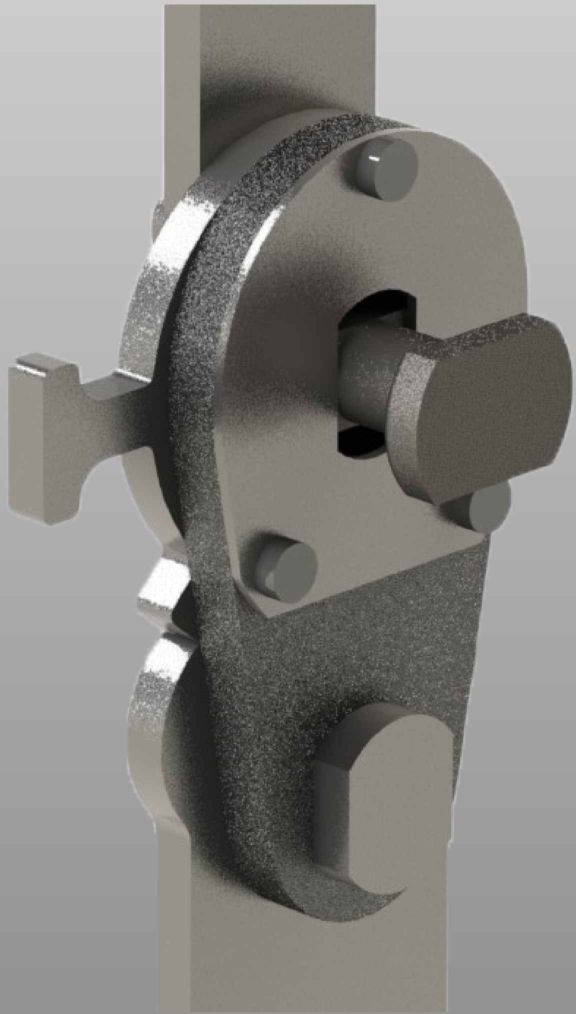
Design of a Hinge-Mechanism for an Ankle-Foot Orthosis that Increases Versatility and Ease of Use among AFO-Users

Jeffrey Deken



MSc Mechanical Engineering

Design of a Hinge-Mechanism for an Ankle-Foot Orthosis that Increases Versatility and Ease of Use among AFO-Users

by

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Abstract

Background: The development of ankle-foot orthoses (AFOs) have come a long way over the past decade. However, most improvements are mainly focused on gait performance. Hereby, other tasks are overlooked. This is also stated by AFO-users. AFO-users want an AFO that can be adjusted to suit different tasks. An adjustable AFO should allow adjustments for different shoes, and improve performance of tasks such as walking slopes, standing up/sitting down. Furthermore, a small, lightweight and durable solution is desired.
Aim: The aim of this study is to design and develop a hinge-mechanism for an ankle-foot orthosis that increases versatility and ease of use among AFO-users.
Problem Analysis: By talking to an AFO specialist and an AFO-user, insights are gathered that help establish the functional requirements and design specifications. This led to two main functional requirements. The first one is being able to easily adjust the alignment angle of the AFO. The second requirement is being able to lock and unlock the mechanism. This will allow the user to have more angular freedom in the ankle joint.
Conceptual Design: To come to a proper design, an overview was made of mechanisms that could fit in the design of the hinge. Using criteria, each mechanism was evaluated and a final design had been chosen. The push-out gear mechanism was chosen to adjust the alignment. For the locking mechanism the locking pin was chosen.
Concept Development: During the design process, the mechanism was iteratively improved. The locking mechanism was replaced by a rotating wedge, and the geometry of the mechanism was adjusted to be able to handle the loads. In the end, the mechanism was fabricated which demanded further changes in the design. The housing was 3D-printed, while other parts where laser-cut or turned on a lathe.
Evaluation: The final product was evaluated by the same AFO-user and specialist who gave advice at the beginning of this study. Furthermore the design was experimentally tested on holding torque using a load test. Lastly the design specifications were compared to the actual design.
Conclusion: In this study, an AFO hinge mechanism was designed and built that increases versatility and easy of use among AFO-users. This was achieved by two mechanisms. A pull-out gear allows to quickly adjust the alignment angle. This allows easy adjustment for wearing different shoes. A rotating wedge mechanism accommodates the (un)locking of the mechanism. Although there are still some improvements to be made, the prototype worked as expected. Also, the prototype was able to bear the load which was set at the beginning of the research. To see its true potential, the mechanism should be fitted inside an AFO. Although this mechanism looks promising, hands-on experience will really tell the added value of an adjustable hinge mechanism.

Acknowledgements

I wouldn't be able to finish my thesis without the help of other people. Therefore, I want to take a moment to thank these people.

First of all, I would like to thank Jaap Harlaar and Gerwin Smit for their supervision, feedback, and guidance throughout my thesis. I would like to thank Ajay Seth, Erin Marcri and my fellow graduates for their presence at the student progress meetings. Not only did I get useful feedback during those sessions, but it was also inspiring and motivating to see the projects of other students.

During my thesis I learned a lot about ankle-foot orthoses. The people from OIM Orthopedie and Basko Healthcare were there for me to provide information and answer my questions. I want to thank Yvette Kerkum, Johan de Jonge, and Peter de Groot from OIM Orthopedie. From Basko Healthcare I would like to thank Harold Jorning and Dirk van Dongen. Additionally I would like to thank the AFO-user for his perspective on AFOs, his suggestions for a new AFO design, and his feedback on the created prototype.

When it came to fabrication, assembly and testing of the design, there where also people who helped me out. I want to thank Damian de Nijs who helped me with the fabrication, Jan van Frankenhuyzen who helped me with some adjustments for fabrication, and Sander Leeflang who assisted with the load test.

Last but not least, I would like to thank my parents and girlfriend for always being there for me and supporting me throughout my thesis.

Contents

Chapter 1

Introduction

1.1 Background

For most people, walking is a part of daily routine, but that is not self-evident for everyone. Patients that suffer from stroke, spinal cord injury, or cerebral palsy often have an impaired ability to walk properly [1]. Muscular weakness or paralysis make it difficult to fully control the feet. A common phenomena among these patients is drop foot. Drop foot is when the front of the foot and toes can not be lifted during walking and could lead to dragging the feet on the ground. To provide support and assistance, people with lower extremity issues can be fitted with an Ankle Foot Orthosis (AFO). AFOs are used to cope with foot and ankle issues that are either biomechanical or neurophysiologic in nature [2]. An AFO provides support around the ankle joint and, depending on the condition, can offer:

- Support body-weight.
- Limit range of motion to avoid over-extension and over-flexion.
- Add-in stiffness to eliminate foot drop.

There are three types of passive AFOs, namely: Solid AFOs (SAFO), Flexible AFOs (FAFO) and Hinged AFOs (HAFO) (see figure: 1.1). Where the solid AFOs provide most support, the FAFO and HAFO allow for the patients to walk more naturally. Using a SAFO, the range of motion (ROM) of the ankle joint is reduced significantly. In certain activities, such as climbing stairs [3] and walking slopes [4] the ROM of the ankle joint is of significant importance. Radtka et al. [3] studied the kinematic and kinetic effects of solid, hinged and no-ankle foot orthoses on stair locomotion. The study showed that hinged AFOs retrieved similar results to normal shoes. Using a SAFO, stair locomotion took more effort. Buckon et al. [5] studied the effect of different types of AFOs on execution of walking, running, jumping, and upper extremity coordination on children with spastic diplegia. The study showed that all AFOs produced an increase in stride step length and a decrease in energy expenditure compared to the barefoot condition. However the HAFO and FAFO provided less support which led to excessive dorsiflexion. These studies show that the right trade-off between stability and flexibility strongly depends on both the patient and the activity. For certain activities a flexible ankle joint is more desired. But, during other activities, not everyone can afford this flexibility and requires the stability of the SAFO.

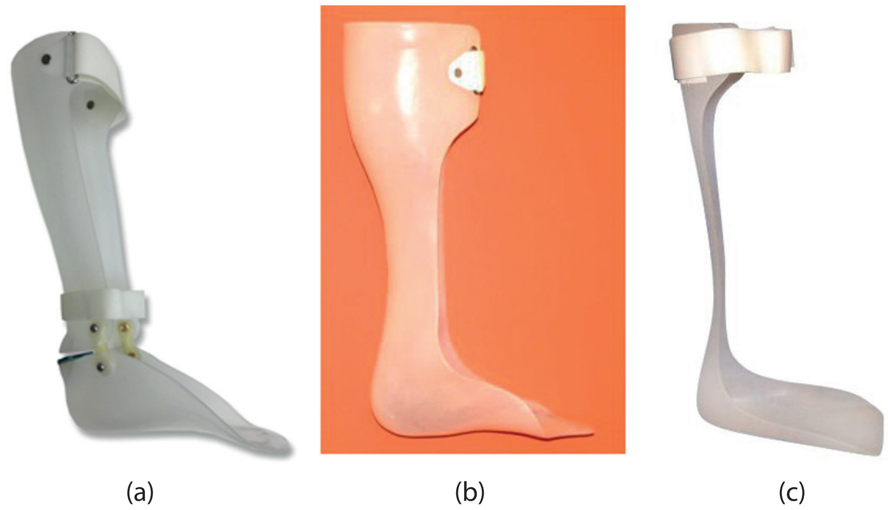


Figure 1.1: Three types of AFOs: (a) a Hinged AFO, (b) a Solid AFO [6], and (c) a Flexible AFO [7]. Where the solid AFO is rigid, the hinged and flexible AFO allow (limited) plantar- and dorsiflexion movements of the foot.

A more advanced AFO that is currently on the market is the Neuro Swing by Fior & Gentz (see figure: 1.2). The Neuro Swing is a hybrid between hinged and flexible since the Neuro Swing uses a hinge and springs to keep the ankle positioned. The Neuro Swing offers a modular system that is customizable to fit the users need. Important properties that can be set on the AFO are:

- Adjust the alignment angle. This is the angle between the foot and the shank.
- Adjust the spring force for both dorsiflexion and plantarflexion by changing the springs.
- Limit the range of motion of dorsiflexion and or plantarflexion.

Figure 1.2: Fior & Gentz Neuro Swing AFO [8]. The Neuro Swing is a hinged AFO where alignment angle, range of motion, and spring force are customizable.

Where the passive AFOs mentioned before give a good overview of the current available options, active AFOs are more and more investigated. Active AFOs have an embedded power source and actuator that can change the characteristics of the orthosis. In the field of prosthetics, this technology is increasingly used as there is sufficient space to implement the technology inside the prosthetic leg. With AFOs on the other hand, there is less space available. The mechanism needs to be placed around the human ankle, which makes it difficult to come up with an elegant solution.

The available AFOs all have their pros and cons. But do these AFOs all fit the needs of the user? A study by Van der Wilk et al. [9] studied the experiences of AFO-users. In general, the AFO enables to walk longer distances and provides more stability. When walking on sloped terrain or stairs, the extra flexibility of a hinged or flexible AFO make it easier compared to the solid AFO. When it comes to durability, there are flaws for all AFOs. The SAFOs of FAFOs can break when for example climbing stairs. The HAFOs can wear out after about 7 months of usage. As shown before, some tasks are easier to perform than others. The subjects of the study where asked which tasks are most important when wearing an AFO. The result is shown in figure 1.3. Logically, walking is the most important task, as this is the main reason to wear an AFO. But there are other tasks that are not considered when thinking of AFO use. The different tasks desire different AFO properties. Activities such as sitting down/standing up, slope walking, and stairs climbing require more flexibility in the ankle joint. Riding a bike or driving a car might not require any support at all. Walking in a swimming pool requires the AFO to be waterproof. And choosing shoes requires the AFO to be compact to fit into different shoes. Furthermore the alignment should be adjusted to compensate for heels and differently shaped soles. The work of Van der Wilk et al. shows that there is unexplored territory when it comes to designing an AFO for tasks other than just walking. AFO-users want an AFO that enables the user to set when the AFO can flex and when it cannot [9]. Being able to adjust the AFO to suit different tasks can add important value to the experience and capabilities of its user. In this research, an AFO hinge-mechanism is designed that can be adjusted to suit specific needs for a specific situation. Thereby, the versatility and ease of use of the AFO is increased.

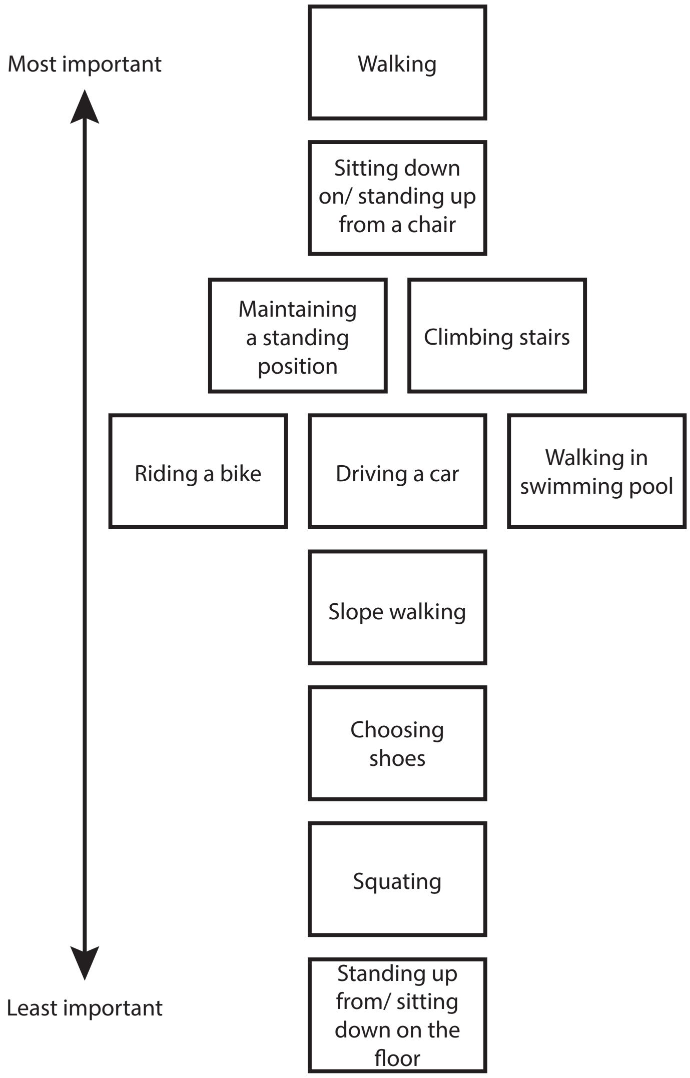


Figure 1.3: Ranking of activities undertaken while using AFOs according to AFO users [9].

1.2 Research Objective

The purpose of this thesis is to design and fabricate a hinge-mechanism for an ankle-foot orthosis which is driven by the needs of the user. The focus lays on increasing versatility and ease of use of the AFO.

1.3 Structure of the Report

In this study, the V-Model development process [10] is used. The V-Model (see figure: 1.4) consists of a v-shaped flow diagram. The left side describes the definition of the project. On the right side, the test and validation of the design are described. During the validation stage, one can go back to the design definition and make iterations. In chapter 2, the requirements of the system are defined. The requirements of the user are translated to system requirements and measurable design specifications. Then, the architecture of the design is chosen using an overview of mechanisms and a decision matrix. Once the architecture is defined, the detailed design is worked out. This part can be found in chapter 4. At the bottom of the V-model, the prototype is build. From here on, the design and subsystems are verified and send back to system architecture or detailed design. A design that does not work as expected may require a change in architecture or details. Going through this loop, will give new input and improves the design. In chapter 6, a load test is performed on the design to verify the requirements defined at the beginning of the study. Lastly, the design is validated by retrieving feedback from the user.

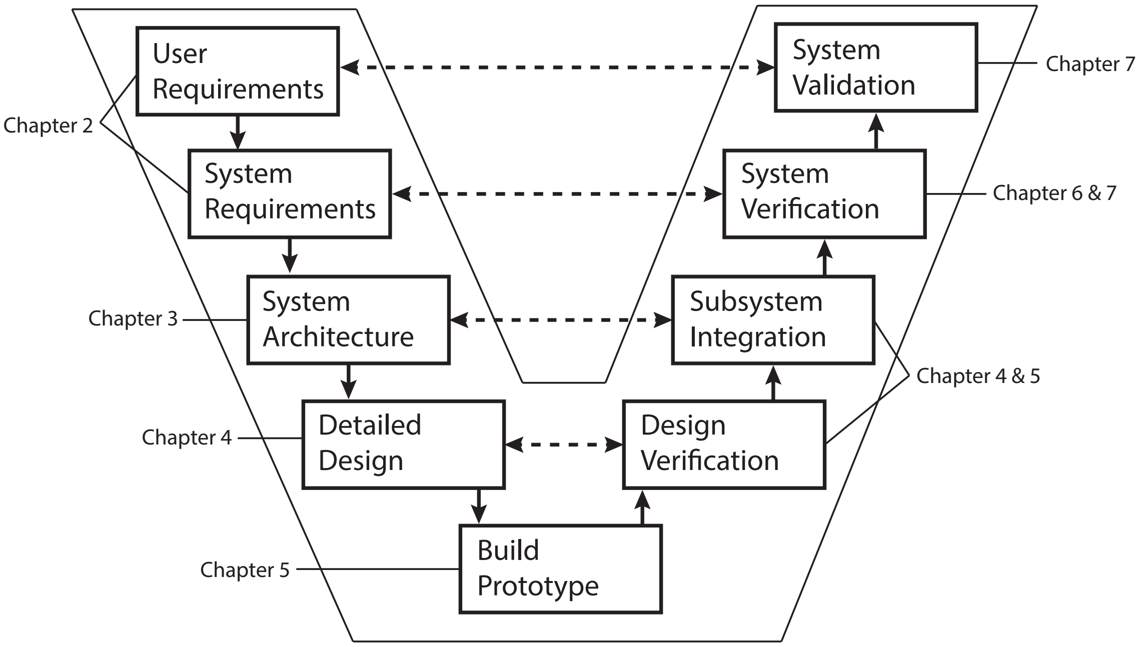


Figure 1.4: The structure of the report using the V-Model and its phases of development. The left side of the v-shape defines the design, whereas the right side serves as multiple steps of validation and verification of the design.

Chapter 2

Problem Analysis

As shown in the introduction, the current AFOs are either solid, flexible or hinged. But, different tasks require different properties. One could need a solid AFO for walking purposes, and a more flexible solution to climb a stairs. In this chapter the requirements for a new AFO hinge mechanism are introduced. By retrieving input from an AFO-user and a manufacturer of orthotic components, requirements of the new mechanism are set up. Furthermore, design specifications are defined using these requirements. These provide measurable values, that can help evaluating the mechanism at the end of this study.

2.1 Stakeholder Analysis

In order to get a good impression on the current AFO issues and room for improvement, people that work with AFOs on a daily basis were interviewed. Since this research is driven by the need of the user, an AFO user is interviewed. For the technical expertise in the field of orthoses, a manufacturer of orthotic components is also added to the stakeholder analysis. Firstly, an AFO user provided insights on the importance of activities and suggestions for an improved ankle-foot orthosis design. Subsequently, a manufacturer of orthotic components was interviewed. This provided another perspective, since these specialists work with a broader range of patients.

2.1.1 AFO User

The participant (male, age: 63) suffers from progressive distal muscular weakness of the legs and uses a BlueROCKER AFO by Allard USA. This is a solid carbon fiber AFO. For walking longer distances, the AFO can provide the stability that is needed. With the AFO, walking goes faster and more efficient by approximately 10 percent. However, certain actions become more difficult as the range of motion provided by the AFO is limited. To see how versatile the AFO is, the participant described how difficult the following tasks were to perform:

- Slope walking: “Difficult”
- Stand up/sit down: “Possible, but tricky”
- Driving a car: “Never tried, seems dangerous”

- Walking stairs: "Very difficult"

Where the main task of an AFO is to provide stability during walking, it would be nice to have greater versatility, so walking stairs, biking and slope walking is possible. When asked for improvements, the following was stated: "The ability to turn it off. On sloping terrain the AFO is very inconvenient, but on flat ground it is pleasant again. It could also be useful to be able to cycle with the AFO. Now it is possible, but it is not pleasant." Lastly, comfort is an important factor. The AFO should be compact and able fit inside a shoe. When adding a hinge mechanism, this mechanism should be strong enough to withstand applied forces, but also be slim and lightweight.

2.1.2 Manufacturer of Orthotic Components

To see the AFO in a different perspective, Basko Healthcare was asked to provide some insight. Basko Healthcare is specialized in the development, production and sales of orthopaedic aids. Ankle foot orthoses are one of their products, so there is knowledge on what the customer needs. When discussing the idea of an unlockable hinge mechanism for AFOs to make certain actions easier, Basko was not sure if less stability is desired. There is a wide variety in AFO users with all different needs. A group that can benefit from an unlocked mechanism may be small. The main focus of AFOs is on getting patients to walk again. Activities such as slope walking and walking stairs are difficult, but it requires some adaptation and getting used to of the patient. By unlocking the mechanism, the stability is lost, and not everyone can afford that. On the other hand, easy alignment adjustment of the AFO can be a useful addition to current AFOs. An adjustable alignment allows the AFO to fit different types of shoes or sloped terrain. There are solutions where alignment can be changed using a wrench (such as Triple Action joint [11]), but there is no easy way to adjust this quickly. Ideally, alignment automatically adapts to sloped terrain or shoes. But, as space in an AFO is very limited, it is challenging to put all this technology inside. Lastly, the mechanism should be robust. It needs to be durable and resist dirt. Also it should be able to withstand the forces applied on it by the human body during walking. This also includes the torsion generated as the hinge is mounted off-centre.

2.2 Functional Requirements

Two different perspectives on AFO improvements were gathered in the previous section. Using these, functional requirements of the new AFO mechanism can be set up. There is a wide variety of patients that use an AFO. The AFO-user, interviewed in the previous section, has mild symptoms and an active lifestyle. This will also be the target group for the mechanism that is developed in this study. Active patients with mild symptoms may benefit from an ankle joint that can be locked and unlocked. Therefore it is decided to add this to the functional requirements.

Adjusting the alignment (see figure: 2.1) of the orthosis is currently done at the orthopedist. This makes it difficult to change shoes, as the alignment needs to be either re-adjusted, or each shoe should have its own orthosis. Being able to adjust the alignment by yourself makes it easier to change shoes. Hereby it needs to be said, that clear instructions by the orthopedist are required to properly align the orthosis. Lastly, both parties state that the mechanism needs to be small, strong and resistant to the elements (such as water and dirt). Hereby, the following list of functional requirements is created:

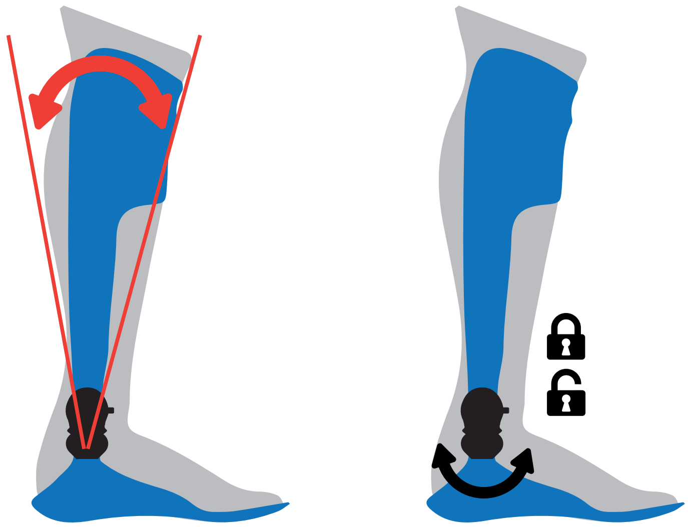


Figure 2.1: AFO with the ability to adjust alignment (left) and lock and unlock the hinge mechanism (right).

- Lock and unlock the mechanism
- When locked, move to aligned position
- Precise adjustment of alignment
- Little to no play in the system
- Operate mechanism with ease
- Lightweight
- Small footprint
- Strong (withstand the forces applied by the human body)

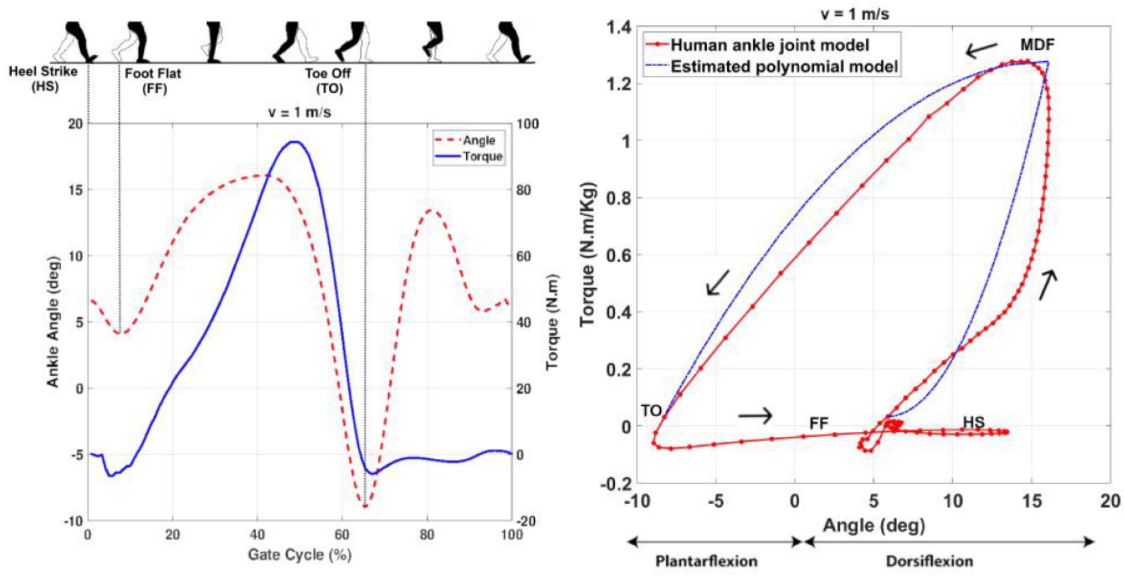
2.3 Design Specifications

When the product is finished, the design will be validated using the design specifications. Where the functional requirements define the function of the mechanism, the design specifications add values to these functions. In the end, the design can be validated using those values.

In general, operating the mechanism should be easy. The patient should be able to adjust the mechanism with the use of one single hand. To come up with specifications for the lightweight and small footprint requirements, two hinge mechanisms of Fior & Gentz are analyzed (see figure: 2.2). On the left, the Neuro Swing is shown. This is an advanced hinge mechanism with several customizable features such as: spring force, alignment and range of motion. On the right side the Neuro Classic is shown. This is a simple hinge without any further capabilities. For this study it was decided to aim for a mechanism smaller than the Neuro Swing. Since the new design had more functions than the Neuro Classic, it may be larger than the Neuro Classic. The specifications of the size are described as: 30x70x15 mm (WxHxT). The weight of the mechanism should stay below 120 gramms.

Figure 2.2: Two AFO hinge mechanism from Fior & Gentz with dimensions and size [12]. The Neuro Swing has more functional capabilities, but comes in a larger size. The Neuro classic is a basic hinge which is significantly smaller in size.

The hinge mechanism should be strong and robust. It should be able to bear weight of the patient during gait. To gain insight on the magnitude of the forces on the ankle joint during gait, experimental data can be used. In the work of Amatya et al. [13] the ankle angle and torque were measured during gait. Figure 2.3a shows the ankle angle and torque of a 70 kg participant at a walking speed of 1 m/s. Figure 2.3b shows the normalized torque of a human during gait. The peak torque in the ankle joint is almost 1.3 N.m/kg. Taking a little bit of margin, a ankle torque of 1.5 N.m/Kg can be taken. Assuming a human of 80 kilogram, the hinge mechanism should withstand a torque of 120 Nm.



(a) (b)

Figure 2.3: (a) Human ankle angle and torque during gait cycle for a healthy test participant (70 kg) walking at a speed of 1 m/s. (b) The normalized human ankle torque with respect to angle at different phases, Heel Strike (HS), Foot Flat (FF), Toe Off (TO) and Maximum Dorsiflexion (MDF) [13].

When it comes to the alignment adjustment, both the step size and the range of the adjustments need to be defined. In the current Neuro Swing model, the angular range in which the alignment can be adjusted is 20 degrees. This should also be the goal for this study. According to an orthosis fitter, an step size of maximum 2 degrees, is sufficient to properly fit the AFO.

For the locking mechanism, the range of motion when unlocked, and the locking positions can be defined. A single locking position allows the user to directly moved to the aligned state. And when unlocked, the angular range of motion of the ankle joint is set to be at least 30 degrees. This is the kind of flexibility that healthy humans use during gait (see figure: 2.3).

Summarizing the design specifications mentioned above, the following list of design specifications is generated:

General Mechanism

- Operate mechanism with one hand
- Weight of mechanism: <120 gramms
- Max width,height and thickness: 30x70x15 mm
- Withstand a torque of at least 120 Nm (Estimate based on a 80 kg patient with 0.15 m arm from ankle to forefoot)

Adjust Alignment

- Maximum step size in angle alignment: 2 degrees

- Minimum range of motion: 20 degrees

Lock and Unlock Mechanism

- When locked, move to aligned position (single locking position)
- When unlocked, the ankle joint has an angular range of motion of at least 30 degrees

Chapter 3

Conceptual Design

In this chapter, several concept solutions for a novel AFO hinge mechanism will be described. But before the concepts are created, the underlying working principles will be discussed. The functional requirements state that the hinge mechanism must be able to be adjusted and (un)locked. There is a wide variety in locking mechanisms and therefore it is useful to create an overview of the possibilities. Later on, the most suitable mechanisms are joint together in a concept design.

3.1 Concept Generation

There are mainly three types of locking mechanisms [14]. The three types are:

- Friction based locking
- Mechanical locking
- Singularity locking

Friction based locking consists of two or multiple parts that are pressed together. The friction coefficient combined with the normal force creates a friction force which keeps the parts coupled.

$$F_{Friction} = \mu \cdot F_{Normal} \tag{3.1}$$

Mechanical locking can be distinguished from friction locking when considering a world without friction. In this situation mechanical locking mechanisms can still operate. Mechanical locking mechanisms use some kind of obstruction of a part by another part [14]. One can think of interlocking shapes such as latches, hooks, pins or interlocking gears.
Lastly there are Singularity locking devices. In a singular position these devices have an infinitely high transfer ratio.

To come up with the right locking mechanisms, the design is divided into two subsystems. Firstly, the alignment system will be investigated. Secondly, the lock and unlock mechanism will be looked at. Different working principles will be discussed that are potentially useful for the final design.

3.1.1 Alignment Mechanism

An alignment mechanism needs to be lockable in multiple positions. The principles used for these mechanisms can be divided in mechanical and friction based.

Mechanical solutions are mainly were the main component of the resistance is not friction based. Most of these solutions are interlocking shapes. Figure 3.1 shows an overview of all considered mechanisms. Besides a division in mechanical and friction based locking mechanisms, there are a few subdivisions. Mechanisms that can lock in any position are continuous, where discontinuous mechanisms have a limited number of positions to be locked in. Lastly, there are differences in the input to adjust the mechanism. Some mechanisms require a translation to achieve a rotation in the ankle-joint, where others are adjusted via a rotation.

Compound Planetary Gear

A planetary gear consists of a sun gear, multiple planet gears and a ring gear. Often, the sun gear is used as input and the planet gears act as output. Planetary gears can offer a large gear ratio in a compact package. To further increase the gear ratio, another ring gear can be added (see figure: 3.2a). This ring gear must have a different number of teeth compared to first ring gear. In this situation the second ring gear acts as the output gear. In a normal planetary gear, the gear ratio is defined as:

$$Gear\ ratio\ of\ planetary\ gear = 1 + \frac{Z_{Ring}}{Z_{Sun}} \tag{3.2}$$

Adding an extra ring gear which acts as the output, will result in the following gear ratio [15]:

$$Gear\ ratio\ of\ a\ compound\ planetary\ gear = (1 + \frac{Z_{Ring1}}{Z_{Sun1}}) \cdot \frac{Z_{Ring1}}{Z_{Ring2} - Z_{Ring1}} \tag{3.3}$$

Using this compound planetary gear, very high gear ratios can be achieved. This makes the gear nearly non-back-drivable. For an AFO-hinge, The ankle joint can be adjusted with ease and a high accuracy of adjusting is possible.

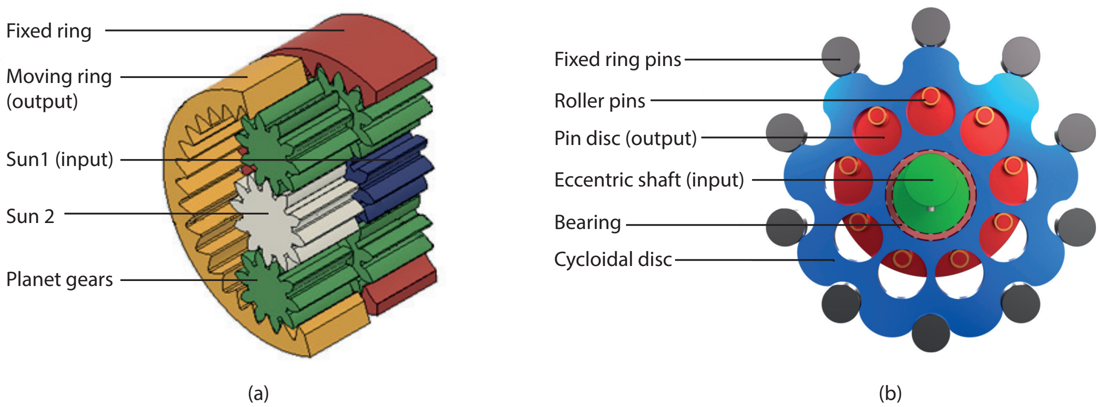


Figure 3.2: Two continuous alignment mechanisms: (a) Compound planetary gear [16], where the blue sun gear acts as the input and the yellow ring acts as output. (b) Cycloidal drive [17], where the eccentric shaft acts as input and the red disc as output.

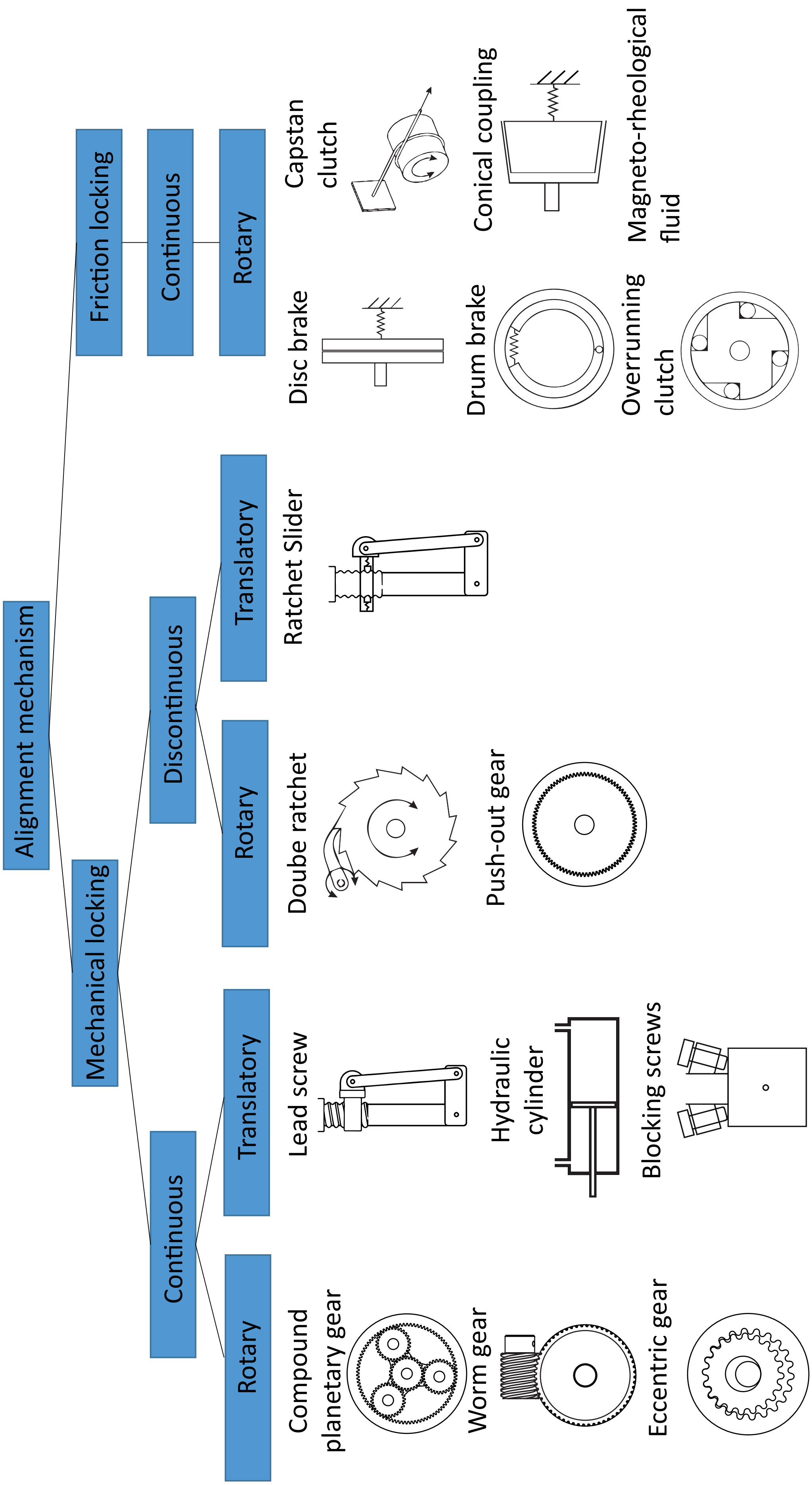


Figure 3.1: Overview of working principles for the alignment mechanism (modified from source: [14]).

Eccentric Gear

The eccentric gear is often also called a cycloidal drive. The mechanism is similar to the compound planetary gear. But, instead of gears, the cycloidal drive uses an eccentric shaft and a cycloidal disc (see figure: 3.2b). Where the planetary gear is more accurate, less efficient and requires more maintenance, the cycloidal gear can run on higher speeds, and is more efficient.

Worm Gear

A worm gear is a non backdrivable-gear. The adjustment can only be made in one direction, which practically means no locking of the input axis is required. When the worm gear is turned, the adjacent gear is slowly rotated. When there is load on the mechanism, it is difficult to make adjustments.

Lead Screw

The lead screw mechanism is similar to the worm gear mechanism but instead of rotating a gear, a lever is added that keeps the joint in a certain position. There is however a difference between the two. The lead-screw allows to set the sensitivity of the alignment adjustment. By having a small lever, the alignment angle changes significantly when the lead-screw is turned. On the other hand, if the lever is further away from hinge joint, only small changes in alignment are possible.

Hydraulic Cylinder

The hydraulic cylinder mechanism can be seen as a piston that is locked by a valve. When the piston is unlocked, the alignment angle can be adjusted. By closing the valve, the hydraulic fluid keeps the piston in a static position. However, in practice the hydraulic cylinder requires an external power source to build up pressure inside the cylinder. And at smaller sizes these cylinders act more as a damper as they can not cope with the high forces that are exerted on the ankle joint. A study conducted by Neubauer et al. [18] designed a hydraulic AFO (see figure: 3.3). This system achieves a high power density and can deliver a torque of 90 Nm. A power supply which is also shown in figure 3.3 adds additional weight as the AFO user needs to carry this device around.

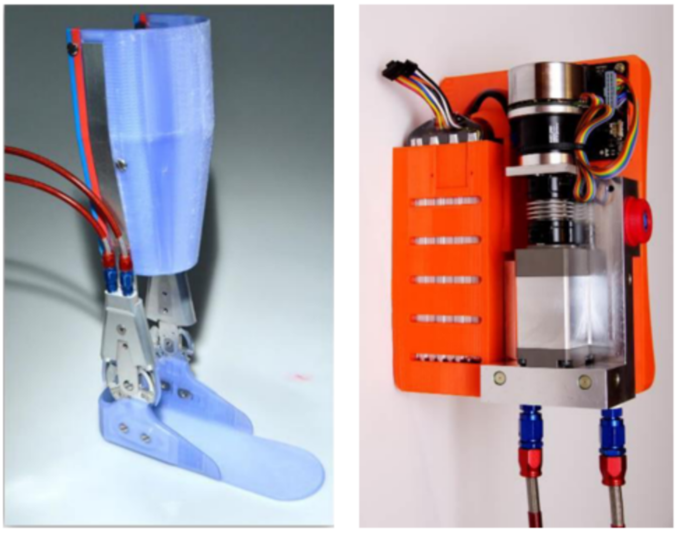


Figure 3.3: Hydraulic AFO (left) and its power supply (right)[18]. The hydraulic AFO can provide 90 Nm of ankle torque and weighs 1.2 kg. The power supply weighs an additional 3 kg.

Blocking Screws

The blocking screws working principle is a very basic idea. To lock the ankle joint in a certain position, the joint is held in that position while the screws get tightened. When both screws press against the lower part of the joint, the joint is fixed. While the mechanism itself is simple, adjusting the angle can be a hassle since the joint alignment will change when only one screw presses against the lower body.

Double Ratchet

A gear that can only rotate in one direction, often uses a ratchet mechanism. This mechanism uses a pin that locks the teeth of a gear in one way. A spring is used to press the pin the gear. The step-size is limited and the locking only happens in one direction. A double ratchet mechanism is needed to lock the gear in two directions.

Push-out Gear

The push-out gear consists of two interlocking gears. When interlocked, the angle of the ankle joint is fixed. The inner gear can be decoupled by pushing it out of the ring gear. This allows the angle to be adjusted. When the gear falls back into the ring gear, the angle is locked again. Although the step size is limited, it is a fast and easy way to adjust the alignment.

Ratchet Slider

The ratchet slider combines the double ratchet mechanism with the lead-screw. There is a main difference between the ratchet slider and the lead screw. Where the adjustability of the lead-screw is continuous, the ratchet slider has a stepped adjustment.

Disc Brake

The disc brake concept comes from the braking mechanism of a car. A rotating disc is clamped between two plates that slow down the rotation of the disc (see figure: 3.4). When this clamping force remains intact, the disc can be locked and thereby hold its angular position.

Drum Brake

The drum brake mechanism also originates from the automotive industry (see figure: 3.4). In this case a rotating tube is clamped by braking shoes from the inside. By pushing the "inner tube" outwards, friction between the two surfaces couple the two parts. Instead of using it for automotive or bike purposes it can be used to hold an ankle joint in a certain angular position.

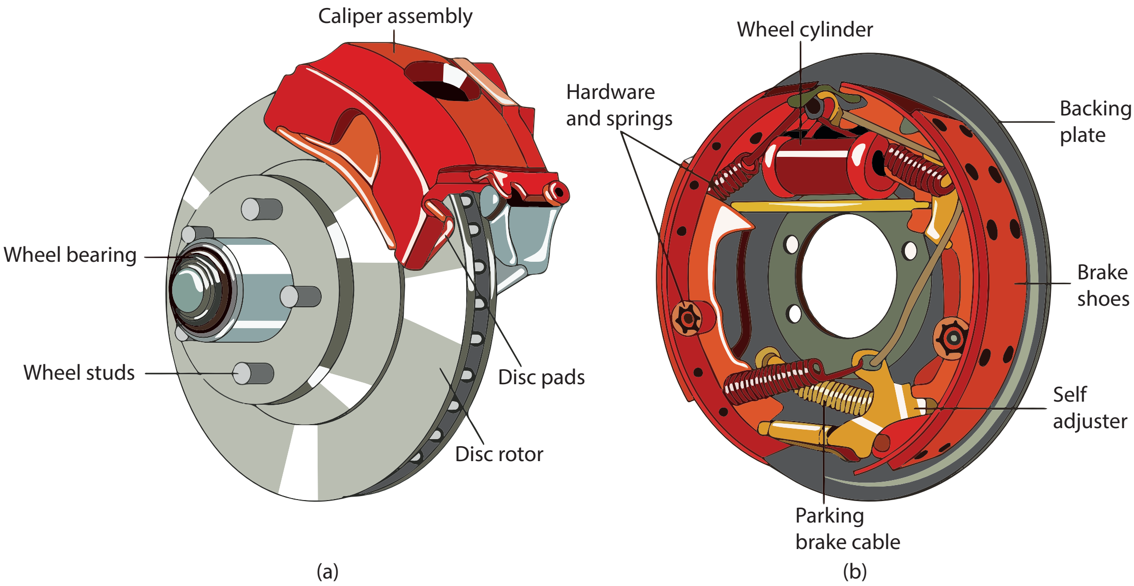


Figure 3.4: Illustrations of braking mechanisms used in the automotive industry. (a) A disc brake mechanism. The disc pads in the caliper assembly can push against the disc rotor to initiate a brake. (b) A drum brake mechanism [19]. When braking, the brake shoes are push outwards by the wheel cylinder causing friction between the brake shoes and an outer cylinder.

Overrunning Clutch

Similar to a ratchet mechanism, an overrunning clutch is a coupling that allows rotation in one direction, but blocks the other direction. However, where a ratchet uses an interlocking pin, an overrunning clutch often uses balls that wedge themselves between two concentric rotating parts. There are overrunning clutches as shown in figure 3.5 that can block rotation in both directions. Only by turning the pink axle the wedging parts are pushed out of their wedging position. In this case it may be applicable in a AFO hinge design.

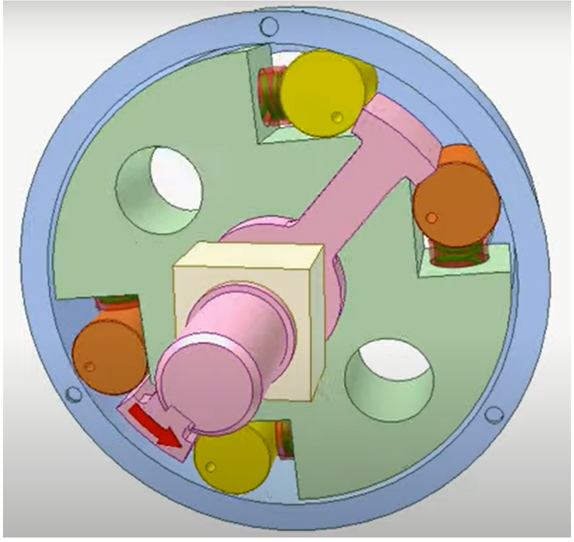


Figure 3.5: A two way overrunning clutch, where the green and blue part are only decoupled when the pink axle is driven [20]. The pink part pushes the spring-loaded cylinders out of a wedge and thereby decouples the green and blue part.

Capstan Clutch

A capstan clutch uses the revolutions of a tether or wire to grip a cylinder. This method is also used to dock boats in a bay. A rope is wound around a pole and this creates enough friction to keep the boat in place. In the same way a joint can be fixed when tension is set on the wire. When the wire is loosened, the joint can move freely. This method is already used in a knee joint. Subra et al. [21] designed a knee joint with a capstan clutch using a coiled wire spring (see figure: 3.6). A solenoid can pull the wrap spring and thereby tighten the lower part shown on the right in figure 3.6.

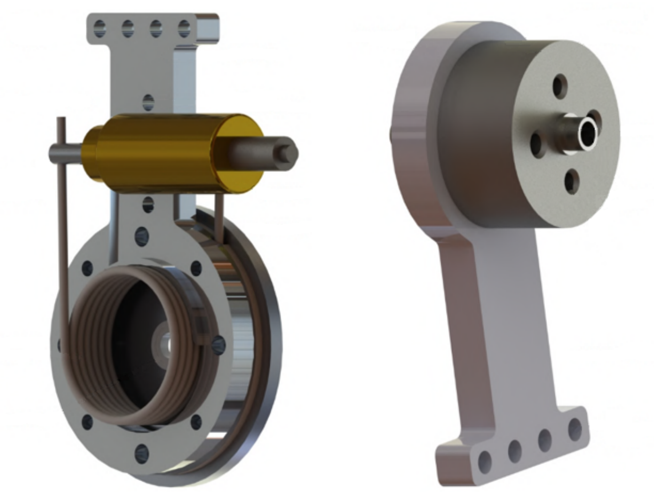


Figure 3.6: Capstan clutch knee joint [21]: The upper part of the joint with the wrap-spring (left), and the lower part of the joint (right). A solenoid actuator can tension the wrap-spring and thereby grab the lower part of the joint.

Conical Coupling

A conical coupling is similar to the drum brake. Where the drum brake has a wide circular friction surface which operates radially, the conical coupling uses a conical shaped friction surface (see figure: 3.7). By pressing to conical parts together, friction forces arise and couple the two cones.

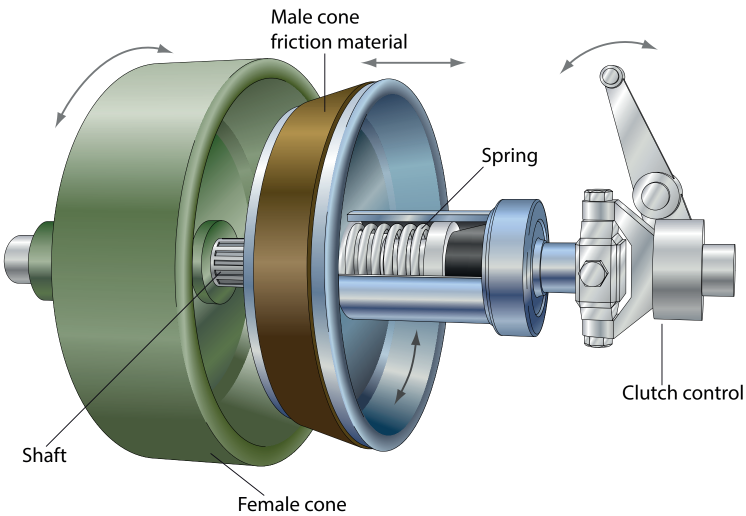


Figure 3.7: A schematic drawing of a conical coupling [22]. The female cone accommodates the shape of the male cone. When the two cones are pressed together, the friction between the to cones establishes a coupling.

Magneto-rheological Fluid

A Magneto-rheological fluid can be used as a medium between two moving parts as shown in figure 3.8. Once the magneto-rheological fluid is exposed to a magnetic field, the properties of the fluid change. The fluid becomes more viscous and can thereby lock the position of the two interacting parts. Zite et al. [23] used this mechanism in the design of an active knee brace. Here the magnetorheological fluid acts as a damper.

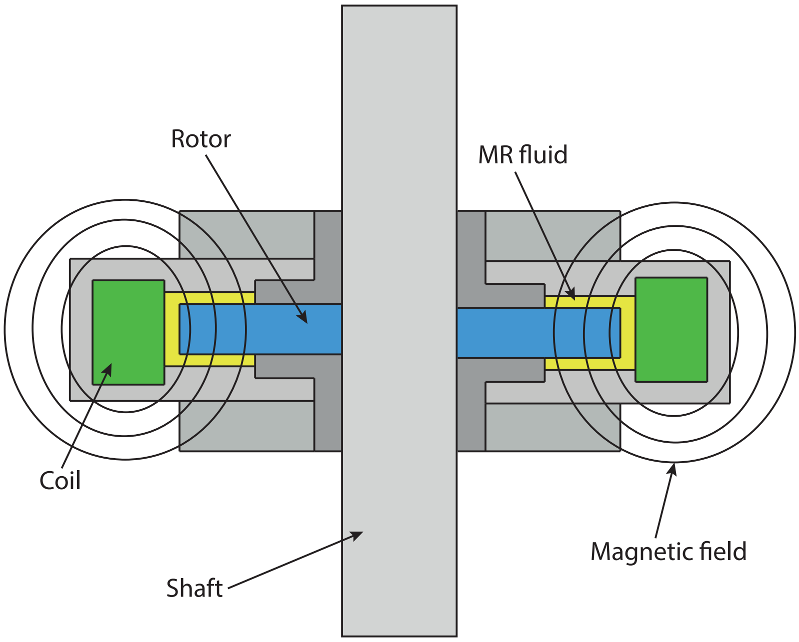


Figure 3.8: A schematic drawing of a magneto-rheological fluid brake. A rotor is attached to the shaft and surrounded by magneto-rheological fluid. Once the coil establishes a magnetic field, the viscosity of the fluid changes, leading to more resistance in the shaft.

3.1.2 Locking Mechanism

The properties of the locking mechanism are different from the alignment mechanism properties and so are the working principles. At first glance one might think these mechanism are interchangeable, but this is not the case. In this situation, a single locking position is required. Otherwise the alignment has to be redone every time the hinge is unlocked. Only mechanical and singularity locking mechanisms are suitable for this application as friction based solutions have more than one locking position. Figure 3.9 shows an overview of the locking mechanisms. In the sections below the mechanisms will be discussed

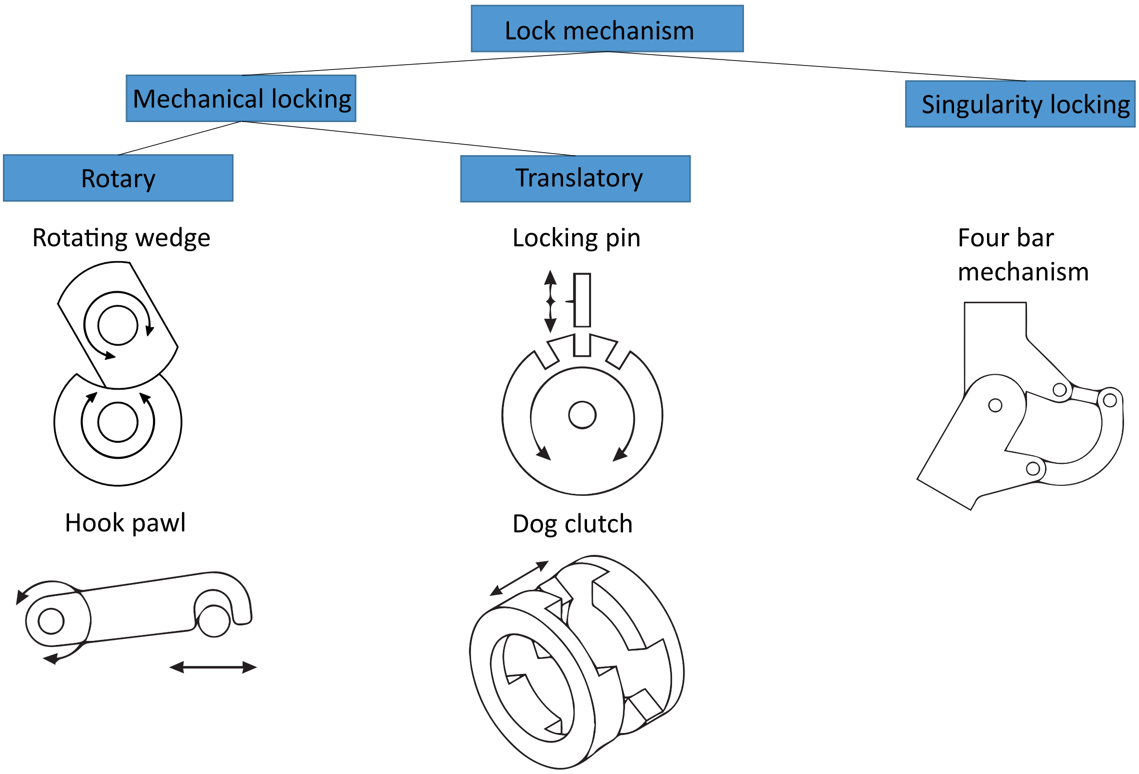


Figure 3.9: Overview of working principles for the lock mechanism (modified from source: [14]).

Rotating Wedge

The rotating wedge mechanism, is locking mechanism where a rotations on the input can lock a rotation on the output. The mechanism consist of a wedging part and a part that accommodates the shape of the wedge. The wedge fits like a jigsaw piece and thereby blocks the rotation.

Hook Pawl

The hook pawl is a mechanism where a rotary input can block a translating output. The hook embraces a pin and thereby locking it in one direction. Depending on the lay-out of the hook pawl mechanism, it can be used to lock an AFO hinge.

Locking Pin

The locking pin is a translating component that can block a rotation of an adjacent part. The pin fits tightly in a hole of the part that needs blocking. Pulling the pin out, unblocks the mechanism.

Dog Clutch

A dog clutch consists of two concentric rings with a tooth shaped surface. When these rings are pressed against each-other, the teeth interlock. By making only one or two teeth, the mechanism achieves a single locking position

Four Bar Mechanism

A four bar mechanism uses a interesting locking principle. Four bars are linked by four hinges. With very little force these bars can be put in a locking configuration. Once in this configuration, the mechanism is locked. Only a certain action will release the tension in the bars and unlock the mechanism.

3.2 Concept Selection

3.2.1 Alignment Mechanism

An overview has been made with the potential solutions for the AFO hinge mechanism. By comparing the various mechanisms, using relevant criteria, a final selection can be made.

The criteria that are used to evaluate the mechanisms are weighted to give importance to the criteria. A criteria with a higher weight is therefore more important. Holding torque, size and ease of use are weighted the highest, since size and usability are of great importance to this design. A mechanism that is too big, will not be worn by the AFO user. Furthermore the adjustments of the mechanism should be performed with ease. Criteria such as number of locking positions and backlash follow up on the importance. These criteria are given a weight of 2. Lastly, robustness, complexity and cost are mentioned. The mechanism should be build to last. Components need to be durable and easy to manufacture. This will in the end also keep the costs down.

	Holding torque	Size & weight	Ease of use	Backlash	Number of locking positions	Robustness	Complexity	Cost	Total score
Weight	3	3	3	2	2	1	1	1	
Compound planetary gear	4	2	5	3	5	3	2	1	55
Worm gear	5	4	3	3	5	5	5	4	66
Eccentric gear	4	2	5	3	5	4	4	3	60
Lead screw	5	3	2	4	5	5	5	5	63
Hydraulic cylinder	4	3	3	4	5	2	3	3	56
Blocking screws	4	4	1	5	5	5	5	5	62
Ratchet	4	4	3	4	2	3	3	4	55
Push-out gear	5	4	5	5	2	4	5	4	69
Ratchet slider	4	3	4	4	2	3	5	4	57
Disc brake	4	2	3	5	5	3	5	3	58
Drum brake	4	3	3	5	5	3	4	3	60
Conical coupling	4	2	3	5	5	3	5	3	58
Capstan clutch	4	2	3	5	5	3	5	4	59
Overrunning clutch	4	4	3	1	5	4	3	4	56
Magneto-rheological fluid	3	3	3	4	5	2	2	3	52

Figure 3.10: Decision matrix for the alignment mechanism. All mechanisms are graded using grades from 1-5. The criteria are weighted to add importance to each criteria.

Holding Torque

Starting of with the holding torque, only three working principles achieved the maximum score. These mechanisms are all non-backdrivable and mechanical. Mechanical solutions have a higher power to size ratio [14] which means that a friction based mechanism needs to be larger to achieve the same amount of holding torque. Other mechanical solutions such as the compound planetary gear and the eccentric gear remain backdrivable which means the input shaft needs additional locking. Hydraulic cylinders and Magneto-rheological fluids act more as a damper, when the system is passive and small. This makes them less suitable for holding torque.

Size & Weight

When looking at size and weight of the mechanism, a simple and mechanical solution is the way to go. A compound planetary gear uses two ring gears with planets and sun-gear inside, which makes the mechanism rather big for this application. Friction based mechanisms require larger surfaces or higher forces to make them as strong as a mechanical solution. This results in a bigger overall size. The worm gear, blocking screws, ratchet, push-out gear, are all simple yet effective solutions that win in this regard.

Ease Of Use

Ease of use is all about user experience. One can think of the time and force it takes to adjust the mechanism. Due to the high transfer ratio, the compound planetary and eccentric gear are easy to adjust. When it comes to quick adjustment, the push-out gear looks promising. The blocking screws mechanism is least easy to adjust. Two bolts need to be tightened to lock the position. By tightening one screw, the angular position can change causing the alignment to be redone.

Backlash

Where interlocking parts are prone to backlash, this is not the case for friction based solutions. The overrunning clutch is an exception to this rule, since the backlash is required to tighten the wedge between the two parts.

Number of Locking Positions

The big advantage of friction based solutions is the number of locking positions. These mechanisms can lock in any position were mechanical solutions are often stepped. However, mechanical solutions can be modified to suit this purpose using additional parts. The push-out gear and the ratchet mechanisms are the ones that have limited locking positions.

Robustness, Complexity and Cost

A robust mechanism requires little maintenance and has a long life span. Moving parts are less desired as they wear out over time, and fluid based mechanisms are susceptible to leaking. When looking at complexity, the number of parts that need assembling and the fabrication methods to make these parts are considered. The used materials and manufacturing of the design have impact on the cost.

Alignment Mechanism Choice

The decision matrix (see figure: 3.10) shows that the push-out gear is the winner of the mechanisms. This mechanism scores high on all criteria except the number of locking positions. The push-out gear is dependent of the number of teeth. Having a large number of teeth, will increase the number of locking positions. But, increasing the number of teeth also increases the size quite drastically. Fortunately, there is a fix to this problem. The number of teeth of the gear give the number of locking positions over and angle of 360 degrees. In the case of an AFO mechanism, this range of motion is not needed. Therefore, by using a lever, a higher number of locking positions can be achieved with a smaller range of motion.

3.2.2 Locking Mechanism

The alignment mechanism and the locking mechanism both need to fit inside the AFO hinge. By choosing a design solution for the alignment mechanism, not all locking mechanisms are still suitable as they might compromise the function of the alignment. As the function of the locking mechanism is rather simple, only two aspects are considered, namely size and operation under load. Where the mechanical solutions excel in size, it is difficult to operate these mechanisms under load. Conversely, a singularity mechanism, is easier operated under load. The downside of a singularity mechanism is its size as it uses four bars connected with four joints. Focusing on size, the locking pin is most suited. The pin does not take up much space and the mechanism is simple and straightforward. The concept of the locking pin will be used in the concept design.

3.2.3 Concept Design

The working principle of the alignment for the AFO hinge is chosen, and this principle is put into a real concept. To form a starting point for the concept development, a design is made. This design is shown in figure: 3.11. Instead of a push-out gear, a pull-out gear is chosen. This has to do with the pin that guides the upper bar on the backside of the mechanism. The upper bar is connected to the shank of the leg, whereas the lower bar is connected at the foot plate of the AFO. The central axis is placed concentric with the ankle joint of the patient. The angle of the upper bar (the alignment) can changed as shown in figure 3.11. By pulling out the red gear, the angular position of the bar can be changed. By pressing the red gear back into the housing, the teeth interlock and the upper bar is fixed. Furthermore, a locking pin style locking mechanism is added. When the yellow pin is pulled out, the lower bar can freely rotate. Pushing the yellow pin back in, locks the mechanism. The yellow and red components can be held in place using springs.

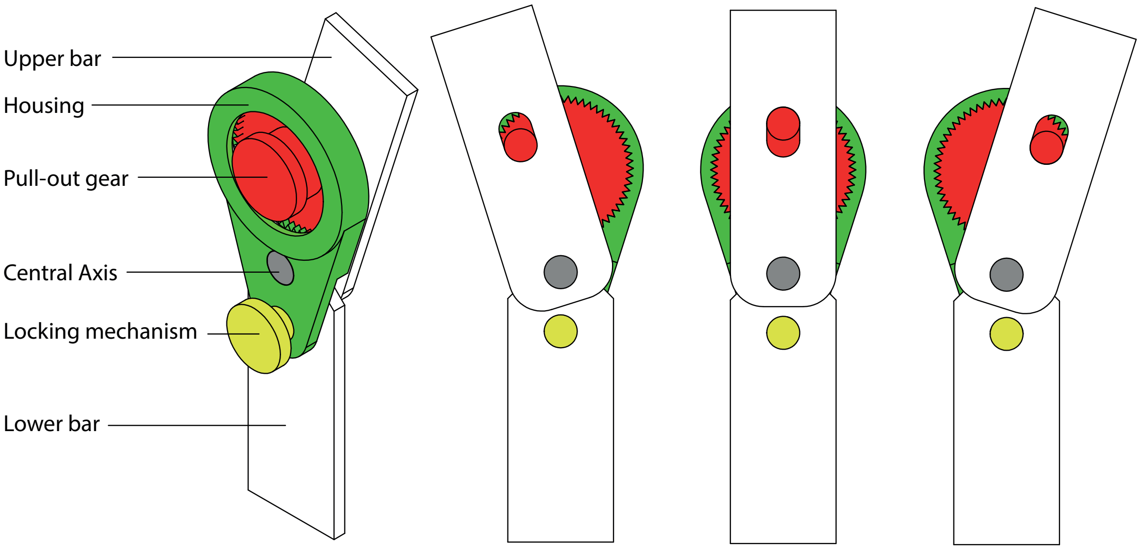


Figure 3.11: A schematic view of the concept design. When the red gear is pulled out of the housing, the alignment can be adjusted. The yellow pin can be pulled to unlock the mechanism.

Chapter 4

Concept Development

In the previous chapter the working principle of the design was chosen. In this chapter, the design will be worked out in detail. It was an iterative process where the focus was shifted as the design progressed. The initial designs are mainly functional and geometrical. As the designs progressed aspects as strength and fabrication came into play.

4.1 The Initial Design

The dimensions of certain parts of the mechanism define the overall size. Furthermore the range of motion and the step-size of the mechanism are defined by the size. The idea is to minimize the step-size by placing the central axis outside the center of the gear. A geometrical sketch is shown in figure 4.1. Here X is the diameter of the gear. R is the distance from the center of the gear to the guiding pin. The guiding pin is mounted on the gear and therefore $R < X/2$. Furthermore, the pin has a thickness and cannot be attached too close to the edge of the gear. Y is the distance between the central axis and the center of the gear. β is the half of the adjustability of the mechanism which is also mentioned in the design requirements. The angular range of motion is set in the design specifications to be at least 20 degrees. This means that $\beta \geq 10\,^{\circ}$. Lastly, α shows half of the angular range of motion of the pin which is mounted on the gear. The pin is actuated by rotating the upper bar. To avoid singularity in the mechanism, the gear must be restricted in its angular range of motion. By pushing the upper bar, the gear should be able to rotate. Limiting the range of motion of the gear can be achieved by setting the right slot-length in the upper bar. The blue segment in figure 4.1 shows a range of motion of $120\,^{\circ}$.

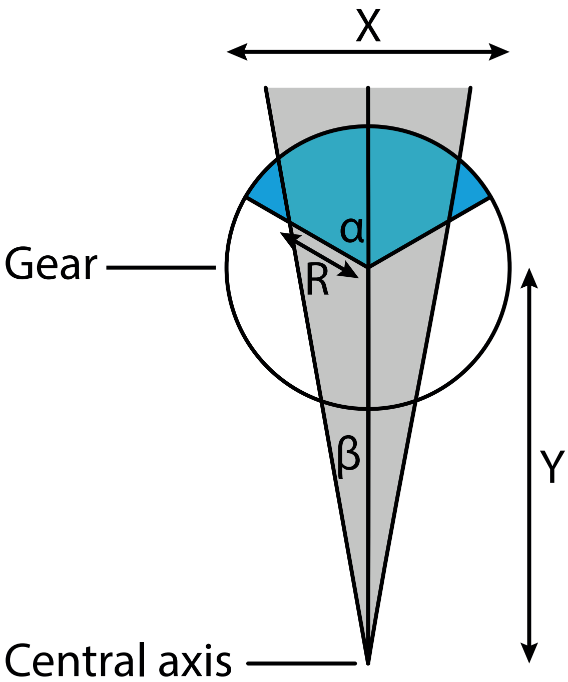


Figure 4.1: Geometrical representation of the concept design. Where Y is the distance between the central axis and the center of the gear. β is the alignment angle in one direction. R is the distance from the center of the gear to the guiding pin on the gear. α is the range of motion of the gear in one direction.

As stated in the design specifications, the maximum dimensions of the mechanism are: 30x70x15 mm. For alignment adjustment a range of motion of 20 ° was set with a maximum step size of 2 °. For the initial design, the specifications are set up a little tighter, so there is room for compromises. The following parameters are used for the initial design:

Parameter	Value
X	$20\,mm$
R	$7\,mm$
α	$60\,°$
β	$17.5\,°$
N_{Teeth}	60

Table 4.1: Parameters initial design

The length of Y can be calculated using the following formula:

$$Y = \frac{\sin\alpha \cdot R}{\tan\beta} - \cos\alpha \cdot R = 15.72\,mm \tag{4.1}$$

A gear with range of motion of 120 ° means that $\frac{1}{3}$ of the gear-teeth define the step size. Giving the gear 60 teeth results in a step size of

$$Stepsize = \frac{3 \cdot 2 \cdot \beta}{N_{teeth}} = 1.75\,°/teeth \tag{4.2}$$

4.2 Iterations

4.2.1 Iteration 1: Increase Thickness of Bars

The initial design was created to have a basis that can be fine-tuned along the way. Looking at AFO hinges from other manufacturers, dimensions of the central axis and the upper and lower bar can be obtained. Of course, these are not the final dimensions, but it serves as a good starting point. The following sizes are implemented into the initial design. Upper bar and lower bar get a thickness of 4 mm and a width of 16 mm. The central axis will have a diameter of 10 mm, where the lower and upper bar have 6mm material around the 10 mm hole. This results in a diameter of 22 mm. Also, the locking pin has been given some extra space to fit in a spring to keep the locking pin in place. The new design is shown in figure 4.2.

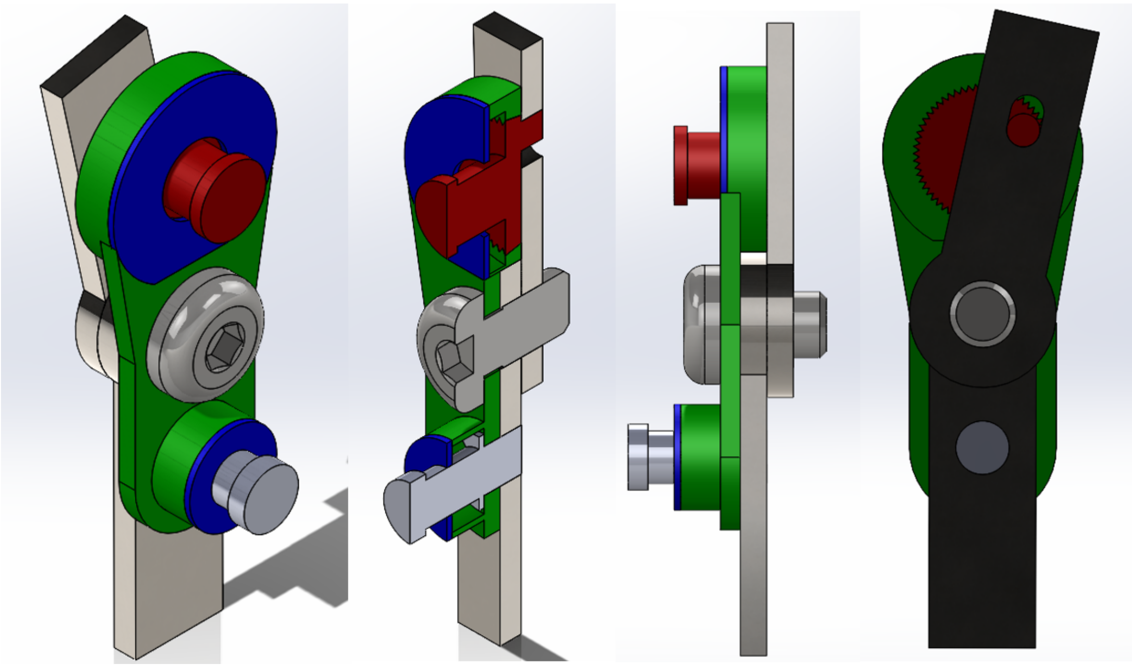


Figure 4.2: Concept design with adjusted dimensions for bars and axle. The red gear can be pulled out to adjust the alignment angle. A spring will cause the gear to return to a locked position. The pin at the bottom can be pulled out to unlock the mechanism.

4.2.2 Iteration 2: Change of Locking Mechanism

As can be seen in the figure 4.2, the size of the locking pin is quite substantial. Imagining someone using this hinge in its AFO, provided insight on the position of the locking pin. The locking pin is currently located below the ankle joint. When wearing shoes, the locking pin interferes with the shoe. Therefore the locking mechanism is changed. Preferably the locking mechanism is placed above the central axis. Here, there is no interference with shoes. However, the alignment mechanism is also placed at this location, which makes it challenging. After going back to the conceptual design and some experimenting with different ideas, a rotating wedge locking mechanism was opted. Using a locking ring, which is positioned around the alignment mechanism, allows to have both subsystems above the ankle joint (see figure: 4.3). Around the red gear and the green housing, a yellow locking ring is placed. By rotating this ring, a wedge can slide into the lower position, locking the lower bar. The lower bar has a curved top-end that accommodates the shape of the wedge. By rotating the wedge upwards, the lower bar is able to rotate in a limited angular region.

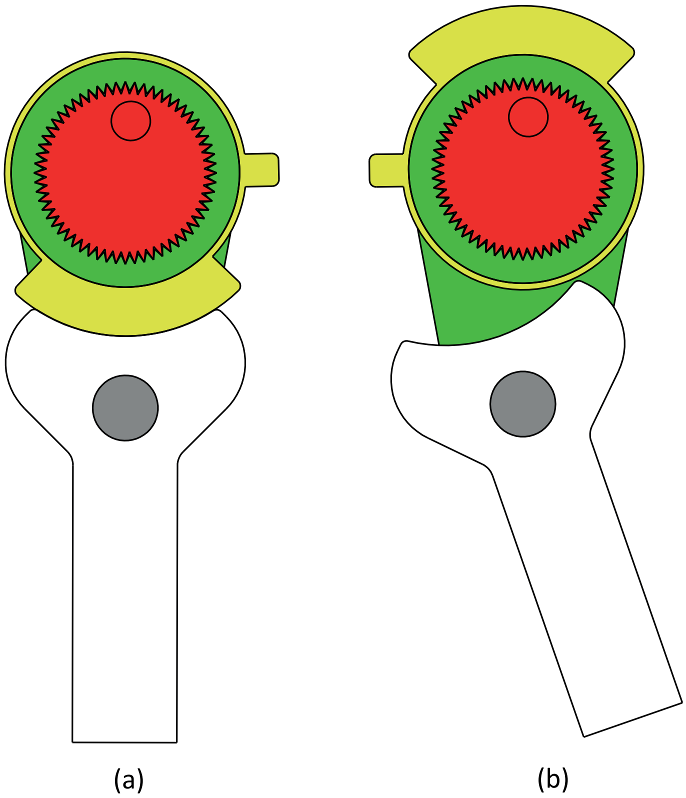


Figure 4.3: Locking mechanism using a rotating wedge: (a) Locked position, (b) Unlocked position. The yellow locking ring can rotate around the green housing. The yellow wedge can be slid between the bottom bar and the housing and thereby lock the mechanism.

4.2.3 Iteration 3: Reduction of the Number of Gear Teeth

Step Size

The two interlocking gears have 60 interlocking teeth to maintain a sturdy and locked position. But due to changes in the design, this amount of teeth is no longer needed. The distance Y as shown in figure 4.1 is enlarged due to changes in axle diameter, and adding the locking ring. Y is now 36 mm, and this limits the angular range of motion to:

$$2\beta = \arctan\frac{\sin\alpha\cdot R}{\cos\alpha\cdot R+Y} = 17.45\,^\circ$$

This means that the step-size of the gear alignment adjustment is now 0.87 ° per step. Reducing the number of gear-teeth will increase the size of the teeth and thereby have a positive effect on the strength of the teeth. 36 teeth are chosen which leads to a step-size of 1.45 ° per step.

Overconstrained Mechanism

Another aspect regarding the gear is the amount of contact points. In most gear like mechanisms, only a few teeth interlock with each other. And this is not without reason. When two rigid bodies interact with each other, they only make contact on three points due to the irregularity of the material. Having more than three contact points will overconstrain the design [24]. Having 36 interlocking gears makes no sense when only a very few take the forces. Therefore the number of the inner gear is reduced to three instead of 36. The ring gear keeps the original 36 teeth to accommodate the adjustability of the mechanism.

4.2.4 Iteration 4: Alignment Gear Locking Mechanism

To keep the alignment gear within the housing, two measures are taken. Firstly the gear is cone shaped, so it will restrict itself from falling out of one side of the housing. On the other hand a spring pushes the gear into the housing and thereby holding it in place. But there are a few downsides to the usage of a spring. A spring needs space also when the mechanism is unlocked and the spring is compressed. Where space is limited inside the housing of the AFO-hinge, this is not desirable. Secondly, a spring with high stiffness is needed to push the gear into the housing. High forces are working on the gear, and this gear should not move when it is not meant to. But, one should be able to adjust the mechanism, and thereby compress the spring which requires a lot of forces. Therefore a solid wedge is chosen lock and unlock the gear.

4.3 Force Calculations

The dimensional design started off with the dimensions used by AFO manufacturers. This formed a baseline on which the mechanism is developed further. Since, the end of the design phase is near, the actual strength of the AFO hinge can be calculated by evaluating critical parts of the mechanism.

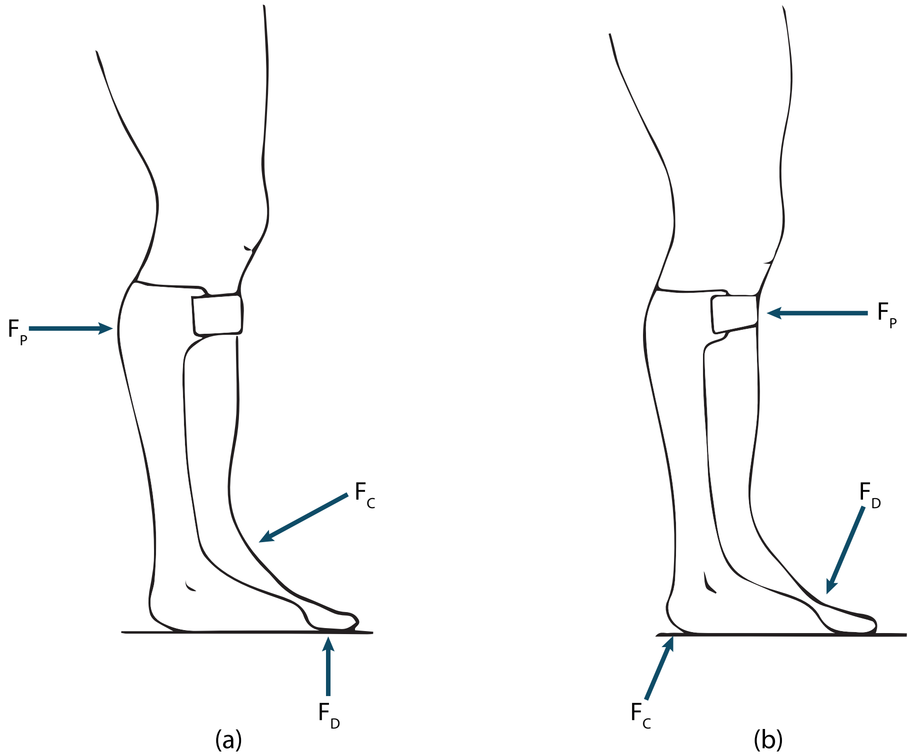


Figure 4.4: Force system in a molded thermoplastic solid ankle-foot orthosis, where the forces shown are exerted on the human body. (a) Plantarflexion during swing phase (b) Dorsiflexion during stance phase. Where F_P is proximal force, F_D is distal force, and F_C is centrally-located stabilizing force. [25]

The starting points for the force analysis are the ankle torque and the weight of the AFO-wearer, which are set in the design specifications (see chapter 2). Here, a maximum ankle torque of 120 Nm was set for a human of 80 kg. A force analysis is used to identify the forces that are applied on the AFO. The work of Folmar et al. [25] showed two force systems when using a solid AFO (see figure: 4.4). On the left, the situation is sketched of the forces exerted on the patient's leg by the AFO during swing phase. The distal force keeps the foot from dropping and the centrally-located stabilizing force keeps the foot positioned in the AFO. F_C is exerted by a AFO strap around the foot. The situation on the right shows the forces exerted on the human leg by the AFO during dorsiflexion in stance phase. Here, the AFO counteracts the dorsiflexion of the foot. During gait, the highest ankle torque occurs at maximum dorsiflexion right before the contralateral leg makes contact with the ground, which means that the right side of figure 4.4 provides the best fit for this analysis. All the information that is needed for this force analysis is gathered. From here on, an accurate estimation of the applied forces that are relevant for this study can be made.

In figure 4.5 the situation is sketched where the wearer is in maximum dorsiflexion. The shown forces are, unlike the figure of Folmar et al. [25], exerted on the AFO. The F_{Shank} and the F_{Foot} are applied by the human body. The F_{Ground} is the ground reaction force countering the weight of the human body. The length of the shank and the foot are chosen in a way that makes it both convenient and realistic. The angle at which the foot is placed on the ground is set on 30 degrees. The F_{Ground} is directed vertically and with a distance of 0.15 m between the foot and the ankle joint.

$$F_{Mass} = F_{Ground} = 800\,N \tag{4.3}$$

The three forces balance each-other out, and having F_{Foot} directed through the ankle joint, simplifies the torque on the ankle. The ankle torque is as described in the section before:

$$T_{Ankle} = F_{Ground} \cdot 0.15 = 120\,Nm \tag{4.4}$$

F_{Shank} is perpendicular to the shank, which leads to an arm of 0.3 m.

$$F_{Shank} = \frac{T_{Ankle}}{0.3} = 400\,N \tag{4.5}$$

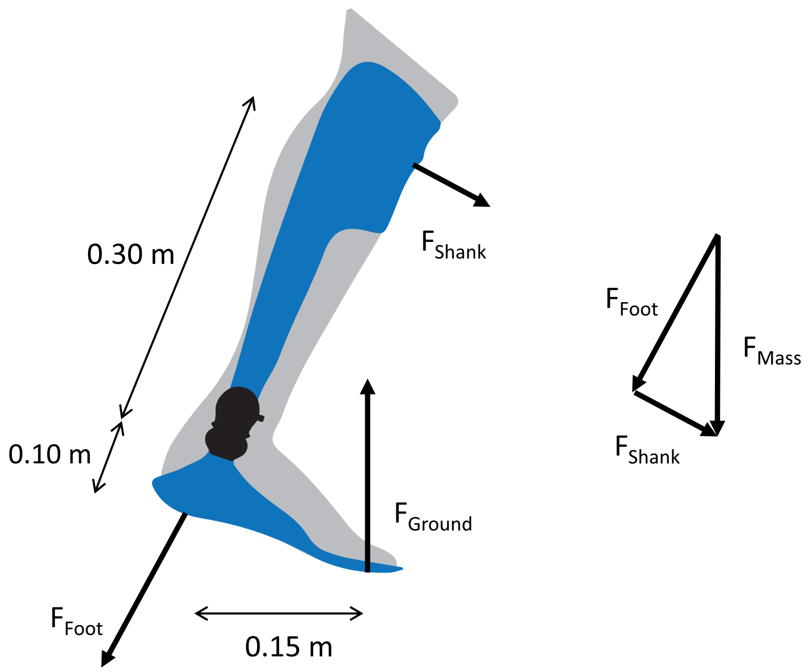


Figure 4.5: Free body diagram of an AFO, right before toe-off. The forces shown are exerted on the AFO. F_{Foot} and F_{Shank} are exerted by the human body, where F_{Ground} is the ground reaction force.

4.3.1 Bending of Components

To find out whether the design of the AFO hinge can withstand usage, critical parts are evaluated for their strength. Stresses that are derived from forces and the geometry of the mechanism give a good impression of the capabilities of the mechanism. Zooming in on the mechanism, the relevant forces for this analysis can be identified. Figure 4.6 shows both the forces exerted on the upper bar (left) as well as the lower bar (right). T_{shank} and T_{Foot} are the torques generated by the shank and the foot in contact with the ground respectively. The upper bar is connected to the central axis and restricted by the gear pin which hold the bar in place. The lower bar is attached to the central axis and restricted by the locking ring.

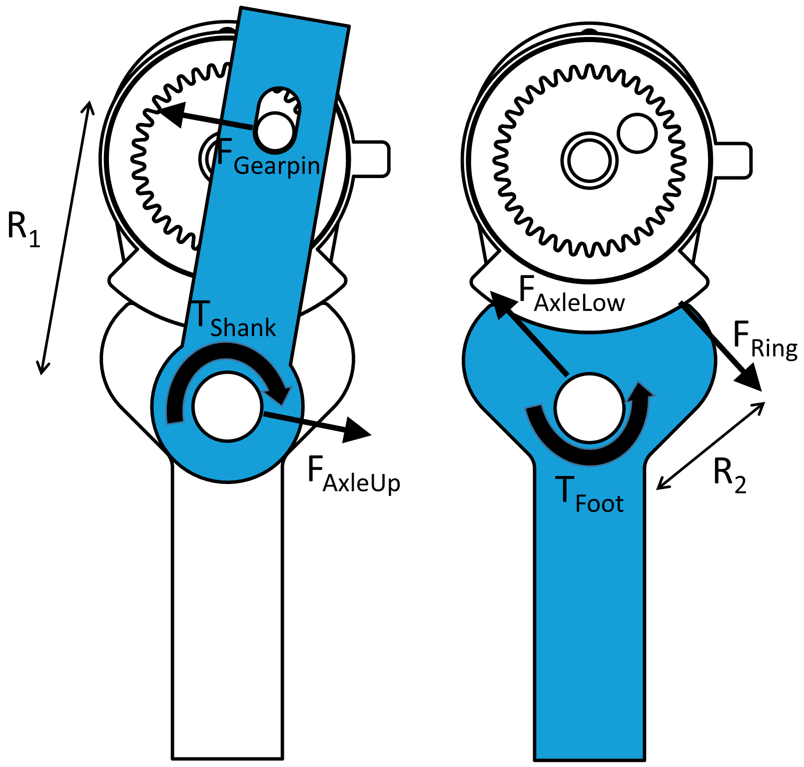


Figure 4.6: Force analysis on AFO, right before toe-off. The forces shown are exerted on the upper bar (left) and lower bar (right).

The following parameters are known:

Parameter	Value
R_1	$40\,mm$
R_2	$15\,mm$
T_{Shank}	$120\,Nm$
T_{Foot}	$120\,Nm$

Using these parameters as input, the unknown forces can be calculated as follows:

$$F_{Gearpin} = \frac{T_{Shank}}{R_1} \tag{4.6}$$

$$F_{AxleUp} = F_{Gearpin} - F_{Shank} \tag{4.7}$$

$$F_{Ring} = \frac{T_{Foot}}{R_2} \tag{4.8}$$

$$F_{AxleLow} = F_{Ring} - F_{Foot} \tag{4.9}$$

Parameter	Value
$F_{Gearpin}$	$2963\,N$
F_{AxleUp}	$2563\,N$
F_{Ring}	$5766\,N$
$F_{AxleLow}$	$4966\,N$

Bending of Lower Bar

The forces are identified, and taking it one step further, stresses inside the parts can be calculated. Stress due to bending results in a linearly tensile stress profile throughout the cross-section of the material (see figure: 4.7). The largest stresses are located at the edge of the material, where the top surface is tensioned and the bottom surface is compressed. The calculated stress is compared to the yield stress of the material. This is the stress a material can withstand before plastic deformation. For 316 stainless steel:

$$\sigma_{Yield} = 240\,MPa$$

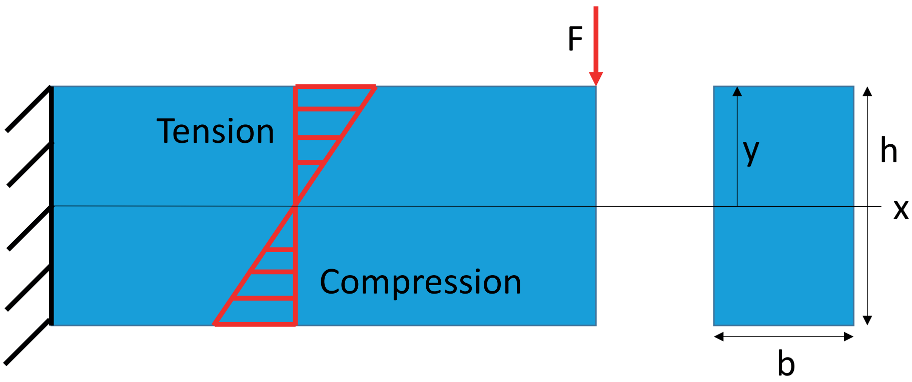


Figure 4.7: Tensile stress distribution in a beam due to bending (left) and the cross section of the beam (right). Here h is the height of the beam, b is the thickness, and y is the distance from the calculated stress location to the center of the beam.

The formula for stress due to bending is formulated as:

$$\sigma_{bending} = \frac{My}{I} \tag{4.10}$$

where M represents the torque which is exerted on the section. In this situation the maximum ankle torque of $120\,Nm$ is chosen. y describes the position of which the stress is calculated (measured from the center line). The maximum tensile stresses due to bending are located at the edge of the beam (see figure: 4.7). Where I represents the moment of inertia. The moment of inertia of a beam is described by the following formula:

$$I = \frac{bh^3}{12} \tag{4.11}$$

Having a Torque of $M = 120\,Nm$, the thickness of the beam $b = 4\,mm$, width of the beam $h = 16\,mm$ gives:

$$\sigma_{Bending} = 703\,MPa > yield\ strength$$

The bar is not sufficiently strong. Making the bar 30 mm wide, gives:

$$\sigma_{Bending} = 200\,MPa < yield\ strength$$

Bending of Upper Bar

Since there is a hole in the upper bar, the beam is weakened. A formula described by the book of Pilkey et al. [26] shows the maximum stress of in-plate bending of a finite-width plate with a central single circular hole (see figure: 4.8). Although the slot in the design is not circular, it gives a proper estimation of the strength of the bar.

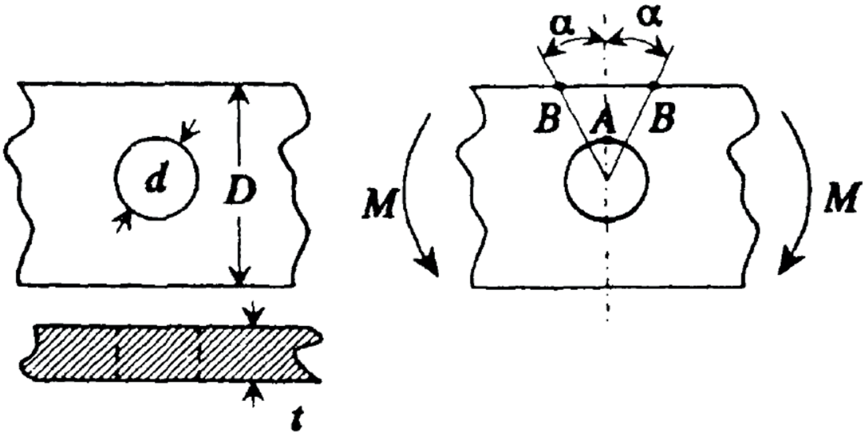


Figure 4.8: In-plate bending of a finite-width plate with a central single circular hole [26].

Formula 4.12 provides the maximum bending stress which is located in point B as shown in figure 4.8.

$$\sigma_{max} = \frac{12dMD}{(D^3 - d^3)t} \tag{4.12}$$

The parameters for this formula are:

Parameter	Value
d	$5.5 \cdot 10^{-3}\, m$
D	$22 \cdot 10^{-3}\, m$
M	$104\, Nm$
t	$4 \cdot 10^{-3}\, m$

The maximum stress due to bending in this segment of the upper bar is:

$$\sigma_{max} = 163\, MPa < yield\, strength$$

4.3.2 Shear

Besides bending, some parts of the mechanism are susceptible to shear. When looking at pure shear, the critical shear stress of a material is defined by the Von Mises yield criteria as:

$$\tau_{Yield} = \frac{\sigma_{Yield}}{\sqrt{3}} \tag{4.13}$$

which means that for 316 stainless steel, the critical shear stress is $138.5\,MPa$. The general formula for shear is stated as follows:

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

In the following sections, shear in the gear pin, central axis and gear teeth will be calculated (see figure: 4.9).

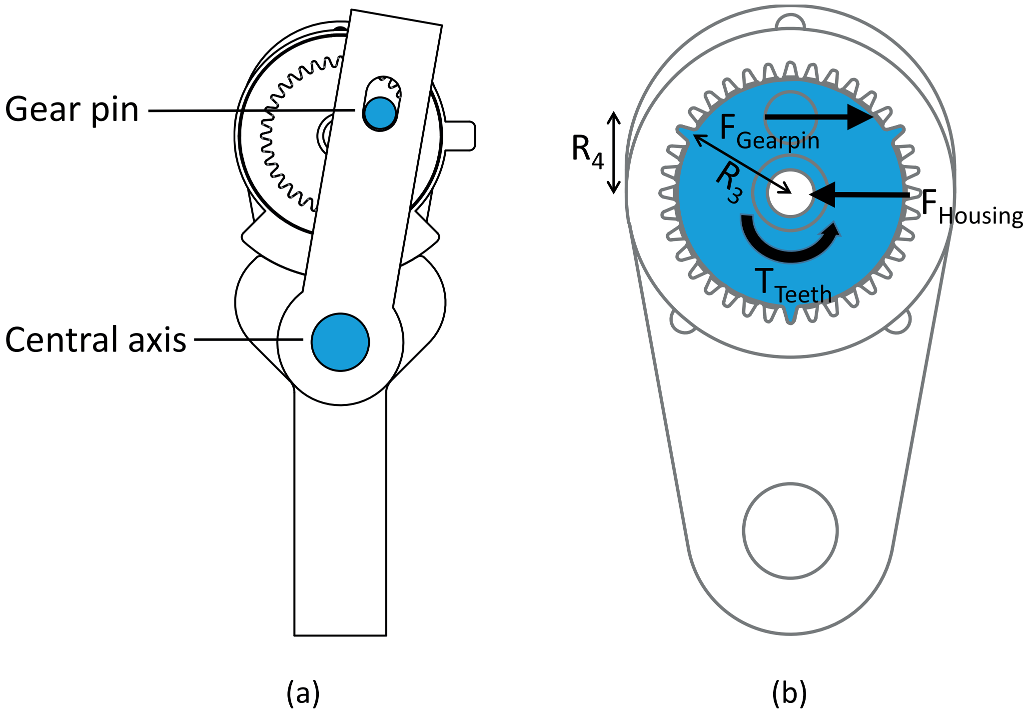


Figure 4.9: Critical parts prone to shear. (a) Central axis and gear pin. These parts connect the assembly and have to bear high loads. (b) Teeth of the gear. A free body diagram of the the gear is shown. $F_{Housing}$ and T_{Teeth} are exerted by the housing and counteracting $F_{Gearpin}$ which is comes from the shank force in the upper bar.

Shear in Central Axis

The central axis is the main joint of the mechanism. But it is also the part where the highest forces are exerted. Therefore is important to show that the central axis is capable of bearing these forces. These are the relevant parameters:

Parameter	Value
$D_{CentralAxis}$	$10\,mm$
$A_{CentralAxis}$	$7.85 \cdot 10^{-5}\,m^2$
$F_{AxleLow}$	$4966\,N$

This gives a shear stress in the central axis of:

$$\tau_{CentralAxis} = 63\,MPa$$

This is well below the critical shear stress.

Shear in Gear Pin

The gear pin is a fragile part that keeps the upper bar positioned. The following parameters are involved to calculate the shear in the gear pin:

Parameter	Value
$D_{Gearpin}$	$5.5\,mm$
$A_{Gearpin}$	$2.38 \cdot 10^{-5}\,m^2$
$F_{Gearpin}$	$2963\,N$

This gives a shear-stress in the gear-pin of

$$\tau_{Gearpin} = 125\,MPa$$

This is still below the critical shear stress, but comes close to the limit of 138.5 MPa.

Shear in Gear Teeth

Lastly the teeth of the alignment gear are evaluated. These teeth have a small profile to fit inside the the housing. And this makes them a fragile component in the overall mechanism. The following parameters are used to calculate the shear in the gear pins:

Parameter	Value
$F_{Gearpin}$	$2963\,N$
R_3	$11 \cdot 10^{-3}\,m$
R_4	$8 \cdot 10^{-3}\,m$
N_{Teeth}	3
A_{Teeth}	$8 \cdot 10^{-6}\,m^2$

The horizontal force exerted on the gear by the gear pin is opposite to the force exerted by the housing on the gear, this leads to:

$$F_{Gearpin} = F_{Housing} \tag{4.14}$$

The force per pin can be calculated using the torque generated by the $F_{Gearpin}$. The stress is then divided by three, since there are three teeth on the gear. This results in the following formula:

$$\tau_{Teeth} = \frac{F_{Gearpin} \cdot R_4}{R_3 \cdot A_{Teeth} \cdot N_{Teeth}} \tag{4.15}$$

$$\tau_{Teeth} = 90\,MPa$$

4.4 Final Design

During the concept development, in almost every step, small changes are made in the design. After the stress analysis, the bars where made a little thicker to withstand the forces. Now, at the end of the development phase, the following concept is created:

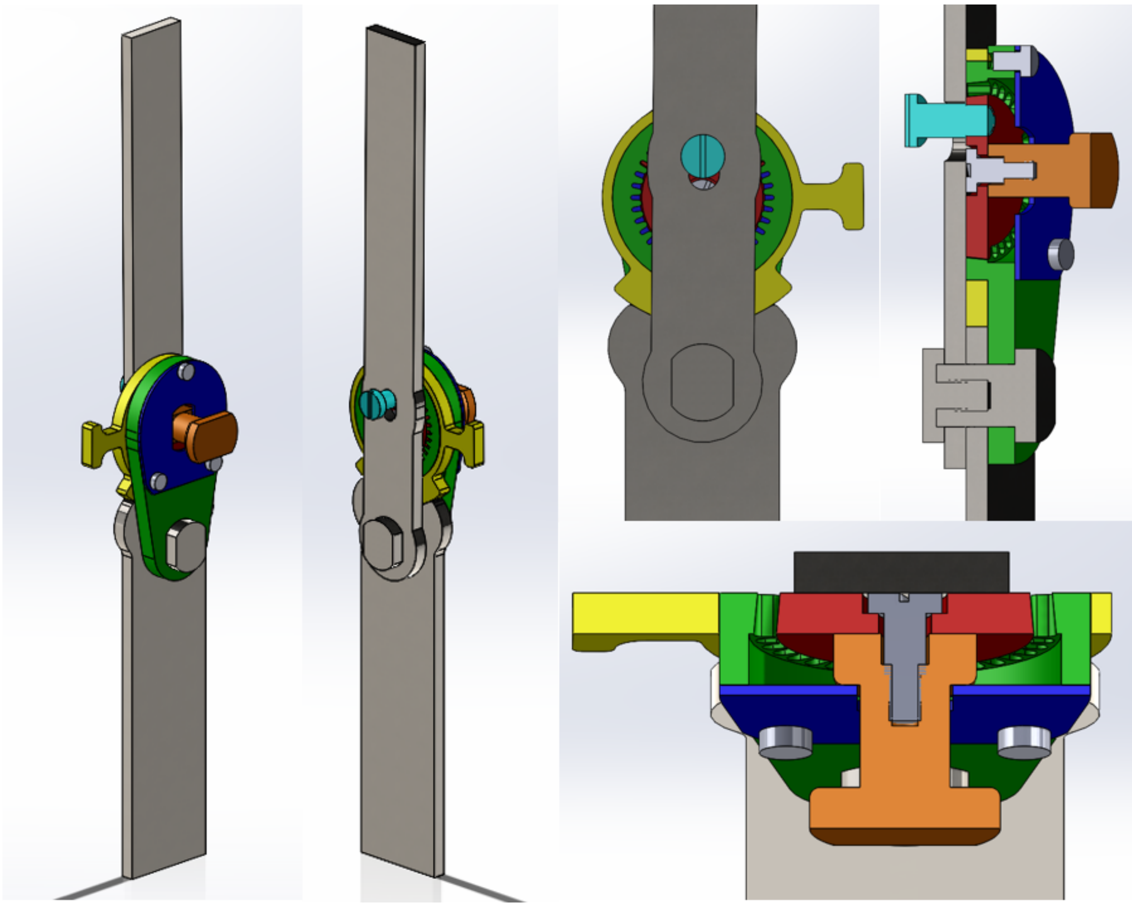


Figure 4.10: Design after development phase with two section views. To adjust the alignment angle, the orange grip is turned 90 degrees and pulled out of the housing. This unlocks the red gear and allows adjustments to be made. By pushing the orange grip back into the housing the new alignment angle is set. Turning the grip a quarter turn will lock the alignment mechanism. To unlock the overall mechanism, the yellow ring can be turned half a turn.

Chapter 5

Build

5.1 Fabrication Considerations

The fabrication phase was kept in mind throughout the whole design process. Considerations where made, so the hinge mechanism could be assembled properly. The initial idea was to 3D-print the housing, gear, and pull-out pin where the locking ring, upper, and lower bar could be laser cut from sheet metal. Laser cutting provides a fast and accurate solution for 2D shapes where 3D printing can deal with the more complex shapes. At every step of the fabrication process, new hurdles emerged. These will be mentioned in the sections below.

5.1.1 PLA 3D-Printing

The first prototype was 3D-printed out of PLA using an Ultimaker. The prototype was printed to see whether the design worked properly. Although the Solidworks model gives a good impression of the mechanism, an actual prototype can truly show its capabilities and limitations. After some tweaking of the printer settings and adjusting the shape of the gears, it was clear that the teeth of both the gear and the housing where too small to print. The resolution of the printer was not sufficient which resulted in gears that did not fit together (see figure: 5.1). The final prototype was to be made out of metal and the available metal printer would have a better resolution. The design was once more adjusted and send to the metal 3D printer. Having seen the results of a base model 3D printer, the flaws of this manufacturing method became clear. The resolution is insufficient which makes the result a little unpredictable. To make progress with the prototype there was opted for a different fabrication technique to serve as a back-up in case the metal print failed. A completely laser-cut model was made to serve as this back-up.

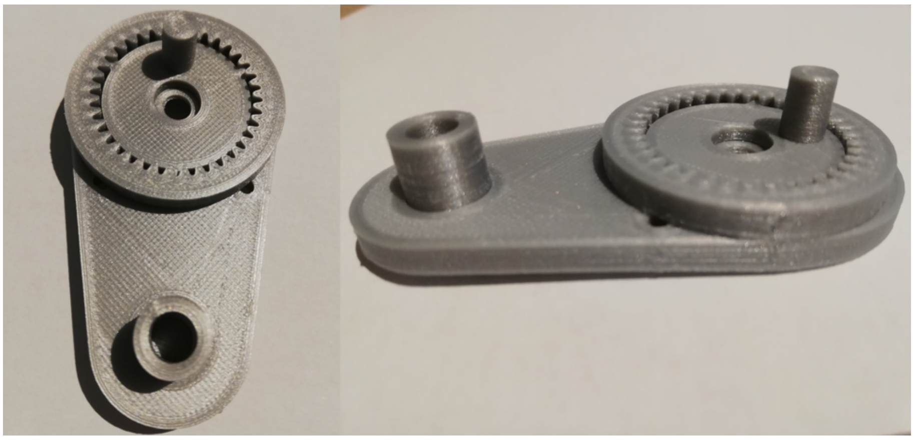


Figure 5.1: PLA print of the gear and housing of the prototype. As can be seen on the right, the gear is not flush with the housing. This is due to limited capabilities of the 3D-printer.

5.1.2 Laser Cutting

Laser cutting is known for its accuracy and speed. Furthermore, labour costs are low as cuts can be made by pressing start on the machine and post processing operations only consist of sanding of the sharp edges. But laser cutting also has its limitations. Firstly, only 2D shapes can be cut. For the design this meant that the housing needed to be split in two layers. One consisting of the ring gear and another having the hole to fit the central axle. For the gear this meant that an extra stopping disc was required to avoid the gear from falling out of the housing. The conical shape the gear initially had is not achievable by laser-cutting. Secondly, the thickness of the layers is limited. Cutting thick sheets of metal results in rougher and more inaccurate edges compared to thin sheets. This phenomena became clear when cutting thick sheets for the first time. In figure 5.2 the housing is shown. The surfaces around the edges are very rough and the teeth of the gear are not consistent.

Figure 5.2: Laser cut housing and gear. The thick material causes the cut surface to be very rough and thereby inaccurate.

For the small teeth of the ring gear, 4 mm thickness did not give satisfying results. Also the surface of the housing was too rough. Therefore it was decided to brake these parts up into two layers each. This yielded a far better result as shown in figure 5.3. To assemble the different layers, several methods were considered. Using bolts to hold the layers together would not work since the gear ring is very thin. Spot-welding the parts together was difficult because of the thickness of the material. Also, there is a chance the parts will deform. In the end, there was opted for dowel pins. Small holes are cut in each layer, and the dowel pin is then pushed through these holes. The pin can be locked into place by soldering.

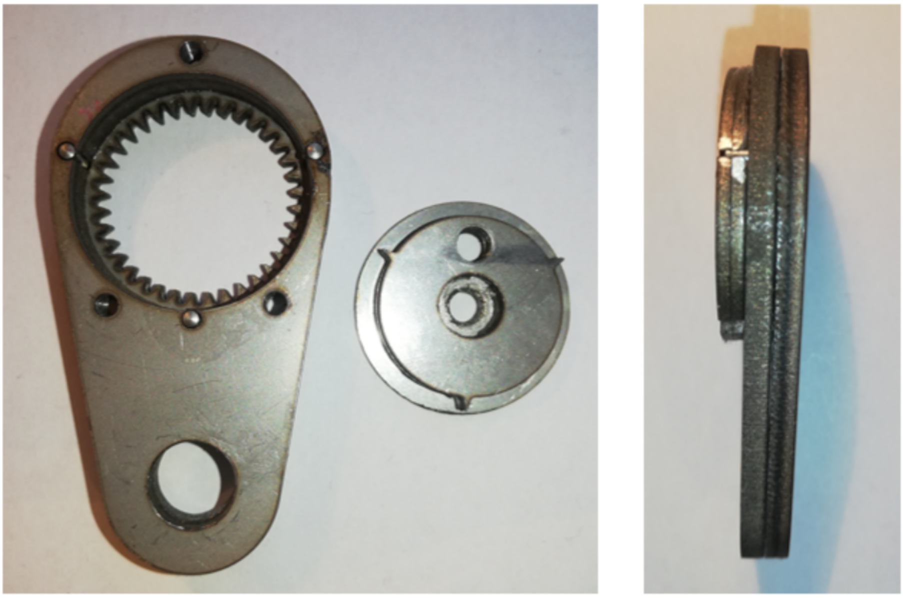


Figure 5.3: Laser cut housing and gear using thin sheets of steel. The gear parts are build up from 2 mm steel. The remainder of the housing is made of 3 mm steel sheets. The Housing is held together using dowel pins.

5.1.3 Metal 3D-Printing

After the laser-cut prototype was made, the 3D-printed metal version came in. The surface of the print was a little rough, but the shapes seemed to be well-printed. Most importantly, the gears do fit together (see figure: 5.4). However, the printed holes are not truly circular, but oval. With a drill, these holes where made circular. It was a tricky process since the drill wanted to bite into the material which can lead to damaging both the drill bit as well as the work-piece. After drilling out the holes, some holes were threaded.

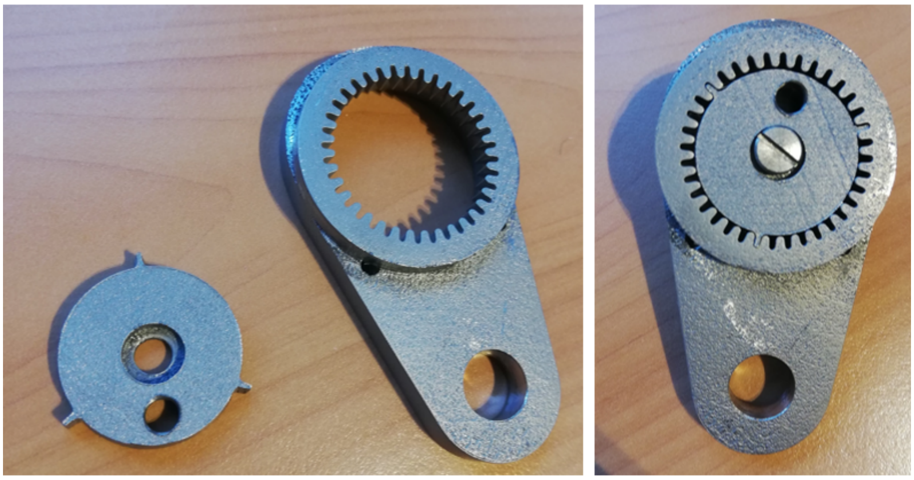


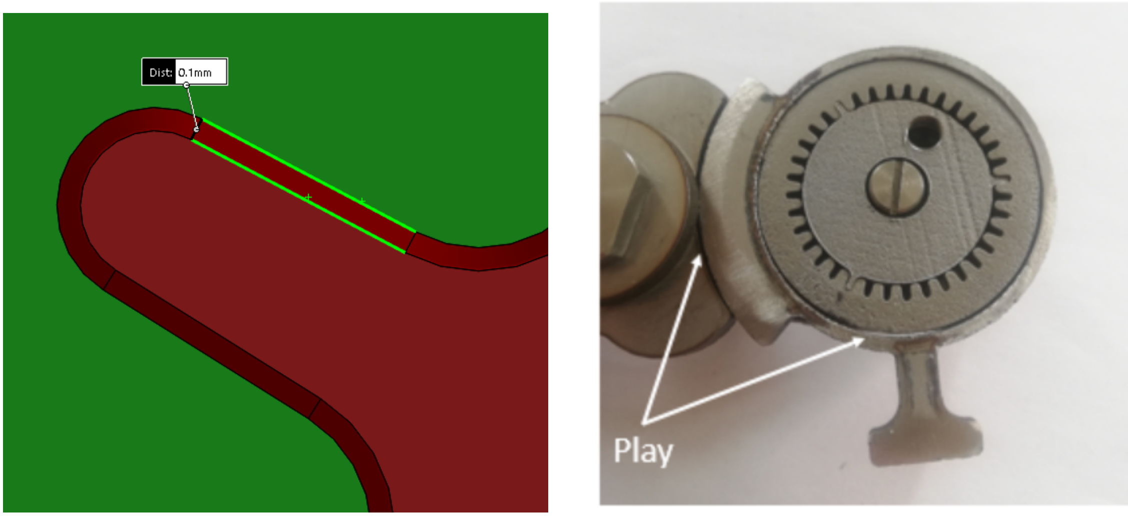
Figure 5.4: 3D printed housing and gear made from 316 steel. As shown on the right, the parts fit together.

5.1.4 Tolerances and Play

During the modeling of the mechanism tolerances were taken into account where it mattered most. As very clearly shown by the first 3d-print in PLA, gears did not fit where they did fit in the 3D-model. Due to mechanical limits in machines, the design is compromised. To avoid this, one can take these tolerances into account whilst designing. Parts that have to fit around a certain part should be made slightly bigger. Parts that need to fit inside a certain part, are made a little smaller.

Housing and Gear

The 3D-printed housing and gear where difficult to design as the accuracy of the printer is not completely defined. Testing on a PLA print gave insights on what might work or not. Sharp and pointy edges are difficult to print, so a minimal radius of shapes was needed. Also the surface is a little rough. To make components fit together, building in clearance is required. As for the housing and gear a space of 0.1 mm around the gear was left to leave space for inaccuracies (see figure: 5.5a).



(a) (b)

Figure 5.5: Tolerances and play in the design. (a) Leaving a 0.1 mm gap between the gear teeth (red part) and the housing (green part) in the model made the parts fit together after fabrication. (b) Undesired play between locking ring and adjacent components due to making the wrong trade-off between fabrication error and designing for the right fit.

Locking Ring

At first sight, the locking ring looks like a simple straightforward component. But fitting the locking ring was quite a challenge. Firstly the ring was laser-cut of 4 mm steel, the accuracy was sufficient, but the edges were rough. sanding these down, resulted in a smoother finish, but also introduced more play. Secondly, the part interacts with two other parts. The locking ring needs to be able to rotate around the housing ring and also slide in the circular shape of the lower bar to lock it. Since both actions required a loose fit, it is difficult to achieve this without introducing a lot of play in the system. In figure 5.5b there is a clear gap between the locking ring and adjacent components. In this situation the inner diameter of the locking ring was made 0.2 mm wider and the outside diameter was made 0.2 mm smaller. But after assembly a gap of almost 1 mm was established between the ring and the lower bar. To reduce this play, an oversized Locking ring was cut and milled to the right dimensions by hand.

Central Axle

On the central axle, the moving parts come together. The upper bar, lower bar, and the housing are all held by this axle. On one hand, these components should be able to rotate around this axle. On the other hand, there shouldn't be any play between the components. A loose fit of H7 was chosen to suit these needs. In this case a H7 fit means that the axle has a diameter of $9.985 - 10.000\,mm$ and the holes have a diameter of $10.000 - 10.015\,mm$. These measurements make sure that the axle fits inside the hole without introducing play.

Prototype

After manufacturing all the parts, the prototype was assembled. In figure 5.6 the prototype is shown. The housing and gear were 3D printed, the pull-out pin and central axis were turned on a lathe and the upper bar, lower bar and locking ring were laser cut from sheet metal.

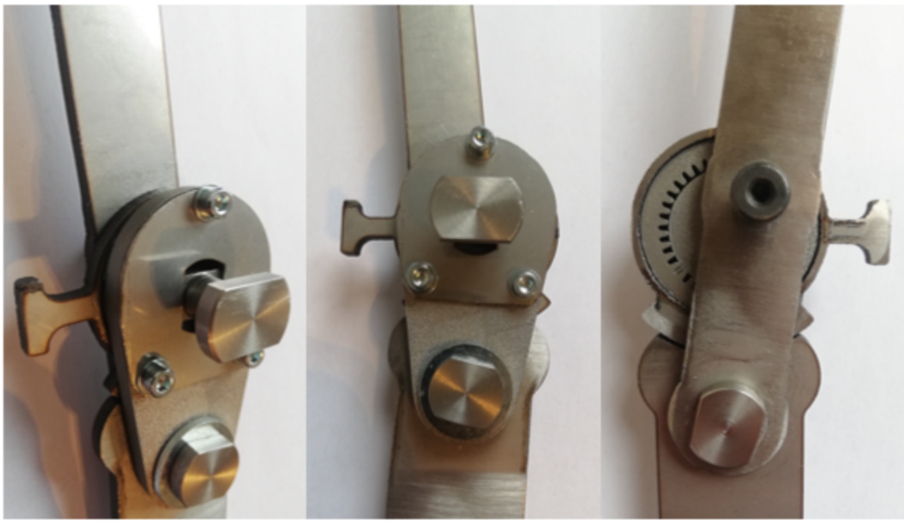


Figure 5.6: The final prototype. The housing and gear are 3D-printed from 316 steel, the locking ring, upper and lower bar are laser cut, and the central axle and pull-out grip are turned on a lathe.

Chapter 6

Load Test

6.1 Test Setup

The mechanism was tested using a Lloyd LR5K testing machine. This machine can pull with a prescribed speed till a maximum load is reached. This allows for a controlled load test. The mechanism was held by a custom designed constraining setup. Steel sheets were bend 90 degrees and bolted to a base plate (see figure 6.2). The upwards directed sheets could hold the mechanism in place using two pins that go through two holes made in the lower bar. At the pull side of the machine a construction is designed to apply the load on the mechanism. Using a pin hole coupling and a fork shape construction, the upper bar of the mechanism can be pulled upwards. The distance from the central axis to the load application point, is 0.1 m. This is done to be able to calculate the applied ankle torque easily. The ankle holding torque is hereby defined as:

$$Holding\,torque = Load\,[N] \cdot 0.1\,[m]$$

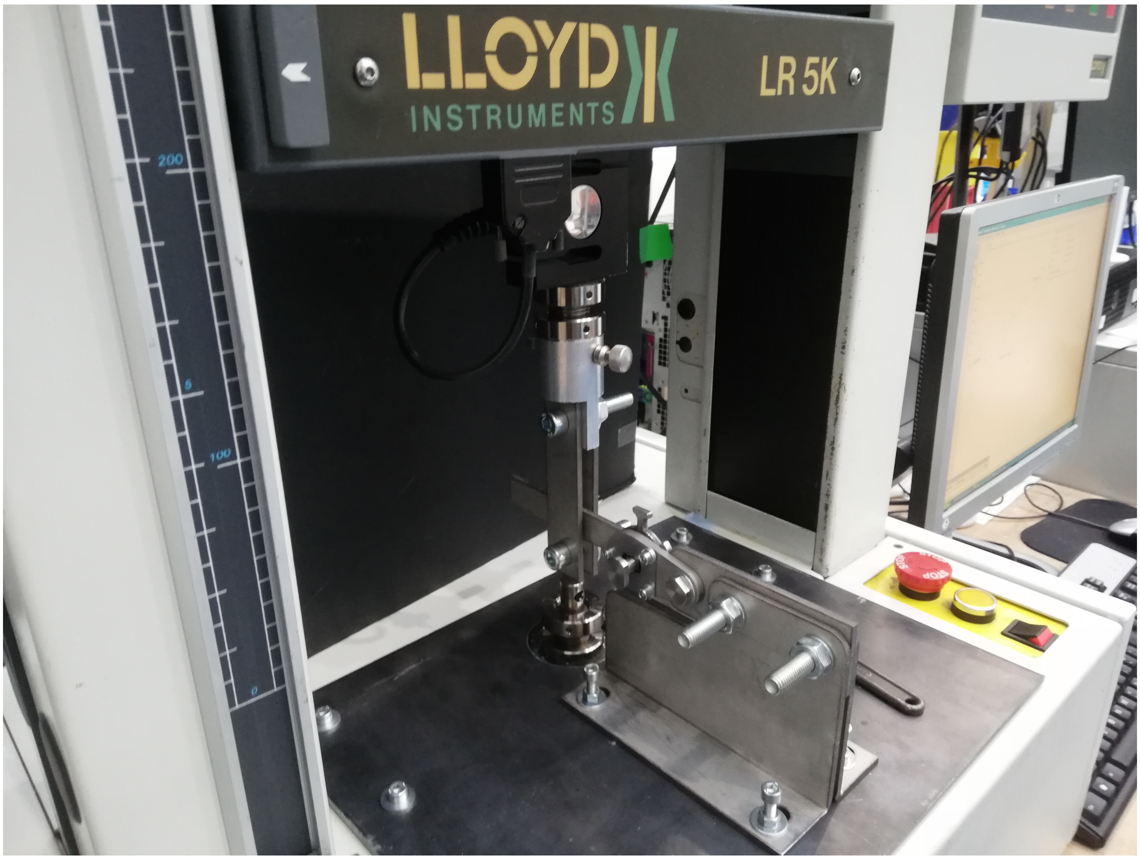


Figure 6.1: Test setup which is used for performing a load test. The prototype is held in place by two bolts slotted in standing steel sheets. A fork like structure with a bolt under the upper bar of the mechanism allows the prototype to be pulled upwards.

6.2 Test Protocol

Since there is only one working prototype, it is important to gain as much information from this prototype before the mechanism fails under the applied load. Therefore, it was decided to do multiple load tests. After each test, the mechanism was tested to validate whether the mechanism was still functional. Both alignment adjustment- and (un)locking mechanism were tested. Furthermore, the mechanism was inspected on failing components. After the initial test with a load of 600 N, the load was increased with steps of 200 N for each subsequent test. After reaching the 1600 N, a "pull to failure" test was initiated. This was done to expose the weak parts in the mechanism.

Another parameter to set in the testing machine was the speed of the upward-pulling motion. To retrieve a proper data set, the duration of the test was important. In the worst case scenario, where all materials are rigid, except the gear. The teeth should brake before an adjustment of 2° takes place. The maximum displacement can then be calculated using

$$Max\, displacement = 0.1 \cdot \sin 2^\circ = 3.5\, mm$$

To retrieve sufficient data, the speed is set to 0.05 mm/s. This will in the worst case scenario result in a test that lasts 70 seconds.

Lastly, a preload of 10 N is applied before the test starts. This is done to eliminate any play in the mechanism which can give noise in the test results.

6.3 Test Results

6.3.1 Pull to Load

The first six tests are shown in figure: 6.2. The displacement and the load are plotted for each test. Each test starts when the preload of 10 N is reached regardless of the displacement.

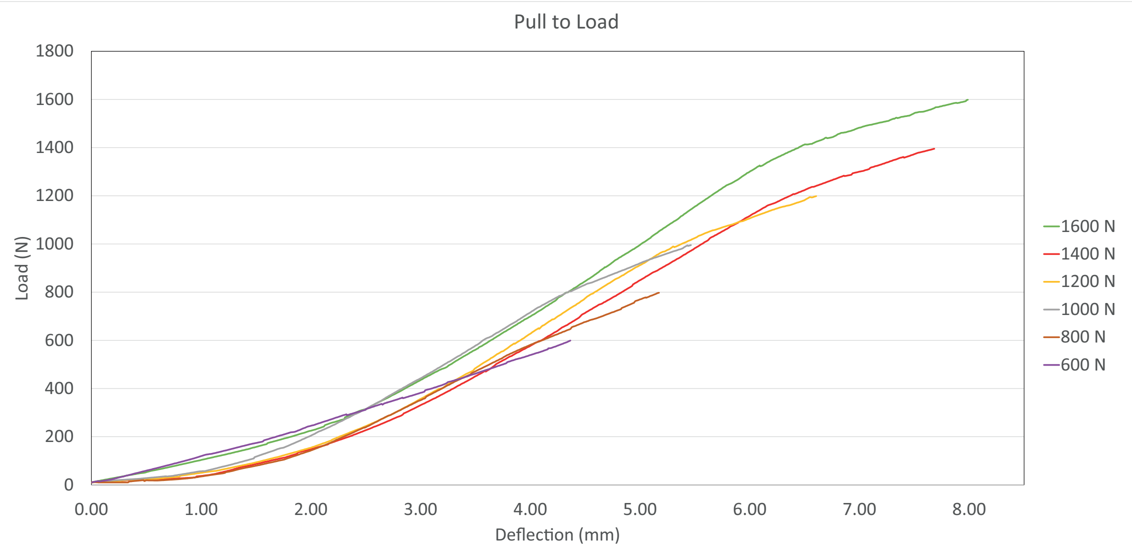


Figure 6.2: Segmented load test, where the mechanism is tested on usability before the load is increased by 200 N. The load is exerted on the upper bar, 0.1 m away from the central axis.

In the test of 600 N, the deformation that occurs seems mainly elastic as the data shows a straight line. However, the subsequent test of 800 N shows a steeper slope of the line which indicates that the mechanism has become less elastic. The stiffness can be calculated using the slope of the linear elastic section of each test. The stiffness of the mechanism of each test are shown in table 6.1. It is clear that the stiffness of the first test is a lot lower compared to the subsequent tests.

	Max Load	Stiffness
Test 1	600 N	140 N/mm
Test 2	800 N	233 N/mm
Test 3	1000 N	264 N/mm
Test 4	1200 N	272 N/mm
Test 5	1400 N	259 N/mm
Test 6	1600 N	274 N/mm

Table 6.1: Stiffness of elastic region per load test.

Another interesting result is the flattening of the curve at the end of each test. This may indicate that plastic deformation takes place in this phase of the experiment. Also the mechanism is hardening, because each subsequent test stays in the elastic region for a longer period.

In addition to the measurements of the testing machine, the prototype was functionally tested on alignment and locking mechanism. Also a visual inspection was conducted to see any points of failure. An overview of these findings are shown in table 6.2. Up to 1000 N the mechanism did not show any sign of deformation. Both locking and alignment mechanism worked properly. After the 1200 N load test, there was increased play in the locking mechanism. Although the functionality was still there, there was a little space between the wedge and the lower bar. Also the upper bar was slightly deformed. The guiding pin had left a mark in the slot of the upper bar. At 1400 N there was a noticeable curve in the housing. This would also explain the space between the wedge and the locking ring. Furthermore the upper bar started to twist due to the off-center loading. At 1600 N these effects are a little more amplified. The teeth of the gear still looked intact and the functionality of both alignment adjustment and (un)locking was still there after a load of 1600 N. This means that the mechanism is still functional after reaching an ankle torque of 160 Nm.

	Max Load	Alignment Functionality	Locking Functionality	Visual Inspection
Test 1	600 N	Yes	Yes	No visual damage
Test 2	800 N	Yes	Yes	No visual damage
Test 3	1000 N	Yes	Yes	No visual damage
Test 4	1200 N	Yes	Yes	Little play in locking mechanism Slight deformation in upper bar
Test 5	1400 N	Yes	Yes	The housing starts to bend. Deformation of the upper bar
Test 6	1600 N	Yes	Yes	Bending of the housing Slight twist in the upper bar

Table 6.2: Functionality of the mechanism and visual damage after load testing.

6.3.2 Pull to Failure

The last test was a "pull to failure" test, where a maximum deflection of 40 mm was set in the parameters of the testing machine. An ultimate load of 2107 N was reached after which the necking phase began (see figure: 6.3). Here the mechanism slowly lost its strength and failed at a deflection of 30 mm.

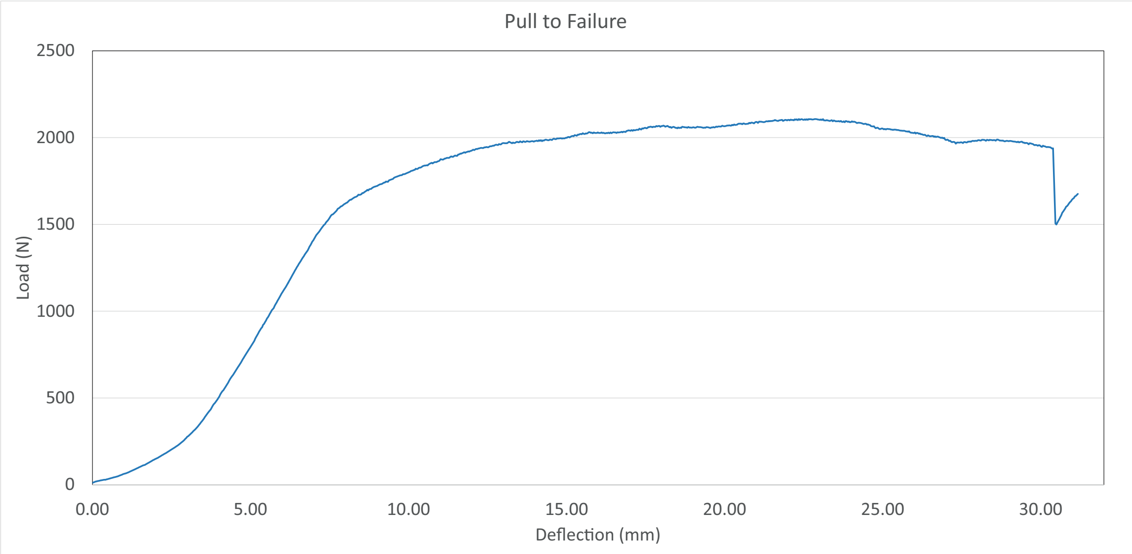


Figure 6.3: Pull to failure test. After reaching an ultimate load of 2107 N the mechanism slowly last its strength. The mechanism failed at a deflection of 30 mm.

After the test, the prototype was significantly deformed (see figure: 6.4). Both the housing and upper bar are bend and the gear is pulled out of the housing. After taking the mechanism apart, mainly three components failed.

(a) (b)

Figure 6.4: Mechanism after failure: (a) the gear came out of the housing of the mechanism (b) top view after pull to failure test. The teeth of the gear were deformed and the housing and upper bar were slightly twisted and bend.

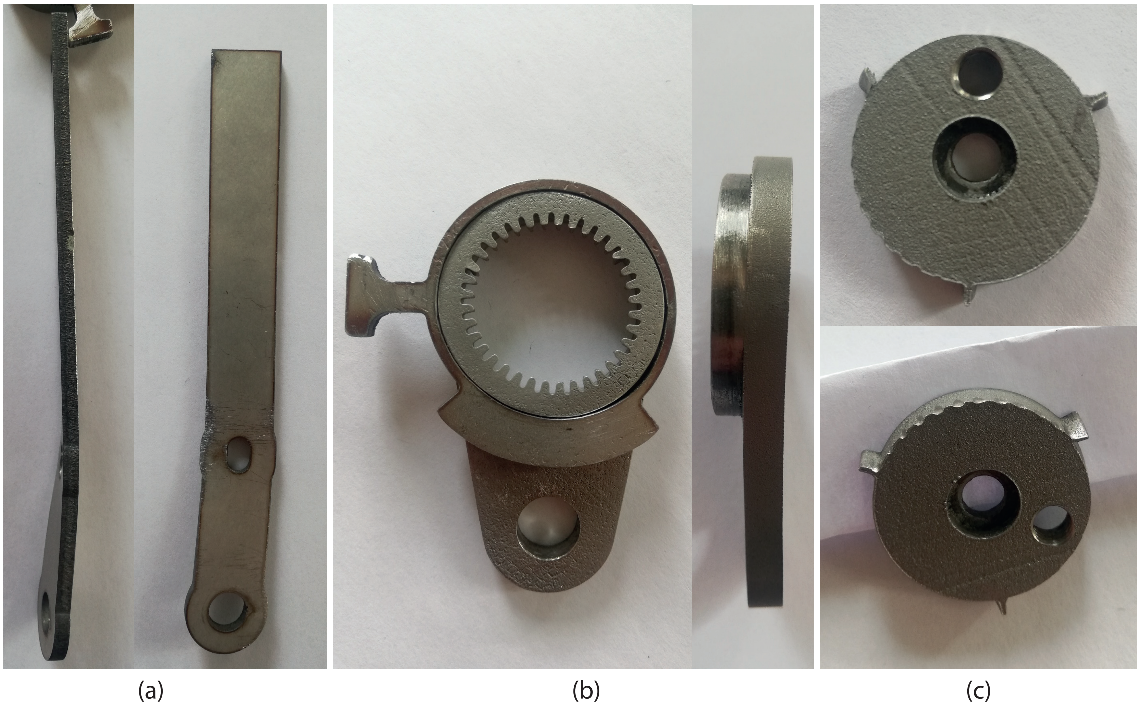


Figure 6.5: Failed components: (a) the upper bar was twisted, (b) the housing ring was no longer circular and the housing was bend, (c) two of the three gear teeth were deformed and teeth of the ring gear had left their marks.

Chapter 7

Evaluation

In this section the design will be evaluated. The specifications of the mechanism are verified by comparing them to the design specifications from chapter 2. Furthermore, the design will be validated. At the beginning of this study, an AFO user and manufacturer of orthotic components were interviewed to gain insight for a new AFO mechanism. This information formed the base of this design. By asking their opinion of the current prototype, the prototype can be validated.

7.1 System Verification

All design specifications from chapter 2 can now be compared to the actual prototype. As shown in table 7.1 not all design specifications were met. The grips to operate the mechanism increased the size of the overall mechanism. With some further improvements, these could be shrunk to better fit the design specifications. Nonetheless, the size is still smaller than the Fior & Gentz Neuro Swing hinge mechanism. The operation of the mechanism for both the alignment and unlocking is possible with one hand. Test results from the load test (see previous chapter) showed slight deformation at a torque of 120 Nm. Nevertheless, the mechanism was still functional up till 160 Nm. When looking at the alignment, the step-size is well below 2° but the range of adjustments is limited to 17.5°. The locking mechanism is in line with specification.

	Design Specifications	Actual Design	Fulfilled
General			
Width	30 mm	39 mm	No
		51 mm incl. locking grip	No
Height	70 mm	67 mm	Yes
Thickness	15 mm	14 mm	Yes
		33 mm incl. alignment grip	No
Weight	$< 120\,g$	125 g	No
Operation	Operate with one hand	Operate with one hand	Yes
Holding torque	120 Nm	120 Nm with a little play	Yes
		Still functional after 160 Nm	
Adjust Alignment			
Step size	$< 2\,°$	1.4 °	Yes
Range of motion	20 °	17.5 °	No
Lock and Unlock			
Locking position	Single locking position	Single locking position	Yes
ROM when unlocked	30 °	36 °	Yes

Table 7.1: Design specifications versus the actual design.

7.2 System Validation

7.2.1 AFO-User

At the beginning of this study, an AFO-user was asked about his current experience with AFOs. The participant uses a BlueROCKER which is a solid AFO (see figure: 7.1). The AFO is made out of carbon-fiber and has a slim profile around the foot. The AFO is lightweight, compact and fits inside a shoe with relative ease. The big drawback of this design is the lack of an unlock mechanism. The participant has a slightly reduced ability to walk. He can push 15 kg per leg using his calf muscles. This means that daily activities are possible without an AFO, but for walking distances, walking is more pleasant and less fatiguing when wearing an AFO. After hands-on experience with the newly designed AFO-mechanism, the following observations were made.

First of all, the addition of an alignment mechanism, was not a useful addition according to the user. The alignment mechanism takes up additional space, and is not something the participant would use. Alignment is only useful when wearing different soled shoes, but this is not the case for this specific user. The unlocking mechanism on the other hand, was a welcome addition. The operation of the mechanism could use some work to make it run smoother, but the overall locking mechanism looked promising. The range of motion seemed sufficient on first impression, but this can only be validated when fitting the mechanism inside an AFO. When it comes to size and weight, the mechanism is still too big. The size is acceptable compared to other hinged AFO mechanisms, but compared to the BlueROCKER, the differences are significant. The BlueROCKER is shaped around the ankle joint, and this is a big advantage. Some suggestions were given to further improve the design. First of all, the operation of the locking mechanism can be placed higher on the shank. This makes it easier to unlock the mechanism from a standing position. Additionally, it can be interesting to look for a way to integrate the mechanism in the design of the BlueROCKER. This is a challenge, since the hinge of the mechanism can not be placed at the ankle joint. And lastly, fit the mechanism inside an AFO, to further evaluate the user experience.

Figure 7.1: The slim and lightweight design of the BlueROCKER AFO [27]. The connection between the footplate and shank goes around the ankle joint and does not protrude.

7.2.2 Manufacturer of Orthotic Components

In addition to the feedback of an AFO user, a different perspective was obtained by interviewing a manufacturer of orthotic components. The key points of the first meeting (see chapter 2), were as follows. First of all, not everyone can afford the range of motion that an unlocked AFO hinge provides. Secondly, an alignment adjustment mechanism could be a useful addition to accommodate different types of shoes. Lastly, a robust mechanism is required that can withstand high loads and is dirt resistant.

During the second meeting, the prototype was presented and discussed. The manufacturer of orthotic components made the following remarks.

Regarding size, the mechanism is comparable to other mechanisms on the market. However, a smaller design would always be better. The prototype looked rigid enough at first sight, but taking a closer look there was some concern about the tiny gear teeth. There was doubt if the mechanism would be strong enough, since the gear teeth seemed fragile.

Operation of the mechanism is easy for healthy people, although it could be hard to adjust for someone with an impaired hand-eye coordination. For further improvement of the mechanism, the division of range of motion in dorsiflexion and plantarflexion direction should be changed. An ankle joint can normally preform a lot more plantarflexion compared to dorsiflexion. In addition, the range of motion of the unlocked mechanism does not seem sufficient to comfortably walk stairs or ride a bike. The developed prototype provides a different view on an AFO hinge. Both the unlocking mechanism and the alignment mechanism can have added value if the prototype is further developed.

Chapter 8

Discussion

8.1 AFO Hinge Performance

When looking at the specifications which were set at the beginning of this study, most specifications are either fulfilled or very close to being fulfilled. This gives confidence that with some further improvements in the design, the mechanism is able to satisfy all specifications.

The grips to adjust the mechanisms, could use some improvement. They protrude from the mechanism and are not comfortable to grip. When it comes to operating the mechanisms, the adjustment of the alignment mechanism worked properly. After some practice, it was easy to adjust the mechanism to a certain position or unlock the hinge.

When the alignment mechanism is locked, there is a little bit of play left in the grip. The grip can shake loose during use and this could result in unwanted unlocking of the alignment gear.

When looking at the strength of the mechanism, the load test provided useful insights. The mechanism was able to withstand the load of 120 Nm, but during the 'pull to failure' test, the weak spots of the mechanism showed. The mechanism was prone to torsion. Both the housing and the upper bar showed deformation due to torsion. Furthermore, the gear failed on two of the three teeth and broke free from the housing. Both the pull-out gear and ring gear could benefit from some design improvements.

The overall performance of the mechanism looks promising. With some minor adjustments, shortcomings of the current prototype can be eliminated.

8.2 Study Limitations

First of all, the mechanism is designed without a clear safety margin. The used ankle torque was derived from a research that measured a maximum ankle torque of 1.3 Nm/kg body-weight during gait (see chapter 2). To be on the safer side, 1.5 Nm/kg was used in this study. However, there were no safety factors added to the mechanism. Higher impacts that may arise from stumbling or running with an AFO could brake the mechanism.

Secondly, using a 3D-printer has its flaws. It is a great way to quickly produce a prototype, but this production technique lacks refinement. Designing for 3D-printing, is making compromises in the design.

Lastly, there is a lack of human experience in the evaluation section. In this study, the mechanism was validated by an AFO-user and manufacturer who had hands-on experience with the prototype. However, to get a much more accurate experience of the AFO hinge mechanism, the prototype needs to be fitted in an AFO.

8.3 Future Research

This study showed the design and fabrication of a versatile and easy to use AFO hinge mechanism. The following improvements can be made to the current design:

- Reduce play in alignment mechanism.
- Change angular range distribution between plantar- and dorsiflexion.
- Add marks to be able to read the alignment angle.
- Improve the shape of the grips.
- Improve design to better withstand torsion

In addition to improving the prototype, fitting it in an actual AFO will further validate the design. Also there is a different topic that can be investigated. As the AFO-user stated there is a desire for a BlueROCKER AFO with an unlocking mechanism.

Chapter 9

Conclusion

This study showed the design, fabrication and evaluation of an easy to use and versatile AFO hinge mechanism. AFOs are primarily made for walking, but there is a strong desire to adapt the AFO for different situations. The design described in this study has achieved this using two different mechanisms. First of all, a pull-out gear allows the user to quickly adjust the alignment of the AFO. This is a useful addition when for example changing shoes. Secondly, an unlocking mechanism is added in the shape of a rotating wedge. When unlocked, the AFO user has angular freedom in the ankle joint to make climbing stairs, cycling and similar tasks easier to perform. Additionally these mechanisms can both be operated with one single hand and no tools are required. It needs to be said that the prototype designed in this study is not suitable for every AFO-user, as not everyone can afford the angular freedom of an unlocked mechanism. The final prototype was assembled from 3D printed steel parts and laser cut sheet material. The prototype is fully functional and the load test showed that the mechanism should be able to withstand the forces applied by the human body during use.

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