research is ended when all steps have been completed. The total experiment will not exceed 45 minutes. Participants will not receive any form of compensation for participating in this research.

4. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it. You do not benefit from taking part in this study. But if you take part you will help the investigators to get more insight into the comfort of the ankle joint off-loading ankle orthosis.

Taking part in the study can have these cons:

- Pressure point due to the ankle joint off-loading ankle orthosis. When pressure points arise, extra padding can be added.
- Breakage of the ankle joint off-loading ankle orthosis. Calculations show enough strength of the material. So, the risk of breakage is low. In the exceptional case that breakage occurs it is expected that either the connection between the shelf and the 'device's leg' is broken and the device will simply slide proximally along the leg or the joint of the 'device's leg' will break and will disconnect indicating that the foot will absorb all body weight again. This should be feasible as we are testing with healthy subjects that can withstand their body weight.
- Taking part in the study will cost you extra time.

You do not wish to participate in the study?
It is up to you to decide if you wish to participate in the study. You do not wish to participate? Then this has no consequences for you.

5. When does the study end?

The investigator will let you know if there is any new information about the study that is important to you. The investigator will then ask you if you want to continue to take part.

In these situations, the study will stop for you:

- All measurements and questionnaires according to the schedule are finished.
- You want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop.
- The investigator thinks it is better for you to stop.

What happens if you stop participating in the study?
The investigators use the data that have been collected up to the moment that you decide to stop participating in the study. If you wish, we will destroy the collected data. Please let the investigator know.

6. What happens after the study has ended?

After the research, the results are used to publish a scientific article. If you would like to read this article, please contact Gabriëlle Tuijthof at g.j.m.tuijthof@utwente.nl or +31 53 489 9322. The results are in no way be traced back to you as a person.

7. What will be done with your data?

Are you taking part in the study? Then you also give your consent to collect, use and store your data for 10 years. We store these data:

- Your age
- Your sex
- Your length and weight
- Lower leg circumference
- Force plate data
- Questionnaire data
- Video recordings of lower legs

We collect, use and store your data to answer the questions of this study and to be able to publish the results. To protect your privacy, we store your data online at a secure location at the University of Twente under a participant number. Only the researchers have access to this information. This means that no one can trace from the publications that you participated in this study. The informed consent forms will be securely stored on a PDrive of the University of Twente. Only UT members of the research group will be granted access to these forms.

Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl. Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is: Gabriëlle Tuijthof of the University of Twente (g.j.m.tuijthof@utwente.nl or +31 53 489 9322). You can also contact the Data Protection Officer of the University of Twente via dpo@utwente.nl .

8. Will you receive compensation if you participate in the study?

You will not receive any compensation if you participate in this study.

9. Do you have any questions?

Do you have any questions after reading this information letter? Then you can ask the researcher present. If you have any questions after the research, you can always send an email to Merel Brughuis via m.d.m.brughuis@student.utwente.nl.

10. How do you give consent for the study?

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, fill in the consent

form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

Appendix A: Informed consent form – subject

Belonging to “Verification of the usability of a redesigned ankle joint off-loading orthosis to aid cartilage regeneration”

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give consent to collect and use my data. The investigators only do this to answer the question of this study
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I want to take part in this study.

My name is (subject): ……..

Signature: …… Date : __/__/__

I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative): .....

Signature:…… Date: __/__/__

The study subject will receive a complete information sheet, together with a signed version of the consent form.

If you have any complaints about this research, please direct them to the Secretary of the Natural Sciences and Engineering Sciences Ethics Committee at the University of Twente, P.O. Box 217, 7500 AE Enschede (NL), telephone: +31 (0)53 489 5607; email: a.m.klijnstra@utwente.nl).

E.2 Protocol

Recruitment

1. Recruiting potential subjects by asking around, an announcement via social media and a flyer on the campus of the University of Twente.
2. The potential subjects will receive the information brochure and the informed consent.
3. The potential subjects have five days to consider their participation.
4. The potential subjects have five days to consider their participation.

Before the experiment

1. The potential subjects must sign an informed consent when agreeing to participate. The inclusion and exclusion criteria will be checked.
2. The researcher will measure the weight of the subject, the lower leg circumference at three different points: two fingers below the patella, maximum calf circumference, and four centimeters above the ankle joint and the height of the ankle joint.
3. The subject will fill out a pre-test survey on the looks of the device.

Setup experiment

1. Place two gray plates without holes on the floor. Place the gray plate with the two holes for the force plate between the gray plates without the holes.
2. Grab two force plates (Only the left one is working). The right force plate will only be used to cover up the hole in the plate.
3. Two squares are made with tape on the force plate, where the subject can place the foot. These are taped at the side of the force plate, so the lever end will be placed on the gray plate.
4. The coloured cable will be connected to the analog box and the force plate.
5. The black cable will be connected to the force plate and the power box. A power cable will be connected to this box as well, for power supply. A light will be switched on at the 'A' symbol.
6. Two tape crosses are placed on the ground with the force plate in the middle, separated by 10 metres.
7. The Qualisys Track Manager system can be opened.
8. Settings Qualisys:
    - Input devices - select 'USB-2533 (serial: 393580)
    - Analog board channels - Select 57 t/m 64
    - Force Data - select force plate 'New-AMTI-Left'
    - Select channels New-L1 t/m New-L8
    - Switch on the camera's
    - Click on capture to add the camera's to the screen.
    - Acquire offset values.

9. Placing weight of 10 kg, 30 kg and 50 kg on the force plate to use as reference.

During the experiment

1. The subject will put the redesigned ankle joint off-loading ankle orthosis on without any instructions.
2. The subject is asked to fill out a NASA Task Load Index (NASA-TLX) questionnaire to assess the workload of this task.
3. Position the camera so the lower extremities of the subject are filmed anonymously while stepping on the force plate. Start the camera at the beginning of each measurement (each step separate) and save the video using the participant's number.
4. Measurement test 1: without the redesigned ankle joint offloading ankle orthosis
   - The subject will walk 10 times over the force plate to measure the subject's normal gait.
   - The subject puts the right foot on the force place each time
   - The data will be averaged over the 10 measurements
5. Measurement test 2: with the redesigned ankle joint offloading angle orthosis.
   - The subject will put the brace on following the instructions
   - The researcher will check the position and tightness of the brace
   - The patient will walk for 5 minutes with the brace using 25% offloading to measure the subject's gait while wearing the device
   - The foot with the device should be placed on the force plate, the lever end should be placed next to the force plate. On one side of the track the subject will turn to the right and on the other side of the track the subject will turn to the left (Figure E.1).
   - The test will be repeated with 50% offloading. The subject is asked to change the stiffness.
   - The data of each step will be averaged and can be compared between the different subjects and offloading percentages.
6. The subject is asked to fill out a NASA-TLX questionnaire to assess the workload of this task
7. The subject is asked to fill out a final questionnaire with specific questions regarding the device.

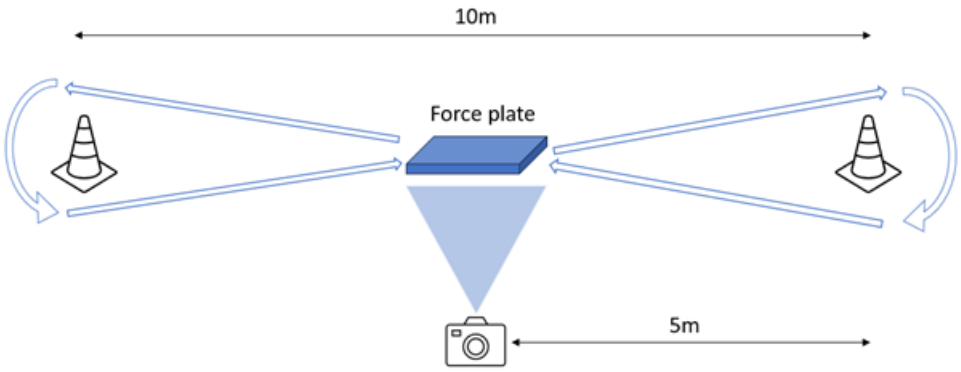


Figure E.1: Caption

Analyzing data

1. Export data to a MAT file
2. Load the Fy data in the Matlab file (Appendix G).

E.3 Inclusion and exclusion criteria

Inclusion criteria

1. Age between 18-60 years
2. Two fully functional legs

Exclusion criteria

1. Weight above 90 kg or below 60 kg
2. Calf circumference bigger than 41 mm
3. Cartilage damage in the ankle
4. History of lower extremity surgery or trauma.
5. Neurological impairments
6. Cardiac impairments

E.4 Checklist subjects

Table E.1: Checklist used before starting the subject tests.

Participant number:	
Age:	
Length	
Weight	
Gender	
Two not functional legs	Yes / No
Known cartilage damage	Yes / No
History of lower extremity surgery or trauma	Yes / No
Neurological impairments	Yes / No
Cardiac impairments	Yes / No
Lower leg circumference: Two fingers below patella Maximum calf circumference Four centimeters above the ankle joint	
Height of ankle joint	

E.5 Pre-test questionnaire

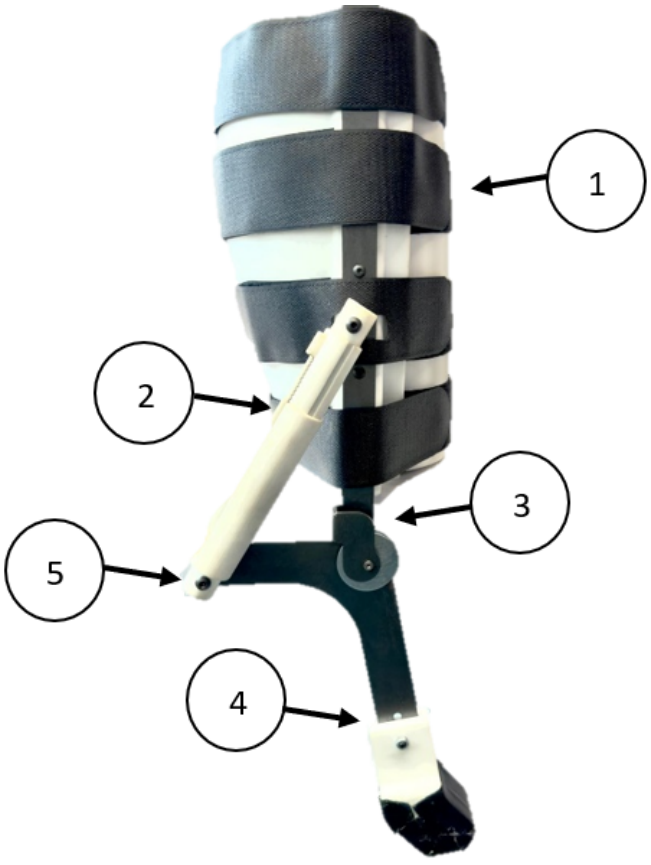
Question 1: On which side of the body should the device be used? (Tick your answer)
☐ Right
☐ Left
☐ Both

Question 2: How would the device fit to one of your lower extremity?
☐ Slide from the back side
☐ Slide from the front side
☐ Slide in as a regular shoe

Question 3: Would you, based on the looks of the design and if necessary, be able to walk with the device all day? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
No										Yes

Question 4: How could you adjust the device so that it fits your height and weight?



E.6 NASA-TLX questionnaire

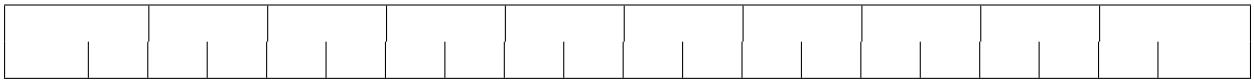
Mental demand

How much mental and perceptual activity was required (e.g. thinking, deciding, looking etc.)?

Low High

Physical demand

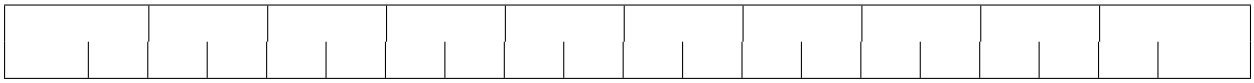
How much physical activity was required (e.g. pushing, pulling, turning, controlling etc.)?



Low High

Temporal demand

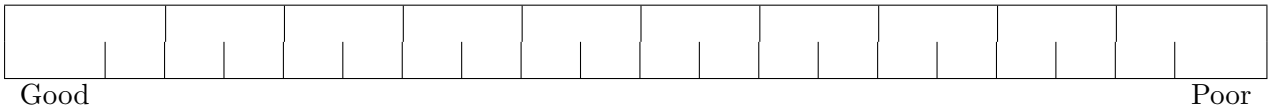
How much time pressure did you feel due to the rate of pace at which the tasks occurred?



Low High

Performanace

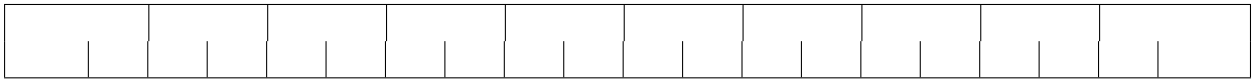
How successful do you think you were in accomplishing the goals of the tasks set by the researcher?



Good Poor

Effort

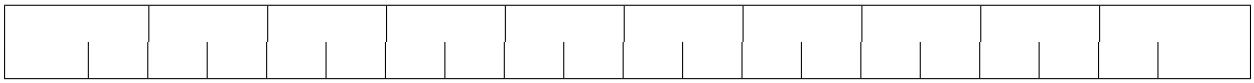
How hard did you have to work to accomplish your level of performance?



Low High

Frustration

How insecure, discouraged, irritated, stressed and annoyed versus secure, gratified, content, relaxed and complacent did you feel during the task?



Low High

E.7 Device questionnaire

Question 1: How comfortable is the weight of the device (Tick your answer)
☐ Too light
☐ Good
☐ Too heavy

Question 2: How comfortable is the weight distribution of the device around the lower leg? (Tick your answer)
☐ Moving upwards
☐ Good
☐ Moving downwards

Question 3: How comfortable is the weight distribution of the device around the lower leg? (Tick your answer)
☐ No
☐ Yes, but acceptable (Mark the pressure point in the figure below)
☐ Yes, it hurts (Mark the pressure points in the figure below)

Question 4: How comfortable is wearing the device around your leg? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Uncomfortable										Comfortable

Question 5: How comfortable is walking with the device? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Uncomfortable										Comfortable

Question 6: How medically professional does the device look? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Unprofessional										Professional

Question 7: Would you trust this device? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Unreliable										Reliable

Question 8: Is the device easy to use? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Not easy										Easy

Question 9: Is the off-loading easy to change? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Not easy										Easy

Question 10: Does the device get in the way of daily activities e.g. walking? (Circle your answer)

0	1	2	3	4	5	6	7	8	9	10
Not easy										Easy

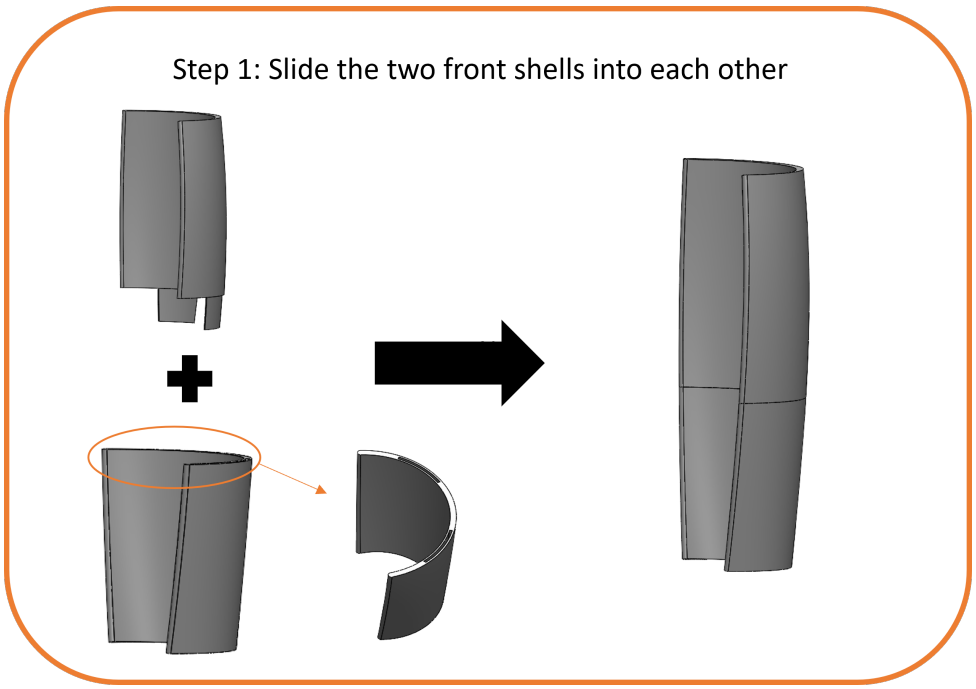
Question 11: How did the offloading of your ankle feel during the experiment? Did you feel a lot of force on your lower leg when offloaded and did you feel any difference between the offloading percentages?

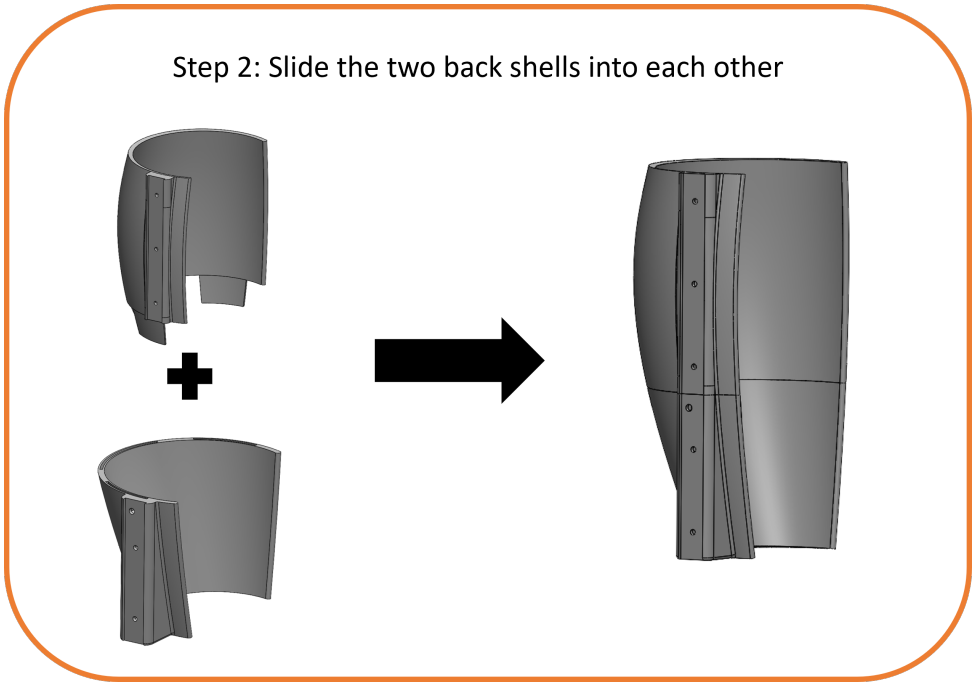
Question 12: Do you have any comments or improvements?

Chapter F

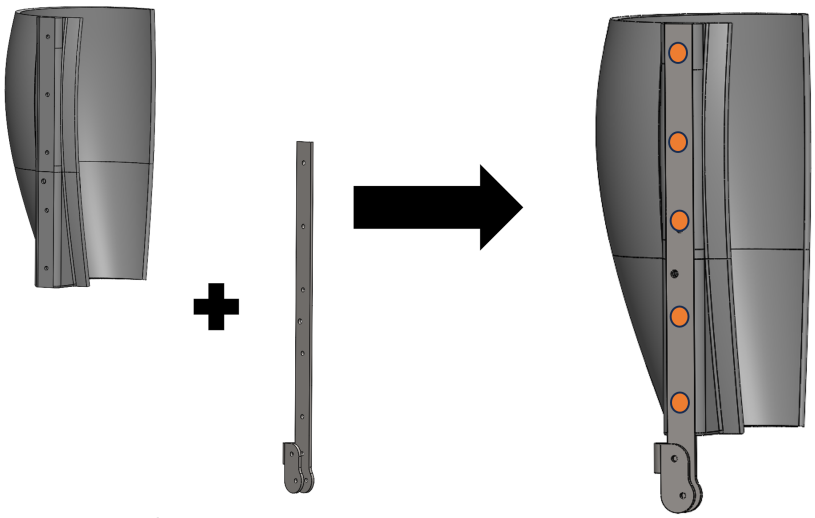
Manual

F.1 Assembly manual



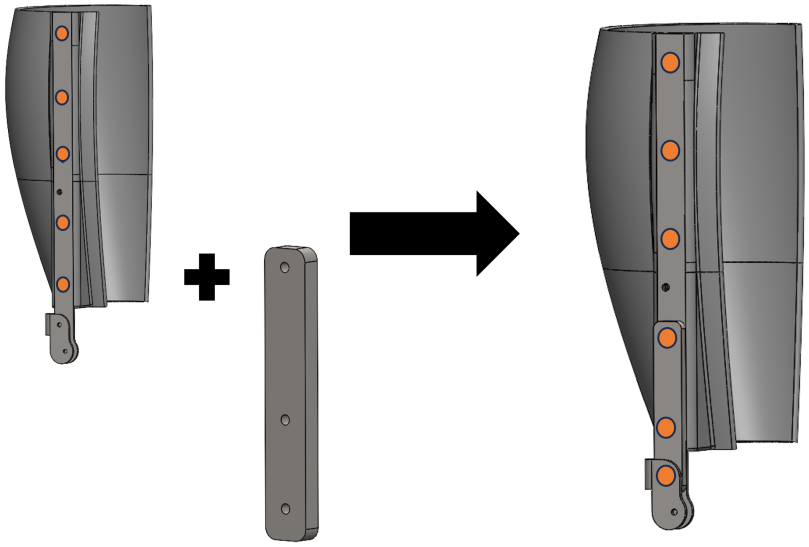


Step 3: Connect the frame to the back shell using five M4 screws

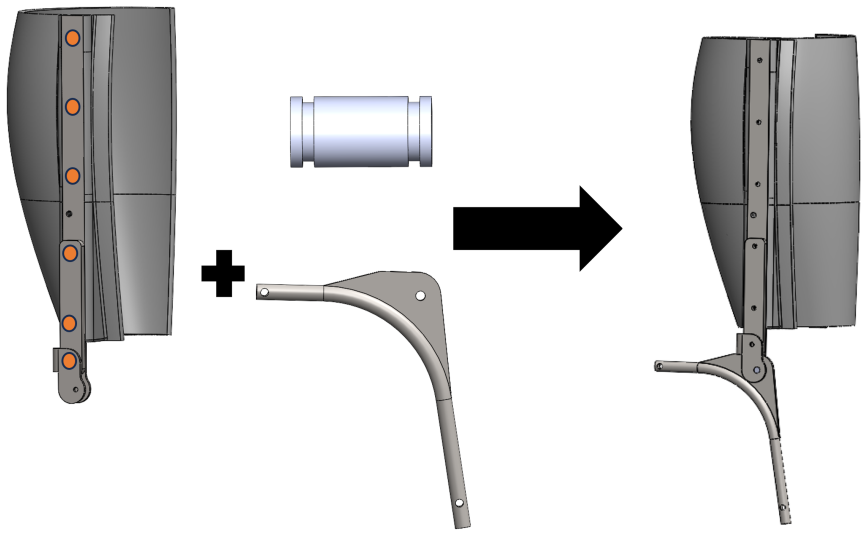


* Orange dots indicate screw placement

Step 4: Add the extra metal plate with one extra M4 screw

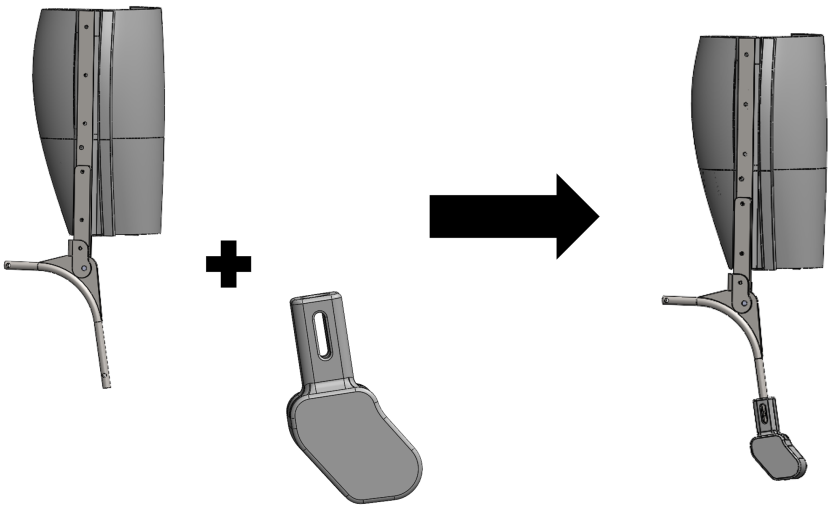


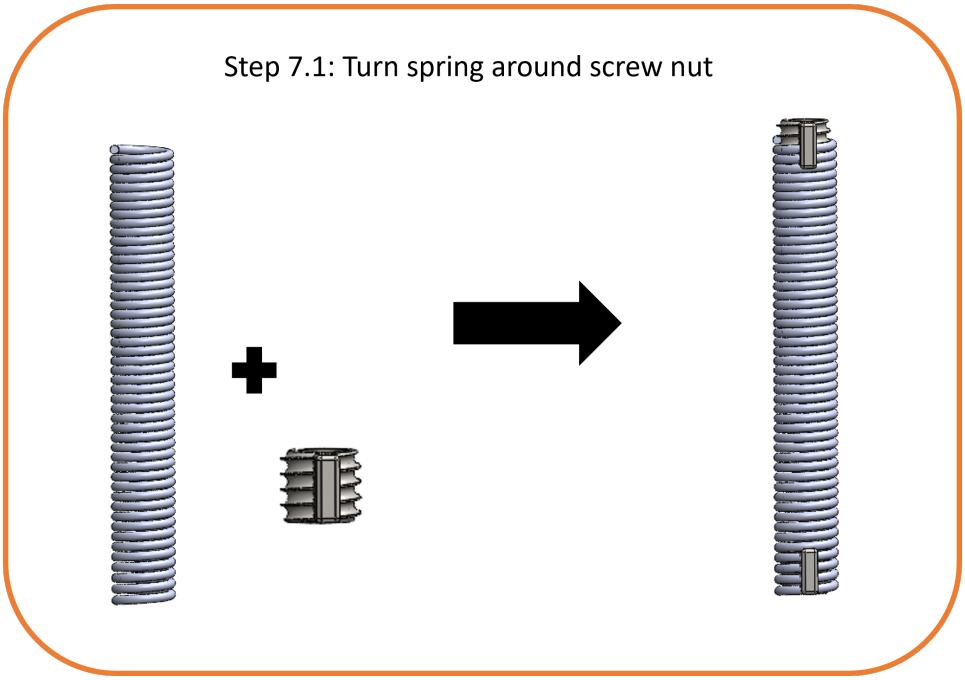
Step 5: Add the lever using a pin and five washers

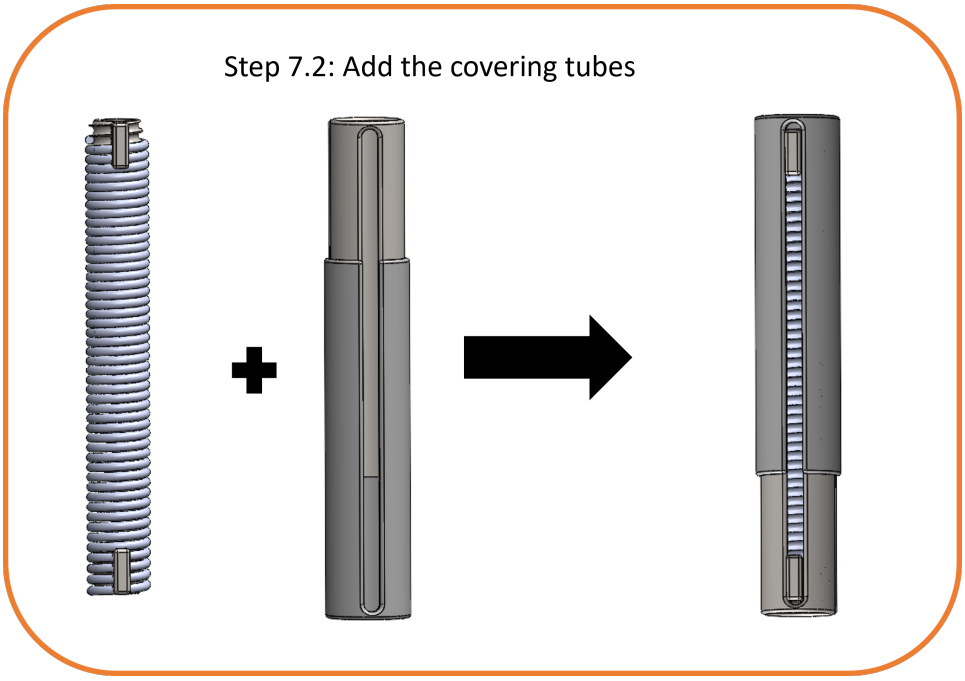


* Fixate using two circlips

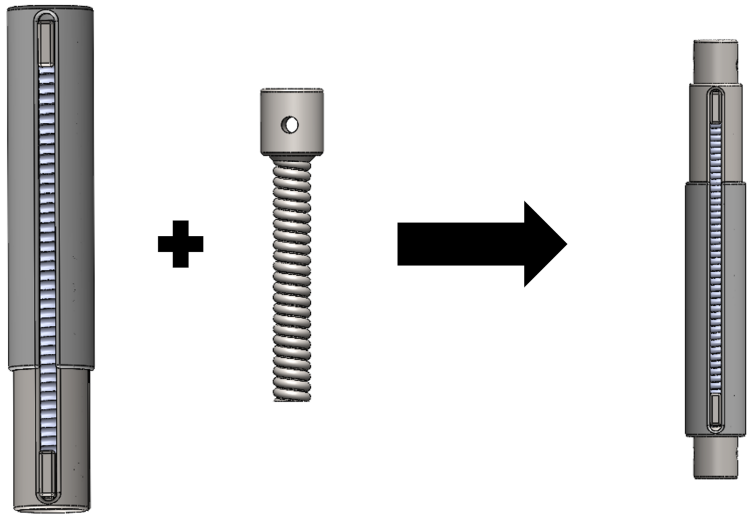
Step 6: Connect the GroundContact using M5 scew and M5 nut



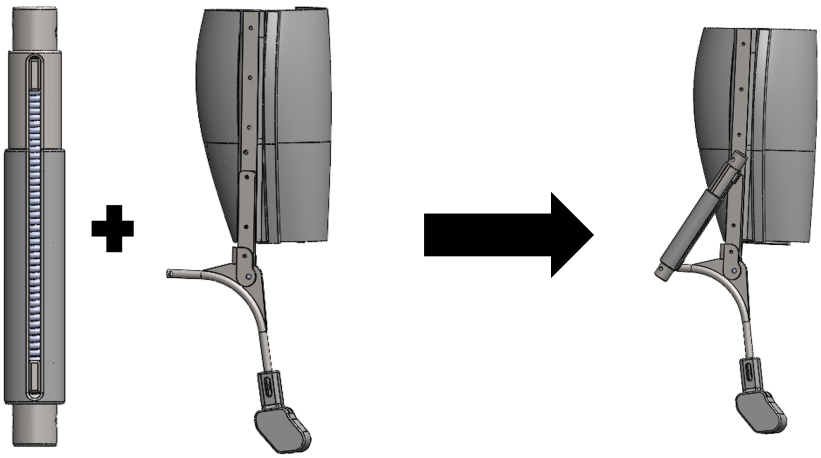

Step 7.1: Turn spring around screw nut


Step 7.2: Add the covering tubes

Step 7.3: Turn the rod parts in the screw nuts



Step 7.4: Add spring mechanism using two M5 screws




Step 8: Add padding, Velcro Bands and Rubber

F.2 User manual

F.2.1 Application

Step 1: Loosen the 4 Velcro bands

Step 2: Remove the front shell from the brace

Step 3: Slide your leg in from the front

* The frame should be on the outer side of your leg

Step 4: Add the front shell to the brace again

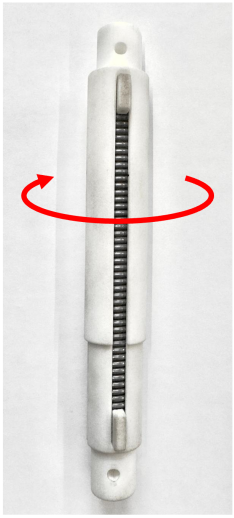
*The front shell should slide within the back shell

Step 5: Compress your lower leg by tighten the Velcro bands

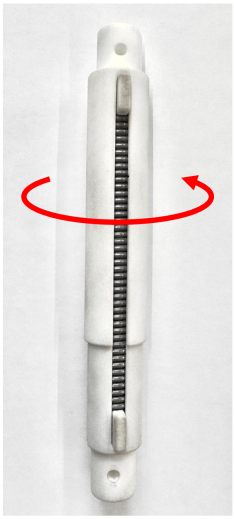
* If it is too loose, extra padding can be added

F.2.2 Adjustment

Step 1: Increase stiffness

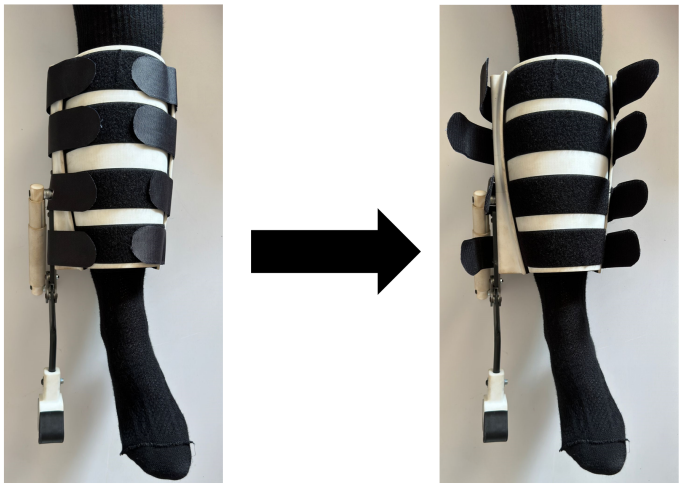


Step 2: Reduce stiffness



F.2.3 Removal

Step 1: The Velcro bands can be loosened



Step 2: The front shell can be removed

Step 3: Your leg can be removed

Chapter G

Matlab

This Matlab code is used for each subject and each offloading percentage.

```
clear all; clc

%% Subject 1 0% offloading
%Bodyweight
BW1 = 78;

%Data of the correct steps
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step2.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step3.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step4.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step5.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step6.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step8.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step9.mat")
load("Subject 2\0%Offloading\Subject2_0%Offloading_Step10.mat")

grf_z1_0_2 = Subject2_0_Offloading_Step2.Force.Force(3,:);
grf_z1_0_3 = Subject2_0_Offloading_Step3.Force.Force(3,:);
grf_z1_0_4 = Subject2_0_Offloading_Step4.Force.Force(3,:);
grf_z1_0_5 = Subject2_0_Offloading_Step5.Force.Force(3,:);
grf_z1_0_6 = Subject2_0_Offloading_Step6.Force.Force(3,:);
grf_z1_0_8 = Subject2_0_Offloading_Step8.Force.Force(3,:);
grf_z1_0_9 = Subject2_0_Offloading_Step9.Force.Force(3,:);
grf_z1_0_10 = Subject2_0_Offloading_Step10.Force.Force(3,:);

%Add all steps together
grf_z1_0 = [grf_z1_0_2, grf_z1_0_3,grf_z1_0_4, grf_z1_0_5, grf_z1_0_6
   , grf_z1_0_8, grf_z1_0_9, grf_z1_0_10];

% Plot the steps
figure
plot(grf_z1_0)

%Find the toe offs and heelstrike of each step
toe_offs_z1_0 = [];
heel_strike_z1_0 = [];

for i = 1:length(grf_z1_0)
    if i == length(grf_z1_0)
        break
    end

```

```
    if grf_z1_0(i) < 46 && grf_z1_0(i+1) > 46
        heel_strike_z1_0(end+1) = i + 1;
    end

    if grf_z1_0(i) > 46 && grf_z1_0(i+1) < 46
        toe_offs_z1_0(end+1) = i;
    end
end

figure
plot(grf_z1_0)
hold on
plot(heel_strike_z1_0, grf_z1_0(heel_strike_z1_0), 'ro', 'MarkerSize', 8, 'MarkerFaceColor','r')
plot(toe_offs_z1_0, grf_z1_0(toe_offs_z1_0), 'go', 'MarkerSize', 8, 'MarkerFaceColor','g')

%Normalized GRF
normalized_grf_z1_0 = [];
for k = 1:length(heel_strike_z1_0)
    data_len = linspace(0, 99, length(grf_z1_0(heel_strike_z1_0(k):toe_offs_z1_0(k))));
    new_len = 0:99;
    grf_z1_0_normalized = spline(data_len, grf_z1_0(heel_strike_z1_0(k):toe_offs_z1_0(k)), new_len);
    normalized_grf_z1_0(:,k) = grf_z1_0_normalized/(BW1*10);
end

figure
plot(normalized_grf_z1_0)

%Mean and std
normalized_grf_z1_0_mean = mean(normalized_grf_z1_0,2);
normalized_grf_z1_0_std = std(normalized_grf_z1_0,[],2);
```

After receiving all data for each subject and measurement, the mean of each condition (0%,25% and 50%) is calculated.

```
%% Plot met gemiddeldes per conditie
% 0 % offloading
Offloading_0_tot = mean([normalized_grf_z1_0_mean, normalized_grf_z2_0_mean, normalized_grf_z3_0_mean],2);
Offloading_0_std = std([normalized_grf_z1_0_mean, normalized_grf_z2_0_mean, normalized_grf_z3_0_mean],[],2);

% 25% offloading
Offloading_25_tot = mean([normalized_grf_z1_25_mean, normalized_grf_z2_25_mean, normalized_grf_z3_25_mean],2);
Offloading_25_std = std([normalized_grf_z1_25_mean, normalized_grf_z2_25_mean, normalized_grf_z3_25_mean],[],2);

% 50% offloading (slecht 1 meting)
```

```
Offloading_50_tot = mean(normalized_grf_z1_50,2);
Offloading_50_std = std(normalized_grf_z1_50,[],2);

figure
plot(Offloading_0_tot,'r')
hold on
fill([1:length(Offloading_0_tot), fliplr(1:length(Offloading_0_tot))
   ],[Offloading_0_tot+Offloading_0_std;flipud(Offloading_0_tot-
   Offloading_0_std)],'r','FaceAlpha',0.2, 'EdgeColor','none')
hold on
plot(Offloading_25_tot, "b")
hold on
fill([1:length(Offloading_25_tot), fliplr(1:length(Offloading_25_tot)
   )],[Offloading_25_tot+Offloading_25_std;flipud(Offloading_25_tot-
   Offloading_25_std)],'b','FaceAlpha',0.2, 'EdgeColor','none')
hold on
plot(Offloading_50_tot, "g")
hold on
fill([1:length(Offloading_50_tot), fliplr(1:length(Offloading_50_tot)
   )],[Offloading_50_tot+Offloading_50_std;flipud(Offloading_50_tot-
   Offloading_50_std)],'g','FaceAlpha',0.2, 'EdgeColor','none')

legend({'0% offloading', "" ,"25% offloading","", "50% offloading",
   ""}, 'Location', 'southoutside', ...
   'NumColumns', 3 )
title("The vertical ground reaction forces during the gait cycle with
    0%, 25% and 50% offloading ")
ylabel('Vertical GRF (BW)')
xlabel('Stance (%))')
```