Graduation Report

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Developing a Load Cycle Test Setup to Evaluate the Durability of Ankle-Foot Orthoses

Master Thesis
Integrated Product Design
Delft University of Technology

TU Delft

- **Sep v.d. Stoep**
- For a Confidential Client

MASTER THESIS
'Developing a Load Cycle Test Setup to Evaluate the Durability of Ankle-Foot Orthoses'

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Preface

This graduation report was written by Sep Abel van der Stoep, MSc Integrated Product Design student at the Delft University of Technology. For a confidential client company, a test setup was designed to load cycle test 3D-printed ankle-foot orthoses (AFOs) to guarantee they can withstand 2 million steps (equivalent to two years of care). A proof-of-concept built was realized and tested to come to the final deliverable of this project: a digital redesign in CAD. This redesign is going to be built by the client company.

While writing this report it is assumed the reader has basic knowledge of industrial design and mechanical engineering. A glossary has been added to the report to assure correct understanding of terms.

During this project, I enjoyed learning a lot about project management, taking a thorough scientific approach, and I had the opportunity to further develop my design hard skills, including sketching, mechanical engineering, CAD, and prototyping.

I would like to thank my TU Delft supervisors Dr. Ir. A.J. Jansen & Ir. F.P. Wilbers for their mechanical engineering expertise, advice on the research & development of the test setup and their supervision during the writing process. I am also thankful for the hands-on design guidance from my company supervisors, fully including me in the R&D team of the company, going on a trip with me to Germany to visit AFO testing expert D. Hochmann, and helping me to come to a tangible end-result of the project.

Delft, March 2025
Sep van der Stoep

Summary

Context
This graduation project is for an organisation that operates in the field of orthopaedic appliances, specialised in personalised hand braces on the basis of 3D-scans. They are now looking into developing personalized ankle-foot orthoses (AFOs), with the use of 3D-printing, see Figure 1.

Initial Problem Definition
However, it is unknown if (partly) 3D-printed AFOs can provide 2 years of care without breaking or significantly losing performance. To address this question, it is necessary to define the target population for these AFOs and establish what activities are viewed as 'normal usage'. In short, AFOs can be required by individuals of all types; however, a distinction is made between an adult category and a children's category due to differences in size and weight. Activities that are viewed as normal usage are: sitting, standing, walking, running, jumping, playing, sports, swimming, climbing stairs, and hiking. From a mechanical engineering point of view these 'normal activities' are translated into static loading (standing), impact (jumping) and load cycling (walking).

Redefined Design Brief
While static loading and impact testing should be performed as well, the chosen focus for this project was testing cyclic loading of the AFO equivalent to 2 years of walking (2 million steps). Developing an affordable version of this type of test setup was chosen because of the following 4 reasons: 1. Affordable stiffness (static loading) test machines are available in the industry. 2. Impact can be evaluated by trial and error product development. 3. The only applicable and available load cycle test setup for AFOs is too expensive (price tag ~€70K). 4. Cyclic loading is the largest reason for (3D-printed) AFOs to fail, as high cycle material fatigue occurs at relatively low stress levels, and cyclic loading testing requires specialized expensive testing equipment and a significant amount of time.

The Realized Test Setup
A proof-of-concept test setup was built. The design, see Figure 2, consists of a dummy lower leg on the end of a linear actuator on which the AFO is strapped, and a platform on which the dummy leg lands. The platform is called the Static Ground Surface (SGS) (see Figure 2) and can be angled to test the 3 most characteristic phases of walking separately: heel, ankle and ***forefoot rocker***. An important question was what the actual load on the AFO should be. This was determined by matching the bending of the AFO in the test setup to the bending of the AFO during normal ***gait***. Displacement was measured with video analysis. Cycle tests were performed to see if the three ***rockers*** could be recreated with this build: Only the ***forefoot rocker*** can be simulated considerably well with the test setup. For the ***heel rocker*** it was found that a dummy foot with ***ankle joint*** is necessary to be able to create the required plantar flexion. For the ***ankle rocker*** the SGS platform needs to rotate. A longer trial run was also conducted to evaluate the reliability of the test setup: next minor necessary engineering improvements (nuts coming loose and the setup moving due to vibration) it was found that a shoe is necessary to keep the AFO properly fixated in the test setup. A full length dummy foot with a forefoot (Meta Phalangeal (***MTP***)) joint is required to allow testing with a shoe. The realized test setup was assessed on Desirability, Feasibility, and Viability against the requirements and the lessons were integrated in redesign.

Figure 1. 3D-printed AFO of a competitor (OTWorld, n.d.).

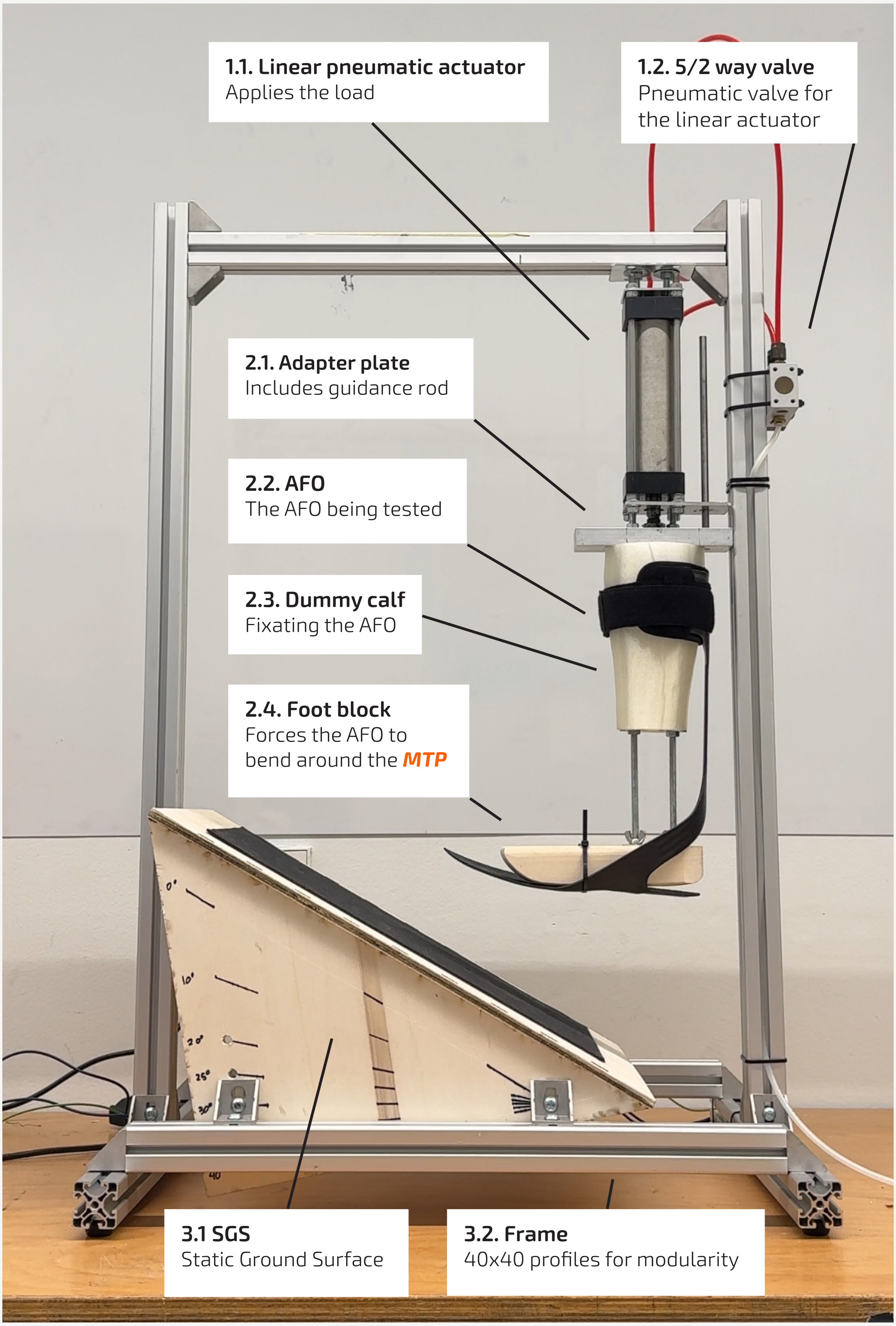

Figure 2. The realized proof-of-concept test setup build.

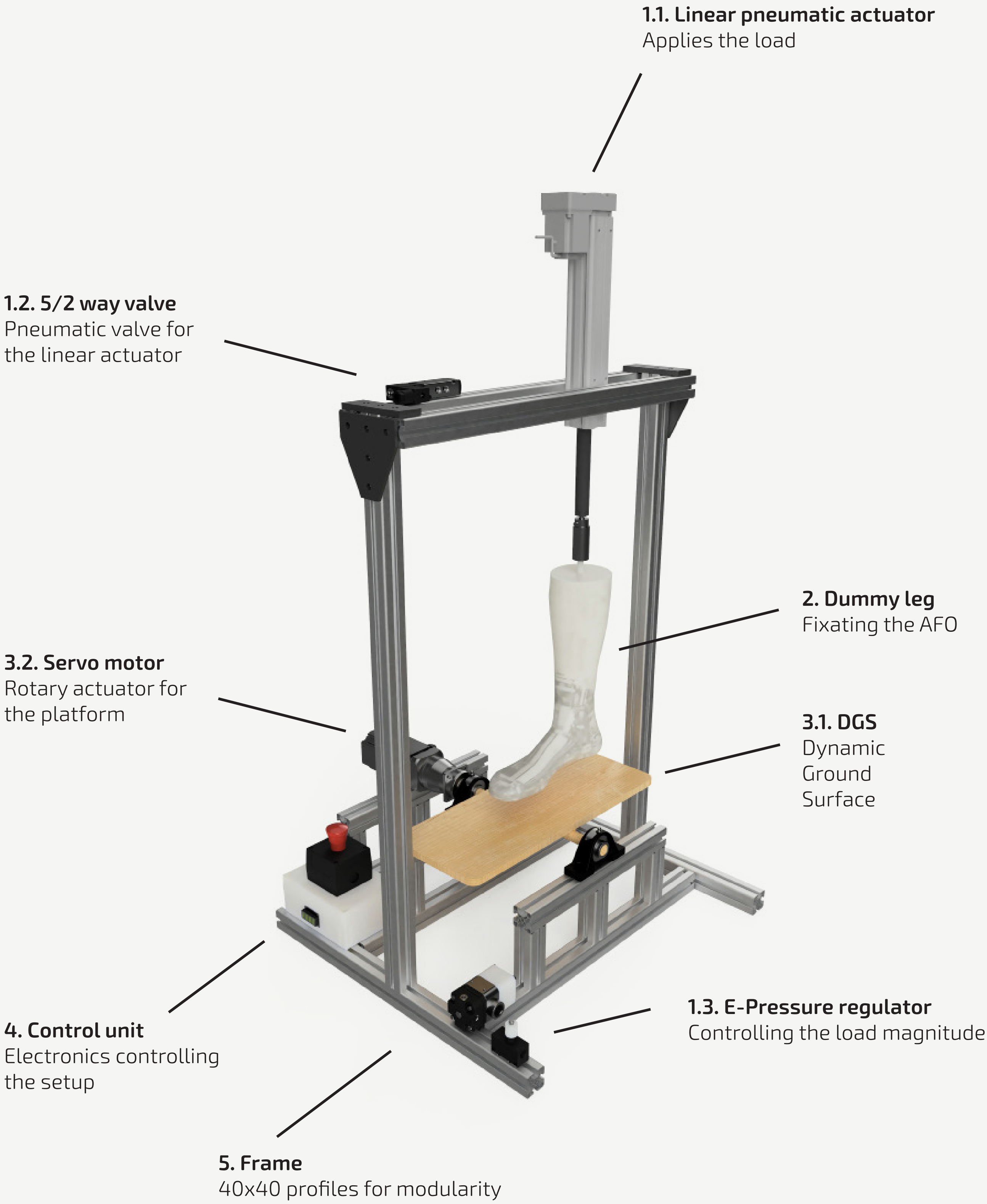

Figure 3. Annotation of the design, highlighting the key components.

The Redesign
A digital redesign of the AFO load cycle test setup was made in CAD. The redesign, see Figure 3, has a ***Dynamic Ground Surface*** (***DGS***) that rotates during a cycle. With this redesign the ***ankle rocker*** phase of ***gait*** can be tested and the 3 ***rockers*** can be linked together to recreate a full representative step in one cycle. The linear actuator and the ***DGS*** combined can simulate the complex movement pattern of the stance phase of a step: the linear actuator replicates the up and down movement and the platform replicates the angle orientation of the lower leg respectively to the ground.

Although time constraints in the project prevented the realization of the rotating platform, the dummy foot with ***ankle*** and ***MTP*** joint was achieved by adapting a prosthetic foot. The foot blade of the prosthetic was modified to allow bending around the ***MTP***. Video analysis indicated that with this design, the ***heel rocker*** can now be simulated as well, and it is predicted that it will also permit testing for the ***ankle rocker*** if a rotating platform (***DGS***) is included. The new foot also demonstrated promising results in maintaining the AFO and shoe in place.

The redesign was again assessed on the basis of Desirability, Feasibility, and Viability. It meets all requirements except the reliability requirements, which can only be proven by physically building and testing the redesign.

Going Forward
After this project, building the ***DGS*** is the next step for the company to finalize a proof-of-concept that can accurately fully simulate a step. This proof-of-concept build could then be used to test and optimize the design with. Leading to a final build that can do multiple test runs of 2 million cycles. If the last is realized, AFO designs can be tested on cyclic loading due to walking to guarantee they can provide two years of care.

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Glossary

All glossary terms in the report are highlighted in bold and italic, as such: ***term***.

Ankle joint
The most important joints relevant to durability testing are the ankle joint and the Metatarsophalangeal (MTP) joints, see Figure 4. The ankle joint actually consists of two joints: Art. talocruralis and Art. subtalaris. The combination of the two allows flexing the ankle and twisting it. During this project the ankle is simplified to one joint.

Anterior (Ventral)
Refers to the front side of the human body. For example, the tibia (shin-bone) is located on the anterior side.

Calf cuff
The upper section of the AFO, positioned around the calf (term used exclusively in this report).

Certified Prosthetist/Orthotist (CPO)
Delivering the product to the client, verifying the fit, and making minor adjustments.

Dorsiflexion
The movement of the foot upwards toward the shin, decreasing the angle between the dorsum (top) of the foot and the lower leg. This motion occurs at the ankle joint and is essential for walking, running, and maintaining balance.

Dynamic Ground Surface (DGS)
The name given to the platform of the redesigned load cycle test setup resembling, the ground on which the dummy leg lands. This platform has an actuator which changes the angle during the load cycle, making it dynamic. This way the 3 most characteristic phases of walking can be tested in one cycle resembling a full realistic step.

Elongation-at-break
The percentage increase in length a material undergoes before it fractures under tensile stress. It is a measure of a material's ductility and flexibility, indicating how much it can stretch before failure.

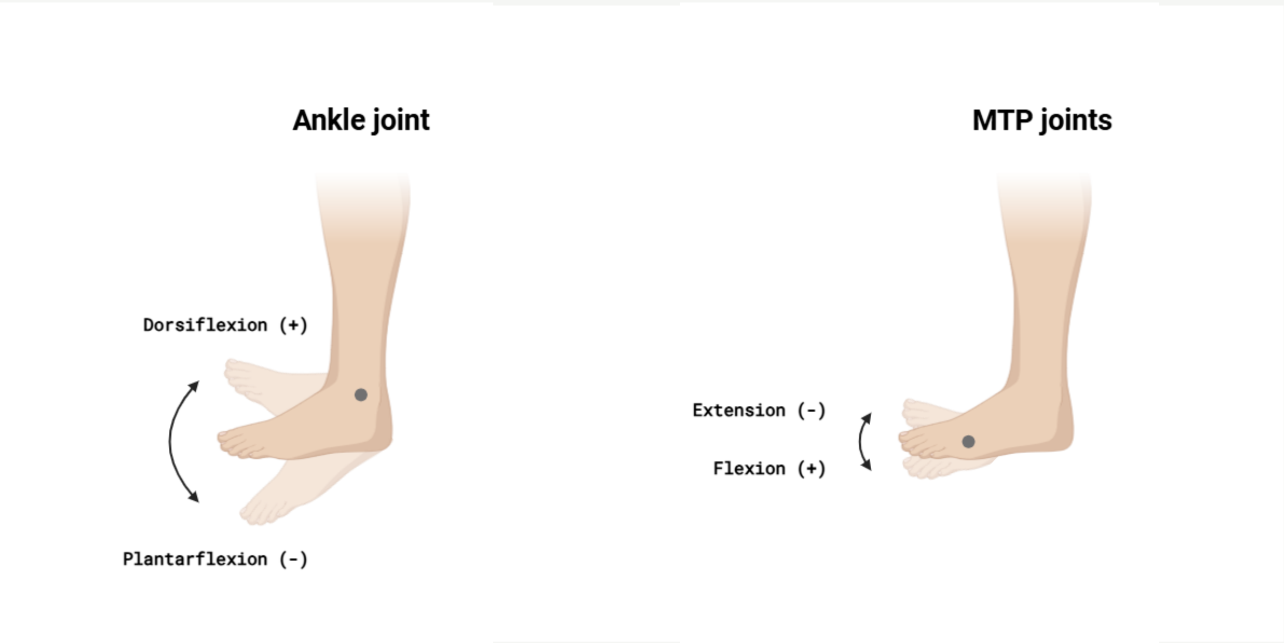


Figure 4. The ***ankle joint*** (***dorsiflexion***/***plantarflexion***) and the ***metatarsophalangeal*** (***MTP***) joints (extension/flexion). Figure created with BioRender.com.

Footplate
The lower section of the AFO that lays under the foot (term used exclusively in this report).

Gait
The coordinated movement pattern of the lower limbs and body during walking, allowing for balance and forward motion. See chapter 4.1. Gait Analysis.

Metatarsophalangeal (MTP) joints
The ***MTP joints*** consist of the joints between the Phalange (the toes) and the Metatarsal bones. It is the joint that allows the bending of the toes, see Figure 4.

Plantarflexion
The movement of the foot downward away from the shin, increasing the angle between the foot and the lower leg. This action enables activities such as pushing off the ground while walking or standing on tiptoes.

Posterior (Dorsal)
Refers to the back side of the human body. For example, the calf muscles are located on the posterior side.

Range Of Motion (ROM)
The range of motion of a joint, meaning the range of angles that are reached in the joint.

Rockers
The three rocking motions of the foot during the contact phase of a step: 1. Heel Rocker. 2. Ankle Rocker. 3. Forefoot Rocker. See chapter 4.1. Gait Analysis for an full explanation.

Sagittal plane
The human body is divided into three planes, as can be seen in Figure 5: the Coronal plane (front plane), the Sagittal plane (side plane), and the Axial plane (mid plane). The Sagittal plane will be mainly used to view the motion and loadings of the leg and AFO.

Static Ground Surface (SGS)
The name given to the platform of the realized load cycle test setup, resembling the ground on which the dummy leg with AFO lands. It can be angled statically to test the 3 most characteristic phases of walking separately.

Strut
The vertical piece of an AFO that connects the foot plate and calf strap.

Tibia
The shin bone.

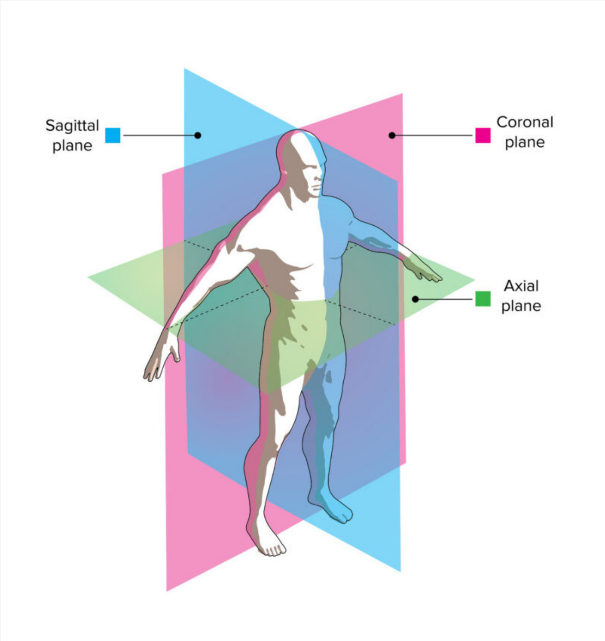


Figure 5. The planes of the human body (Lecturio, n.d.).

1. Introduction

The context
This graduation project is for an organisation that operates in the field of orthopaedic appliances. They currently specialise in personalised hand splints and braces on the basis of 3D-scans. The splints and braces provide support for patients with conditions like osteoarthritis, hypermobility, Ehlers-Danlos syndrome, and reumatoïde arthritis. Personalised fit splints and braces provide more support and more comfort than traditional braces.

The company is now looking at expanding beyond hand braces to also develop 3D-scan based ankle braces, known as ankle-foot orthoses (AFOs). The AFOs are used for medical conditions like drop foot, where patients are not able to properly lift their foot or perform pushing off on the floor while walking.

Unlike standardised conventional AFOs, personalized AFOs differ in shape and size each time, thus they are usually not tested in an extensive product trial. Custom-made AFOs made with traditional industry standard fabrication methods are checked and approved by a Certified Prosthetist/Orthotist (***CPO***). They can make this assessment as they are well familiar with how the traditional fabricated orthoses behave in their use cases.

The R&D department is now working on developing the first AFO products with the use of 3D-printing, see Figure 6. However, it is unknown if (partly) 3D-printed AFOs can provide 2 years of care without breaking or significantly losing performance. The structural body of the AFO cannot be made really thick, weight and volume need to be minimised as user acceptance to wear the product is essential. The ***CPOs*** cannot check and approve the product, because they do not have long term experience with them yet. Thus the initial problem definition is:

Problem Definition*
How do we ensure that 3D-printed AFOs can provide 2 years of care without breaking or significantly losing performance?

*Note that the assignment in the project brief, see *appendix 10.1*, is described as:

"Design and build a test setup to measure the durability of ankle-foot orthoses"

The problem statement as given here is one step back; it is the reason behind this original assignment. During the first research phase of the project this underlying reason was deducted based on conversations with R&D department and ***CPOs*** of the company.

Figure 6. 3D-printed AFO of a competitor (OTWorld, n.d.).

1.1.Scope

The main scope of the project is measuring the durability of 3D printing AFOs. The task in this graduation project is to provide a method to assess if the newly designed AFOs with 3D-printed parts will be able to provide care for these 2 years. This encompasses both ensuring lasting safety, as performance.

The company is also planning to make AFOs with two traditional production methods: AFOs made with polypropylene (PP) and AFOs made with prepreg (pre-impregnated carbon fibre) composites. It would be beneficial if these can also be evaluated with the same setups.

Understanding of the materials and production methods to be tested is viewed as relevant. It will define what failure mechanisms will occur and thus how they should be tested.

Product development and user research for AFOs itself is defined out of the scope. Any information about the AFO product designs will be included in the classified appendix. As this graduation report will be publicly published by the TU Delft and developments of these products are regarded as Intellectual Property (IP) of the company.

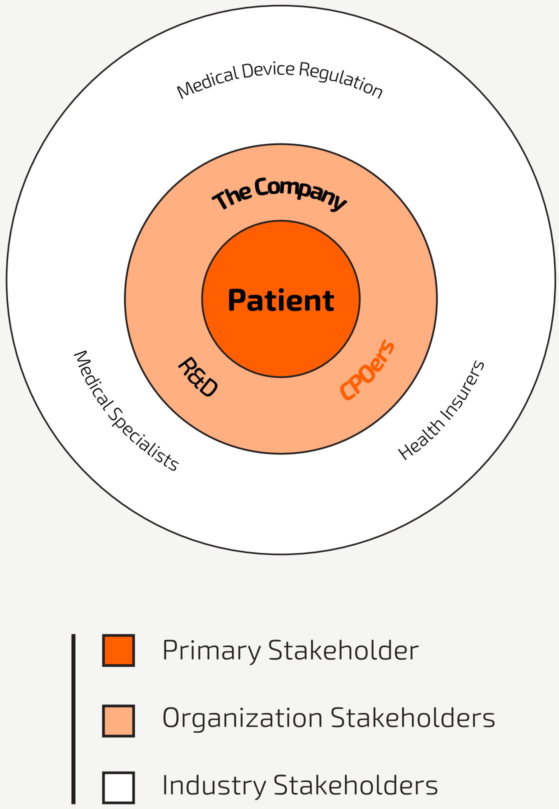


Figure 7. Overview parties who are stakeholders of the durability of AFOs.

1.2. Stakeholders

An overview of the stakeholders and their importance in the project is given in Figure 7. Explanation is given below:

Patients -
Patients for which the AFOs are designed are the prime stakeholders. Assuring the AFOs safe for them is the core goal of the project.

The company -
The client company developing and producing the AFOs is the second most important stakeholder, as it is the party which wants to achieve this goal for their (future) patients. Within the company there are two departments with the most knowledge and influence:

- R&D - Research & Development department developing the 3D printed AFOs. They will be the users of the test setup.
- ***CPOers*** - Certified Prosthetist/Orthotist (***CPO***) fitting the AFO at the company. Internally they have the most medical knowledge about AFOs and the conditions they address.

Tertiary stakeholders -
Parties that need to be convinced that the 3D-printed AFOs are safe in order to (legally) supply patients with this product. These are the following parties:

- Medical Device Regulation (MDR) - This regulation must be adhered to by Dutch law to provide patients with AFOs.
- Medical specialists - These are the doctors referring patients to the company. They need to be confident that the product the client company makes is safe.
- Health insurers - Paying for the AFO. They also need to be convinced that the 3D AFOs are safe in order for them to reimburse the products.

1.3. Report structure & Approach

The approach for this project consisted of six phases, with a final part concluding the project and giving direction for how to continue and use the results. The report is structured based on these phases, see figure 8. The six phases resemble a triple diamond approach, an extension of the double diamond (Design Council, 2005) typically used in design projects. The first two diamonds are the Introduction & Analysis phase. The third consisted of concept development, modelling, experiment and redesign phases. A more in-depth explanation of the contents of each phase is given below.

1.3.1. Introduction phase

This is the first diamond in which an orientation in the domain and the durability aspects of AFOs is performed. This includes an in-depth explanation of what an AFO is, how the product is used, how the use translates into different types of mechanical loading and failure, the safety risks of product failure and the relevant regulations. Based on this orientational research, important knowledge gaps that need to be analysed are defined as research questions.

1.3.2. Analysis phase

The research questions that are defined in the Introduction phase are explored and researched in this phase. These include: *1. How do traditional & 3D-printed AFOs fail?* (in which is analysed what the failure mechanisms of currently existing AFOs are) *2. Material Properties Analysis*. (in which material properties are analysed to discover if 3D-printed AFOs have a higher risk of failing than the traditional production methods), and *3. Selecting the AFO Test Setup Type to Build*, in which the types of relevant test setups and the choice for which one to develop are discussed. The choice being to focus on realizing an AFO load cycle test setup that can simulate two years of walking. After, a specification of the specific test setup that needs to be designed and its requirements is defined in chapter *2.4. Redefined Design Brief*. Key Design Questions are identified within this design brief to clearly define what are the most important sub-problems that need to be solved.

1.3.3. Concept phase

With this redefined design brief, ideation was done on the Key Design Questions. Existing solutions were analysed and a few new conceptual layouts were created. On the basis of the chosen solutions on the Key Design Questions and on formulated assessment factors, a conceptual layout was chosen to proceed with. This concept and its key components were iteratively prototyped. Resulting in a proof-of-concept test setup built.

1.3.4. Model phase

Simultaneously to designing and building the test setup, an underlying model of human ***gait*** was made. This model involved analysing ***gait*** patterns and making necessary simplifications to be able to accurately represent and replicate them. It defines key parameters such as loads, dimensions, angles, cycle count, cycle speed, and the number of test runs required. Throughout the development process, continuous experimentation, testing, and comparison with real-life ***gait*** was conducted to refine both the model and the test setup. A approach known as **research-through-design**.

1.3.5. Experiment phase

Two experiments were performed with the realized test setup described in this phase:
1. A final single-cycle movement test was conducted and compared to real-life ***gait*** using video analysis, followed by 2. A full test run was conducted to assess reliability. Lastly, the test setup was evaluated on Desirability, Feasibility, and Viability against the main requirements.

1.3.6. Redesign phase

Insights gained from testing the realized setup led to a **digital redesign** in CAD, which is presented alongside its key components. The improvements on the realized setup are discussed, and the redesign is also assessed the Desirability, Feasibility, and Viability requirements.

CONCLUSIONS & RECOMMENDATIONS

At last, conclusions are made on the outcome of the project in reference to the goals and requirements and recommendations are written. The recommendations include instructions on how the test setup should be further developed and how the final test setup should be used to answer the initial problem definition.

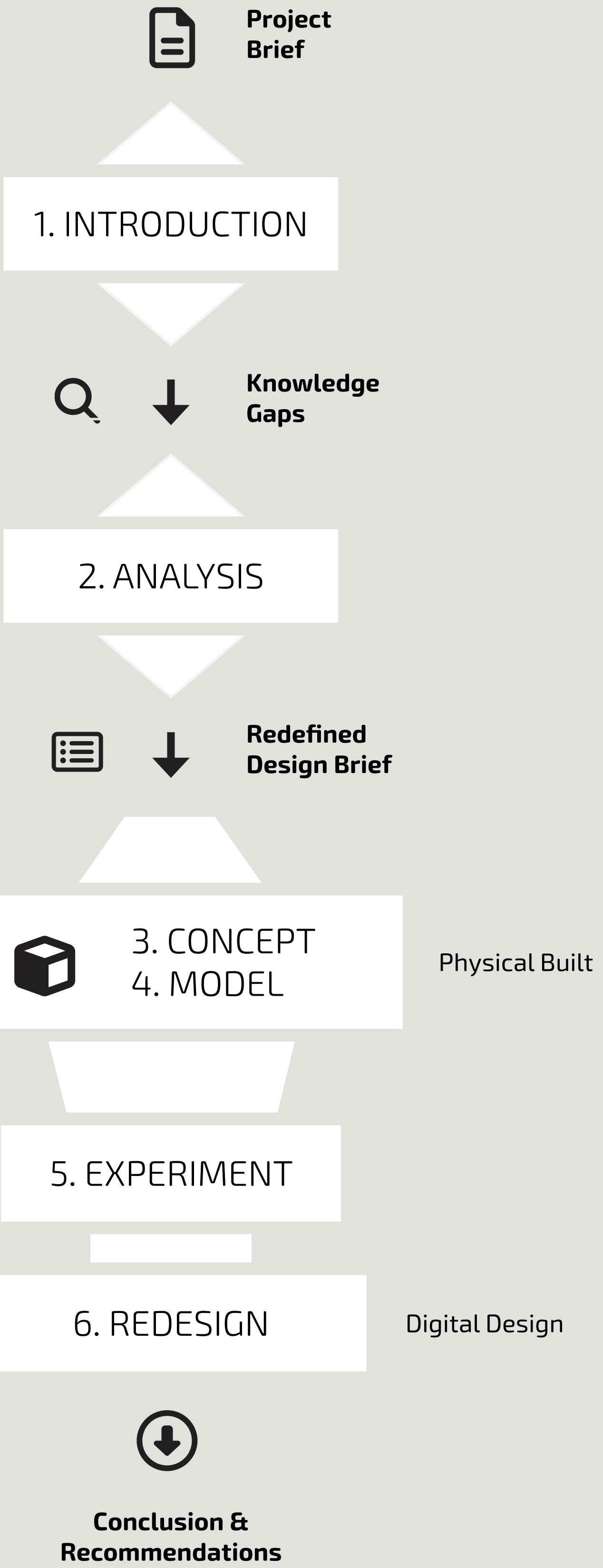


Figure 8. Overview of the structure of the report based on the approach taken in the project and its phases.

1.4. What is an AFO?

Before diving into how to evaluate the durability of AFOs, it is important to know what an AFO is.

An Ankle-Foot Orthosis (AFO) is a medical device designed to support and stabilise the ankle and foot. It is typically used by individuals who have weakened muscles, limited mobility, or neurological conditions that affect their ability to walk. The AFO helps maintain proper alignment of the foot and ankle, assists with walking mechanics, and can prevent deformities or injuries caused by abnormal gait patterns. Made from lightweight materials such as plastic or carbon fibre reinforced plastic, an AFO can be custom-fitted to the patient's leg and foot to ensure both comfort and effectiveness during use. There is a wide range of different types of AFOs, it is not defined yet at the company what types of AFOs are going to be made with the 3D printing production technique. Thus the aim is to be able to test with all types of AFOs. For an overview of all the types of AFOs, see appendix 10.2.

The client company considers three production methods to produce AFOs. These fabrication methods are *pre-impregnated (prepreg) carbon fibre* (Figure 9) and *Thermoformed PP* (Figure 10), which are considered 'traditional' methods, and *3D-printing* (Figure 11), specifically: *HP Multi Jet Fusion (MJF) PA-12*. The last will be the main focus of this project, the first two 'traditional' methods will serve as a reference for comparison. More info on the AFO production methods can be found in appendix 10.2.3.

Figure 9. Carbon prepeg AFO (Tillges Technologies, n.d.).

Figure 10. Polypropylene (PP) AFO (Ambroise, 2022).

Figure 11. 3D-printed AFO (3D Ortho, 2023).

1.5.Product Usage

Method used: - Personas
[from the Delft Design Guide (DDG) by Zijlstra & Daalhuizen (2020)]

To define what 2 years of care means for an AFO, the activities considered as normal use and the anatomical measurements of the patients must be investigated. With this information the loads exerted on the AFO can be defined.

The company currently splits their patients up in two groups: adults and children. This distinction is made as 3D printing is currently viewed as a production method only suitable for children due to their lower weight and size. This means the loads on the AFO are within the range that the 3D-printed parts can hold. Exact length and weight categorization still has to be defined at the company. The results of this project could help to define these categorization limits.

Activities that are chosen as 'normal usage' are: sitting, standing, walking, running, jumping, playing, sports, swimming, climbing stairs, and hiking. This is based on user research done by the company. The most critical activities, that are within 'normal use' of an AFO, are considered to be jumping due to the high impact and walking for cycle loading, because of the high occurrence of this activity.

The most important anthropometric measurements are: weight, foot length, and popliteal height (lower leg length), as these define the magnitude of force and the levers working on the AFO. Persona overviews of the activities and anthropometric measurements for adults and children can be seen in figure 12 and figure 13 respectively. The measurements for these properties are from DINED (TU Delft et al., n.d.), see *appendix 10.4*. No conclusions are drawn from these visualizations, these persona's only provide an overview of the activities and the relevant anatomical measurements, which are translated into mechanical loading cases in the next chapter *1.6.Types of Loading*.

1.5.1. The Impact of Shoes

Most AFOs only function when they are worn with a proper shoe. The shoe keeps the AFO in place and provides additional support. The shoe has thus an important role in the loads that are exerted on the AFO.

For example, the angle of the foot while walking has a great influence on the flexion and thus forces in the AFO. The two most important factors in change of the angles with regard to a normal gait are: 1. Frequently walking on uneven terrain. 2. Wearing shoes with heel lift that is not taken into account with the design of the AFO.

Levit Ottobock for example recommends wearing shoes with 0 cm of heel lift as almost all AFOs are designed with 0 cm heel lift in mind (Livit Ottobock Care, n.d.). Based on the interview with **CPOs** (*appendix 10.3*) it happens that people do not take this in regard or neglect this and break their orthosis because they wear heels. This is viewed as misuse and thus will not be taken into consideration during the durability evaluations in this project.

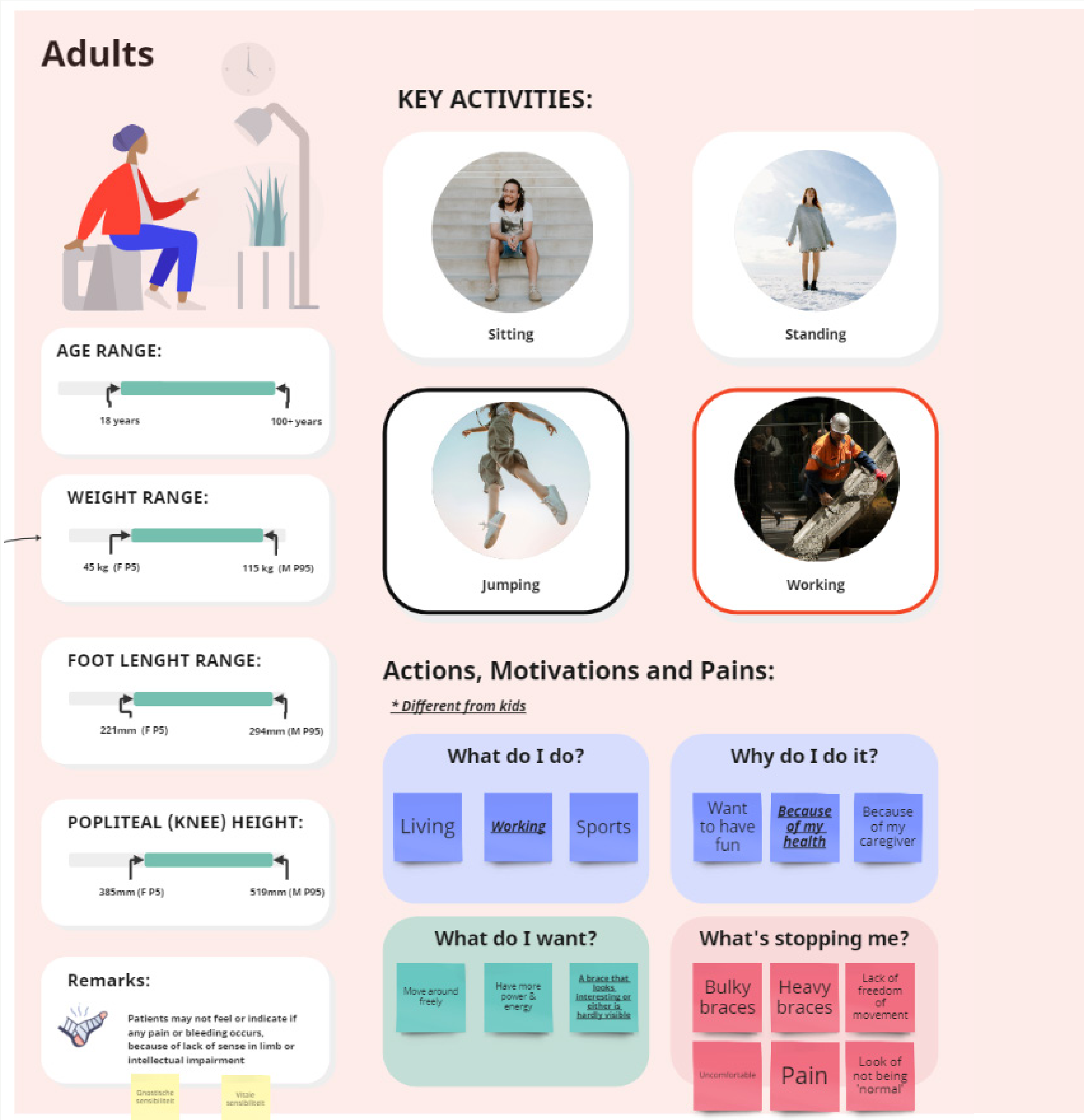
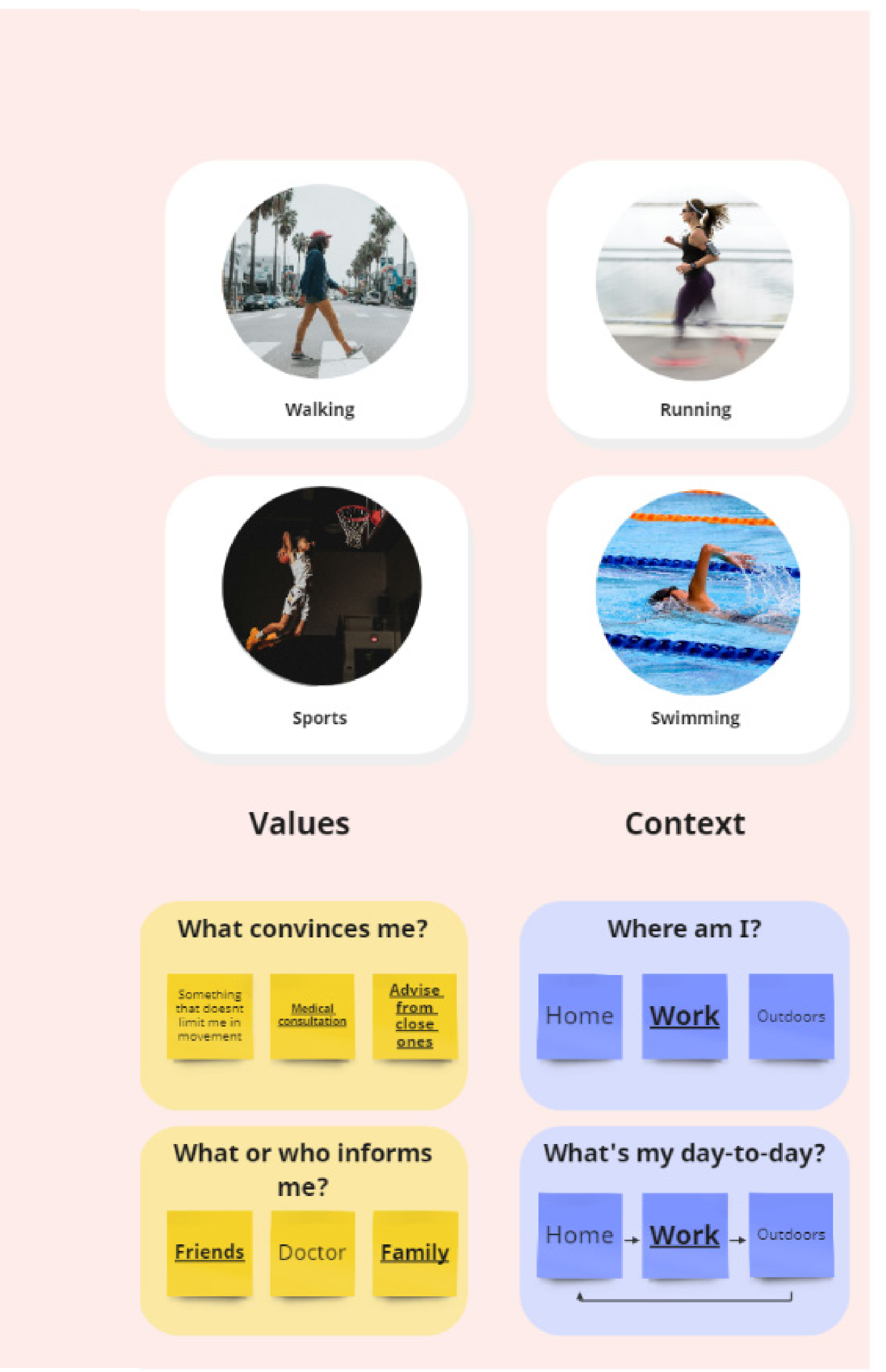


Figure 12. Persona overview of the most important activities and human anatomical measurements of adults. The anthropometric measurements are from DINED, see appendix 10.4.


Walking
Running
Sports
Swimming
Values
Context
What convinces me?
Something that doesnt limit me in movement
Medical consultation
Advise from close ones
Where am I?
Home
Work
Outdoors
What or who informs me?
Friends
Doctor
Family
What's my day-to-day?
Home
Work
Outdoors

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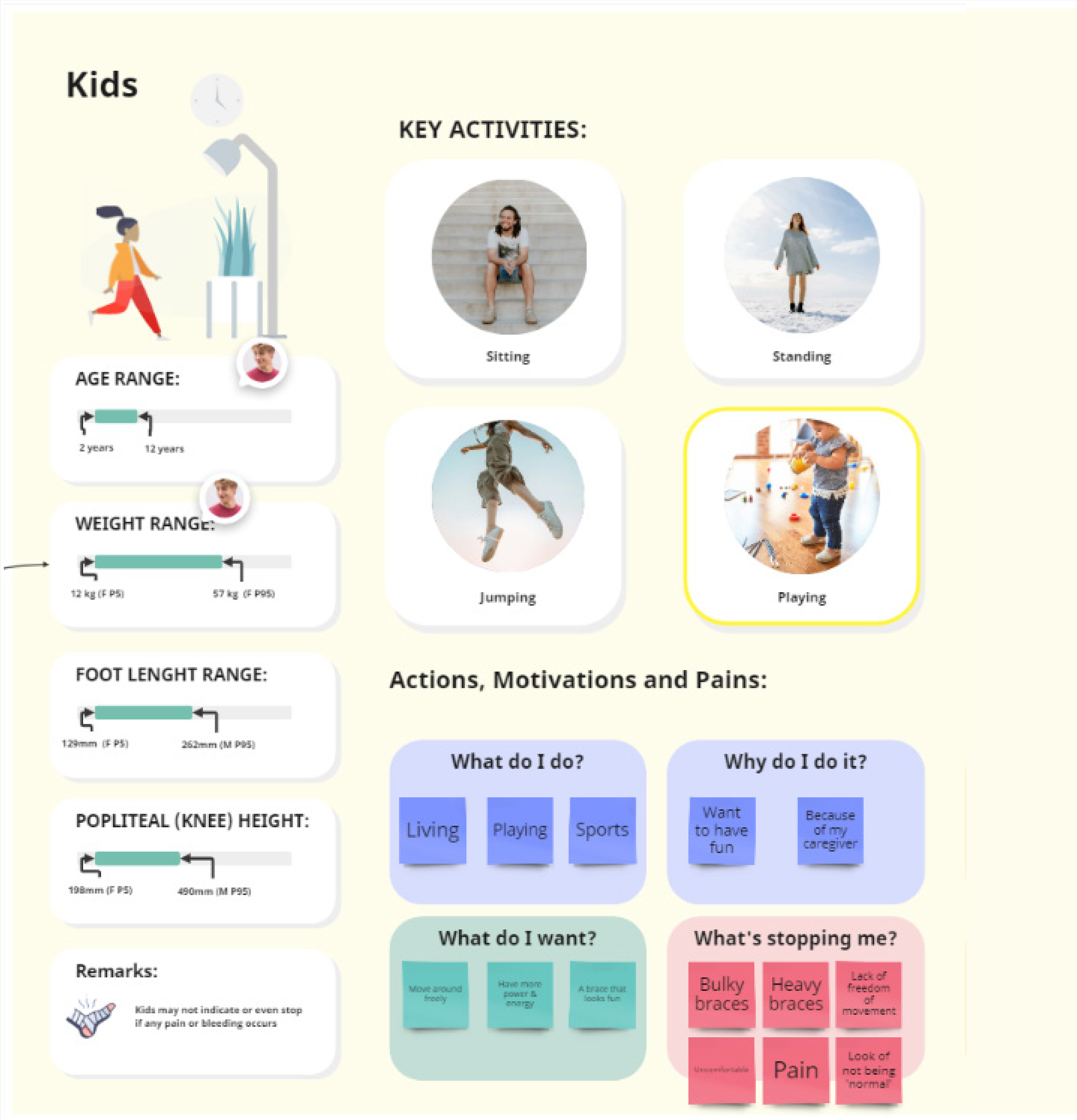
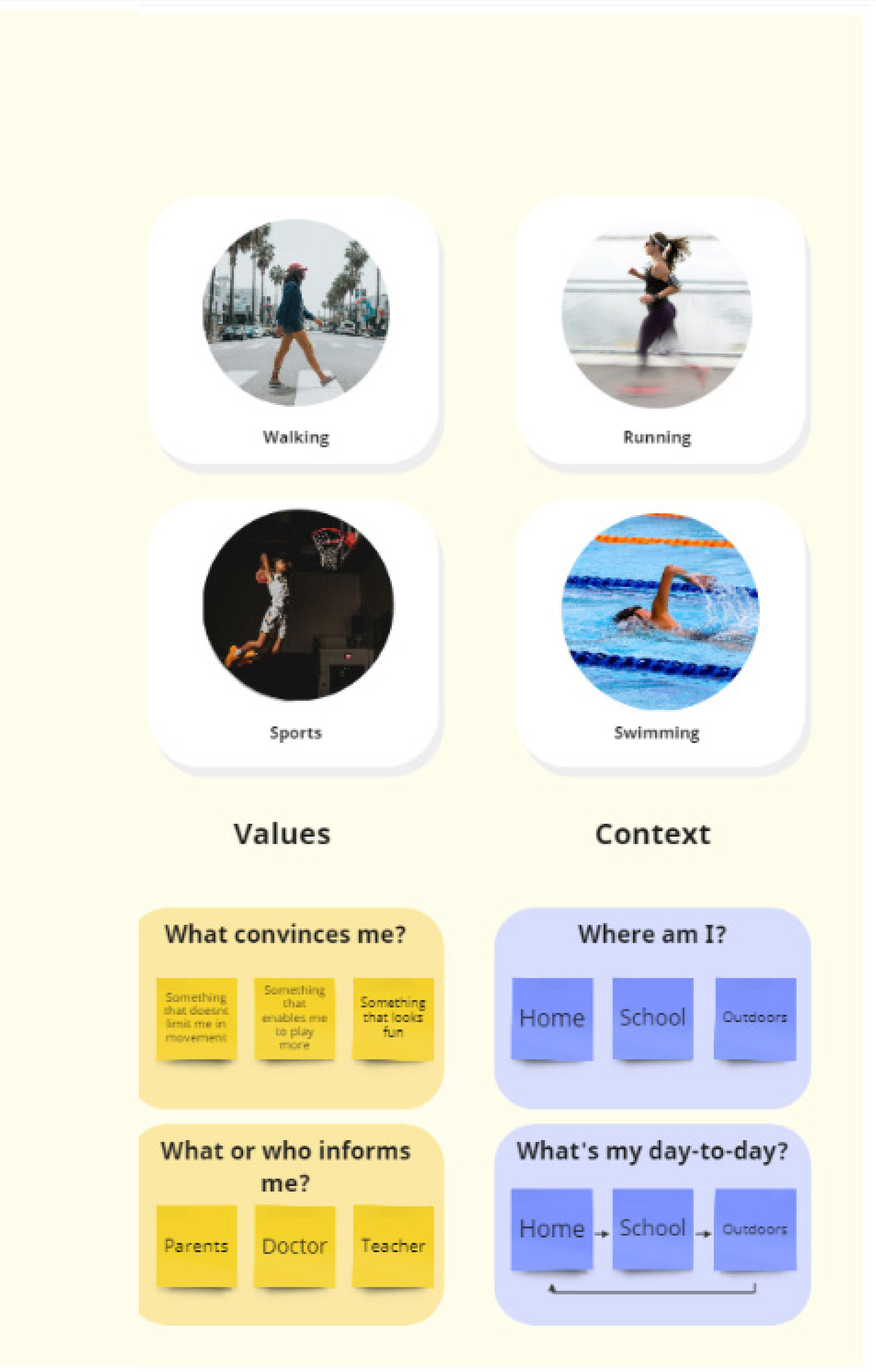


Figure 13. Persona overview of the most important activities and human anatomical measurements of children. The anthropometric measurements are from DINED, see appendix 10.4.


Walking
Running
Sports
Swimming
Values
Context
What convinces me?
Something that doesn't limit me in movement
Something that enables me to play more
Something that looks fun
Where am I?
Home
School
Outdoors
What or who informs me?
Parents
Doctor
Teacher
What's my day-to-day?
Home
School
Outdoors

1.6.Types of Loading

From a mechanical engineering point of view all these user activities of the previous subchapter can be categorised into static loading (standing), impact (jumping) and load cycling (walking). See A, B, and C respectively in Figure 14. These loadings can result in a loss of performance or permanently deforming or breakage.

Further in-depth analysis of the failure mechanisms of AFOs can be found in chapter *2.1.How do traditional & 3D-printed AFOs fail?*.

Types of loading and resulting product failure:

A. **Static Loading:** The AFO is subjected to a constant force beyond its designed capacity, leading to permanent deformation of fracture.

B. **Impact:** A sudden force or shock, such as a fall or collision, causes the main body to permanently deform or cause brittle fracture.

C. **Cyclic Loading:** Repeated stress over time, such as continuous walking or running, leads to fatigue, resulting in loss of stiffness and eventual breakage.

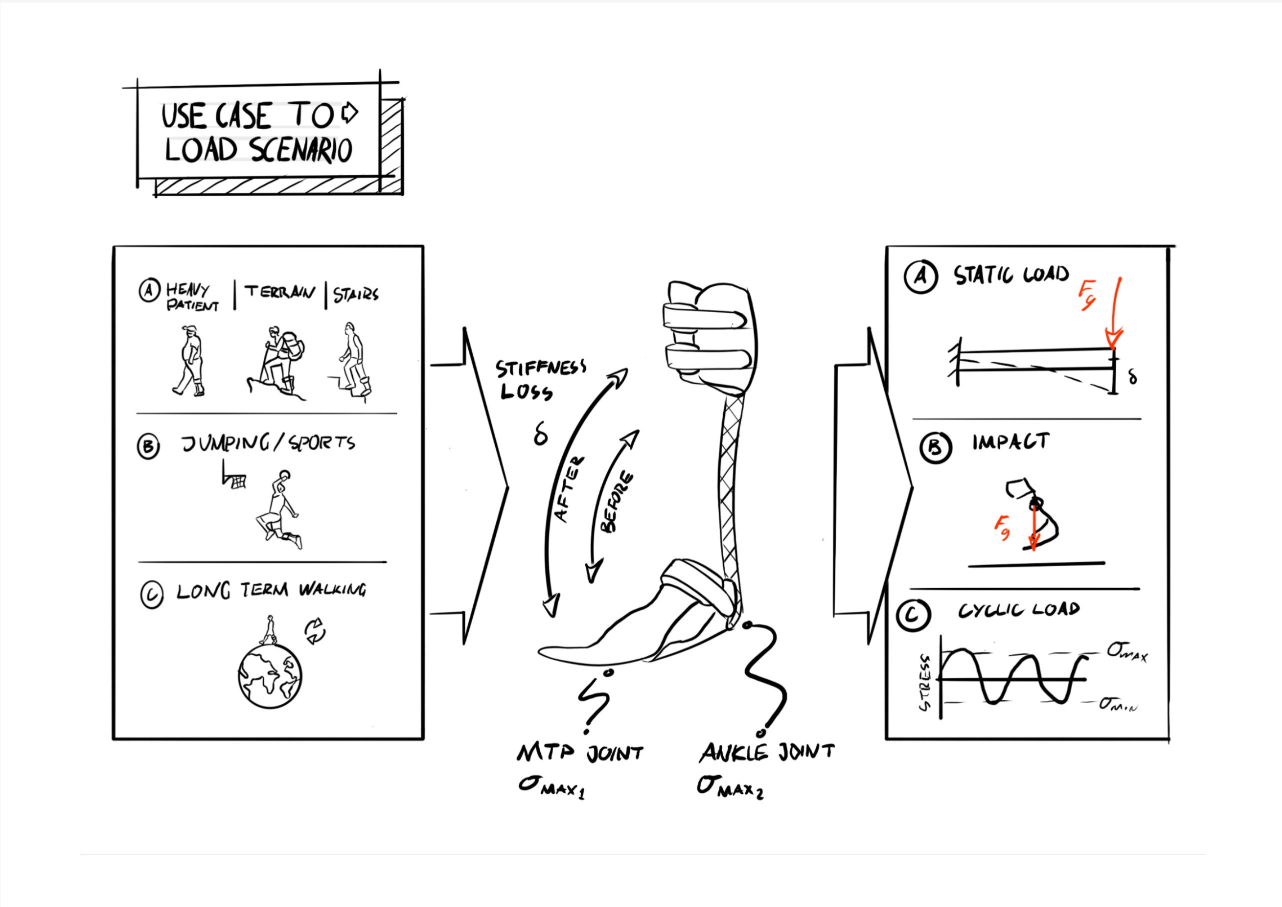


Figure 14. Overview of the 3 types of critical use cases and in which mechanical loading types they translate: A. Heavy patient | Uneven terrain | Stairs = Static load, B. Jumping | Sports = Impact, C. Long term walking = Cyclic loading.

1.7.Safety Risks

Excessive product displacement or breakage due to the loads described in the previous subchapter can lead to two safety risks:

A. **The patient falling:** The sudden breakage of the AFO can cause loss of support, resulting in the patient losing balance and falling.

B. **The patient cutting him/herself:** Sharp edges from the snapped parts can cause cuts or abrasions on the patient's skin.

1.8.Regulation

Like hand braces, AFOs fall under class 1 of the Medical Device Regulations (MDR) (EU) 2017/745, which means that it is necessary to provide evidence that efforts were made to reduce the safety risk described above and ensure general safety of the product. There are, however, no specifics or standards for how this should be proven (Shuman et al., 2023).

Hochmann (2014) states that EN ISO 22523 (NEN, 2006) requires the manufacturer of prostheses and orthoses to define and document required strength parameters and the test methods to measure them. However, again the size of the load or duration of the tests are not specified. These thus have to be defined within this project.

Hochmann, chairman of the DIN subcommittee of "Development of test methods for lower limb orthoses", is currently working on introducing a DIN standard for testing lower limb orthoses in the coming year (personal communication, 2024). He aims to later transfer this DIN standard into an ISO standard. He is basing his standard on the ISO 22675 Fatigue ankle-foot device Prosthetic Test Equipment (ISO, 2016). As long as this DIN standard is not published, it is thus best to to follow the ISO 22675 standard. The company will be in the right direction for complying to the upcoming DIN standard, potentially way earlier than any other competitors.

1.9.Research Questions

To conclude 1. Introduction chapter knowledge gaps were identified that need to be filled, before attempting to address the initial defined problem. These translate into the following research questions:

1. *How do traditional & 3D-printed AFOs fail?*
2. *Are 3D-printed AFOs more prone to mechanical failure than traditional AFOs based on their material properties?*
3. *What types of AFO test setups already exist & what type of loading should be tested in this project?*
4. *What is the redefined design brief based on this orientation and analysis?*

These Research Questions will be addressed in the subchapters of the following chapter 2. Analysis.

2. Analysis

2.1.How do traditional & 3D-printed AFOs fail?

Limited knowledge is available on how and where 3D-printed AFOs break, because the production technique is not widely adopted yet. Thus failure of 'traditional' personalised AFOs is analysed, as is the limited knowledge on 3D printed AFOs. See chapter *1.4. What is an AFO?* for explanation on what is considered a 'traditional' personalised AFO.

Based on interviews from **CPOs**, see *appendix 10.3*, it is known that AFOs made with 'traditional' production methods, mostly fail and lose stiffness due to repeated loading. This is because this is the most demanding type of loading scenario, compared to static loading and impact. It provides the most strict engineering requirements: According to Ashby et al. (2013, p. 240), the endurance stress limit (σ_e, the amount of stress a material can handle for an infinite amount of cycles) is for most materials around 1/3 of the yield strength (σ_{ts}). While at the same time this fatigue strength is the hardest to test, as it requires specific testing equipment and a significant amount of testing cycles and thus time. These two aspects are the reason why this type of failure is seen the most with AOFs.

The places where these 'traditional' AFOs mainly breakdown are the strut in the area around the ankle and the ***footplate*** in the area around the ***MTP***, as these are the areas where the most stress is built up due to bending. In the next subchapters, figures and description showing the exact most common breaking spots for each fabrication method.

CPOs are unfamiliar with 3D-printed AFOs. They thus have limited knowledge on the exact spots where these 3D-printed AFOs are prone to break. It is therefore assumed that they will break in the same areas as the 'traditional' AFOs.

Based on interviews with the orthopaedic technologists (*see appendix 10.3*), past experience of the R&D team at the company, and literature (Polliack et al., 2001), failure mechanisms were identified of the 3 fabrication methods and their materials, Carbon prepreg, Thermoformed PP, and HP Multi Jet Fusion (MJF) PA-12. These will be described in the next three subchapters.

Figure 15. In this picture a carbon AFO made through wet lamination is shown, as no broken carbon prepreg AFOs was at hand. The failure hotspots, however, are the same in carbon prepreg AFOs, 50% around the **MTP** and 50% around the neck area of the AFO.

2.1.1. Carbon Prepreg AFOs

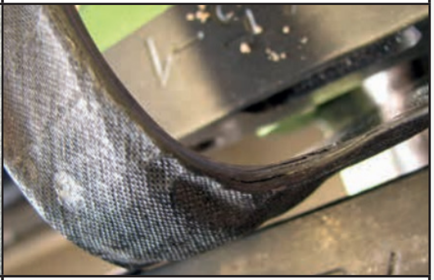
The carbon prepreg production method is mostly used to make Passive Dynamic AFOs. These AFOs can load like springs to provide energy return. They provide great stiffness-to-weight ratios, but are expensive and cannot be refitted.

The ***CPOs*** indicated that 10% of prepreg AFOs break (the most experienced ***CPOs*** had prescribed ~5000 AFOs in their career). The hotspots for breakage in carbon prepreg AFOs are around the ***MTP joint*** for 50% of the time and 50% of the time around the neck area of the AFO, see figure 15.

Material Failure Behavior

Carbon prepreg cracks or delaminates before complete failure, which results in loss of stiffness which can be noticed beforehand, making it a relatively safe product failure behaviour. Making it less important to evaluate the durability of these braces. In Table 1 the material failure mechanisms of carbon-reinforced plastic in AFOs can be seen.

Table 1. Table 1. Failure mechanisms of carbon prepreg..

Carbon prepreg		
Failure mechanism	Cracks	Delamination
Picture		
Main type of loading causing it	Cyclic loading	Cyclic loading
Possible production defect cause	Wrong place of junction between leaf spring and foot plate	Air bubbles in the laminate

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2.1.2. PP AFOs

AFOs made with this production method are cheap and are used mainly for footlifter AFOs, to address foot drop, or for static AFOs, in order to fully fixate the ankle. Compared to Passive Dynamic AFOs stiffness and energy return is less relevant. Thus these AFOs can be made of the cheaper PP. The PP AFOs are mainly prone to loose stiffness over time due to cyclic loading. The areas where the material is bent most, stress-whitening occurs, which results in a lower stiffness of the material in that area. This again mainly happens around the ***MTP*** and neck area (see Figure 16),

With SAFOs the required stiffness can be changed by compassing the foot more or less, creating a big or smaller U-profile respectively. However with enough force the flanges of the neck area of the AFO, enduring the biggest moment, tend to fold outwards. As indicated by one of the ***CPOs*** in an interview, these folds most often happen in the centre of the neck or just above. On the long-term this leads to fracture as can be seen in Figure 17.

Figure 16. Failure hotspots in PP AFOs, some wear around the ***MTP*** and but mainly around these two spots in the neck area of the AFO.

Material Failure Behavior
PP is ductile, as it will yield and plastically deform significantly before it will break. Repeatedly yielding will lead to stress-whitening, eventually creating a fracture, as can be seen in Figure 17. This is one of the safest kinds of failure as it will not lead to sudden failure: the yielding and loss of performance due to loss of stiffness will be noticed by the patient before fracture. Again, making it less important to evaluate the durability of these braces.

Figure 17. Failed PP AFO, repaired with a metal strip.

2.1.3. 3D printed AFOs

As 3D printed AFOs are not widely used yet, the failure mechanisms are still relatively unknown with AFOs. There is a large range of printing techniques and materials, which all have a big impact on the durability of the AFO. Most 3D-printed AFOs are printed with MJF PA-12. Thus it was chosen to look specifically at MJF PA-12. If 3D-printed AFOs are used, they are used for children, as the experience is that for adults they break too often. This is logical, as the forces and moments on kids' AFOs are smaller due to the lower weight and smaller dimensions.

The ***CPOs*** at the company have limited experience with the product failure of 3D-printed AFOs. Based on analysing 3D-printed AFOs from competitors the following is known: Next to the ankle and the ***MTP***, the additional predicted spots to lookout for could be the flaps encompassing the foot, see Figure 18. These have to be thin to allow bending and to not take up too much space in the shoe.

As MJF PA-12 has low ***elongation-at-break*** (max 20%, as discussed in the end of the next chapter), the material cannot handle the deformations regularly done with these flaps. The same can happen in the ***calf cuff*** while pushing the U-profile open or closed. The flaps & ***calf cuff*** breaking this way, however, does not create major safety risks and thus will not be further investigated in this project.

Material failure behavior
MJF PA12 is relatively brittle and only deforms a bit before fracture. Different from carbon prepreg and PP, this material has a more so-called sudden failure, which is a decidedly unsafe failure mechanism (Tempelman, 2020). As, in this situation the load acting on the AFO is suddenly no longer supported and the patient could fall because of this reason. Thus it is especially important to evaluate the durability of AFOs made with this material and production technique.

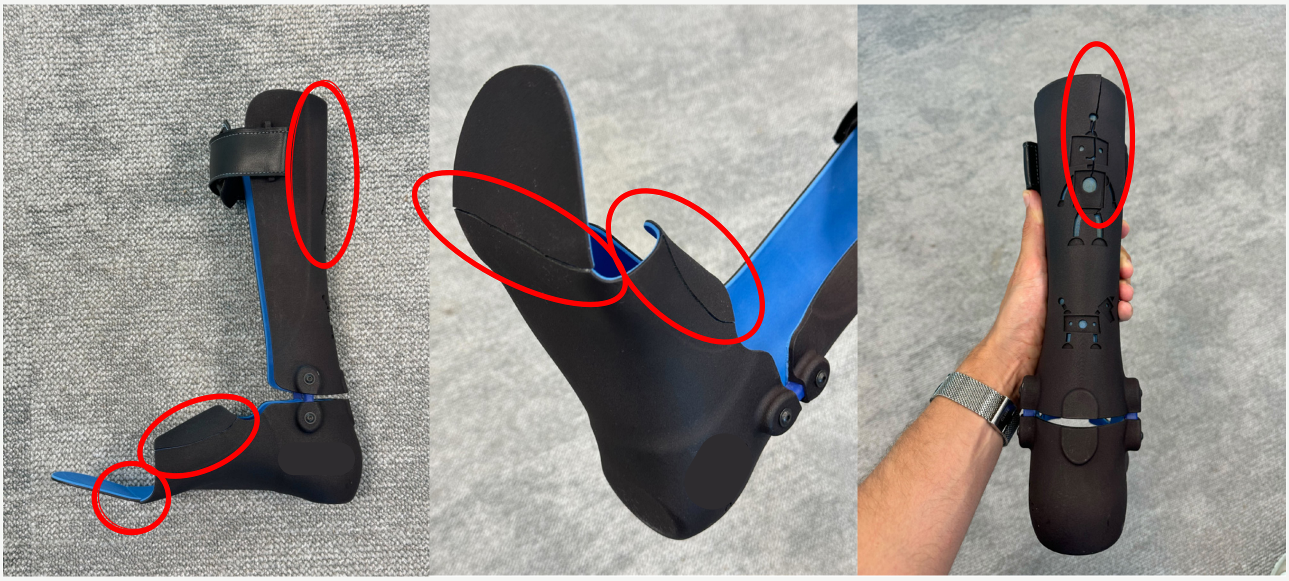

Figure 18. Failure hotspots in MJF PA12 AFOs, fracture around the ***MTP***, in the flaps over the foot, and the middle of the calf.

2.2. Material Property Analysis

Research question

Are 3D-printed AFOs more prone to mechanical failure than traditional AFOs based on their material properties?

Based on information gained by the company through contact with competitors and building/breaking prototypes, it is known that 3D printed AFOs are more prone to break than 'traditional' AFOs.

But why is this? Can an answer be provided by looking at a simplified mechanical model and the mechanical properties of traditional AFO materials and the 3D-printed materials? Is it possible to compensate for the mechanical properties of the 3D-printed material with alternated design? For example by changing the section profile of the different parts in the AFO that are under bending? To answer these questions a theoretical mechanics of materials model was made and calculations were performed.

Materials

For the materials the following properties are compared: Young's Modulus, Tensile strength, ***Elongation-at-break*** (see Table 2). Unfortunately, no specific endurance limit stress is known for MJF PA-12. Thus we cannot compare the materials on this property for fatigue strength in relation to cyclic loading.

Analysis

It is clear that the tensile strength and stiffness of carbon prepreg is significantly higher than PP or MJF PA12, see table 2, resulting in a stiffer and slimmer design that does not easily break. These properties also allow the carbon fibre to function as a spring. Carbon prepreg and PP AFOs are mostly used for different applications. In general most AFOs can be made with carbon prepreg, it is however more expensive than PP and function integration like hinges is also less easy.

PP is usually used for Static AFOs (SAFOs) or Hinged AFOS (HAFOs) that fixate the ankle and are not designed to bend and return energy. It will be most important to compare PP and MJF PA-12 as based on their material properties these materials could be best interchangeable.

However based on the interviews with ***CPOs*** (see appendix 10.3) it is known that PP AFOs will not fail for adults, while the experience is that MJF PA12 AFOs will fail. What slight material properties differences cause MJF PA12 AFOs to fail, while AFOs made from PP will not? Two material properties are identified as potential reasons for the difference:

1. **Young's modulus (stiffness) in combination with tensile/yield strength**
   The young's modulus of PP and MJF PA-12 are relatively similar if compared to carbon fibre. However if PP and MJF are compared, the latter can be up to 30% stiffer, see table 2. The higher stiffness of the MJF PA-12 material would require a smaller cross-sectional area to get the same stiffness out of the AFO design. This could lead to an increase in stress concentration. In this analysis calculations are made to see if this increase in stress will cause fracture in 3D-printed AFO.

2. **Elongation-at-break**
   Another factor at play could be the ***elongation-at-break***. This is the amount of strain the material allows before breaking. This could be relevant as a certain deflection results in a certain amount of elongation of the material within the AFO. If this elongation passes the ***elongation-at-break*** the material will fracture leading to sudden failure of the AFO. PP has an exceptional ***elongation-at-break***, while MJF PA-12 has a way lower elongation at break. This could be another reason that MJF PA-12 3D printed AFOs fracture.

Model

To evaluate the impact of these material properties a theoretical model is made of a generalised AFO. This model is used to calculate if the material properties will lead to product failure.

For the model, we only look at the ***calf cuff*** of a dorsal design AFO. The strut is modelled as a simple beam with a rectangular cross-section that is fixed at the point where it meets the foot plate. At the other the force is applied, simulating the lower leg pushing on the AFO. It is chosen to look at ***dorsiflexion*** (see Glossary) during the push-off phase of normal gait, as at this moment the most weight is on the leg and the angles are the most extreme (see chapter 4.1. Gait Analysis and Figure 33).

Table 2. Table 1. Failure mechanisms of carbon prepreg..

AFO production type	Material	E (GPa)	TS (MPa)	Elongation (%)
Prepreg AFOs	Unidirectional carbon fibre	129 - 156	1,74e3 - 2,17e3	1,2 - 1,4
PP AFOs	Polypropylene	1,37 - 1,58	26 - 50*	52,1 - 232
3D-printed AFOs	MJF PA12	1,7 - 1,8	48	15 - 20

Assumptions:

- A common approach is using a static load to represent the complex dynamic load in this scenario. This is commonly done in the mechanical engineering courses on the faculty of Industrial design at the TU Delft to simplify the situation. It will provide a first check on static mechanical loading theory. If failure already occurs in this static model, it will certainly happen in dynamic models.
- The situation is modelled in 2D in the sagittal plane as the main forces and moments occur in this plane.
- The mass of the AFO itself can be neglected.
- Shear forces can be neglected as they are generally way smaller than the bending forces as described by the book NSFD: Engineering Essays on structures & materials by E. Tempelman (2020).
- The forces:
  To be able to calculate the exact force pulling on the strut of the AFO the gravitational force of the patient is used. It is assumed that the AFO strut carries all the patient's weight. As we are mainly concerned with the stress due to bending, the forces resulting in bending of the brace will be calculated based on the gravitational force, the dimensions of the lower leg and the angles of the hip and ***ankle joint*** during the push-off phase.

All exact parameters used for the calculation can be found in appendix 10.5 Model of Material Properties Analysis.

With these assumptions a model is drawn, see Figure 19. To calculate the force on the AFO the model is built up from part AB, which represents the upper leg, and part BC, which represents the AFO carrying all the moment (assuming the patient has full muscle weakness). BC is consequently modelled as a beam with a U-shape section profile. With this model, the maximum stresses and deflections are calculated.

The critical stress is the tensile stress. The calculation will determine whether this stress exceeds the tensile strength. The stress between the AFOs being compared will be equal, as the material properties (like for example the Young's modulus) do not have an impact on the amount of stress.

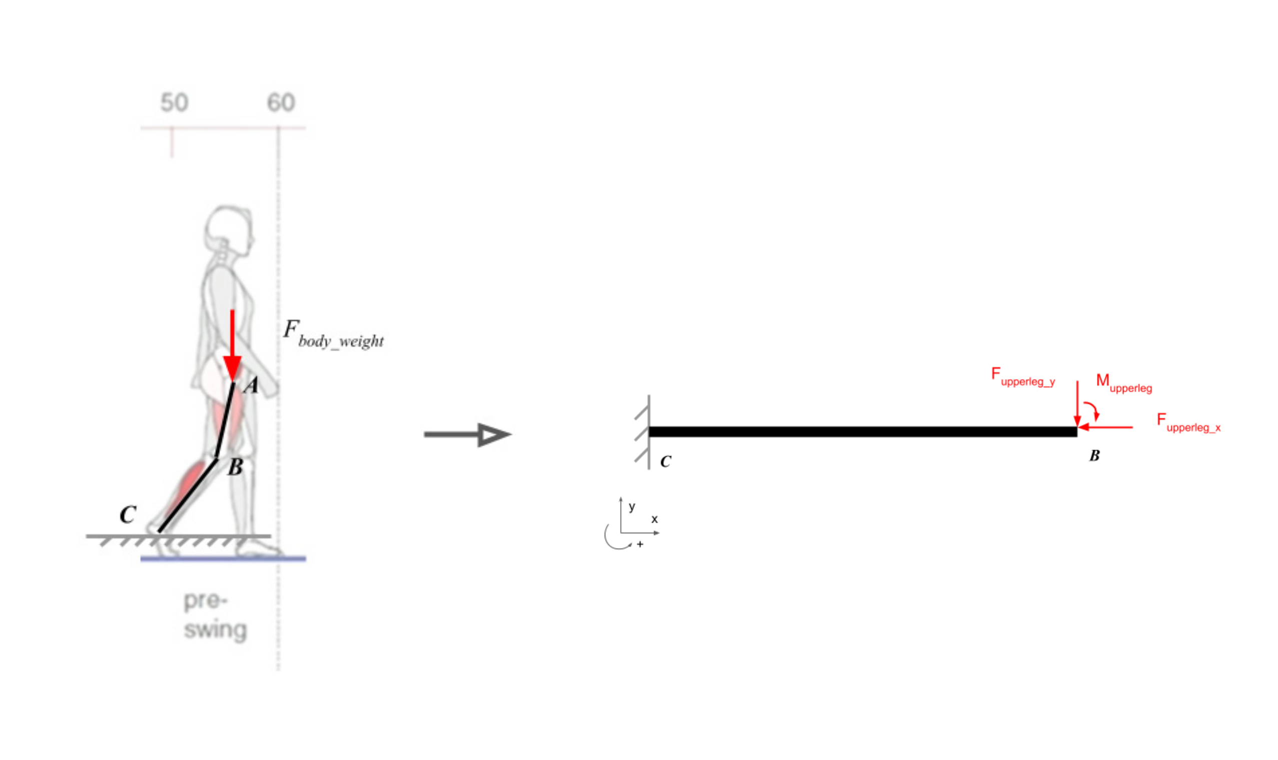

Figure 19. Failure hotspots in PP AFOs, some wear around the ***MTP*** and but mainly around these two spots in the neck area of the AFO.

Resulting stresses
With the chosen parameters, the maximum tensile stress for both AFOs is:

$\sigma_{max\_tensile}$ = 21.6 [MPa]

This is within the yield strength of PP (26 MPa) and the tensile strength of MJF PA-12 (48 MPa). This material property is thus not the reason for the failure of MJF PA-12 AFOs. Full calculations can be found in appendix 10.5 Model of Material Properties Analysis.

Matching deflection
Because MJF PA-12 is stiffer than PP it will have less deflection under this load. It could be tried to match the deflection of the PP AFO by decreasing the wall thickness of the MJF PA-12 AFO. Consequently, it is checked if with this new wall thickness, the max stress in the MJF PA-12 AFO does not exceed the tensile strength.
However, it was found that the U-shape section profile causes PP AFOs to be quite stiff, resulting in little deflection, only 0.23 degrees under this load.

If the thickness is decreased, the yield strength of the PP will be reached before major larger deflections can occur. The thought was that some larger deflexions would be seen before yielding, however, because the deflection is so small, it is not relevant to match this same deflection with the MJF PA-12 AFO by decreasing its area moment of inertia.

Elongation-at-break
At last, ***elongation-at-break*** is looked at. Deflection is limited in the strut of the AFO. In the ***footplate***, however, significantly greater deflection is required to enable bending around the ***MTP***—up to 30 degrees. For this reason, the ***footplate*** has a thin and flat section profile.

Elongation-at-break for PP ranges from 50% - 230%. While MJF PA-12 has ***elongation-at-break*** of around 20%. This means that MJF PA-12 can deform significantly less before it fractures. As MJF PA-12 elongates only about 20%, a ***footplate*** of this material could maybe have trouble handling the 30 degree deflection angle.

However, we know that in static loading conditions, MJF 3D-printed AFO ***footplates*** can handle this deflection. Problems may however occur when this large deflection is cycled for a large amount of cycles. This needs to be tested, as no data is available on the endurance limit stress of MJF PA-12.

Conclusion
Overall we can conclude that the combination of stiffness and tensile strength is not the cause for the failure of MJF PA-12 AFOs in the strut around the ankle area, as the maximum tensile stresses stay well below the tensile strength. The MJF PA-12 AFO will thus in theory not break here due to these material properties.

Deflection and thus deformation is limited in the strut, but in the ***footplate***, deflection has to be way larger to allow bending around the ***MTP***. Up to 30 degrees, see Figure 33 of chapter *4.1. Gait Analysis*.

It is known that in static loading conditions, MJF 3D-printed AFO ***footplates*** can handle this deflection. Problems may however occur when this large deflection is cycled for a large amount of cycles. Thus it will be important to test the MJF PA-12 AFOs on cyclic loading. The relevance of testing static loading and impact, however cannot yet be excluded.

2.3. Selecting a Test Setup Type to Build

Based on the three loading types, three different types of test setups were identified relevant for the development, durability, and safety evaluation of AFOs. This was done on the basis of a literature review, and by speaking to Hochmann (2024). The types are: stiffness testing, impact testing and load cycle testing. An overview of all the found test setups can be found at: https://tinyurl.com/AFO-test-setups

2.3.1. Stiffness Testing

The first type of setup tests the stiffness of the AFOs around the ankle and ***MTP joint*** at each angle of ***dorsiflexion*** and plantar flexion. This stiffness test resembles static loading. These setups could be used to test max dorsal and plantar static loading in AFOs. Thus no special test setup has to be built for static load testing. Most of the time the lack of stiffness occurs earlier than yielding or fracture, making this the critical design property. This type of testing is well researched in the industry and a range of stiffness test setups have been built, like BRUCE (see Figure 22), as demonstrated in the article of Shuman et al. (2023). Thus it was decided to advise the company to outsource this type of testing, though N. Waterval or D. Hochmann. Either by letting these tests be performed at their locations and/or possibly acquiring these stiffness setups from them.

2.3.2. Impact Testing

An existing impact test setup build by Polliack, Swanson, Landsberger, and Mcneal (2001) can be seen in Figure 21. This simulates impact for example in the use scenarios of jumping or playing sports. This is also highly relevant testing, as these impact scenarios are referred to as the next

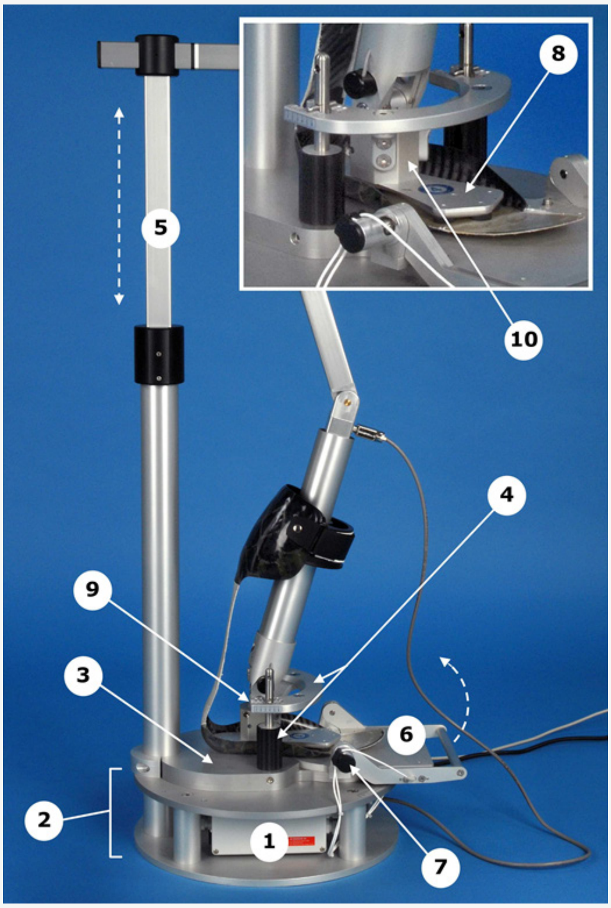

Figure 20. The Bi-articular Reciprocating Universal Compliance Estimator (BRUCE) developed by Bregman et al. (2009). See source for annotation.

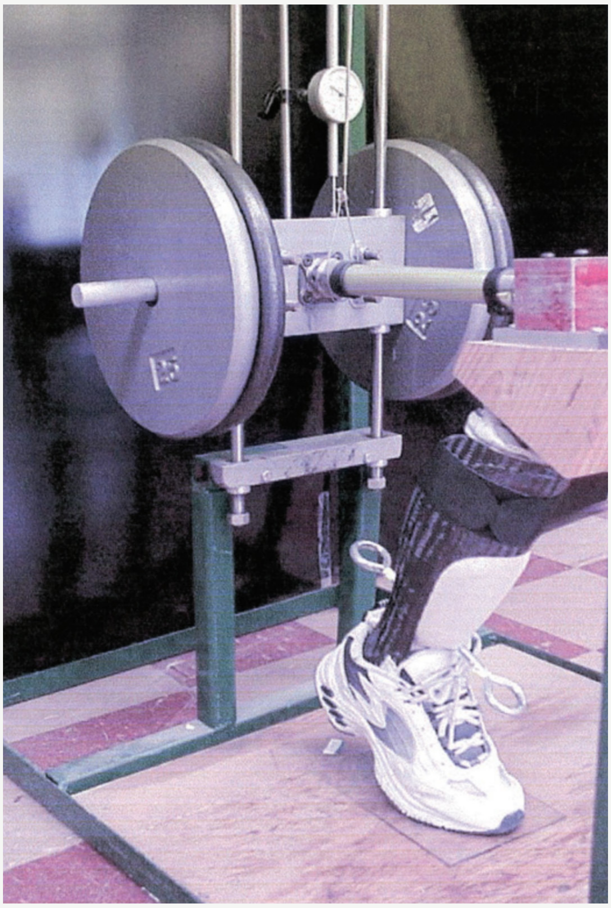

Figure 21. Impact testing apparatus from Polliack, Swanson, Landsberger, and Mcneal (2001).

most common reason, after material fatigue, for product failure by **CPOs** (see appendix 10.3). Building impact test setups is however less difficult, expensive and time consuming than building a load cycle test setup, as the setup does not have to run on its own for extended time. The R&D department at the company would be able to build such a test setup within a relative short time span. Alternatively impact good also be well evaluated by jumping on the brace with a test user.

Note that stiffness and impact testing is a quicker and cheaper type of durability testing than cycle load testing and thus should always be performed before load cycle testing.

2.3.3. Load Cycle Testing

The third addresses the main product failure according to **CPOs** (see see appendix 10.3) and industry experts such as D. Hochmann: material

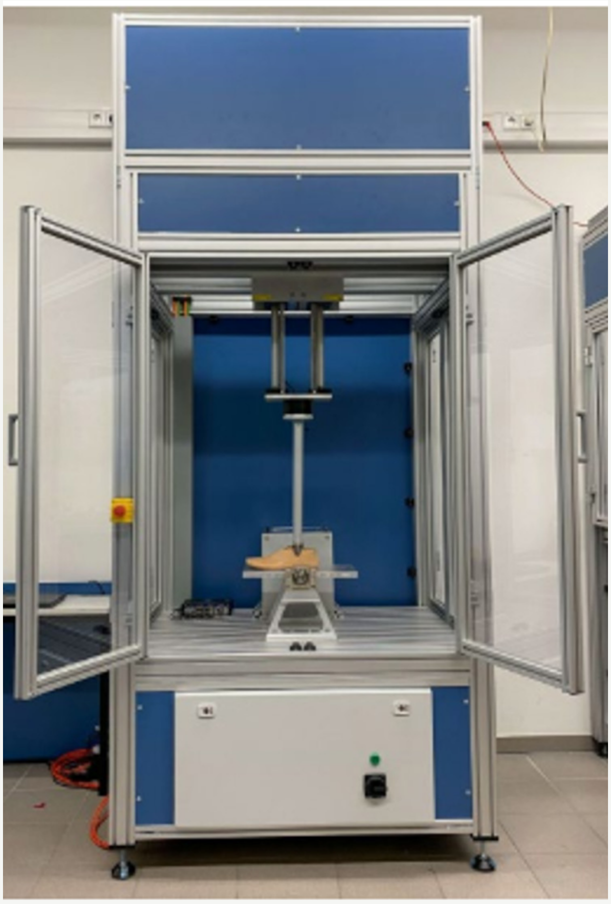

Figure 22. The AFO load cycle test setup of Hochmann (2024).

fatigue. This test setup cycles the load of walking for 2 million cycles (equivalent to 2 years of walking) to test material fatigue. See figure 22 for an example. There are only a few existing load cycle test setups known and the one that can be bought is expensive: ~€70K.

Note that material fatigue first leads to loss of stiffness before product breakage (Hochmann, 2014). With most AFOs loss of stiffness occurs gradually over the amount of steps (cycles) that has been taken with the AFO.

2.3.4. Conclusion

After evaluating the most prominent safety risks, the time frame of the project, and the added value for the company, a decision was made to focus on building a load cycle test setup. With the following as the 4 main reasons for the decision: 1. Stiffness test machines are less expensive and more widely available. 2. Dynamic impact setups can be more easily built and the product development of this failure mechanism can be evaluated by trial and error. 3. There are only a few existing load cycle test setups known and the one that can be bought is expensive: ~€70K. 4. Cyclic loading is the largest reason for (3D-printed) AFOs to fail, as high cycle material fatigue occurs at relatively low stress levels, and cyclic loading testing requires specialized expensive testing equipment and a significant amount of time.

2.4. Redefined Design Brief

The main redefined design goal:

Design a proof-of-concept load cycle test setup which can simulate 2 million steps (~2 years of walking) with an AFO

While static loading and impact testing should be performed as well during the development of the 3D-printed AFOs, the focus for this project is load cycle testing.

Before choosing to develop a load cycle test setup, it was already identified that building such a test setup which could do multiple test runs of 2 million cycles, would be unachievable within the time frame. Thus the aim for this project was set at developing a proof-of-concept build.

This proof-of-concept test setup should be prototyped cheaply and quickly, to learn what is required to develop the right test setup. This proof-of-concept will allow the company to develop and optimise this design into a final load cycle test setup that can endure test runs of 2 million cycles.

2.3.5. Key Design Questions

Method used: - How-To's (DDG)

For the design of a load cycle test setup, several Key Design Questions were identified, see Figure 23. These Key Design Questions are formulated in How-to? questions. They were formed based on findings of the *1. Introduction* and *2. Analysis* phases. In the *3. Concept* phase they are ideated, prototyped, iterated, and decided on.

Identified Key Design Questions formulated as How-to questions:

1. *How to define the load that should be cycled on the AFO and for how many cycles?*

- *Gait analysis: What is gait from a biomechanical point of view and which gait pattern to simulate normal/abnormal?*
- *How do we simplify this gait into a model to be able recreate it in the test setup?*
- *What should the dimensions and angles be in the test setup?*
- *How many and at what speed should the loading cycles be performed and how many test runs should be completed to guarantee product safety?*

2. *How to apply the correct load on the AFO?*

3. *How to test: simulate gait in one or in separate actions?*

4. *How to fixate the AFO in the test setup?*

5. *How to evaluate test results?*

6. *How to test safely?*

In the subchapter *3.1.Ideation on Key Design Questions* elaboration is given on why these Key Design Questions are important and how they are answered.

2.3.6. Requirements

Method used: - Requirements (DDG)

Based on the findings of the *1. Introduction* and the *2. Analysis* phase, a set of main requirements were defined, see Table 3. A full set of requirements can be found in *appendix 10.6*.

Key Design Questions:

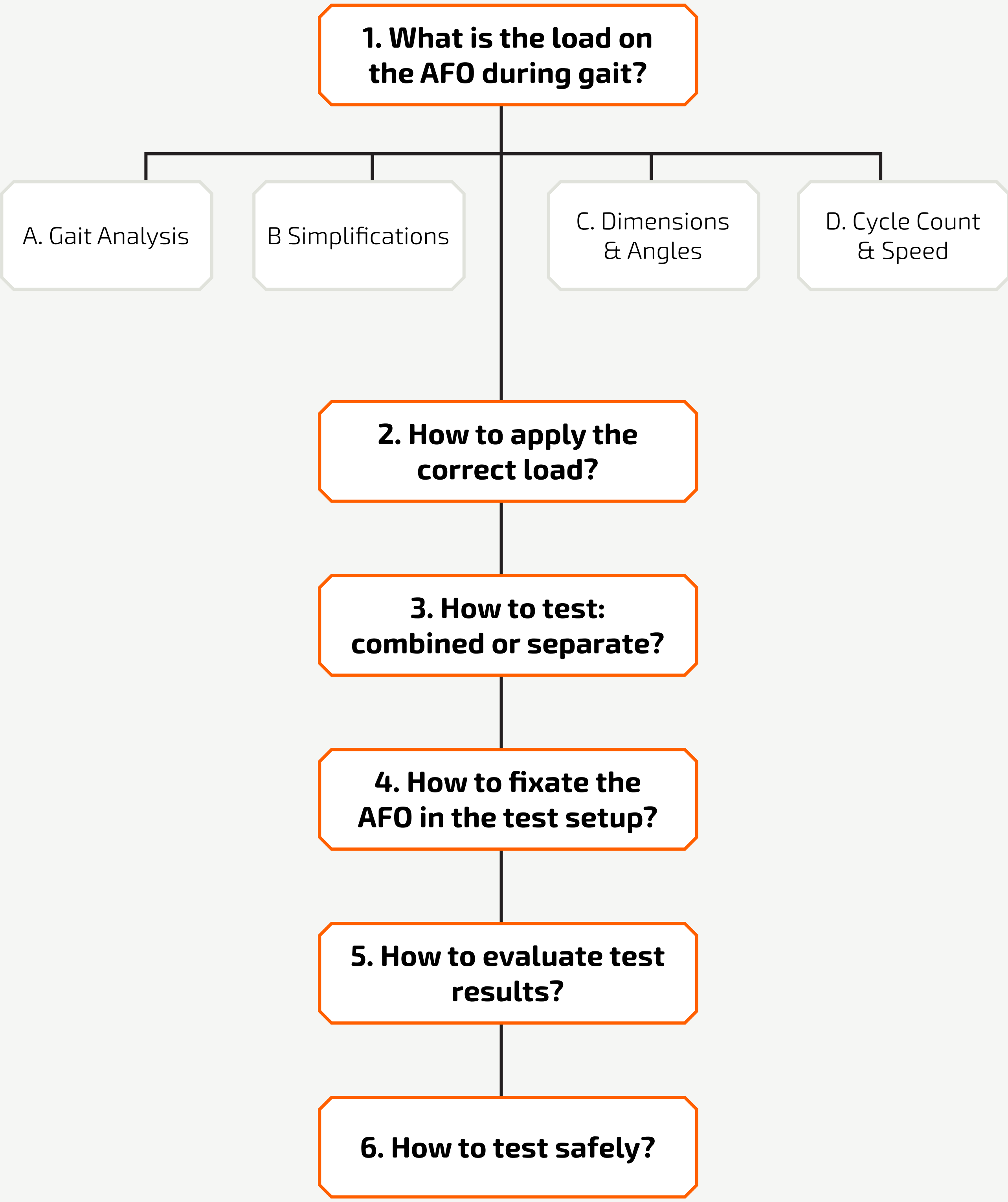

Figure 23. Key Design Questions of the Redefined Design Brief.

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Main guiding requirements		
#	Requirement	Source
R1	**Enable load cycle testing simulating 2 years of walking**	This was the conclusion of researching the product usage and breakage of AFOs and cataloging all existing AFO test setups that could be found on the internet. See chapter *2. Analysis*.
R2	**The loads on the AFO during gait should be recreated in the test setup**	In the reviewed literature there is data available on how much force there is on the leg while walking, but there is no data or knowledge available on how much force an AFO carries when a patient walks with it. By speaking to AFO testing expert D. Hochmann, it is known that this is a critical challenging task to solve.
R3	**Gait should be simulated by recreating the 3 *rockers***	The research-through-design process of iteratively building the test setup and comparing it to real life gait led to this discovery. See chapter *4.1. Gait Analysis* and chapter *5.2. Cycle Testing*.
R4	**Allow testing of normal and a wide variety of abnormal gait patterns**	Based on findings from analysing gait with AFOs: chapter *4.1. Gait Analysis*.
R5	**Enable testing for a wide variety of AFOs**	As communicated by the supervisors from the client company (personal communication, 2024).
R6	**Simulate bending around the ankle & *MTP joint***	This is based on the experience of ***CPO'ers*** at the company, see subchapter *2.1.How do traditional & 3D-printed AFOs fail?* and appendix 12.3.
R7	**Allow evaluation of the tested AFO on damage**	As communicated by the supervisors from the client company (personal communication, 2024).
R8	**Safe for R&D operators and all other by-passers**	Common safety precautions.
R9	**Minimum amount of cycles per test run > 2 million**	This is directly taken from ISO 22675:2016 - *Testing of ankle-foot devices and foot units*.
R10	**Amount of runs > 20**	This is an estimation as it depends on the building price of the test setup. Once this price is known, it is advised to the client company to make a quick calculation with their budget what the minimal amount of runs would be to make a test setup viable.
R11	**Run time < 50 days**	As communicated by the supervisors from the client company (personal communication, 2024).
R12	**Cost price < ~€15.000**	As communicated by the supervisors from the client company (personal communication, 2024).
R13	**Allow testing at the office of the company**	As communicated by the supervisors from the client company (personal communication, 2024).

Table 3. Main requirements based on findings of the introduction and analysis phase.

Category	Explanation
Desirability	Developing a load cycle test setup was chosen because of the following 4 reasons: 1. Stiffness test machines are available in the industry. 2. Impact can be evaluated by trial and error. 3. The only purchasable load cycle test setup is too expensive (price tag ~€70K). 4. Cyclic loading is the largest reason for AFOs to fail.
Feasibility	In order to simulate cyclic loading on an AFO due to walking, it must be known what the forces are on the AFO. These forces consequently need to be recreated in the test setup.
Desirability	The movement of gait can be best described based on the 3 rocking motions of gait: ***heel rocker***, ***ankle rocker***, and ***forefoot rocker***.
Desirability	AFOs are worn to correct a wide variety of inefficient abnormal gaits to normal gaits. The test setup should allow to minimally simulate a normal gait as a representation of all abnormal gaits. Ideally it should also allow setting up the testing of a wide variety of abnormal gait patterns.
Desirability	The test setup should be able to test a wide variety of AFOs and a wide variety of sizes in order to keep the AFO design space of the company completely open.
Desirability	The test setup must simulate the bending in the AFO around the ankle & ***MTP joint***, as these are the spots where the most stress occurs due to bending.
Desirability	At each chosen amount of cycles it should be possible to evaluate the state of the AFO.
Desirability	The test setup should be safe while being setup, while running and should not cause any fire hazards.
Feasibility	2 million cycles is the chosen amount of cycles to represent two years of walking. This is based on an activity level of ~5000 steps per day (~2500 per leg).
Feasibility	Total number of runs that the test setup should last is at least 20 to deem this setup viable for its testing purpose.
Viability	The total run time of a test run should not exceed 50 days otherwise it takes too long to test products and iterate on them and it will prevent the test run from becoming too expensive. A cycle speed of at least 1 [Hz] is desired, as this will keep the run time ~42 days.
Viability	Target is somewhere below ~€15.000. Because the company is new to LE orthoses, they want to keep initial investments low.
Viability	This way prototypes can be tested on site to enable quick iteration on them. Therefore the device must not cause a fire hazard or produce more than 75 decibels (equal to the sound of a vacuum cleaner)

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3. Concept

After the 2. Analysis phase was concluded the design phase of the load cycle test setup was started. This phase had the following structure, see Figure 24.

First a concept for the test setup was made. In this phase the Key Challenge for realizing the design were identified and ideated on. Based on the chosen direction for the Key Design Questions a conceptual layout was chosen from newly ideated layouts and existing load cycle test setups. With this layout the embodiment design and building of the test setup was started.

While developing the test setup, continuous experimentation, testing, and comparison to real life gait was performed. A method called research-through-design. A model of the human gait was made. In this model, gait was analysed and simplifications were made in order to be able to comprehend and recreate the loadings of the human gait on the AFO. The loads, dimensions, angles, amount of cycles, cycle speed, and amount of test runs that the test should have, are all defined in this model.

The realized proof-of-concept test setup as a result of this process, is described in the chapter after. A final single cycle test of the movement was performed and compared to real life gait. Also a test run of the test setup is performed to evaluate the reliability. At last the test setup is assessed on desirability, feasibility, and viability against the main requirements.

With the learnings gathered from experimenting with the realized test setup a digital redesign was made. The redesign and its key components are presented, improvements over the realized test setup are discussed, and the redesign is also assessed on desirability, feasibility, and viability.

Chapter 3-6 are presented in this structure.

3.1. Ideation on Key Design Questions

Below, elaboration on the Key Design Questions, an outline of the ideas formed on them, and the key decisions made, are given. The ideas how to solve them were formed based on findings of the 2 Analysis phase.

1. How to define the load that should be cycled on the AFO?

The first question in designing a load cycle test setup is what should the load be that is going to be cycled on the AFO? This question has more sub questions and has proven to be difficult to answer. So it deserves its own subchapter in which the approach to answering this question is discussed, see chapter 4. Model. In the next How-to questions it is assumed that this correct load is known.

2. How to apply the correct load on the AFO?

After defining the correct load, the next key question is: how are we going to apply the correct load, and how are we going to cycle this load? This How-to can be divided into 3 main questions:
With what mechanisms can we simulate this load in the test setup?
With what types of actuators should we drive the(se) mechanism(s)?
How to measure if the correct load is applied?

CONCLUSION:

The choice of how the load is exactly applied and with what mechanism is one of the first core design questions. It has a broad range of options and solutions, and thus has to be thoroughly investigated. While it is one of the first core design questions, answering the next How-to questions first will give context and guidance in what type of mechanisms could be desirable, thus these are answered first in this chapter. Based on the chosen solutions of these How-to questions a

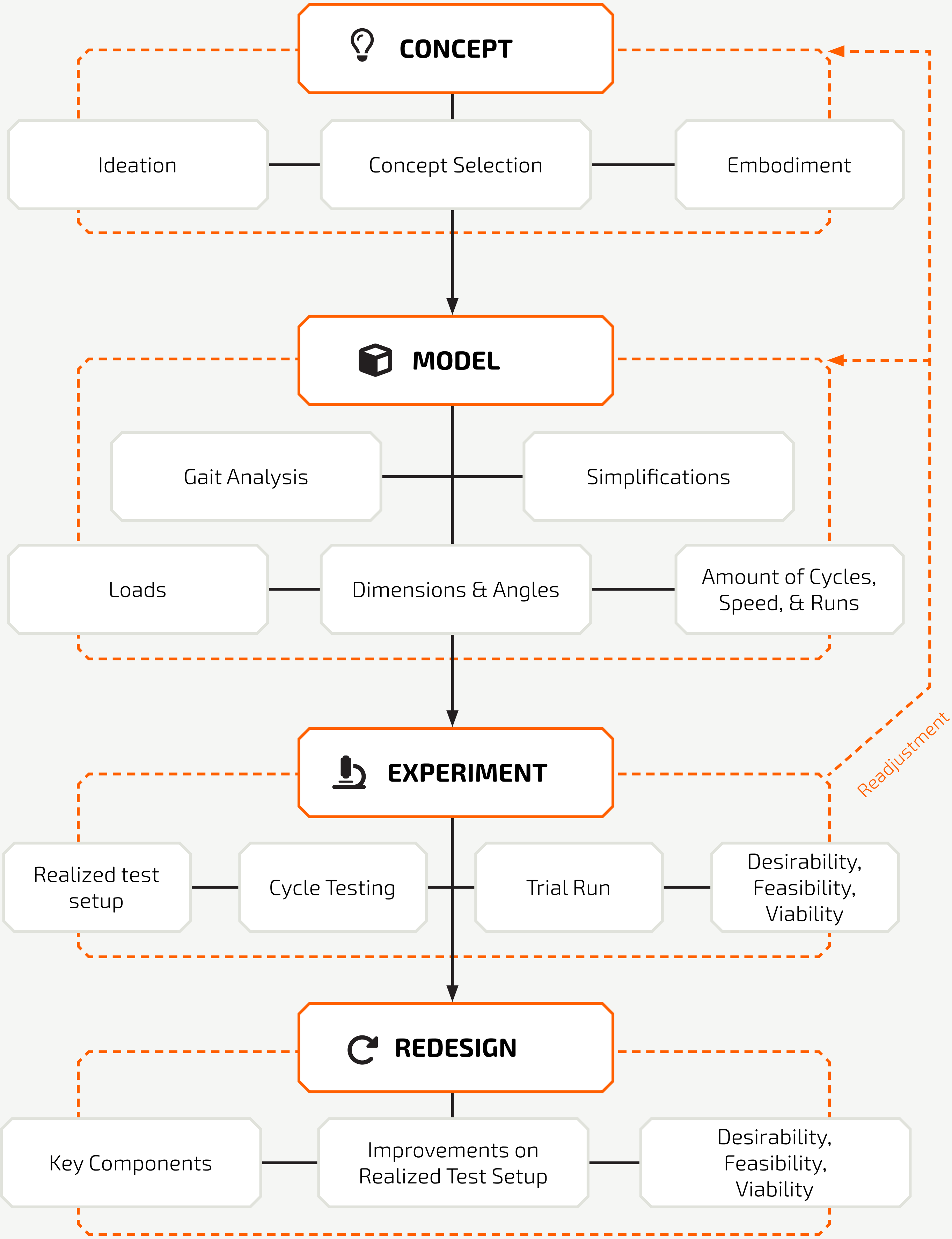

Figure 24. Structure of the design phases of the project.

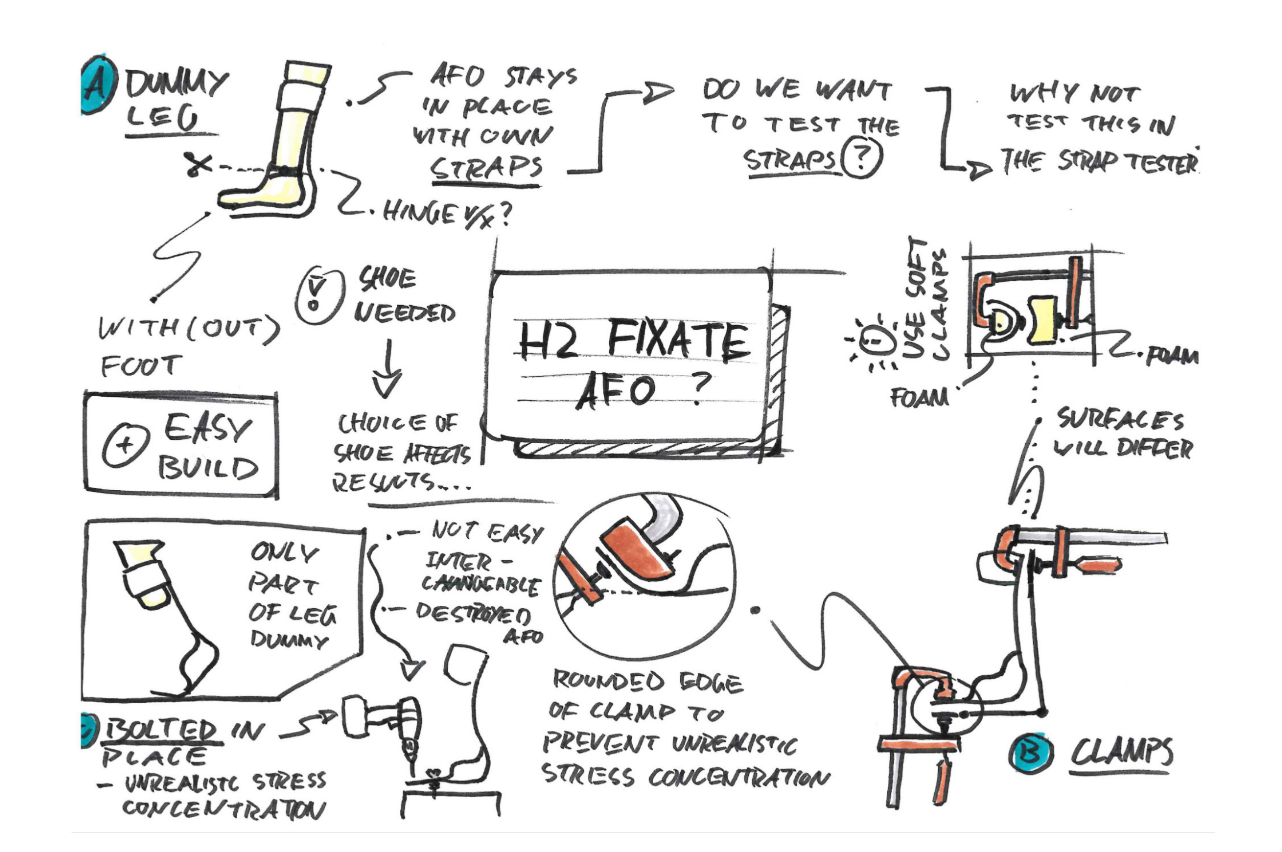

Figure 25. Ideation on 'How to fixate the AFO in the test setup?'.

conceptual layout is chosen. This is the content of the next subchapter 3.2. Concept Selection. The conceptual layout of the test setup will define which mechanism is used to recreate gait. Sub-research is performed in which actuators could best drive the chosen mechanism. This is found in appendix 10.8.2.

3. How to test: Ankle and MTP combined or separated?

In the ANALYSIS phase two hotspots for breakage in AFOs were identified: around the ankle and around the ***MTP***. A main consideration thus is whether to test bending and movement around the ankle and ***MTP joints*** combined or separately.

IDEATION:
It could be easier to test the loading of these hotspots in the brace separately, because this could split up the complex movement of gait to simpler linear or rotary motions.
On the other hand, it could be that splitting the loading of the strut and ***footplate*** creates less combined stress, making the test less realistic. Additionally, separate tests would require the development of distinct mechanical drives for each joint, which could increase development time. If the test setup were designed in a way that it could be configured for either bending around ***MTP*** or bending around ***ankle joint*** testing, the process would require two individual test runs—one for the ***MTP joint*** and another for the ankle. This approach would double the testing time to fully evaluate the brace.

CHOSEN SOLUTION:
Given these factors, it was chosen to go with a setup that tests both the ***MTP*** and ***ankle joint***s simultaneously. The loading of the ankle and ***MTP*** will be done within one mechanical action, as this will give the most resembling simulation of reality, while creating a compact test setup that can test the whole AFO with one test run.

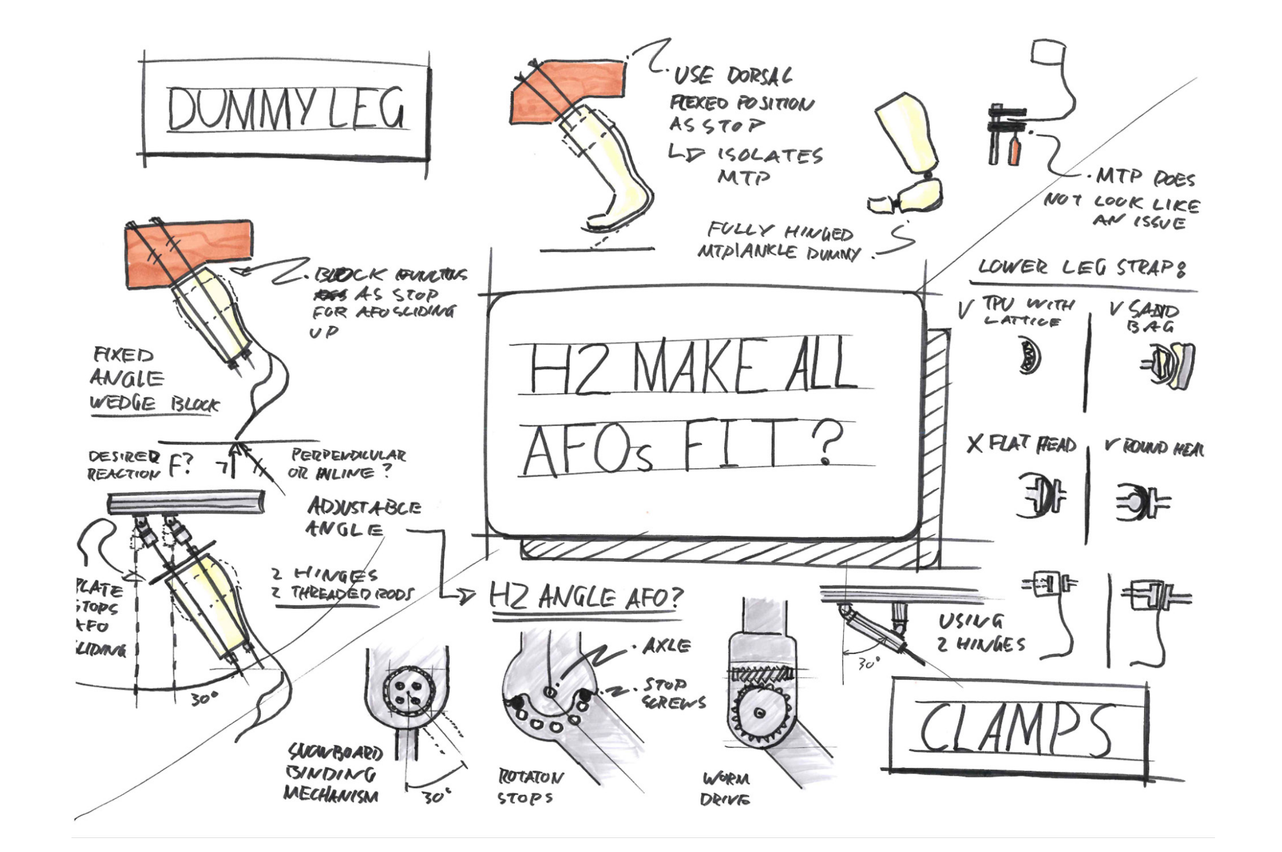

Figure 26. Ideation on 'How to make all AFOs fit in the test setup?' later reformulated to the Key challenge 'How to fixate the AFO in the test setup?'. How to angle the AFO is also ideated on.

4. How to fixate the AFO in the test setup?

In order to apply and cycle the same load each time, the AFO has to be fixated in place well. This fixation needs to allow holding the AFO in place for 2 million cycles, it should also be able to hold a wide variety of AFOs, and at last it should not create any unrealistic stress concentrations. Another part of this consideration is whether to include the straps/fixation of the AFO itself to the lower leg or to exclude this from the test.

IDEATION:
For this How-to question, two main solution directions were identified that had a significant impact on the working of the test setup. Two of the main idea directions were to: A. Secure the AFO with its own strap to a dummy lower leg or B. To clamp it down using (custom-made) clamps. See Figure 25 and Figure 26. To choose between the two, the following things were considered:

- Using a dummy leg offers a more realistic representation of how the AFO performs under actual conditions, then clamping it down. As the latter creates unrealistic stress concentrations.

- Leveraging the resources at the company makes the dummy leg approach easily accessible: With multiple scans of lower legs available, printing a dummy leg is both quick and straightforward. Making this a quick approach to prototype.

- A downside to dummy leg is however that this method introduces additional variables, potentially leading to less reproducible results. Hochmann experienced this effect during the development of his test setups (2024). For instance, the straps used to secure the AFO may loosen or break before the AFO itself fails, affecting the test outcomes.

- Clamping also presents its own challenges, particularly the need for adaptable clamp heads to accommodate various AFO designs. In contrast, the dummy leg can fit any AFO, as all AFOs are designed to fit lower legs, simplifying the setup process.

CHOSEN SOLUTION:
The final decision was to proceed with a dummy leg. The AFO will be strapped to and if needed a shoe is added to fix the ***footplate*** to the foot. With the main reasons being the ability to test all types of AFOs and to prevent any unrealistic stress concentrations. While it could lead to less reproducible test results, the aim is to see if we could avoid this with the right engineering.

5. How to evaluate test results?

This How-to can be divided into 2 questions:
How are we going to measure any emerging defects in the AFO?
How are we going to evaluate loss in stiffness during and/or after load cycling the AFO?
The test setup should test whether the tested AFO could provide 2 years of care: this includes not breaking down during the 2 million steps, while retaining its stiffness to an adequate level. The test setup should, however, also mainly aid in the development of AFOs to get these products to these standards. The ability to evaluate the effect of the cycled load on the AFO is thus of high importance.

IDEATION:
The most simple approach would be to count the amount of cycles electronically or mechanically and do a visual inspection after a certain amount of cycles. If the load cycle test setup is combined with a AFO stiffness test device like BRUCE (Bregman et al., 2009), the performance in the form of stiffness retention could be measured as well. This is the exact method Hochmann (2014) used in his load cycle test setup.

A more automated solution could be integrating one or multiple cameras in the test setup to take pictures of the AFO after each (or a certain amount of) cycle(s) to both inspect emerging structural weaknesses. This method provides a higher resolution of the emerging structural weaknesses. This high resolution comes with the disadvantage that a high quantity of image data needs to be stored. The question is if taking pictures every cycle is necessary.

CHOSEN SOLUTION:
The approach will be to develop the test setup first and evaluate the AFO with visual inspection, as it is expected that this is adequate to properly evaluate the AFO during and after load cycle testing. If based on that process, it is concluded that pictures need to be taken after each (couple) cycles, this automated system could be later developed and easily added.

6. How to test safely?

Concerning the safety of the test setup, there are the following main considerations:

1. How do we prevent the operator or any other bystander from getting hurt by the mechanical action of the test setup?
2. How are we going to make sure the machine stops running if the test setup or AFO breaks or misaligns to ensure the safety of the operator, the device and the test specimen?
3. What are the general safety precautions?

IDEATION & CHOSEN SOLUTIONS:

1. It is possible to create an enclosure around the mechanical action to prevent the operator and bystander from putting any limbs in the mechanical operation. The door of the enclosure could be wired to prevent the mechanical action ever from starting while the operator is mounting or dismounting an AFO in the test setup. However, the test setup will by the motion and sound running alone also give a clear impression that distance should be kept from the mechanical operation. Ideally an enclosure should be built, but it could also be chosen to leave out the enclosure and put the test setup in a room where it can run without any by-passers, to save development time and costs. The last was the decision made for now as it was not a priority. The enclosure could however be built after this graduation project if desirable.

2. The test setup should stop running immediately when a cycle deviates from the intended load profile. This way no unrealistic damage could be done to the AFO or the machine, due to misalignment or breakage of either one. How this can be exactly realised can depend on the conceptual layout of the test setup. But 2 general options are foreseen: 1. Measure the load profile with each cycle with the use of force and/or torque sensors. 2. Measure AFO position and displacement with the use of computer vision during each cycle. The choice is made to go with the first, as this will be a good indication if the machine and test is operating as it should and as it seems the easiest to realise at probably the same costs.

   [Note: Later on it was decided that it was not necessary to incorporate a force sensor into the design. It is however advised to add a solution in the final built to automatically stop the test setup if the the AFO or test setup itself breaks down]

3. General safety precautions are the following:

- Include a large kill switch to immediately cut all electronics.
- Isolate all electronics and wiring with cases and cable management to prevent electrocution or short-circuiting the electronics.
- Check proper heat management to prevent burns by touching components and prevent potential fire hazards.
- Always do trial runs with the test setup with a person keeping an eye on the test setup, before letting it run unattended.

The chosen directions were used in the next subchapter to shape and choose the general layout of the test setup.

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3.2. Concept Selection

During the Orientation phase, a desk research was performed in which existing solutions for load cycle testing AFOs were identified, see Table 4. Due to the important requirements to have a solution for a budget of max €15.000 (R12) and to be able to test at the company's own office (R13), the decision was made to build a test setup instead of buying one or outsourcing the testing. For the conceptual layout the existing test setups and newly ideated layouts (see appendix 10.7) were considered. A conceptual layout of an existing test setup was chosen to continue with: the ISO 22675 test setup (number 3. in Table 4). The decision, further explained in the next part, was made on the basis of the chosen ideation on the Key Design Questions and on the following factors (ordered based on perceived importance):

1. **Realism of the load simulation:**

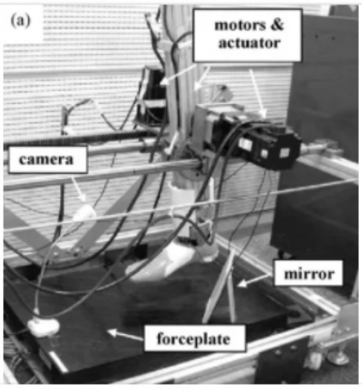
- Possibility to test both ***dorsiflexion*** and plantar flexion?
- Bending around the ***MTP*** integrated?
- Scientific backing?

2. **Possibility to test wide variety of AFOs**
3. **Standards (ISO, NEN, DIN)**
4. **Cycle speed**
5. **Simplicity**
6. **Predicted costs**
7. **Adaptability:**

- Freedom to change the gait pattern to a variety of abnormal gaits
- Possibility to expand to 3D: include loads and moments outside of the sagittal plane

8. **Date of publication: is it state-of-the-art or old-tech?**

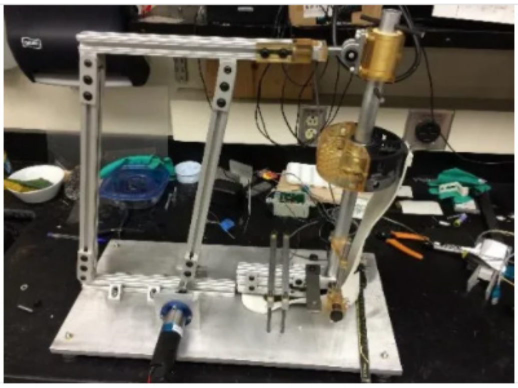
1. MAKstride AFO Durability Testing



4. AFS apparatus

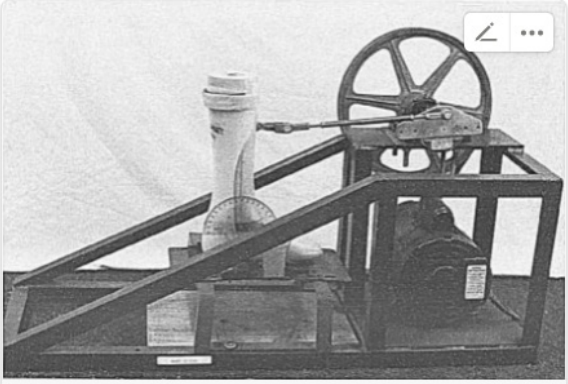
Aa Paper/Apparatus name	Type
1. MAKstride AFO Durability Testing	Load cycle
2. Gait cycle analysis and mechanical design of ankle foot orthosis testbed	Load cycle
3. ISO 22675 Fatigue ankle foot device Prosthetic Test Equipment	Load cycle
4. AFS apparatus	Load cycle
5. Viscoelastic Properties of Plastic Pediatric AFOs	Load cycle
6. Double Short Flexure Type Orthotic Ankle Joints	Load cycle

Table 4. Overview of existing load cycle test setups and their considered properties, that were found online.

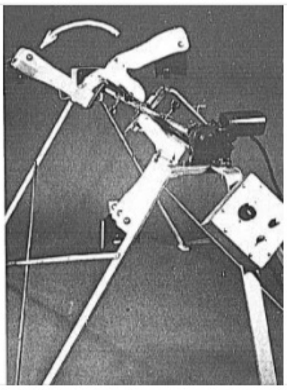


2. Gait cycle analysis and mechanical design of ankle foot orthosis testbed

3. ISO 22675 Fatigue ankle foot device Prosthetic Test Equipment



5. Viscoelastic Properties of Plastic Pediatric AFOs



6. Double Short Flexure Type Orthotic Ankle Joints

Joints	Flexion	Axis plane	cycles/s	Author	Publication	Source
Ankle	Plantar Dorsal	Sagittal	1.75	MAKstride	2021	(Thrive Orthopedics, 2021)
Ankle	Plantar Dorsal	Sagittal	?	Yin	2014	(Yin, 2015)
Ankle MTP	Plantar Dorsal	Sagittal Axial	1	Hochman	2014	(Hochmann, 2014)
Ankle MTP	Plantar Dorsal	Sagittal	0.56	Lai	2010	(Lai et al., 2010)
Ankle	Plantar Dorsal	Sagittal	2.17	Lunsford	1994	(Lunsford et al., 1994)
Ankle	Plantar Dorsal	Sagittal	?	Carlson	1990	(Carlson et al., 1990)

Chosen conceptual layout:

3. ISO 22675 Fatigue ankle-foot device Prosthetic Test Equipment

The ISO 22675 Fatigue ankle-foot device Prosthetic Test Equipment is a test setup for testing lower leg prosthesis, see Figure 27. It can however be adopted to test AFOs with it, as demonstrated by Hochmann (2014 & 2024), see Figure 22 in the before going *2.3. Selecting a Test Setup Type to Build* chapter. To see the working of this test equipment visit: www.youtube.com/watch?v=4R7qW9EXk9k. It was chosen to recreate this setup and redesign it, so that it allows testing of AFOs.

The layout of this test setup was chosen, because it simulates gait realistically with a simple design: solely a linear and a rotary actuator.

Figure 27. ISO 22675 based load cycle test equipment for prostheses made by STEP Lab (2024).

These actuators provide the Ground Reaction Force and angling of the leg to the ground as input respectively. Because these actuators can be precisely controlled they allow testing of a wide range of different abnormal gaits. The cycle speed of 1-20 [Hz] is also an acceptable-to-really-fast speed range. As the test setup is defined in an ISO standard, it is well proven (numerous test setups based on this standard are already built and being used) and there is excellent documentation on: how the test setup works, how it should be built and be operated.

Next to this, it was also possible to contact an expert on using this type of test setup for orthosis testing, who was willing to help us: D. Hochmann. He has been working on this orthosis testing for at least a decade. As a chairman of AFO testing for the DIN standard in Germany, he is developing a DIN standard for AFO durability testing with the use of this test setup. After the DIN standard is approved he aims to also make it an ISO standard. As Germany has one of the largest AFO markets in the world and because the company has its focus on expanding to Germany, it is highly desirable to adhere to this standard as soon as it is out there. Buying an existing test setup however is costly: ~€70.000 (origin of price indication is given in the next paragraph). Hochmann is however also open for performing testing or helping with the development of testing equipment for a reasonable fee, more on that in the next paragraph.

Outsourcing vs. In-House Development of Test Equipment

Test setups built according to ISO 22675 are produced by research labs or companies that need the equipment to test themselves, but there are also companies that build and sell the equipment to others. The Biomechatronics lab led by Hochmann at the Hochschule of Münster is an example of one such research lab that builds the test equipment for its own use.

One of the companies that sells this test equipment, STEP Lab, was approached for a quotation. The price of this test machine is €70.000. Quantify BV, a company that performs consulting and testing for other companies in Belgium (Quantify BV, 2025), was also referred to if outsourcing of testing is desired.

With Hochmann (2024), testing at his lab was also discussed. His rough price indication was €5.000 - €6.000 to test 2-3 AFOs. Additionally, Hochmann suggested a paid collaboration for the development of our own testing equipment.

The decision was made to try to develop and adapt the load cycle testing equipment within this graduation project. The focus will be on building a proof-of-concept with the right load cycle. After the project, the test setup should be further developed to reach the 2 million required cycles.

3.3. Embodiment

As just described, based on the ideation and chosen solution on the Key Design Questions, a conceptual layout was chosen: the conceptual layout from the ISO 22675 standard for testing prostheses.

As test setups built according to this standard are highly complex and expensive, it was deemed to be too challenging to fully recreate one and adapt it for orthosis testing within this project completely. Thus it was chosen to develop a first proof-of-concept built in this graduation project, as the first step to developing the final full fledged test setup.

An iterative approach was taken for building this proof-of-concept test setup, to be able to learn quickly how it should be adopted for orthosis testing.

The approach was split into two-stages:

1. First get the loading of the AFO in the test setup right of the most critical loading moments during gait separately.
2. After, chain these loadings together to create one complete load cycle in the test setup.

If stage one would be finished, stage two could be continued.

As described later on, in this graduation project a physical build of stage one was achieved. This is the realized test setup of this project. Based on the learnings with testing with this realized test setup a design was made of stage 2. This design is referred to as the Redesign (chapter 6 Redesign) in this report.

Start of Embodiment of Stage One

A quick concept was made to start the embodiment design and building of the test setup with. A sketch of this concept can be seen in Figure 28.

Directly after, a test setup frame was built based on this concept to prototype, test and iterate the solutions to the Key Design Questions on. Prototyping these components on the same frame provided a continuous holistic check on the design, as the test setup could be tested and evaluated as a whole.

In appendix 10.8 the performed embodiment design and prototyping is elaborated on in detail in a chronological order. View this appendix to read about the findings of the performed prototyping and how the design came to be.

The fundament of the test setup is its model of the chosen representation of gait in reality. This model was developed iteratively with the test setup. The learnings from prototyping and testing with the test setup were used to improve the model with. This is the core of the research-through-design approach as used in this project.

Next the final model of the realized test setup will be discussed. After the realized proof-of-concept test setup will be presented, the testing performed with it and the found learnings.

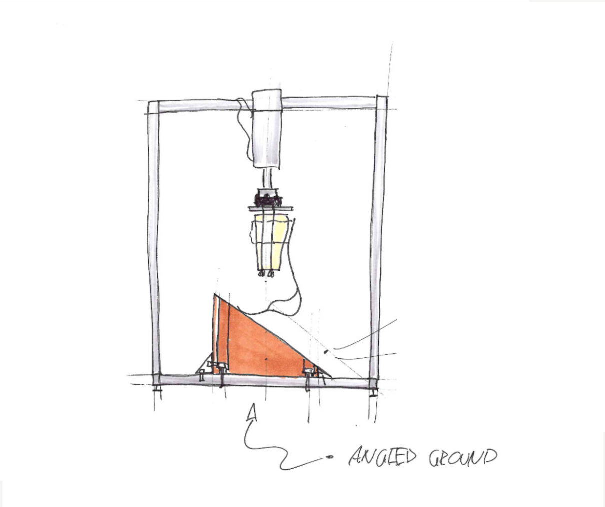


Figure 28. Sketch of the concept adopted for testing orthoses instead of prosthetics.

4. Model

After choosing a conceptual layout for the test setup, a model was made to define the exact forces and angles that should be created during a cycle.

The five most important identified questions for making this model are:

1. **Gait analysis: What is gait from a biomechanical point of view and which gait pattern to simulate normal/abnormal?**
2. **How do we simplify this gait into a model to be able recreate it in the test setup?**
3. **What are the loads on the AFO during gait?**
4. **What should the dimensions and angles be in the test setup?**
5. **How many and at what speed should the loading cycles be performed and how many test runs should be completed to guarantee product safety?**

Why are these the most important questions? First of all it needs to be known what ***gait*** is from a biomechanical standpoint to be able to understand the movement and forces at play. This is done by literature research and video analysis of gait. There is also a wide variety of abnormal gaits with a wide variety of AFOs trying to correct this abnormal gait to a normal one. It must be possible to recreate them all in the test setup or find a good representational gait pattern of all possible gaits. This first question **1.** is essential as it will determine which forces and angles need to be controlled in the test setup and it will determine their exact values during a cycle.

Next this gait must be translated to a simplified model to be able to understand and recreate it. This model includes simplification and defines how gait is seen in this project from a mechanical standpoint. This is question **2.**

Within this biomechanical model it needs to be defined what the magnitudes and directions of the loads on the AFO during gait are. This is question **3**

It also needs to be defined what the exact dimensions and angles need to be in the test. This is question **4.**

At last if the load cycle is defined it must be determined how many cycles in a test run represent 2 years of walking and how many test runs should be made to guarantee product safety. This is question **5.** These 5 main questions will be answered in this chapter.

4.1. Gait Analysis

To be able to create a load cycle that simulates the cyclic loading of walking, it is essential to understand human gait. Gait is the term used to describe the way a human walks. It captures the movement of one leg during its stance and swing phase, see Figure 29. For the load cycle test setup only the stance phase will be relevant as only during this phase the leg and AFO are loaded.

Ground Reaction Force (GRF)
In the human gait cycle, the ground reaction force, the reaction force the ground exerts on the leg, varies and forms a characteristic “M-curve” when plotted over time, see Figure 32. This curve shows two peaks with a dip in between. When a patient walks with an AFO, the leg and AFO combined will carry a force similar to the GRF plot.

Initially in the project the main identified critical loading phases were these 2 peaks in GRF during gait. These were thought to be during ***initial contact*** (also called heel strike) and ***terminal stance*** (push-off), see Figure 29. However, during the process of iteratively building the test setup and comparing it to real life gait, it was found that in reality the first of the two peaks does not occur during ***initial contact***, but after during ***loading response***. As indicated with the red vertical line in the red accented phase in Figure 33. During this phase, the foot lays flat with the ground and the body weight is slowly fully transferred to this leg. The lower leg hinges over the ankle, creating a ***rocker*** motion called the ***ankle rocker***. This finding is based on video comparisons as later described in chapter 5.2. Cycle Testing.

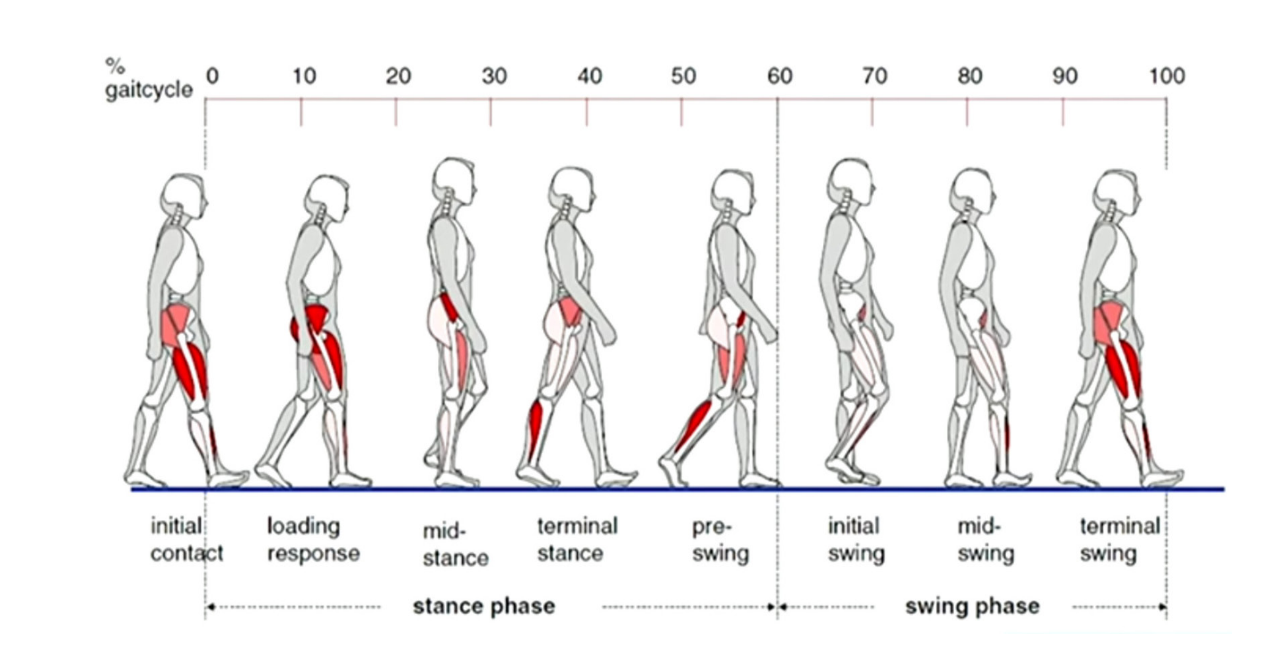


Figure 29. Overview of the phases during gait (Livit Ottobock Care, n.d.-b).

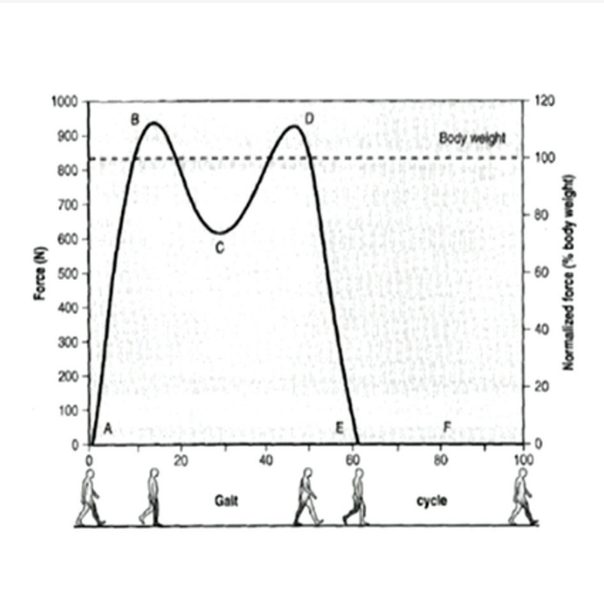


Figure 30. The Ground Reaction Force during normal gait (Livit ottobock care, n.d.).

After finding this out, the conclusion was made that the three ***rockers*** during gait best describe the most distinct phases of the loading of the AFO.

The Three Rockers

What are the three ***rockers***? During a step the foot undergoes three distinct motions, the three rockers:

1. ***Heel rocker***
2. ***Ankle rocker***
3. ***Forefoot rocker***

These three rockers, see Figure 31, best describe the main loadings of an AFO within a step.

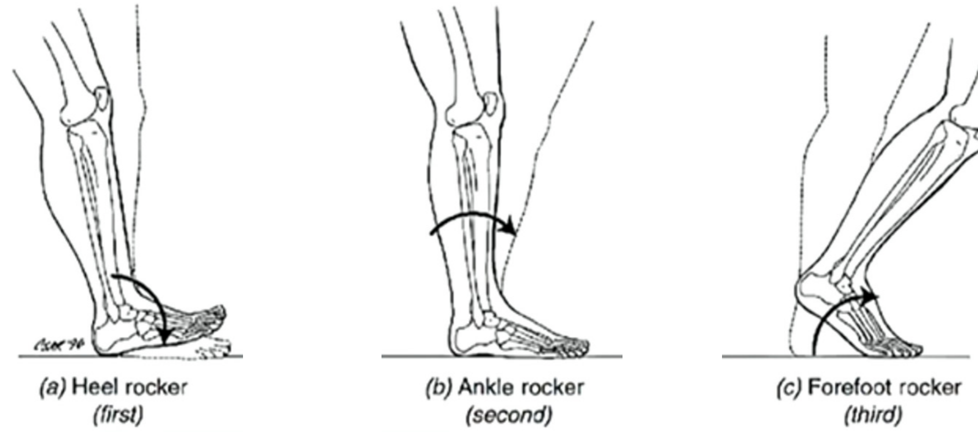


Figure 31. The three ***rockers*** of human gait.

Explanation of the three ***rockers*** and how the AFO deforms during these phase:

In the (1st) ***heel rocker*** the foot lands on the ground during initial contact. The foot rolls over the heel in plantar flexion until the foot lays flat with the ground, see the blue phase in Figure 33. In this motion the AFO is loaded in plantar flexion in the area of the ankle. The most extreme deformation of this phase is shown in the top image of Figure 32. The bending seems little, but from experience of CPOs it is known that due to this rocker there is alot of stress in the junction between the AFO footplate and strut. *Note that in this figure a healthy person is wearing this brace, the deflections are however similar. The exact moment of the image is indicated with the blue line in Figure 33.

From this point the (2nd) ***ankle rocker*** starts, see the red phase in Figure 33. The foot stays flat with the ground, while the leg rocks over the ankle in ***dorsiflexion***. During this motion the weight is slowly transferred to the leg during loading response, this can be seen in the GRF M-curve as the first peak. Because of the momentum the force exceeds the body weight by around 20%. Here the AFO bends around the ankle area in ***dorsiflexion***, see the middle image of Figure 32. This image again shows the most extreme deformation and is at the red line in Figure 33. At the end of this ***rocker*** the bodyweight is dropped, relieving the pressure on the foot for a moment, this is the dip in the GRF M-curve.

After the ankle rocker is completed, the (3rd) ***forefoot rocker*** starts, see the yellow phase of Figure 33. The heel starts to lift and the foot starts to rock over the forefoot. In this motion the toes and foot plate of the AFO are bent in the ***MTP*** area to match the ground, see the bottom image of Figure 32. This image again shows the most extreme deformation and is at the yellow line in Figure 33. The GRF reaches its second peak during this push-off movement to propel the body forwards. At the end of this phase the other foot starts its stance phase. Allowing the weight to be shifted from this from this foot. The initial foot leaves the ground and the stance phase transitions into the swing-phase. The cycling of these phases form the human gait pattern.

In the test setup the 3 ***rockers*** need to be recreated to accurately simulate gait with an AFO, as each ***rocker*** causes a different deflection in the AFO. A load cycle representing the three ***rockers*** can be recreated with the following data: lower leg and foot dimensions of the largest patient the AFO is designed for, and the Range of Motion ***(ROM)*** plots over time of the angles of the 3 most important joints during gait: the ***ankle joint***, the knee joint and the hip joint. At last the load on the AFO during gait needs to be known.

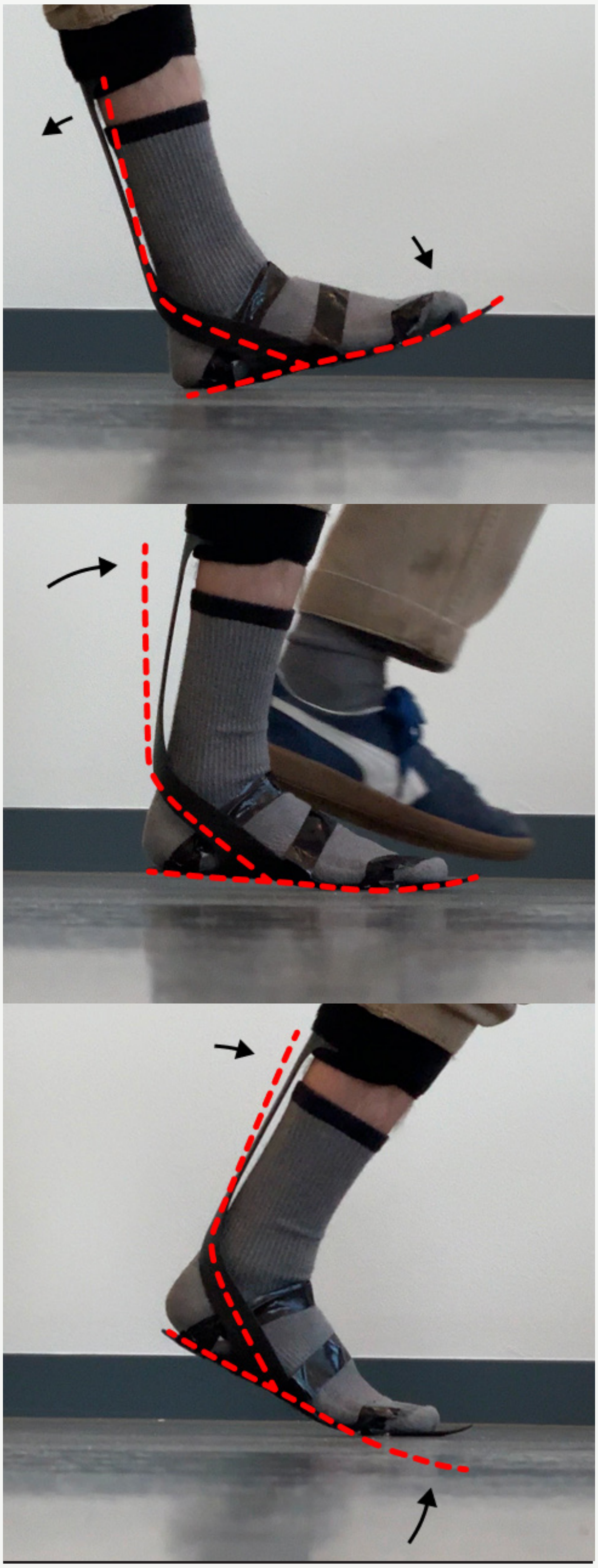


Figure 32. The most extreme deformations of the AFO during the three rockers: ***heel rocker*** (top image), ***ankle rocker*** (middle), ***forefoot rocker*** (bottom). Instead of wearing a shoe, the AFO is taped to the foot to be able to see the deformation. The red dotted line shows the AFO without deformation. Arrows indicate bending direction.

Load Distribution Between Leg and AFO

Although the total load on the leg is known, it is not known what the exact forces on the AFO are during gait. The distribution between AFO and leg also differs per AFO type and the specific gait deviations of the patient. What the exact force is on the AFO during gait is one of the fundamental challenging questions that needed to be answered in this project. The answer is given in detail in the upcoming subchapter 4.3.Measuring and Recreating the Loads. First it is discussed which gait pattern is going to be simulated.

Which gait pattern to simulate?

A wide variety of pathologies cause abnormal gait patterns (Cvoha & Deckers, 1996). These pathologies cause muscle weakness or spasms that affect the gait pattern, resulting in less efficient and slower walking. This change in pattern can be seen in the ***ROM*** angle plots of the joints. AFOs are used to assist patients with such an abnormal gait pattern to allow them to walk closer to a normal gait.

The wide variety of abnormal gait patterns, brings up the question of what gait to simulate? Ideally, the typical abnormal gait pattern associated with the condition for which the specific orthosis is designed for, should be simulated. However, it might be quite challenging to obtain the data of the specific abnormal gait. It must either be found in existing databases or be created with the specific patients. Given the wide variety of abnormal gaits, it will also not be possible to test them all. The chosen approach is to simulate a normal gait with the dummy lower leg and brace. This approach is chosen, as the goal of AFOs is to correct/allow patients to walk in a normal manner. This will provide a less specific type of testing, but it will provide a generalistic type of testing that can be used for all AFOs. This saves time and makes comparing AFOs test results possible. The test setup is however built to allow testing of a wide variety of gaits. As it might later be desired to test specific abnormal gaits. These different abnormal gaits can be recreated by adjusting settings of the test setup.

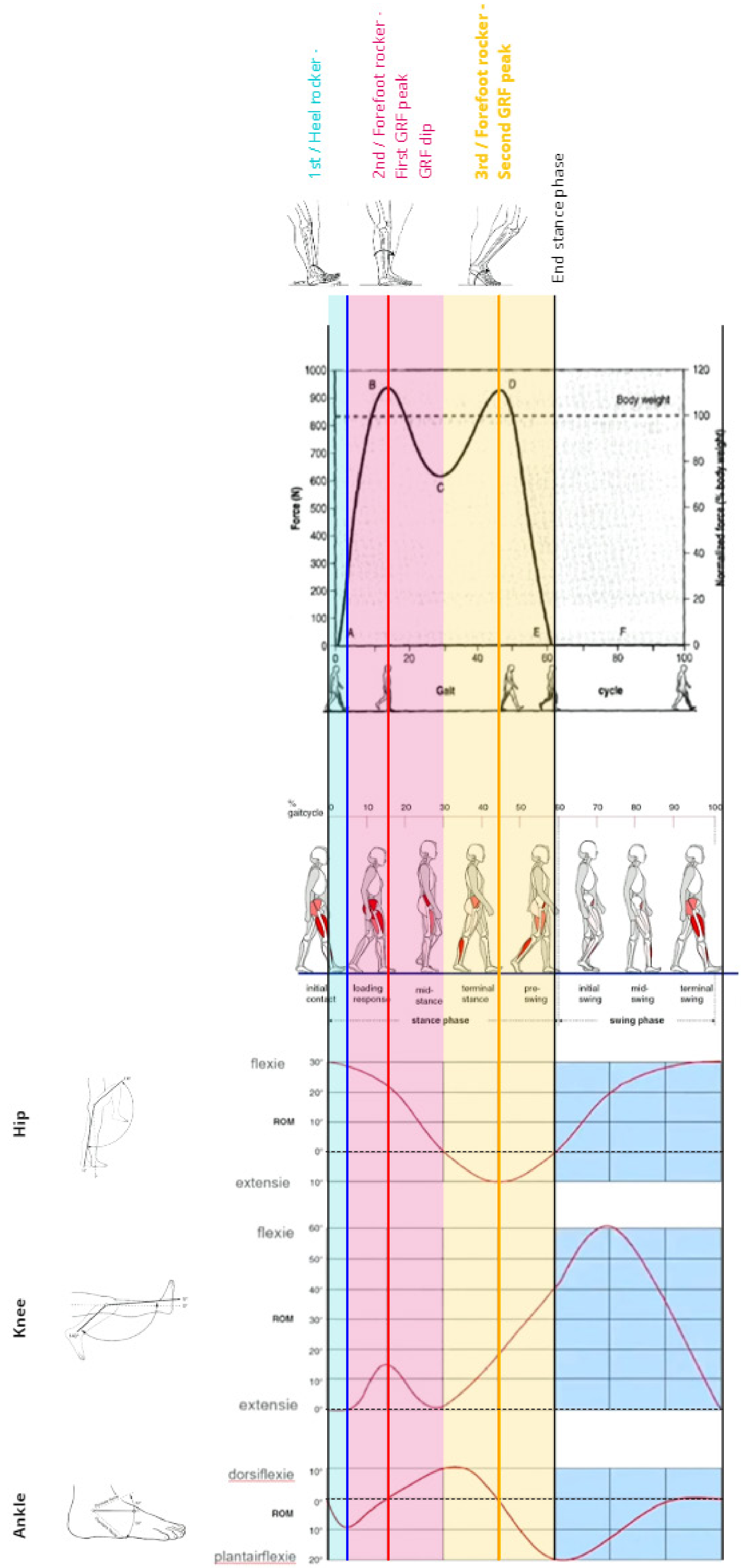

1st / Heel rocker -
2nd / Forefoot rocker -
First GRF peak
GRF dip
3rd / Forefoot rocker -
Second GRF peak
End stance phase
Force (N)
Normalized force (% body weight)
Body weight
Gait
cycle
% gaitcycle
initial contact
loading response
mid-stance
terminal stance
pre-swing
initial swing
mid-swing
terminal swing
stance phase
swing phase
Hip
Knee
Ankle
flexie
extensie
ROM
dorsiflexie
plantairflexie

Figure 33. The ***Rockers***, GRF, the different phase of gait and Range of Motions (ROMs) of the essential joints aggregated in one time-line (verified with video analysis of gait). The blue phase is the ***heel rocker***, the red the ***ankle rockers***, and the yellow the ***forefoot rocker***.

Conclusions

- In the test setup the 3 ***rockers*** need to be recreated to accurately simulate gait with an AFO, as each ***rocker*** causes a different deflection in the AFO.
- A load cycle representing the three ***rockers*** can be recreated with the following data:
- lower leg and foot dimensions of the largest patient the AFO is designed for, and the plots of angles over time of the 3 most important joints during gait: the ***ankle joint***, the knee joint and the hip joint.
- The total force over time is known by measuring the GRF during gait. However, the critical unknown is the load distribution between the leg and the AFO. In this project a method must be made to define the loads on the AFO in order to recreate them.
- It is chosen to simulate a normal gait as a representation of all possible abnormal gaits. The test setup should however allow to also test each abnormal gait by tweaking parameters or adjusting the setup.

4.2. Simplifications

The next question is how should this gait be modelled?

The starting point is looking at literature on the relevant forces and angles of real life gait, as described in the last subchapter. This model is based on that knowledge.

The AFO will be loaded during the stance phase of gait, from initial contact to pre-swing (see figure 29). During the stance phase the body weight is carried by the standing leg and by the AFO that is worn. The swing phase will not be of relevance, because the leg will not endure any loading in this phase.

In this model the stance phase of gait is split into three parts, the three ***rockers*** of gait: 1. ***Heel rocker***; 2. ***Ankle rocker***; 3. ***Forefoot rocker***. The ***rockers*** provide the rolling motion of a step and create the forward motion of walking. The 3 ***rockers*** also define the three most characteristic different types of loading on the AFO during gait. See (1), (2), and (3) respectively in figure 34. Also look back at chapter 4.1 Gait Analysis for more explanation.

List of simplifications Made:

- The 3 ***rockers*** will be tested separately in the realized test setup, to reduce complexity.

- The situation will be simplified to 2D. In this case the sagittal plane (side view of the human body). This is common simplification in literature when looking at gait analysis (Cvoha & Deckers, 1996). As the significant loads during walking operate in this plane.

- For the biomechanical model it is chosen to look only at the lower leg, consisting of everything below the knee, as the AFO only interacts with this part of the leg.

- The shoe keeps the ***footplate*** of the AFO stuck to the foot. In the model the lower leg, shoe and AFO are thus seen as one body. Internal loads are neglected.

- The weight of the shoe and AFO are not considered within this model.

- In the designed test setup the perspective is switched: the orientation of the leg is kept the same, while the angle of the ground changes between the 3 ***rockers***. See figure 35. This is done as it splits up the up and down movement and the angle between the ground and the leg, making it easier to influence these parameters separately. It will also allow easy integration of a ***dynamic ground surface*** (***DGS***) in a redesign allowing to link the 3 ***rockers*** together, creating one full step in one cycle.

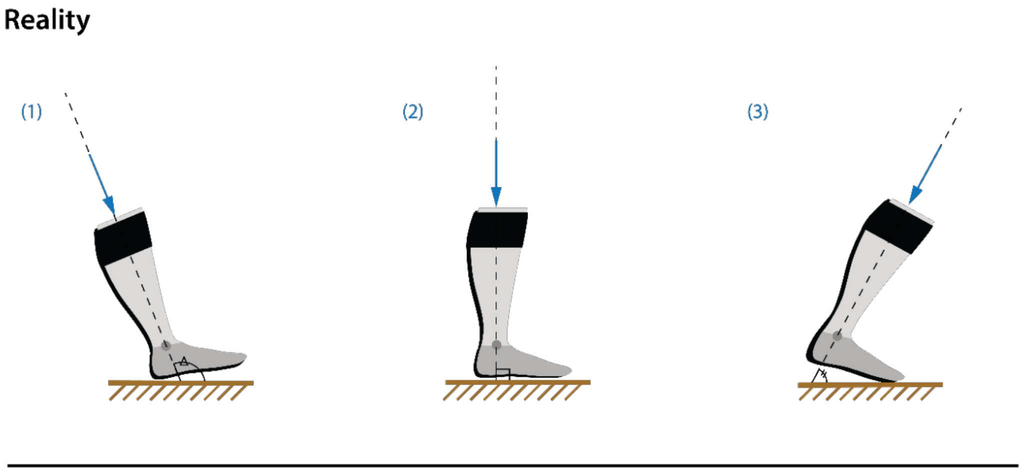


Figure 34. **Analysis of real life gait:** In this project gait is viewed as consisting of the three ***rockers***. The first (1) is ***heel rocker*** creating plantar flexion of the foot. The second (2) is ***ankle rocker*** in which the foot goes from plantar to dorsal flexion. The third (3) is the ***forefoot rocker*** in which the foot rolls over the toes. Blue arrows indicate the weight of the body on the leg.

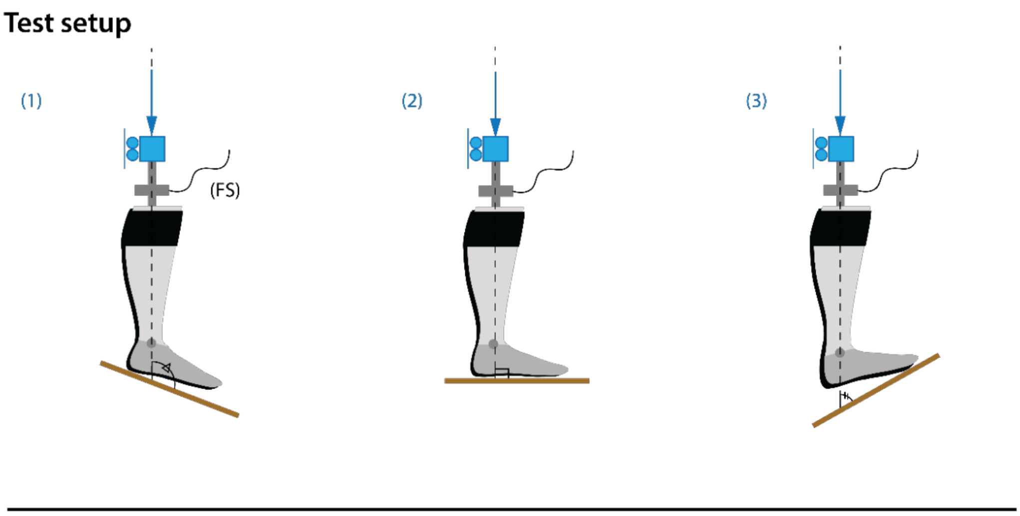


Figure 35. **The test setup:** The orientation is changed. The up and down movement is still being performed by the leg, but the orientation of the ground is changed for each ***rocker*** instead of the orientation of the leg..

4.3.Measuring and Recreating the Loads

The gravitational force of the body weight is the load applied to the leg during gait. As a result, the ground provides an equal reaction force to the leg called the Ground Reaction Force (GRF), see subchapter *4.1. Gait Analysis*. This GRF during gait can be measured in real life with force-measuring plates. The plot of the GRF overtime during the stance phase is known as the M-curve and is well-established scientific knowledge (Cvoha & Deckers, 1996). During this gait it is however unknown how much of this force is carried by the AFO and how much is carried by the lower leg. This is essential to figure out, in order to be able to recreate the loads on the AFO in the test setup. This will be the next question answered below.

Two approaches are foreseen to determine the force on the AFO:

A. Use an instrumented AFO with strain gauges to measure the forces.
B. Measure displacement of the AFO during gait with video analysis.

A. Measuring the Forces with an instrumented AFO

It is possible to measure the forces by integrating strain gauges in an AFO. With this measuring device you could measure the strain in reality and in the test setup to align the latter with the first. This approach was taken by Hochmann (2024), see Figure 36. While this method provides data on the exact strains in the brace, it seems hard to tweak the test setup based on this data. If the strain is too much in a specific spot in the test setup, how do you know which angle or force to change? This approach is also not easily transferable to other AFO designs. Another factor is also that building such an AFO with strain gauges could be a graduation project in itself. As it is fairly complex to build such an instrumented AFO, while a cheap and simple solution is desired. It is possible to ask if Hochmann is willing to share this AFO with strain gauges or the data, to be able to tweak the test setup built in this project. This would however create a big dependency. Because of the above reasons this direction was deemed undesirable.

Figure 36. Top: Orthosis with integrated strain gauges on a patient in order to measure loads on AFO during real life gait. Bottom: Same orthosis with integrated strain gauges on a dummy leg in a load cycle test setup to verify if the applied loads are correct (Hochmann, 2014).

B. Measure displacement of the AFO with video analysis

The other approach is using displacement as a starting principle: if we can accurately capture the realistic deflection over time of a brace during gait and replicate it in the test setup, the load on the AFO will be the same, if it is assumed that the stiffness of the brace does not change over time. As the deflection of an object is a direct and consistent result of the force applied to the object (Hooke's law). As displayed in standard tensile tests or 3-point bending tests. With this approach the displacement in the test setup needs to be measured and controlled to match the real-world displacement.

This can for example be done with the use of video comparison. Shoot a reference video of a person with normal gait walking with the brace and shoot a video of the brace in the test setup. Compare the displacement by, either comparing screenshots of the 3 most important identified phases during gait, the three ***rockers***, or by doing complete motion tracking. The first was tried out during the project, see Figure 37 and *appendix 10.8.5*. This method will be used to evaluate the realized test setup to determine if it simulates loading of the AFO during gait adequately. This approach is a new idea not seen in the AFO testing literature yet. It is a way simpler solution to figure out the load on the AFO than the instrumented AFO with strain gauges. A major result of this project and possibly for the industry was the idea to determine the load during gait on the AFO with this method.

Approach B. raises the question if the displacement during gait of every different AFO, that is desired to be tested, needs to be measured. Ideally yes, but a solution to prevent this could be to use a benchmark AFO that is matched on displacement. If the assumption is made that the same amount of force would be applied to all other AFOs, this could be used as the chosen load settings for each test with the load cycle test setup. To verify this assumption, it is advised to test this process with a couple of AFOs and see if the deflections and required forces are acceptably similar.

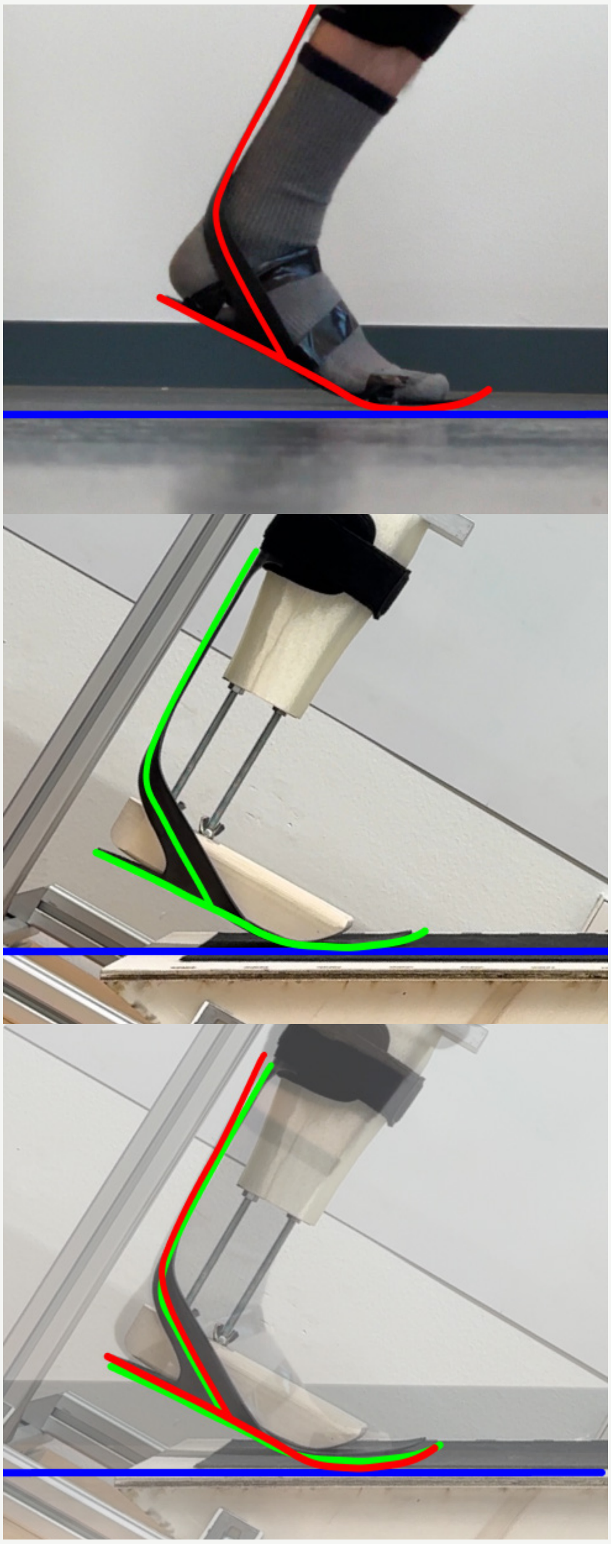


Figure 37. 1st image: Screenshot of ***forefoot rocker*** from the reference video shot of a person with normal gait walking with an AFO. The form of the AFO is accented by the red line. 2nd image: Screenshot of video shot of the same AFO under load in the test setup trying to simulate ***forefoot rocker***, the form of the bent AFO is accented by the green line. 3rd image: Comparing displacement between reference video and test setup by laying the images on top of each other. In this example the right bending was not yet acquired in the test setup.

Decision

The decision was made to go with approach B. Measure displacement in the AFO. It saves time compared to developing an AFO with strain gauge, which only represents that typical AFO. While this method seems easy to scale generalise for all the different kinds of AFOs out there.

Controlling Displacement in the Test Setup

With approach B. the way to get the right displacement on the AFO within the test setup is either; 1. Applying more or less force to match the displacement as seen in the reference video, or 2. Applying an overload of force and limiting the brace to only bend to the same angles or displacement as seen in the reference video.

Initially the first was desired as in this manner the force could be deducted with this method, which could be interesting to know. However, to acquire the correct bending in the ***footplate*** it was necessary to introduce a footblock to force bending in the area around the ***MTP***. This meant that the footblock would also carry force applied to the brace and thus the second approach had to be continued with.

4.4.Dimensions & Angles

Dummy Leg Dimensions

What should the dimensions be of the dummy leg?

The relevant dimensions of the dummy leg are the popliteal height (height of the lower leg measured from the ground until the knee) and the foot length, as defined in chapter *1.5 Product Usage*. These dimensions are the most important for fitting an AFO. The dummy leg should match these dimensions with the patient desired to simulate. If testing with only one patient, which should represent a larger patient group is required, the dimensions should be based on the largest person for which the brace is designed. This way the levers and resulting moments are the largest and the safety of all patients with smaller dimensions can be assured.

Ground Surface (GS) Angles

What should the exact angles during the 3 ***rockers*** *be of the GS?*

The set angle of the GS resembles the angle between the tibia (shin bone) of the lower leg and the ground. This angle is created by the hip and knee joint angles combined. They change in each ***rocker***. These angles can be taken from the reference video and can be checked on correctness against ***ROM*** angle plots of the joints as described in literature, see Figure 33 in subchapter *4.1. Gait Analysis*. As described earlier in that chapter the angles of the joints during gait are for everybody with a normal gait around the same. With abnormal gaits the change of angle during walking in these joints is different and thus the walking efficiency and speed is affected.

The exact angles during the different ***rockers*** are shown in Table 5.

Table 5. Ground Surface (GS) angles

Rocker	Hip (°)	Knee (°)	GS (°)
1. Heel rocker	-30	0	**-30**
2. Ankle rocker	-20	15	**5**
3. Forefoot rocker	10	20	**30**

For the ***heel rocker*** this is -30° in flexion for the hip and 0° for the knee (the blue line on the end of the blue phase of the ROM plot in Figure 33). Giving a total of -30° for the GS.

For the ***ankle rocker*** this is -20° in flexion for the hip and 15° in flexion for the knee (the red line in the middle of the red phase in Figure 33). Giving a total of 5° for the GS.

For the ***forefoot rocker*** this is 10° in extension for the hip and 20° in flexion for the knee (the yellow line in the middle of the yellow phase in Figure 33). Giving a total of 30° for the GS.

4.5. Amount of Cycles, Cycle Speed, and Amount of Runs

Amount of Cycles

Each test run should consist of 2 million cycles. ISO 22675 defines this amount of steps/cycles as the standard to test with (ISO, 2016).

Cycle Speed

ISO 22675 defines that the cycle speed should match the speed of walking, 1 Hz (one step per second), to assure the most realistic simulation. 2 million at 1 Hz cycles takes around 23 days of continuous running of the test setup. It would thus be desirable to speed up the cycle speed to shorten the time it takes to do a test run. However, according to Hochmann (2024) faster speeds cause heating in the material, speeding up the wear unrealistically.

Amount of Runs

According to ISO 22675, a load cycle test run with a minimum of 2 different prosthetics should be done to claim compliance with the standard (ISO, 2016). Again it is advised to follow this standard for orthosis as well.

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5. Experiment

5.1. Realized Test Setup

The build test setup (see Figure 39) utilizes a Static Ground Surface (SGS), rather than a ***Dynamic Ground Surface*** (***DGS***). This choice was made in order to do testing of the three ***rockers*** separately, before adding the complexity of a rotating platform. This Static Ground Surface can be changed in angle to replicate the different angles during gait. This test setup allows for the initial evaluation of the loading of the AFO during the three ***rockers*** separately. The testing and evaluation in this chapter is done with this realized test setup.

The test setup consists of these components, see Figure 39:

1.1. Linear pneumatic actuator. Including an guidance rod to fixate the rod around its axis.

1.2. Electric 5/2 way valve to operate the pneumatic actuator.

1.3. Seeeduino Lotus with relay connected to the power grid to control the 5/2 way valve (Figure 38).

2.1. Adapter plate to mount the dummy calf to the rod of the linear actuator. Includes a guidance rod to prevent the rod from turning around its axis.

2.2. The AFO being tested.

2.3. Printed calf mounted on the actuator. The AFO is strapped to this calf.

2.4. Foot block to mount the AFO (and possibly shoe) to and to force bending around the ***MTP***. (2.3 and 2.4 together make up the dummy lower leg.)

3.1. Static Ground Surface which can be adjusted in angle.

3.2. The frame consisting of modular 40x40 aluminium profiles.

Dummy Lower Leg

The lower leg dummy consists of a 3D print made of a 3D scanned calf (male p50) and a simple foot block to mount the AFO and shoe to and to force bending around the ***MTP***. See 2.3 and 2.4 in Figure 39 respectively. The foot block is not the full foot length, but the length from heel until where the ***MTP joints*** in the foot are located, see figure 100. This is to allow bending of the ***footplate*** of the AFO past the ***MTP***. The foot block is screwed rigid to the calf. No artificial joint is concluded yet in this realized dummy leg.

Automation

The test setup automation was prototyped with the use of an Arduino micro-controller, see Figure 38. However, the final version of the test setup might require a different micro-controller. The electric 5/2 way solenoid valve for operating the pneumatic linear actuator is controlled by the Arduino. The valve used required an operating voltage of 230 [V]. A relay was used to control the valve. Code was written to switch the flow of the valve for each cycle automatically. This setup allowed the autonomous cycling of the test setup. Mechanical control by hand is also still possible.

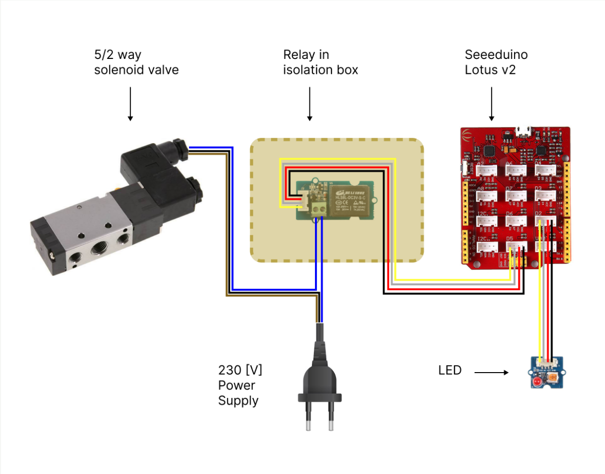


Figure 38. The test setup automated with an Arduino micro-controller, a solenoid valve and relay to control the valve with the Arduino.

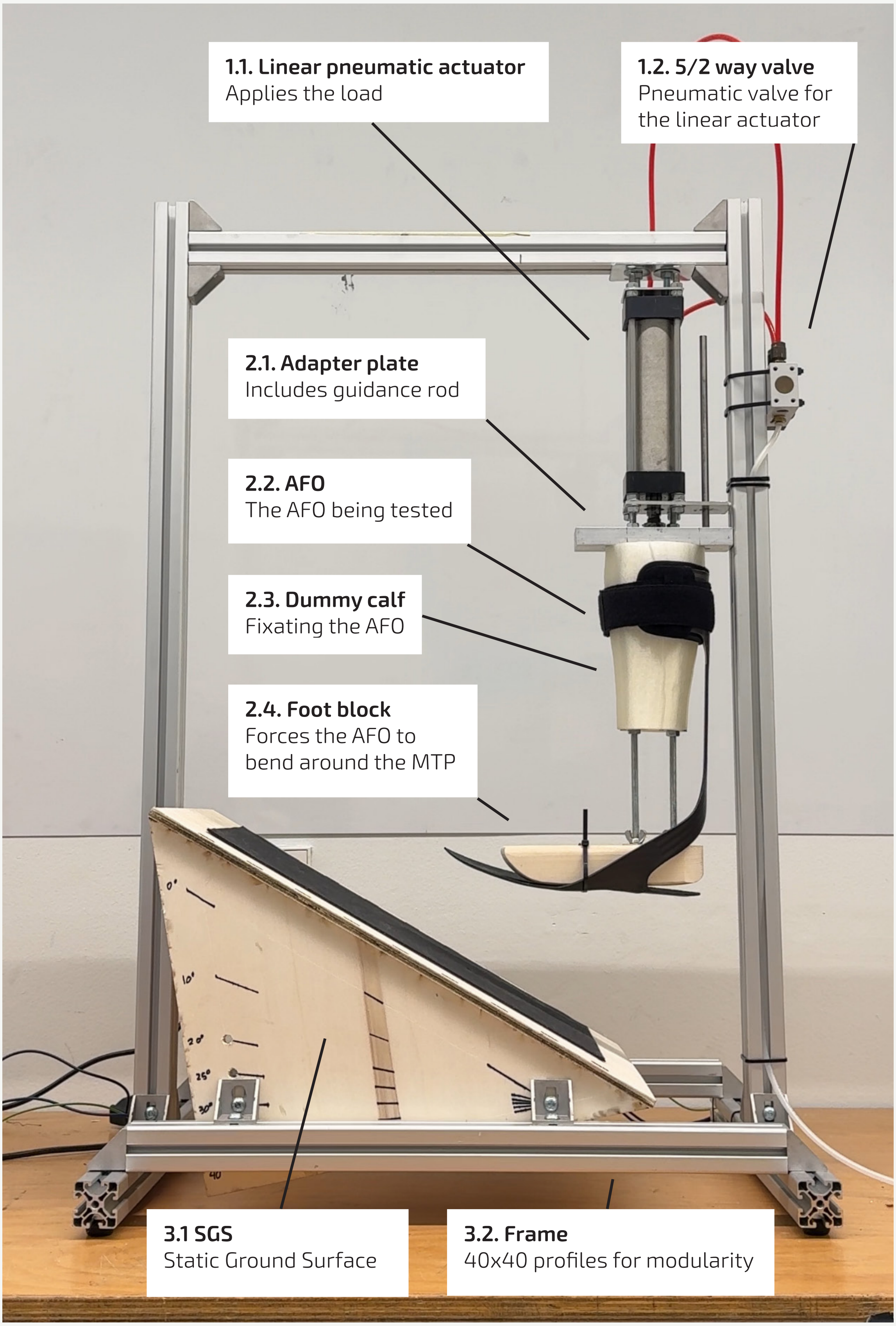


Figure 39. The test setup built within the project with a Static Ground Surface. Annotation of the components included.

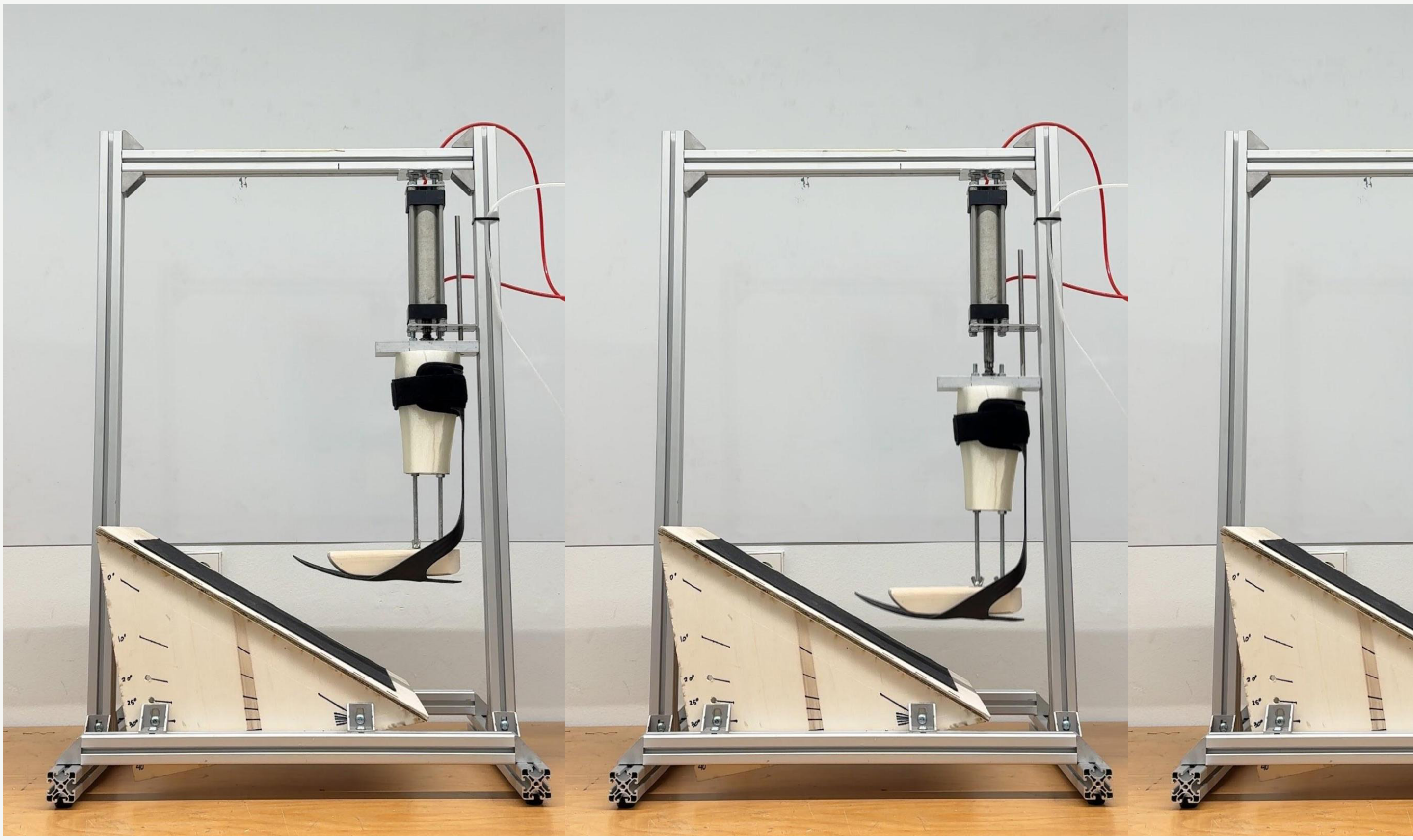
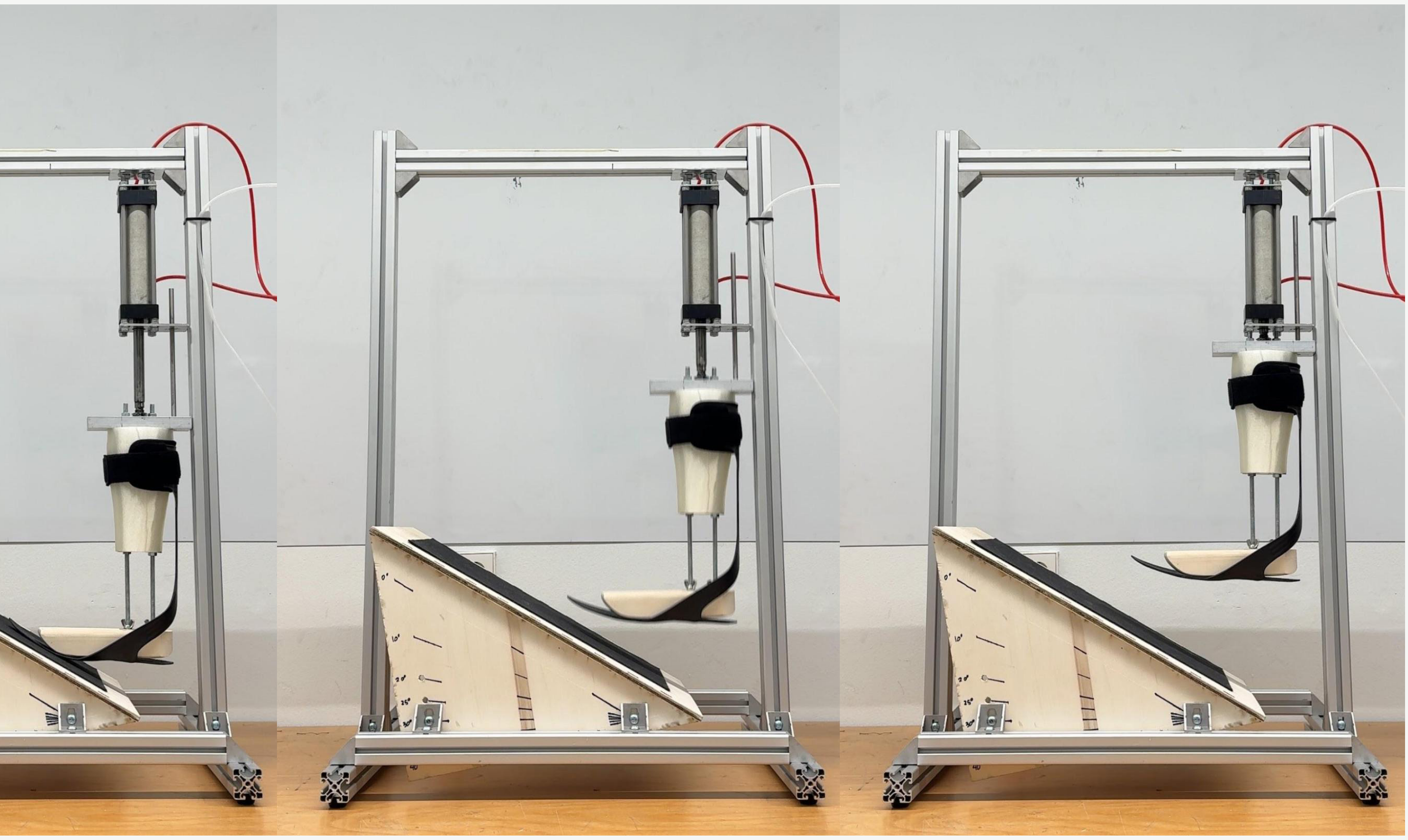


Figure 40. Load cycle motion of the realized test setup. In this example the ***forefoot rocker*** is depicted.

How does it work?

The stepping motion is simulated by strapping the AFO to the dummy leg. This dummy leg is attached to a linear actuator, which replicates the up-and-down movement of a step. The dummy lower leg with the AFO lands on a platform, the Static Ground Surface (SGS) representing the ground. See Figure 40. With the force of the pneumatic actuator the AFO bends when it is the SGS, recreating the loading of the AFO during real life gait.

In real gait, the lower leg rotates in relation to the ground. In this test setup, the perspective is inverted: the leg is not angled and only moves vertically, while the ground surface is angled. This is done as it splits the up and down movement and the angling of the leg. This allows the complex motion of a step to be simulated with only one linear and one rotary actuator. The change of perspective can be made as the resulting forces and their direction stay the same.



The angle of the SGS can be changed to test the different angles of the three ***rockers***. The pneumatic actuator and the dummy leg can be moved along the top 40x40 profile to change the test setup from ***heel rocker*** to ***forefoot rocker*** setup.

5.2. Cycle Testing

The three ***rockers*** (1. ***Heel rocker***, 2. ***Ankle rocker***, and 3. ***Forefoot rocker***) were tested with this realized test setup separately. Video analysis of the test setup was used to compare the bending of the AFO in the test setup with the bending of the AFO in the reference video of a person walking with the same brace.

The angle of the Static Ground Surface for each ***rocker*** was based on the angle found in the reference video and this angle was checked with the literature. See chapter *4.4.Dimensions & Angles*. See Table 5 for the exact angle of the GS for each ***rocker***. The pressure of the linear pneumatic actuator was set excessively high, so that the AFO always fully deformed as far as the dummy leg and Ground Surface allowed.

[Initially it was the aim to create the deflection with the output force of the pneumatic cylinder. However the inclusion of the foot meant the AFO could bend not further than the foot block allowed. Thus the correct bending was recreated by restricting the movement to the correct angles instead.]

Findings of comparing each ***rocker*** in the test setup to the reference video:

Heel Rocker

With the current rigid dummy leg without an ***ankle joint***, ***heel rocker*** is not possible, see Figure 41. For this motion the foot has to drop to match the ground surface. This movement is called plantar flexion (see Glossary and the middle image of Figure 41). It is also a critical movement in the loading of the AFO, as only in this phase the AFO is bent in an overextension direction. This is not possible with the current rigid dummy leg, see bottom image of Figure 41, as it does not allow rotation of the foot. A dummy foot with an ***ankle joint*** is necessary to allow this movement. Without this, the ***heel rocker*** cannot be properly simulated.

Figure 41. Testing ***heel rocker*** with the realized test setup (top image) and comparing it to the reference video (middle and bottom image).

Ankle Rocker

Initially in the project the main identified critical loading phases were the 2 moments during gait where the GRF reaches its peak. See the GRF M-curve of Figure 30 in chapter *4.1. Gait Analysis*. These moments were thought to be initial contact (heel strike) and terminal stance (push-off), see Figure 29 of that chapter.

However, by analysing the reference video it was found that in reality these two peaks occur during loading response and terminal stance (push-off), see Figure 33. The main loading of the AFO strut and first peak of the GRF actually occurs during loading response and not initial contact (heel strike). During this phase, the foot lays flat with the ground and the lower leg hinges over the ankle, see Figure 42, creating a ***rocker*** motion: the ***ankle rocker***.

After finding out that the strut of the AFO was mainly loaded due to this ***ankle rocker***, the insight was acquired that the three ***rockers*** best describe the most distinct phase of the loading of the AFO during gait. The three ***rockers*** were consequently used as the 3 main phases to evaluate the loading of the AFO on. This was incorporated in the model as described earlier in chapter *4. Model*.

In the realized test setup with the static ground surface, the ***ankle rocker*** however can not be recreated, as the dummy leg and the ground have to rotate in relation to each other to recreate this ***ankle rocker*** motion.

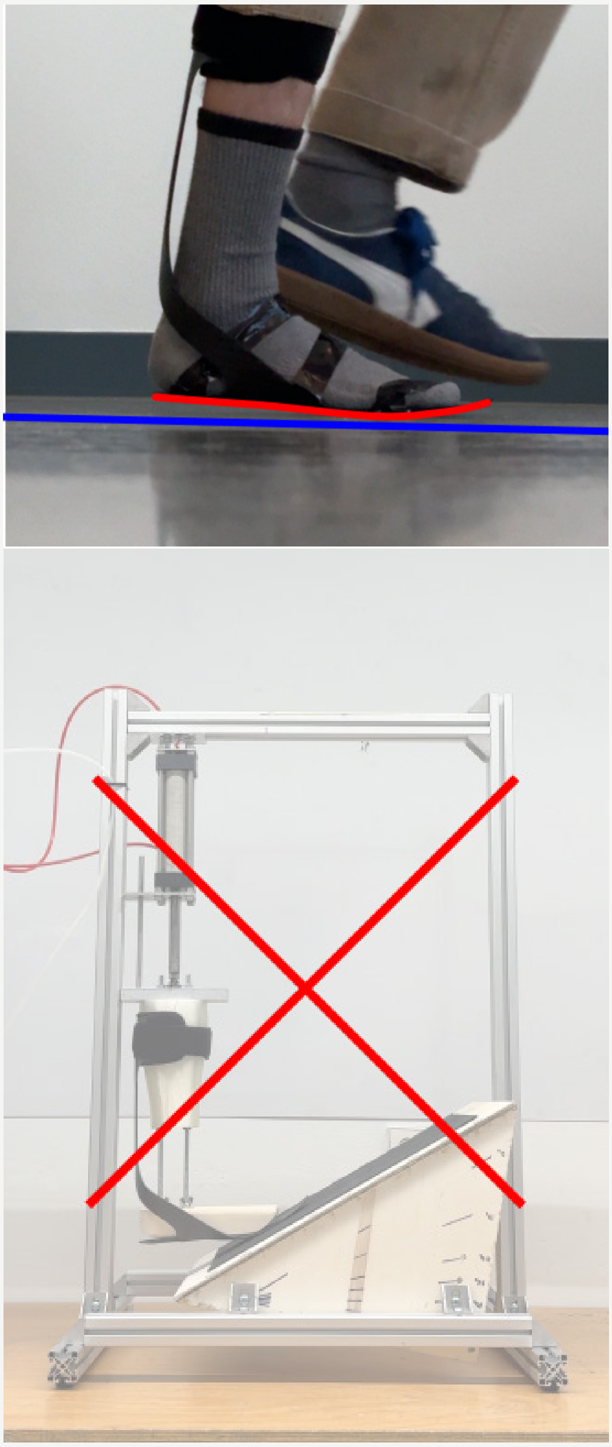


Figure 42. Top is the reference video showing ***ankle rocker***, in which can be seen that the backstrut of the AFO is fully loaded. Bottom shows the test setup with which this ***ankle rocker*** cannot be evaluated with.

Forefoot Rocker

With this test setup the ***forefoot rocker*** can be simulated. As can be seen in Figure 43 , the deflection of the brace in the test setup matches reality well.

During this phase of gait the AFO mostly bends in the ***footplate***, as can be seen in the reference video. In the test setup the same deflection is acquired. The foot block forces the ***footplate*** of the AFO to bend around the ***MTP*** as intended.

During this phase there is little bending of the strut as can be seen in the reference shot. Again this is the same in the test setup.

Thus it can be concluded that the ***forefoot rocker*** can be evaluated with this realized test setup.

Conclusion

The proof-of-concept test setup provided valuable insights into how the test setup layout functions for each individual ***rocker***. The main findings are:

1. **Three rockers**
   Instead of looking at only the two peak GRF moments, the three ***rockers*** of gait should be looked at and recreated to properly simulate the loading of an AFO. These 3 ***rockers*** are integrated in the gait analysis and model, after this insight was made in this testing.

2. **Heel rocker cannot be simulated**
   With the current rigid dummy leg without an ***ankle joint***, ***heel rocker*** is not possible. For this motion the foot has to rotate to match the ground surface.

3. **Ankle rocker cannot be simulated**
   The second ***rocker***, the ***ankle rocker***, can not be simulated with this test setup, as it also requires a rotating movement of the foot. To recreate this rotating movement the foot needs to rotate together with the ground surface during the cycle.

4. **Forefoot rocker can be simulated**
   The ***forefoot rocker*** can be accurately simulated with the test setup. During this phase the AFO mostly bends in the ***footplate***. In the test setup the same deflection is acquired.

Figure 43. Testing ***heel rocker*** with the realized test setup and comparing it to the reference video. Top is the test setup, middle the reference and bottom the comparison.

5.3. Trial Test Run

A trial test run was performed to test the reliability of the test setup. The plan was to conduct a one-hour trial run with the realized test setup, simulating the ***forefoot rocker***, and spot any reliability issues that may occur during the run.

Research Goal
This trial test run aims to evaluate the test setup's reliability. Reliability is a crucial factor in designing the load cycle test setup, as it must be capable of conducting test runs of 2 million cycles autonomously without failure. Achieving reliable execution of multiple test runs of 2 million cycles is expected to be one of the significant engineering challenges. Thus, it is best if this is evaluated early and throughout the process of designing the desired test setup.

With this test, we aim to evaluate the AFO fixation (will the AFO remain in place after numerous cycles?) and assess the test setup's build quality. Testing these two reliability factors will provide an initial indication of the test setup's durability and highlight any points of failure. The insights gained will be instrumental in creating a redesign.

Research Question
Will the test setup cycle for 1 hour at 1 Hz without breaking down? If it fails, where will it break down?

Hypothesis
The test setup will <u>not</u> be able to do a test run of 1 hour of cycling at 1 Hz without misaligning or breaking down.

It will misalign or break down at the following points, ordered by likelihood:

1. The AFO may slip off the dummy due to the conical shape of the dummy calf. The absence of a shoe, which typically helps secure the AFO ***footplate*** to the foot, may contribute to this issue.
2. The wooden platform (Static Ground Surface) will break in half due to the repeated impact of the dummy foot.
3. The pneumatic cylinder will begin to leak more air with each cycle because of the impact of the rod moving in and out.
4. The bolts connecting the frame will loosen due to the vibrations caused by the test setup's cycling.
5. The bolts joining the dummy foot to the dummy calf will also loosen due to the vibrations during cycling.

The other components are expected to remain intact through this number of cycles and do not pose a concern regarding the reliability of the test setup.

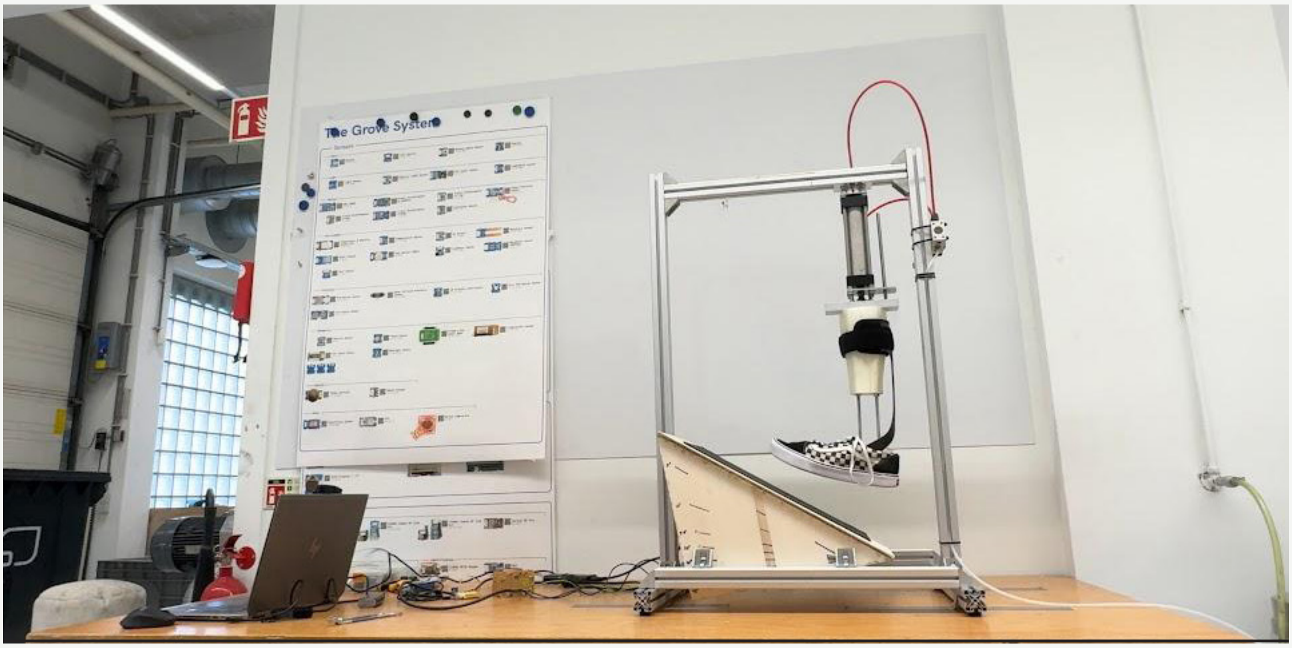


Figure 44. The setup of the trial test run. The setup is placed on a table for good accessibility and before a white background to capture the testing without any background disturbance.

Method
In this trial run, the test setup and an example test AFO are used to perform a trial run of one hour of cyclic loading of the ***forefoot rocker*** at 1 Hz, see Figure 44.

Analysis approach:
A timelapse during the trial run will be recorded to record any failures over time, see Figure 45. Pictures of the test setup will be taken before and after the trial run. After the trial run, the test setup and AFO will be manually inspected for fixation and breakage.

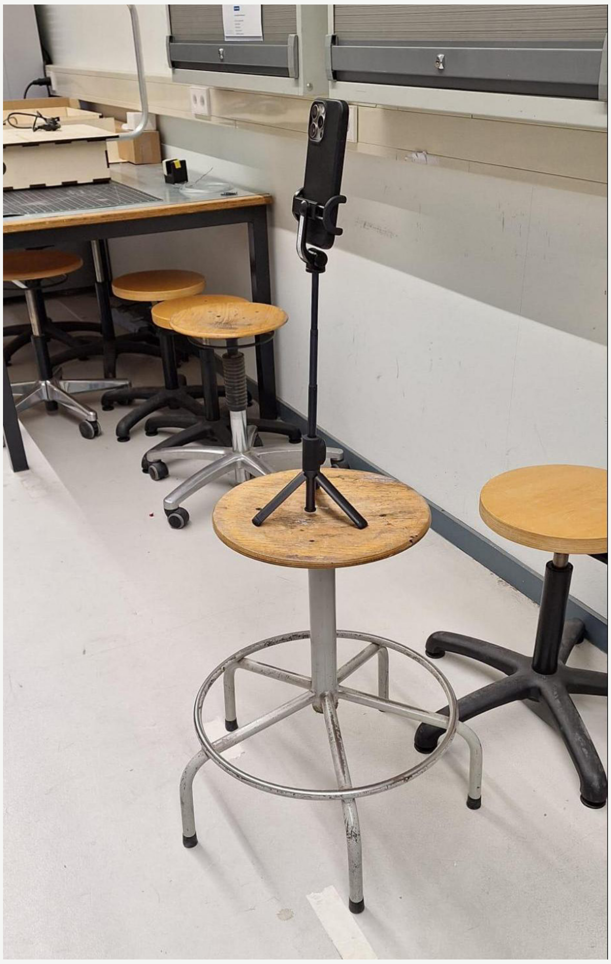


Figure 45. The camera on a tripod setup to capture the test setup from a consistent camera angle.

Results
About 10 seconds (10 cycles) into the trial run, the AFO slipped off the dummy calf (see Figure 46), as expected in hypothesis point 1. Three times, a new test run was started in the same manner. All three test runs gave the same result.

Thus, a tie-wrap was used to strap the ***footplate*** to the dummy foot; see the top picture of Figure 47 on the next page. Initially, this seemed to be the solution, preventing the AFO from slipping off the dummy calf. However, the AFO started to slip forward along the bottom of the foot; see the bottom picture of Figure 47. Due to this issue, the run was stopped after 10 minutes (~600 cycles),

Next, the tie-wrap was removed, and a shoe was added to keep the AFO fixated on the dummy leg. This initially kept the AFO in place without it slipping down or forward/backwards. However, after cycling for some time, the heel of the shoe started to slip from the dummy foot (see Figure 48). Due to this reason and other reliability issues described in the next paragraph, the run was stopped after 18 minutes of cycling (~1080 cycles). A more realistic full-length dummy foot was tried to address this issue (see *appendix 10.8.6* for this and more on testing with a shoe), but this prevented the proper deflection of the AFO around the ***MTP joints***.

After this the trial run test was concluded.

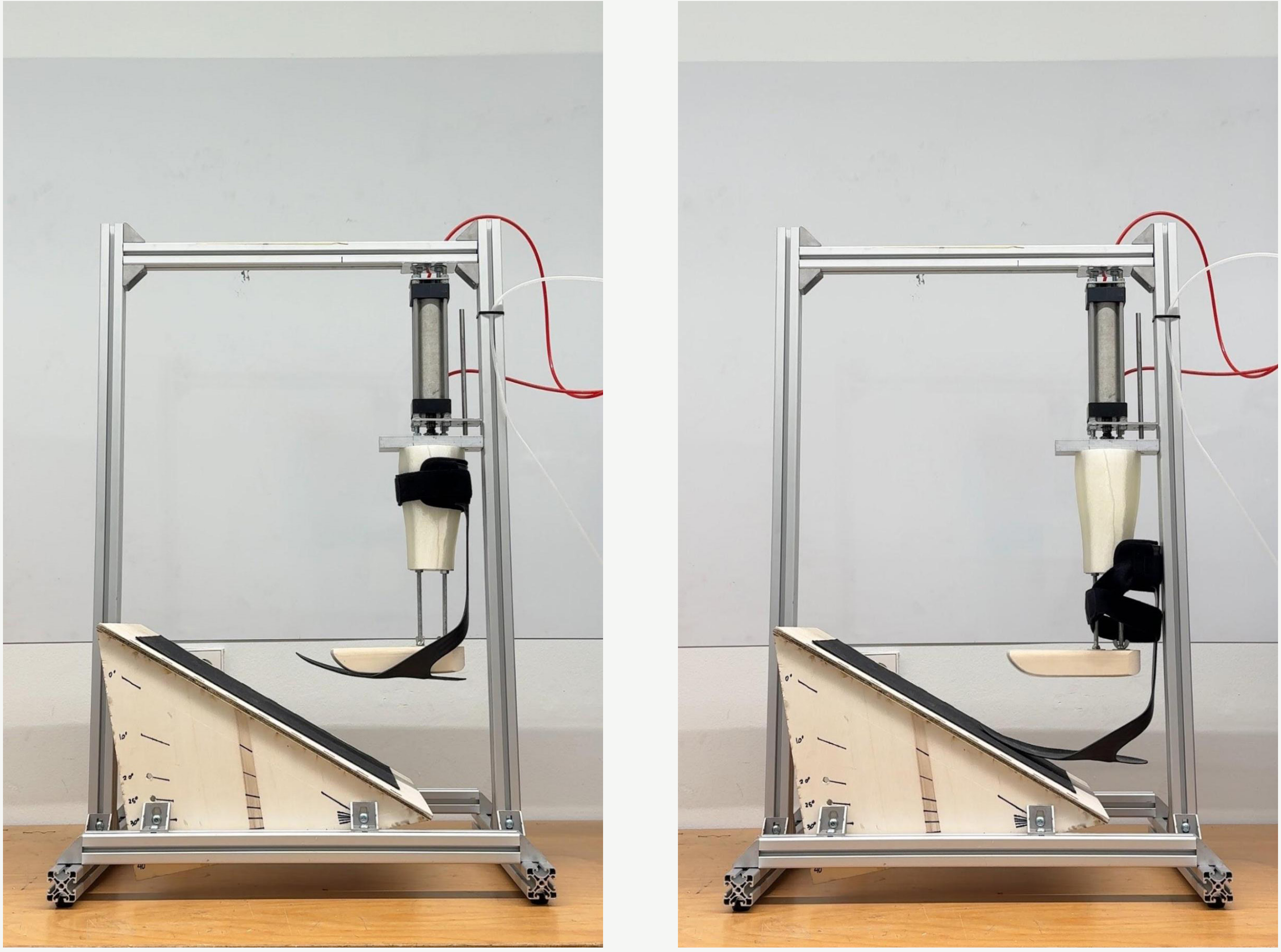


Figure 46. The original test setup and the slipped-off AFO after ~10 cycles.

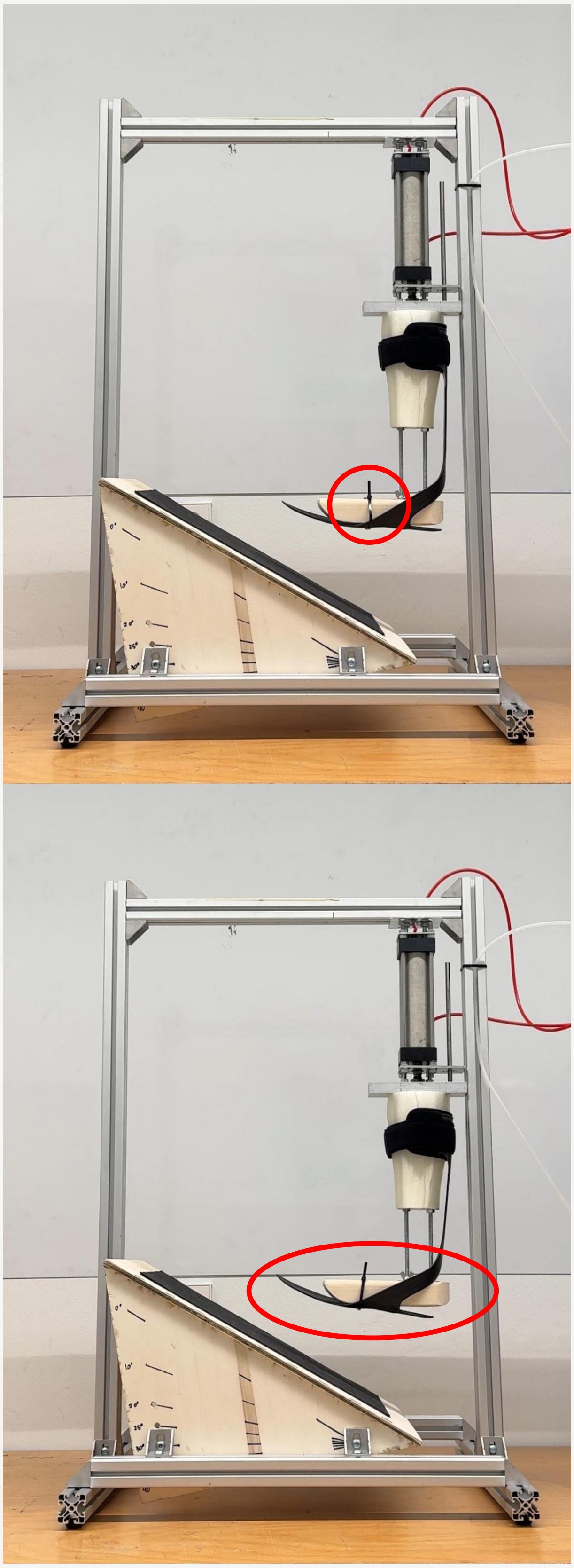


Figure 47. Trying to fixate the AFO with a tie-wrap. Unfortunately, the AFO ***footplate*** slid forward. Run ended after ~600 cycles.

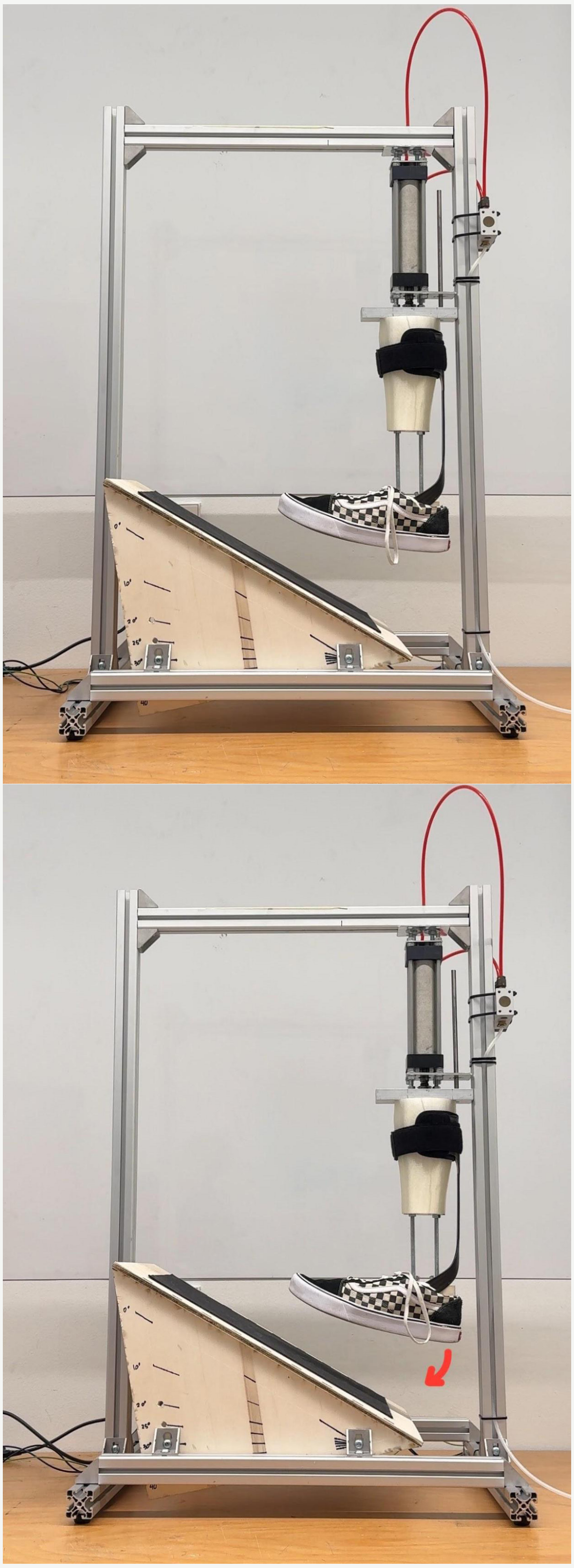


Figure 48. Trying to fixate the AFO by using a shoe. Unfortunately, the shoe started slipping off at the heel. Run ended after ~1080 cycles.

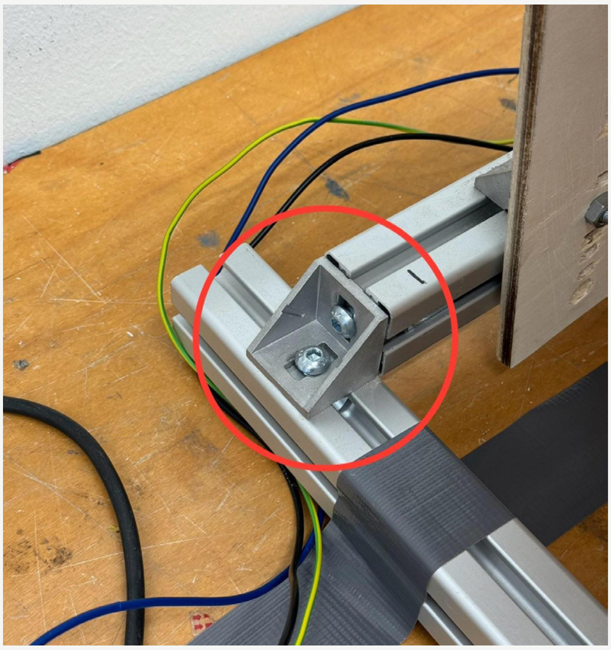


Figure 49. The bolts of the frame came loose due to the vibration of cycling.

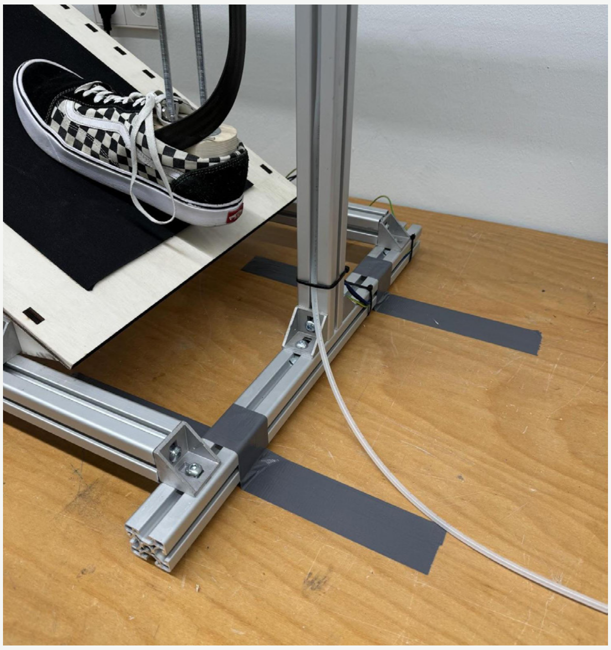


Figure 51. The test setup needed to be taped down to prevent it from moving off the table due to the vibrations.

Figure 50. The bolts of the dummy leg came loose due to vibration of cycling. The lower ones are hand tightened. Thread-locker and nuts could fix this.

In the last test run of ~1080 cycles, the following reliability issues were noticed in the test setup:

- The bolts and nuts of the frame became loose, Figure 49. Proving hypothesis 4.
- The bolts and nuts of the dummy leg became loose, see Figure 50. Proving hypothesis 5. They loosened so much that the dummy foot could tilt during the load cycle. For this reason, the trial run was stopped to prevent damage to the test setup.
- The test setup started drifting off the table due to vibrations. This was a new, unexpected finding that needs to be addressed. It was temporarily fixed in the trial run tests by taping the test setup to the table, see Figure 51.

The other components stayed intact.

Discussion

As expected, the realized test setup was not able to do a test run of 1 hour at 1 Hz without misaligning or breaking down. Both issues occurred.

Strapping the AFO to the dummy calf is not enough to fixate for more than a couple of cycles, as the conical shape of the calf will cause the AFO strap to slip off the dummy calf (confirming hypothesis point 1). For this reason, something is needed to keep the AFO ***footplate*** stuck to the dummy foot.

First, a tie-wrap was tried. However, the ***footplate*** of the AFO still slid forward within ~600 cycles. Note that after analysing the results, a small oversight was spotted in the testing with fixating the AFO ***footplate*** with a tie-wrap: a second tie-wrap could have been added on the heel, which could have prevented the heel of the AFO from coming loose and slipping forward.

Nonetheless, the trial run shows that testing with a shoe is also a better option. It will keep the AFO fixated on the dummy leg, just as the AFO is fixated on the real leg in real life. The heel of the shoe, however, slipped off. This could be because an old, inappropriate sneaker was used. An adequate shoe to wear with the AFO, as prescribed by a Certified Prosthetist Orthotist, could already solve this problem. But the main issue is probably that the dummy foot does not have the full foot length (it only has the length from the heel to the ***MTP joints***).

Implications

It is advised to incorporate a full-length dummy foot that allows flexing around the ***MTP joints*** to be able to use a shoe to fixate the AFO to the dummy leg. The stiffness of the foot is not relevant, it should allow the desired range of motion.

The wooden platform (Static Ground Surface) was expected to break in half (disconfirming hypothesis point 2. as of yet); even though there was clearly bending in the platform in each cycle, it did not break within the number of cycles performed (at least ~1080 cycles continuously). However, this still remains a concern when doing test runs of 2 million cycles; thus, it is advised to increase the thickness of the plate.

By manual inspection, no noticeable difference could be found in air leakage in the pneumatic cylinder (hypothesis point 3). It is assumed that this effect exists but will only be noticeable after more cycles are performed. Thus it is advised to add a damping mechanism to mitigate the impact of the rod moving in and out.

An unexpected effect was that the quite heavy test setup would start to move/drift from its standing position because of the vibrations of cycling. This was addressed temporarily with tape and could be done so again. Adding a weight to the test setup or bolting it to the floor could be a permanent solution.

The bolts connecting the frame and dummy leg came loose due to the vibrations caused by the test setup's cycling (confirming hypothesis points 4 & 5). Split lock washers should be added to prevent the nuts from coming loose due to cycling vibrations. Another option could be to use a thread-locker to prevent this effect.

Strengths and limitations of the study

As determined in the previous chapter, a redesign of the test setup is needed to test a full gait pattern, including heel and ***ankle rocker***. However, this trial run already indicates the reliability issues prone to this test setup design. It is necessary to do this testing again in an iterative process while developing the redesign to continuously stress test the test setup to spot shortcomings and reliability issues early on.

Conclusion

Will the test setup cycle for 1 hour at 1 Hz without breaking down? If it fails, where will it break down?

The trial test run confirmed the hypothesis that the current test setup **cannot** yet complete a one-hour cycle at 1 Hz without misalignment or breaking down.

The most critical issue was the fixation of the AFO, which repeatedly slipped off the dummy calf after ~10 cycles due to its conical shape. Attempts to secure it with a tie-wrap or a shoe showed partial improvement, increasing the amount cycles that could be performed to ~600 and ~1080 respectively, but did not provide a lasting solution. A redesign incorporating a full-length dummy foot and an appropriate shoe is recommended to improve fixation.
The main reliability concerns that were observed, included loosening bolts due to vibrations and unexpected drifting of the test setup. The first was the main reason to stop the trial run to prevent any further damage from occurring.

To improve reliability, split lock washers or thread-locker should be added to secure bolts, and a permanent stabilization method—such as adding weight or bolting the setup to the floor—should be considered.

The wooden platform withstood the test, its long-term durability however remains uncertain. The increase in air leakage in the pneumatic cylinder was not noticeable, but it also still remains a concern for longer cycle runs.

Moving forward, iterative trial run testing will be essential to refine the design and ensure the setup can in the end reliably sustain extended test runs of 2 million cycles.

5.4. Assessment on Desirability, Feasibility, Viability

In this part a qualitative assessment of the test setup will be given on desirability, feasibility and viability (Figure 52) based on the main requirements, see Table 6.

Here the ability of the design to address the redefined design goal will be discussed by looking at the goal and the main requirements for achieving that goal.

The redefined design goal:
Design a proof-of-concept load cycle test setup which can simulate 2 years of walking with an AFO

Which conditions are still unmet for the project result to achieve the redefined design goal?

As intended a proof-of-concept version test setup was prototyped cheaply and quickly within the short time window of the second half of this project. This proof-of-concept version does however not yet meet all the requirements for the project to become desirable, feasible and viable.

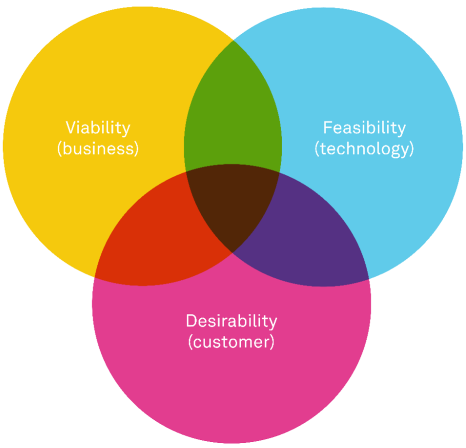


Figure 52. Desirability, feasibility, and viability; the essential design thinking triangle for realizing and validating a good design (Vinney, 2023).

Unmet desirability conditions:

- With the realized test setup the client cannot load cycle test AFOs yet to guarantee the product can withstand 2 years of walking.
- The current test setup is only able to test the ***forefoot rocker***. The heel and ***ankle rocker*** cannot be simulated yet.
- The current test setup cannot test with shoes yet, as a shoe will slip off the current realized dummy foot.

Unmet viability conditions:

- If ***heel rocker*** and ***ankle rocker*** were made to work in this realized test setup, they would still be tested separately, meaning that at least 3 test runs of 2 million cycles have to be performed to guarantee an AFO can withstand 2 years of walking.

  This will mean 3 times longer testing time, which is significant as a test run of 2 million cycles at 1 [Hz] takes ~23 days. It will also mean that 3 times as much energy is used for testing which could cost a significant amount.

Unmet feasibility conditions:

- As found in the trial test runs, the realized test setup can not yet test runs of 2 million cycles without misaligning the AFO or breaking down. Let alone multiple test runs. It can do test runs of ~1000 cycles.

  To acquire reliability for multiple test runs of 2 million cycles, proper development and optimisation will need to be done. Primarily by integrating a full length realistic dummy foot and by including split lock washers. This can be integrated into the redesign that allows the testing of the three ***rockers*** within one cycle.

Which conditions are met? What is the value the realized test setup brings?

This proof-of-concept realized test setup was used to learn what is required for a good simulation of gait (the three ***rockers***), how to define what the actual loads are on the AFO during gait (matching displacement of the AFO) and what the challenges are to make the test setup reliable for the high amount of cycle that it needs to perform.

Met Desirability conditions:

- The realized test setup can be used to evaluate the ***forefoot rocker*** of gait for a limited amount of cycles.
- For the ***forefoot rocker*** it is able to recreate the same displacement and thereby also the same forces on the AFO as it endures in real life.
- During this simulation it recreates the critical bending around the ankle and around the ***MTP joints*** in the AFO.
- It also allows further development of the dummy leg in order to allow plantar flexion during ***heel rocker*** and in order to evaluate how a shoe can be incorporated in the load cycle test.

Met Viability conditions:

- This realized test setup and its final build is going to be significantly cheaper than buying and adapting an existing ISO 22675 test setup of €70.000.

  The budget spent on materials and components for prototyping and building the realized test setup is only €634,42. This is mainly so low because the pneumatic actuator and valve were received from university tutors for free. If the man hours would be included (€2238,81, including travel expenses) the total is €2873,23 spent on this project.

- It is however desirable to have the test setup at the R&D department of the company to mostly allow quicker product iteration, to save testing costs and to get the valuable knowledge acquired by performing tests inhouse. With the realized test setup in house testing can be done at the company, but only an operator keeps an eye on the test setup to ensure safety and stop the test run when breakdown of the test setup occurs.

- The method of determining and recreating the force on the AFO during gait by matching deflection is simpler, more scalable and cheaper than the solution came up by the most specialized industry expert of AFO testing D. Hochmann (2024): determining the loads during gait with an AFO instrumented with strain gauges. This new method is a major added value result of this project.

- The current realized test setup built could be used to continue building a redesign with. This can either be done by building further on the current built or by dismantling it and using the components. This saves material and component costs for developing the final version.

  This is possible as from the start building the test setup it was intended to have this flexibility. For that reason the frame is built from modular 40x40 aluminium profiles and all connections are bolts and nuts that can be lossend again.

Met Feasibility conditions:

- It is proven that the load on the AFO can be recreated by matching the deflection as observed in video analysis of real life gait and matching that deflection in the test setup.

  This matching of deflection in the realized test setup is performed by allowing a maximum deflection and applying an overload of force to bend the AFO in that form.

- It is also proven that the general layout and frame of the test setup can at least withstand test runs of ~1000, if the loosening of nuts is fixed.

- Following and adapting ISO 22675 *Fatigue ankle-foot device Prosthetic Test Equipment* gives a lot of guidance and confidence in the feasibility of building the test setup, as the design described in this standard is proven and standardised.

Conclusion

The learnings from the validation of the ***forefoot rocker*** and the invalidation of the other two ***rockers***, will allow the company to develop a final load cycle test setup inhouse that can do test runs of the three ***rockers*** in one cycle for 2 million cycles. This will allow them to guarantee AFO product safety for 2 years of walking. All against lower costs than buying an existing test setup or by outsourcing testing. The realized test setup has brought a lot of insight in how gait with an AFO looks from a biomechanical standpoint and provided a new method on how to measure and recreate the forces on the AFO due to walking.

Main guiding requirements

#	Requirement	Source
R1	**Enable load cycle testing simulating 2 years of walking**	This was the conclusion of researching the product usage and breakage of AFOs and cataloging all existing AFO test setups that could be found on the internet. See chapter *2. Analysis*.
~~R2~~	~~**The loads on the AFO during gait should be recreated in the test setup**~~	~~In the reviewed literature there is data available on how much force there is on the leg while walking, but there is no data or knowledge available on how much force an AFO carries when a patient walks with it. By speaking to AFO testing expert D. Hochmann, it is known that this is a critical challenging task to solve.~~
R3	**Gait should be simulated by recreating the 3 *rockers***	The research-through-design process of iteratively building the test setup and comparing it to real life gait led to this discovery. See chapter *4.1. Gait Analysis* and chapter *5.2. Cycle Testing*.
~~R4~~	~~**Allow testing of normal and a wide variety of abnormal gait patterns**~~	~~Based on findings from analysing gait with AFOs: chapter *4.1. Gait Analysis*.~~
~~R5~~	~~**Enable testing for a wide variety of AFOs**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R6~~	~~**Simulate bending around the ankle & *MTP joint***~~	~~This is based on the experience of ***CPO'ers*** at the company, see subchapter *2.1.How do traditional & 3D-printed AFOs fail?* and *appendix 12.3*.~~
~~R7~~	~~**Allow evaluation of the tested AFO on damage**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
R8	**Safe for R&D operators and all other by-passers**	Common safety precautions.
R9	**Minimum amount of cycles per test run > 2 million**	This is directly taken from ISO 22675:2016 - *Testing of ankle-foot devices and foot units.*
R10	**Amount of runs > 20**	This is an estimation as it depends on the building price of the test setup. Once this price is known, it is advised to the client company to make a quick calculation with their budget what the minimal amount of runs would be to make a test setup viable.
R11	**Run time < 50 days**	As communicated by the supervisors from the client company (personal communication, 2024).
~~R12~~	~~**Cost price < ~€15.000**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R13~~	~~**Allow testing at the office of the company**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~

Table 6. Overview of main guiding requirements that were met with the realized test setup.

Category	Explanation
Desirability	Developing a load cycle test setup was chosen because of the following 4 reasons: 1. Stiffness test machines are available in the industry. 2. Impact can be evaluated by trial and error. 3. The only purchasable load cycle test setup is too expensive (price tag ~€70K). 4. Cyclic loading is the largest reason for AFOs to fail.
~~**Feasibility**~~	~~In order to simulate cyclic loading on an AFO due to walking, it must be known what the forces are on the AFO. These forces consequently need to be recreated in the test setup.~~
Desirability	The movement of gait can be best described based on the 3 rocking motions of gait: ***heel rocker***, ***ankle rocker***, and ***forefoot rocker***.
~~**Desirability**~~	~~AFOs are worn to correct a wide variety of inefficient abnormal gaits to normal gaits. The test setup should allow to minimally simulate a normal gait as a representation of all abnormal gaits. Ideally it should also allow setting up the testing of a wide variety of abnormal gait patterns.~~
~~**Desirability**~~	~~The test setup should be able to test a wide variety of AFOs and a wide variety of sizes in order to keep the AFO design space of the company completely open.~~
~~**Desirability**~~	~~The test setup must simulate the bending in the AFO around the ankle & *MTP joint*, as these are the spots where the most stress occurs due to bending.~~
~~**Desirability**~~	~~At each chosen amount of cycles it should be possible to evaluate the state of the AFO.~~
Desirability	The test setup should be safe while being setup, while running and should not cause any fire hazards.
Feasibility	2 million cycles is the chosen amount of cycles to represent two years of walking. This is based on an activity level of ~5000 steps per day (~2500 per leg).
Feasibility	Total number of runs that the test setup should last is at least 20 to deem this setup viable for its testing purpose.
Viability	The total run time of a test run should not exceed 50 days otherwise it takes too long to test products and iterate on them and it will prevent the test run from becoming too expensive. A cycle speed of at least 1 [Hz] is desired, as this will keep the run time ~42 days.
~~**Viability**~~	~~Target is somewhere below ~€15.000. Because the company is new to LE orthoses, they want to keep initial investments low.~~
~~**Viability**~~	~~This way prototypes can be tested on site to enable quick iteration on them. Therefore the device must not cause a fire hazard or produce more than 75 decibels (equal to the sound of a vacuum cleaner)~~

6. Redesign

A redesign, see Figure 53 - Figure 55, has been developed based on the insights gained from testing with the realized test setup. The redesign of the test setup integrates several key components to simulate realistic loading and fatigue over time, ensuring that AFOs can be tested and redesigned to withstand typical use conditions over a two-year period. Again the ISO 22675 standard for testing prosthetics serves as the main reference for the design of the load cycle test setup. The designed test setup is however adopted to test orthoses.

The two main changes of the redesign are:

1. **The addition of a Dynamic Ground Surface (*DGS*)**, which allows to test ***ankle rocker*** and allows chaining the 3 ***rockers*** of gait into one cycle, creating a full realistic stepping motion in the sagittal plane.

2. **A prosthetic foot containing an ankle joint** to allow plantar flexion for ***heel rocker***, dorsal flexion for the ***ankle rocker*** and flexibility in the foot around the ***MTP*** to allow testing with shoes for the ***forefoot rocker***

   The dimensions of the frame are the same as the realized test setup. The redesign is still modular, meaning that components can be moved on the frame and the whole setup can be disassembled. This is to allow experimentation with the build, before finalizing component placement. Thus technical drawings are also not yet specified.

What does this test setup do?
This test setup is designed to perform load cycle testing on AFOs (Ankle-Foot Orthoses). It simulates a stepping motion (the applied load) and repeatedly cycles this load for a predetermined number of repetitions. This setup enables evaluation of 2 main things: 1. Can a brace endure 2 million steps? 2. In combination with a stiffness test setup, the loss of stiffness of the brace can be evaluated after a certain amount of steps.

How does it work?
The stepping motion is simulated using a dummy leg equipped with an AFO and an appropriate shoe. This dummy leg is attached to a linear actuator, which replicates the up-and-down movement of a step. The dummy lower leg with the AFO lands on a platform, the ***Dynamic Ground Surface*** (***DGS***) representing the ground. It rotates during the cycle to simulate the foot rolling over the ground. In real gait, the lower leg rotates in relation to the ground. In this test setup, the perspective is inverted: the leg moves vertically, while the ground platform tilts rather than the lower leg rotating. This is done as it splits the up and down movement and the angling of the leg. This allows the complex motion of a step to be simulated with only one linear and one rotary actuator. The change of perspective can be made as the resulting forces and their direction stay the same. An overview of the cycle motion and its main phases and angles can be seen in Figure 57.

What parameters can be set?
The test setup aims to simulate a realistic, normal gait cycle. However, it's also possible to simulate alternative gait patterns by modifying the force applied to the AFO and the change of angle of the ***DGS***.

What is measured?
The test setup simply simulates a repeated number of steps and keeps track of the step count. Observations regarding the product's effects must be visually inspected during the cycling process or by pausing the run and taking the AFO out for analysis. However, if proven to be desired, a camera recording the AFO at each cycle could be added to be able to spot wear at each cycle.

Figure 53. Render of the redesign with ***Dynamic Ground Surface***.

Figure 54. Front view render of the redesign.

Figure 55. Side view render of the design.

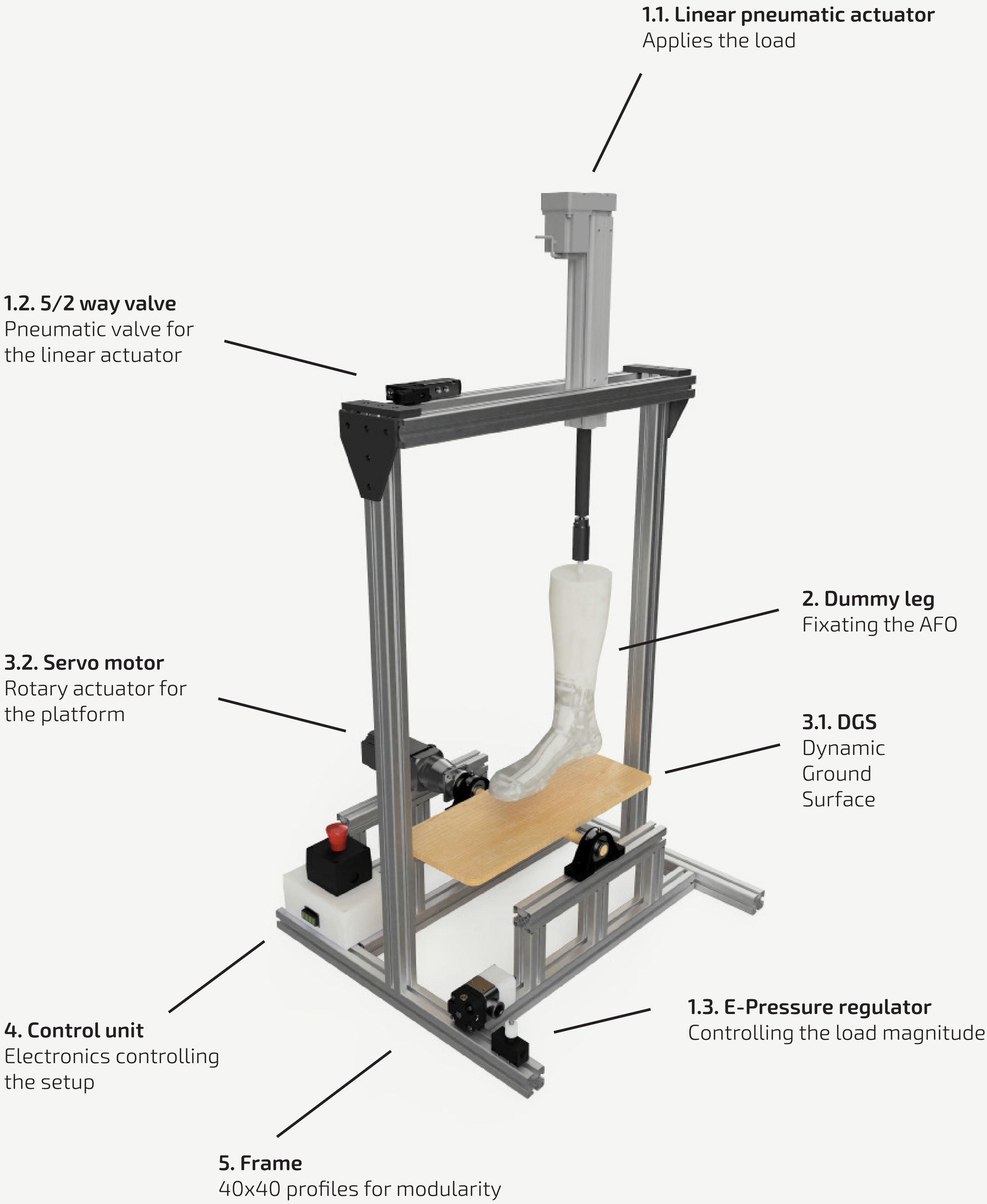


Figure 56. Annotation of the design, highlighting the key components.

6.1. Key Components

Below the main components of the setup are described, in figure 56 the placement can be seen.

1.1. Linear Actuator
The linear actuator is the core driver of the load cycle testing: it simulates the up and down movement of the leg. A pneumatic actuator was selected due to its high-speed operation and robust performance over extended testing periods, something for example an electronic actuator could not. Hydraulics could also be an option, but it is more expensive.

1.2. 5/2 way valve
Controls the airflow direction for the pneumatic linear actuator, enabling extension and retraction.

1.3. Pressure regulator
The pressure regulator controls the amount of pressure that is put on the pneumatic cylinder and thereby the force and stroke speed of the pneumatic cylinder can be dialled.

2. Dummy Leg
The AFO is strapped to a dummy leg, which mimics the shape and joints of a human lower leg. A commercially available prosthetic foot in combination with a 3D-printed calf section is used to create a realistic dummy leg. The used prosthetic foot has an ***ankle joint*** built in with an adjustable hydraulic damper.

3.1. DGS
The ***Dynamic Ground Surface (DGS)*** is a rotating platform which represents the ground. This simulates the angling of the lower leg respectively to the ground. Together with the linear actuator, which simulates the up and down movement, these two simple actuators can replicate the complex movement pattern of a step (gait). The plot of the angle of the ***DGS*** during a cycle can be seen in figure 55, indicated in the first plot with the green linen. In the same figure the resulting angles of the ankle and ***MTP joint*** can be seen, red and purple line respectively. The exact data of this plot is taken from ISO 22675. The position of the axle of the ***Dynamic Ground Surface*** relative to the foot should be based on the dimension given in the ISO 22675 standard.

4.2. Servo motor
A large servo motor drives the angling of the ***DGS***. It consists of a servo motor with gearbox and a driver to control the motor. A servo type motor is required in order to have exact control over the angle of the platform. Furthermore, it allows the possibility to change the simulated gait pattern without changing any physical parts.

5. Control unit
The actuators are controlled by a micro-controller. A simple LED screen, start and emergency button are included to operate the system.

6. Frame
The frame consists of 40x40 aluminium profiles, chosen for their strength, modularity, and ability to enable quick setup and easy layout adjustments if needed. The profiles offer necessary stiffness and allow for added reinforcements if required. Corner connectors and joining plates hold the frame together, with four support feet mounted on the bottom to prevent sliding. The flipped T-frame configuration is chosen in order to have a wide base for stability and to mount the frame for the ***Dynamic Ground Surface*** (***DGS***) to. Custom mounting plates mount the components to the frame. Pillow bearings and mount the axle of the ***DGS***.

What is the status of the design?

The redesign with ***DGS*** shown here consists of a design on paper based on the learnings from the realized test setup. The buying of parts and building of the ***DGS*** is the next step after this project for the company to finalise a proof-of-concept that can accurately simulate gait with an AFO.

After that this proof-of-concept build will need to be refined through an iterative process to allow it to reliably do test runs of 2 million cycles. With this final build the company could do test runs with AFOs to guarantee they can withstand 2 years of walking.

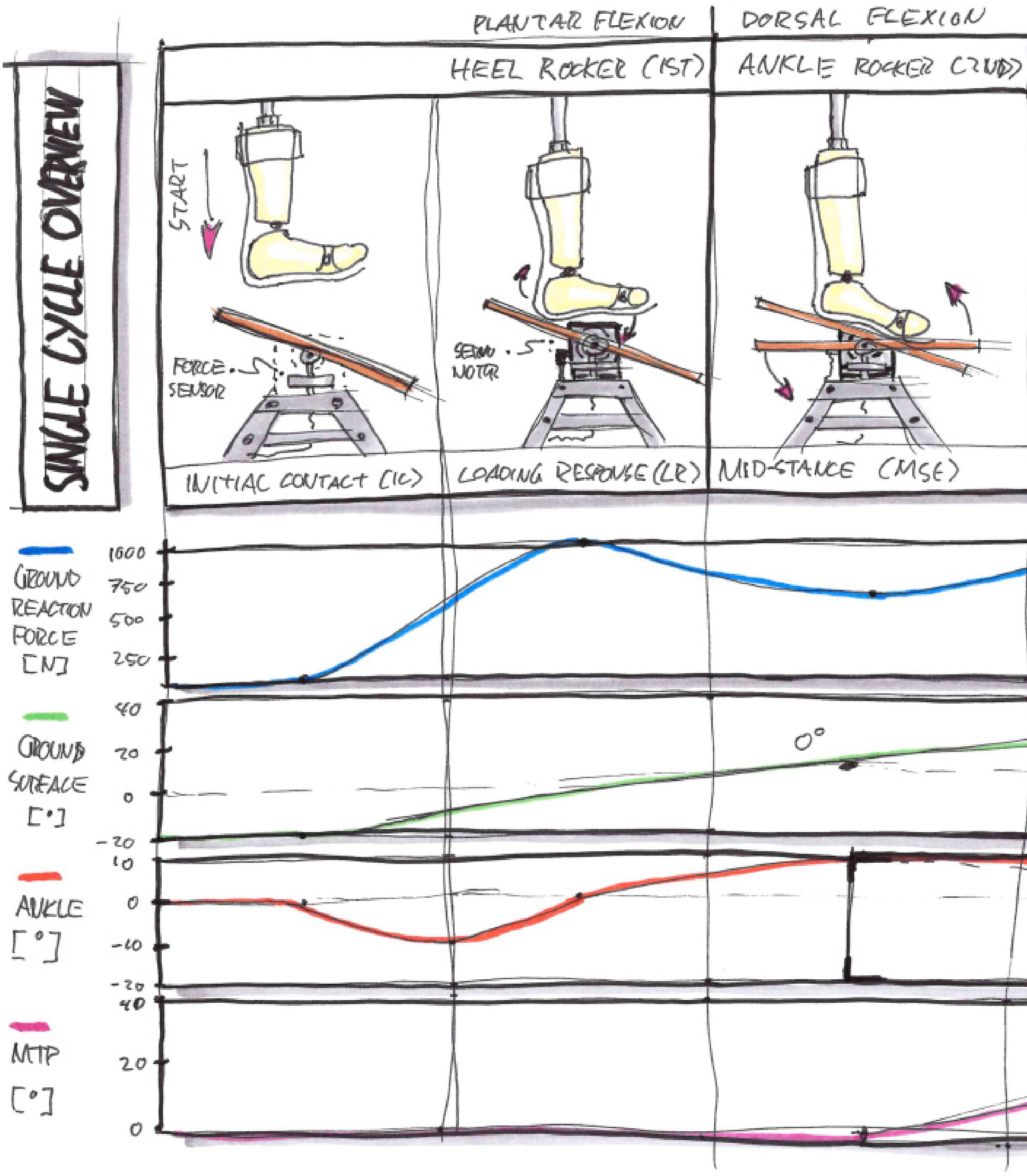
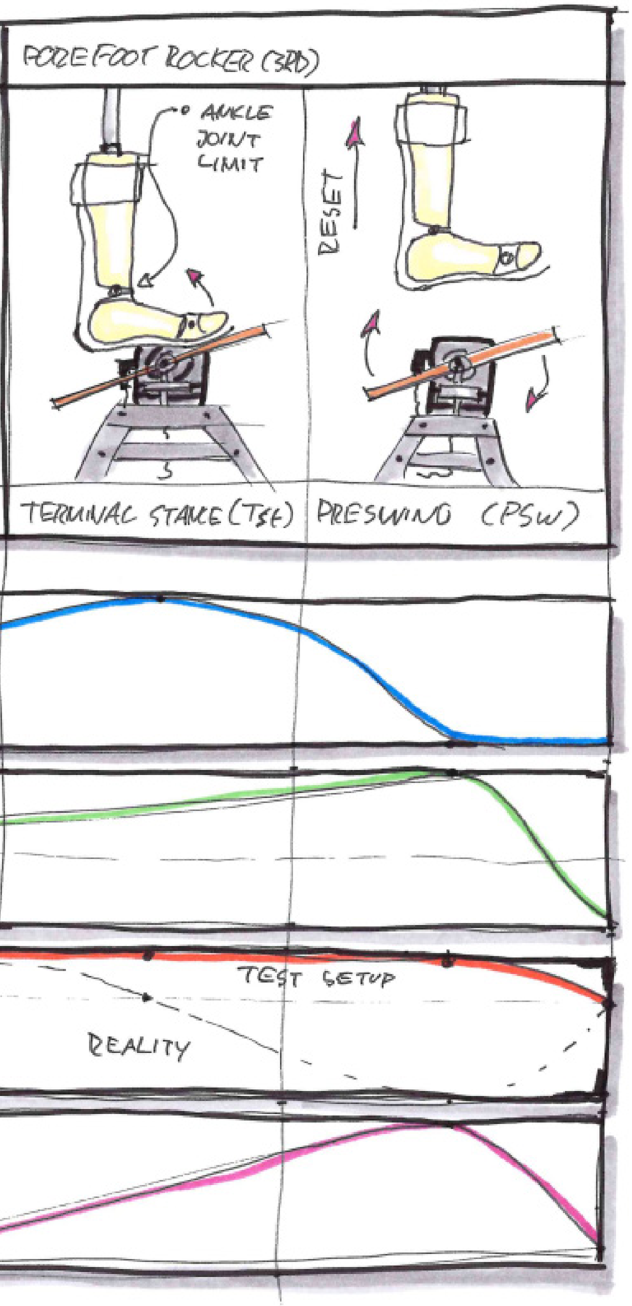


Figure 57. Load profile overview: the main phases that occur in the test setup with the corresponding applied load by the linear actuator, input angle of the platform and resulting angles in the ankle and around the ***MTP*** in the dummy leg.


FOREFOOT ROCKER (3RD)
ANKLE JOINT LIMIT
RESET
TERMINAL STANCE (TSt)
PRESWING (PSw)
TEST SETUP
REALITY

6.2. Integrating a Prosthetic Foot

Towards the end of the graduation project, there was still time to prototype integrating a flexible prosthetic foot with an ankle joint. As described earlier, this ankle joint is needed to allow the heel and ankle rocker motions. The flexible foot is necessary to be able to test with a shoe while still allowing bending around the MTP. This dummy leg improvement is a critical part of the redesign. Thus, it was chosen to prototype this part. The Dynamic Ground Surface (DGS / rotating platform) was not prototyped, as it was predicted that it would take too much time to solve this mechatronic challenge. In this chapter, the integration of the prosthetic foot is shown and tested.

Research Goal
This test aimed to evaluate the AFO fixation (will the AFO remain in place after numerous cycles?) and assess whether the AFO's bending during heel and forefoot rocker is properly recreated. The ankle rocker will not be evaluated as this rocker can not yet be tested without the DGS.

Research Questions
1. *Is the bending of the AFO during the heel rocker properly recreated?*
2. *Is the bending of the AFO during the forefoot rocker properly recreated?*
3. *Will the AFO and shoe remain in place during a test run of 1 hour of cycling at 1 Hz (3.600 cycles)?*

Hypothesis
1. The heel rocker's bending in plantarflexion will be properly recreated with the ankle joint in the prosthetic foot.
2. The bending in dorsiflexion during the forefoot rocker will still be properly recreated with the prosthetic foot.
3. The AFO and shoe will remain in place in a test run of 1 hour of cycling at 1 Hz (3.600 cycles).

Method

Integration of the prosthetic foot -

The prosthetic foot configuration and mountings are longer than the previous dummy foot. Thus, the pneumatic cylinder had to be mounted to the head instead of to the back to allow the prosthetic to fit in the frame while still having room to move up and down. See Figure 58. This design also provides better stability and less wear for the pneumatic cylinder. Top before, bottom after switching the mounting position. A new calf had to be printed as well to fit the prosthetic mounting.

Within the realistic foot hull of the prosthetic, there is a leaf spring as the structural component which carries the weight of the user. The bending of the foot during the forefoot rocker cannot be properly recreated with the default leaf spring, as this leaf spring is too stiff and does not specifically bend around the MTP. Thus, it had to be replaced. It was tried to replace it with a more flexible polymer. The polymer, however, could not provide the necessary bending and broke, see Figure 59. The solution was to combine a super flexible full-foot PP plate with a stiff aluminium plate running until the point where the MTP joints are located, see Figure 60. This way, the toes of the foot will be able to bend, see Figure 61.

Analysis approach:

To validate if the correct bending is acquired in the test setup, video analysis will again be used. For analysing the deflection of the brace, cycles without a shoe were performed, see the bottom image of Figure 58. To check if the AFO with shoe will stay in place, a trial run of 1 hour of cycling at 1 Hz (3.600 cycles) will be performed, see the arrangement in Figure 63.

A time-lapse during the trial run will be recorded with a camera on a tripod to capture the test setup from a consistent camera angle and record any failures over time. Pictures of the test setup will be taken before and after the trial run to check for misalignment. After the trial run, the AFO and shoe will also be manually inspected to see if they are still properly fixated.

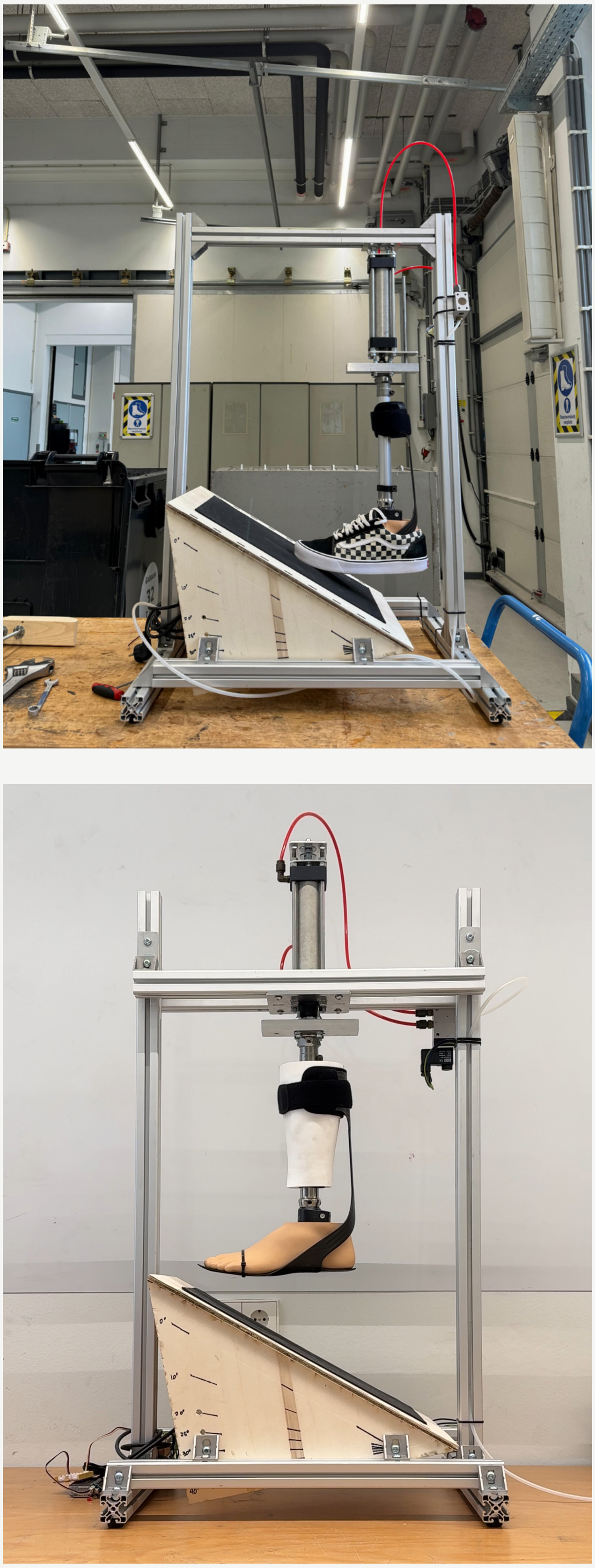


Figure 58. The cylinder had to be mounted to the head instead of to the back to allow the prosthetic to fit in the frame while still having room to move up and down. Top before, bottom after switching the mounting position. A new calf had to be printed as well to fit the prosthetic.

Figure 59. The original leaf spring making within the foot part of the prosthetic was too stiff, so it was tried to replace it with a more flexible polymer. The polymer, however, could not provide the necessary bending and broke.

Figure 60. The solution: combination of a super flexible full-foot PP plate with a stiff aluminium plate running until the point where the MTP joints are located. This way, the toes of the foot will be able to bend.

Figure 61. Top before with the original leaf spring, bottom after replacing the leaf spring with the PP and aluminium plate combination. See how, in the bottom image, the foot bends around the toes.

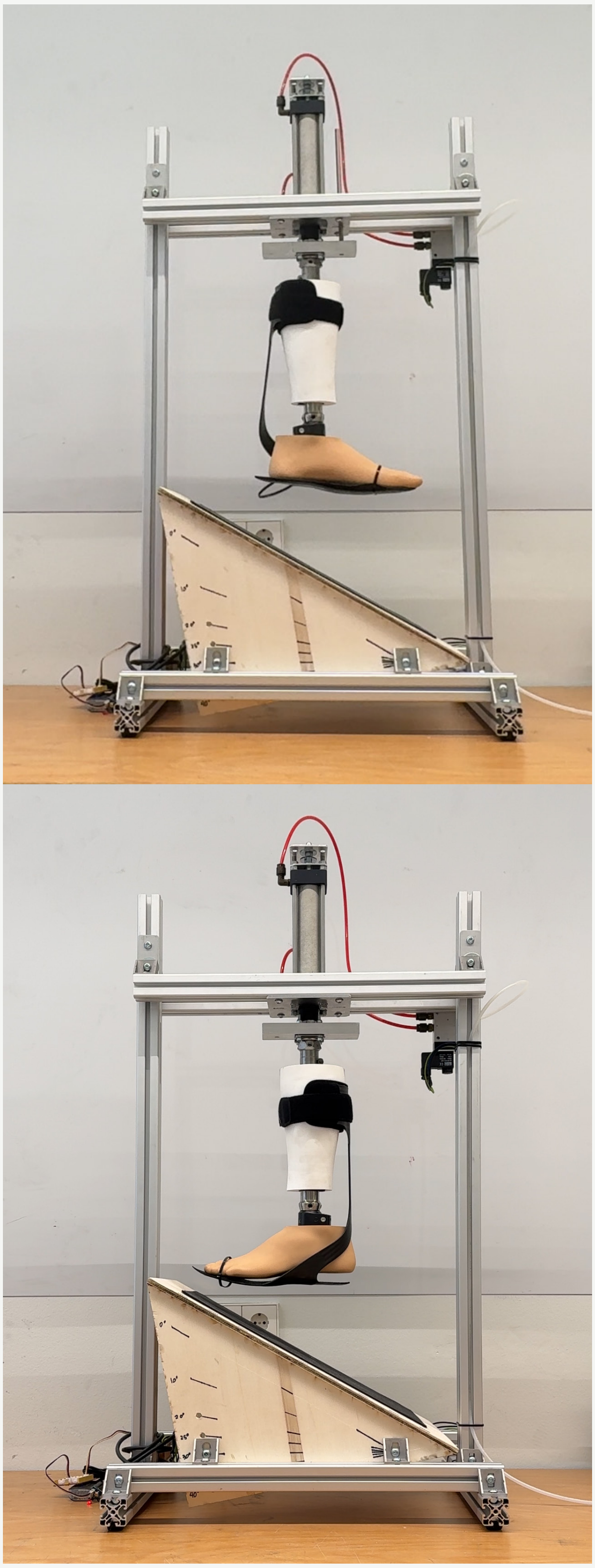


Figure 62. Trying to fixate the AFO with two tie-wraps for heel rocker. Unfortunately, the AFO footplate and tie-raps again slid off after 7-12 cycles.

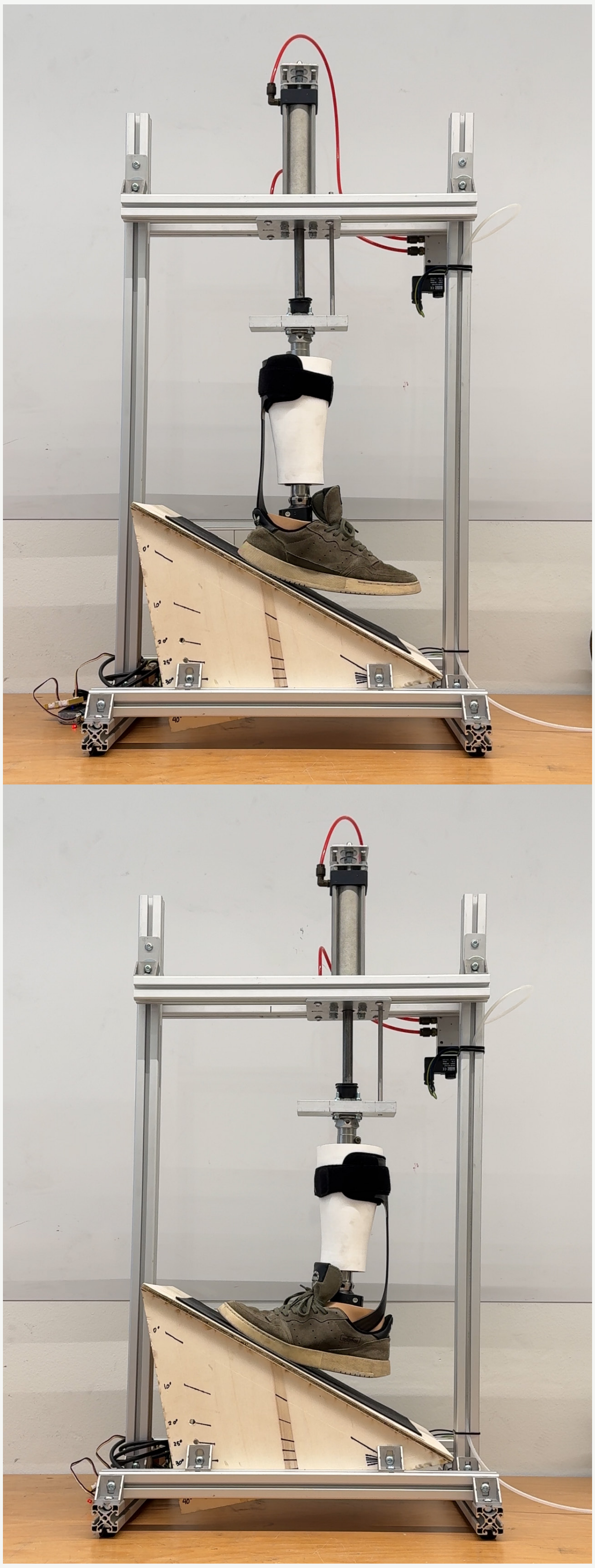


Figure 63. The arrangement for this trial run with the newly integrated prosthetic foot and shoe. Top heel rocker, bottom forefoot rocker.

Results

1. **Heel rocker -**
   The newly integrated prosthetic foot can properly simulate the heel rocker (see Figure 66 and Figure 67 on the next page). It matches the deflection of the reference material quite well (see Figure 64). The strut has only a bit more deflection.

2. **Forefoot rocker -**
   The forefoot rocker can still be simulated with the newly integrated prosthetic foot (see Figure 68 and Figure 69 on the second next page). However, the prosthetic foot flexed more in dorsiflexion than the foot of the person in the reference video (see Figure 65), resulting in more deflection in the strut.

3. **AFO fixation -**
   For the heel rocker, it was tried again to keep the AFO in place on the prosthetic foot, but now with two tie-wraps. It was found that again, after seven cycles, one of the tie-wraps slid off because the AFO was slipping off at the heel (see top image of Figure 62).

   It was also tried to keep the AFO in place with a tie-wrap for the forefoot rocker. Again, after 12 cycles, one of the tie-wraps slid off because the AFO was slipping off at the toes (see bottom image of Figure 62).

   However, the combination of the prosthetic foot with the shoe keeps the AFO well in place. The AFO stayed neatly aligned in the trial run of 1-hour cycling at 1 Hz (3.600 cycles).

Conclusion

1. *Is the bending of the AFO during the heel rocker properly recreated?*

   Yes, the heel rocker can now be properly simulated because of the prosthetic ankle joint. The deflection matches the deflection in the reference video of a normal person walking with the brace quite well. There is only a little bit more deflection in the plantar direction.

2. *Is the bending of the AFO during the forefoot rocker properly recreated?*

   Yes, the forefoot rocker can still be simulated with the prosthetic foot. The deflection matches the deflection, as can be seen in the reference video of a person walking with the brace a bit more poorly than before. There is more deflection in the dorsiflexion direction.

3. *Will the AFO and shoe remain in place during a test run of 1 hour of cycling at 1 Hz (3.600 cycles)?*

   Using tie-wraps instead of a shoe was again not enough to keep the AFO fixated; it slipped off within 7-12 cycles.

   However, the combination of prosthetic foot and shoe keeps the AFO well in place. The AFO stayed neatly aligned in the trial run of 1-hour cycling at 1 Hz (3.600 cycles). This test proves promising results that this is a solution that can be used to achieve test runs of the desired 2 million cycles.

Figure 64. Testing ***heel rocker***. The top image is the test setup, the middle is the reference video, and the bottom is the comparison.

Figure 65. Testing ***forefoot rocker*** . The top image is the test setup, the middle is the reference video, and the bottom is the comparison.comparison.

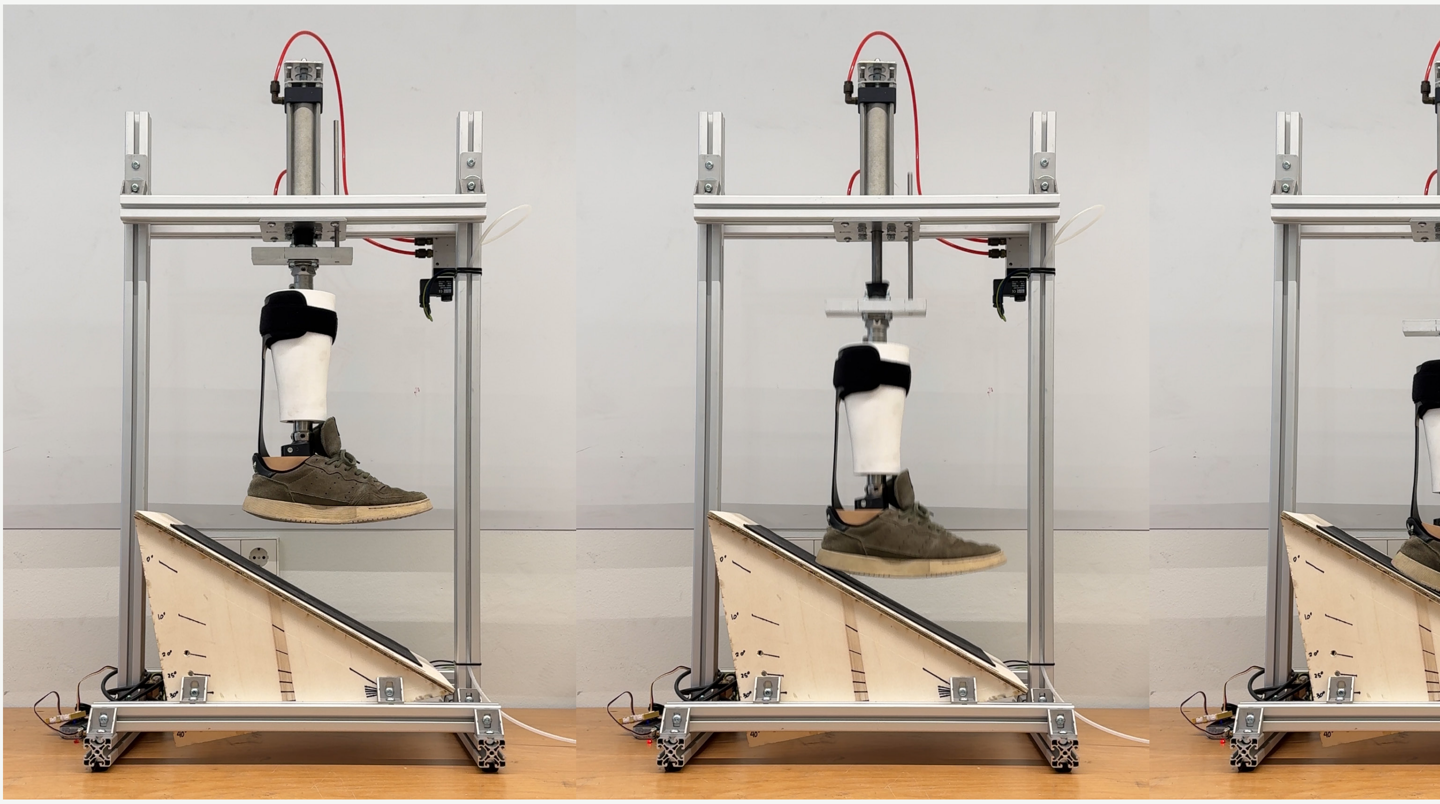


Figure 66. Load cycle motion with prosthetic foot with shoe. In this example the ***heel rocker*** is depicted.

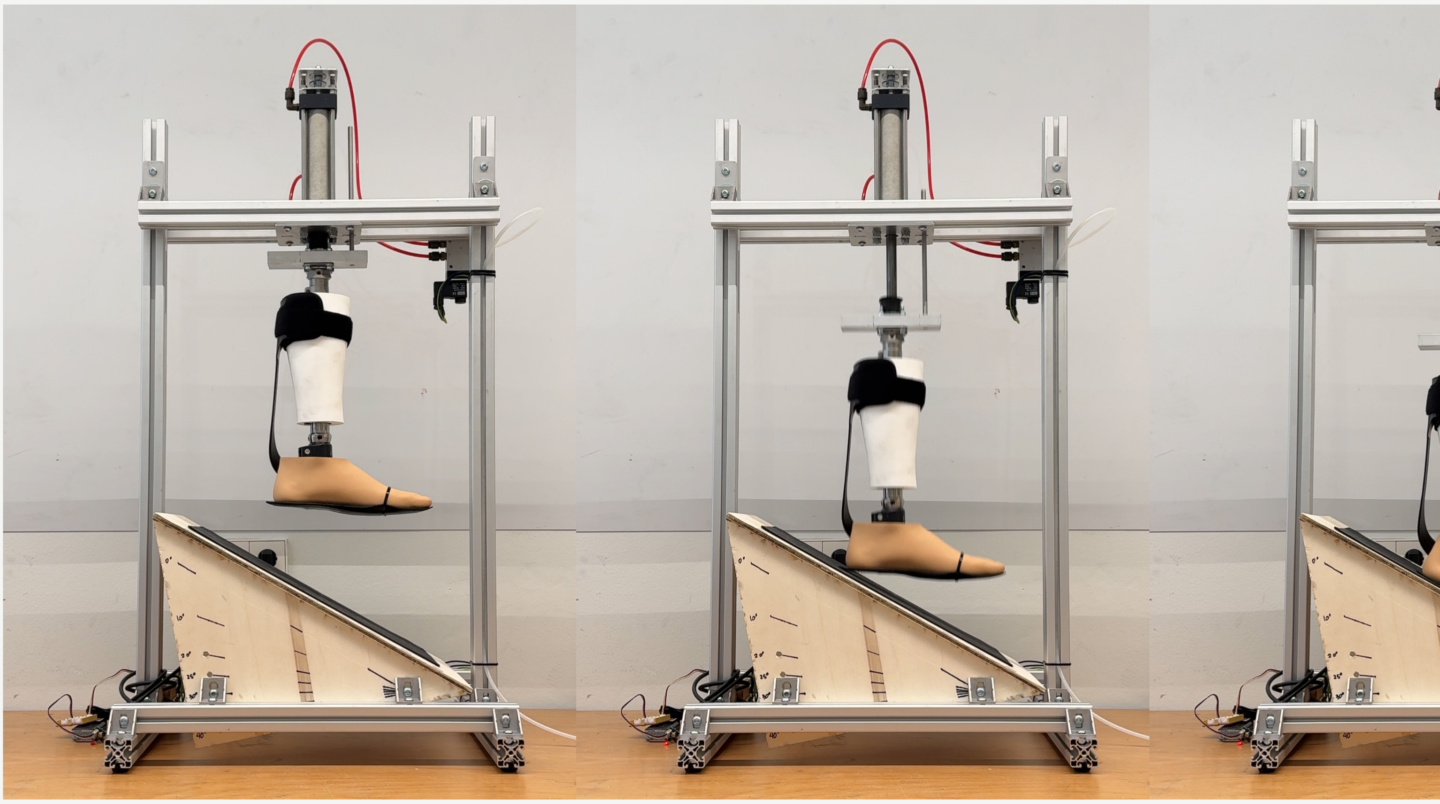
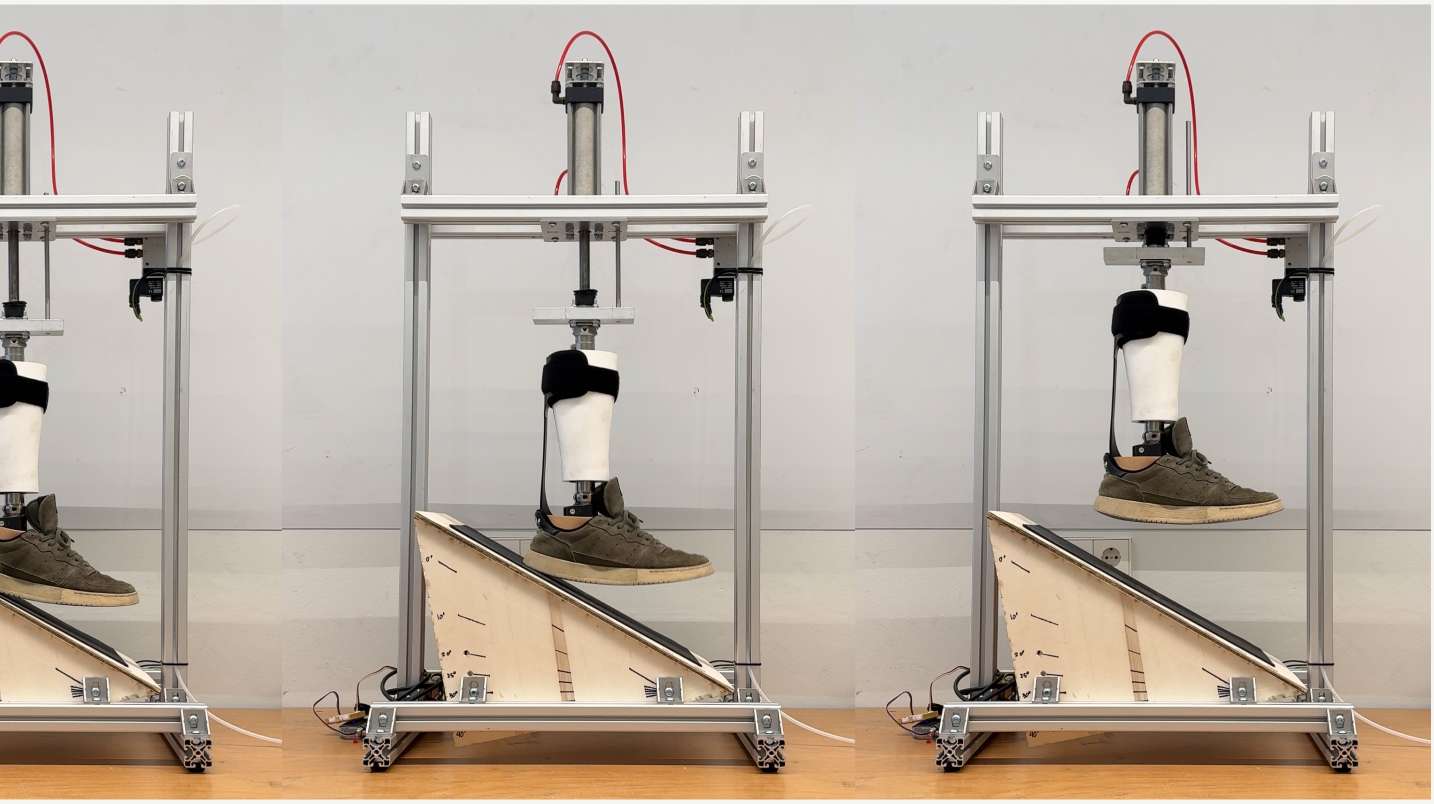
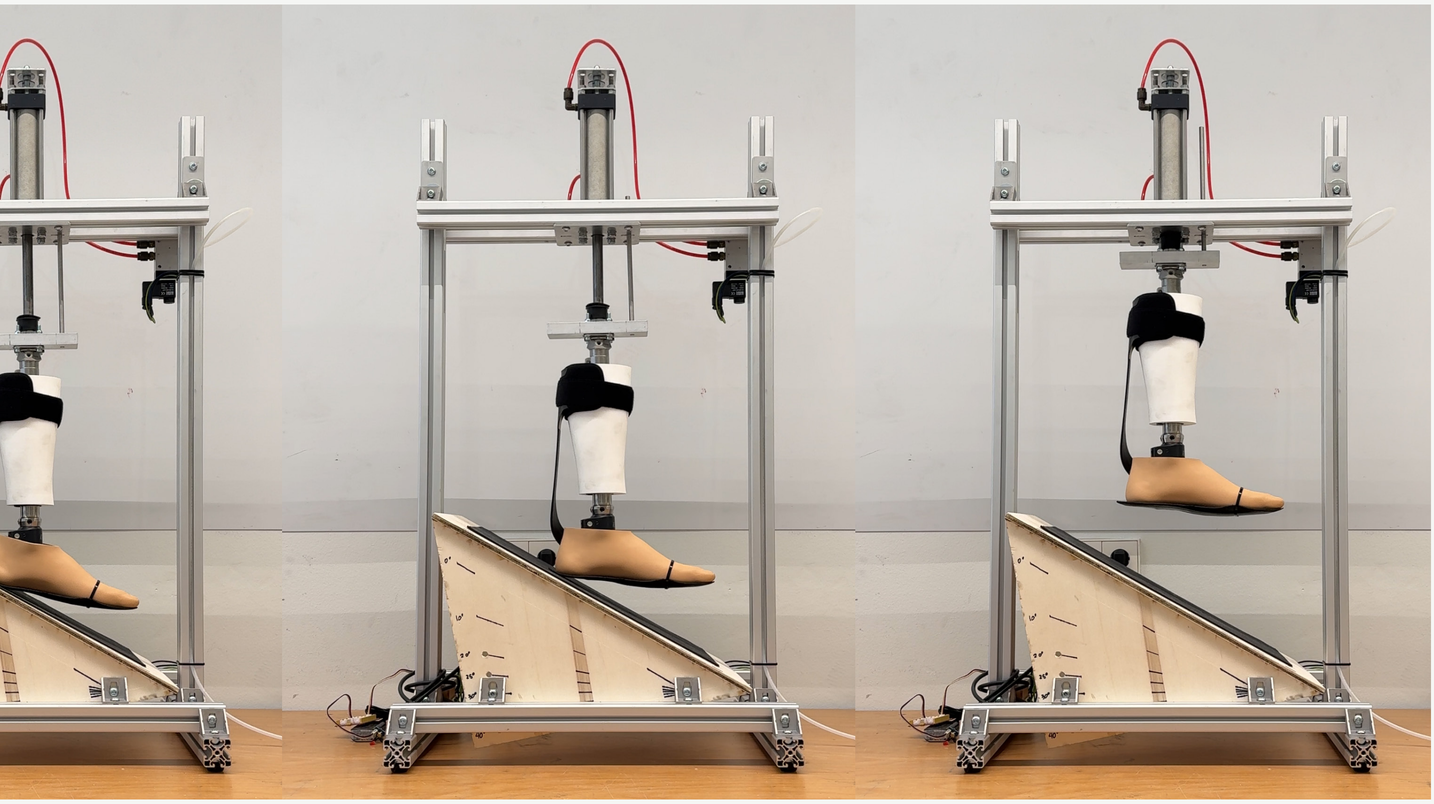


Figure 67. Load cycle motion with prosthetic foot without shoe. In this example the ***heel rocker*** is depicted.





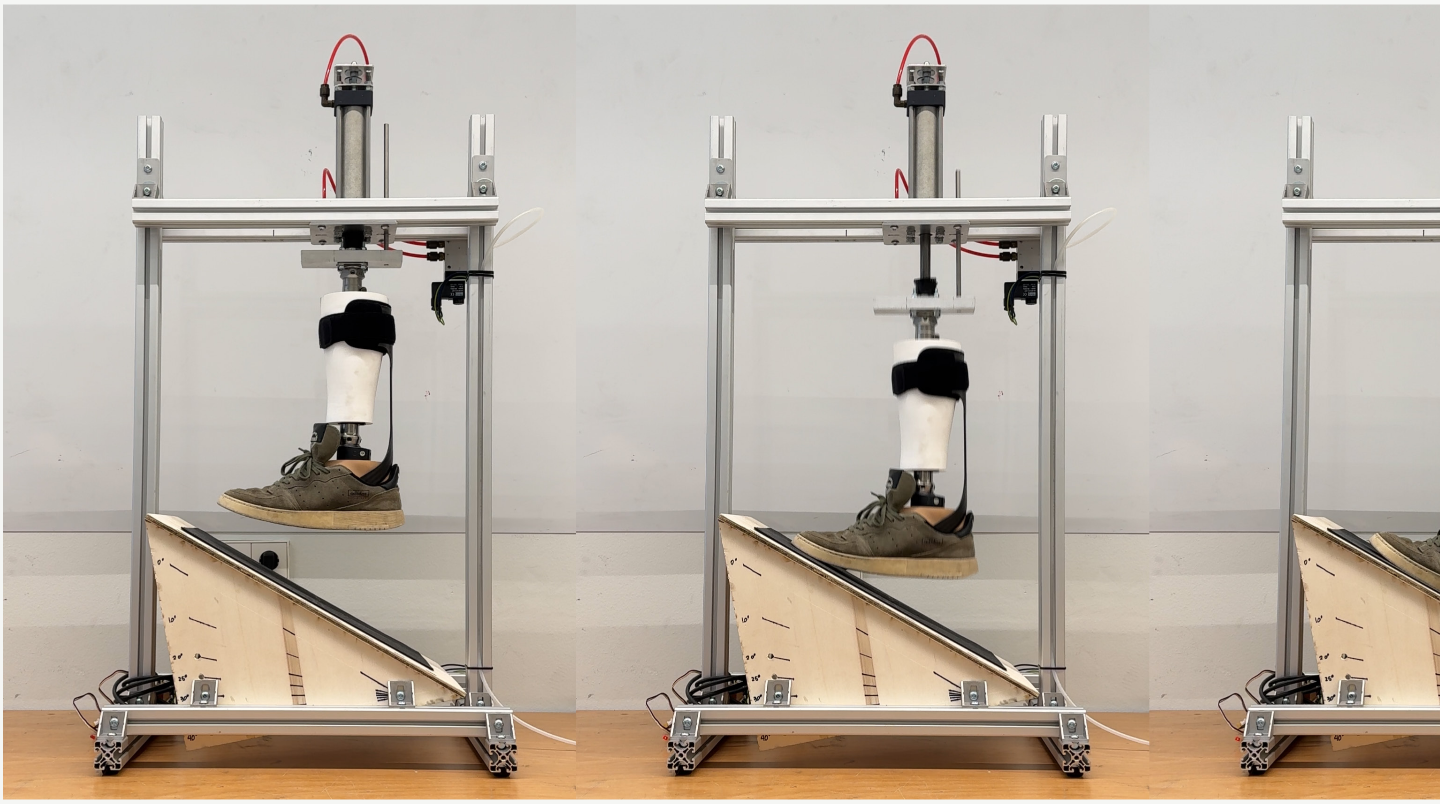


Figure 68. Load cycle motion with prosthetic foot with shoe. In this example the ***forefoot rocker*** is depicted.

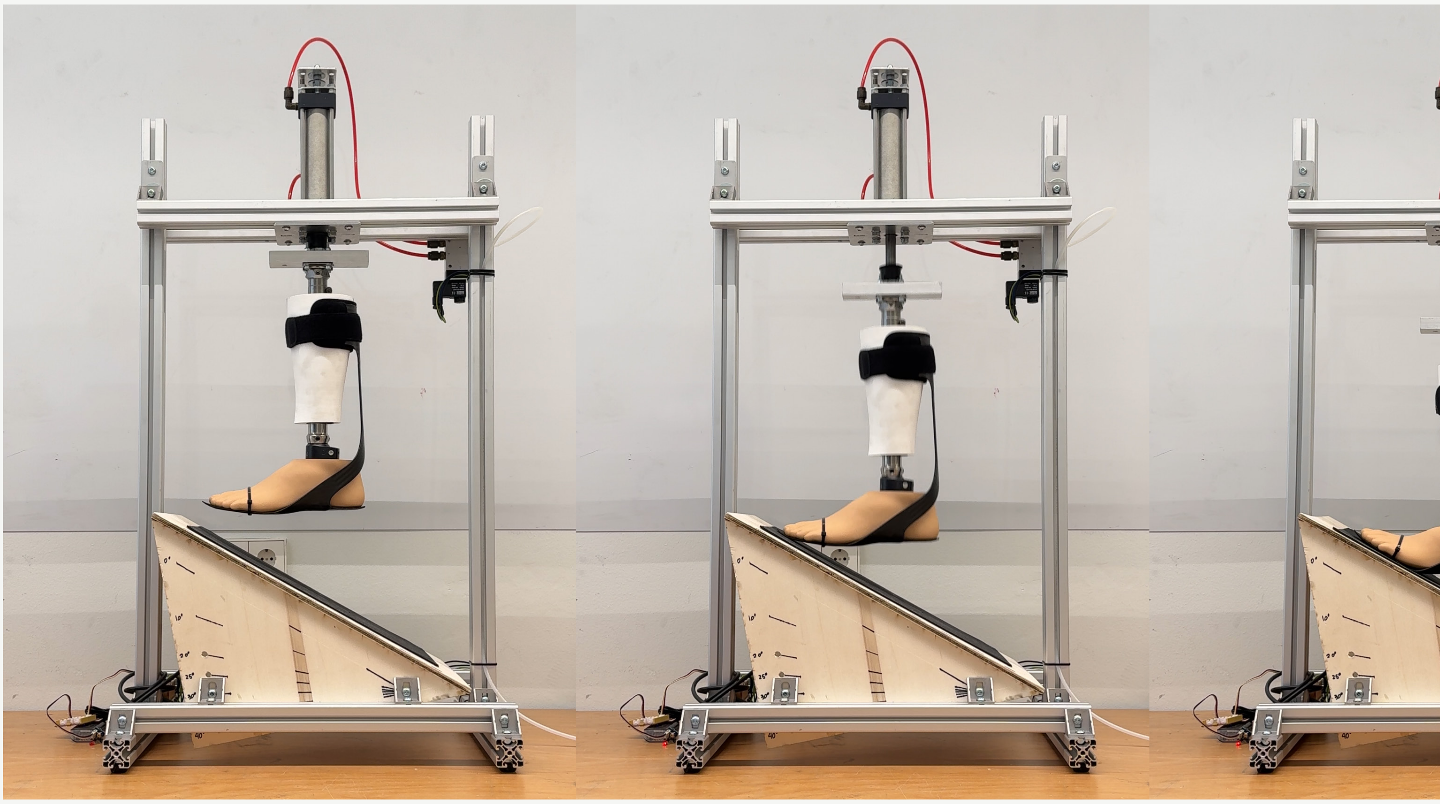
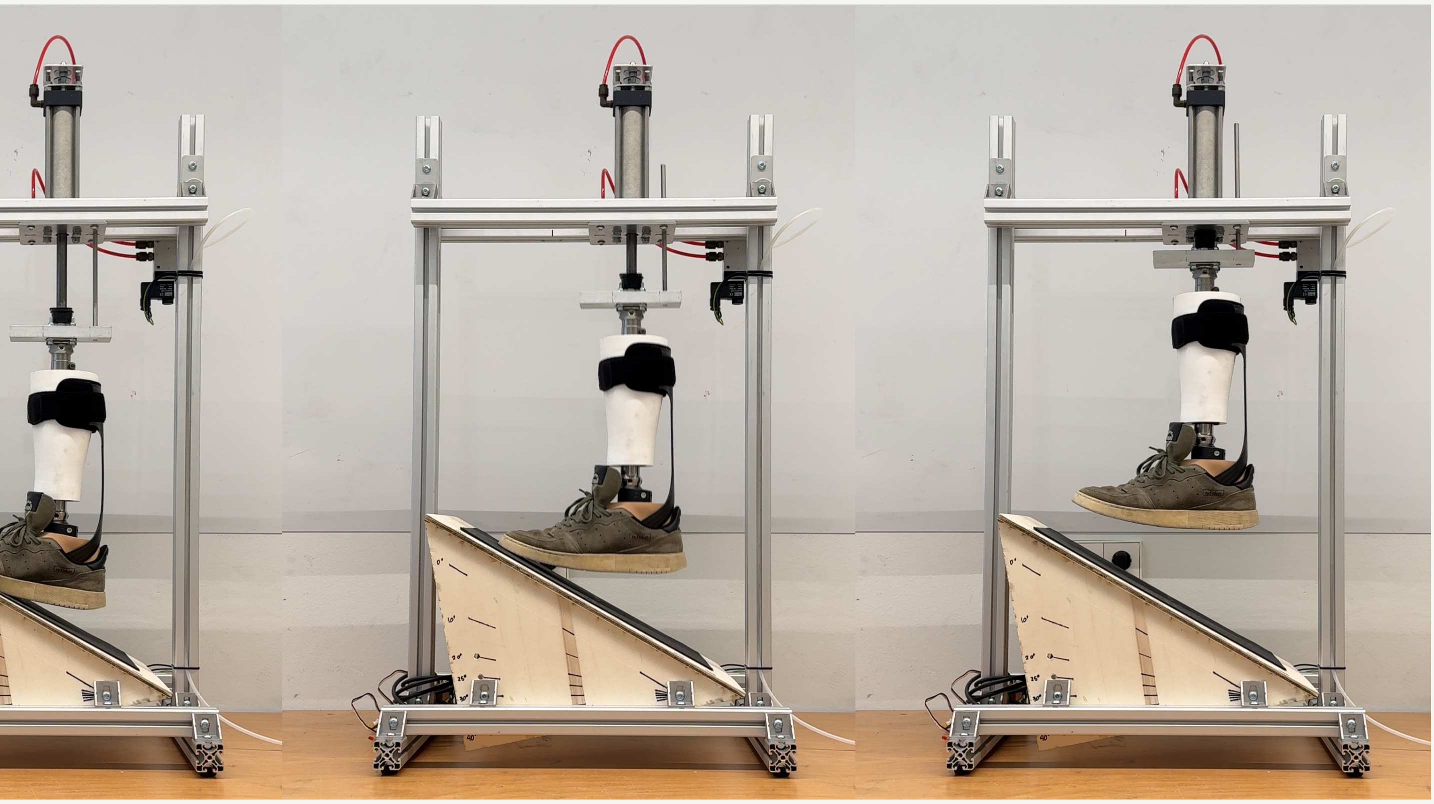
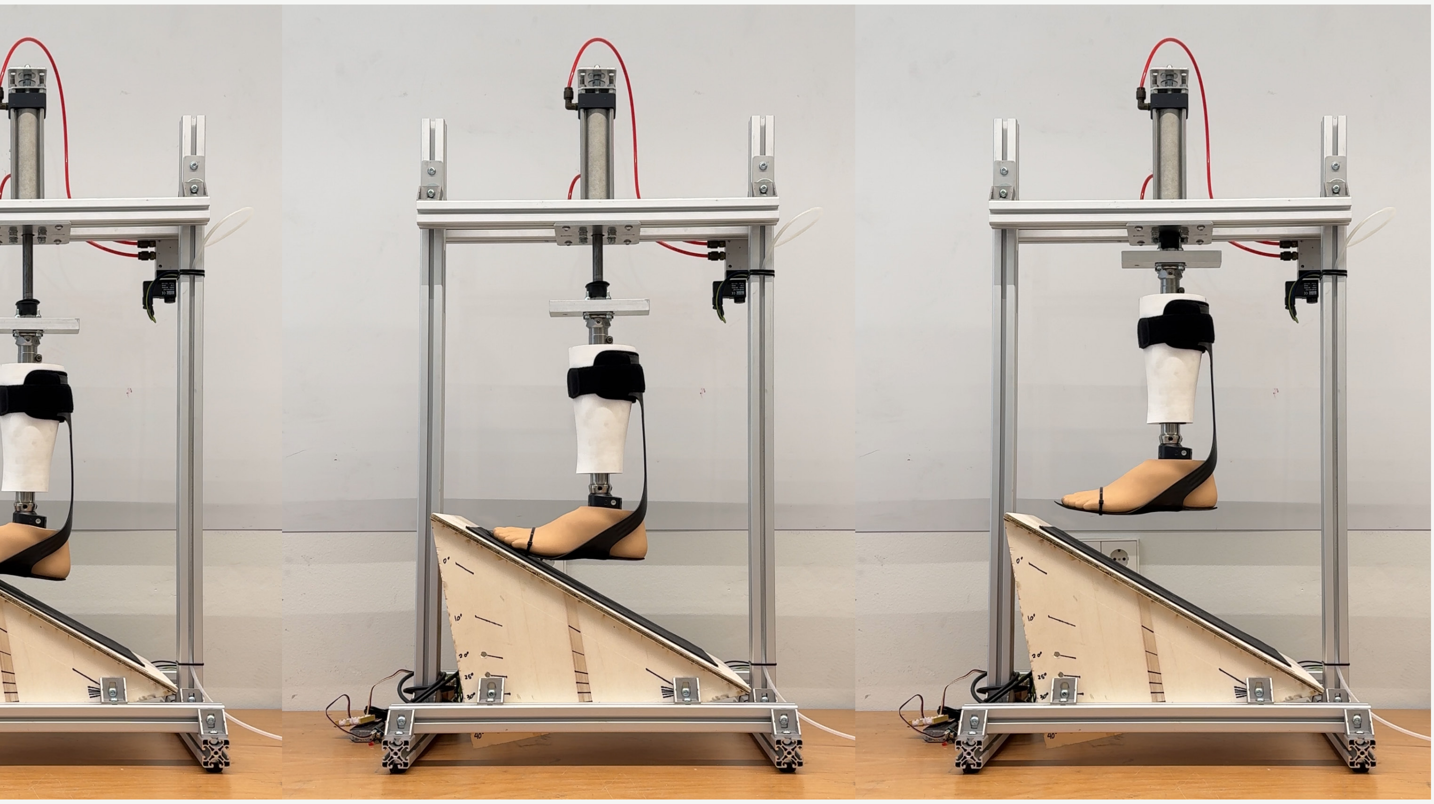


Figure 69. Load cycle motion with prosthetic foot without shoe. In this example the ***forefoot rocker*** is depicted.





6.3. Reassessment on Desirability, Feasibility, Viability

In this part a qualitative assessment of the redesign will be given on desirability, feasibility and viability based on the main requirements, see table 8.

Here the ability of the redesign to address the design goal will be discussed by looking at the goal and the main requirements for achieving that goal. Table 8 shows all requirements, which were met with the redesign and which are still yet to be proven if they are met.

The redefined design goal:
Design a proof-of-concept load cycle test setup which can simulate 2 years of walking with an AFO

Which conditions are now met with the redesign?

Met Desirability conditions:

- With the redesign the client should be able to load cycle test AFOs to guarantee the product can withstand 2 years of walking.
- The redesign should be able to test all the three ***rockers*** in one cycle.
- During this cycle it should be able to recreate the critical bending around the ankle and around the ***MTP joints*** in the AFO.
- The redesign should be able to test with shoes because of the full-size prosthetic foot functioning as a dummy foot.

Met Viability conditions:

- Because all 3 ***rockers*** can be simulated in one cycle, only one test run of 2 million cycles has to be performed to guarantee an AFO can withstand 2 years of walking.
- This will at 1 [Hz] take ~23 days and use one third of the energy and accompanying costs compared to the previous realized test setup.
- This redesign is still going to be significantly cheaper than buying and adapting an existing ISO 22675 test setup of €70.000 or to outsource the testing at ~€6000 per test.

Met Feasibility conditions:

- With the new dummy foot and split lock washers the redesign should be able to do significant longer test runs. However, to assure it can do test runs of 2 million cycles, trial run testing should again be performed.
- The method of recreating the force on the AFO during gait by matching deflection is assumed to also work with the DGS. This however needs to be checked.
- Again the design follows and adapts ISO 22675 Fatigue ankle-foot device Prosthetic Test Equipment, giving a lot of guidance and confidence in the feasibility of building the test setup, as the design described in this standard is proven and standardised.
- At last a motion study in CAD was performed with the redesign to evaluate digitally if the desired motion can be acquired with the redesign. The motion study was performed in Autodesk Fusion 360. Unfortunately no bending can be simulated in this software, so the bending of the AFO and shoe is not shown. The motion however of the cycle was simulated and animated. Figure 70 shows screen captures of the animation of the essential 3 ***rockers***. The motion study shows that the desired motion in the cycle is possible with the redesign. Acquiring the right synchronisation between the linear actuator of the dummy leg and the rotary actuator of the ***Dynamic Ground Surface*** (***DGS***) will be essential and probably quite a mechatronic challenge that needs to be tackled.

Conclusion

The reassessment of the redesign demonstrates that it successfully meets the key conditions of desirability, feasibility, and viability. The setup enables reliable load cycle testing of AFOs, ensuring they can withstand two years of walking by efficiently simulating all three ***rockers*** in a single cycle. Additionally, the redesign offers significant cost and energy savings compared to the previous design by combining the three ***rockers*** in one cycle, enhancing its viability. While feasibility is supported by the use of standardized ISO 22675 guidelines and an improved dummy foot, further testing is needed to validate long-duration test runs. The latter are the only requirements not met in this assessment on paper. Overall, the redesign presents a promising and cost-effective solution for AFO durability testing.

1. Heel rocker

2. Ankle rocker

3. Forefoot rocker

Figure 70. **Motion study** of the load cycle of the redesign in Fusion 360. A full animation was made, this figure shows screen captures of the essential 3 ***rockers***.

Main guiding requirements

#	Requirement	Source
~~R1~~	~~**Enable load cycle testing simulating 2 years of walking**~~	~~This was the conclusion of researching the product usage and breakage of AFOs and cataloging all existing AFO test setups that could be found on the internet. See chapter *2. Analysis*.~~
~~R2~~	~~**The loads on the AFO during gait should be recreated in the test setup**~~	~~In the reviewed literature there is data available on how much force there is on the leg while walking, but there is no data or knowledge available on how much force an AFO carries when a patient walks with it. By speaking to AFO testing expert D. Hochmann, it is known that this is a critical challenging task to solve.~~
~~R3~~	~~**Gait should be simulated by recreating the 3 *rockers***~~	~~The research-through-design process of iteratively building the test setup and comparing it to real life gait led to this discovery. See chapter *4.1. Gait Analysis* and chapter *5.2. Cycle Testing*.~~
~~R4~~	~~**Allow testing of normal and a wide variety of abnormal gait patterns**~~	~~Based on findings from analysing gait with AFOs: chapter *4.1. Gait Analysis*.~~
~~R5~~	~~**Enable testing for a wide variety of AFOs**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R6~~	~~**Simulate bending around the ankle & *MTP joint***~~	~~This is based on the experience of ***CPO'ers*** at the company, see subchapter *2.1.How do traditional & 3D-printed AFOs fail?* and *appendix 12.3*.~~
~~R7~~	~~**Allow evaluation of the tested AFO on damage**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R8~~	~~**Safe for R&D operators and all other by-passers**~~	~~Common safety precautions.~~
R9	**Minimum amount of cycles per test run > 2 million**	This is directly taken from ISO 22675:2016 - *Testing of ankle-foot devices and foot units*.
R10	**Amount of runs > 20**	This is an estimation as it depends on the building price of the test setup. Once this price is known, it is advised to the client company to make a quick calculation with their budget what the minimal amount of runs would be to make a test setup viable.
~~R11~~	~~**Run time < 50 days**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R12~~	~~**Cost price < ~€15.000**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~
~~R13~~	~~**Allow testing at the office of the company**~~	~~As communicated by the supervisors from the client company (personal communication, 2024).~~

Table 7. Overview of the additional main guiding requirements that were met with the redesign (highlighted in dark green).

Category	Explanation
~~**Desirability**~~	~~Developing a load cycle test setup was chosen because of the following 4 reasons: 1. Stiffness test machines are available in the industry. 2. Impact can be evaluated by trial and error. 3. The only purchasable load cycle test setup is too expensive (price tag ~€70K). 4. Cyclic loading is the largest reason for AFOs to fail.~~
~~**Feasibility**~~	~~In order to simulate cyclic loading on an AFO due to walking, it must be known what the forces are on the AFO. These forces consequently need to be recreated in the test setup.~~
~~**Desirability**~~	~~The movement of gait can be best described based on the 3 rocking motions of gait: ***heel rocker***, ***ankle rocker***, and ***forefoot rocker***.~~
~~**Desirability**~~	~~AFOs are worn to correct a wide variety of inefficient abnormal gaits to normal gaits. The test setup should allow to minimally simulate a normal gait as a representation of all abnormal gaits. Ideally it should also allow setting up the testing of a wide variety of abnormal gait patterns.~~
~~**Desirability**~~	~~The test setup should be able to test a wide variety of AFOs and a wide variety of sizes in order to keep the AFO design space of the company completely open.~~
~~**Desirability**~~	~~The test setup must simulate the bending in the AFO around the ankle & ***MTP joint***, as these are the spots where the most stress occurs due to bending.~~
~~**Desirability**~~	~~At each chosen amount of cycles it should be possible to evaluate the state of the AFO.~~
~~**Desirability**~~	~~The test setup should be safe while being setup, while running and should not cause any fire hazards.~~
Feasibility	2 million cycles is the chosen amount of cycles to represent two years of walking. This is based on an activity level of ~5000 steps per day (~2500 per leg).
Feasibility	Total number of runs that the test setup should last is at least 20 to deem this setup viable for its testing purpose.
~~**Viability**~~	~~The total run time of a test run should not exceed 50 days otherwise it takes too long to test products and iterate on them and it will prevent the test run from becoming too expensive. A cycle speed of at least 1 [Hz] is desired, as this will keep the run time ~42 days.~~
~~**Viability**~~	~~Target is somewhere below ~€15.000. Because the company is new to LE orthoses, they want to keep initial investments low.~~
~~**Viability**~~	~~This way prototypes can be tested on site to enable quick iteration on them. Therefore the device must not cause a fire hazard or produce more than 75 decibels (equal to the sound of a vacuum cleaner)~~

7. Conclusion

The purpose of this project was to provide an answer to the initial problem definition:

How do we ensure that 3D-printed AFOs can provide 2 years of care without breaking or significantly losing performance?

From all the activities considered 'normal' use, it was chosen to focus on testing cyclic loading due to walking. AFO-specific load cycle test setups are not available on the market for an affordable price, and cyclic loading is the most prominent reason AFOs fail.

Thus, the redefined design goal of this project was set to the following:

Design a proof-of-concept load cycle test setup which can simulate 2 years of walking with an AFO

In this project, the first version of this proof-of-concept AFO load cycle test setup was built. An essential question for building this setup was: What is the load on the AFO during walking? The answer was provided by a newly created approach novel to the industry: matching the displacement of the AFO in the test setup to the displacement of the AFO during real-life walking with the help of video analysis. With this realised test setup, the three most characteristic phases of walking could be cycle tested separately: heel, ankle and ***forefoot rocker***. Based on video comparison, only the last (the ***forefoot rocker***) can be simulated considerably well with this first version. For the ***heel rocker***, it was found that a dummy foot with an ***ankle joint*** is necessary to create the required plantar flexion. For the ***ankle rocker***, a rotating ground platform is needed to recreate the hinging motion of the ankle in ***dorsiflexion***.

A trial test run, testing the ***forefoot rocker*** for 1 hour at 1 Hz, was performed to test the reliability of the realised test setup. The trial test run showed that the current test setup cannot yet complete such a run. Next to bolts coming loose and the test setup drifting away due to vibrations, the most critical issue was the fixation of the AFO. The AFO repeatedly slipped off the dummy calf after ~10 cycles. Attempts to secure it with a shoe showed partial improvement, increasing the amount cycles that could be performed to ~1080. It did not provide a lasting solution, as the dummy foot with partial foot length allowed the shoe to slip off. A full-length dummy foot with an ***MTP joint*** to allow the bending of the toes is necessary to fixate the AFO properly with a shoe.

These lessons were integrated into a digital redesign made in CAD. The redesign should fulfil the goal of the redefined design brief: simulating 2 years of walking (~2 million steps) with an AFO to assess loss of stiffness and product failure due to material fatigue.

Although time constraints in the project prevented the realization of the rotating platform, the dummy foot with ankle and MTP joint was achieved by adapting a prosthetic foot. Video analysis indicated that with this design, the heel rocker can now be simulated as well, and it is predicted that it will also permit testing for the ankle rocker if a rotating platform is included. The new foot also demonstrated promising results in maintaining the AFO and shoe in place.

A reassessment of the redesign demonstrates that it successfully meets almost all main requirements based on desirability, feasibility, and viability. The redesign offers significant cost and energy savings compared to the previous design by combining the three ***rockers*** in one cycle, enhancing its viability. While feasibility is supported by using ISO 22675 guidelines and integrating a prosthetic dummy foot, further testing is needed to validate long-duration test runs. The latter are the only requirements not met in this assessment.

The company's recommended next step following this project is to construct and test the redesign with rotating platform. If this redesign is successfully realised and optimised, AFO designs can be tested under cyclic loading due to walking to ensure they can provide two years of care.

8. Recommendations

8.1. How to Proceed the Development of the AFO Load Cycle Test Setup?

After this project, building the redesign with ***Dynamic Ground Surface (DGS)*** is the next step for the company to finalize a proof-of-concept that can accurately and fully simulate a step. This proof-of-concept build could then be used to test and optimize the design. If the last is realized, AFO designs can be tested on cyclic loading simulating 2 years of walking. The following things still need to be designed to be able to build this redesign:

8.1.1. Base the exact Test Setup Dimensions on ISO 22675

The exact dimensions of the ***DGS*** and the frame should be based on the dimensions given in ISO 22675, as this standard describes the exact dimensions for the test setup to recreate gait realistically with this type of test setup. As for example the location of the axis of the Dynamic Ground Surface. See TA in Figure 71. The standard has to be bought to view the exact dimension.

8.1.2. Include Damping in the Linear Actuator

Vertical dampening in the pneumatic actuator is required at retraction to reduce the wear of the cylinder (top circle in Figure 71). Horizontal dampening around the linear actuator, as described in ISO 22675 (see 3 in Figure 71), has to be included to reduce the non-realistic horizontal reaction forces that occur due to the linear actuator pushing on the angled ground surface.

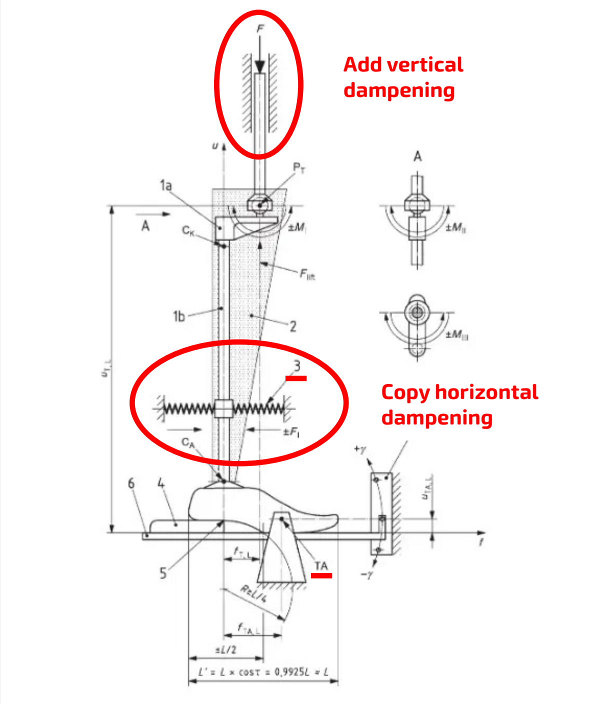


Figure 71. The technical drawing from ISO 22675 (ISO, 2016).

8.1.3. Validation of Cycle with DGS

Video analysis to validate the deflection of an AFO is necessary with the redesign to validate if the test setup with the ***DGS*** has a load cycle that creates the same movement and deflection as in a real-life step. This can be done in the same manner as described in chapter *5.2. Cycle Testing*. If any deviations are seen with this analysis, they will need to be addressed before finalizing the design.

8.2. Trial Run to Test Reliability

With the new dummy foot and split lock washers to prevent nuts from vibrating loose, the redesign should be able to do significantly longer test runs. However, to ensure it can do test runs of 2 million cycles, trial run testing should again be performed.

8.3. How to Use the Redesigned AFO Load Cycle Test Setup?

It is advised to do the following testing procedure in order to guarantee an AFO can withstand 2 years of walking:

Conduct two test runs of 2 million cycles with two exemplars of the AFO that is being tested.

For prosthetics to adhere to ISO 22675, two separate test runs with two different prosthetics must be performed without product failure to claim they are safe. For this reason, it is advised to do the same with load cycle testing AFOs.

An appropriate shoe that can be worn with an AFO needs to be used in the test setup. ***CPOs*** at the company can advise on which type of shoe to use in the testing. This Orthoses shoe, by Fior and Gentz (Orthoses Shoe CROSSROADS, n.d.), see Figure 72, is a good example given by one of the ***CPOs***.

The method of recreating the loads of gait on an AFO by matching the displacement in the test setup raises the question: "Does the displacement of every different AFO, that is desired to be tested, need to be captured with video analysis?".

To answer this question, it is advised to video analyse a couple of AFOs and see if the deflections are acceptably similar.

During the load cycle test run, the AFO can be taken out at a chosen number of cycles to visually evaluate emerging damage and test the loss of stiffness with a separate stiffness test setup. This could, for example, be done after 400.000, 800.000, 1.600.000, and 2.000.000 cycles. These are the same amount of cycles Hochmann chose in his testing as described in his article in the Orthopädie Technik (2014).

The stiffness tests should be performed with a BRUCE test setup (Bregman et al., 2009). This test setup is the industry standard for testing the stiffness of orthoses.

Figure 72. An example of a shoe that should be worn with an AFO with the right heel height and a flexible side part to give space to the AFO in the shoe (Orthosis Shoe CROSSROADS, n.d.).

9. References

3D Ortho. (2023, August 10). Piro. https://3dorthopro.com/orthotics-prosthetics/afos-smos/

Ambroise. (2022, January 10). Klassische Knöchel- und Fußorthese. https://www.ambroise.nl/de/beinorthesen-2/knochel-und-fussorthesen/klassische-knochel-und-fussorthese/

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ANSYS. (2022). Granta EduPack 2022 R1 (22.1.2) [Dataset; Software].

Ashby, M. F., Shercliff, H., & Cebon, D. (2013). Materials: Engineering, Science, Processing and Design. Butterworth-Heinemann.

Bergzeit. (n.d.). Schoenmaat: conversietabellen & voetlengte meten. bergzeit.nl. Retrieved September 17, 2024, from https://www.bergzeit.nl/maatgidsen/maatgids-schoenen/?srsltid=AfmBOopgtjxPG3RLh3clMs-GGXqVi4Ha8JsqVlf3qmqDuqr9gRNTI5dk

Bregman, D., Rozumalski, A., Koops, D., De Groot, V., Schwartz, M., & Harlaar, J. (2009). A new method for evaluating ankle foot orthosis characteristics: BRUCE. Gait & Posture, 30(2), 144–149. https://doi.org/10.1016/j.gaitpost.2009.05.012

Carlson, J. Martin M.S. (Engineering), C.P.O.; Day, Bruce; Berglund, Gene C.O.. Double Short Flexure Type Orthotic Ankle Joints. JPO Journal of Prosthetics and Orthotics 2(4):p 289-300, Summer 1990.

Choo, Y. J., & Chang, M. C. (2021). Commonly Used Types and Recent Development of Ankle-Foot Orthosis: A Narrative Review. Healthcare, 9(8), 1046. https://doi.org/10.3390/healthcare9081046

Cvoha, D., & Deckers, J. (1996). Ganganalyse en looptraining voor de paramedicus. Bohn Stafleu van Loghum.

Design Council. (2005). The Double Diamond: a universally accepted depiction of the design process. Retrieved December 8, 2024, from https://www.designcouncil.org.uk/our-resources/the-double-diamond/

Desksign - Boxes. (n.d.). https://boxes.hackerspace-bamberg.de/Desksign?language=en

Festo. (n.d.-a). Balgcilinder EB-385-230 | Festo NL. https://www.festo.com/nl/nl/a/193791/?q=%7E%3AsortByCoreRangeAndNewProduct%7E%3ACC_Stroke_combined_mm_C_FP_GLOBAL%7E%3A230.0

Festo. (n.d.-b). Fluidic Muscle DMSP Online kopen | Festo NL. https://www.festo.com/nl/nl/p/fluidic-muscle-id_DMSP/?q=%7E%3AsortByCoreRangeAndNewProduct

Festo. (n.d.-c). Zwenkaandrijving DSMI-40-270-A-B | Festo NL. https://www.festo.com/nl/nl/a/561691/?q=%7E%3AsortByCoreRangeAndNewProduct

↑↑↑ Fior & Gentz. (n.d.). Orthosis Shoe CROSSROADS. Retrieved February 10, 2025, from https://www.fior-gentz.de/en/products/shoes/orthosis-shoes/orthosis-shoe-crossroads/orthosis-shoe-crossroads.html

↑↑↑ Firgelli Automations, & Li, M. (2023, March 7). Which is best Pneumatic vs Electric Actuators? Pros and Cons for Diffe. Firgelli Automations. https://www.firgelliauto.com/blogs/news/which-is-best-pneumatic-vs-electric-actuators-pros-and-cons-for-different-applications#:~:text=Longer%20lifespan%3A%20Pneumatic%20actuators%20have,can%20wear%20out%20or%20fail.

↑↑↑ Hochmann, D. (2014). Testing procedures for Ankle-Foot orthoses. In OrthOpädie Technik (Vol. 5/14, pp. 102–103). https://360-ot.de/wp-content/uploads/2019/10/1310_SD_Hochmann_5_14_OB_GB_ger.pdf

↑↑↑ Hochmann, D. (2024, June 20). Biomechatronics SIGMA3D: Simulation-assisted med-tech platform for providing custom 3Dprinted devices [Slide show].

↑↑↑ IKEA India. (2019, November 27). IKEA Test Lab [Video]. YouTube. https://www.youtube.com/watch?v=wFtsatcQtDc

↑↑↑ IKEA Museum AB. (2023, August 16). Testing sparked both interest and anxiety - IKEA Museum. WordPress På Azure. https://ikeamuseum.com/en/explore/the-story-of-ikea/quality/

↑↑↑ ISO. (2016). ISO 22675:2016 Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods. https://www.iso.org/standard/70203.html

↑↑↑ It's Triggy! (2019, December 29). Control Pneumatic Cylinder with Arduino [Video]. YouTube. https://www.youtube.com/watch?v=iXNNjtK5hp8

↑↑↑ Lai, H., Yu, C., Kao, H., Chen, W., Chou, C., & Cheng, C. (2010). Ankle–foot simulator development for testing ankle–foot orthoses. Medical Engineering & Physics, 32(6), 623–629. https://doi.org/10.1016/j.medengphy.2010.03.008

↑↑↑ Lecturio & Leiden University Medical Center. (n.d.). Lecturio - Drawing Sagittal, coronal and transverse plane - English labels. anatomytool.org. Retrieved July 24, 2024, from https://anatomytool.org/content/lecturio-drawing-sagittal-coronal-and-transverse-plane-english-labels

↑↑↑ Leigh. (2021, March 25). Ortho Europe MDR Statement – April 2021. Ortho Europe. https://www.ortho-europe.com/ortho-europe-mdr-statement-april-2021/

↑↑↑ Livit Ottobock Care. (n.d.-a). Enkel Voet Orthese (EVO) | Livit Ottobock Care. https://www.livit.nl/orthesen-braces/enkel-voet-orthese-evo/

↑↑↑ Livit Ottobock Care. (n.d.-b). Livit Webinar - EVO type keuze.

↑↑↑ Lunsford, R., Ramm, T., & Miller, A. (1994). Viscoelastic Properties of Plastic Pediatric AFOS. JPO: Journal of Prosthetics and Orthotics, 6(1), 3–9. https://journals.lww.com/jpojournal/abstract/1994/00610/Viscoelastic_Properties_of_Plastic_Pediatric_AFOs.2.aspx

↑↑↑ NEN. (2006, October 1). NEN-EN-ISO 22523:2006 en. Retrieved February 7, 2025, from https://www.nen.nl/nen-en-iso-22523-2006-en-107630

↑↑↑ OTWorld. (n.d.). Piro: 3D printed SMO & AFO. Retrieved December 8, 2024, from https://www.ot-world.com/exhibitors-products/product/otworld/425080/176605

↑↑↑ Polliack, A. A., Swanson, C., Landsberger, S. E., & Mcneal, D. R. (2001). Development of a testing apparatus for structural stiffness evaluation of Ankle-Foot orthoses. Journal of Prosthetics and Orthotics, 13(3), 74–82. https://doi.org/10.1097/00008526-200109000-00012

↑↑↑ Protolabs. (n.d.). What is MJF (HP's Multi Jet Fusion) 3D printing? Protolabs Network. https://www.hubs.com/knowledge-base/what-is-multi-jet-fusion/

↑↑↑ Quantify BV. (2025, January 7). Quantify. Quantify. Retrieved January 14, 2025, from https://quantifybv.be/

↑↑↑ RapidCenter B.V., & Stam, F. (2024, June 10). HR PA12 (nylon). RapidCenter.nl. Retrieved July 19, 2024, from https://www.rapidcenter.nl/nl/materialen/hr-pa12-hp-multi-jet-fusion

↑↑↑ Rogati, G., Caravaggi, P., & Leardini, A. (2022). Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: a review study. Journal of Foot and Ankle Research, 15(1). https://doi.org/10.1186/s13047-022-00547-2

↑↑↑ Shuman, B. R., Totah, D., Gates, D. H., Gao, F., Ries, A. J., & Esposito, E. R. (2023). Comparison of five different methodologies for evaluating ankle–foot orthosis stiffness. Journal of Neuroengineering and Rehabilitation, 20(1). https://doi.org/10.1186/s12984-023-01126-7

↑↑↑ STEP Lab. (2024, April 4). ISO 22675 - Testing of ankle-foot devices and foot units - STEP Lab. https://step-lab.com/iso/iso-22675/

↑↑↑ tameson.nl. (n.d.). Enkelwerkende Hydraulische Cilinders. Tameson.nl. https://tameson.nl/collections/enkelwerkende-hydraulische-cilinders

↑↑↑ Tempelman, E. (2020). NSFD: engineering essays on structures & materials [Paperback]. Boekengilde. https://www.tudelft.nl/en/2020/io/april/new-book-erik-tempelman-out-now-nsfd

↑↑↑ Thrive Orthopedics. (2021, August 12). AFO Testing | Thrive F3 AFO Durability Testing | Carbon Fiber AFO Cycle testing to ~1 million cycles [Video]. YouTube. https://www.youtube.com/watch?v=RqwpGa4OJU0

↑↑↑ Tillges Technologies. (n.d.). Propulsion® Bracing. Tillges. https://www.teamtillges.com/technologies/propulsion/

↑↑↑ Vinney, C. (2023, November 9). Desirability, feasibility and viability diagram: What does it mean? - UX Design Institute. UX Design Institute. https://www.uxdesigninstitute.com/blog/desirability-viability-and-feasibility/

↑↑↑ Worth, J. (2022, December 16). What are the different types of linear actuators? Igus® Engineer's Toolbox. https://toolbox.igus.com/4527/types-of-linear-actuators

↑↑↑ Yin, C. (2015). GAIT CYCLE ANALYSIS AND MECHANICAL DESIGN OF ANKLE FOOT ORTHOSIS TESTBED [Master thesis, Northeastern University Boston]. https://repository.library.northeastern.edu/files/neu:349745/fulltext.pdf

↑↑↑ Zijlstra, J., & Daalhuizen, J. (2020). Delft Design Guide (revised Edition). Macmillan Publishers.

↑↑↑ Zilvertron B.V. (2024, September 10). SMC80S-0075-30QBK-5LSU AC servo - Zilvertron. Zilvertron. https://products.zilvertron.com/motoren/ac-servomotor/smc80s-0075-30qbk-5lsu/ki00118/

10. Appendix

The appendix of this report is a confidential separate document due to Intellectual Property reasons of the client company. In this appendix only the original project brief is given.

TUDelft

DESIGN FOR our future

IDE Master Graduation Project

Project team, procedural checks and Personal Project Brief

In this document the agreements made between student and supervisory team about the student's IDE Master Graduation Project are set out. This document may also include involvement of an external client, however does not cover any legal matters student and client (might) agree upon. Next to that, this document facilitates the required procedural checks:

- Student defines the team, what the student is going to do/deliver and how that will come about
- Chair of the supervisory team signs, to formally approve the project's setup / Project brief
- SSC E&SA (Shared Service Centre, Education & Student Affairs) report on the student's registration and study progress
- IDE's Board of Examiners confirms the proposed supervisory team on their eligibility, and whether the student is allowed to start the Graduation Project

STUDENT DATA & MASTER PROGRAMME

Complete all fields and indicate which master(s) you are in

Family name	van der Stoep 7179	IDE master(s)	IPD ✔ / DfI / SPD
Initials	S A	2nd non-IDE master	
Given name	Sep	Individual programme *(date of approval)*	
Student number	4660145	Medisign	
		HPM	

SUPERVISORY TEAM

Fill in he required information of supervisory team members. If applicable, company mentor is added as 2nd mentor

Chair	Arjen Jansen	dept./section	Sustainable Design Engineering
mentor	Freerk Wilbers	dept./section	Sustainable Design Engineering
2nd mentor	[redacted]		
client:	confidential, referred as company		
city:	[redacted]	country:	The Netherlands
optional comments	The chair and mentor are from the same department, however they both have different relevant expertises: Arjen Jansen will provide knowledge on biomechanics and ortheses; Freerk Wilbers will assist in the mechanical engineering and prototyping part of the assignment.		

! Ensure a heterogeneous team. In case you wish to include team members from the same section, explain why.

! Chair should request the IDE Board of Examiners for approval when a non-IDE mentor is proposed. Include CV and motivation letter.

! 2nd mentor only applies when a client is involved.

APPROVAL OF CHAIR on PROJECT PROPOSAL / PROJECT BRIEF -> to be filled in **by the Chair** of the supervisory team

Sign for approval (Chair)

Digitally signed by tudelft.protect Jamf Protect CSR Identity
Date: 2024.05.29 12:05:28 +02'00'

Name A.J.Jansen Date 29 May 2024 Signature

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CHECK ON STUDY PROGRESS

To be filled in **by SSC E&SA** (Shared Service Centre, Education & Student Affairs), after approval of the project brief by the chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total ____ EC

Of which, taking conditional requirements into account, can be part of the exam programme ____ EC

★	YES	all 1st year master courses passed
	NO	missing 1st year courses

Comments:

Sign for approval (SSC E&SA)

Rik Ledoux Digitally signed by Rik Ledoux Date: 2024.05.29 15:40:28 +02'00'

Name Rik Ledoux Date 29 May 2024 Signature

APPROVAL OF BOARD OF EXAMINERS IDE on SUPERVISORY TEAM -> to be checked and filled in by IDE's Board of Examiners

Does the composition of the Supervisory Team comply with regulations?

YES	★	Supervisory Team approved
NO		Supervisory Team not approved

Comments:

Based on study progress, students is ...

★	**ALLOWED** to start the graduation project
	NOT allowed to start the graduation project

Comments:

Sign for approval (BoEx)

Monique von Morgen Digitally signed by Monique von Morgen Date: 2024.05.30 10:05:55 +02'00'

Name Monique von Morgen Date 30 May 2024 Signature

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Name student Sep Abel van der Stoep **Student number** 4,660,145

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

Project title Developing a test setup to measure durability aspects of ankle-foot ortheses

Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

The context and domain:
This graduation project is for the confidential client referred to as M2, a company that operates in the field of orthopaedics. They currently specialise in personalised hand splints and braces on the basis of 3D-scans. The splints and braces provide support for patients with conditions like osteoarthritis, hypermobility, Ehlers-Danlos syndrome, and reumatoïde arthritis. Personalised splints and braces provide more support and more comfort than traditional braces. M2 is now looking at expanding beyond hand braces to also develop 3D-scan based ankle-foot orthoses (AFOs) to address medical conditions. The AFOs are used for medical conditions like drop foot, where patients are not able to properly lift their foot or perform pushing off on the floor while walking. An example of a traditional AFO can be seen in figure 1.

The stakeholders:
The patients using the ankle-foot orthoses, the medical specialists prescribing the ankle-foot orthoses, the Orthopaedic Technologist (OT) involved in fitting the orthoses, and the developing team at M2 developing and producing the ankle-foot orthoses. Patients desire a comfortable and most supportive ankle-foot orthosis. The medical specialists and OTs desire better treatment and fit as well. M2 aims to develop economically viable ankle-foot orthoses that do not fail over their life span to avoid resulting injuries, liability and warranty claims.

→ *space available for images / figures on next page*

introduction (continued): space for images

image / figure 1 Example of a traditional ankle-foot orthosis (the Super Ortho Peroneusveer from Podobrace.nl).

image / figure 2 A possible to be developed test setup: a load cycling machine (example ski boot tester by STEP lab).

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

M2 has the first prototypes for the new ankle-foot orthoses (AFOs) ready. However, it is unknown how the braces react under the different movements and loads of their use cases. Ankle-foot orthoses endure larger forces than hand splints or braces, because full body weight is applied on them when walking. The consequences of product failure are higher as they can lead to serious injury. Thus it is highly important for M2 to be able to evaluate the durability of ankle-foot orthoses. Currently it is also unknown what factors are important on the topic of durability for the different stakeholders. Durability aspects to be considered are: static loading for stiffness assessment, dynamic impact testing for immediate failure analysis, life cycle testing (encompassing material fatigue and repeated mechanical joint loading), spring-like energy return form the braces before and after wear, surface finish wear, and potentially more aspects.

If these factors can be measured it will allow M2 to optimise upon them in order to develop high quality, durable personalised braces. Patients thus will have comfortable, light and more supportive leg braces that will not break during its lifespan. Medical specialists will have access to personalised treatment. OTs will be able to fit fully personalised leg braces with a better fit within a shorter time span. These added values will give M2 a competitive advantage in the market.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

Design and build a test setup to measure the durability of ankle-foot orthoses (AFOs) for M2.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

Approach:
1. ORIENTATING - The perception of users, medical specialists and OTs on durability is considered to be essential, as they determine what enduring a full lifespan entails. Understanding when a brace is considered durable for M2 as the producer is equally essential. Figuring out and selecting the most important durability factors of ankle-foot orthoses across different use cases is thus the first step of the project.
2. ANALYSING - The second step is to understand and capture the exact biomechanical movement and resulting loads of the use cases. This is needed in order to accurately replicate the use cases in a test setup.
3. DESIGNING - The third step is to iteratively design and build a test setup that can measure one or multiple durability factors. Preceding desk research needs to be done on existing durability testing solutions on the market. Preferably we build as little proprietary tooling as possible. Consideration should be given to how and which data should be recorded to properly measure these aspects.
4. TESTING - At last a first trial of measurement should be performed with the build setup and documentation should be written for how M2 should use the test setups.

Project planning and key moments

*To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a **kick-off meeting**, **mid-term evaluation meeting**, **green light meeting** and **graduation ceremony**. Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	14 May 2024
Mid-term evaluation	19 Aug 2024
Green light meeting	11 Oct 2024
Graduation ceremony	8 Nov 2024

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	
For how many project weeks	
Number of project days per week	

Comments:

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

I want to start this project as it is a highly technical assignment at a company that is changing this industry with technical innovation. They create desirable products by combining high comfort and functionality with appealing design. A combination I adore as an industrial designer. I would like to work at M2 if they are happy with my graduation project results. The assignment also allows me to work on my own personal learning ambitions.

Competencies I want to prove and further develop:
1 - CAD-modelling en motion analysis
2 - High fidelity prototyping: 3D printing and/or other digital fabrication methods.
3 - Mechanical engineering: Beam bending, Material fatigue, and Biomechanics.
4 - Electronics: Arduino/Raspberry Pie, Coding, Data collection, and Data visualisation.
5 - Design rendering: Digital rendering, animation, and (Digital) design sketching for ideation and communication.

Personal learning goals: - I want to learn to be highly effective in project management by regularly and effectively updating my chair, mentor and client in meetings bi-weekly. Having each meeting well prepared with 3 slides containing progression, question and goals. - I also aim to get to know the culture and people at M2 to see if this would be a place I would be eager to work.

GRADUATION STUDENT
Sep Abel van der Stoep
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+31 6 34 68 00 99

SUPERVISORY TEAM
Chair: Dr. Ir. A.J. Jansen
Mentor: Ir. F.P. Wilbers

COMPANY
Confidential

COMPANY SUPERVISORS
Confidential