ACTIVE CYCLING ORTHOSIS

MASTER THESIS

DESIGN OF AN ASSISTIVE CYCLING ANKLE-FOOT ORTHOSIS FOR CHARCOT-MARIE-TOOTH PATIENTS

SUBMITTED BY
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THIS GRADUATION PROJECT IS FOR THOSE
WHO CARE ABOUT THEIR BODY,
BUT IN WHICH THEIR BODY
IS FAILING TO CARE FOR THEIR MOBILITY.

- PATRICK RAEDTS

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Lastly, I like to share a few words appointed to my family and friends. As this graduation project is the closing of my study carriere. In which I have met many visionary people and was challenged with some very interesting design assignments, of which this last graduation project was the most provocative.

This topic however and the assignment were inseparably connected with Rachèl and her lovely family, because shortly after I started to study at the University (of Twente) I met her. Unfortunately, over the course of this graduation project, Rachèl and I had to make some difficult decisions, that was heavily affecting my state of mind for a while. Although, I'm very grateful for all the love and support that I got from everybody who helpt me through some harsh times within this most difficult period of my life up until now. Knowing this, I especially like to thank Zoltán and Ernest for their understanding and patients during this peroid.

This master thesis report constitutes a (medical) product design project which is about the design of an active cycling ankle-foot orthosis (AFO) for Charcot-Marie-Tooth (CMT) patients' with muscle atrophy in the lower leg (I.e. CMT; neuro-muscular disease). The muscle deterioration caused by the CMT disease comes with several functional limitations. One of which is the lack of muscle strength to perform plantar and dorsal flexion of the foot (I.e. lifting and lowering of the toes).

Currently, passive AFO's are prescribed by clinicians to restrict the ankle joint movement to overcome foot drop, foot slap, toe-off and other conditions to conserve walking. Because there are no effective treatments to slow down the CMT disease, passive AFO's are useful and provide a simple and wearable solution for CMT patients. However, it can be stated that the development of passive AFO's has come to an ultimatum in which commonly found problems are related to comfort, functionality, usability (e.g. shoe compatibility), durability and aesthetics.

For active AFO's the challenges are different, the functional benefits of active AFO's are recognized. However, the deployment of an affordable, lightweight, comfortable, and compact solution remains necessary. AFO's for walking need to withstand average torques around the ankle joint in the order of 100 Nm, with an average maximum torque of 130 Nm during plantar flexion. Therefore, the general consensus is, that active AFO's are still too bulky, expensive and power intensive to be practical for commercial usage and only exist in laboratory settings.

For CMT patients, supportive treatment is offered based on therapeutic exercises and surgical corrections of skeletal (foot) deformities (Hoyle et al., 2016). Although, according to Tidy (2014), patients should be managed by a multidisciplinary team which has experience with this disorder. Within the user-analysis phase of the project, interviews are executed with important users within the rehabilitative pathway of the patient. User attributes and their role in the rehabilitation process are elucidated and it was recognized that AFO usage is absent within the current trajectory of therapeutic exercise and in the assessment of disease progression. Therefore, the aim of the ACO is to enhance the involvement of the physical therapist and rehabilitation doctors by introducing an innovative completion to the rehabilitative treatment program whereby the progression of the disease can be closely monitored (quantitatively) so that changes in direct and perceived mobility can be managed.

Cycling can be seen as a suitable rehabilitation therapy for the employment of a future ACO. The symbiosis between bike and human functioning can be carefully monitored, which is less difficult compared to conventional AFO's for walking. Also, from a technological perspective, the cycling activity

EXECUTIVE SUMMARY

is showing great technological advantages. The research was showing that the required ankle torque for cycling (around 50 Nm) is approximately two to three times lower compared to walking (around 130 Nm) with similar physical effort (i.e. power). Inherently, this implies that power requirements are lowered, which is a key attribute for robustness and compactness for a future Active Cycling Orthosis (ACO).

When adequate knowledge of user characteristics, AFO design characteristics and the cycling characteristics was obtained. A user test was carried out with a CMT patient and a healthy participant to investigate the design challenges in practice. During the user test abnormal ankle joint angles were measured. This resulted in the design goal to retain muscles function of the lower limb by assisting in both plantar- as dorsal- flexor torque of the ankle joint by means of a double-acting pneumatic actuator. Four design solutions were presented with the common goal to mimic the plantarflexor and dorsalflexor motion of the ankle joint of a healthy cyclist throughout a full pedal cycle. Several alternative positions for the artificial joint are allocated and reflected on the dynamic behaviour of the lower leg. In parallel with the creation of design concepts a demonstrator was built to demonstrate a simplified working principle for plantar- and dorsalflexion of the ankle. The demonstrator revealed adequate challenges for sensor data reception for control and sensor placement.

The process of embodiment design stood in the context of achieving the simplest technological architecture in the preparation for building a proof-of-principle prototype. An industrial design was proposed in which optimal force range application was reviewed for assistive ankle joint torque and operational speed requirements. This industrial design constitutes a single operational (i.e. left or right orthosis without intercommunication) stand-alone cycling orthosis which could be mounted on any standardized crank-arm of an ergometer bike.

Although, after evaluating the industrial design on its manufacturability with the available resources and the compatibility of the design for a proof-of-principle prototype testing. The importance of a design modification step was acknowledged. With the reviewed criteria a simplified design was developed with integrated mechanical components, electronic components, and pneumatic components. During a proof-of-concept testing exercise with a CMT patient it was justified that the functionality of the envisioned ACO is proven. The prototype showed the potential to yield the proposed working principle of the ACO by providing assistance torque while performing a full pedal cycle. This statement is corroborated by examination of the measurements as well as the verbal feedback of the CMT patient while he was executing the cycling exercises.

PRE-PHASE

ANALYSIS PHASE I

CONCEPT PHASE II

EMBODIMENT PHASE III

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- MEGAN GIGLIA, RIO 2016 PARALYMPIC CHAMPION.

PRE-PHASE 1

For people who are experiencing difficulties during physical activity in daily life or during sports. (Neuro-)muscular diseases or other types of conditions cannot be the reason for this suffering, in a time where state-of-the-art technologies are at hand.

One can find true passion to spend ages on a bicycle, and,
One can find joy of being physically active for as long as he/she can.

Just as for Megan Giglia there are design solutions that break barriers, and create the possibilities to win gold during the Paralympic Games in Rio 2016 with a custom-made ankle-foot orthosis.

1.1 INTRODUCTION

Charcot-Marie-Tooth (CMT) patients with muscle degradation in the lower limb are currently supported by clumsy ankle-foot orthoses (AFO's) or exoskeleton systems (Ramdharry et al, 2012). AFO's are externally applied devices that encompass the joints about the ankle and foot. By modifying the structure and function of the neuromuscular and skeletal system. They are used to manage mobility disabilities caused by a wide range of conditions (McMonagle et al, 2016).

AFO's are making it possible for CMT patients to participate in a variety of daily activities. However, conventional 'passive' AFO's generally limit ankle joint motion resulting in limited dorsi/plantarflexor torque and inversion/eversion rotational torque of the ankle joint. Inherently, making it inconvenient and uncomfortable for patients to participate in a variety of activities (Phillips et al, 2011; Ramdharry et al, 2012).

On the other hand, active AFO's (i.e. exoskeleton systems) are more advanced devices, but usually equipped with expensive robotic equipment. Though they can be useful, they are far away from a solution that fits within the needs of CMT patients (Shorter et al, 2013). In addition, daily-wearable assistive (i.e. active) AFO's capable of providing a supplemental torque at the ankle joint are still not commercially available hence do not meet the personalized requirements of CMT patients.

The first step into solving these problems will be through the design of an assistive cycling ankle-foot orthosis, called ACO (short for; Active Cycling Orthosis).

1.2 ASSIGNMENT

English:
Design of a smart assistive cycling ankle-foot orthosis (ACO) for patients who are suffering from Charcot-Marie-Tooth (CMT) disease. The goal is to assist in torque of the ankle joint during cycling – to provide a personalized level of assistance – to stimulate accessibility of cycling and enhance rehabilitation.

The smart feature of the orthosis can be recognized by 'sensing' and 'acting' upon the available muscle function of the patient while cycling. As data will be collected about the level of activity over time. The progression of the disease can be monitored and the development of the disease can be made visible. To predict personal therapy and enhance future management of the progression of the CMT disease or other disabilities.

Dutch:
Het ontwerpen van een 'slimme' enkel-voet orthese voor HMSN-patiënten. Het doel van de slimme orthese is om de progressie van de ziekte te controleren (d.w.z. management) door middel van een fiets specifieke revalidatie toepassing, waarbij (indien nodig) passende ondersteuning kan worden geboden aan de koppelkrachten in het enkel gewricht gedurende het fietsen.

De 'slimme' eigenschap(pen) van de orthese vindt haar toepassing: in 'het herkennen van' en 'reageren op' eventuele ondersteuning van de spierfunctie. Aansluitend bestaan er mogelijkheden tot het koppelen/monitoren (i.e. IoT) van deze patiënt specifieke data aan een gepersonaliseerd advies voor revalidatie en/of behandeling (e.g. fitnesstracking). Op basis van de levensloop in de progressie van de ziekte kan er een voorspelling worden gemaakt en kan er eventueel ter preventie worden opgetreden.

1.3 PROBLEM DEFINITION

Currently, state-of-the-art active AFO's fall short in a day scale portable orthoses (McMonagle et al., 2015). The core challenges to overcome to these shortcomings for rehabilitation. According to Shorter et al. (2013) the solution is a compact orthotic device featuring efficient electronical components and control schemes that efficiently and effectively apply assistance during the functional tasks that an individual may be expected to encounter on a daily basis. These challenges imply that for active AFO's, the design, but mostly, technologies are causing the delay for commercially available active AFO's.

Clinicians report problems with acceptance and use of AFO's amongst people with CMT (Ramdharry et al, 2012). A discrepancy between recommended use and actual use can be seen among CMT patients. This was thought to be due to pain and patient reluctance to wear the orthotic devices. McMonagle et al (2016) reported that compliance in using AFO's is as low as 20% for patients with CMT disease. They noted that people choose not to wear their orthoses, because it highlighted their disability and caused discomfort. Nevertheless, people who do use their AFO as recommended, are reporting less impairment, lower activity limitations and lower participation restrictions (Bakker et al, 1997; McMonagle et al, 2016).

Rehabilitation is the key to limit the progression of the disease (Kenis-Coskun & Matthews, 2016). Different rehabilitative approaches have been used for treatening CMT. There is evidence that mild to moderate exercise is effective and safe for patients with CMT and leads to a significant improvement in walking ability and lower-limb strength. Intervention aimed at improving posture and balance is also considered to be useful (Pareyson & Marchesi, 2009).

Furthermore, rehabilitation and therapeutic management requires a multidisciplinary approach, with a close collaboration between the neurologist, physical therapists and other professional figures (Pareyson & Marchesi, 2009). This is indicating that for a successful implementation of a future assistive (i.e. active) AFO for rehabilitation the design needs to be in accordance with current therapeutic protocols and rehabilitation programs.

"I DON'T SEE DISABILITY I SEE BAD TECHNOLOGY."

- Hugh Herr, Bionic Man

1.4 VISION

English:

It is commonly known for active AFO's that they are bulky and do not meet the requirements of the wearer. This implies a strong need for an efficient, lightweight, compact, ergonomic, elegant, cheap and reusable design solution that is in accordance with personalized requirements of CMT patients.

As mentioned earlier, rehabilitation is key, and the progression of the CMT disease is manageable by doing exercise (Pareyson & Marchesi, 2009; Kenis-Coskun & Matthews, 2016). However, there are related concerns that the use of AFO's may lead to further loss of function – 'use it or lose it' – is a commonly known sentence among CMT patients (Phillips et al, 2011). The consensus can be made that there is a gap between how much muscle strength 'is needed' for the activity or specific movement – and 'how much muscle strength a patient 'can apply' to perform the movement or activity. Thus, on the one hand, it is desirable to make use of the human power to 'use it'. So, the patient will not 'lose it'. On the other hand, the disease can be in a stage, wherein the patient cannot provide enough muscle strength to perform the movement. Therefore, a smart situation-adaptive AFO is favourable. Wherein a well-balanced human-machine interaction can be seen (i.e. consideration between human powered and/or machine powered). Thus, A 'hybrid' AFO – which is able to assist the patient in mobility (when needed). While providing the right level of assistance of the muscle function based on the available muscle strength. For example, 60% human and 40% machine.

Analogy to this vision can be recognized in the working principle of the electric bike. As the paddling assistance can be adapted in proportion to the desired assistance during cycling. This helping hand in enables and enhances for example accessibility, preparedness and engagement in doing exercise.

Dutch:

Het is onder patiënten en orthopeden algemeen bekend dat de huidige actieve enkel-voet ortheses niet voldoen aan de eisen en wensen van de gebruikers. De eerste stap in het ontwikkelen van een efficiënte, lichte, compacte, ergonomische, elegante, betaalbare, en comfortabele enkel-voet orthese zal worden gedaan middels een actieve enkel-voet orthese voor het fietsen. Het doel hiervan is om de progressie van de ziekte te controleren gedurende een fiets specifieke revalidatie toepassing, waarbij (indien nodig) passende ondersteuning kan worden geboden aan de koppelkrachten in het enkelgewricht.

Revalidatie is de sleutel om progressie van de ziekte HMSN te beperken (Kenis-Coskun & Matthews, 2016; Pareyson & Marchesi, 2009). Echter kan er een discrepantie worden gezien tussen 'het aanbevolen gebruik' en 'het daadwerkelijke gebruik' van ortheses bij HMSN patiënten. Dit blijkt uit een weerstand om de orthopedische apparaten te dragen. Patiënten maken zich zorgen dat het gebruik van ortheses kan leiden tot additioneel functieverlies – 'if you don't use it, you will lose it' (Phillips et al, 2011). In de huidige productfamilie van orthesen wordt geen persoonsgebonden- en situatie-afhankelijke oplossing geboden, die ondersteuning bieden op basis van de 'nog aanwezige (zenuw-)spierfunctie', voor het maken van een dergelijke bewegingsuitslag in het enkel gewricht. Het stadium waarin de ziekte zich manifesteert, zou daarmee idealiter kunnen worden vertraagd door een aangepaste training die het gebruiken van de (zenuw-)spierfunctie stimuleert. De nog voorhanden spierfunctie wordt 'deels' dan wel 'volledig' ondersteund bij het maken van een bewegingsuitslag. Uitgangspunt daarbij is harmonieuze mens-machine interactie waarin bijvoorbeeld, 60% mens en 40 % machine een interactie aangaan.

Een analogie op deze visie is de trapondersteuning van een elektrische fiets. De trapfunctie ondersteund (indien nodig) en stimuleert daarbij lichamelijke inspanning en verlaagt voor een grote groep mensen de drempel om op de fiets te stappen. Ondertussen is het inzicht overigens algemeen dat deze trapondersteuning niet leidt tot degeneratie van de resterende spierfunctie maar juist een verbetering ervan. Dit zal ook voor HMSN de drempel voor acceptatie van een ondersteunende oplossing verminderen.

1.5 CHOICE ARGUMENTATION

Orthotics may be either a barrier or a facilitator to a range of activities. According McMonagle et al. (2015) there are to date no activity specific AFO's available on the market for the majority of AFO users. Nonetheless, activity specific AFO's are favorable among CMT patients.

The considerations to go for the cycling activity focusing on the main functional criteria. These criteria are generally compared to walking. Walking can be seen as a more popular choice of physical activity among researchers and AFO developers. Because walking is the most problematic activity among CMT patients in daily life. The lack of sufficient muscle strength among patients is causing a manifold of issues. For a brief explanation about muscles and muscle function consult Jenkins, 2002.

Inherently, participating alongside healthy people is difficult and is not just walking in a straight line, being physically active "as if the disease is not there", is a very complex and challenging design task that incorporates all possible motion scenario during daily life activities. However, as previously mentioned, the underlying cause for this disability is the degradation of the muscles surrounding the ankle joint. During cycling a subset of muscles are used to provide supplemental torque in the ankle joint. Furthermore, cycling is primarily targeting the anterior- and lateral compartment muscles of the tibia that are responsible for the heavy torque loads.

In addition, while cycling, toe clips can be used to limit inversion/eversion rotational torque of the ankle joint. Thus, partly fixate the foot on the pedal in the transverse plane of the body. This limits the complexity for design and will 'simplify' a few ergonomic design requirements, compared to the activities such as: walking, running, stair climbing, and among other activities, by making it possible to (only) focus the design on assistive dorsi-/plantar flexor torque of the ankle joint.

Furthermore, the cycling movement is a repeatable and continuous motion pattern that can be recognized in a cycling event which counts for numerous cycling disciplines ranging from road cycling to mountain biking.

Additionally, the bike (or parts of it) are 'connected' to the user. Creating a array of possibilities in the connectivity levels to the user. For example by a cyber-physical connection between human and machine (e.g. pedal to foot, pedal to upper limb, foot to upper limb, etcetera.) mechanical, electrical and intelligently.

Cycling is one of the main means of transportation for people all over the world, because long distance walking requires more effort. So, there are also sociocultural benefits that makes cycling one of the most popular and most functional activities. Moreover, cycling is a popular sport discipline and is therefore often used for rehabilitation purposes. One of the reasons for this is, because cycling is less invasive for the joint compared to walking due to marginally applied loads for the joints.

Finally, the extent to which research is executed on the topic of cycling is relatively low. Thus, the potential for contribution to scientific research in the field of orthotics and possibilities for innovation is more lucrative.

So, why cycling?
Compared to walking gait pattern cycling advantages are seen in:

- Exercise complexity – limited number in degrees of freedom (DOF) and the range of motion (ROM);
- Continuity of the movement – a continuous motion pattern is suitable for "recognizing" (measuring) and "assisting" (actuation) of the system;
- Cyber-physical system – human-machine interaction (bike/human)
- Suitable activity for rehabilitation – cycling exercises are less invasive for the joints and in accordance with rehabilitation applications.
- Research opportunities – less research is executed on cycling orthoses (room for innovation).

1.6 WORKING PRINCIPLE

Cyber-Physical System components

The illustration provides an overview of the main components that are integrated in the system.

The goal is to eventually compose a new rehabilitation program for CMT patient to delay the progression of the disease by assisted exercise on an ergometer.

‘Sensing’ and ‘assisting’ for desired pedalling stroke

The AFO is measuring (i.e. sensing) the existing muscle strength of the subject over time. The data will be communicated towards the AFO. In turn, the AFO will recognize (i.e. process) a gap between existing power output and desired power output. Subsequently, the AFO will assist (i.e. actively support in torque) the subject in performing a pedalling stroke.

Rehabilitation program and performance tracking

The collected data is stored and visualized in a ‘web-based’ application to track the performance of the subject. After a certain time- span a valid expectation can be made of the progression of the disease.

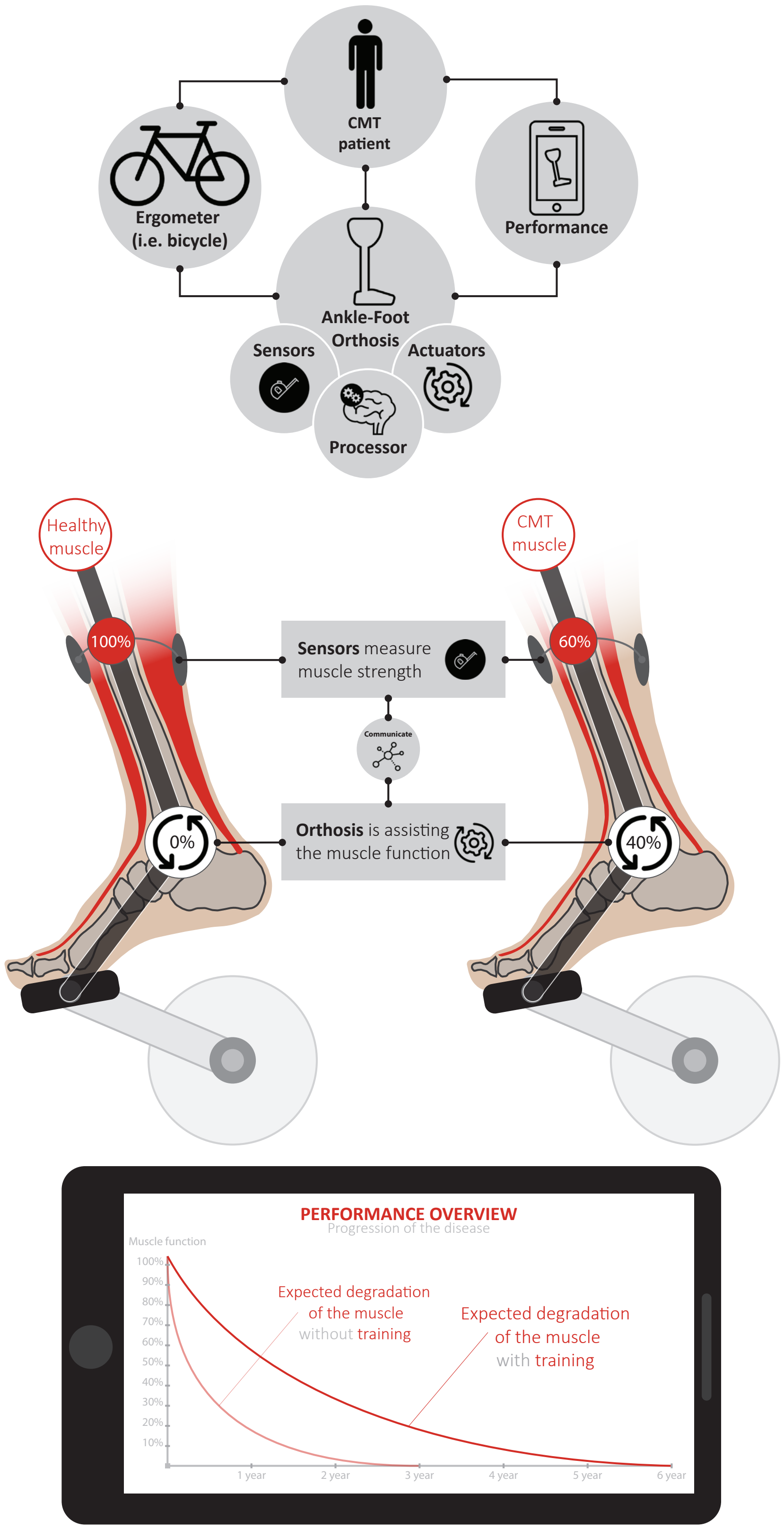


Figure 1: Illustration of the working principle for the envisioned ACO.

1.7 GOALS & CHALLENGES

A framework is needed to set goals and boundaries for the assignment to maneuver. To determine the target direction, a choice is made between different expertise areas, ranging from rehabilitation (i.e. research) to a day-to-day scale product (i.e. commercial) respectively, from a research point of view and from a commercial point of view. This definition is important to make sure it is clear what to expect and what is (not) feasible within the domain of this master graduation project.

1.7.1 GOALS: FROM A RESEARCH POINT OF VIEW

Primary research question:

- What is the effect of an assistive cycling AFO on the cycling experience of CMT patients?

Secondary research question:

- How to achieve the optimal level of assistance?
- What is the desired level of assistance?
- How to enhance the cycling experience?

Subquestions:

1. Who are the users/stakeholders?
2. What are the requirements of the users/stakeholders?
3. What are the problems/difficulties with current AFO design among users/stakeholders?
4. What are the problems/difficulties for CMT patients during daily cycling activities?
5. What are the needs for rehabilitation among users/stakeholders?
6. How to identify individual muscles?
7. How to measure individual muscle activity?
8. Is it possible to relate muscle activity to muscle volume?
9. What is the range of motion (ROM) of CMT patients during cycling?
10. What is the desired level of assistance?
11. How to derive and connect present muscle capacity with desired level of assistance?
12. How to identity different stages of the disease?
13. How to derive and connect performance to stadium of the disease?
14. How to assist the muscle towards desired values?
15. How to collect data of individual muscles?
16. How to process personalized data?
17. How do users experience additional assistance of the muscle function during cycling?

Result verification:

Verification of the applicability, effectivity and usefulness of a cycling assistive AFO, this includes:

- Applicability – do they want to use it?
- Effectivity – does it work like expected?
- Usefulness – is it functional?

1.7.2 GOALS: FROM A COMMERCIAL POINT OF VIEW

These (higher) commercial goals (1.7.2.) are included with the vision (1.4) and are only applicable when it is clarified that the AFO works as expected (out of scope for this Master Graduation Project)

Primary research question:

- What is the effect of an assistive cycling AFO on the progression of CMT disease (i.e. rehabilitation)?

Secondary research question:

- Improve walking ability by strengthening the muscles in the lower-limb through cycling exercise.
- New rehabilitation program for CMT patients or other (neuro-)muscular diseases or disabilities.
- Enhance and stimulate cycling activity/exercise for CMT patients among other (neuro-)muscular diseases or disabilities.
- Possible design configuration towards walking AFO.

ANALYSIS PHASE

USER ANALYSIS 2

Many products are designed based on designers' own preferences, abilities, and environment. However, people with mobility disabilities often have different needs. Thus, also people with CMT or people with similar conditions. Unfortunately, it is impossible to connect all the needs of all different users in one superior product. But it is important and doable to strive for the most optimal solution that meets most of the user preferences, abilities, and environment.

USER ANALYSIS 2

2.1 INTRODUCTION

Current AFO's are worn by a wider variety of people, including patients who are suffering from other (neuro-) muscular diseases. Besides people with physical disabilities, also other people are involved in the lifecycle of orthotic devices. Those people who are playing a role in the product lifecycle of AFO's have valuable contribution on current AFO designs and the envisioned ACO. The values and characteristics of (a few of) those users/stakeholders are sourced through this User Analysis (UA).

This User Analysis (UA) is investigating, 'who' are playing a role in the rehabilitation process of CMT patients, and 'what' role they play in AFO development and treatment pathway for CMT patients, the needs of those individual users and their recommendations for a future ACO.

This information is collected by means of user interviews and additional literature research to become acquainted with the product users' environment and terminology. This process is followed by analyzing the context of use to generate a user overview and research what role those users play in the context of the assignment.

This user analysis comprises the following four paragraphs:
2.2. Interviews
2.3. Users
2.4. User attributes
2.5. Conclusion

2.2 INTERVIEWS

Five different users are interviewed, that all have a separate role in the rehabilitation process, ranging from patient care till product development, namely:

2.2.1. Orthopaedic advisor at LIVIT orthopaedics
2.2.2. Rehabilitation doctor at Scheper hospital
2.2.3. Academy director EMEA at Össur orthopaedics
2.2.4. Physiotherapist at FysioPlus
2.2.5. Patient with CMT type 2

Prior to the interview an introductory one-pager (see Appendix B) was send to the interviewees per mail including a summary of the assignment and a concise description of the vision. The interviews are recorded and are conducted in a semi-structured manner (except 2.2.1. without recording).

During the interviews a variety of topics are discussed such as: questions on AFO design, AFO development, rehabilitation, patient treatment and exercises, cycling for CMT patients, among other questions. Based on these topics dedicated questions are composed and firmly discussed with the interviewee.

The recorded interviews are rewritten (i.e. transcript), which can be found in Appendix C. After which the interviews are translated into a concise description with recommendations and needs of the interviewees.

2.2.1 INTERVIEW 1: ORTHOPAEDIC ADVISOR (OA)

The interview with the orthopaedic advisor (OA) was held in an early stage of the project to verify whether the assignment was sound and interesting.

Since the OA is familiar with all the new trends regarding AFO's. The majority of the questions were about AFO design and AFO development. Thus, the purpose of this interview was to investigate the potential of the assignment, possible design directions and networking for possible interests and involvement in the project.

The OA saw potential in the assignment and noted that he was not aware of any research related to the topic that concerns a specific active cycling orthosis. Furthermore, the direction of the assignment was discussed. There were two suggestions given by the OA. Namely; (1) 'design for rehabilitation' or (2) 'design for daily use'.

Given that the direction on the project was relatively research based. It was recommended to focus the assignment on rehabilitation. Also from a needs perspective, rehabilitation was the favorable option. Because, there are additional risks involved (in terms of safety), when cycling is performed with an active orthosis for daily use trust in electronic devices is low among patients. The cycling activity however is a suitable activity for rehabilitation wherein dynamic product features can be tailored to personal/ individual preferences.

Summary of recommendations and needs of OA:

- Focus on design for rehabilitation (rather than 'design for daily use').
- Maintain trust; for (electronic) mobility products (i.e. safety of the device).
- Personalization; tailor the dynamic characteristics/ features of the product to the personal/individual preferences.

2.2.2 INTERVIEW 2: REHABILITATION DOCTOR (RD)

The interview with the rehabilitation doctor (RD) was semi-structured and primarily focused on medical issues and the performed tasks/activities by RD. The interview was therefore subdivided into; medical background/diagnostics, patient activity, and rehabilitation & treatment.

RD's are usually not involved in the development of AFO's. The activities are generally from medical nature. According to RD the first step is taken by diagnostics of patient symptoms and supporting the 'help-question' for the patient – mostly improving activity of daily living (ADL) and participation. For this, methods such as 'the International Classification of Functioning, Disability and Health (ICF)' are used. This process is followed by providing a suitable (mostly medical) solution for the individual. This can be done by for example performing surgery or prescribing help-functions, such as AFO's and/or treatment.

RD described that (neuro-) muscular diseases with progressive loss of muscle function is a complex problem. Since mobility issues often go hand in hand with psychological, sociological and communicative consequences. Not to be forgotten – physical inactivity impedes rehabilitation and is a major health concern. Resulting in for example overweight and cardiovascular issues.

Nonetheless, RD argues that usability of current AFO design is limited and there are very little alternatives for this target group. Thus, to date AFO's and bracings are the most suitable solution to overcome mobility issues. He encourages to increase mobility (i.e. usability and functionality) and stimulate physical activity – to decrease muscle degradation and physical inactivity.

Summary of recommendations and needs of RD:

- Improve user compliance; enhance engagement and utility.
- Orthosis personalization and adjustability.
- Improve ADL and Participation.
- Visual communication of results – convincing and understanding among users.
- Conformation and recognition of the urge to exercise to slow down the progression of CMT.
- Stimulate physical activity; physical inactivity increases health concerns (e.g. overweight).
- Consider widening target group – try to make the product useful for patients with similar symptoms or needs. Example, patient who have had a broken leg for a long period can perform similar rehabilitation programs to strengthen the muscles.

2.2.3 INTERVIEW 3: ORTHOPAEDIC EXPERT (OE)

The Academy Director EMEA (considered orthopaedic expert; OE) at Össur in Eindhoven, intermediaries between R&D and Sales department. With a background in physiotherapy and mobility sciences. OE was a valuable candidate for sharing knowledge on the topics concerning the medical limitations of the patient, orthotic development, a future cycling orthosis, and users and other stakeholders.

According to OE the company Össur (orthotic design company) generally considers two product categories (i.e. Osteoarthritis solutions and injury solutions). Their passive AFO's are covered by the injury solutions segment. He however confirmed a strong demand for neurovascular (or neuromuscular) solutions, in which the ACO would be a suitable additive by the potential active characteristics. Nevertheless, OE highlighted that the magnitude of the target group population is relatively small and results in a lack of attention and reimbursement difficulties.

Currently, the common goal for both prosthetic and orthotic designs, is conserving a "normal" walking gait pattern. Even though walking is not the main activity for this assignment it can still be achieved says OE. Concerning the envisioned ACO. If the orthosis is capable of targeting adequate muscles, adaptable to loss of volume of the muscle and is providing comfortable biomechanical support, it is expected to improve 'direct' and 'perceived' mobility. Thus, 'Quality of life (QL)', 'Activity of Daily Living (ADL)' and compliance to use it, of which, improving/conserve mobility/muscle function should be the main objective.

Nevertheless, acceptance of ACO in the rehabilitation context is also depended on other users. Thus, it is essential that the ACO fits within the contemporary work routine of the people who are going to utilize the ACO. So, the ACO should be an additive in their current treatment program.

Summary of recommendations and needs of OE:

- ACO is suitable for (neuro-) muscular and vascular solutions
- Improve direct mobility of the user; functional.
- Improve perceived mobility for the user; quantitative versus qualitative data.
- Improve compliance to use it – quality; does it work like it should, and comfort; ease of use and experience of wearing it.
- Integrate ACO in current treatment programs/ processes.

2.2.4 INTERVIEW 4: PHYSIOTHERAPIST (PT)

The main topics that are discussed with the physiotherapist (i.e. physical therapist; PT) are questions on treatment and exercise. Wherein the therapeutic approach and the corresponding physical ability of the patient were dominant.

The PT is one of the main contact persons for CMT patients. CMT patients are visiting the PT generally between one to three times a week and undergo a variety of training and mobilizing exercises.

According to PT the main goal of the PT is conservation of function. For people with neuromuscular diseases the general approach is: to first look at what they still can and cannot do (i.e. baseline), then search for a smart and responsible therapy to conserve function.

A typical treatment for CMT patients is mobilization of the joint and strength training exercises with low to moderate intensity. For mobilization a variety of exercises are available of which cycling is frequently performed. An example of a rather intuitive (current) treatment approach goes as follows: based on this previously determined baseline (reference point) achievements in joint mobility are examined. The effectiveness of therapy can be validated by examining a possible increase or decrease in joint ROM. This increase or decrease in ROM is visible for both parties and therefor previous therapy is perceived as effective. According to PT the ACO should follow a similar working principle. For both, acceptance and work routine purposes.

According to PT, cycling is an exceptionally suitable physical activity. Because, on the one hand, it mobilizes the joint and on the other hand, it strengthens the muscles with minimal impact loads on the joints. Therefore, almost all people with (neuro-) muscular diseases are able to perform these exercises even when their medical condition is severe (e.g. MS patients).

Moreover, the PT suggests using artificial intelligence to track and identify changes in abnormal physical behaviour such as spasms, or use artificial intelligence to stimulate nerve activity.
Furthermore, PT is not acquainted with disease classification/stages (e.g. labelling severity of condition) within the different types of CMT. However, he does see possibilities to detect certain stages regarding degradation of different muscle groups that can be connected to certain immobilies. Nerve stimulation for instance, can be a technique to capture morbidity. Another interesting feature of the ACO could be to implement artificial intelligence in order to recognize and act upon spasms.

Summary of recommendations and needs of PT:

- Typical treatment goal is conservation of function, rather than improve function.
- Visibility of effectiveness (transparency) – acceptance.
- Integration with current exercise equipment and work routine.
- Recommended artificial intelligence: recognize and act upon spasm.
- Recommended additional features: nerve stimulation.

2.2.5 INTERVIEW 5: CMT PATIENT (P)

The interview with P comprises topics regarding treatment, mobility, orthosis design, and cycling ability. The previous experiences and life history of P provided insight in the physical capabilities of the user, user needs, and AFO design flaws. P mentioned characteristics of the target audience that are exceptionally useful for a user-centered design approach.

P was diagnosed with CMT type 2 at the age of 42 (approx. 12 years ago) after which AFO's were prescribed directly. He chose not to wear them initially due to endurable aesthetics. Thereafter an alternative treatment was proposed namely to surgically fixate the ankle joint that he declined. After 2 or 3 years his disability forced him to wear AFO's because of the inability of making short walks without the orthosis (or holding on to an object). Within 10 years he had worn a wide variety of custom-made AFO's with different materials, ranging from hard plastics to carbon fibre. According to P the most suitable AFO in terms of functionality (i.e. stiffness) are custom made carbon fibre AFO's, such as the pair he is wearing nowadays (see fig. 2).

The general complaints of P are related to comfort (e.g. fit), quality (e.g. durability) and aesthetics (e.g. appearance). Over the course of time the disease became more severe and he experienced increasing physical restrictions. P is going to the PT once every week for treatment (without AFO). At the PT strength training exercises and mobilization of the joint is performed. After approximately 4 years, strength training was not possible anymore. To date, P is capable of performing mobilization exercises among which is cycling. In addition, P also

Figure 2: Custom-made carbon ankle-foot orthosis of the CMT patient (worn for half a year)

mentioned that he prefers cycling over walking in daily life. Because cycling is less painful, exhausting and slow. However, it can be difficult for him during acceleration and stay in-balance while stopping (e.g. for traffic lights). During race cycling he is constantly on guard for possible danger, because he is not able to respond quickly.

Summary of recommendations and needs of P:
- Improve comfort (e.g. fit), quality (e.g. durability) and aesthetics (e.g. appearance).
- Scenario recognition; e.g. difficulties during acceleration phase and stopping phase.
- Regain confidence during cycling activity; risk assessment of falling.

2.2.6 EVALUATION

The statement can be made that all interviewees see potential in the envisioned ACO. However, as expected there are different needs and recommendations for further development among each other.

According to the RD and OE the ACO is suitable for a wider audience seen the versatility of the proposed working principle for the CMT disease. They suggested integration of the ACO in a more general rehabilitation program for users with similar needs ranging from patients with a broken leg (long term) to patients' with multiples sclerosis (MS). Nevertheless, the aim of this graduation project will remain a design for people with CMT.

Furthermore, the interviewees noted that the implementation of an ACO should meet the contemporary work routine of the users. A seamless transition within the current rehabilitation therapy is preferred for acceptance of both parties – patients' and professional figures.

According to the OA electronically assisted orthotics need special attention for trust issues. Additionally, the CMT patient mentioned that he is constantly on guard and tries to maintain stability especially during cycling. As for the CMT patient, the experienced assistance (i.e. fit and functional assistance) with corresponding (appealing) design are valuable needs. To achieve this, a design solution needs to be sought for wherein comfort (e.g. fit), quality (e.g. ease of use) and aesthetics (e.g. appearance) are in-balance.

In addition, the RD and OE are both highlighting the importance of quality and comfort – the ACO needs to 'adapt' to user attributes and 'assist' user immobility. They noted the importance of functional design adjustability and personalization. Because, functionality and usability are key for usage compliance this lack of versatility in todays' AFO's is seen as a barrier for patients to wear the orthoses.

Furthermore, it can be concluded that a suitable ACO for rehabilitation needs to conserve/improve 'direct' and 'perceived' mobility. The users recognize the urge to stimulate mobilization of the ankle joint muscles by doing therapeutic exercise. However, to date, patients perceive little difference by following current therapy. Thus, in terms of acceptance. Utility of the ACO needs to be clear. One way of doing this, is by show effectiveness of the therapy. Whereby, achieved physical performances can be made visible for all parties.

However, according to OE improved 'direct' mobility is a must, and should not be confused with design for physical inactivity (related to for example risk of overweight, diabetes, cardiovascular issues). According to the OE, design for physical inactivity is an inaccurate consideration for a business case (i.e. different financial pocket). Because insurer companies are not interested in other issues that are related to immobility and can improve quality of life. The origin and intended purpose of current AFO's are to improve mobility. Consequently, insurers will only fund the ACO (i.e. AFO's in general) if they are supporting (perceived and direct) mobility issues. Whereas the RD justly argues that from a medical point of view, 'physical inactivity' and 'disability' often go hand-in-hand and is causing a downwards spiral for rehabilitation. Thus, to conclude, the main focus is on mobility, with a wink to stimulate physical activity (i.e. prevent physical inactivity).

2.3 USERS

Interviews with five different users (see Ch. 2.2) are collected and provide a clear understanding of the most important figures within the lifecycle of conventional AFO's, that of the envisioned ACO and their possible role in the treatment process. Those figures are merged and visualized in a user overview (see fig. 3).As previously mentioned, it is important to consider the current work routine of the users and their direct surrounding, in order to understand the context of use.

The interviewees were asked to describe the general activities they perform with respect to the (physical) rehabilitation pathway of CMT patients. The mental health specialists (i.e. psychologist/psychiatrist) are out of consideration. Even though CMT often accompanies psychological evaluation and treatment of anxiety, depression, and other psychosocial consequences (McCorquodale et al, 2016). Based on their answers, it can be stated that the most important figures are the physical therapists (PT) – e.g. physiotherapists and occupational therapists, orthopaedic advisors (OA) and rehabilitation doctors (RD) for conventional AFO's.

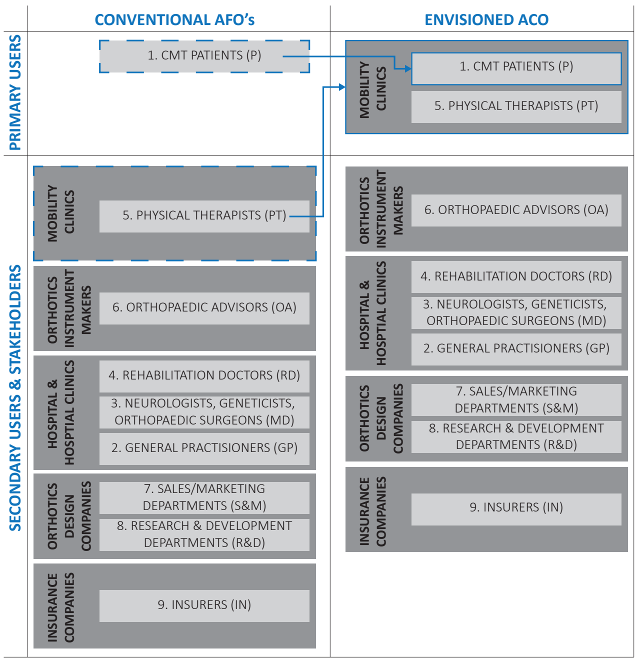


Figure 3: User overview; shows the primary, secondary users and stakeholders within the conventional AFO lifecycle (left column). Potentially PT becomes a primary user and their user environment (i.e. mobility clinic or similar) changes the lifecycle of the ACO (right column).

However, in terms of contact hours, involvement differs greatly among those figures. The RD is usually employed at the hospital or rehabilitation centre and is therefore an expensive figure that is mostly consulted during the early stage of rehabilitation and for AFO prescription. PT on the other hand, is consulted between one to three times a week for private coaching in a mobility clinic and has an important role in the creation and execution of a rehabilitative program. Besides, OA are exclusively consulted for orthopaedic applications – that concern allocation and enhancement for AFO usage.

Furthermore, it is important to note that traditional AFO's are not intended for rehabilitation and are in essence not contributing to conserve nor improve (nerve-) muscle functioning. AFO's are devices that assist during locomotion in daily-life to cope with the disability. Since the ACO is intended for rehabilitation and therefore will be positioned inside the environment of rehabilitation physicians. The active participation and/or interest of certain rehabilitation physicians in the envisioned ACO is enhanced. Therefore, ACO features need to spring from the needs and values of those who will mostly interact with the product.

When looking at the user overview (see fig. 3), the first column shows the involvement of users for current/traditional AFO's, and the right column shows the changed involvement of users for the envisioned ACO. A displacement can be observed regarding the physical therapists. The main reason for this, is because traditional AFO usage is currently not linked with rehabilitation therapy. Movement scientists (including rehabilitation doctor, physical therapists, and among others) are composing treatment programs/rehabilitation therapy for the patients based on their medical disability without AFO involvement. Respectively, considering the possible consequences of daily worn AFO's on the rehabilitation of the patient.

The envisioned ACO is part of the rehabilitation process. Therefore, movement scientists will probably interact with the ACO relatively more often (e.g. during therapy supervision) and are therefore seen as primary users. The other parties, constitute the secondary user group and other figures that are involved regarding development and funding.

A concise patient journey is created (see fig. 4) to provide insight in the different levels of user involvement (i.e. ready, supervision and employed) within five different stages (i.e. diagnosis, rehabilitation therapy, pre-use AFO, during-use AFO and AFO revision) of the treatment pathway of the patient. The most important figures are chronologically listed from the composed operational sequence diagram (see fig. 5). The parties 7 (R&D), 8 (S&M) and 9 (IN) are withdrawn from the patient journey, because there is relatively no involvement from a patient point of view. The operational sequence diagram represents an abstract decomposition of workflow among users, and captures the sequence of subtasks as they are performed by those figures. The operational sequence diagram is created to graphically illustrate the positioning of those figures, their mutual relations, and their relationship with AFO's.

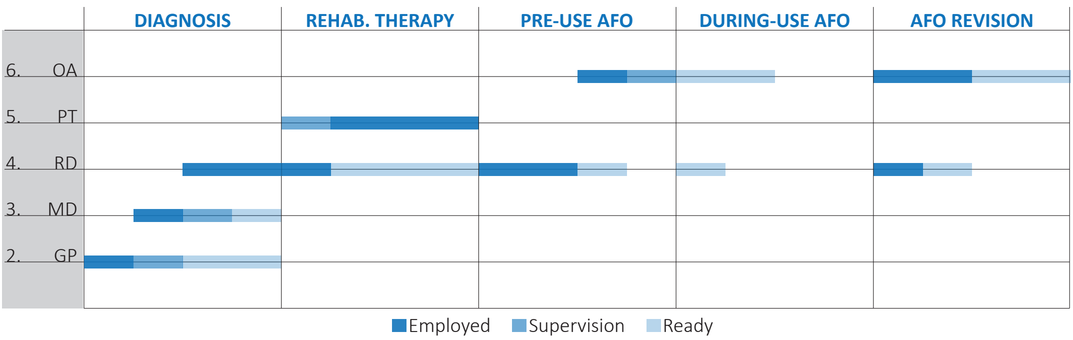


Figure 4: Patient journey concerning conventional AFO's; current employement of selected users in the treatment pathway of CMT patients'

2.4 USER ATTRIBUTES

Usually it is important to create a complete description of the potential user population, this includes characteristics such as age, gender, education level, physical size, physical ability (or disabilities), familiarity with the type of product, and task-relevant skills (Wickens et al, 2004). Since the user population is relatively big. As previously mentioned (in Ch. 2.3.) the contact hours with the patient differs greatly. Therefore, only a complete description of the most important figures in the rehabilitation process is composed (see appendix D). Thus, only the user attributes of CMT patients, rehabilitation doctors (RD), physical therapists (PT) and orthopaedic advisors/specialists (OA) are adopted for the envisioned ACO.

The user attributes are showing that task-relevant skills of the RD and PT are different. Both could be employed in a rehabilitation centre. However, the active working environment of the RD is generally the hospital and the PT usually works at a mobility clinic. Because, the ACO will enhance the

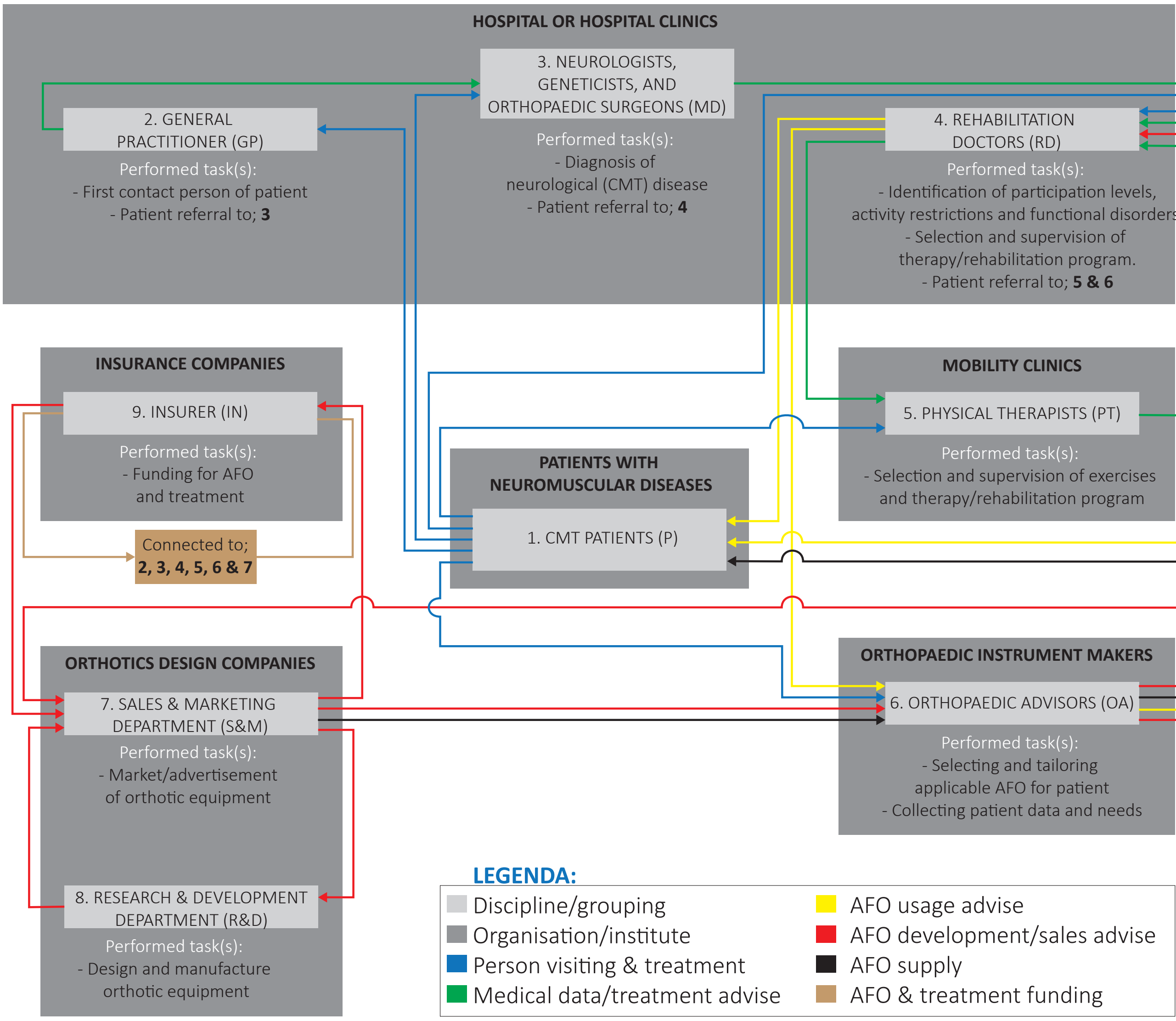


Figure 5: Operational sequence diagram; illustrates the position and workflow of users in the rehabilitative environment of CMT patients and the presence of traditional AFO within this environment.

involvement of PT it is presumable that the ACO will be implemented in a gym-like environment for rehabilitation (i.e. mobility clinic or rehabilitation centre).

The operational sequence diagram (see fig. 5) is showing a distinction between two main users groups, one of which is primarily focusing on the medical condition of the disability, and is primary dealing with the treatment and rehabilitation of the patient. The other main user group is more product oriented and specialised in AFO development and usage. Moreover, the corresponding task-relevant skills within treatment/rehabilitation are dominant for GP, DM, RD and PT. Among which the RD is creating the link between treatment and AFO developers. The first contact point of the RD is the OA, who possess the (technical) knowledge and expertise for tailoring the AFO onto the specific demands of the wearer. When there are sufficient grounds for AFO prescription, the RD refers to the OA. After which a suitable solution is being searched for. From this point onwards, the OA is basically the main contact person for the patient if any issues or dissatisfaction with AFO usage arises.

2.5 CONCLUSION

Currently there are no effective treatments to slow down the CMT disease. Supportive treatment is offered based on therapeutic exercises and surgical corrections of skeletal (foot) deformities (Hoyle et al., 2016). Patients should be managed by a multidisciplinary team which has experience with the disorder (Tidy, 2014). Standardized clinical instruments to assess disease progression and disability, and increasing recognition of patient-reported factors will probably make improvements to CMT patients' QoL (McCorquodale et al., 2016)

Within this user analysis, interviews are executed with important users within the rehabilitative pathway of the patient. User attributes and their role in the rehabilitation process is elucidated. It is seen that AFO usage is absent in the current trajectory of therapeutic exercise concerning assessment of disease progression. Therefore, a striking change is put forward compared with the current situation for user- and AFO (i.e. envisioned ACO) involvement.

Nowadays the physical therapist is the main contact person for the patient within management of CMT. The medical condition/disability of the patient is extensively diagnosed by multiple users along the process and forms the basis for AFO prescription as well as prescribed rehabilitation therapy. However, both are still regarded separately and should be seen complementary. AFO usage is subordinate, although AFO usage and rehabilitation therapy need to go hand-in-hand. Because AFO usage is effecting mobility and progression in multiple ways. The ACO will enhance the involvement of the physical therapist, whereby the progression of the disease can be closely monitored (quantitatively) so that changes in direct and perceived mobility can be managed.

Moreover, active AFO's (i.e. active exoskeletal systems) are not without risk. Trust issues cannot be neglected. A healthy physical therapist who is supervising during rehabilitation therapy could take away this first lack of trust and enhance acceptance on both sides. Since the ACO comprises features in the context of robotic assistance. The design should be handled with caution, so that the perceived experience in terms of comfort and quality can be predominant.

PRODUCT ANALYSIS 3

Orthotics known as ankle-foot orthoses (AFO) are relatively commonly used among all sorts of physical sequelae. Even though the CMT disease is a relatively unheard. It is seen in 1 in 2.500 patients (Kenis-Coskun & Matthews, 2016). There are numerous of products developed in the past to deal with CMT or similar conditions. Even though AFO's are usually designated for the walking activity. It is wise to learn from the already existing designed solutions and design mistakes for improvement of the ACO.

3.1 INTRODUCTION

Ankle-foot orthoses (AFO's) are commonly prescribed by clinicians to overcome foot drop, foot slap, toe-off and other conditions to conserve walking. Apart from CMT there are numerous of other physical sequelae in the rehabilitation world wherefore AFO's are useful. Such as stroke, Post-Polio Syndrome, Muscular Dystrophy, Spinal Cord Injuries, Neuropathy, Multiple Sclerosis, Traumatic Brain Injuries, Guillian-Barre Syndrome, Myelomeningocele, Cerebral Palsy (Fakhoury & Klager, 2016). However, those conditions will not be considered within this report as for the envisioned ACO in this stage.

Before looking into existing AFO's, it is wise to first acquire some knowledge about the basic biomechanics of the ankle joint. The healthy ankle joint is dealing with a large amount of forces that are generated by the muscles in the lower limb. These forces are used for plantarflexion and dorsiflexion (see fig. 6; left), those movements are typically supported by 'passive' AFO's and actively assisted by 'active' AFO's. However also more subtle movements are carried out by the healthy ankle joint, such as inversion and eversion of the joint (see fig. 6; right) that are often neglected (or not considered) in existing AFO designs. This already says something about the difficulty to design for this complex (human) joint. Nevertheless, within this chapter the different types of AFO's (Ch. 3.2.), the AFO attributes (Ch.3.3.) and alternative solutions (Ch. 3.4.) are discussed to provide some clarity about the existing features of conventional AFO's and the current state of AFO development.

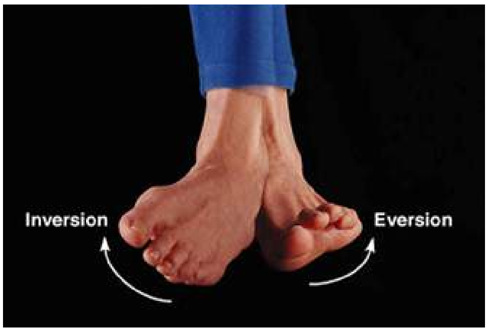


Figure 6: Ankle joint motions; (left) dorsiflexion and plantar flexion, and (right) inversion and eversion.

3.2 DIFFERENT TYPES OF AFO'S

AFO's can be divided into two categories, namely; 'passive' AFO's (Ch. 3.2.1) – coined PAFO's, and 'active' AFO's (Ch. 3.2.2) – coined AAFO's. PAFO's are subdivided in 'static' or 'dynamic' AFO's that use spring-force for motion assistance. AAFO's are equipped with electric controlled components to provide motion assistance of the ankle joint complex.

3.2.1 PASSIVE AFO'S (UNPOWERED AFO'S)

Passive AFO's contain no control or electronic devices, but they could be equipped with basic mechanical elements such as hinges, springs or dampers to support the motion of the ankle joint (see fig. 6). Commonly prescribed AFO's are: Anterior Floor Reaction AFO (FRO), Posterior Leaf Spring (PLS) AFO, University of California Biomechanics Laboratory (UCBL) AFO, patellar tendon–bearing (PTB) AFO, hinged (or articulating) AFO (HAFO).

HAFO's typically allow free motion at the ankle, to allow limited range of motion (i.e. allow dorsiflexion and stop plantarflexion, or the inverse), or to provide some assistance to dorsiflexion (Gao et al., 2011).

AFO's are generally designed in a way to allow the wearer to 'lean' into a pretibial shell or 'against' the shin bone. Furthermore, PAFO's are compared to other alternatives, mostly cheap, lightweight and relatively compact. Therefore, PAFO's are generally prescribed by clinicians for ankle joint disabilities. The decision for prescribing AFO's may come down to trade-offs between a customized PAFO or an "off the shelf" prefabricated PAFO. The advantages each confers are distinct. For example, a custom-made (i.e. molded) AFO offers the ability to create an optimal fit and provides maximum control of the limb, due to spring characteristics of carbon fibre orthoses (Bartonek et al., 2007; Wolf et al., 2007). In contrast, while mass-produced prefabricated orthoses may sacrifice quality of fit and limb control, they can be used as an evaluative tool or a short-term fix during the rehabilitation process, but are therefore in theory not a suitable solution for CMT patients seeing the progression of the disease.

The prefabricated AFO's are generally made of plastics, composites or silicon's. These orthoses are often bulky and lack durability. Because it has been shown that they decrease in stiffness and may fatigue rapidly due to cyclic loads (Lunsford et al., 1994; Dufec et al., 2014). Unfortunately, custom-made orthoses are also not there yet. Even though they are showing improved durability, control, and fit. Because, the alignment of custom-made AFO's permits effective function with minimal compression on pressure sensitive tissue. Thus, the shape and material of PAFO's are playing an important role. Inherently, custom-made AFO's are usually manufactured out of carbon fibre or kevlar reinforced plastics to cater the stiffness and thinness characteristics. Nevertheless, these composite-fibre materials tend to be fairly stiff causing fatiguing on the foot and skin breakdown due to higher peak plantar pressures (Dufek et al., 2014; Hoyle et al., 2014). Thus, can be detrimental when the wearer is using the AFO's for a long time. Factoring into the equation, how well AFO's fit in the shoes, which typically don't leave much room to manoeuvre due to space limitations presented by shoes (Daniel, 2014). Furthermore, temperature differences (outside) can play a role in the perceived comfort of AFO's (e.g. foot swell changes the shape of the foot, so different pressure points arise for custom-made AFO's).

Thus, there are important pros and cons for each type of AFO, with stiffness, material, comfort, cosmesis, cost and weight the most common factors (Fakhoury & Klager, 2016). The drawbacks are generally associated with the use of AFO's that include compliance secondary to comfort, cosmesis, and limited ankle motion. Even though these AFO's have their limitation on a functional level for the wearer (e.g., restricted range of motion during stance) they are still more popular compared to active AFO's which will be discussed in Ch. 3.2.2.

Figure 7: A selection of passive AFO's. The shape and material of which utilize energy storing properties for mild to moderate foot drop. Among which; (A) Össur's light, (B) Össur's Dynamic, (C) Ottobock's WalkOn, (D) Ottobock's WalkOn Reaction, (E) Ottobock's Thermoplastic, (F) Matrix's Curve, and (G) a custom-made 'hinged or articulating' AFO to allow for limited range of motion .

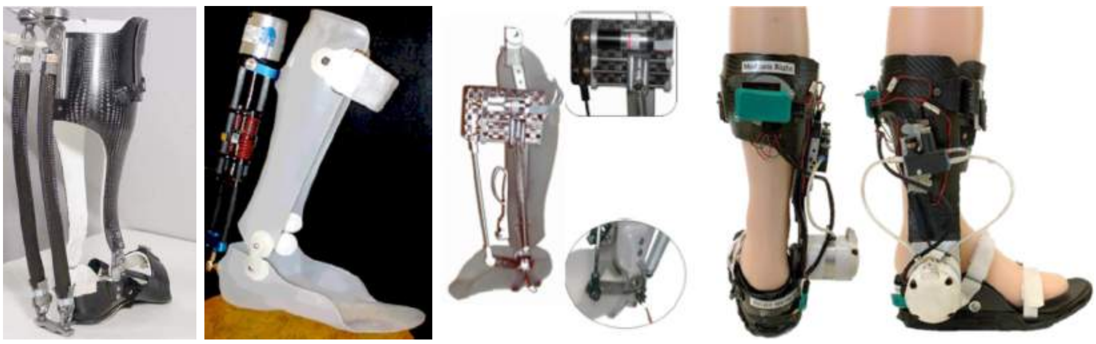
3.2.2 ACTIVE AFO'S (POWERED AFO'S)

Active Ankle Foot Orthosis (AAFO) are computer controlled (in real time) to vary compliance or damping of the ankle joint. AAFO's are equipped with an on-board or tethered power source, and usually possess one or more actuators to actively move the ankle joint. In addition, sensors and other electronic components are used to control the application of torque.

AAFO's are known for their complex technological advantages. However, these types of AFO's are currently only used for research in laboratory environments. Because the expensive applied technologies are causing the delay in commercial availability. As may be noticed, active AFO strive for full integration in daily wear, which is an extremely complex task to fulfil seeing the additional needs of the users – among which disease severity plays a role. Wherein for example, a 'compact' and 'portable' power source is needed that is well-integrated in the design. Furthermore, AAFO's need to provide high torques that are comparable to forces generated by 'healthy' subject. So, on a technological scale there are (still) a lot of challenges in terms of efficiency, compactness, weight, functionality and applicability. Nevertheless, active AFO development remains important. Since artificial assistance in locomotion is required for patients with severe immobility.
To date, promising inventions are made. A few of which are presented in figure 8 and described below, namely; AFO using artificial pneumatic muscles, AFO using series elastic actuator (Blaya, 2003), and the Insertion Point Eccentricity controlled (IPEC) AFO (Polinkovsky, 2010). A great example of an artificial pneumatic actuation AFO is developed by the Department of Movement Sciences at the University of Michigan (Gordon et al., 2009). This AAFO (see fig. 8; A) primarily assist in plantar flexor activity and according to Polinkovsky (2010) generates around 57% of peak ankle plantar flexor torque, and 70% of plantar flexor work of a healthy subject during walking. The AFO makes use of an external air source and is therefore only suitable for in-house or a lab environment. But could be valuable for 'in-office' walking gait rehabilitation.

Another AAFO was made by Blaya & Herr (2004) at Massachusetts Institute of Technology (MIT), regarding a series elastic actuator (see fig. 8; B), which comprises a motor driven lead screw in series with a spring. The position of the lead screw dictates an equilibrium position of the ankle joint. The torque resistance at the joint can be adapted by changing the equilibrium position of the lead screw. Their findings are indicating that a variable resistance AFO's may have certain clinical benefits for treatment of foot-drop compared to the conventional passive AFO's.

At last, the Insertion Point Eccentricity Controlled (IPEC) AFO is highlighted (see fig. 8; C). The IPEC AFO is part of a Hybrid Orthosis Robotic System (HORSe) project (see appendix F.) This AAFO is designed in order to delay muscle fatigue of subjects with Spinal Cord Injuries (SCI) or other paralyzing conditions.



A B C D

Figure 8: (A) Active AFO with two pneumatic artificial muscles, (B) Active AFO with series elastic actuator, (C) Insertion Point Eccentricity Controlled (IPEC) AFO, (D) Design of a compact high-torque actuation system for portable powered ankle-foot orthosis.

The IPEC is motoric driven and comprises a four-link mechanism (see Ch. 3.2.3.). Higher up the leg the slider mechanism is located that comprises the bulk mass of the AFO in order to reduce the moment of inertia, and therefore allows for minimal power application. A pivot spring is attached to the slider link and produces a torque at the ankle joint when the position of the slider is changed. That allows for both dorsi- and plantar flexion torque that will prevent toe drag during swing phase and foot slap when standing.

Nevertheless, there is to date a lot more in development, among which the portable powered ankle-foot orthosis (PPAFO) for rehabilitation that is capable of providing bidirectional-assistive torque at the ankle joint (see fig. 8; D). Figure 9 is showing multiple phases in which the PPAFO is providing assistance during walking. It was designed for untethered operation away from the confines of a lab or treadmill (Shorter et al., 2011).
Furthermore, actuation mechanics are used that are powered by magnetics, pneumatics, hydraulics and several robotic configurations, such as; a bio-inspired soft wearable robotic device for ankle-foot rehabilitation (Park et al., 2014), hydraulic AFO (Neubauer & Durfee, 2016), pneumatic power harvesting AFO (Chin et al, 2009), AFO using a magnetorheological-fluid rotary damper (Naito at all, 2009), motor-driven AFO's (Mazumder et al., 2016), and AAFO for a robotic gait rehabilitation system (Villa-Parra et al., 2015) among others.

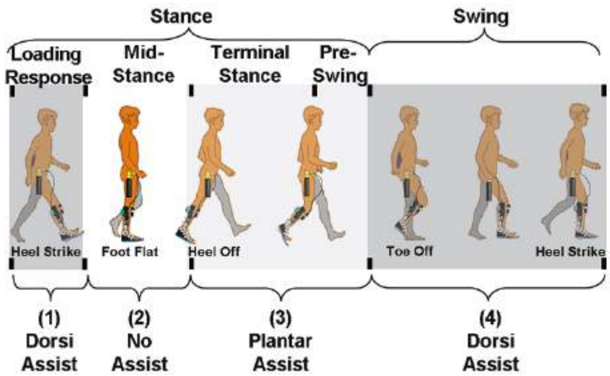


Figure 9: Multiple phases in which the PPAFO is providing assistance during walking (Shorter et al., 2011).

3.3 CHARACTERISTICS OF AFO'S

AFO's are generally prescribed for conserving a 'normal' walking gait pattern. Most active and passive AFO's aid in either dorsiflexion, plantarflexion, or both. This means that mechanical requirements of the AFO will be different among patients. Mechanically, the foot/ankle complex and the AFO are tightly coupled and interact with each other.

Furthermore, the mechanical characteristics of an AFO can be described within the sagittal plane and should support a system of forces that create a state of equilibrium (see fig. 10A). The moments that are created by these forces also relates to this equilibrium. Although a force may be considered as being applied at a single point, in clinical practice forces are usually applied over a larger area to reduce point pressure. According to Lopez (2012) a three point pressure principle is forming the mechanical basis for orthotic correction to control angular motion at the joint; a single force (F2) is placed at the area of deformity or angulation; two additional counter forces (F1 and F3) act in the opposing direction. In order to control ankle plantarflexion (or dorsalflexion) a triangle of forces should be created to maintain equilibrium (see fig. 10B). From a practical viewpoint (see fig. 10C), the force which is placed at the area of angulation (F2) should act in a diagonal direction towards the dorsum of the foot in order maintain equilibrium with F1 and F3 (Meadows et al., 2016).

During locomotion (i.e. dynamic situation) the presence of an external moment such as a ground reaction force (GRF) tends to cause motion of the joint and requires activation of an opposing internal muscle moment to control this motion. This external moment is created when the line of action of the GRF lies at a distance from the center of rotation of the ankle joint. The internal moments generated by muscles activation should be slightly greater or less than the external moments in order to control angular motion at the joints. During a walking gait cycle (see fig. 11) the alignment passes from one side of the ankle joint to the other. Thereby switching from an external plantarflexion moment to an external dorsiflexion moment at the ankle when ground contact of the heel is switched to toe contact (see fig. 11; phase 1 to 2). This requires a transition from dorsiflexor muscle activity to plantarflexor muscle activity. This implies that when muscle atrophy occurs the AFO should act accordingly – i.e. dorsiflexion assistance to plantarflexion assistance.

However, sometimes the need for muscle activity is reduced or even removed when for example posterior alignment of the GRF to the ankle extends and stabilizes the ankle joint without the need for muscle activity (see fig. 11; phase 3).

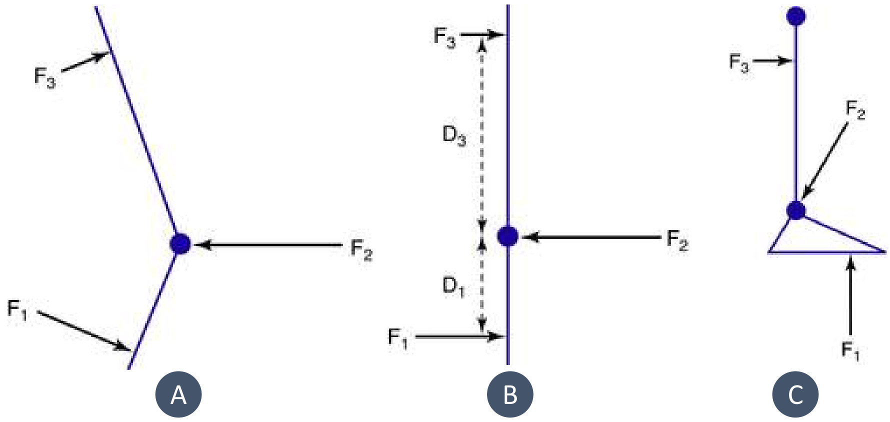


Figure 10: Three point force/pressure principle; (A) a minimum of three forces is required for control of angular motion at a joint. (B) the three-point force system is set up to be in equilibrium so that forces and moments balance, (C) the three-point force system applied by an AFO to control ankle plantar flexion. (Meadows et al., 2016).

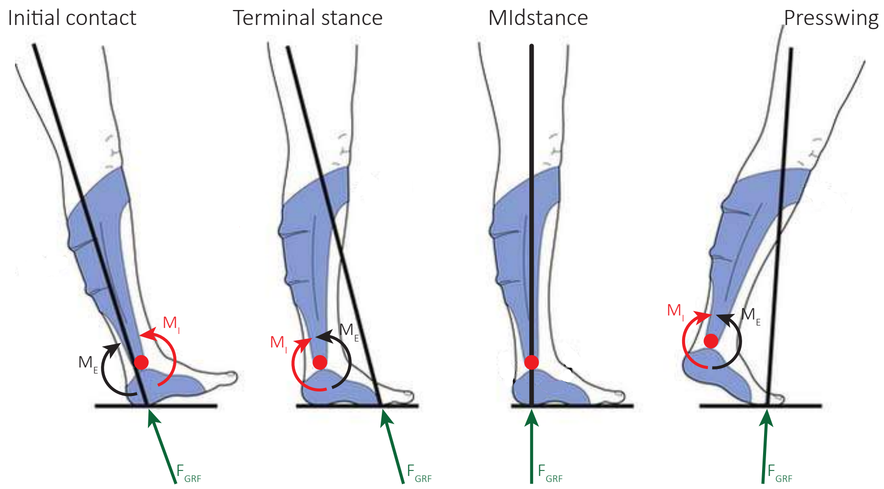


Figure 11: mechanical characteristics of an AFO during walking gait; the ground reaction force (GRF) is aligned as closely to the joints as possible, minimizing the external moments and thus minimizing the biomechanical demand on the neuromuscular system. Within different gait phases the GRF alignment passes from one side of the joint to the other, "switching" the internal and external moments (Meadows et al., 2016). Abbreviations: M_I: internal moment, M_E: external moment, F_{GRF}: ground reaction force.

Some active AFO's use a four-bar mechanism design or a modified four-bar called a slider-crank mechanism (see fig. 12). A four bar mechanism is a mechanical structure built of four links: the ground link, the drive link, the transmission link, and another driven link. In a slider crank-mechanism the only difference is that the driven link is constrained in such a way that it moves in a linear and not a rotational manner (Wilson & Sadler, 2003; Polinkovsky, 2010).

The design of the IPEC AFO (see Ch. 3.2.2.) features a four-link slider mechanism to actuate the ankle joint. When braced the ankle is constrained to move only in the sagittal plane, due to this the only actuated movements that it can perform are dorsiflexion and plantarflexion. Figure 12B, shows the typical slider mechanism that is used in the IPEC AFO to assist in both dorsiflexed and plantarflexed movement of the ankle joint.

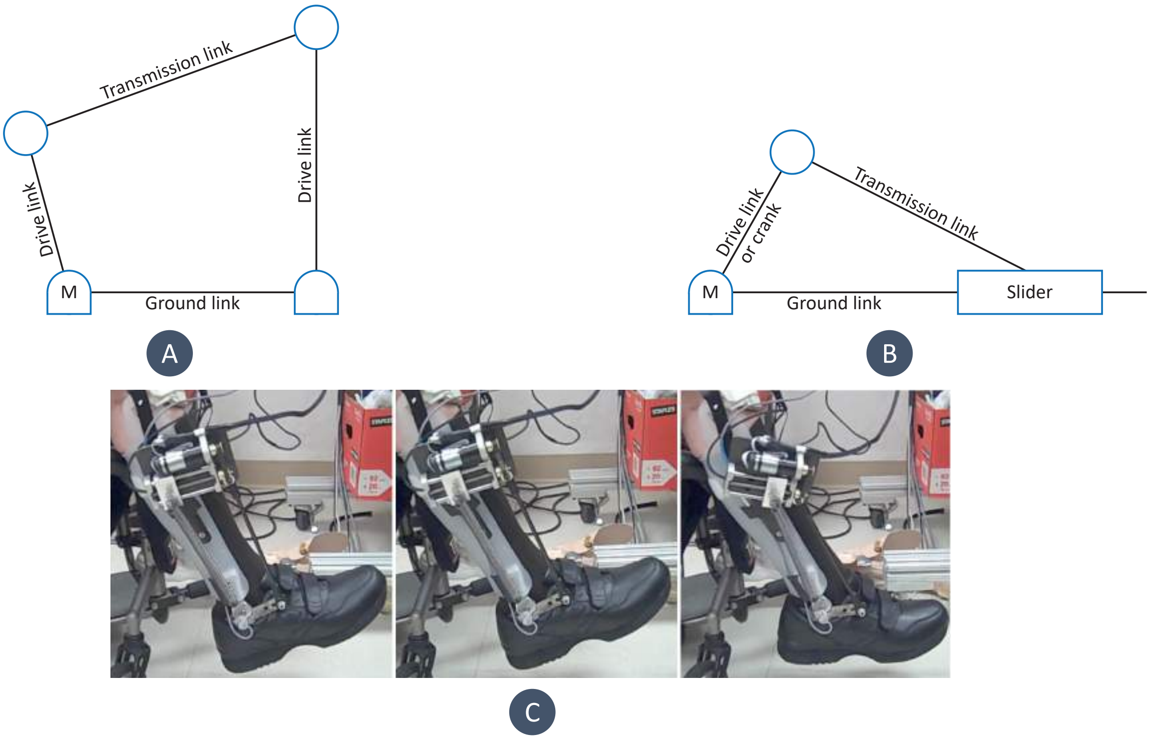


Figure 12: (A) A four bar mechanism; four rotational joints, (B) and slider-crank mechanism; three rotational joints and one slider joint, (C) Illustration of a slider mechanism working prototype of the IPEC AFO (Polinkovsky, 2010).

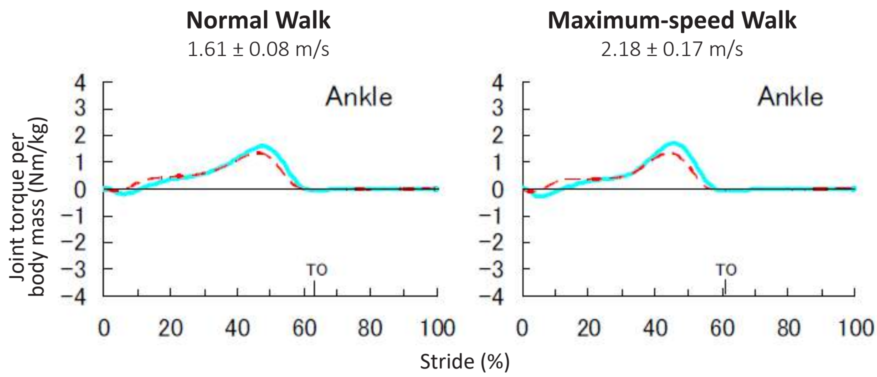


Figure 13: Lower limb joint torques calculated by Okada et al. (2007) in normal walk and maximum-speed walk speed. An average ankle joint torque was calculated with ground reaction force and lies in the order of 100 Nm for a person of 75 kg.

When looking at the applied moments that are subjected about the ankle joint. It is solely possible to investigate the biomechanics of healthy subjects. Since no related research could be found for dynamic characteristics of the ankle joint for people with CMT. Nevertheless, the report of Crowell et al. (2002) on the biomechanics of the human body, implies that the average maximum torque of 130 Nm occurs at the ankle joint during plantar flexion (i.e. push-off), at around 50% of the stride. Okada et al. (2007) calculated lower limb joint torques in two different ways – usual and simulated with ground reaction force (see fig. 13). On average the torque about the ankle joint during normal walking is in the order of 100 Nm for a person with 75 kg of body weight. Even though the torques are very small during the swing phase (i.e. toe-off), which occurs after 60% of the stride.

AFO's are designed in different configurations and vary in material and shape. The flexibility, adjustability and stiffness of the AFO is dependent on various design properties such as the wall thickness and trimline around the ankle, and among other things. A study by Creylman et al. (2010) showed the influence of stiffness and neutral angle of an AFO on muscle activation patterns. It was found that the muscle activation decreases when AFO stiffness is increased.

Another important AFO design characteristic is the effect of joint types and joint alignment on

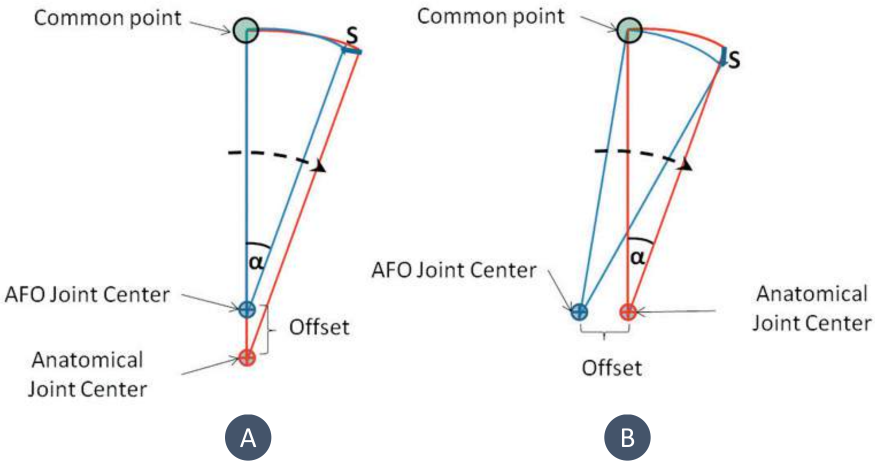


Figure 14: Illustration of the strap motion induced by joint offset. A: Superior alignment. B: Posterior alignment. The anatomical joint corresponds to the center of the motor shaft; S = change in distance between the common point (attached to the strap) and the AFO joint center; αα= angular displacement. (Gao & Kapp, 2012).

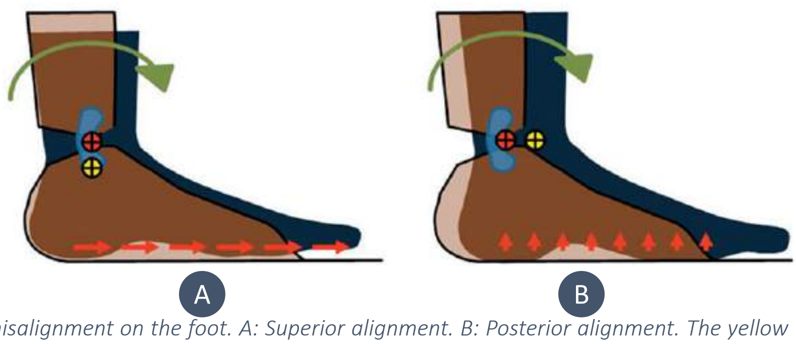


Figure 15: Effects of joint misalignment on the foot. A: Superior alignment. B: Posterior alignment. The yellow (i.e. anatomical joint center) and red circles (i.e. mechanical joint center). With the mechanical joint aligned superior to the anatomical joint, the foot will see more tangential stress pointing anteriorly (red arrows). With the mechanical joint aligned posterior to the anatomical joint, the foot will experience more normal stress pointing upward (red arrows). (Gao & Kapp, 2012).

the mechanical properties of an AFO (Gao et al., 2011). Optimal alignment (i.e. central alignment) shows minimum resistance and stiffness while posterior and anterior alignment shows significantly higher resistance and stiffness compared to other alignment conditions (see fig. 14 and 15). Misalignments clearly demonstrated effects on the AFO's mechanical properties, though those effects were variable. Gao et al. (2011) are suggesting that anterior and posterior (mis-)alignment should be avoided as much as possible to avoid potential skin irritation and increased stress around the ankle joint.

Thus, taking into account the whole system including both the AFO and the foot/ankle complex requires adequate knowledge on AFO design characteristics. Because changes are attributed to an interaction between the device and the foot/ankle complex.

3.4 ALTERNATIVE (FES) SOLUTIONS

Beside passive and active AFO's, also alternative solutions are thought of to deal with morbidities such as foot-drop. One of which seems a popular concept among nerve related conditions, which is the Functional Electric Stimulation (FES). FES is a concept that activates muscle groups that can no longer be activated by the subject's own nerve. FES is accomplished by delivering electrical impulses to a nerve that hampers activation of the muscle.
FES can either be externally applied on the skin (see fig. 16), or it may be internal, in which case the electrode is inserted directly into the muscle. A well-known FES device is a Pacemaker. Similarly, the following three concepts (i.e. WalkAide, Saebo, and HORSe) are using the FES technology in order to stimulate neurological impairment, which can be found in appendix F.

Figure 16: Examples of an FES solution (Lusardi, 2016)

3.4.1 TRENDS

The 3D printing technology opens up new doors for the design of prosthetics and orthotics. A trend is arising that can be typically recognized by the aesthetic features of certain 3D printed orthotics (see fig. 17). This is probably because the shape of a human body is difficult to copy with conventional manufacturing strategies (e.g. milling, among other things). Moreover, the advantages of 3D printing technology is for now still within the prototyping stadium. However, the presence of advanced 3D printers that are suitable for a range of new materials (e.g. metals), stiffness and surface roughness properties can be achieved.

Figure 17: Examples of 3D printed prosthetics

3.5 CONCLUSION

Passive AFO's are useful and provide a simple and wearable solution for the wearer. However, it can be stated that the development of passive AFO's has come to an ultimatum. Passive AFO's are compared to other alternatives, mostly cheap, lightweight and relatively compact. They come in different configurations ranging from 'prefabricated AFO's' composed of plastics, composites or silicon's, to 'custom-made AFO's' composed of carbon fibre or Kevlar reinforced plastics. The material is chosen by the orthopaedic specialist, based on the spring characteristics (i.e. stiffness) of the material for deflection while 'leaning' into the pretibial shell or 'against' the shin bone. The problems regarding passive AFO's are commonly found in comfort, functionality, usability (e.g. shoe compatibility) and durability aspects.

For active AFO's (AAFO's) the challenges are different. The functional benefits of AAFO's are recognized. Several AAFO have been designed in the past, whereby actuation mechanics are used that are powered by magnetics, pneumatics, hydraulics and several robotic configurations. Nevertheless, the elaboration of a lightweight, comfortable, and compact solution remains favourable.

As a side note, the technical requirements for active assistance during physical activity are high. AFO's in general need to deal with average torques about the ankle joint in the order of 100 Nm, with an average maximum torque of 130 Nm during plantar flexion. Therefore, the general consensus can be made that AAFO's are still too bulky, expensive and power intensive to be practical for commercial usage and only exist in laboratory settings. Nevertheless, significant design challenges remain for AAFO design and have the potential to yield advancement for rehabilitation and daily assistance.

A variety of AFO design characteristics are explored that account for both passive as well as active AFO's. One of the important mechanical properties is a matching (central) alignment of both AFO joint and human joint. If misalignment occurs it might pose high shear stress and lead to a potential risk of skin breakdown and tissue injury due to repetitive loading (Gao & Kapp, 2012).

Furthermore, alternative solutions are thought of to deal with morbidities such as foot-drop. One of which is the Functional Electric Stimulation (FES). FES is a concept that activates muscle groups that can no longer be activated by the subject's own nerve. A well-known FES device is a Pacemaker.

CONTEXT ANALYSIS 4

Cycling has become a well-accepted mode of physical activity in transportation, recreation, physical rehabilitation, and competition. According to the study by the National Sports Goods Association (2009), bicycle riding is the 7th most commonly participated physical activity among people older than 7 year-old, with over 38 million participants in the US. Despite its variety in purpose, cycling always possesses the objective of propelling the cyclist forward by transferring the energy from the cyclist's body to the bike.

CONTEXT ANALYSIS 4

4.1 INTRODUCTION

Pairing findings of previous research (i.e. Ch. 2 and 3.) with the project vision defines the purpose of the context analysis. The context analysis comprises the literature research, which is done to investigate the main characteristics of the cycling activity. The cycling characteristics on his turn will be projected on the meaning for the envisioned ACO. Therefor this context analysis is intended to research the symbiosis between bike and human functioning. Although cycling mechanics are extensively studied, the most comprehensive information about the basic biomechanics in terms of cycling- kinematics and kinetics will be summarized in this report. Furthermore, the context analysis explains the possible consequences for CMT patients with respect to the cycling activity.

4.2 CYCLING CHARACTERISTICS

4.2.1 CYCLING COMPONENTS

Cycling knows important features that accumulate motion. A correct interplay between bike- and human "mechanical" components is needed to translate applied human forces into motion of the bike. There are 3 points of contact in cycling. Meaning 3 points of the body that make contact with the bike: (1) Pelvis on the saddle, (2) Hands on the handlebars, (3) Foot on the pedal (Lee et al., 2016).

Cycling – i.e. foot on the pedal – can be decomposed into three main components; (1) human, (2) agent – i.e. connective component, and (3) bike.

Within the cycling context of the ACO the 'normal' main components possess the following elements that play an essential role during cycling (see fig. 18).

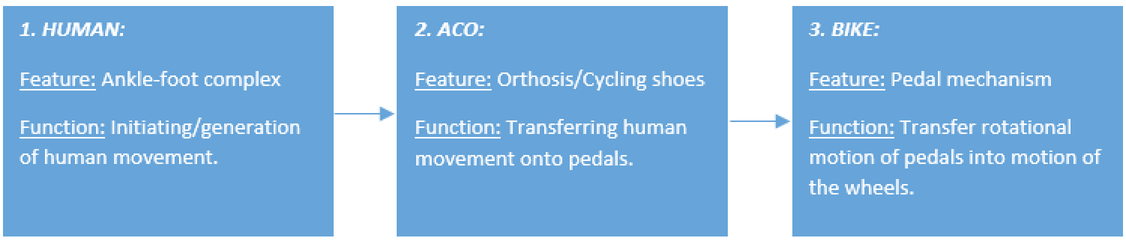


Figure 18: Decomposition of base components within the 'normal' cycling context.

4.2.2 HUMAN

The human component (see fig. 18) can be designated to the lower limb of the cyclist (e.g. CMT patient) that generates and initiates human movements. However, the (bio-)mechanics regarding this component will be discussed in Ch. 4.3.3 and 4.3.4.

4.2.3 ACO

Furthermore a connective component (CC) can be recognized, this connective component translates human movement onto the pedals of the bike – linkage between human and bike. For a (healthy) cyclist this usually comprises a (rigid) cycling shoe. Therefore, within the context of the assignment, the connective component is the envisioned ACO.

Moreover, the 'cycling shoes' and 'conventional AFO's' have a matched functional property/feature. Cycling shoes and conventional AFO's are both usually manufactured with a rigid foot sole (Symon, 2014). The rigidity of both 'cycling shoe sole' and 'AFO sole' is intended to transfer human movement to a contact surface. Respectfully, AFO's – ground contact, and cycling shoes – pedal contact. Even though the underlying purpose of activity is fairly different (e.g. walking versus cycling). The rigid foot sole of both supports a similar working principle – when looking at the biomechanical characteristics. Currently, AFO's are generally designed with a rigid foot sole in order to support the biomechanics of the ankle-foot complex during walking. The large forces that are generated by the upper- and lower leg can be translated towards a turning point – the toes or heel of the foot in order to switch between multiple walking gait phases. Minimal (to no) effort/activation of foot muscles should be needed. Since most AFO wearers are not able to use those muscles.

Similarly, this working principle can be seen in the rigid cycling shoe, regarding translation of forces onto the pedals of the bike. Thereby, the underlying working principle is to lower loss of force generated by the large upper leg muscles, caused by flexion of the foot and minimizing effort of relatively small foot muscles to enhance performances during pedaling.
Thus, if the ACO will possess a rigid foot sole, there will be no loss in functionality. In fact, it will be in accordance with the working principles of both and is a valuable product feature/characteristic for the project context. However, as previously discussed (in Ch. 4.2.1.) the base components are changing due to the presence of an ACO. As mentioned (in Ch. 2.) the presence of an AFO Interferes with shoe support and is causing discomfort that has major consequences for the experience of the wearer. Inherently, this scenario will also count for the envisioned cycling context and results in the following composition of base components (respectfully, 2a and 2b) are according to figure 19.

Nevertheless, in order to gain comfort during active assistance of the ACO, interference and a natural motion cycle should be complimentary. Besides, a good reason to help actuate the ankle is because the ankle joint plays a large role in determining the frequency of motion cycles. Research of Crowell et al. (2002) is showing that it is likely that the lower limb becomes more efficient, when the potential of the ankle joint is properly used. So, if a suitable design can be realized, wherein the active attention during assistance and support can be minimal. It is achievable to enhance the experience of a natural and comfortable motion cycle for CMT patients.

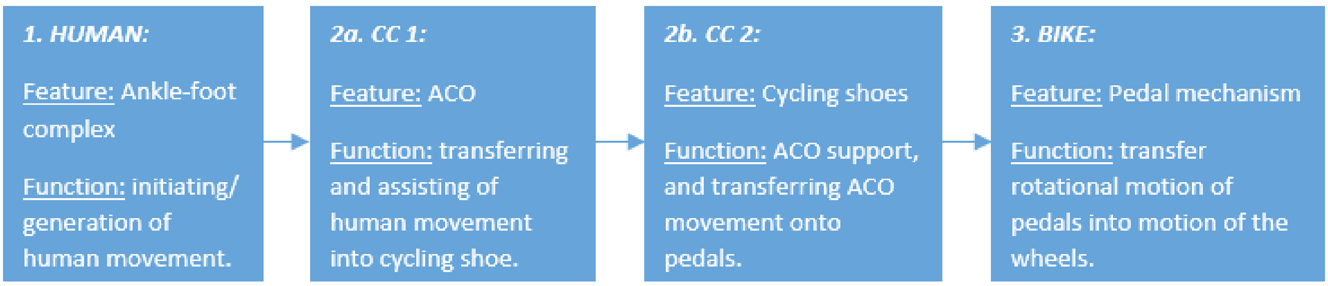


Figure 19: Decomposition of base components within the 'ACO' cycling context.

4.2.4 BIKE

At last, on a bike component level, the pedal mechanism is one of the essential elements to consider in the concept phase of the project. The pedal mechanism plays a major role in transferring the rotational motion of the pedals into motion of the wheels. Within the assignment, the traditional bike pedal mechanism will be used as a base reference for design. Since this conventional pedal mechanism is well-known, applied on cycling ergometers and extensively used in cycling related research.

4.3 CYCLING BIOMECHANICS

4.3.1 CYCLING TECHNIC AND MECHANICS

The (traditional) pedal mechanism allows for a pedal technic that comprises two main phases within a single pedal cycle (see fig. 20); the push – power phase (i.e. propulsive phase) and the pull – upstroke phase (i.e. recovery phase). The pedal cycle can be explained by means of imagining a clock, starting with the pedal at 12 o'clock, which is known as Top Dead Centre (TDC; 0°). Within the propulsive phase, forces are the highest and is generally used during acceleration. In order to propel the bike forward. The pedal is then pushed down from 12 o'clock towards 6 o'clock, this position is known as Bottom Dead Centre (BDC; 180°). The transition from BDC when the pedal is pulled back up to TDC is known as the Upstroke Phase. The actions that are performed between the two phases can be subdivided into four actions that collectively fulfil a perfect pedal cycle (see fig. 20).

The cycling biomechanics can be described by two different terms in the branch of classical mechanics. Namely, kinematics and kinetics. Kinematics is concerned with the relationship between motion of bodies and describes the movement (e.g. translator, rotary movement, and general motion; translation plus rotation), position (e.g. axis of rotation, planes of motion) and location of anatomical feature (e.g. actions of muscles are referenced from anatomic position). Kinetics can be described by the relationship between the motion of bodies (i.e. velocities and accelerations) and the forces that act upon them (e.g. torque). The cycling kinematics and kinetics are extensively studied. The research which is carefully executed by Hanaki-Martin (2012) is particularly useful, and is therefore partly used as background information for the biomechanical analysis part of this report.

Figure 20: Phases within the pedal cycle; including 4 different actions.(Mooney, 2010)

4.3.2 CYCLING KINEMATICS

Several methods exist in order to measure body kinematics while cycling. Among which photography, flashing LEDs (see fig. 21), strobe lights, and accelerometers (Buonocunto & Marinoni, 2014). The motion capture methods and kinematic recordings generally comprises applied marker on the joints. The resulting motions must be interpreted by tracing the locations of the joint markers (Gilbertson, 2008).

The segmental angles (see fig. 22) are kinematic variables for cycling mechanics analysis. The pedal angle are mostly anteriorly tilted relative to horizontal, which can be seen in actions 2, 3 and 4 of figure 20. However, during the first action of the propulsive phase (see fig. 20), the pedal is posteriorly tilted – 'heel-down' pushing position. Some has suggested that this 'heel-down' position is accompanied with ankle dorsiflexion. That accumulates a strategy to improve the pedaling effectiveness by involving the stretch shortening cycle of the muscle.

Figure 21: An illustration of motion capture strategy developed by Gilbertson (2008). The flashing LED circuit attached to a cyclist's leg can be used for cycling kinematics analysis. in the treatment pathway of a CMT patient

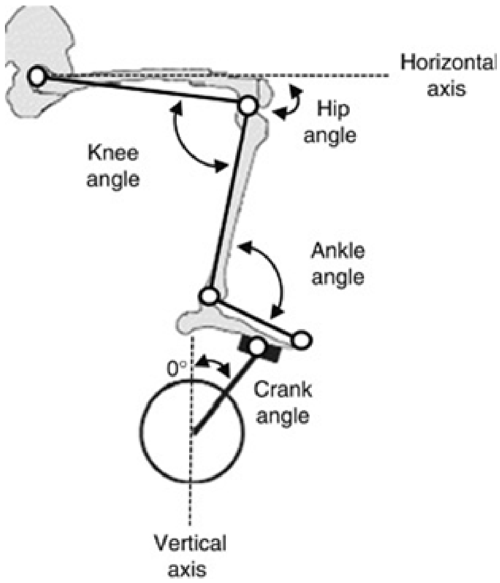


Figure 22: Kinematics recordings; Position of the reflective markers (○) fixed on the lower limb and pedal axis allow calculation for the hip, knee, and ankle angles through all 360° of the pedaling cycle (Lericollais et al., 2011).

4.3.3 ROLE OF THE JOINTS IN THE LOWER LIMB DURING CYCLING

The pelvis is the start of the lower limb complex (see figure 23), and is compromised of the ischium and the ilium. The pelvis bone is where the origin of some large upper leg muscles are located that comprises the hamstrings – Bicep Femoris (long head) among others. The hip is a type of 'ball and socket' joint, that connects the pelvis with the femur and allows for a large degree of multi-directional movements. During cycling the hip joint allows for hip flexion, extension and small degree of rotation.

Further down the lower limb complex, the knee joint is found that connects femur and tibia. The knee is a type of 'hinge' joint that acts as a lever to the femur and is usually subjected to the largest amounts of torque during cycling. Furthermore, the patella can be found within this hinging knee joint. The patella is a sesamoid type of bone that connects the quadriceps muscles (i.e Rectus Femoris, Vastus, Medialis, Vastus Intermedius and Vastus Lateralis) to straighten the knee (knee extension).

As can be seen in figure 24, either extension or flexion of the joints occur concurrently during each of the two pedaling phases. During the propulsive phase, extension at both hip and the knee joint occur, whereas flexion of those joints occur during the recovery phase.

Moving further down the lower limb complex the ankle joint is located that connects the tibia, fibula and talus. The ankle joint is a 'hinge' type of synovial joint that allows for dorsiflexion and plantarflexion during cycling. The cyclic movement of the foot during a pedal stroke is called 'ankleing'. Whereby the movement of the foot starts from a dorsiflexed position followed by a plantarflexed position while moving through the bottom of the pedal and turning back to a dorsi-flexed position.

Below the ankle joint the talus bone connects many small joints of the foot. One of the primary functions of the foot is maintaining stability during stance, and transferring forces that are generated by the lower limb complex onto the pedal.

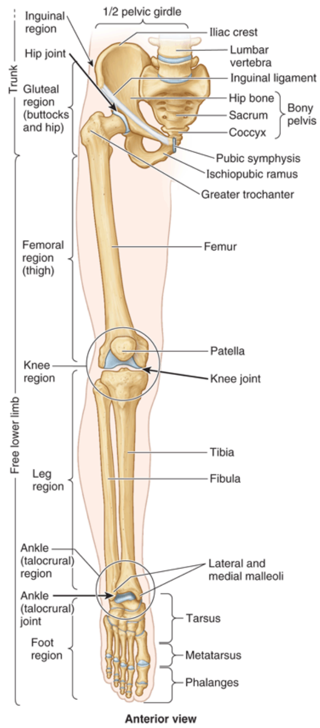


Figure 23 Regions and bones of the lower limb.(image soucre PicQuery)

4.3.4 ROLE OF THE MUSCLES OF THE LOWER LIMB DURING CYCLING

The role of the main muscles used during cycling is described by means of the figures 24 and 25 (Timmer, 1991; Hanaki-Martin, 2012; Schultz, 2015). The general pedal cycle starts at TDC with the propulsive phase, pushing down the pedal towards 6 o'clock. Starting at flexed position of the knee, collectively leg extensors are pushing the hip and knee in extension by activation of the majority of lower limb muscles (see fig. 24). The quadriceps (i.e Rectus Femoris, Vastus, Medialis, Vastus Intermedius and Vastus Lateralis) work in close partnership with the Gluteus Maximus. These two large powerful muscle groups are responsible for the largest amount of torque and are primarily active in the propulsive phase.

The Rectus Femoris, which is part of the four quadriceps muscles, is activated in both phases – propulsive phase and recovery phase. Namely, because the Rectus Femoris is the only muscle that is crossing both the hip and knee joint. Giving it duel responsibility of hip flexion and knee extension. However, depending on the position that is adopted by the cyclist (if for example on an upright bike). The hamstrings (i.e. Biceps Femoris, Semimembranosus and Semitendinosus) are also acting as antagonist during hip extension. Shortly after TDC and further down the lower leg the Soleus and biarticular calf muscles (Gastrocnemius Lateral and Gastrocnemius Medialus) become active, and stay active till half way recovery phase.

The main role of the hamstrings is knee flexion and occurs while pulling the heel upwards through BDC up until recovery phase. When the crank reaches BDC at 6 o'clock and knee is (almost) fully extended. Hip flexors among which hamstrings and Rectus femoris are pushing the pedal through BDC. When the crank passes BDC the biarticular calf muscles are lowering activation. When, half way through the recovery phase, the Tibialis Anterior muscle begins its activation and stay active until crank reaches TDC.

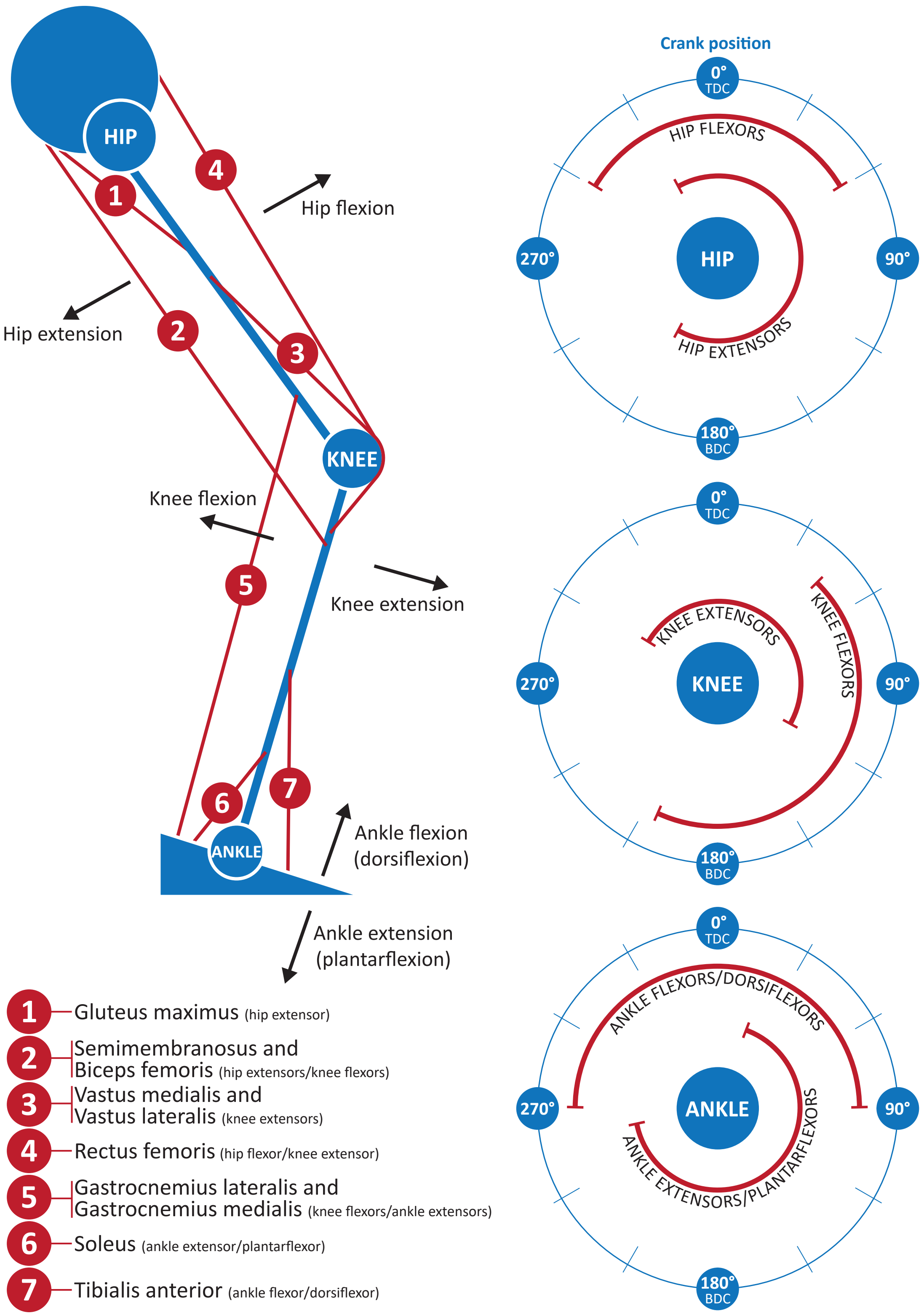


Figure 24: Compiled schematic overview created by Hanaki-Martin (2012) and Wozniak Timmer (1991), wherein major leg muscles are involved during cycling. Muscles are alternating based on their agonistic/antagonistic role within the pedal cycle/phase – i.e. corresponding crank positions for hip, knee and ankle flexors/extensors.

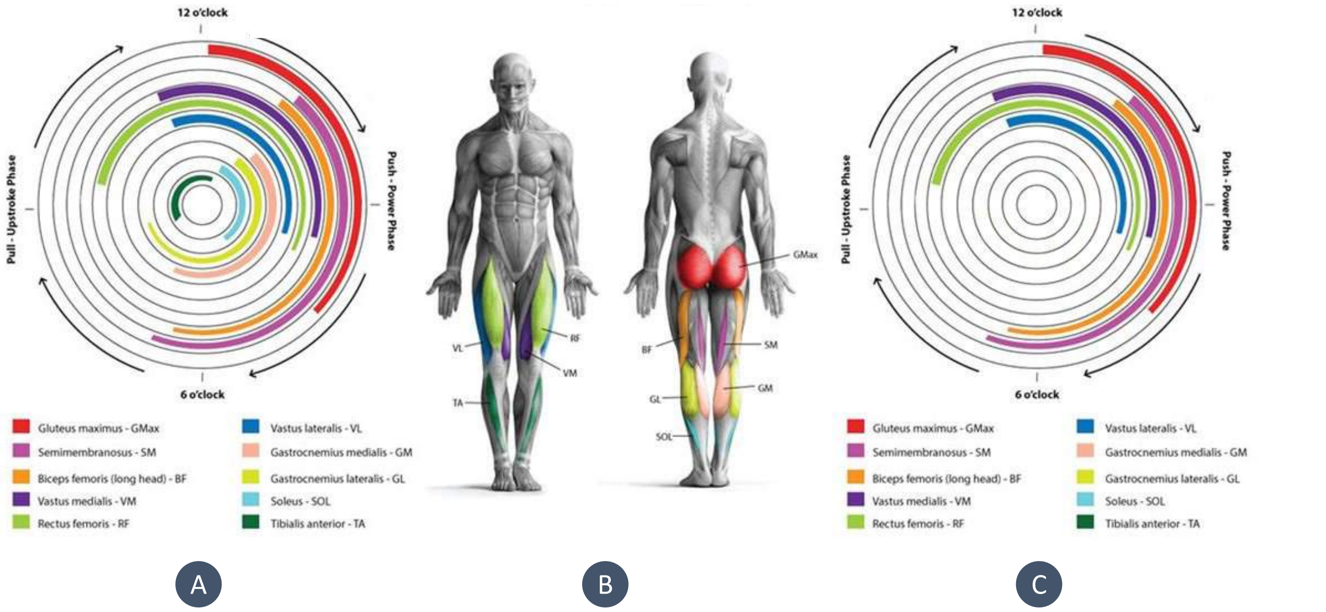


Figure 25: Compiled activation diagrams of muscles used during a full pedal stroke; (A) Activation diagram of the muscles used during a full pedal stroke among healthy cyclists. (B) Anatomical positioning of muscles. (C) A theoretical perception of the change in muscles activity caused by CMT muscle atrophy in lower leg during a full pedal stroke. (Schultz, 2015).

When looking at the physical limitation caused by the CMT disease. It is fair to assume that the muscles in the lower leg are not contributing to the fulfilment of a full pedal cycle. Therefore, they can be withdrawn from the muscle activity diagram shown in figure 25. This implies a substantial lack of strength needed to perform a full pedal stoke. The effected muscle bundles are at their turn creating a gap in transfering forces onto the pedals. It is expected that the impact of which is softly expressed 'notable' during practise. Since forces generated by the large upper leg muscles are also losing their full potential while pedaling. How these physical limitations come into force is unclear. And unfortunately there is no comprehensive cycling research performed with CMT patients or people with similar symptoms. A user test (in Ch. 5) is executed to gain some clarity on the kinematic difficulties that CMT patients experience during cycling.

4.3.5 CYCLING KINETICS

kinetic measurements are performed in several studies. The cycling kinetic variables can be measured by means of crank arm torque or pedal forces instruments. Commonly used instruments are illustrated in figure 26. These pedal or crank arm based power meters (such as SRM power meter, Schoberer Rad Messtechnik, Welldorf, Germany) are the two major types of the measuring devices to determine crank torque and joint moments (Hanaki-Martin, 2012).

In appendix G, the mathematical equations are given that describe the pedal forces, which could be useful during the prototype phase of the assignment for determining the desired torque assistance about the ankle joint.

The study executed by Korff et al. (2007) is looking at the torque about the crank for different pedaling techniques, including: circling, pulling up and pushing. A custom-made force pedal with two triaxial piezoelectric force sensors (Kistler, model 9251AQ01) was used. They found that maximum crank torque of approximately 45 Nm was produced with the pushing technique (see fig. 27).

Furthermore, Bini & Diefenthaeler (2010) studied the kinetics and kinematics during an exhaustive exercise with eleven competitive cyclists. The hypothesis that cyclists would modify their technique during exhaustive incremental exercise was supported by their findings. Differences in joint kinetics and kinematics were indicating that pedaling technique was affected by combined fatigue and workload effects. Higher plantar flexor moments (32%), knee (54%) and hip flexor moments (42%) were observed. In addition, higher dorsiflexion (2%) and increased ROM (19%) were found for the ankle joint. This increased ROM of the ankle joint may be related to an attempt to increase ankle joint power by increasing muscle shortening velocity. Which is in accordance with the research presented by Skovereng et al. (2017) They saw an increased ankle joint angular velocity when cadence increased above 80 RPM (see fig 29A). Besides, they found a tendency for reduction of ROM as cadence increased (see fig. 29B).

Furthermore, it is interesting to investigate the required torque about the ankle joint for the ACO. In order to determine the required maximum torque for assistance. Li & Caldwell (1998) studied the joint moments about hip, knee and ankle joints of eight subjects. The participants maintained a relatively constant pedaling frequency, with a work rate of 250 W. Five trails were performed with a pedal cadance ranging from 60 to 85 RPM, which corresponds to three different postures; (LS) level seated, (US) uphill seated, and (ST) uphill standing (see fig. 28).

As can be seen in figure 28, the maximum ankle moments of about 130 Nm occur during uphill standing (i.e. ST), and are of a magnitude similar to normal walking (see Ch. 3.3.5.). However, when the pedal cycle is performed while seated (i.e. LS and

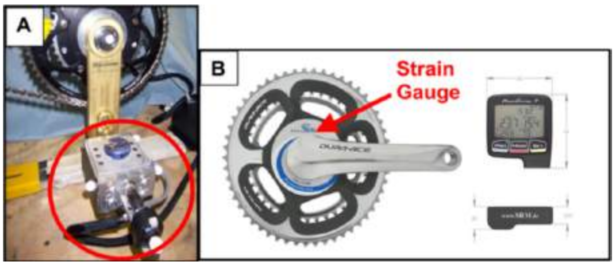


Figure 26: Examples of kinetic cycling instruments; (A) 2-D force pedal. Deformation of the octagonal strain ring force transducer located in the middle of the pedal causes electrical signals. Normal and tangential forces are measured. (B) RSM power meter. The torque applied to the crank arm is detected (Hanaki-Martin, 2012).

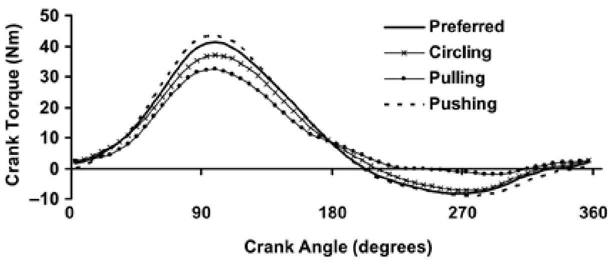


Figure 27: Crank torque profiles of the ankle joint for different pedaling conditions (Korff et al., 2007).

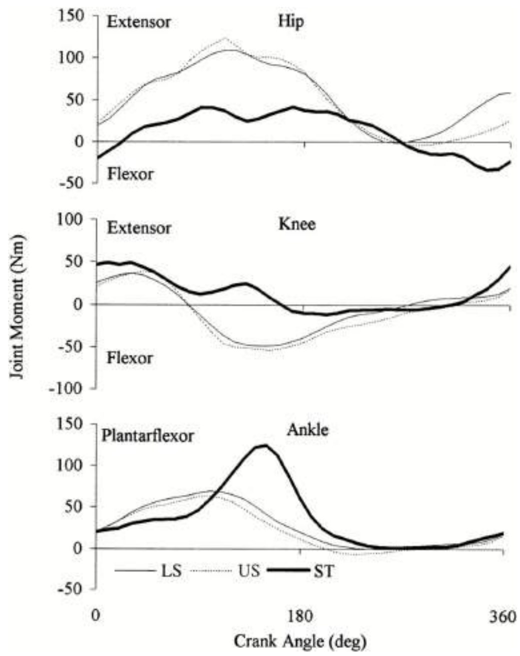


Figure 28: Exemplar joint moment pattern (ensemble of 5 trials) for 1 subject. Joint moments were calculated by using an inverse dynamics model with measured pedal forces and lower extremity kinematics. Data was gathered for three different postures on the bike; (LS) level seated, (US) uphill seated, and (ST) uphill standing. (Li & Caldwell, 1998).

US), the maximum torque is about 50 Nm. Thus, it can be stated that – when seated, the majority of the body weight is supported by the bike itself. Which result in an increased hip joint moment, but a decreased ankle joint moment. Because the ACO needs to provide assistance and is intended to be useful for rehabilitation rather than competitive cycling. The expected maximum torque generated by the ACO is assumed be in the order of 50 Nm.

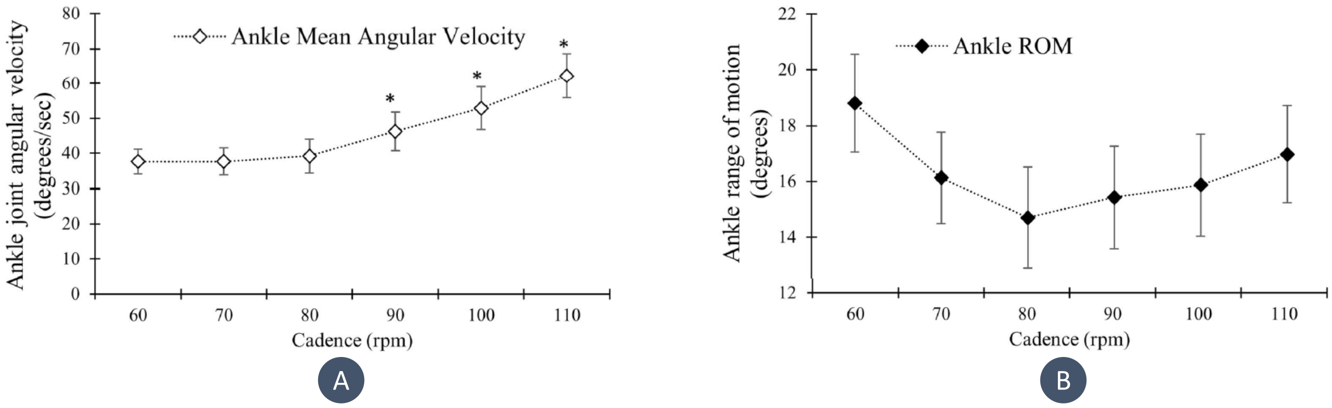


Figure 29: Effect of cadence on joint kinematic variables over the whole pedal cycle; (A) Absolute ankle joint angular velocity averaged in degrees/second. (B) Ankle joint range of motion (ROM) presented in degrees. (Skovereng et al., 2017)

4.4 CONCLUSION

Cycling can be seen as a suitable rehabilitation therapy for the employment of a future ACO. The symbiosis between bike and human functioning can be carefully monitored, which is less difficult compared to conventional AFO's.

Besides, the 'cycling shoes' that are usually worn by cyclists and 'conventional AFO's' have a matched functional feature. Namely, a rigid foot sole. The rigidity of the foot sole among both is intended for transfer human movement on a contact surface. This feature can be taken into the envisioned ACO for similar purposes. Namely, to translate additional assistance torques that are initially subjected to the (healthy) ankle joint. So that possible foot muscle fatigue can be overtaken and functional activation of plantar- and dorsiflexor torques can remain while performing rehabilitation therapy.

In total there are four main muscle bundles in the lower leg that support plantar- and dorsalflexion of the ankle joint. Namely, the Gastrocnemius Lateralis Gastrocnemius Medialis, Tibialis anterior and the Soleus. Of which all are potentially affected by the CMT disease and are causing difficulties for a CMT patient to fulfil a full pedal cycle.

Thus, adequate assistance will be needed, a design solution should be sought for that encompasses the joint and deviant body parts (due to the loss of muscle). In addition, assistance of the ACO needs to be within desired range of motion (ROM) values, this can be seen within the theme of ergonomic support and should be limited to avoid contractures.

Furthermore, also from a technological perspective this context analysis is showing a great technological advantage in terms of power conversion. The research is showing that the required ankle torque for cycling (around 50 Nm) is approximately two to three times lower compared to walking (around 130 Nm) with similar physical effort (i.e. power). Inherently, this implies that power performances are lowered, which is a key attribute for robustness and compactness of active AFO's. A portable design solution is therefore "easier" to fulfil compared to AAFO's assigned for walking.

USER TEST 5

In the Netherlands we say ‘meten is weten’. This comprehensive sentence is key for most technical research and can reveal underlying proceedings that are often overlooked. Especially when it concerns physical limitations that are unfamiliar to many. The impact of lower extremity disabilities during cycling are yet undiscovered and strictly speaking, inimitable without usability testing. The main purpose of this user test is therefore to provide meaning and reasoning of what a future ACO could offer in the world of rehabilitation.

5.1 INTRODUCTION

The user test includes a cycling activity with two participants; a 54 years old male CMT (type 2) patient and a healthy 58 years old male amateur cyclist (control participant). Both participants will undergo a series of cycling exercises in the multi-sense lab in the Industrial Design Engineering department of the Delft University of Technology.

This user test is held in order to study "*the difference between the 'healthy' kinematic motion and the 'disabled' kinematic motion of a CMT patient*" that is cycling without wearing the ankle-foot orthosis (that he usually wears in daily life). Furthermore, the muscle activity of the lower limb was measured to examine the efficacy of the muscle to the corresponding cycling kinematics.

Purpose of the user test:
- Research user performance/characteristics within context of the project
- Define requirements for Concept phase
- Try-out for user test 2 (Embodiment phase)

5.2 PRE-USER TESTING

To create the right set-up for the user test, a variety of considerations are made concerning component selection, exercise selection, measuring instruments and recording equipment selection, and muscle selection. These considerations are described in appendix H1 till H6.

An integrated overview of all the elements that play their part in the user test is created (see fig. 30). Figure 30 shows which components can be manually or wirelessly adjusted. One of which are the measuring equipment (see fig. 31) that are applied on the participants. Furthermore, all measurement

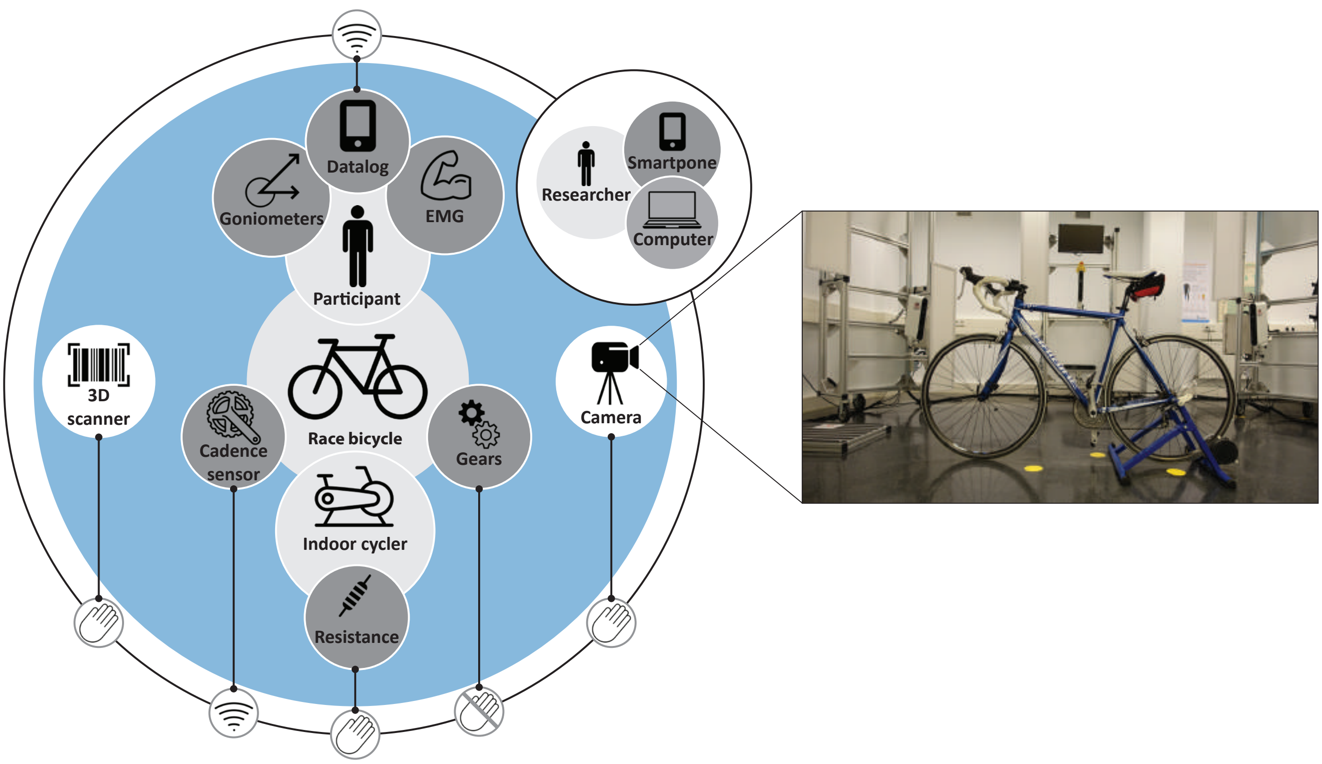


Figure 30: User test set-up overview and camera view of bike set-up within the multi sense lab of the TU Delft.

equipment needed to (re-)set zero before running. The angular motion is calibrated and set zero while standing. Thus angular motion values are relative to the standing posture.

In de run-up for the user test a pilot test (see appendix H) was executed wherein the main uncertainties, such as desired resistance, desired cadence, placement/output values of goniometers and Biometric Datalog software, 3D scanning performance and adjustability of the bike are examined.

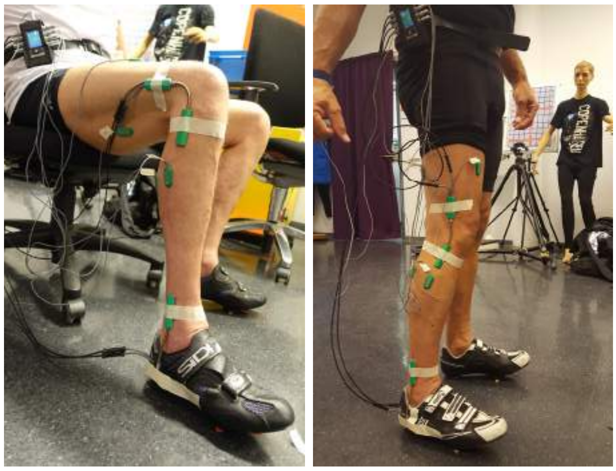


Figure 31: Placement of measurement equipment; patient (left) and control participant (right).

5.3 RESULTS

The two participants successfully executed the user test. Three different exercises; (1) L60; Low resistance – Low cadence, corresponds to low speed seated flat road cycling; (2) L80; Low resistance – high cadence, corresponds to high speed seated flat road cycling and (3) H60; high resistance – Low cadence, corresponds to low speed seated hill climbing. By these exercises angular motion performance expressed in range of motion (ROM), and surface EMG are examined. Indicated for patient (P) specific as PL60, PL80, and PH60. Likewise for control (C) specific as CL60, CL80, and CH60. A continuous sequence of 14 full pedal cycles is shown in figure 49 and 50 of appendix H1. The peak values of the 14 full pedal cycles are subtracted from the graphs created by the Biometric Datalog software and collected in the data sheet that can be found in figure 51 of appendix H1.

5.3.1 EMG MEASRUREMENTS

When looking at the EMG measurements, it is quite remarkable that some muscle strength in both lower legs is present after approximately 12 years of having the CMT disease. Although with a small magnitude muscle activity was still measured in the lower leg of both limbs. Unfortunately, something went wrong with the EMG signal for CL60 and CL80 and these are not reliable. However, figure 49; PH60 clearly shows that P is compensating for the lack of muscle strength in the lower leg by an increased muscle activation of the upper leg, whereas C is having a balanced distribution of muscle activity across both upper- and lower leg. The EMG signals clearly show that the pedal cycle is starting with activation of the Rectus Femoris (RF; hip flexor/knee extensor) and Tibialis Anterior (TA; dorsiflexor) during propulsive phase, followed by activation of the Biceps Femoris (BF; hip extensor/knee flexor) and Gastrocnemius Lateralis (GL; knee flexor/plantarflexor) from halfway propulsive phase up to the recovery phase.

5.3.2 RANGE OF MOTION (ROM) PERFORMANCE OF THE KNEE

Starting with the knee, figure 32B is showing that ROM values for L60 and L80 are quite similar between P and C although the average ROM is different. The average knee ROM is always highest for P, whereby an average difference between both participants of 0,6° for L60 and 3,3° for L80 is measured. By which it can be stated that they are small and deviate minimally. In contrast, H60 values are further apart from each other, with an average difference of 10,8° between both participants. These differences in knee ROM are remarkable and will be explained later.

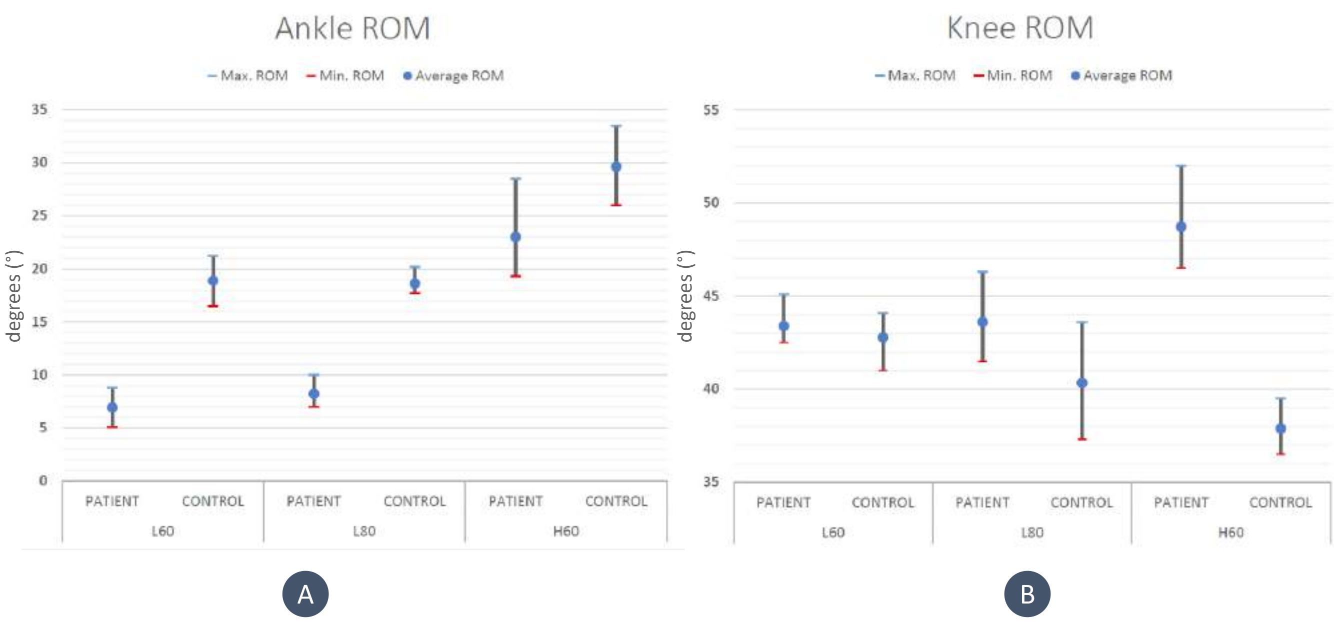


Figure 32: Diagram of ankle- (A) and knee (B) range of motion (ROM) for exercises L60, L80 and H60 in which a sequence of 14 pedal cycles is examined. ROM descibes angular motion difference between flexion and extension of the joints expressed in degrees.

5.3.3 RANGE OF MOTION (ROM) PERFORMANCE OF THE ANKLE

When looking at the ankle (see fig. 32A), the average ankle ROM's are always highest for C. However, P and C are both following an increased trend line. Because average ROM values for PL60 and PL80 are similar (i.e. small changes between min. ROM and max. ROM), PL60 and PL80 are merged (PL60/80) and together account for an average ankle ROM of 7,6°.

Likewise, CL60 and CL80 are merged (CL60/80) and together account for an average ankle ROM of 18,8°. Resulting in a noticeable difference among both participants of 11,2°. Moreover, the increased cycling resistance for exercise H60 is causing a major shift in ROM values. Minimum and maximum ROM values of P are fluctuating with a mutual difference of 9,2° (between max. 28,5° and min. 19,3°) with an average ROM of 23°. Whereas, minimum and maximum ROM values of C are fluctuating with a mutual difference of 7,5° (between max. 33,5° and min. 26°) with an average ROM of 29,6°.

Due to the increased cycling resistance of H60 exercise, both participants are forced to apply more force on the pedals while maintaining desired cadence. The increased force on the pedals (i.e. torque about the ankle joint) is causing a larger deviation in ankle ROM compared with exercises

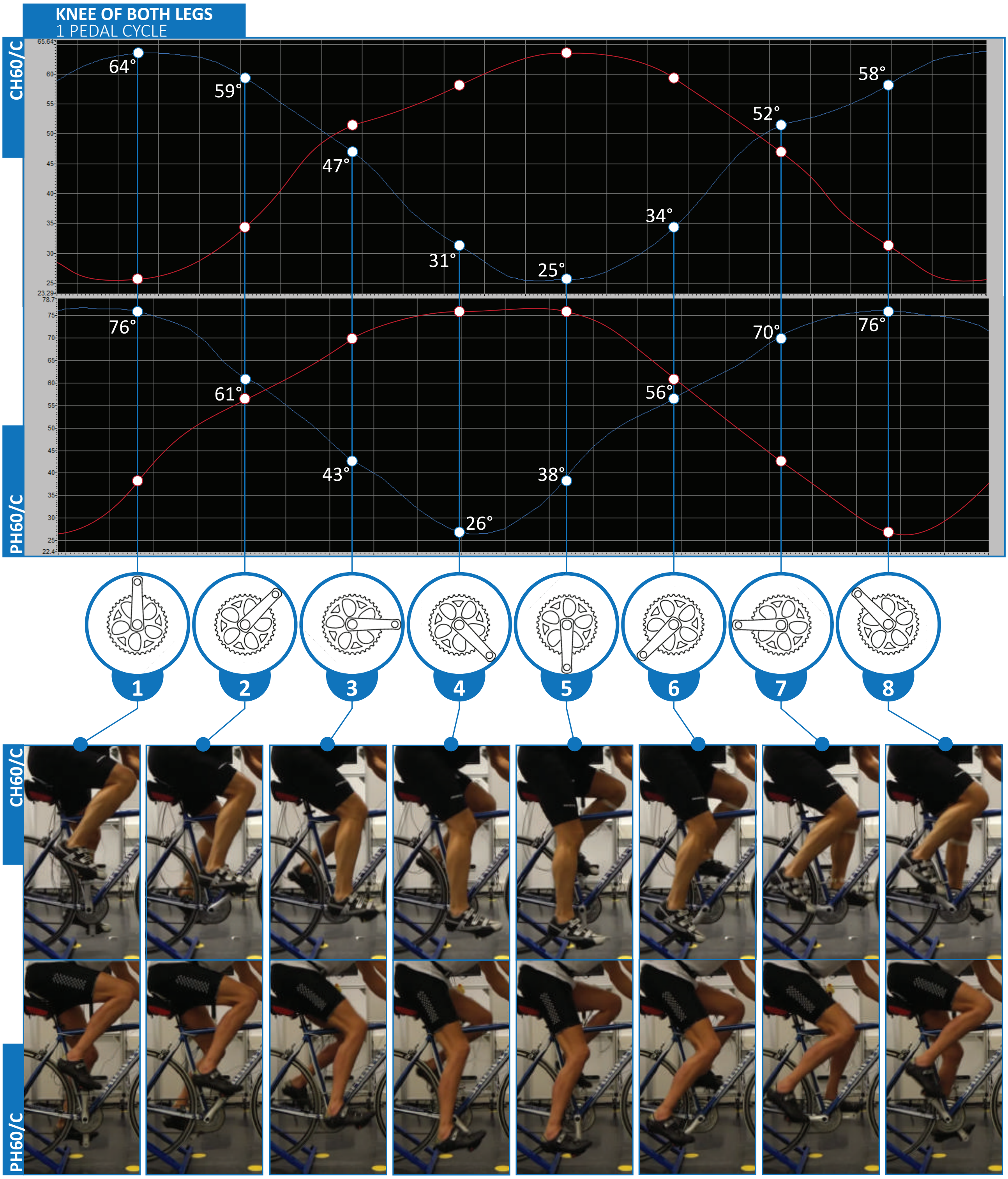


Figure 33: Angular motion profile of the knee joints of CH60 and PH60. Green line corresponds to the right leg and can be seen in the images below. Red line is the derived motion profile for the left leg mages

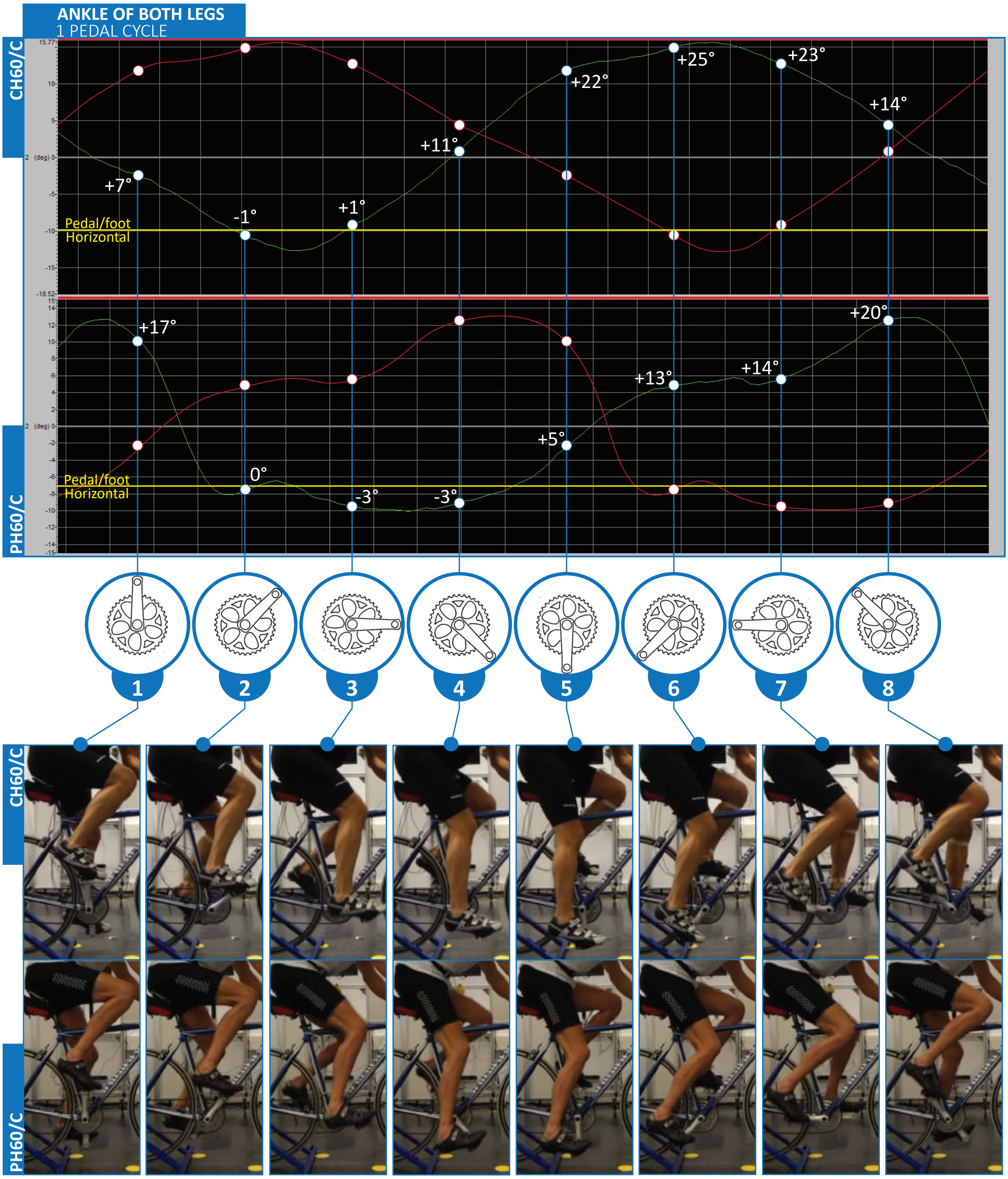


Figure 34: Angular motion profile of the ankle joints of CH60 and PH60. Green line corresponds to the right leg and can be seen in the images below. Red line is the derived motion profile for the left leg. In addition, numbers are relative to pedal/foot horizontal line.

L60 and L80. Hence pushing the heel further down during propulsive phase and pulling the heel further back up during recovery phase. As a consequence, a mutual difference of 15,5° is calculated for average ROM values PH60; 23° compared with PL60/80; 7,6°. Likewise for C a mutual difference of 10,9° is calculated for average ROM values of CH60; 29,6° compared with CL60/80; 18,8°. Noteworthy is the whopping maximum of 22° angular difference while comparing PL60 with PH60.

5.3.4 EFFECT OF INCREASED RESISTANCE ON KNEE- AND ANKLE ROM

To clarify what is happening at the ankle and knee joint during exercise H60, a closer look at one full pedal stroke is needed. Figures 53, and 54 in appendix H3 and H4 are illustrating a converged sequence of five pedal cycles: (H60/A) segmented in two pedal cycles, (H60/B) further segmented in a single pedal cycle (H60/C) for PH60 and CH60. Within these figures the relationship between ankle and knee motion can be observed. The motion profiles are screen captured and reflected with the camera images at eight different crank positions; (1) 0°, (2) 45°, (3) 90°, (4) 135°, (5) 180°, (6) 225°, (7) 270°, and (8) 315°.

As previously mentioned, the increased cycling resistance of exercise H60 requires more muscle strength to maintain the desired cadence. Because the resistance of exercise L60 and L80 is lower, P and C are both considerably capable of controlling their ankle joint angle, thus try to maintain a constant small ankle ROM. When cycling resistance is increased – applied ankle torque increases and larger ankle ROM's are observed.

First the performance of P is studied. Figure 33 and 34 is showing that P is experiencing major difficulty in gradually applying the additional forces onto the pedal during propulsive phase. The heel is falling down rapidly causing a steep slope between point 1 and 2, after which the heel stays down till point 4 mainly due to activation of Rectus Femoris.

Consecutively knee extension limit is reached at point 4 (i.e. 'full' extension of the knee joint) when Bicep Femoris among others take over when a crank position of 180° is reached at point 5 (i.e. BDC). After point 5 the pedal cycle continues with the recovery phase. This is the turning point in the pedal cycle which can be explained on the basis of two phenomena by means of the figures 30, 31 and 50. On the one hand the hip- and knee flexor muscles are lifting the heel. On the other hand, the pedal (i.e. heel) is lifted/assisted throughout the recovery phase by activation of the hip- and knee extensor muscles in the other leg – which is starting the propulsive phase at point 5. After point 5 the ankle joint is relatively relaxed during recovery phase while angular motion of the ankle joint is increasing slowly between points 5 and 6. A 'plateau' can be recognized between points 6 and 7, because of a short delay in regaining load on the pedal – control in the ankle joint while hip flexor muscles are becoming activated.

5.4 DISCUSSION

The previously discussed results (see Ch. 5.3) are providing a direction for further development of the ACO. Although the reliability of the results can be considered trustworthy, it is likely that small biomechanical differences among the two participants have a certain influence on the results. Even though most of the variables are considered at forehand such as desired posture, seat height, pedal position, pedal rate, small differences among them can lead to slight changes in posture on the bike causing differences in muscle activation and angular motion of the joints. In addition, the evaluation of results are based on pedalling symmetry that appeared to be logical during cycling is not true. According to Wazniak Timmer (1991) relative contributions of each leg is not symmetrical among recreational cyclists. Wazniak Timmer argues that the nature of the asymmetry is unrelated to limb dominance, but rather caused by changes in pedaling rate. However, no consistent relationship was found. Because a targeted cadence is aimed for pedal cycles could varying over time small changes in pedaling rate could occur thus it is expected that changes are relatively small.

Nevertheless, considering the severity of the CMT2 disease in the leg region of both lower limbs of P. Muscle strength is almost completely absent after approximately 12 years, causing severe drop foot and substantial lack of control over the ankle joint. Especially, when medium to high plantar- and dorsi-flexor torques is required maximum assistance of the ACO is needed.

Regardless of the minimal amount of (two) participants this user test provides a clear direction for defining assistance goals based on the general physical ability/disability of CMT patients. Assuming that physical ability of P is at its limit – i.e. worst case scenario given the lack in muscle strength versus desired physical performance during the user test exercises. Therefore, it can be argued that P is representative for a large population of CMT patients given the fact that human limit was observed – that shows/suggests maximum values for the assistive mechanism of the ACO. For example, when a healthier CMT patient would participate (who is logically more able to perform the exercises) it is expected that the physical performance is better than is executed by P and consequently less assistance of the ACO is required.

Because the purpose of the ACO is ‘to assist’ and not ‘to take-over’ muscle function during therapeutic cycling exercises, this user test provides reasonable results for assessing the desired level of assistance of the ACO within the different phases of the pedal cycle.

Moreover, when looking at the low resistance exercises (PL60 and PL80), it stands out that control over the ankle joint is retained. Although an abnormal motion profile is observed when looking at a single pedal stroke. The study is indicating that a healthy motion profile is sinusoidal and similar to that of C. In addition, throughout the exercises PL60 and PL80 relatively small fluctuation between min. ROM and max. ROM of the ankle joint are visible (see fig. 32, 33, 34, 51 or 52) and deviates greatly from the literature presented by Skovereng et al. (2017) in figure 26. One explanation for this could be that during speeding up (i.e. from 0 RPM to a targeted 60 or 80 RPM) larger ROM’s occurred. When a desired constant speed (i.e. cadence) was reached it is expected that ankle torques become smaller and P is capable of performing the exercises with minimal losses in control over the ankle joint. This was observed with the camera recordings, because goniometer measurements were running when target cadence is reached and are therefore not included in the data. Besides, recordings are showing that concentration levels are high and the general impression was received that full attention is required during all cycling exercises. It is arguable that P is controlling ankle positioning by actively controlling hip and knee motion to compensate for his lack in control over the ankle joint. Because during low resistance exercises fluctuations are minimal and the motion profiles stay relatively constant which is not the case during the high(er) resistance exercise.

In contrast, the data of exercise PH60 is showing that the patient lost (motion-) control over the ankle joint to overcome the increased resistance. Larger ROM values were found that are substantially higher than presented by Skovereng et al. (2017) in figure 26. According to McCorquodale et al. (2016) joint range of motion (ROM) needs to be limited and protected to avoid the possibility of contractures and maximize functional use of all extremities. A comprehensive evaluation of ROM, sensation, reflexes, strength, and balance should be performed when deciding which ACO settings are suitable for each individual patient.

5.5 CONCLUSION

The results of this user test are indicating that CMT patients with muscle athrophy in the lower legs are experiencing major difficulties in the execution of a full pedal cycle. Mainly due to unsufficient muscle strength in the plantarflexor muscles, which causes difficulties to perform the power phase. Opposingly, similar performances were seen in the recovery phase movements caused by the effected dorsiflexor muscles.

In figure 35, a single pedal cycle is shown, which depicts the current motion profile of the patient (red line), reflected motion profile of the control participant (orange line) and the desired motion profile (green line). It may be noticed that the current motion profile trajectory is inconsistant.

Thus, the goal is to achieve a more (natural) 'smooth' transition and less extreme dorsal flexion of the ankle joint in the power phase, between position (1) and (3). Therefor, additional plantarflexor assistance is needed (see fig. 35). Continuation of the pedal cycle beyond the BDC (5) position will reverse the direction of rotation of the ankle joint, hence will require external assistance in opposite direction to enable dorsiflexor assistance. A bidirectional actuation system should be designed, which is able to control the level of assistance with the required amount of torque.

As previously stated, the amount of torque at the ankle joint is in the order of 50 Nm, inherently the desired level of assistance will range between 0 Nm and 50 Nm. The expected maximum amount of assistance torque will mainly be required for assistance during power phase. By tilting the slope upwards – extend the duration of the slope during push down, the moment at which knee extension occurs can be managed. When sufficient assistance can be subjected during push down, the peak plantarflexor loads can be controlled and the heel will rise directly after push down, hence a more smooth movement can be obtained during power phase.

Furthermore, relative small amounts of assistance torque will be needed to assist the dorsiflexor muscles during recovery phase.

One of the main criteria to overcome a smooth transition between power phase and recovery phase is to control the transition from neutral to a positive ankle joint angle (position). In order to increase pedal efficiency positioning of the ankle joint should be controlled.

It can be concluded that large differences in ankle ROM are caused by pedal resistance rather than pedal cadence. In addition, large differences in ankle ROM is correlated with knee ROM. Thus, rash movements are related – 'hyper' plantar-flexed position (of the ankle) corresponds to 'hyper' flexion of the knee, whereas 'hyper' dorsi-flexed position (of the ankle) corresponds to 'hyper' extension of the knee. However, these circumstances should be avoided a smooth transition is desired between assistance and natural movement thus positioning – i.e. dorsiflexed and plantarflexed position needs to be actively managed. Also, because stability is a point of concern among CMT patients, there must be extra care to avoid falling because fractures take longer to heal in someone with an underlying disease process. Additionally, the resulting inactivity may cause the CMT to worsen (McCorquodale et al., 2016)

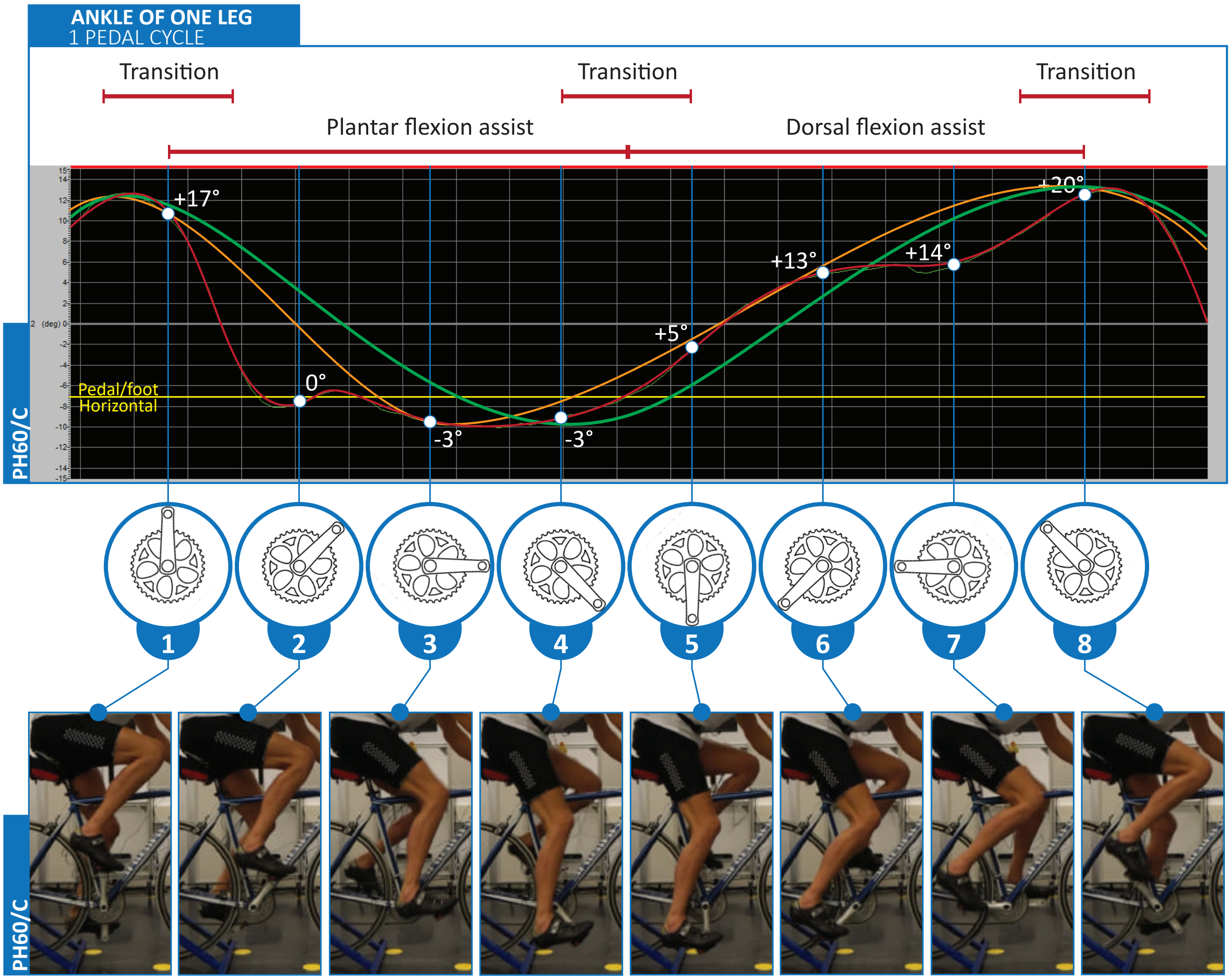
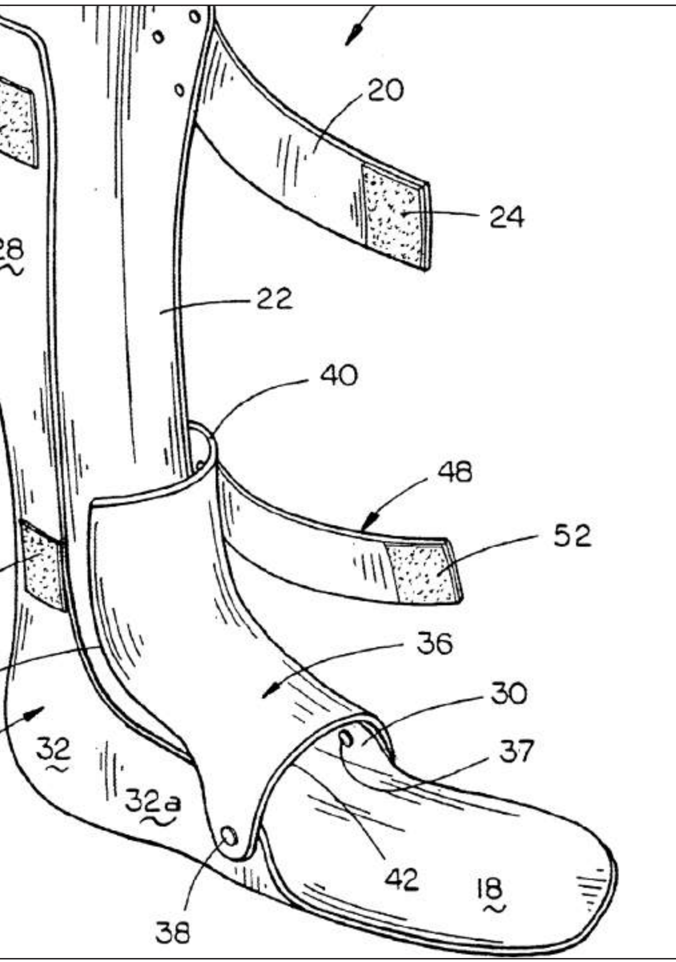


Figure 35: Visualization of the CMT patient motion profile (red line), the reflected motion profile of the control participant (oranje line) and the desired motion profile (red line) which is the reflected interpretation of the analysis in Ch. 4.3. A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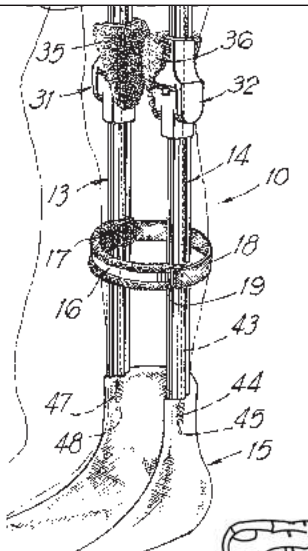
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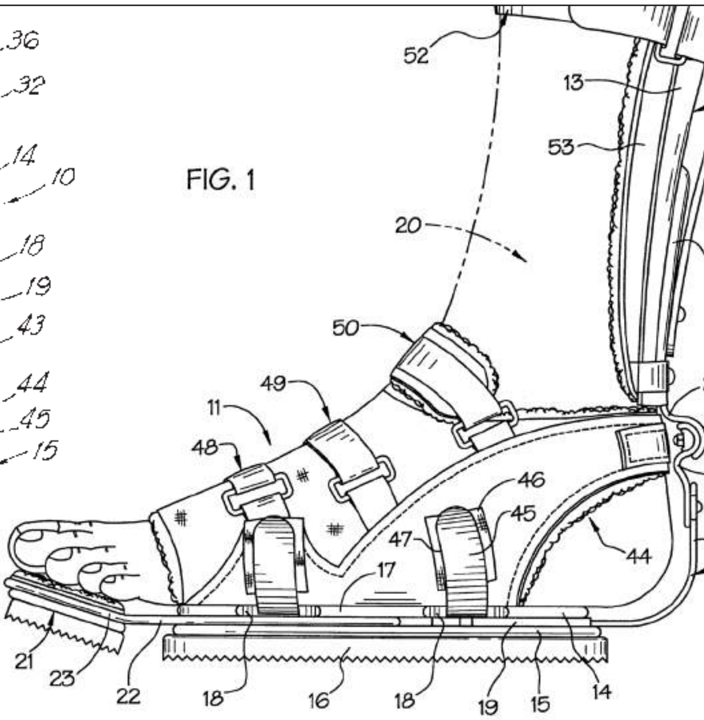
FIG. 1
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YNTHESIS 6

SYNTHESIS 6

6.1 REFLECTION ON THE PROCESS

The process followed in the analysis phase is aggregated in this synthesis section of the report to reflect on the acquired knowledge. After assignment formulation in the pre-phase, the analysis process continued with investigating the experiences of different users with conventional AFO's and their recommendations for future development of the ACO. The data gathered is providing a clear understanding of the design direction in terms of positioning and requested functionality, which converge into a desired rehabilitative tool for physical therapists to treat CMT patients in the process of retaining muscle function. Thus, a cycling orthosis that will be used with professional supervision for rehabilitative treatment rather than an orthosis that can be worn by the patient for daily usage.

After this user analysis the knowledge was gained on a product level, which provided insights about the developments in the field of passive and active orthoses and their characteristics. This product analysis revealed information about orthosis functionality (e.g. transferred forces by the orthosis) and shortcomings for the users.

The next section was seen in the context of the proposed vision. Namely, the cycling activity, in which important aspects that concern biomechanical characteristics of cycling (and associated) are reflected on the design for the envisioned ACO. This context analysis showed the complexity and adaptability of orthoses for the cycling activity. The acknowledged design direction suggested that the active capabilities of the envisioned ACO meets the mechanical performance in terms of cycling mechanics, human mechanics, and actuation characteristics for desired assistance. These aspects are indicating a potential advantage to overcome the transition from a laboratory settings towards a practical orthosis for rehabilitation. Because, ankle joint torques are lower and the presence of a bike that adds to the already existing human-machine interaction.

When adequate knowledge on user characteristics, AFO design characteristics and the cycling characteristics was obtained. A user test was carried out with a CMT patient and a healthy participant to investigate the design challenges in practise. This user test suggested a primary focus on plantarflexion assist and a secondary focus on dorsiflexion assist of the ankle joint. In which range of motion and pedal cadence are important variables to create the desired level of assistance for the CMT patient.

6.2 DESIGN OBJECTIVE

The essence of orthoses can be seen under the umbrella of the desire to improve mobility. An essential element for a successful cycling orthosis is hidden within the final cycling experience. Cycling in this context is a mean to achieve improved mobility (see fig. 36). Inherently, physical utility and mental persuasion among users should be met by the ACO to gain acceptance. Therefore, these two key objectives are seen in the context of two separate design fields. Namely, the functional/mechanical field of design that comprises the physical interaction and physical experience with the ACO. And the communicative/informative field of design that comprises data gathering, processing and conveyance of physical performance data to the users. Both are essential for acceptance and both are contributing to desired usage. However, due to time limitation for this assignment, the primary focus for this assignment is on the functional/mechanical field of design to proof the envisioned working principle that should answer the question ‘if improved direct mobility can be achieved’.

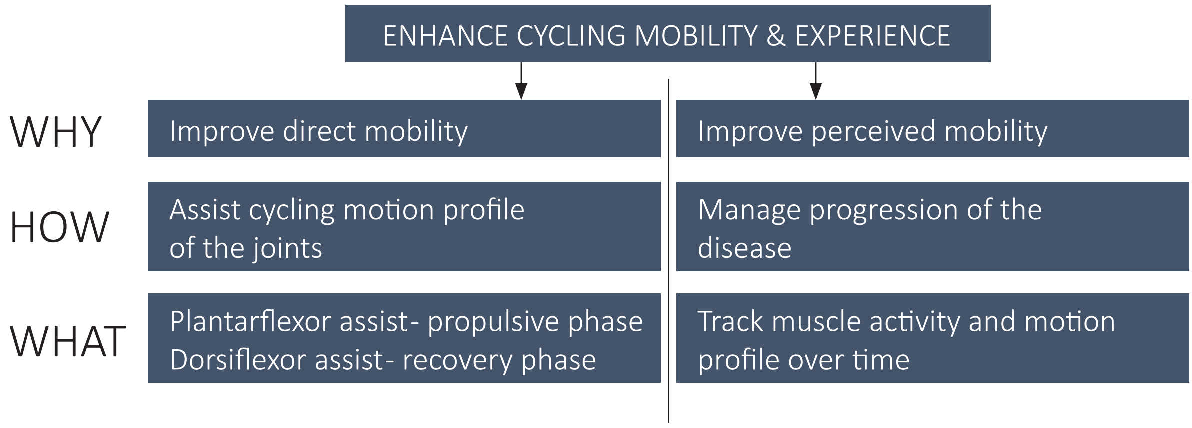


Figure 36: The two different objectives of the ACO that should be met for enhanced cycling mobility and cycling experience.

Based on the insights the functional design objective is formulated as following:

Design of an assistive cycling ankle-foot orthosis that can be mounted on an ergometer bike and used by physical therapist in a rehabilitation program to support the rehabilitative journey of CMT patients to retain muscles function of the lower limb by assisting in both plantar- as dorsal-flexor torque of the ankle joint and can adapt to the anthropometric difference among users.

6.3 DESIGN REQUIREMENTS

Performance

1. Torque assistance of the ACO should be up to 50% (~25 Nm) of the average maximum ankle torque while seated. Average ankle torque with specific healthy anthropometry is around 50 Nm (~0,65Nm/kg body weight).

2. The ACO should enable assistance with a minimal pedal cadence of 60 rpm/min. Therefore, a minimal ankle joint angular velocity of 40 degrees/sec is required. A maximal pedal cadence of 110 rpm/min (i.e. ankle joint angular velocity of 60

degrees/sec) is desired to overcome the full range of cycling disciplines (i.e. seated and standing flat-road cycling – hill climbing).

3. Assistance should be provided for max. 20 degrees of plantar flexor torque starting from a 90 degree angle of the ankle (i.e. horizontal pedal position) to prevent muscle contractures. Derived from the desired full ROM of the ankle joint during cycling.

4. Assistance should be provided for max. 10 degrees of dorsal flexor torque starting from a 90 degree angle of the ankle (i.e. horizontal pedal position) to prevent muscle contractures. Derived from the desired full ROM of the ankle joint during cycling.

5. The pedal range-of-motion should not exceed 30 degrees while performing a full pedal cycle.

6. Assistance should overcome a smooth transition from TDC to BDC. This requirement asks for a smooth transition from dorsiflexion to plantarflexion of the ankle joint with a cushioning effect to maintain comfort during cycling. Referring to the performance of the user test.

7. The left and right ACO should be actuated separately for independent usage. This implies that a separated power source is required for each ACO.

8. The required biomechanical performance of the lower limb should be retained to allow for maximal functional independence to enhance muscle strengthening – i.e. slow down muscle atrophy and sensory losses. Therefore, the ACO should have rehabilitation/training capabilities that promote adequate paddeling to improve cycling gait mechanics.

Installation & ease of use

9. The ACO should be stand-alone attachable and detachable to the crank-arm of an existing ergometer bike (i.e. portable). The pedal axis shaft should be composed according to the standardized pedal axis shaft dimensions of Ø 14mm.

10. The ACO should enable an intuitive entering interaction to ‘step-in and out’ of the ACO. The preferred step-in is to enter the ACO from behind (i.e. toe step in).

11. The ACO should be entered without assistance by physical therapist among others.

12. The ACO should be shoe compatible. However, shinbone needs to be exposed/direct-contact with the ACO for EMG measurement possibility.

Ergonomics

13. Assistance should be within the sagittal plane of the lower limb to overcome foot drop and isolates inversion and eversion movement of the ankle joint (i.e. provide stability of the ankle joint in transversal and frontal plane).

14. The ACO should comply with the body anthropometric morphology.

15. The ACO should comply with the joint excursion.

16. Adaptability of the ACO should comply with the biometric differences among users – i.e. foot size, tibial length, circumference of the different body parts, muscle strength and body weight.

17. The rigid parts of the ACO that are in contact with the skin should prevent skin breakdown due to hard contact surfaces and/or edges.

18. The weight of the ACO carried by the user due to imbalance of the ACO should be < 25% of total weight (max. 2,5 kg).

Materials

19. Padding for sufficient cushioning in the strapping parts, foot sole and shin support elements. A spacer/sandwiched material is preferred with pressure reduction textures/structures to avoid skin breakdown and skin irritation.

20. Materials that are in contact with the skin should be breathable to avoid heat build-up and support moisture drainage.

21 Rigid foot-sole of a lightweight and form-retaining material to gradually transfer forces onto the pedal. This requirement is important to minimize effort of foot muscles.

22. The selected constructive materials should withstand the applied forces for structural integrity and force transfer conversion.

Safety & Reliability

23. A release system is required for quick step-out and acute actuation stop. The connection points to the body should be designed in a way that the user can release itself independently from the ACO with minimal effort.

24. The ACO should measure muscle activity.

25. The ACO should be able to keep track of performed pedal cycles

26. The ACO should maintain proper alignment concerning ACO hinge joints versus human joints to prevent potential (skin) irritation/friction and increased stress around the ankle joint. A maximal displacement of 10 mm superior, inferior, anterior and posterior with respect to the ankle centre of rotation and hinging mechanism of the ACO is required.

Life duration

27. The ACO needs to provide assistance with a minimal of 30 min. per exercise. Thus, the ACO should be able to assist during 1800 full pedal cycles per exercise (i.e. 60 rpm/min * 30min = 1800 cycles per exercise). This requirement is derived from the American Heart Association (AHA) guidelines for a person who is not obese nor very out of shape. AHA calls for a minimum of 30 minutes of aerobic physical activity performed at moderate intensity (60-80 percent maximum heart rate) either in one continuous period or in intervals of at least 20-minute.

28. The ACO should have a minimal life expectancy of minimal 2 years of usage. With 3 exercises per day, the life expectancy of the ACO should be in the order of 5400 cycles per day, gives an approximate lifespan of 3.942.000 cycles (i.e. 5400 cycles/day * 730 days = 3.942.000 cycles).

Size & weight

29. The maximum height of the ACO is 470 mm. Based on distance between knee and foot sole (~420 mm) according to the DINED database among adult users (age 20 and older), plus constructive space (~50 mm).

30. The maximum width of the ACO is 400 mm. Based on foot length (~275 mm) according to the DINED database among adult users (age 20 and older), plus shoes (~50 mm), plus constructive space (~75 mm).

31. The maximum depth of the ACO is 195 mm. Based on foot breadth (~105 mm) according to the DINED database among adult users (age 20 and older), plus space between foot and crankarm (~40 mm), plus constructive space (~50 mm).

32. The majority of the weight should be carried by the crankarm of the bike. Other functional components should be close to the Centre of Mass (CoM) of the ankle joint. The preferred CoM of the ACO is vertically aligned with pedal axis to prevent imbalance of the ACO (i.e. weight carried by the pedal instead of weight carried by user).

33. The total weight of the ACO should not exceed 10 kg.

Maintenance, Reuse and Recycle

34. It is expected that the ACO will be used by multiple users, cleaning and maintenance of individual components is required. Especially, the shin support padding should be cleanable by hand (or washing machine). Because, the shinbone of the user will be exposed to its designated contact surface.

35. The design should be compatible to replace

worn out components to extend life duration and conserve performance.

Costs

35. The overall costs for production of the ACO should be in the range of ~2500 Euros. Based on sales price of ~2000 Euros for passive custom-made carbon fibre AFO's.

6.3.1 LIST OF REQUIREMENTS

NR.	REQUIREMENT	VALUE
1	Minimal Torque assistance	~25 Nm
2	Enable assistance with a minimal pedal cadence of 60 rpm/min (expressed in ankle joint angular velocity)	40 degrees/sec
3	Maximum plantar flexion angular rotation, starting from a 90 degree angle of the ankle (i.e. horizontal pedal position)	20 degrees
4	Maximum dorsal flexion angular rotation, starting from a 90 degree angle of the ankle (i.e. horizontal pedal position)	10 degrees
5	Maximum pedal range-of-motion	30 degrees
6	Assistance should overcome a smooth transition from TDC to BDC	N/A
7	Left and right ACO should be actuated separately for independent usage	N/A
8	Biomechanical performance of the lower limb should be retained to allow for maximal functional independence	N/A
9	Add-on existing bike/ergometers (stand-alone/portable)	Pedal shaft Ø 14mm
10	Step-in from behind (i.e. toe step in)	N/A
11	Entering without assistance by physical therapist	N/A
12	Shoe compatible	N/A
13	Assistance within the sagittal plane of the lower limb	N/A
14	The ACO should comply with the body anthropometric morphology.	N/A
15	The ACO should comply with the joint excursion.	N/A
16	Adaptability of the ACO should comply with the biometric differences among users	N/A
17	Prevent skin breakdown due to hard contact surfaces and/or edges	N/A
18	Maximal weight of the ACO carried by the user	~2,5 Kg
19	Padding for sufficient cushioning in the strapping parts, foot sole and shin support elements	N/A
20	Breathable material selection to avoid heat build-up and support moisture drainage	N/A
21	Rigid foot sole of lightweight and form-retaining material	N/A

Table 1: Design Requirements summarized in List Of Requirements *(continued on next page)*

NR.	REQUIREMENT	VALUE
22	Constructive materials should withstand the applied forces	N/A
23	Release system for quick step-out and acute actuation stop	N/A
24	Track muscle activity	mV
25	Track of performed pedal cycles and muscle activity	RPM
26	Maximal misalignment between human joint and ACO hinge joint	10 mm
27	Minimal assistance (actuation time) of 30 min. per exercise	1800 cycles/exercise
28	Minimal life expectancy of minimal 2 years of usage (with 3 exercises per day)	3.942.000 cycles
29	The maximum height of the ACO	470 mm
30	The maximum width of the ACO	400 mm
31	The maximum depth of the ACO	195 mm
32	Weight distribution on crankarm of the bike	~7,5 Kg
33	Total weight of the ACO	~10 Kg
34	Cleaning and maintenance of individual components by hand (or washing machine)	N/A
35	Compatible to replace worn out components	N/A
36	Costs for production of the ACO	~1500 EUR

Table 1: Design Requirements summarized in List Of Requirements

CONCEPT PHASE II

7 DESIGN EXPLORATION

7.1 INTRODUCTION

DESIGN EXPLORATION 7

The final design direction was derived from the analysis and synthesized into a theoretical statement, which essentially lays the foundation to proceed with the concept phase. The gathered knowledge on user-, product- and contextual needs as well as requirements are accumulating a fundamental basis for concept development. Hence, in this phase of the project, design explorative knowledge (Ch. 7) is generated which evolved from each creative design step that, among others, is constituted in the constructive design chapter (Ch. 8). Therefore, this concept phase is subdivided into an explorative part and a constructive part. The explorative design part (Ch.7) addresses practical/functional foreknowledge to create feasible concepts which includes design considerations, aspects of motion, and aspects of actuation. In the constructive design part (Ch. 8) design ideas are translated into 3D modeled concepts that are ready for review and concept choice.

7.2 ABSTRACT WORKING PRINCIPLES

After the product analysis (Ch. 3) it was noticed that active orthoses often appear to be heavy, rigid and bulky with few exceptions (e.g. bio-inspired soft wearable robotic device by Park et al., 2014). According to Veale & Xie (2016), this is caused by robust mechanical structures and industrial actuator components. Whereas an effective active orthoses must, in general, be light, compliant and portable (Veale & Xie, 2016). Thus, in this line of thought, a first iterative design step was made with the design of abstract schematic working mechanisms wherein cable-based, gear-based and linkage-based, or with combined power transmission methods.

7.2.1 CABLE-BASED WORKING PRINCIPLE

The process of ideation started with defining the anchor points for a cable-based linkage to obtain maximal torque assistance around the ankle joint. Figure 37 shows the first thoughts on this matter – the anchor point should be as far away as possible from the joint to increase the torque (see fig. 37). In addition, the cable which is responsible for plantarflexion (red line) should enable a clockwise rotational direction and is attached to the heel. Whereas, the cable for dorsiflexion (green line) is attached on the toe-side and is guided above the ankle joint to enable a counter-clockwise rotation. By means of two hydraulic actuators (‘heelpump’ and ‘toepump’, see fig. 38 and 39) a distinction was made between Active Assistance (AA) – i.e. in-line with the intended movement of the joint, and Active Resistance (AR) – i.e. which can be seen as a slip characteristic to delay the plantarflexion/ dorsiflexion motion when releasing (see fig. 37).

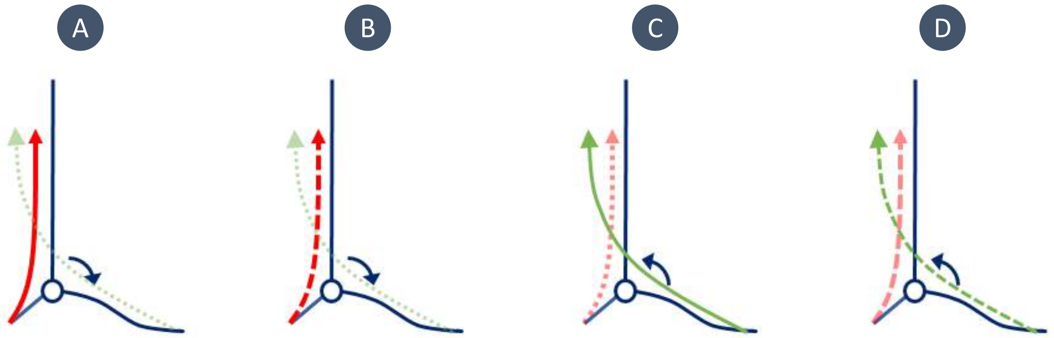


Figure 37: Visualisation of the anchor point fixation and movement trajectories for a cable-based working principle. Plantarflexion assist (A and B), dorsiflexion assist (C and D). Powered gear pump – creates active assistance, because $F_{actuator}$>F_{human} (solid line), Unpowered gear pump – released/freewheeling of cable (round-dotted line), Active resistance of gear pump – creates slipping effect (striped-dotted line).

7.2.2 GEAR-PUMP MECHANISM

A mechanism was designed (see fig. 38) which possess two hydraulic cylinders, a buffer vessel, and an active 'gear pump' unit for activation/pulling of the cables. The active 'gear pump' principle works as following; if one cylinder (e.g. heelpump) is pulling on the cable (i.e. AA; wherein $F_{actuator} > F_{human}$), the other one (e.g. toepump) should be released. Releasing (or freewheeling) can be combined with resistance (of the gear pump) if gear pump is activated/controlled with low speed (i.e. AR/PR; wherein $F_{actuator} < F_{human}$). Resulting in six control possibilities for the schematic mechanical structure (M1) shown in fig. 39.

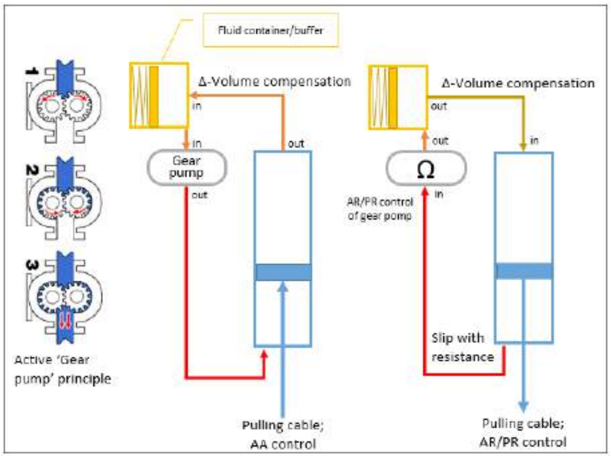


Figure 38: System composition and hydraulic flow for activation of a gear-pump working mechanism.

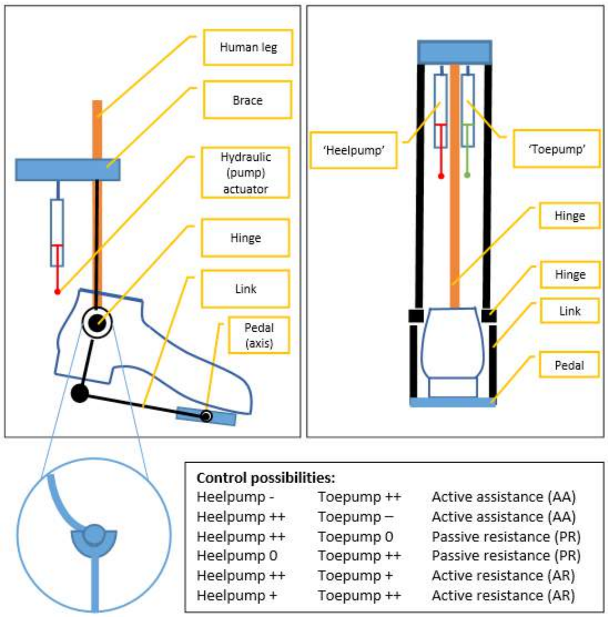


Figure 39: Schematic mechanical structure (M1) for a cable-based gear-pump mechanism with control possibilities scheme.

7.2.3 DESIGN VARIATIONS

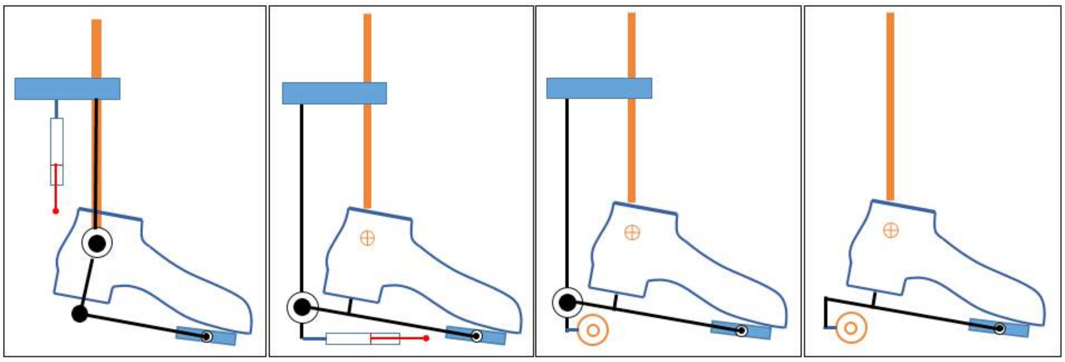


Figure 40: Overview of the designed abstract working mechanisms.

With the previously discussed working mechanism several configurations were designed (see fig. 40). Note that, M2 and M3 have a similar cable-based working principle, wherein the gear-pump mechanism in M2 is replaced by an electric motor for activation of the cables (see fig. 41). Within mechanisms M2 and M3 a sliding link is integrated, which allows for a sliding movement of the hinge (located behind the heel). This feature enables the assistive motion of the ankle joint as shown in figure 42. When the cable is retracted by the actuator, the cable trajectory lifts the heel of the patient in order to assist in plantarflexion. Likewise, when the actuator releases the tension on the cable the

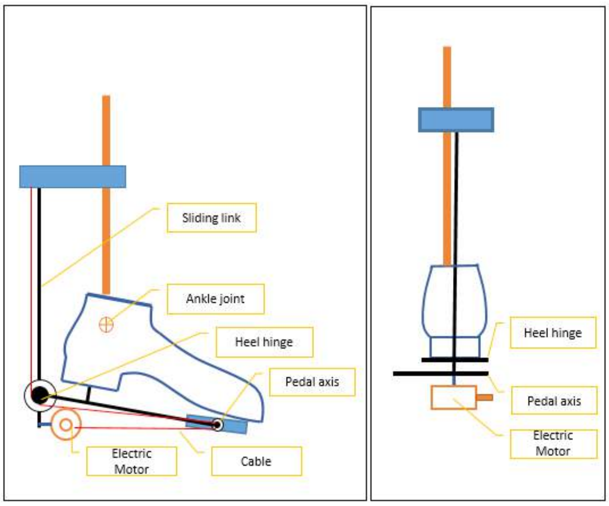


Figure 41: Schematic mechanical structure (M3) with an electric motor for retraction/release of the cables.

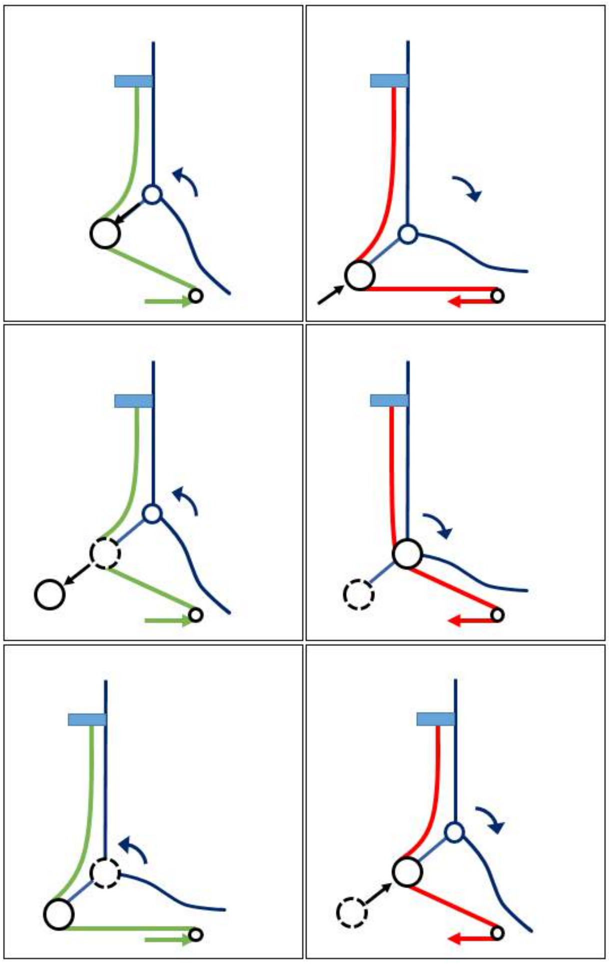


Figure 42: Plantarflexion(A)/dorsiflexion(B) assistance technique for M2 and M3.

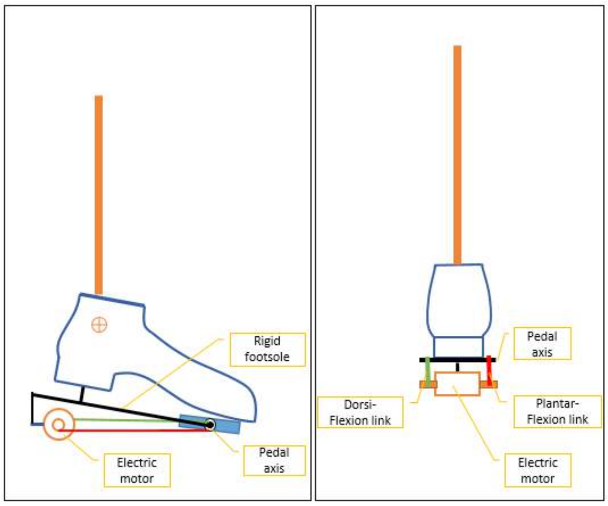


Figure 43: Schematic mechanical structure (M4) including an electro motoric mechanism with geared- or chain-based transmission links to enable rotational motion of the pedal-axis.

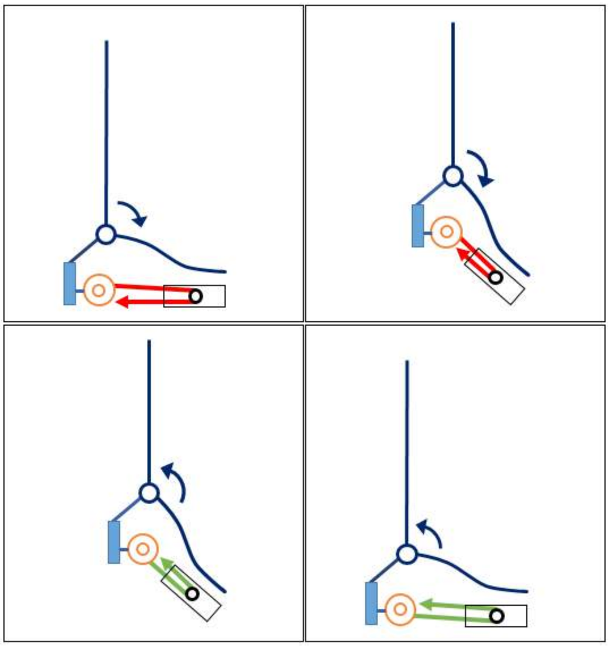


Figure 44: Plantarflexion(A)/dorsiflexion(B) assistance technique for M4.

heel of the patient will fall down and assist in the dorsiflexed motion (see fig. 42). In a similar fashion the gear-pump mechanism of M2 will function at which two hydraulic actuators are responsible for activation as described in 7.2.2.

Mechanism M4 (see fig, 43) introduces a different strategy to assist in plantarflexion/dorsiflexion by solely controlling the position of the pedal. The pedal is connected with the electric motor by means of a geared- or chain-based linkage, which enables the changing position of the pedal (see fig. 44). However, after assessing the kinematic behaviour of the ankle joint it is expected that this configuration causes instability of the ankle joint (due to absence of support in external/internal rotation of the tibia supported by the brace) which is not preferred considering the rehabilitative management of CMT patients.

7.3 DESIGN CONSIDERATIONS

The ACO is a mechatronic device that combines elements of a mechanical structure, sensor, actuator and controller. In this design stage, some important considerations had to be made concerning the degrees of freedom, assistance technique, application interference, human intention detection, actuator type, sensing and control strategies.

7.3.1 DEGREES OF FREEDOM

The development of the ACO is dependent on the maximum number of independent displacements or motions at the joints, which is defined as the degrees of freedom (DOF's). To avoid contractures (i.e. safety), and maximum comfort on the bike, a natural ankling movement of the lower limbs should be preserved. Inherently, the ACO should possess ergonomic properties that fit the anthropomorphic characteristics of the patients' lower limbs. For instance, cycling is a three-dimensional activity whereof the ankle, knee and hip joints are all cooperating to perform a full pedal cycle.

Thus, when looking at the joints of the lower limb, the hip joint allows 3 DOFs to perform flexion/extension (f/e), abduction/adduction (ab/ad) and internal/external (i/e) rotation. At the knee, 2 DOFs are allowed for flexion/extension (f/e) of the knee and to rotate the knee around the center of rotation of the joint when flexed. At the ankle, there are 3 DOFs, namely plantarflexion/dorsiflexion (p/d), abduction/adduction (ab/ad) and inversion/eversion (i/e) motions (Crowell, 1995).

Moreover, the ankle joint is able to perform two specialized movement types (i.e. supination/pronation) based on a combination of the previously mentioned ankle joint movements. Thus, ideally the ACO should also possess 3 DOFs in order to cater the natural cycling motion.

However, when only focusing on the leg region of the lower limb the primary activity of the cyclist occurs in the sagittal plane. Furthermore, despite the desire to meet the 3 DOF's of the complex ankle joint, CMT patients are frequent recipients of ankle instability which is caused by the bilateral strength differences and progressive foot deformity due to muscle atrophy and the progressive character of the disease which is causing an imbalance of the ankle joint (McCorquodale et al., 2016). In aid to overcome the aforementioned limitations the decision was made to fixate the i/e and ab/ad movements and only focus the design on p/d movements (i.e. 1 DOF) to regain mediolateral stability of the subtalar joint which are generally poor among flexible AFO's (ICRC, 2018).

7.3.2 APPLICATION INTERFERENCE

The spatial freedom for design of the ACO should be kept in mind for the context of use. Within the current set-up, a stationary ergometer bike is used for the application which could cause obstruction with the orthosis (i.e. because the bike will affect the freedom of movement) while performing a full pedal cycle if the design becomes too bulky. Inherently, account must be taken while dimensioning the ACO to avoid possible interfere with the floor, crank-arm, upper leg and front-wheel (e.g. when the ACO is potentially suitable for the application on a 'normal' road bike among others). Furthermore, anthropometrics data was gathered from the DINED database (2018) to shape an artificial lower leg to create a realistic representation of the available space by measuring the minimal distances with the measuring 3D CAD tool (SolidWorks 2017).

The kinematic motion analysis of Gilbertson (2008) is used as an under-layer to trace the trajectory of the instantaneous bone/joint positions (see fig. 45). The extracted data is shown at 1/5 cycle increments from the side view for each position.

At position C, a minimal distance of ±100mm was measured between pedal-axis and floor when pedal is positioned at BDC.

At position B, there is limited space available on the anterior side of the lower leg. The toes of the patient are close to the front-wheel and could cause obstruction if the design deviates more than ±10 mm relative to the toes, and ±200 mm relative to the shinbone.

Furthermore, at the posterior side of the leg interference with the upper leg is possible due to flexion of the knee joint which can be seen during the recovery phase of the pedal cycle (i.e. positions D and E). Although, if the design is no longer than ±370 mm relative to the heel there is relatively 'infinite' space available behind the calf muscles. From a lateral viewpoint there is no limitation for the design, whereas on the medial side of leg caution must be taken for interference with the crank-arm, a small space is available of ±20 mm between the current foot-position and the crank-arm design considerations can be made to marginally extend the pedal-axis to create more spatial freedom.

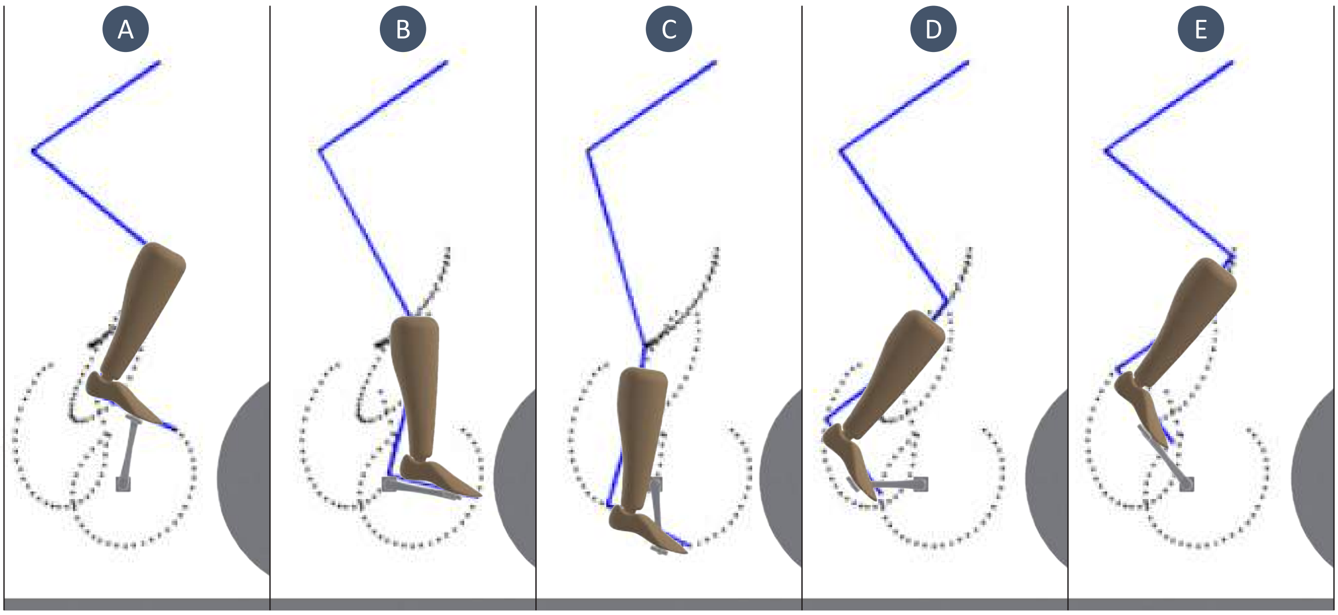


Figure 45: Merged visualisation of spacial freedom with kinematic motion analysis of Gilbertson (2008).

7.3.3 ASSISTANCE TECHNIQUE

According to Viteckova et al. (2013) an important aspect to consider for exoskeleton systems is the initial technique of assistance. One of the key concerns for the ACO is the attainment of an optimal assistance technique. There are in essence three main approaches that all have their implications on the composition of the ACO in terms of sensing, actuation, and control of the system. The first approach concerns a constant assistance technique in which the ankle of the patient is fixed and guided throughout the full pedal cycle (i.e. ankle receives constant assistance). Although, it is expected that this technique requires the least complexity for the composition of the system – i.e. autonomous/self-contained system. This technique does not meet the intended functionality of the ACO. Because of the decomposed involvement of the human element that plays an essential role in the rehabilitation process of the patient.

A second approach is a partial assistance technique with mixed conditions in which the level of assistance is segmented according to the pedal phases within the full pedal cycle (e.g. power phase; constant assistance – recovery phase; variable assistance). Referring to the user test and the biomechanics of cycling, it can be stated that the largest amount of effort is requested during the power phase and constant assistance is preferred. Consecutively, variable assistance can be applied when less effort is requested – e.g. recovery phase. Although this approach seems interesting to consider it is expected that major challenges arise to overcome a smooth transition between the two states.

The third approach, is expected to be the most desired assistance technique for the ACO. Namely, it will assist the patient only when needed and only as much as needed, so that the patients are encouraged to make the effort whenever they have the motor output to do so. Within this approach, the system is reaching its full potential, because the assistance technique is taking into account the intra- and inter-individual differences among patients to gain optimal (personalized) physiological performances.

7.3.4 HUMAN INTENTION DETECTION

To control the ACO and provide intelligent, effective, and comfortable assistance to the cyclist, it is essential to deploy different types of component to gather motion data of the human-orthosis system to recognize the patients' motion intention, analyse the motion status, cyclic continuity of the pedals, and evaluate the motion performance. The sensors that can be used for this can have either a cognitive-based or physical-based nature.

The cognitive-based sensors (or bioelectric sensors) are able to detect electrical signals from the nervous- or muscular system of the patient. For example, muscular activity can be measured by means of electromyography (EMG) and mechano-myography using a muscle stiffness sensor (MSS), muscle tenseness sensor, and ultrasonic muscle activity sensor. Bioelectric sensors have been used in many active orthoses. However, there are some inherent limitations to overcome. For example, the calibration of bioelectric sensors takes substantial time, and neighbouring sensor nodes and noise easily interfere with the collected bioelectric signals (Chen et al., 2016).

Physical-based sensors are able to measure the motion of the cyclist or motion of varies bike components. For example, encoders, potentiometers, accelerometers, inclinometers and gyrometers capture position and motion. In addition, force and pressure can be measured by a force sensor, torque sensor, pressure sensor, strain gauge and a piezoelectric sensor (Aliman et al., 2017).

Currently, mechanical (MEC) signals and electromyography (EMG) signals, or a combination of both, are the main measured signals among lower limb orthoses, prostheses, and exoskeletons (Jiménez-Fabián & Verlinden, 2012; Yan et al, 2015).

Another option would be to implement tactile sensor arrays that detect foot switch phases (Veneva & Boiadjiev, 2009). However, these switching sensors seems more applicable for walking gait activities since deformation of the foot is not favourable for the cycling activity.

Furthermore, it is important to consider the actual movements of bike components, such as orientation of the pedals and/or orientation of the crank-arms. The same applies to measuring the intended movement of the ankle joint of the cyclist and/or movement of the artificial joint – in order to help patients to guide the trajectory of their movements (e.g. motion profile of the ankle joint) and facilitating labor-intensiveness by decreasing the load action (e.g. measuring the physical capacity – i.e. muscle strength for the intended movements). Thus, the ACO should be equipped with both, cognitive-based sensors and physical-based sensors to achieve rehabilitative, assistive and empowering capabilities.

7.3.5 CYCLIC CONTINUITY

From a sensing and control perspective it is therefore interesting to consider the cyclic motion of the ankle in both legs with a cyclic opposite position of the pedal (e.g. when right pedal is TDC, right pedal is BDC). This continuity is a useful control variable and is usually divided into two main phases – i.e. the power phase and the recovery phase. For example, when the right pedal is at TDC, the right leg enables the power phase. Whereas, on the other side of the bike, the left leg enables the recovery phase. Exploiting the fact that pedaling is predominantly cyclic and that the pedal cycles can be divided into different subphases for which a particular mechanical behaviour of the ankle can be distinguished.

There are numerous ways to detect the cyclic movement of the pedals – partly because the centre of rotation is around the crank-axis. A variety of sensors can be used that are previously discussed in Ch.7.3.4.. The recognition of this cyclic behaviour can be either by sensing the angular position of the crank-axis itself, by sensing the angular position of the pedal, or examine the relationship between the orientation of the pedal relative to the opposing pedal (or crank-arm).

Note that during cycling the rotation of the pedal-axis is contrary and proportional to the rotation of the crank-axis – i.e. crank-axis rotation; clockwise, pedal-axis rotation; counter-clockwise. Thus, when controlling the assistance motion of the brace account must be taken with the natural rotation of the pedal.

7.4 MOTION DATA ACQUISITION AND CONTROL

The insights of the user test in Ch. 5 are providing a clear understanding of the desired working principle to aim for the right motion assistance. The desired motion profile of the ankle joint is established and provides a clear design challenge (see fig. 35 in Ch. 5). Assistance in the power phase of the pedal cycle is therefore one of the core features that could make great improvements in the overall kinematic behaviour of the disabled cyclist. From this theoretical approach it was recognized that existing sensor technologies, control mechanisms and different types of actuators needed to be explored before going further into concept development.

7.4.1 SENSOR SELECTION

On acquiring motion data, the ACOs' motion assistance can be initiated according to the human intention. To sense the kinematic state of the cyclist a multiple sensor system is selected as following;

The selected cognitive-based EMG sensor is selected to detect innervation patterns (i.e. onset and offset of muscle contractions) of the lower leg muscles (i.e. Gastrocnemius Lateralis (GL), Gastrocnemius Medialis (GM), Tibialis Anterior (TA) and potentially Soleus (SOL)). Thus, for management of the actuator the patients' muscle activity pattern shell be used for two reasons. Firstly, to detect onset activation patterns of the muscles to enable the right onset for assistance. Secondly, to identify the level of assistance needed within the different stages of the pedal cycle based on the magnitude of the signal.

In each cycling phase the control system tries to emulate the behavior of a healthy leg, considering the typical direction of motion (i.e. plantarflexion or dorsalflexion) and the level of muscle activation (reflected by the EMG signals). The patients' voluntary effort could be estimated based on the measured interaction forces between the wearer and the orthosis. Assistance from the device could then be adjusted in real-time in accordance with the patients' effort and need.

The desired physical-based sensor is a gyro sensor which will be applied on the pedal and artificial joint. This sensor is capable of sensing angular velocity – to sense the amount of angular velocity produced, and angle sensing – to sense the angular velocity produced by the movement of the sensor itself on the pedal/joint. Angles are detected by a CPU. Thus, the moved angle is fed to and reflected in an application. However, Dollar & Herr (2008) reported that it took them two months to optimally calibrate the system for a specific user. An alternative, and probably less time-consuming option, would be to select an encoder type (e.g. rotary or optical) to sense angular velocity and angle of the pedal and joint.

7.4.2 CONTROL STRATEGIES

Due to the growing field of wearable robotics there are numerous of ways to control the ACO. In order to make the right decision on how to control the ACO it is wise to explore the possible opportunities that existing control systems have to offer. Generally, the patient and active orthosis are forming a closed loop, as shown (see fig. 46) in the human-exoskeleton cooperation system developed by Chen et al. (2016).

According to Chen et al. (2016) control strategies for rehabilitation can be divided into two main categories: (1) trajectory tracking, and (2) assist as needed (AAN). Trajectory tracking control is the most widely used control strategy for exoskeletons in human locomotion assistance applications. In trajectory tracking control, the predefined trajectories which are usually collected from healthy

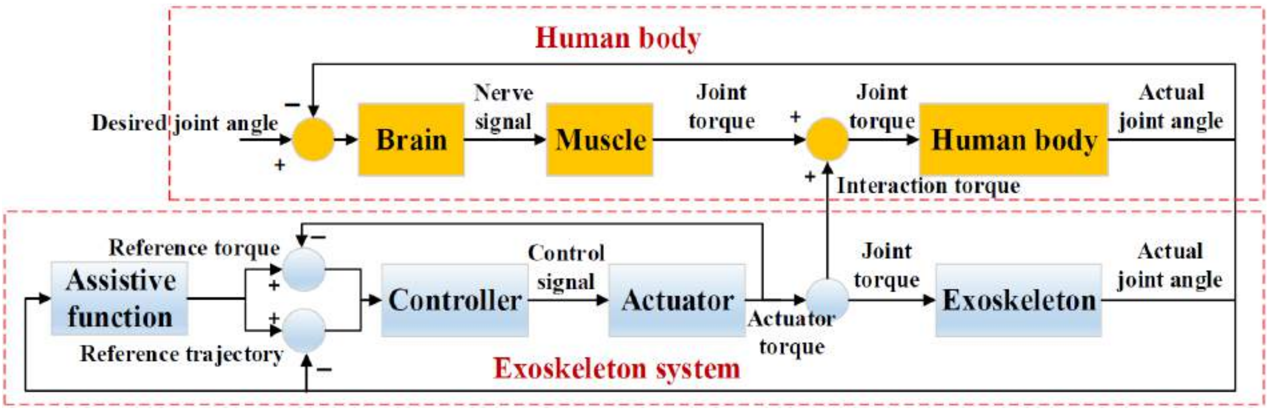


Figure 46: Schematic of the human-exoskeleton cooperation system (Chen et al., 2016)

individuals, are used as control targets. However, by using this kind of control, the wearers are normally passively trained to follow a predefined reference trajectory and their initiatives or motivations are usually not considered.

By contrast, the AAN strategy suggests that the assistive devices only supply as much effort to the patient as a needs to accomplish rehabilitative tasks by assessing the patients' performance in real-time. The assistance from assistive device is expected to be intelligently adjusted according to the patients' physical conditions and efforts in rehabilitation to encourage their voluntary participation.

Several studies emphasise on different distinctive control strategies for assistive devices, such as; position control, predefined (gait) trajectory control, predefined actions based on gait patterns, supervisory control, model-based control, impedance control, adaptive/variable impedance control, high-sensitivity control, adaptive oscillator-based control, fuzzy control, muscle stiffness control, proportional myoelectrical control, and hybrid control strategies (Anam & Al-Jumaily, 2012; Jiménez-Fabián & Verlinden, 2012; Yan et al, 2015; Chen et al., 2016; Aliman et al., 2017). However, these control strategies are generally adapted to the type of exoskeleton in which type of joint, type of activity, and type of actuator play their part. For multi- and single-joint assistive devices the most common strategy seems to be model-based. The most interesting for the ACO seems to be fuzzy-control, proportional myoelectric control (see fig. 47) or model-based control (see fig. 48).

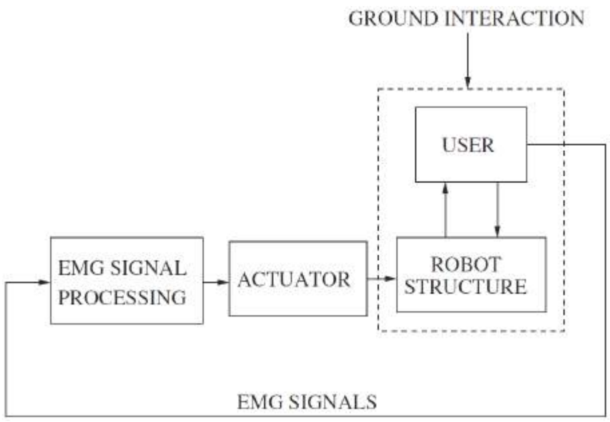


Figure 47: Schematic proportional myoelectric control scheme (Jiménez-Fabián & Verlinden, 2012)

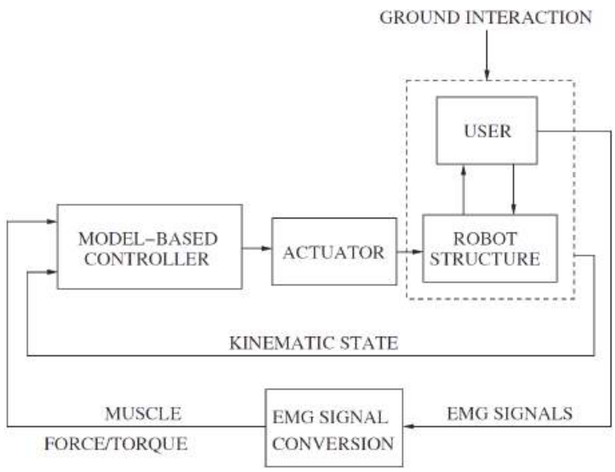


Figure 48: Schematic model-based control scheme (Jiménez-Fabián & Verlinden, 2012)

7.4.3 CONTROL SELECTION

In the previous section, several control strategies were mentioned. After assessing the different control strategies, fuzzy-control, proportional myoelectric control and model-based control are favourable.

Moreover, Kochhar et al. (2016) suggests that active AFO's require a control system which can train by itself to adapt on the situation to support assistive movements. Therefore, a potentially suitable control method for the ACO could be to make use of the fuzzy logic control method described by Kochhar et al. (2016). Wherein, motion data collected by means of a gyro sensor and muscle activation patterns collected by EMG sensors can be fed into the fuzzy inference system (FIS). Hence, EMG signals, angular velocity and angle (of the pedal) can be used as input variables (i.e. membership functions) for actuation of the system. Subsequently, the input data can be compared with a rule base that describes the 'perfect pedal cycle' with corresponding membership functions at given phases within the cycle. Based on the difference between the fed data and the kinematic state of the cyclist a real-time learning algorithms may be implemented to compensate for variations in muscle response (or even lack of muscle response), so that desired assistance of the ankle joint may be achieved. According to Kochhar et al. (2016) the FIS is capable of predicting phases of (walking) gait with high degree of accuracy and repeatability, invariant of the level of motor impairment. Thus, use of fuzzy networks can prove to be a viable option for correcting gait pattern of an affected patient (Kochhar et al, 2016).

Even though, the fuzzy controller seems to be a promising control technique for the ACO it will not be selected for implementation, because the method currently only exists in a MATLAB simulation environment for active AFO development described by Kochhar et al. (2016).

Furthermore, preferences go to the proportional myoelectric controller, because of intuitive AAN strategy. However, the trajectory of the pedal or joint is not implemented in this configuration needed for validation of a correct kinematic posture on the bike.

Therefore, the decision is made to choice a model-based strategy for controlling the ACO (i.e. including kinematic state data). Even though, Veneman et al. (2006) is suggesting that physical guiding may decrease motor learning, and the patients' effort and participation in training – the level of guidance is programmable and can eventually be tuned/tailored to the individual.

Hence, the model-based control strategy can be devided into two types: the dynamic model and the muscle model based control (Anam & Al-Jumaily, 2012). The dynamic model can be obtained through three ways; the mathematical model, the system identification and the artificial intelligent method described by Anam & Al-Jumaily (2016). Besides, the dynamic models, the muscle model predicts the muscle forces deployed by the patients' EMG signals (i.e. input; EMG signals, output; force estimation). Thus, the EMG signals shell be converted to muscle forces and serve also as inputs for the model-based controller. Moreover, angular velocity and pedal or joint angles (i.e. angles of the ankle) input variables can be fed into a position control system. For example, the position control scheme depicted in figure 49 can be used to enable the actuator of the ACO to turn to the desired angle. The model-based controller should estimate the kinematic state of the user and the intrinsic mechanical impedance of the joint for establishing the desired level of assistance.

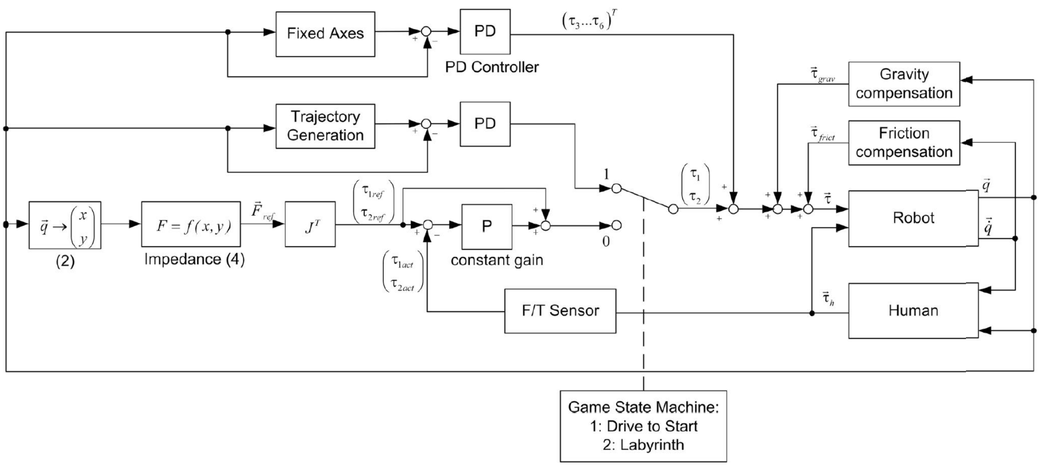


Figure 49: Example of a position control system applied in the ARMin III exoskeleton(Nef et al., 2007).

7.5 ACTUATION

Previously, it was mentioned that a substantial component for concept selection is determined on the basis of the actuator. The actuator is in essence the artificial muscle of the patient and is the component responsible for exerting assistive force/torque. Therefore the actuator is essential for energy conversion, which transforms electric current, hydraulic fluid pressure, or pneumatic pressure into mechanical motion of the ACO.

7.5.1 ACTUATORS

The criteria for a suitable actuator emerged from the knowledge on the desired motion profile of the patients' ankle joint on the bike. Together with the main performance requirement for plantar- and dorsal flexor assist with required torque of around 25 Nm and with an angular velocity of minimal 40 degrees/sec a suitable actuator can be found. Alongside these main performance requirements, also other criteria play their part which is proposed in the list of requirements (see Ch. 6.3.1.). In addition, the compactness/shape, the overall weight, noise, efficiency, cost, and external force control capabilities of the actuator – i.e. cushioning effect/spring characteristics for smooth transferral of external (human) forces. According to several studies, this last criteria is one of the essential criteria for an assistive devices, because the actuator should mimic the performance of a healthy human (muscle) functioning. Moreover, actuators should enable these spring characteristics to collaborate between human muscle and artificial muscle. These actuators are generally known as Series Elastic Actuators (SEA) and characteristics of which appear in the core linear actuator technologies. Namely, electric motors (EC-SEA), hydraulic cylinders (HC-SEA), pneumatic cylinders or PMA's (PC-SEA), examples of those are shown in figure 50. In addition, figure 51 summarizes the primary selection reasons composed by Veale & Xie (2016) which is consulted for the selection of a suitable actuator technology in Ch. 7.5.2..

Actuator technology	Selection reason
Electric motors	High specific power
	Easy to control
Hydraulic cylinders	Compact
	High specific power
	High force output
	Wide control bandwidth
	Low mass
	Compact
	Smooth actuation
	Fast response to a change in input
	Actuator can be remotely located
	Force output and speed scales with actuator dimensions or operating pressure
Pneumatic cylinders and PMA	High specific power
	High specific force
	Inherent compliance
	Low mass
	Low cost
	Hygienic
	Flexibility and softness of biological muscle (PMA)
	Elastic load-displacement characteristics
	Low profile
	Quiet
	No energy required to generate a blocking force
	Compliance similar to human joint
	Reduced control bandwidth due to compliance
	Backdrivable
	Easily integrated with orthosis and user's clothing
	Variable compliance through antagonistic actuation
	Robust to wet and dirty environments
	Force output scales with actuator dimensions or operating pressure

Figure 51: Core actuator technology selection reasons (Veale & Xie, 2016)

Figure 50: Examples of the core linear actuator (Series Elastic Actuator) technologies; (A) Electric motor (Apptronik, 2017), (B) Hydraulic or Pneumatic cylinders (SMC, 2017), (C) Pneumatic Muscle Actuator (PMA) (Festo, 2017).

7.5.2 ACTUATOR SELECTION

Series elastic actuators (SEA) are seen as one of the possible well-adapted technologies in the field of assistive devices. Double SEA solutions are generally composed of two electric motors coupled with coil springs for EM-SEA's, a double acting hydraulic or pneumatic cylinder for HC-SEA's or PC-SEA's, or of two antagonistic pneumatic muscles for PMA's. The advantages of EM-SEA's are that it has low impedance, the motor is isolated from shock loads, and the effects of backlash, torque ripple, and friction are filtered by the spring. A further advantage is that the SEA exhibits stable behaviour while in contact with the human muscle (Veale & Xie, 2016).

Double-acting pneumatic cylinders (PC-SEA) have the advantage of combining bi-directional features plus compliance to act upon plantar- and dorsal flexion assistance in a single unit (Wenger et al., 2016). Thus, it can reduce both the bulkiness and the weight of the actuator, which is an important feature for the cycling application. Moreover, the double-acting behaviour allows for elastic load displacement without the need for additional transmission, which can be seen in electric motors. Hence, the elastic behaviour of pneumatic solutions is achieved through compressibility of the gas and can be controlled by modulating the gas pressure in each chamber of the cylinder (see fig. 52) giving it the capability to exert a smooth transmission between human muscle force and artificial muscle forces. In contrast, an important disadvantage of hydraulic cylinders is the elastic performance characteristic caused by the compressibility of the fluid in the chambers of the actuator which makes these type of actuators less compliant for assistance devices compared with electric or pneumatic actuator technologies.

Alongside the advantages of current actuators, there are a number of fundamental limitations that prevent their successful application in compliant and wearable active orthoses (Veale & Xie, 2016). Electric actuators are limited by their need for transmission elements to convert their high-speed, low-torque output to the low speeds and high torques which are generally needed to drive orthoses. Furthermore, the weight of the actuator and power supply are important drawbacks.

Moreover, a significant limitation of hydraulic and pneumatic actuators is their dependence on non-portable pressure supplies that are needed for

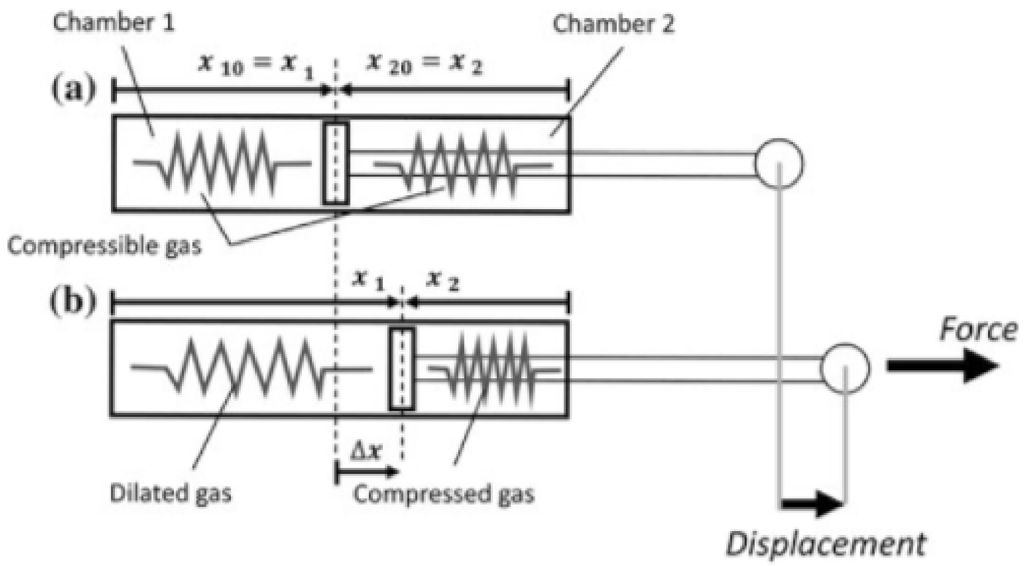


Figure 52: Illustration of a double acting pneumatic cylinder and its elastic reaction to an external force. (A) Cylinder at equilibrium without load, and (B) Cylinder under a given force. (Wenger et al., 2016).

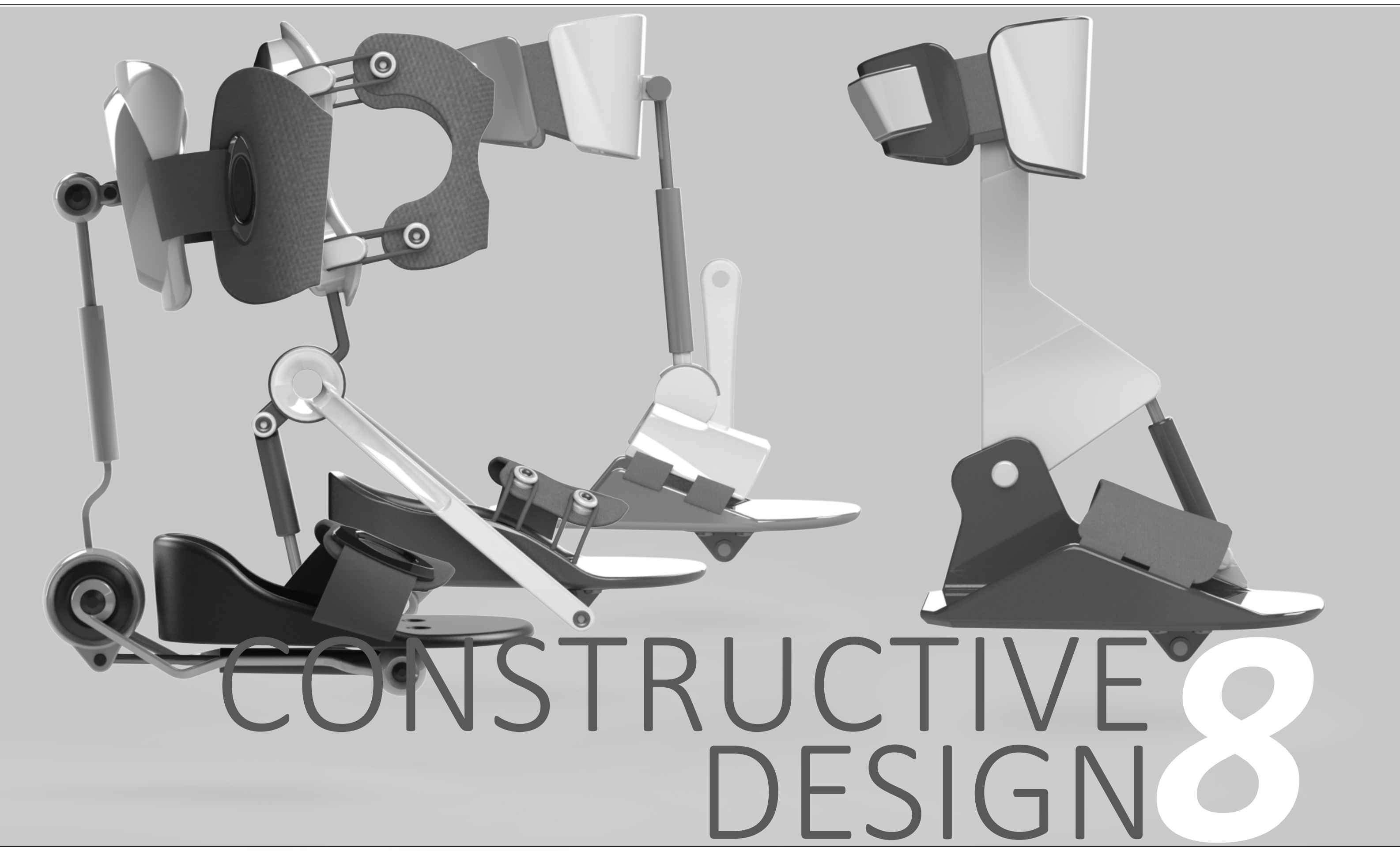
the walking gait application within today's active orthoses (Veale & Xie, 2016). The prime movers, pumps or air compressors that currently pressurize fluids (both air and liquids) are too heavy and large. It is therefore imperative that the actuator complies with a suitable power source that satisfies the requirements concerning weight, size, and cost. However, for the cycling application (i.e. ACO) the required torque is significantly reduced compared to walking, which means that a less powerful actuator is needed. Which subsequently means that the amount of pressurized fluid can be reduced within the cycling application. Hence, the applicability for a portable pressure supply is plausible.

A Harris profile (see table 2) is created to make a thorough decision on the chosen actuator technology, a selection of the most important criteria were assigned for evaluation. Hence, performance requirements for the actuator emerge in the form of; (1) force/torque control capabilities, (2) bandwidth of output forces / torques, (3) frequency of actuation, (4) elastic load displacement, (5) weight, and (6) required power supply and its nature. However, for a thorough evaluation on a suitable actuator in the context of a user-centered design approach this decision should also be taken from the perspective of the users' needs and requirements, which are described in Ch. 2. Hence, (7) comfort/acceptance, (8) affordability, (9) durability, (10) portability, (11) easy to maintain/repair, and (12) safety.

It was found that the electric motor (SEA) and pneumatic cylinder are both equally compatible for implementation. However, an electric motor in a SEA configuration are generally custom made for assistive devices, expensive and to-date not readily available for purchase. Thus, the choice was made to select an double-acting pneumatic cylinder for the ACO.

		Electric motors (SEA)				**Hydraulic cylinders**				**Pneumatic cylinders (or PMA)**			
	Weight	-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2
Performance requirements	1												
1. Force/torque control capabilities	1				+2			+1				+1	
2. Bandwidth of output force/torque	1				+2				+2		-1		
3. Frequency of actuation	1			+1				+1				+1	
4. Elastic load displacement	1			+1			-1					+1	
5. Weight	1	-2						+1					+2
6. Required power supply	1		-1				-1					+1	
User needs and requirements													
7. Comfort/acceptance	1			+1			-1					+1	
8. Affordability (incl. PS)	1	-2						+1				+1	
9. Durability (incl. PS)	1			+1				+1			-1		
10. Portability (incl. PS)	1			+1			-1				-1		
11. Easy to maintain/repair (incl. PS)	1				+2			+1				+1	
12. Safety	1			+1				+1				+1	
Score	12	-4	-1	+6	+6	0	-4	+7	+2	0	-3	+7	+3
Sum		+7				+5				+7			

Table 2: Harris profile for choosing a suitable actuator technology considered for the cycling application. Note, some requirements are evaluated including consideration of power supply (PS).



CONSTRUCTIVE DESIGN 8

CONSTRUCTIVE DESIGN 8

8.1 INTRODUCTION

As mentioned in the introduction of the explorative part (Ch. 7) of the concept phase, the constructive part of this report comprises the documentation of the constructive design process. Including a first iterative prototype (i.e. demonstrator), four concepts and concept choice.

In this section of the report, the four concepts are featured by means of the objective, approach, design objective, design description, design details and reflection on design. These concepts have been evaluated based on the Weighted Objectives Method (van Boeijen et al., 2013) wherein a selection of essential design requirements are reflected on the designed concepts to make a weighted decision for the final design.

8.1.1 OBJECTIVE

The objective for concept development was to find a design solution that is able to mimic the biomechanical motion of the lower leg of a healthy cyclist with assistive torque support for plantar- and dorsal flexor motion of the ankle joint in order to perform a full pedal cycle. As described in Ch. 5.5 the ACO should support assistance characteristics to overcome the desired motion profile represented by the dotted line of figure 35. Seeing portability requirements and the relatively large demand for assistive torque to comply with the healthy muscle function, the challenge was to find a construction that meets the design requirements presented in Ch. 7. Wherein the possibility to apply sufficient assistive torque is the first challenge, closely followed by requirements regarding compactness, durability and comfort of the orthosis.

8.1.2 APPROACH

After a short sketching try-out it was noticed that the rotating elements in the context were making it difficult to grasp how features of the orthosis would act upon the lower legs' cycling kinematics. For instance, how the artificial joint will act upon the human joints when the artificial joint is displaced from the natural ankle joint position – i.e. non-concentric rotation between artificial- and ankle-joint. Factoring into the equation, the bike features such as the (clockwise; CW) rotation of the crank-arm and the subsequent (counter-clockwise; CCW) rotation of the pedal-axis are contributing to the overall complexity. Therefore, 3D CAD (SolidWorks 2017) was used to obtain a clear understanding of the direct consequences for elementary range of motions during cycling, with the goal to ensure feasibility of each concepts´ construction.

An important feature in the ACO, is a suitable actuator type which is depended on a variety of factors among which spring characteristics and force exertion. As described in Ch. 7.5. the preference for an actuator goes out to a linear-actuator type. Therefore, different concepts are designed by means of a linear actuator type which was chosen to be the prime (linear) mover of the active cycling orthosis. A suitable design construction was searched for in which composition of essential components such as foot sole, shank, artificial joint, and braces initiates variations in dynamic behaviour of the orthosis to overcome a change in the kinematic state of the lower leg of the cyclist. Resulting in four different concepts wherein a direct difference can be observed in the location/position of the artificial joint that converts linear motion into rotational motion of the orthosis.

A form-follows-function approach was followed in which a change in composition of components evokes a change in functionality and subsequently a change in shape – i.e. geometry. Thereby taking into account the rigidity of the construction and the available space for design constructive parts described in the application interference section (see Ch. 7.3.2.) to ensure a compact design solution.

8.2 CONCEPT 1

8.2.1 DESIGN OBJECTIVE

Design of an ACO with a fixed artificial joint articulating at the posterior side of the human ankle joint to utilize the space behind the calf for construction described in Ch. 7.3.2. with a lower portion underneath the foot and an upright portion behind the calf. The objective was to preserve a fixed connection between foot sole and artificial joint that can freely rotate around the pedal-axis, whereas the upright portion should provide the assistive torque while mimicking the intended motion of the patients' lower leg.

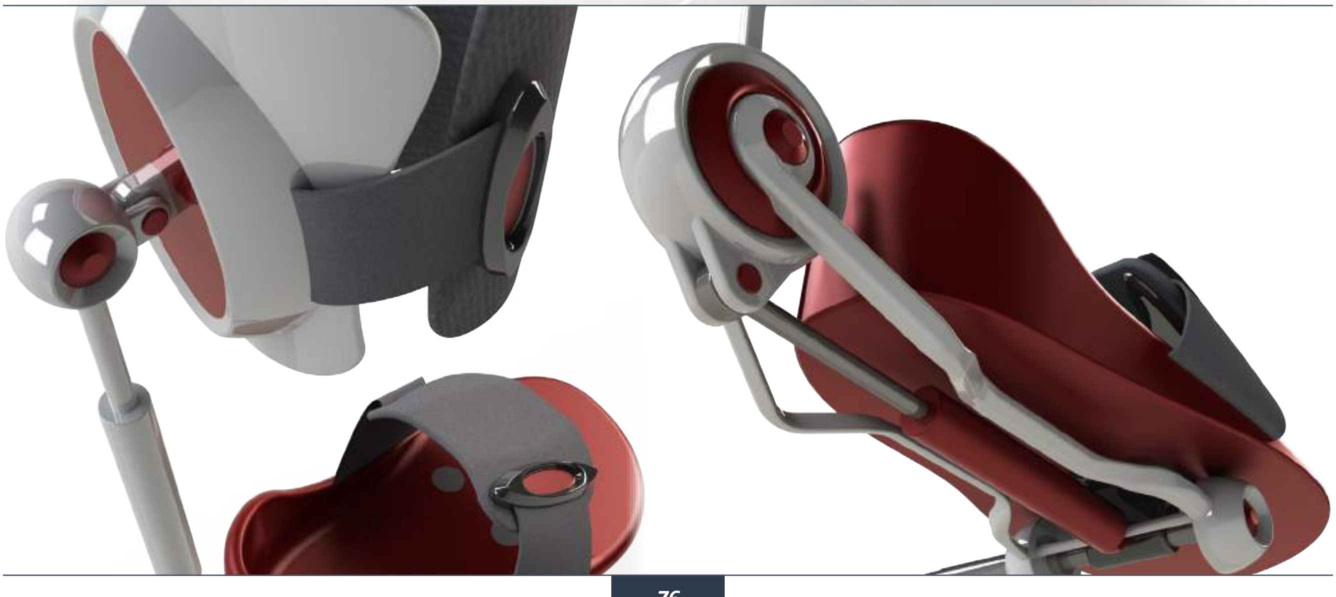
Figure 53: Concept design C1

8.2.2 DESIGN DESCRIPTION

C1 comprises a system with a coupler (i.e. bearing) which acts as an artificial joint at the rear side of the orthosis. Starting at the heel, this coupler is connected to a shank (i.e. upright portion) and a lower portion running underneath the foot. Subsequently, this lower portion consists of a foot sole, rigid support structure and pedal-axis. The rigid support structure runs on both sides of the coupler following the length of the foot sole and is attached to both the foot sole and the pedal-axis, whereof the end-points enable free rotation along the pedal-axis (see fig. 56). In between this support structure, a linear-actuator is situated to impart motion against a lever on the bottom of the coupler to transfers motion onto the shank. The length of this lever partly defines the amount of torque which can be used for pedal assistance. Accordingly, the linear-actuator provides dorsiflexion assist when extended and plantarflexion assist when retracted (i.e. described by Δs_a) as shown in figure 54.

A linear slider mechanism is implemented in the shank to create the preferred dynamic behaviour of the upright portion of the orthosis. When looking at the trajectory of the upright portion without slider mechanism it was observed that misalignment occurred between the archway of the shank end-point and the trajectory of the calf anchor point caused by displacement of the artificial joint position related to the initial ankle joint center of rotation (see fig. 54). Hence, the trajectory of the shank end-point and the anchor point on the calf are not concentric, which causes shear stresses on the calf and tibia. A simple slider mechanism therefore enables the preferred dynamic behaviour (i.e. described by Δs_s) by gradually following the trajectory of the calf (i.e. calf anchor point radius originates about the ankle joint) so that shear stresses can be avoided when the brace is properly tightened around the calf. Additionally, the slider mechanism and calf brace joint are allowing for personalized positioning of the brace and can be donned along various positions of the lower leg to abide by the wish for comfort and adjustability. Furthermore, it provides flexibility in adjustability of the orthosis for patients' individual anthropometrics.

A clear disadvantage of this design can be seen in the technique for stepping in and out (i.e. donning and doffing) of the orthosis. The upright portion restricts entering the orthosis from behind and is therefore less suitable for usage on an upright ergometer bike.



8.2.3 DESIGN FEATURES

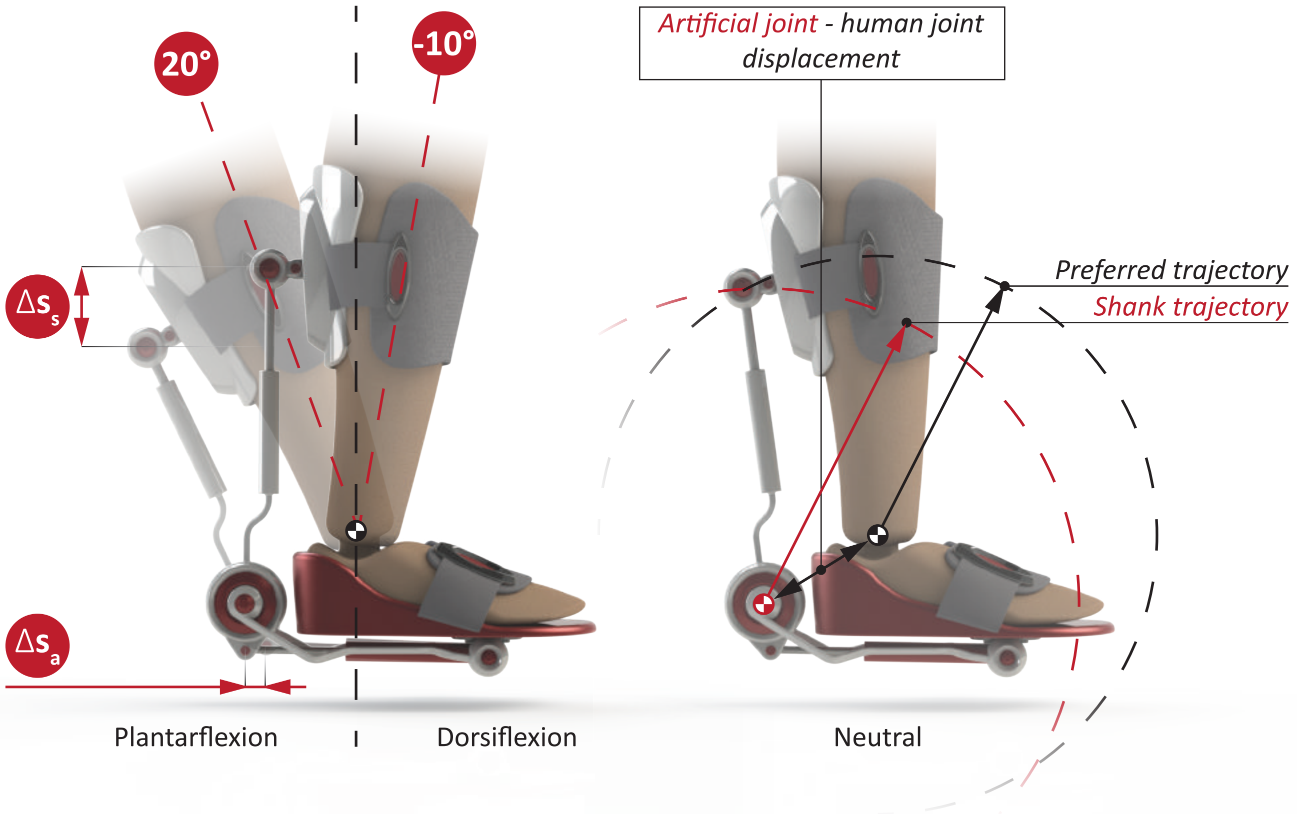


Figure 54: Activation of the linear-actuator supports different modes of assistance ranging from +20° (plantarflexion) till -10° (dorsiflexion) around the neutral position of the ankle joint (vertical line is 0°) with corresponding displacement of linear-actuator (Δs_a) and slider mechanism (Δs_s) (left). Component trajectories and solution for misalignment of the archways caused by displacement of the artificial joint center of rotation versus human joint center of rotation (right).

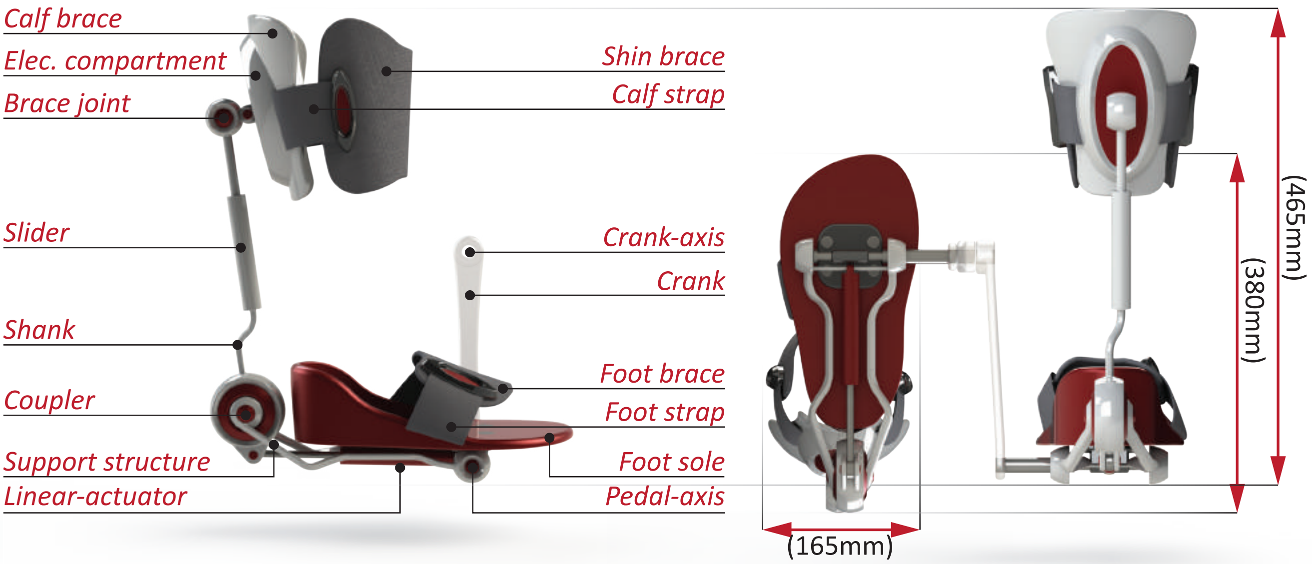


Figure 55: Design composition of components (left) and dimensioning of concept 1 (right).

8.2.4 DESIGN DETAILS

GENERAL

- Fixed artificial joint (i.e. attached to the foot sole) articulating at the rear side of the foot
- Slider mechanism to compensate for displaced/ misaligned trajectory of the brace

PRO´s

- Force transfer; stroke direction of linear actuator
- Calf brace adapts to patient muscle volume
- (Tibial) length adjustability; slider mechanism
- Space for electronic components

CON´s

- Step-in and out at the toe side of the orthosis
- Dual mechanism; actuator and slider
- Space for power supply
- Weight distribution
- Rigidity
- Freedom for design of (safety) release

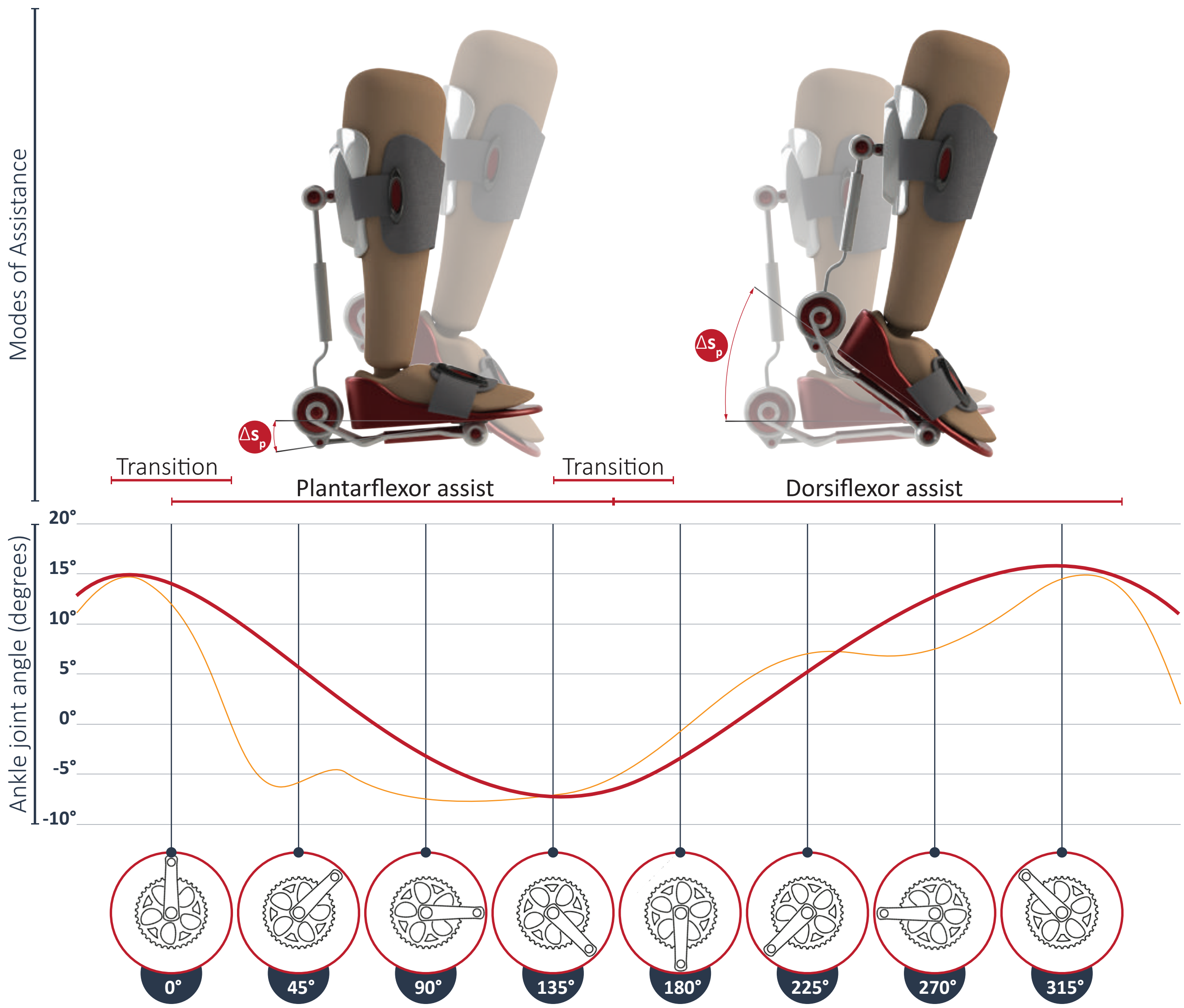


Figure 56: Design modes of assistance: ankle plantarflexor assist (-7,5°) with pedal angle; S_p = -5° and ankle dorsiflexor assist (15°) with pedal ankle; S_p = 35°. Motion profiles: compiled motion profile of CMT patient performance during user test described in Ch. 5.(orange line) and reflected (desired) motion profile of control participant (red line).

8.3 CONCEPT 2

8.3.1 DESIGN OBJECTIVE

Design of an ACO with a 'movable' artificial joint that is able to mock the intended natural kinematic movement of the patients' lower leg.

Figure 57: Concept design C2

8.3.2 DESIGN DESCRIPTION

Concept 2 aims at mimicking the dynamic behaviour of the lower leg in a confined space by means of a moveable coupler (i.e. artificial joint) that moves along a curved trajectory around the ankle joint (see fig. 58). This customized coupler is the connecting element in the design by acting as a bearing type component that is able to transfer rotational movements of three separate components. Namely, (1) rigid support structure; which is embracing the ankle on both sides of the foot sole to preserve a certain distance between pedal-axis and coupler, and to exploit rigidity and stiffness of the orthosis, (2) linear-actuator; which provides motion for pedal assistance, and a (3) shank; which is transferring the assistive forces onto the brace.

Furthermore, the linear-actuator which is connected with a bridge to the bottom of the rear foot sole, imparts the motion of the coupler (i.e described by Δs_a) by lifting or lowering the rear foot to assist in plantar- or dorsiflexion (see fig. 58). Thus, the design can be characterized by a flexible construction of beams that are allowing the coupler to move within the curved trajectory by a joint action between the linear-actuator and the rigid support structure described by Δs_c in figure 58.

When looking at the brace, there are two cones attached to the rear side of the orthosis which are fastening the upper portion of the orthosis to patients' lower leg with a lacing system. Moreover, the upper cone is a storage compartment for electrical components, such as an EMG sensor to detect muscle activity of the calf muscles. Whereas, the lower cone possess a spring mechanism allowing a small shank-arm to glide into the bottom of the cone to overcome a small displacement between the trajectories of the shank and the archway of the calf with a cushioning feature for a smooth transition between the modes of assistance (see fig. 60).

A clear disadvantage of this design can be seen in the technique for stepping in and out (i.e. donning and doffing) of the orthosis. The rigid support structure is surrounding the ankle joint and limits the freedom of release which is cause of concern seen the criteria for safety. Furthermore, stepping in at the front is less suitable for usage on an upright ergometer bike and would be more suitable for a recumbent bike.

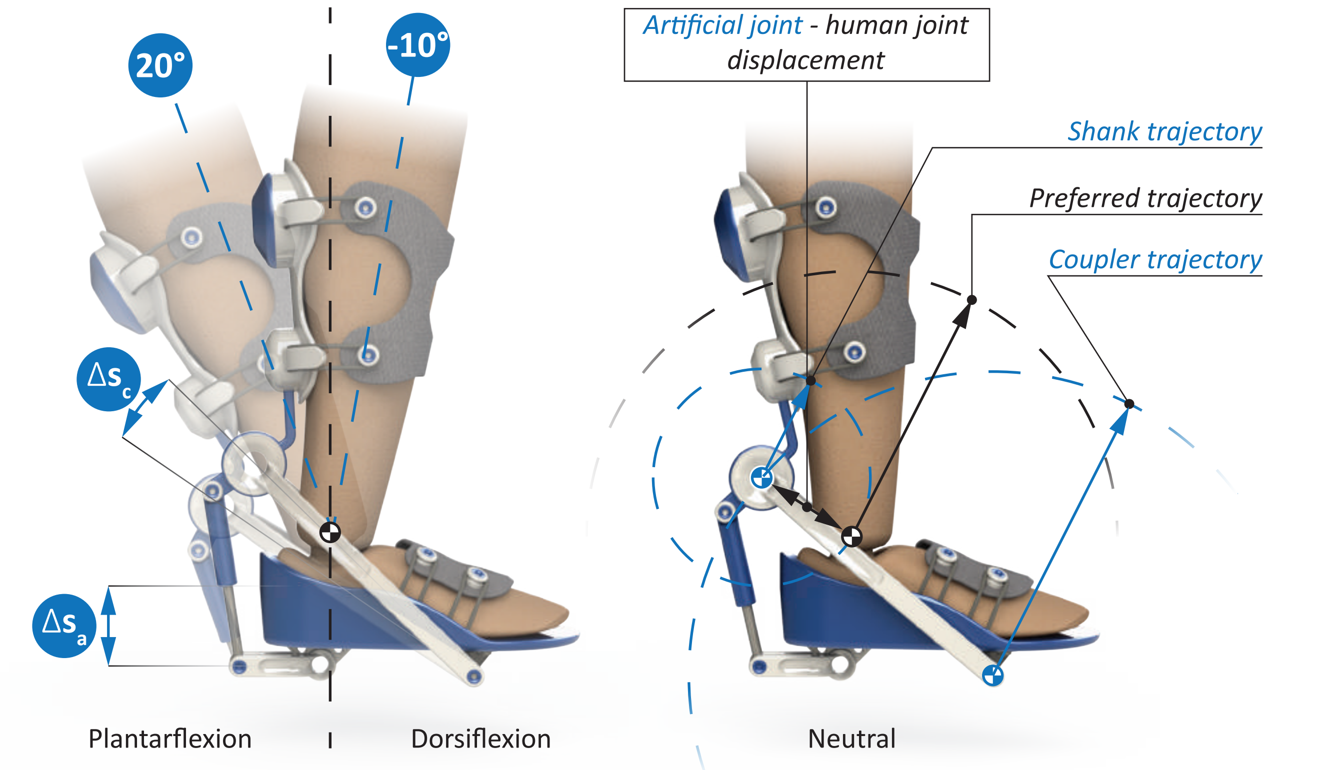


Figure 58: Activation of the linear-actuator supports different modes of assistance ranging from +20° (plantarflexion) till -10° (dorsiflexion) around the neutral position of the ankle joint (vertical line is 0°) with corresponding displacement of linear-actuator (Δs_a) and coupler (Δs_c) (left). Component trajectories and solution for misalignment of the archways caused by displacement of the artificial joint center of rotation versus human joint center of rotation (right).

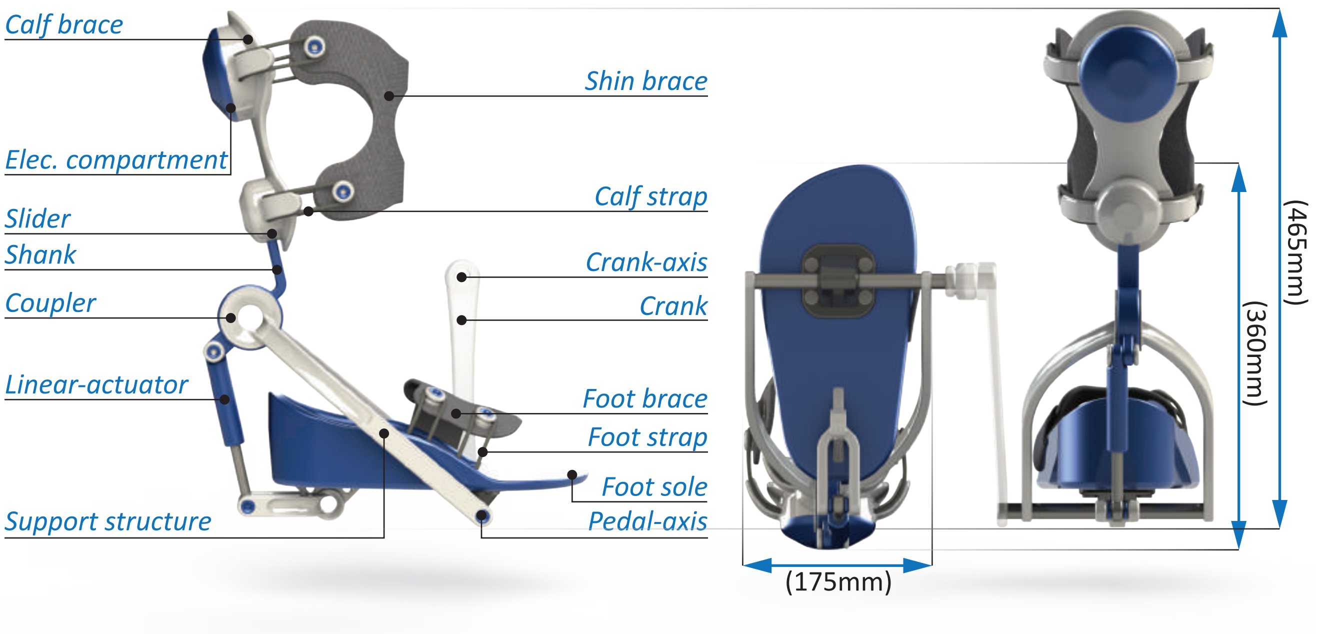


Figure 59: Design composition of components (left) and dimensioning of concept 2 (right).

GENERAL

- Moveable artificial joint (i.e. guided trajectory of the coupler) articulating at the rear side of the foot
- Slider mechanism to compensate for displaced/misaligned trajectory of the brace

PRO´s

- Force transfer; stroke direction of linear-actuator
- Dynamic behaviour of the orthosis for assistance
- (Tibial) length adjustability; slider mechanism
- Space for electronic components
- Rigidity

CON´s

- Step-in and out at the toe side of the orthosis
- Dual mechanism; actuator and slider
- Space for power supply
- Weight distribution
- Range of adaptibility tibial length
- Calf brace adapts to patient muscle volume
- Freedom for design of (safety) release

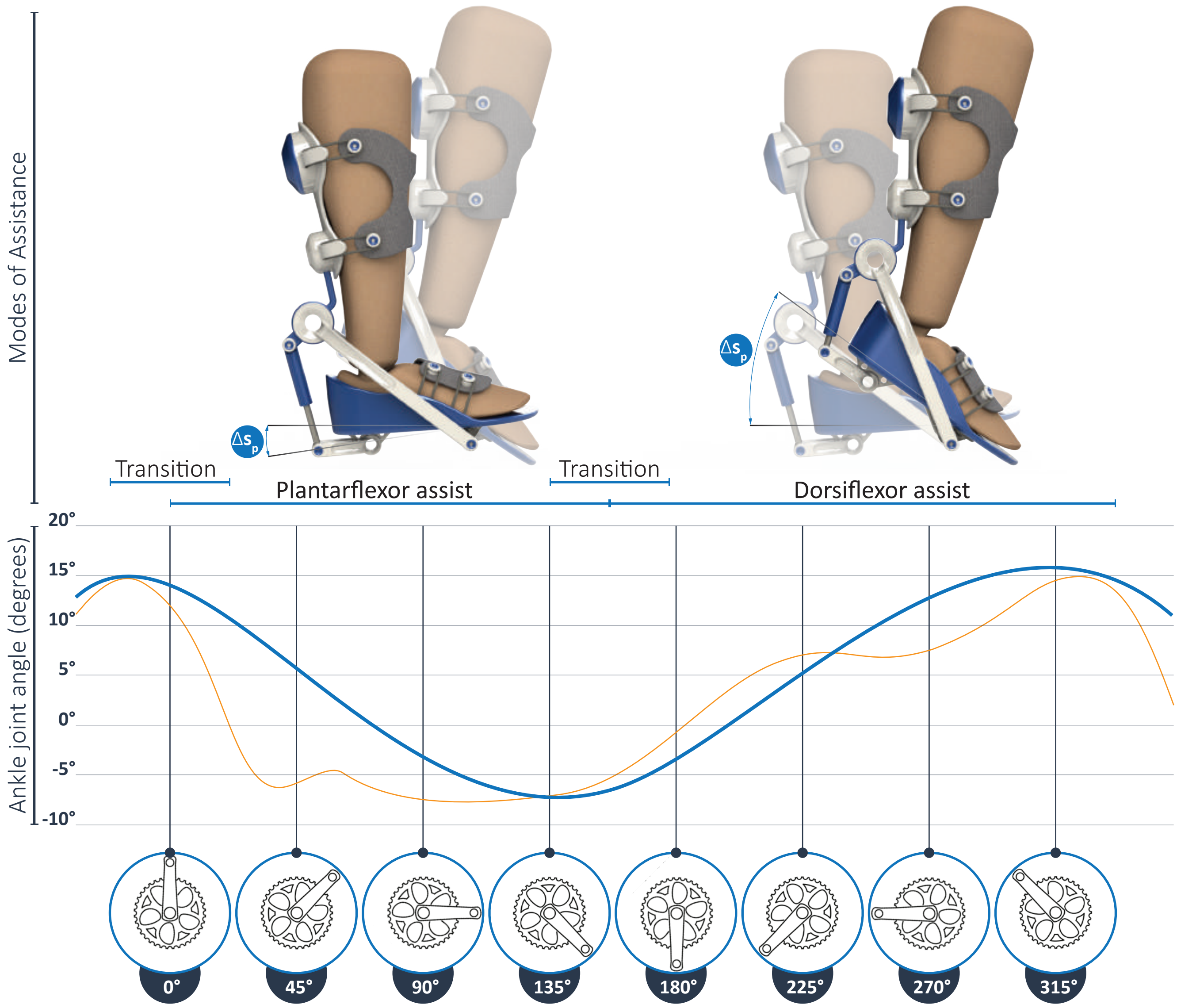


Figure 60: Design modes of assistance: ankle plantarflexor assist (-7,5°) with pedal angle; S_p= -5° and ankle dorsiflexor assist (15°) with pedal ankle; S_p= 20°. Motion profiles: Motion profiles: compiled motion profile of CMT patient performance during user test described in Ch. 5.(orange line) and reflected (desired) motion profile of control participant (blue line).

8.4 CONCEPT 3

8.4.1 DESIGN OBJECTIVE

Design of an ACO with a fixed artificial joint articulating at dorsal region of the foot (i.e. on top of the foot) to utilize the space between foot and shin for actuation described in Ch. 7.3.2. Another objective was to evenly distribute the systems' weight along the vertical component of the pedal-axis (i.e. to lower the load subjected to the human lower leg).

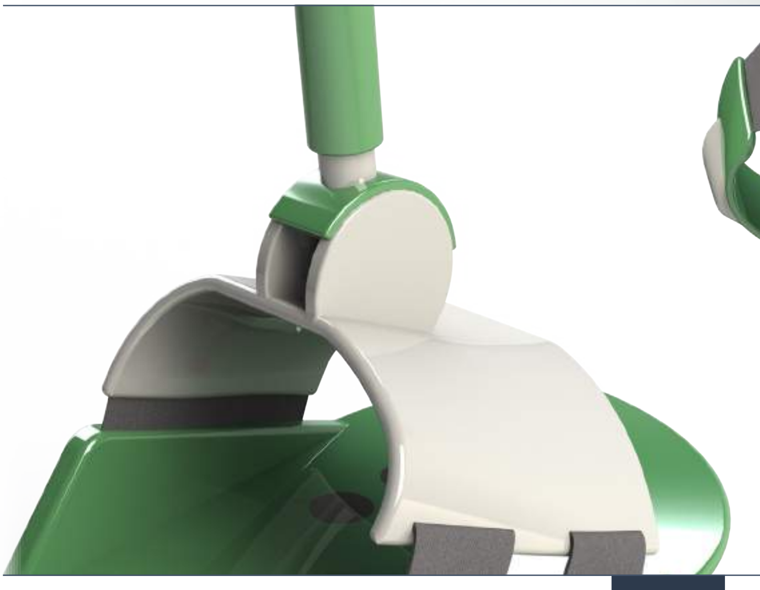
Figure 61: Concept design C3

8.4.2 DESIGN DESCRIPTION

C3 comprises a bracket (i.e. artficial joint)at the dorsal region of the foot which is attached on top of a rigid foot plate connecting a linear-actuator with the foot sole. This bracket can rotate freely and acts as a hinging mechanism to allow movability of the linear-actuator in either a clockwise or counter-clockwise direction depending on the initiated human motion (see fig. 64). After detecting the kinematic state of the human leg via a motion sensor, the linear-actuator will be powered and transfers a force onto the shin-brace for assistance in dorsal- or plantar flexion. The pedal-axis in this configuration can rotate freely and the composition of functional components are mostly assembled above the pedal axis for distribution of weight along the vertical component of the pedal-axis. Hence, the mass is partly carried by the pedal-axis which is decreasing additional loads on the lower leg of the patient.

Moreover, a decisive disadvantage of the design are the possible shear stresses/friction along the shin when the linear-actuator is exerting the movements over the shinbone for pedal assistance. The forces are transferred along the vertical component of the brace which is likely to cause friction on the shin. Subsequently, affecting comfort of wearing the orthosis and allowable assistive torque. Ideally the exerted force should be perpendicular to the shin to allow for maximal torque assistance (see fig. 62) .

Nevertheless, a typical advantage of concept 3 is the minimal amount of components used to enable the desired motion and the possibility to step in from behind. This entering technique enables the intuitive step-in interaction of the orthosis which is similar to the design of cycling toe clips and is therefore a beneficial feature from a safety point of view.



8.4.3 DESIGN FEATURES

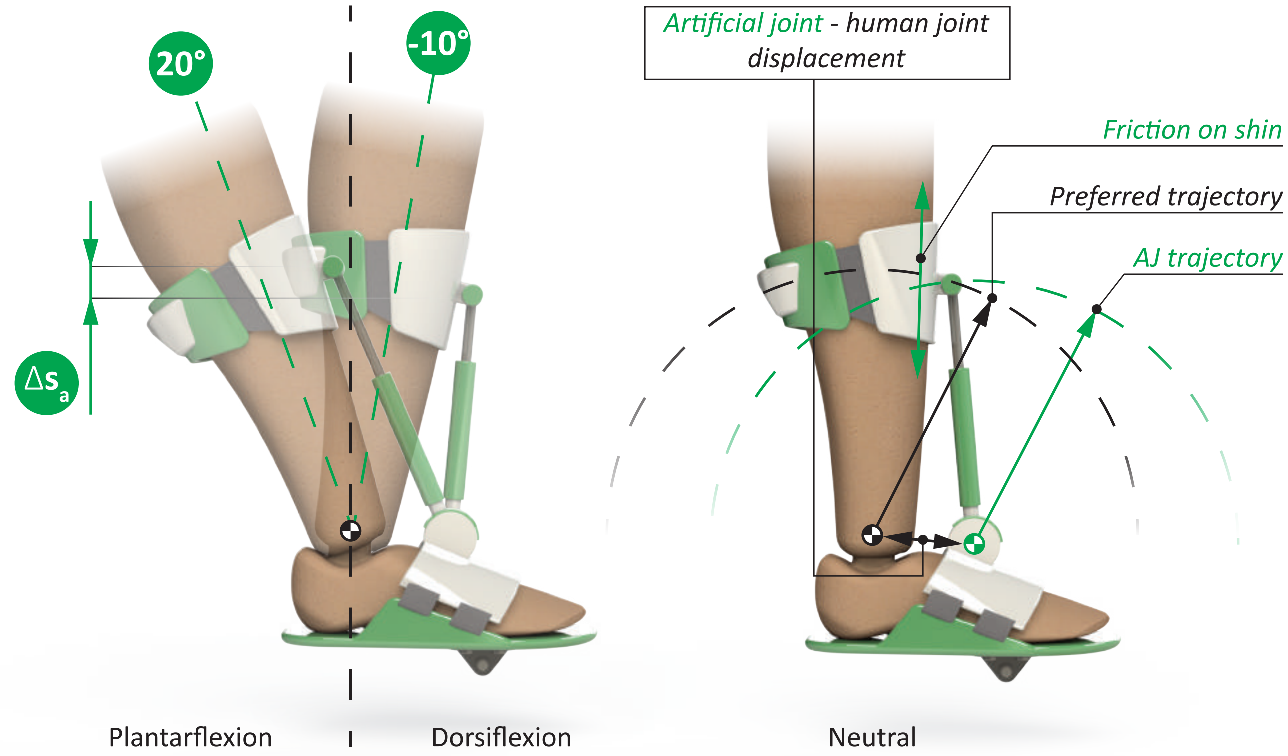


Figure 62: Activation of the linear-actuator supports different modes of assistance ranging from +20° (plantarflexion) till -10° (dorsiflexion) around the neutral position of the ankle joint (vertical line is 0°) with displaced movement (Δs_a) of the rod anchor-point of the linear-actuator (left). Misalignment of the archways affected by displacement of the artificial joint center of rotation versus human joint center of rotation is causing friction on the shin due to exerted forces over the vertical component (right).

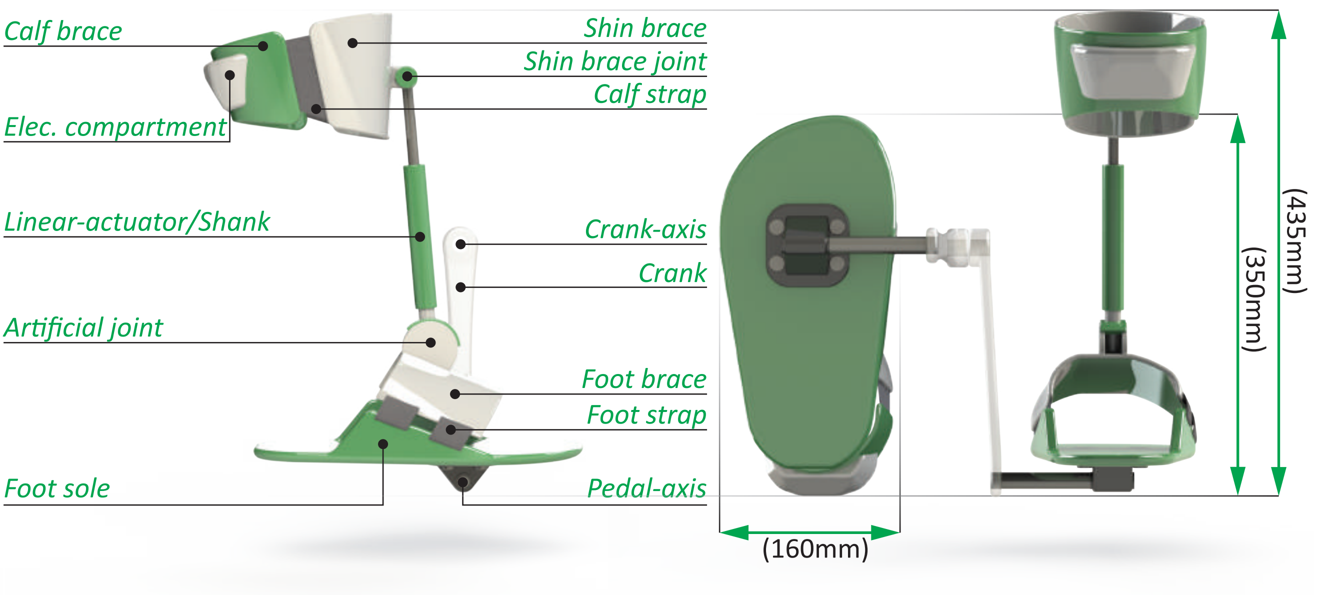


Figure 63: Design composition of components (left) and dimensioning of concept 3(right).

8.4.4 DESIGN DETAILS

GENERAL

- Fixed bracket type of joint articulating at the dorsal region of the foot with passive motion control by the cyclist.

PRO´s

- Weight distribution
- Step-in and out from behind
- Adaptable with patient muscle volume
- (Tibial) length adjustability; controllable by means of the linear actuator.
- Space for electronic components
- Freedom for design of (safety) release

CON´s

- Force transfer; stroke direction of linear actuator
- Possible friction at the shin
- Rigidity

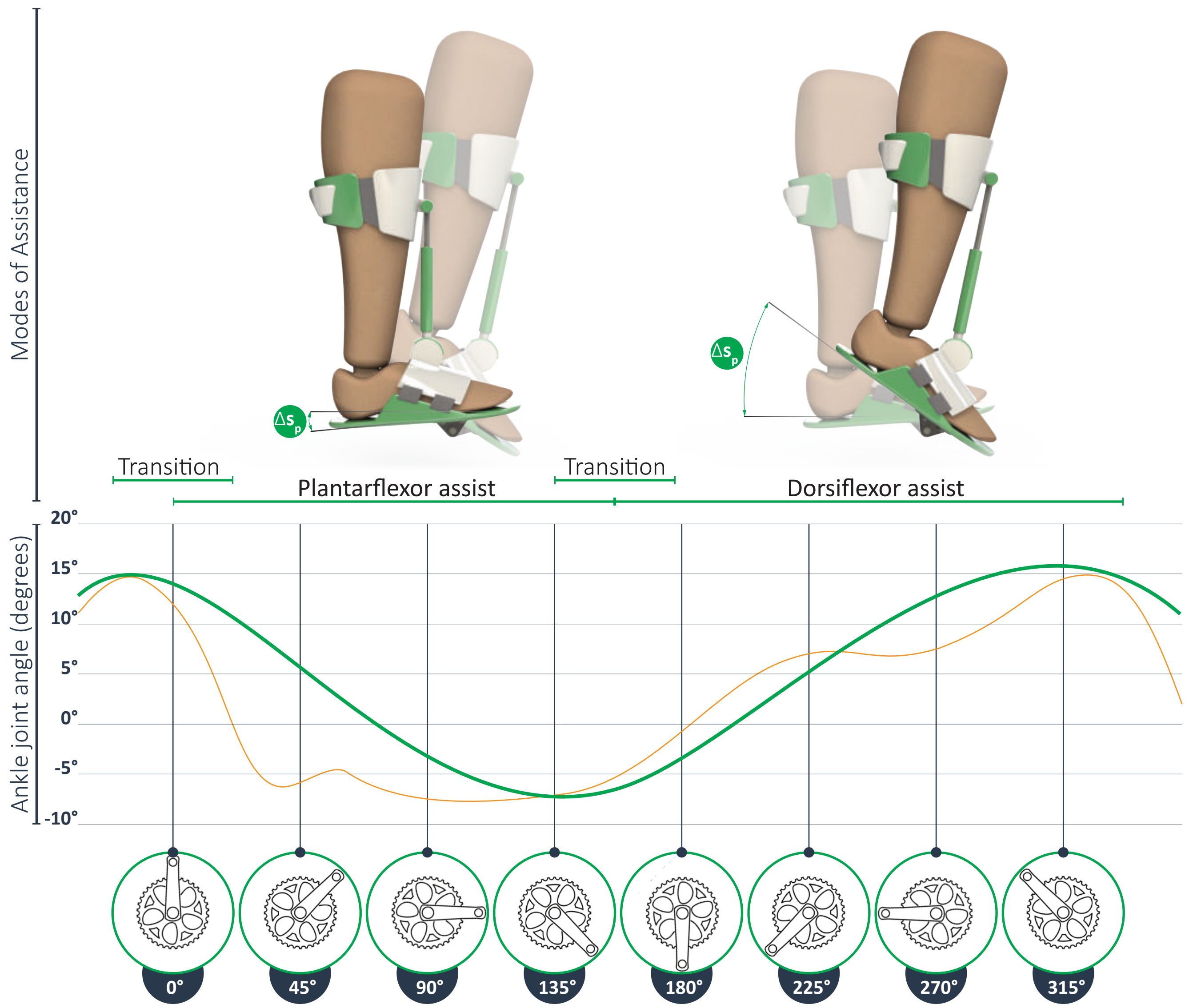


Figure 64: Design modes of assistance: ankle plantarflexor assist (-7,5°) with pedal angle; S_p= -5° and ankle dorsiflexor assist (15°) with pedal ankle; S_p= 20°. Motion profiles: Motion profiles: compiled motion profile of CMT patient performance during user test described in Ch. 5.(orange line) and reflected (desired) motion profile of control participant (green line).

8.5 CONCEPT 4

8.5.1 DESIGN OBJECTIVE

Design of an ACO with a fixed artificial hinge joint which is concentrically aligned with the human ankle joint. The typical 'L' shaped design of conventional AFO's shell be used for inspiration and applied into the contextual space of the human-bike environment.

Figure 65: Concept design C3

8.5.2 DESIGN DESCRIPTION

C4 is built upon a conventional composition of components that are used in current (articulating) AFO's, such as shank, hinge, and foot sole. Eventhough, the 'L'-shaped design of traditional AFO´s can be noticed, the modification of the shank is adopted to the context of use. The modification of the shank defines the allowable amount of torque which can be exerted around the hinge joint (i.e. artificial joint) which may be a fixed bearing connection that is concentrically aligned with the human ankle joint. The potential torque can be defined based on the distance (i.e. force-arm) between the hinge and the rod anchor point of the linear-actuator. The linear-actuator is attached to both, the foot sole and the shank at the medial side of the ankle joint and permits a substantial degree of flexibility for tuning the performance parameters to increase of decrease the level of assistance for dorsalflexion and plantarflexion (see fig. 66). Because the exact position of the bracket is flexible as well as the position of the rod anchor point, this construction utilizes the available space between the crank-arm and the human ankle joint described in Ch. 7.3.2. Therefore, a compact design solution is created on which electrical components can be assembled. Hence, this composition of components enables the possibility for creating a safe release system, allowing the patient to step-in and out of the orthosis from behind or from the lateral side of the orthosis to enhance safety in the case of an accident.

Furthermore, at the posterior side of the calf brace an electronical component compartment is designed to store electric components for muscle activation measurements of the calf muscles which can be fed to the actuator for a natural onset and offset of muscle innervation patterns to accommodate a natural assistive pedal motion.

However, a point of attention within this concept is the concentric alignment between the hinge and the human ankle joint. According to Bottlang et al. (1999) misalignment of the two joints can cause shear stresses on the foot which should be avoided seeing the characteristics of the CMT disease and the anthropometric differences among patients (see Ch. 3.3. on p.28). Thus, for further development of this concept, the position of the hinge joint should be made adaptable so that the hinge can be aligned with the position of the human ankle joint.

8.5.3 DESIGN FEATURES

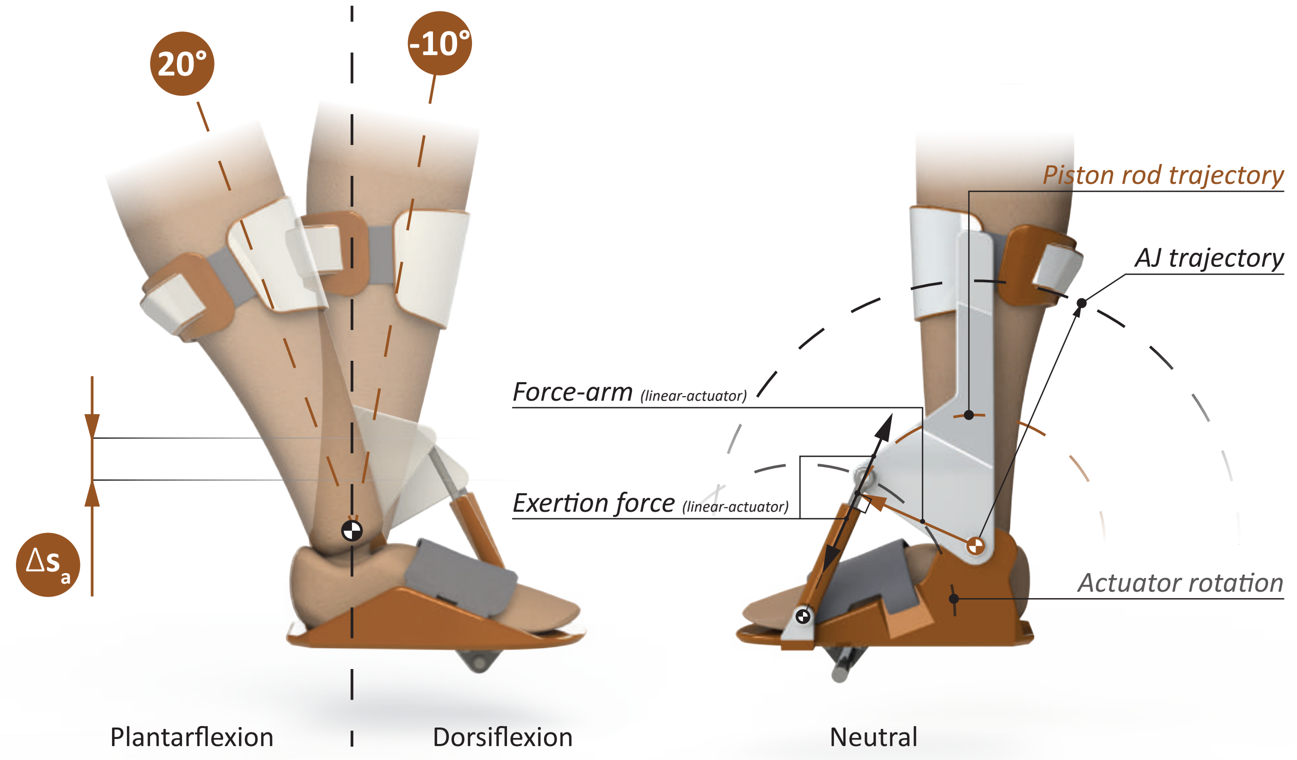


Figure 66: Activation of the linear-actuator supports different modes of assistance ranging from +20° (plantarflexion) till -10° (dorsiflexion) around the ankle joint (neutral position; vertical line is 0°) with corresponding displacement of linear-actuator (Δs_a) and coupler (Δs_c) (left). Component trajectories and solution for misalignment of the archways caused by displacement of the artificial joint center of rotation versus human joint center of rotation (right).

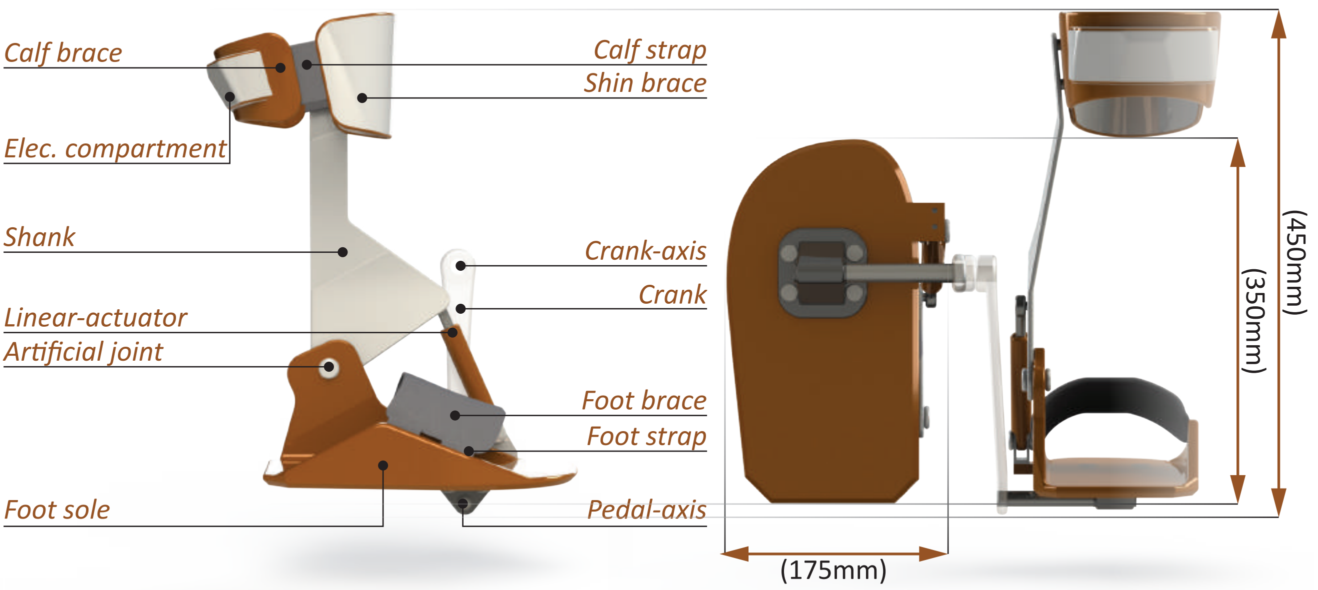


Figure 67: Design composition of components (left) and dimensioning of concept 4 (right).

8.5.4 DESIGN DETAILS

GENERAL

- Fixed artificial joint articulating in concentric allignment with the human ankle joint.
- Rigidity
- Step-in and out at the toe side of the orthosis
- Freedom for design of (safety) release

PRO´s

- Force transfer; stroke direction of linear-actuator
- Dynamic behaviour of the orthosis for assistance
- (Tibial) length adjustability; calf/shin-brace can be mounted on shank at different hights
- Calf brace adapts to patient muscle volume
- Space for electronic components

- ***CON´s***
- Possible misalignment between ankle joint and artificial joint
- Space for power supply
- Weight distribution
- Range of adaptibility tibial length

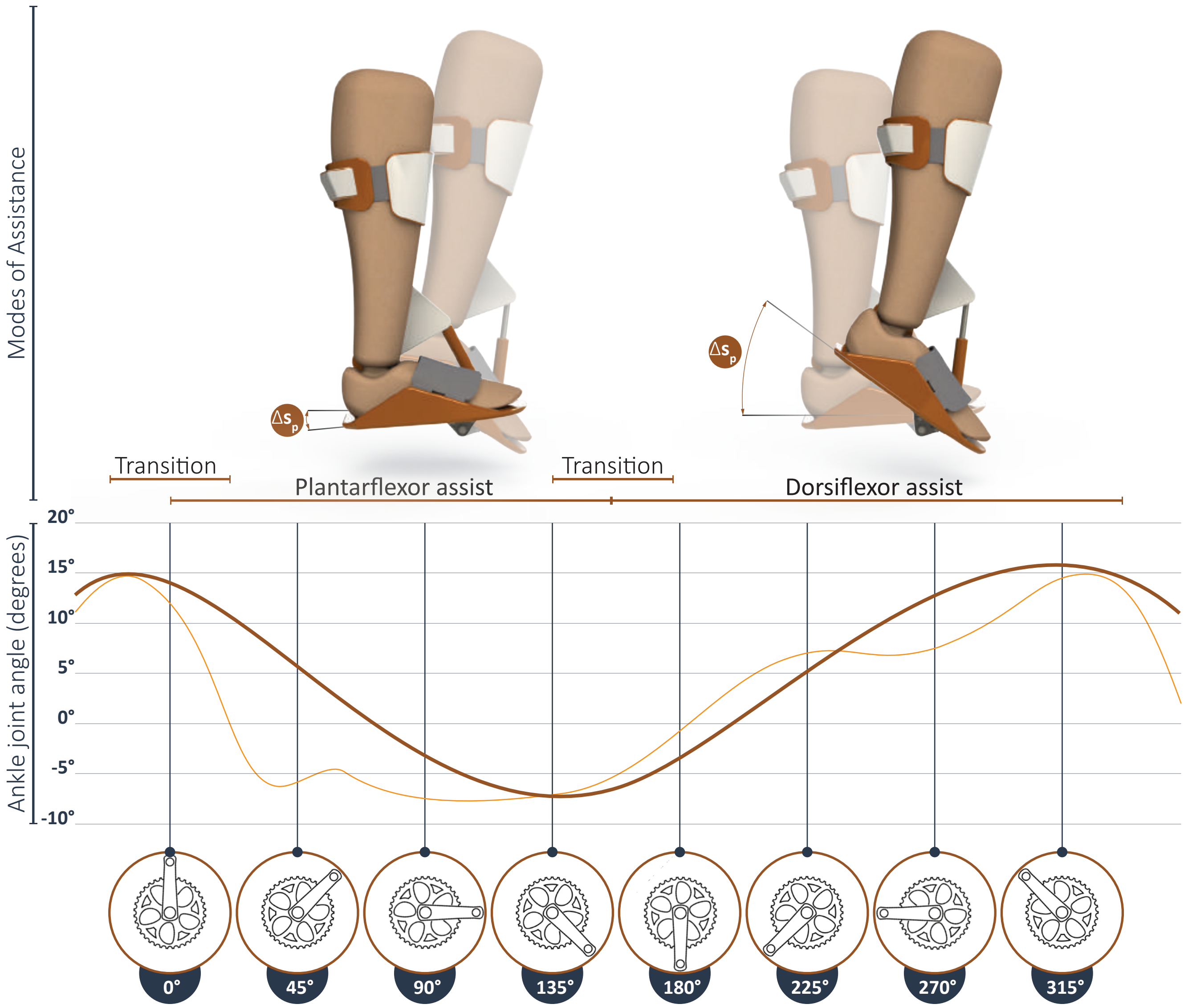


Figure 68: Design modes of assistance: ankle plantarflexor assist (-7,5°) with pedal angle; S_p= -5° and ankle dorsiflexor assist (15°) with pedal ankle; S_p= 20°. Motion profiles: Motion profiles: compiled motion profile of CMT patient performance during user test described in Ch. 5.(orange line) and reflected (desired) motion profile of control participant (brown line).

8.6 CONCEPT CHOICE

Within the four different concepts several design solutions are presented with the common goal to mimic the plantarflexor and dorsalflexor motion of the ankle joint of a healthy cyclist throughout a full pedal cycle. Hence, variations in supportive technique are explored to provide sufficient torque assistance for patients with muscle atrophy in the lower leg (e.g. CMT patients).

Even though, in theory, all four concepts comply with the main performance features concerning preferred modes of assistance (i.e. plantar- and dorsal flexion in a certain pedal phase) with corresponding range of motions. The core design criterium is to allow sufficient torque which should be close to an expected maximum torque of 25 Nm around the ankle joint needed to assist the lower leg of CMT patients.

Several alternative positions for the artificial joint are allocated and reflected on the dynamic behavior of the lower leg. After changing the position of the artificial joint posterior-, anterior-, underneath-, above- or combinations of which relative to the human ankle joint. It was found that the trajectories/archways of components (e.g. shank) are not compliant with the biomechanics of the lower leg. Additional spring/sliding mechanism were designed for C1 and C2 in order to follow the intended movements. However, additional mechanisms are increasing the amount of components needed in the system which also increases the risk of failure.

Moreover, these design variations can be allocated by a changing shape and function of constructive features (such as the support structure or shank-arm) which are needed in C1, C2 and C4 to comply with rigidity, stiffness and force transfer capabilities. However, these variations in design affect the balance (i.e. weight distributed around the pedal-axis), the freedom of step in and out of the orthosis, and torque characteristics. The dissimilarity among features are further elaborated in the design features section of the individual concepts. Nevertheless, a thorough design decision could be made based on the (dis)advantages between these design features. For instance, concepts with front entrance step-in technic are more suitable for recumbent cycling rather that cycling on a conventional ergometer bike. Thus, C4 is scoring best according to these criteria. Another, advantage of C4 is the actuator point of engagement at the toe side of the foot sole. Hence, exerted torque around the pedal-axis complies with the natural pressure practise of the foot for plantarflexion and complies with balance issues around the pedal-axis.

Furthermore, in order to examine whether or not a certain concept has the potential to provide sufficient torque, a simple calculation is performed by comparing the outcome of different torque equations (i.e. $T = F * r$) in Appendix I. By assigning a constant variable to the force that can be exerted by the linear-actuator for plantarflexion and dorsiflexion results in an internal moment around the ankle joint for assistance. Thus, the force-arm (r) defines the magnitude of the overall torque. After critically reviewing the applied force exerted to the brace, it was found that the largest amount of torque can be exerted by C4 which creates significant advantage for the application because a smaller double-acting cylinder can be integrated. For instance, a smaller double-acting cylinder uses less air (i.e. small volume in chambers), is less expensive, is more lightweight and is more compact. In addition, it was observed that the majority of the forces for C3 are largely transferred along the vertical component of the brace which is likely to cause friction on the shin (see fig. 62). Subsequently, affecting comfort of wearing the orthosis and allowable assistive torque. Hence, this feature is losing forces for pedal assistance and ideally the force should be perpendicular to the shin to allow for maximal torque assistance.

Furthermore, in table 3 the different concepts are weighted by means of the Weighted Objectives Method (van Boeijen et al., 2013) to score the design alternatives. Whereof, the score per criterion can be aggregated into an overall score for the design. With a notable difference C4 has scored best on the Weighted Objectives Method and together with the above mentioned reasoning C4 will be used for further development.

	Weight	C1	C2	C3	C4
Performance requirements					
1. Force/torque control capabilities	4	3	4	3	5
2. Bandwidth of output force/ torque (tune-ability)	4	4	5	4	5
3. Rigidity	3	3	5	4	4
4. Force transfer/elastic load displacement	3	4	5	2	3
5. Weight-distribution	3	3	2	5	4
6. Amount of moving components	1	3	3	5	4
User needs and requirements					
7. Range of anthropometric adaptibility	3	5	4	3	4
8. Comfort/acceptance	4	4	4	2	3
9. Step in/out technique	3	3	2	4	4
10. Alignment (artificial joint vs. human ankle joint)	3	3	4	5	4
11. Portability/bulkyness (excl. power supply)	3	3	2	4	2
12. Easy to maintain/repair (excl. power supply)	1	3	3	4	3
13. Safety	4	3	2	4	4
Total score		134	138	142	150

Table 3: Concept design alternatives are weighed by means of the Weighted Objective Method (van Boeijen et al., 2013). The criteria are selected from the list of requirements and corresponding concept features.

8.7 DEMONSTRATOR

8.7.1 DESIGN OBJECTIVE

The objective of building this demonstrator was to provide clarity on the dynamic behavior of the envisioned ACO and become acquainted with the Arduino and the physical challenges that arise through this design inclusive research approach.

8.7.2 DESIGN APPROACH

In parallel with the creation of design concepts a demonstrator was built to demonstrate a simplified working principle for plantar- and dorsalflexion of the ankle (see fig, 70) of an active cycling orthosis by means of a 3D printed model (see fig. 69).

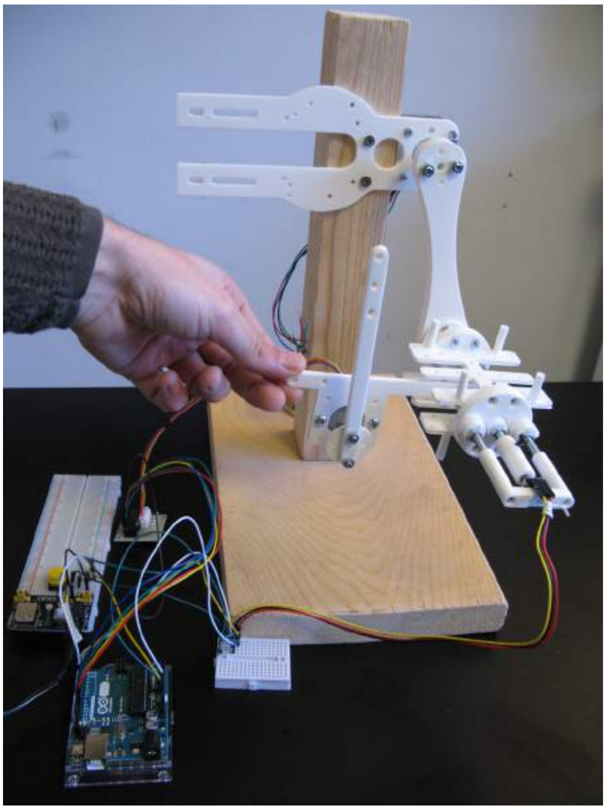


Figure 69: Prototype design of the demonstrator

8.7.3 REFLECTION ON THE DEMONSTRATOR

The demonstrator comprises a simplified working mechanism wherein a stepper motor acts upon the rotational displacement of a rotary-encoder (i.e. sensor) which is located at the end of the pedal-axis. When the pedal is rotating during cycling the rotary encoder counts the angular displacement and direction of movement (i.e. CW or CCW). After which a pedal phase (i.e. power phase versus recovery phase) can be derived that subsequently determines motion of the stepper motor. A microcontroller (i.e. Arduino) was used to gather data from the rotary encoder and controls the stepper motor rotation ranging between 20 and -10 degrees according to the orientation of the pedal (see fig. 71). Figure 70 illustrates movement of the stepper motor.

The demonstrator revealed some interesting insights. For instance, the cycling movement of the pedal was simulated by hand (as shown in fig. 69) because the demonstrator is a scaled model and was not strong nor large enough to withstand a human leg. However, absence of the human leg clearly showed that the ACO creates an imbalance of the pedal due to its weight distribution. This implies that the weight of the ACO that is subjected to the human leg should be avoided to lower additional loads and therefore should be considered in the design to minimize the load on the human leg caused by weight displacement. For instance, a possible design consideration could be to position the weight of the design mostly above the pedal so that the majority of the weight is carried by the bike itself.

Furthermore, possible sensor placement and movement detection strategies of the rotating elements in the system were observed. For instance, when performing a full pedal cycle rotation of the pedal and crank are continuous whereas the stepper should vary in rotational movement between 20 and -10 degrees.

Eventhough, the demonstrator largely operated as intended, the allowable step-count of the rotary-encoder determines the accuracy of the stepper for the large part. Since, a cheap rotary-encoder was used, sometimes rotation of the pedal remained undetected which is a cause of concern with the eye on safety if the actuator not responds to actual movements.

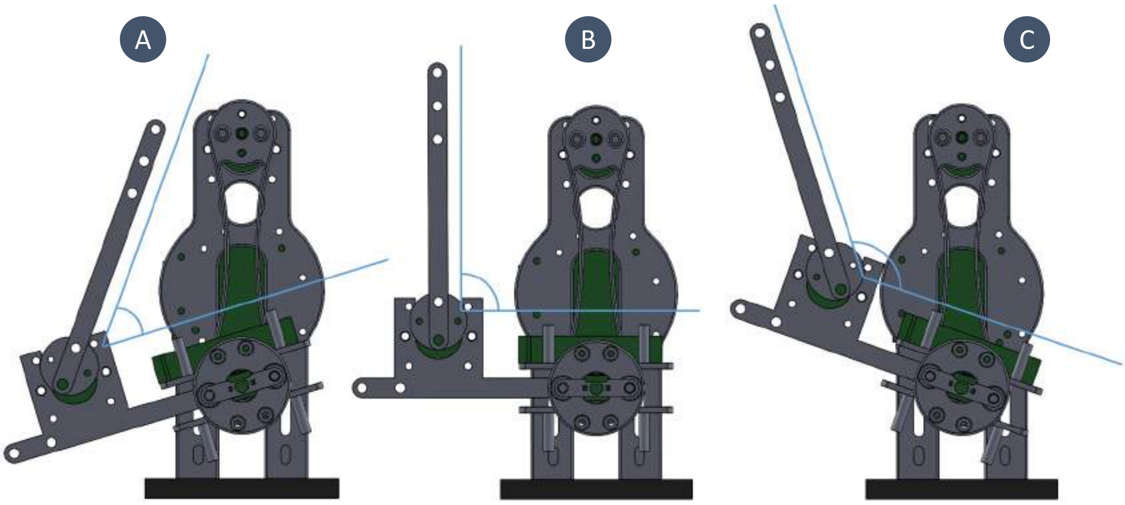


Figure 70: Intended movement of the demonstrator for dorsiflexion (A), neutral position (B), and plantarflexion (C).

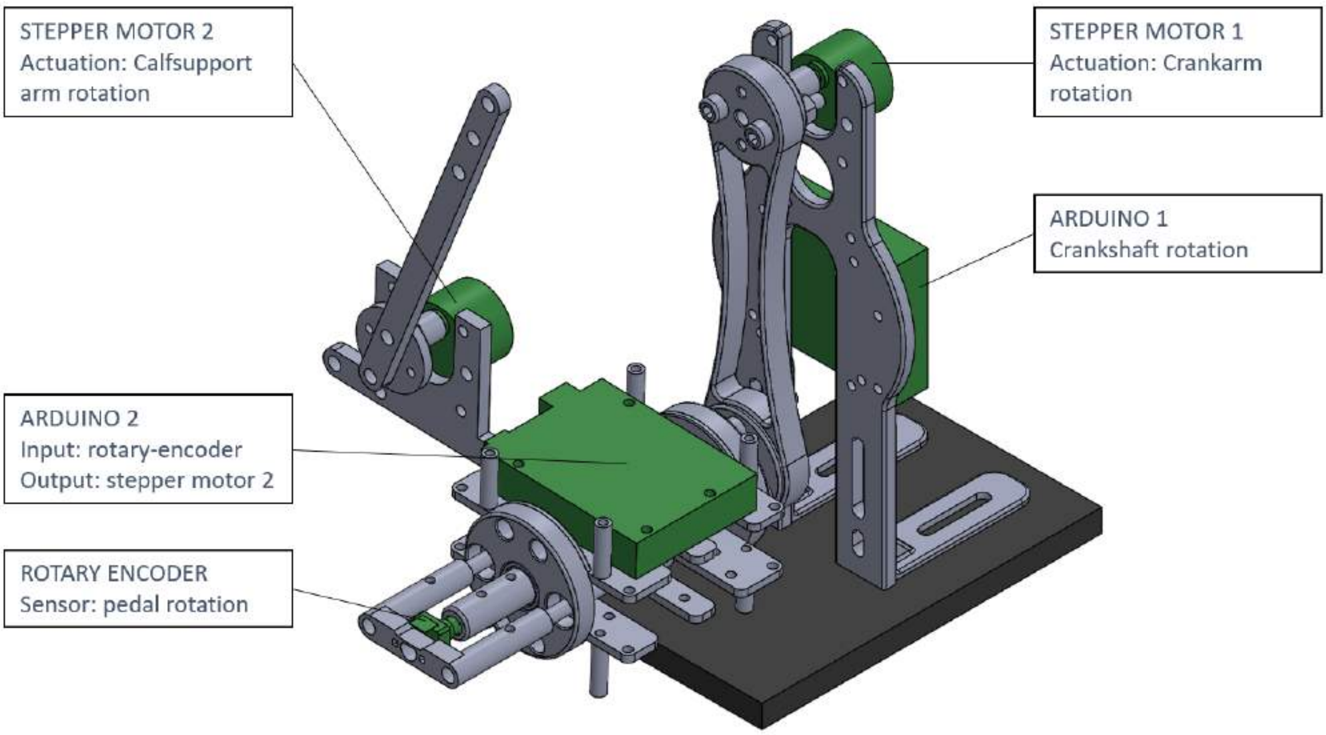


Figure 71: Composition of components of which the gray parts are 3D printed and green parts are electronic components

8.8 CONCLUSION

This section concludes the explorative and constructive part of the concept phase. Within explorative part a first iterative design step was made with the design of abstract schematic working mechanisms. It was noticed that a shank component (i.e. brace) is needed in the design to retain stability concerning eversion/inversion movements of the ankle joint for the rehabilitative management of CMT patients. Within this line of thought design considerations are made to frame the design freedom. For instance, by combining a 3D CAD model of the lower leg and the kinematic motion analysis of Gilbertson (2008), the spatial freedom for design is assessed to avoid possible interference with the floor, crank-arm, upper leg and front-wheel. Another important aspect to consider for exoskeleton systems is the initial technique of assistance. It is expected that the most desired assistance technique for the ACO is to assist the patient only when needed and only as much as needed instead of a fixed constant assistance technique that guides the ankle of the patient throughout the full pedal cycle (i.e. ankle receives constant assistance).

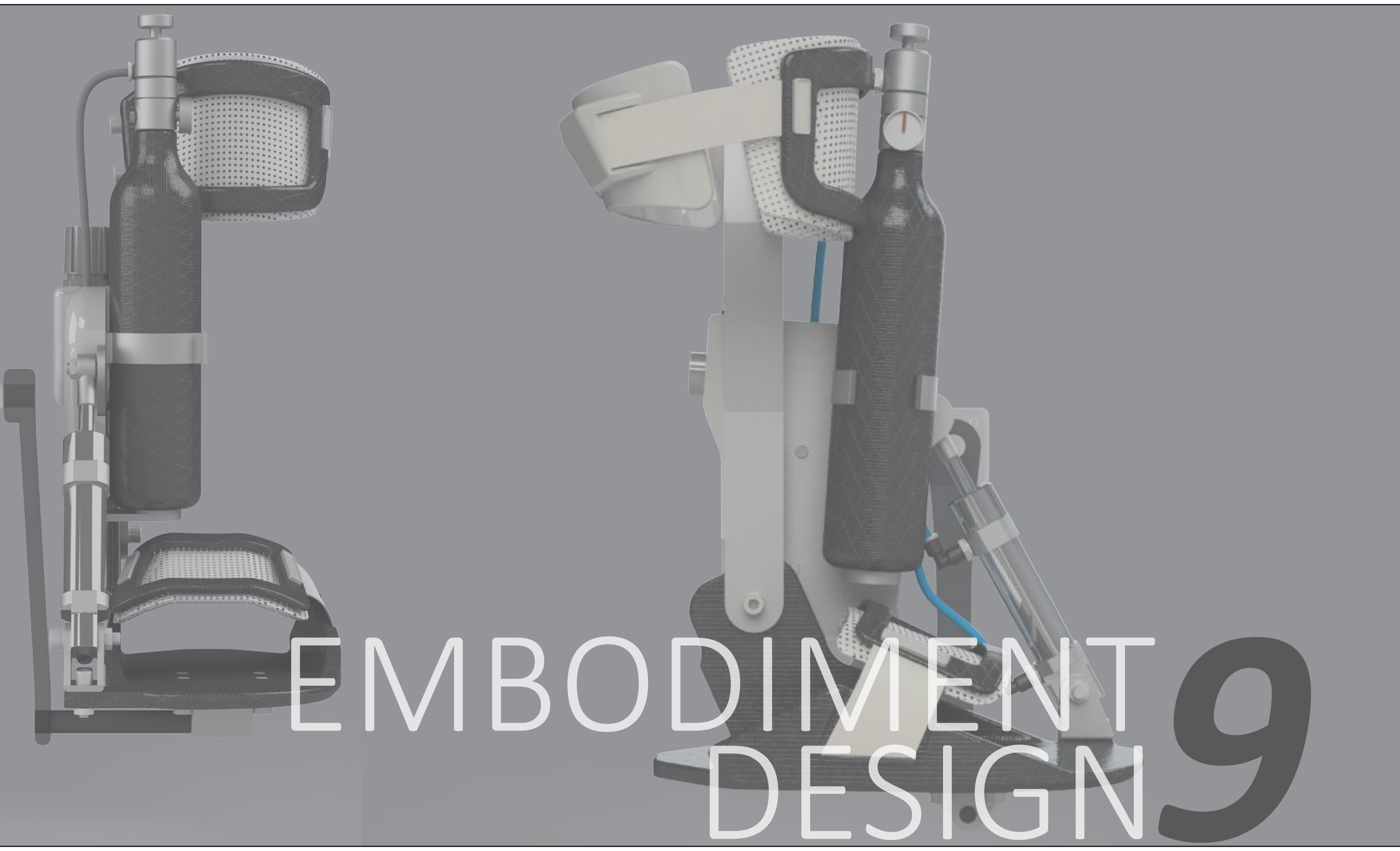
Thus, to control the ACO and provide intelligent, effective, and comfortable assistance to the cyclist, it is essential to deploy different types of component to gather motion data of the human-orthosis system to recognize the patients' motion intention, analyse the motion status, cyclic continuity of the pedals, and evaluate the motion performance. For the application a variety of cognitive- and physical-based sensors are selected to detect motion specific variables. For instance, an EMG sensor is selected to detect innervation patterns (i.e. onset and offset of muscle contractions) of the lower leg muscles and multiple gyro sensors are selected to detect rotary movements of the ACO, with an alternative option to make use of rotary encoder types if calibration issues arise. Furthermore, a suitable (model-based) control strategy is chosen to, for example, convert EMG signals into levels of artificial muscle forces, and position control strategy to control the stroke length of the selected double-acting pneumatic cylinder (i.e. actuator) of the ACO towards desired values.

Within the constructive part four different concepts are designed by means of 3D CAD modelling. A form-follows-function approach was followed in which a change in composition of components evokes a change in functionality and subsequently a change in shape – i.e. geometry. Thereby taking into account the rigidity of the construction and the available space for design constructive parts to concur with different body parts and the application on the bike.

Several design solutions are presented with the common goal to mimic the plantarflexor and dorsalflexor motion of the ankle joint of a healthy cyclist throughout a full pedal cycle. Several alternative positions for the artificial joint are allocated and reflected on the dynamic behaviour of the lower leg. Even though, in theory, all four concepts satisfy the main performance features concerning preferred modes of assistance with corresponding range of motions. The core design criterium is to allow sufficient torque, the torque calculations of the different concepts are suggesting that concept 4 possess the best torque capabilities. Together with the advances in tune-ability of performance parameters, point of engagement, compactness, weight distribution and safety are important selection criteria to choose concept 4 to proceed with. Although, a point of attention within this concept is the concentric alignment between the hinge and the human ankle joint. Because misalignment of the two joints can cause shear stresses on the foot which should be avoided seeing the characteristics of the CMT disease and the anthropometric differences among patients.

Furthermore, in parallel with the creation of design concepts a demonstrator was built to demonstrate a simplified working principle for plantar- and dorsalflexion of the ankle. Due to absence of the human leg the demonstrator showed that weight distribution is an important point of attention to prevent addition loads on the lower leg. Also, the demonstrator revealed adequate challenges for sensor data reception for control and sensor placement.

EMBODIMENT PHASE III



EMBODIMENT DESIGN 9

The process of embodiment design stood in the context of achieving the simplest technological architecture in the preparation for building a proof-of-principle prototype. By modifying design concept 4 the embodiment design process elaborates on embodying the functional vision of the ACO towards a mechatronic design system with integrated mechanical components, electronic components, and pneumatic components. which is the end-result of the design process for this report.

EMBODIMENT DESIGN 9

9.1 INTRODUCTION

The main objective of the embodiment design exercise was to work towards a functional prototype (i.e. proof-of-principle prototype design) in which an optimal architecture for a pneumatic- and electrical control system is sought for. Furthermore, the parametric locations on the shank and force range application of a pneumatic actuator for assistance of the ankle joint, in order to maximize the actuator force and torque requirements for the biomechanical motion of the cycling activity. An optimal solution would have the minimum number of components, and maximal possibilities for torque assist and retainment of the intended cycling cadence to be able to make the necessary motion requirements for CMT patient cycling assistance.

After elaborating on the industrial design in Ch. 9.2. and the proof-of-principle prototype design in Ch. 9.3 in which the explanation of geometry parametrization (i.e. shape, function and composition) are predominant. Followed by the selection of a suitable control system and is therefore subdivided into a pneumatic system (Ch. 9.4.) and electrical system (Ch. 9.5.) that mutually collaborate to enable the preferred product behaviour for a functional prototype.

9.2 INDUSTRIAL DESIGN

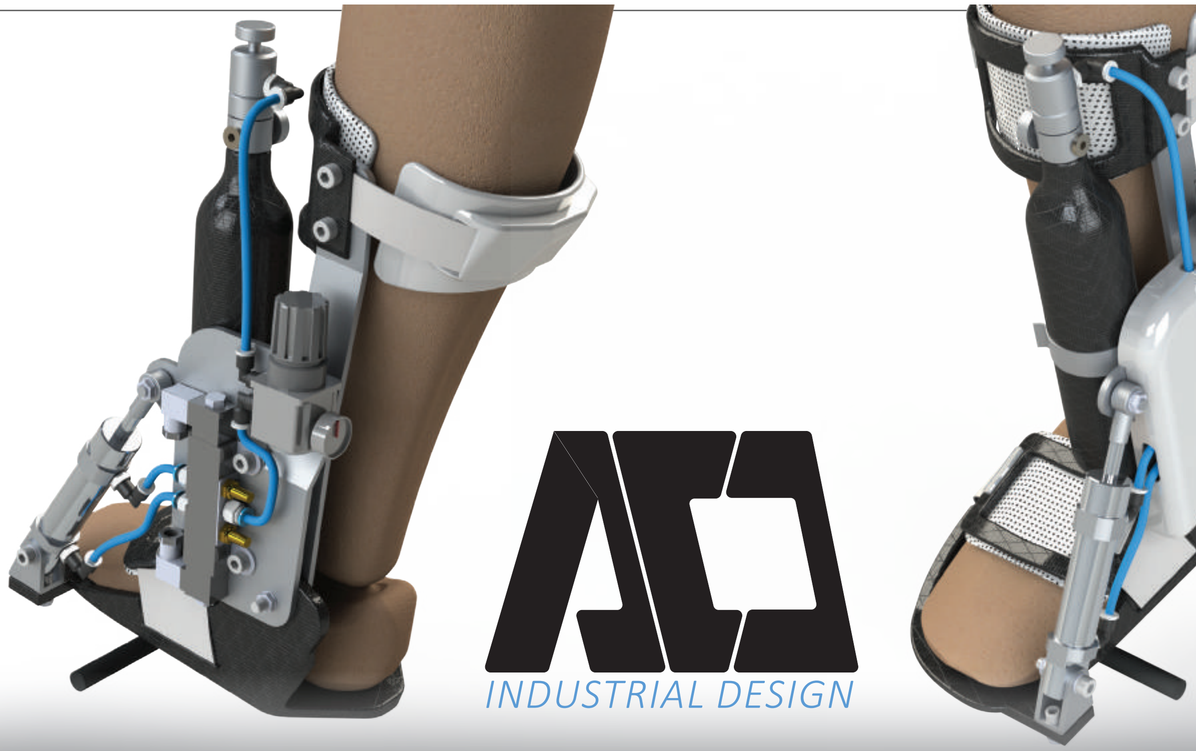
The embodiment design exercise builds upon concept 4 with an industrial design proposal (see fig. 72) that possesses most of the required features of the envisioned ACO in the preparation for a functional prototype. The objective for this industrial design was to create a single operational (i.e. left or right orthosis without intercommunication) stand-alone orthosis which could be mounted on any standardized crank-arm of an ergometer bike.

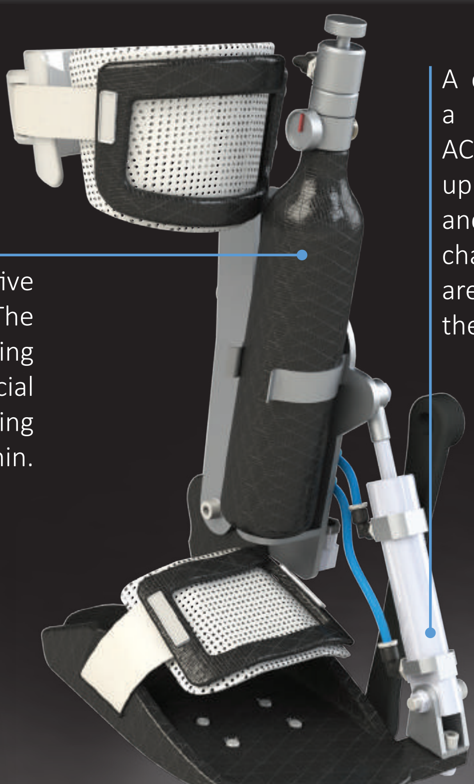
Within this industrial design, parametrization of the shank-arm geometry and cylinder size is reviewed for optimal force range application for assistive ankle joint torque and operational speed requirements which are calculated in the pneumatic system section (see Ch. 9.4.1.).

Another important aspect is the composition/ allocation of operational components. As shown in figure 73, the components that are used in this industrial design are carefully selected out of (mostly) industrial stock items to increase reliability and feasibility (i.e. to suppress costs and time for manufacturing of custom components). The argumentation for choosing this technological architecture will be elaborated upon in Ch. 9.4. Hence, the shank-arm is modified and acts as a console to mount all the necessary pneumatic and electrical components closely in order to minimize wiring distances and store the components in a casing (see fig.72) to ensure safety and damaging the components. Moreover, the majority of components are mounted on the medial side of the orthosis (in between the foot and the crank-arm) to preserve the space on the lateral side of the orthosis for aesthetic reasons and the possibility to design an exit strategy to safely step off the bike or a design a release system when the design is in a further development phase.

9.2.1 THE NEED FOR A DESIGN OPTIMIZATION STEP

The design intention was to develop this industrial design concept towards a proof-of-principle prototype. However, after assessing the compatibility of the design some shortcomings were seen. For instance, the rigid foot sole of this industrial design should be universal for different foot anthropometrics (i.e. size and shape) to comply with CMT patients' foot deformities – while knowing from the analysis on passive AFO designs (see Ch. 3.2.1.), that one size (usually) does not fits all. Although, it was considered to design an adaptable/ modular version for different foot anthropometrics. However, This decision was withdrawn, because it is expected that in order to design a comfortable





The ACO is intended for rehabilitative usage on a bike ergometer. The compressed air tank of 0,5 L is providing sufficient air supply for the 'artificial muscle' to assist the patient during cycling exercises for up to 30 min.

A double acting pneumatic cylinder is a substantial component within the ACO. This 'artificial muscle' is creating up to 50% of assistance during plantar- and dorsiflexion motion. The spring characteristics of the pneumatic cylinder are providing an elastic response to the movements of the human muscle.

Figure 72: Industrial design proposal for a stand-alone active cycling orthosis

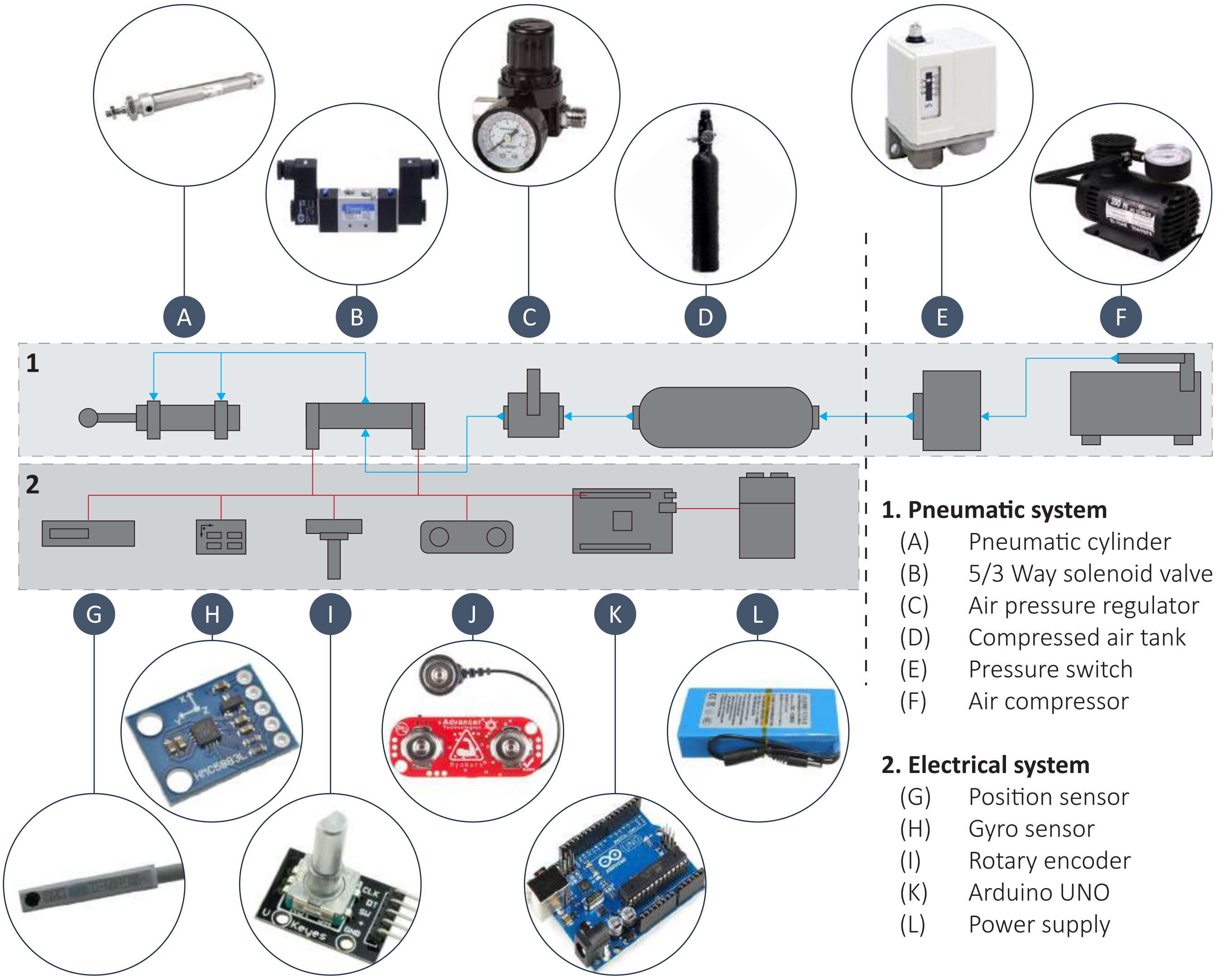


Figure 73: Industrial design system architecture; this diagram represents a simplified connection relationship between components of both the pneumatic system (1) and electrical system (2). The components E and F are connected to a 24V power supply and are only needed to feed the air compressor with compressed air, when the compressed air tank is full it can be dismounted from the system after which the ACO is free from stationary equipment.

foot sole, probably more (custom) components would be added which increases the complexity and subsequently the risk of failure, increased weight and costs. Thus, going in this direction the design process would diverge from the main objective of building towards a functional prototype that enables testing the assistance mechanism.

Furthermore, shortcomings were seen in the context of safety. Namely, the alignment of artificial joint with the human ankle joint needed revision, because with the (current) industrial design it is not possible to adjust the alignment between the two joints. Moreover, the possibility to release the orthosis while mounted on the bike or releasing the bike while wearing the orthosis is seen as considerable importance during testing.

Thus, notable design adaptations had to be made to make the design ready for a proof-of-principle testing. Nevertheless, the technological architecture of this industrial design is preserved so that the next design focus lies on a mechanical solution to deal with above mentioned shortcomings.

9.3 PROOF-OF-PRINCIPLE PROTOTYPE MODEL

After evaluating the industrial design on its manufacturability with the available resources and the compatibility of the design for a proof-of-principle prototype test (see Ch. 9.2.1.). The importance for a design modification step was acknowledged. Therefore, the design objective was to (re)design a simple mechanical construction that caters to simplicity and flexibility to enable the core working principle (i.e. assistance technique) of concept 4 and industrial design.

This first version of the proof-of-principle prototype design which is shown in figure 74 was designed by means of the following design criteria:

- Simple constructive method to accurately align artificial joint with ankle joint.
- Hight adjustability of the brace to act upon different tibial lengths (i.e. length of lower leg).
- Flexibility in positioning the anchor point of the cylinder piston to vary in force range.
- Simple ergonomic design solution for the foot sole.
- Foot sole should allow different (abnormal) foot anthroppometrics to be fit in.

Figure 74: First physical model of the functional prototype

9.3.1 ERGONOMICS

With the previousy described criteria a simplified design was created for the mechanical part of the prototype by means of 3D CAD. The design study suggested that there was essentially no need for foot sole optimization. Instead, the decision was made to replace the foot sole with (ordinary) cycling shoes that have standardized insertion holes for clipless pedals (see fig. 75). Because of this, the patient (i.e. cyclist) can wear their own (comfortable) cycling shoes, which eliminates the need for a customizable foot sole. provides a couple of benefits. Namely;

- It is expected that when the patient is able to wear their own cycling shoes it increase comfort of wearing the orthosis.
- The sole of the cycling shoe is generally made of a stiff material (see context analysis at Ch. for the importance of this requirement).

Figure 75: Shimano SPD clipless pedal system; with (A) SPD pedal and (B) the SPD cleat which will be attached to the bottom of the prototyped baseplate.

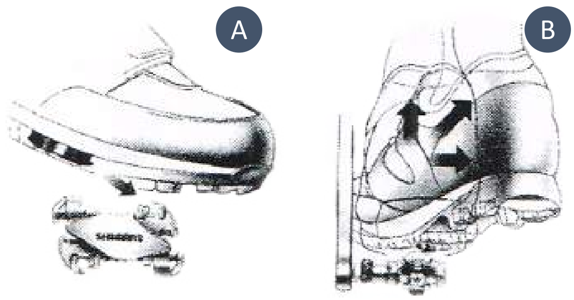


Figure 76: (A) Technique of engaging the clipless pedal; by stepping onto the pedals (click to secure the feet in place), and (B) technique of releasing; by making a swing movement to the outside of the pedal.

- Cycling shoes are generally lightweight which will reduce the total weight of the orthosis.
- The clipless pedals are a reliable mechanism to release the orthosis from the bike.

Furthermore, to support the foot and among other parts of the orthosis, a baseplate is designed out of sheet metal which is sandwiched between the cycling shoe and the pedal cleat for clipless pedals (see fig. 77). This baseplate makes it possible to releasing the bike (i.e. from pedal) while wearing the orthosis by making a swing movement to the outside of the pedal, which increases the element of safety (see fig. 76).

As shown in figure 78, the brown colored parts of the design are a manufactured out of sheet metal with keyways to adjust the distances between relative parts. On the rear side of the orthosis these keyways are allocated for ergonomics in terms of adjusting the orthosis to the anthropometrics of the cyclist. For instance, the baseplate enables adjustability for different shoe sizes (i.e. rear foot stance) by means of point D and ankle height by means of point C. Moreover, point C can be used to accurately align the artificial joint with the human ankle joint. Whereas, points A and B can be used for positioning of the shank in which point A is specifically assigned for adjustability of the brace. In which small adapter tubes can be implemented to properly align the brace (i.e. in the sagital plane)onto the shinbone to make sure that the brace lies in the extension of the foot.

Figure 77: shows the envisioned set-up for a functional prototype; a regular cycling shoe used which is bolted onto the baseplate, subsequently the baseplate is sandwiched between the cycling shoe and an SPD mounting bracket which can be (dis)mounted onto the Shimano SPD pedal.

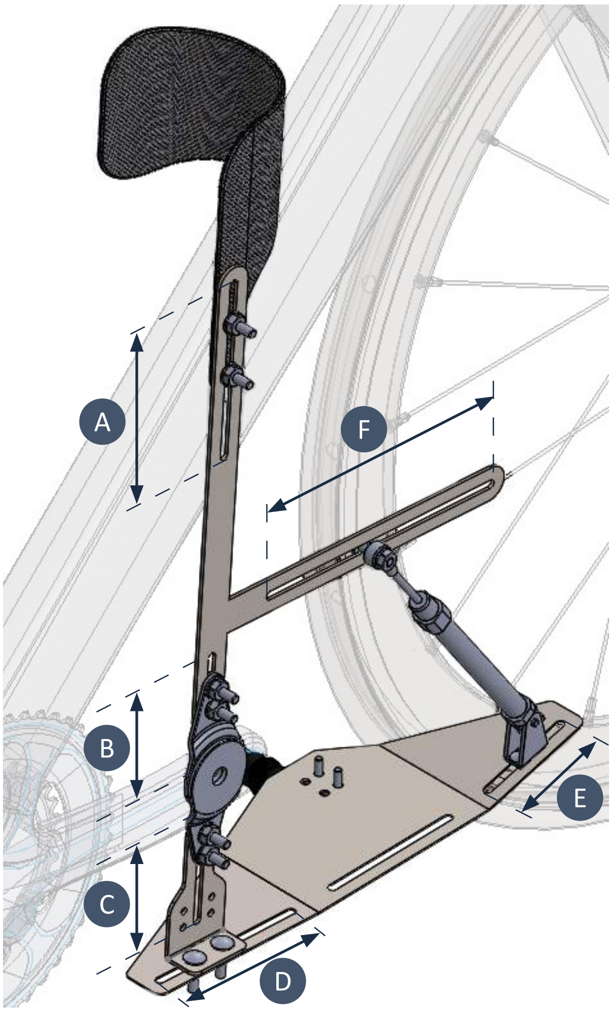


Figure 78: Allocation of keyways for adjustment of the prototype geometry to the anthropometrics of the cyclist; the keyways allow for adjusting (A and B) tibial height, (C) ankle height, (D) rear foot stance, (E) cylinder bracket anchor point, and (F) cylinder piston rod anchor point.

9.3.2 FUNCTIONALITY

Furthermore, on the front side of the orthosis two keyways are allocated for adjusting the position of the pneumatic cylinder and are therefore effecting the the assistive performance of the orthosis. Hence, point E and F can be used for torque range application. As higher assistive torques can be created by distancing the anchor points from the (ankle) joint.

In addition, the cylinder generally has a fixed stroke length (i.e. extension/retraction range) therefore by distancing the cylinder further away or more close to the joint it will effect the ROM of the ankle joint. A Camber-Axis Hinge joint developed by David J. Hoy (Ottobock, 2018) permits solid ankle or variable anterior/posterior stop settings and can be set in seven different ROM settings by changing the keys (see fig. 79). Hence, the Camber Axis Hinge joint is therefore a valuable addition to the orthosis prototype, because it creates the possibility to tune torque performance parameters without effecting the required ROM in performing a pedal stroke.

Furthermore, a functional modification of the shank is implemented. Unlike the industrial design, the shank of the prototype model is moved to the lateral side of the lower leg for a couple of reasons. Namely;

- Space between lower leg and crank-arm of the bike is limited and therefore impedes the design freedom for prototyping.
- Tubing and wiring is easily accessible at the lateral side to make adjustments during testing (when a person is on the bike).
- The possibility of (electrical) wires and (pneumatic) tubing wrapping around the crank-arm during cycling is decreased.

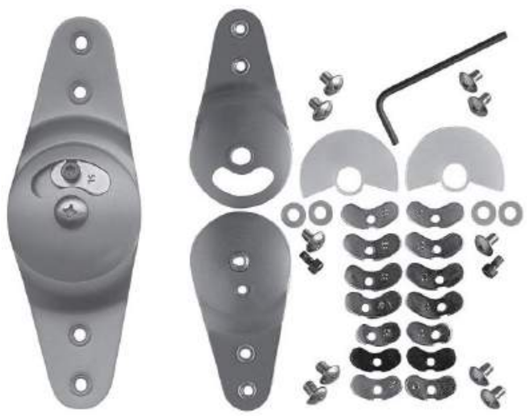


Figure 79: Camber-Axis Hinge joint developed by David J. Hoy to limit ankle joint movability in seven different ROM settings by changing the keys.

9.3.3 DEFORMATION ANALYSIS

Seeing the previously mentioned functional modifications for the prototype. Consequently, the shank is providing assistance at a single side of the leg. Hence, it was expected that the sheet metal parts will deform while loaded.

Therefore, an explorative study on the stresses and displacement of the shank and baseplate was executed to define the thinkness of the sheet metal parts (see fig. 80). The deformation analysis was executed for 1mm, 2mm and 3mm thick 316L Stainless Steel (SS) sheet metal on which forces are applied – 40 Newtons exerted by the cylinder and 133 Newtons exerted by the cyclist. For further reading on the deformation analysis see Appendix J.

The choice was made to manufacture the parts out of 2 mm 316L SS sheet metal on the basis of the simulation results for the shank. The connection

Futhermore, 2 mm sheet metal is chosen to allow for a certain degree of flexion seen the potential harm which can be done with a rigid construction. In addition, minimal weight, cost, delivery time, and machining method (i.e. lasercutting) were considered while choosing the prefered thickness (see Appendix K for technical drawings for lasercutting the parts).

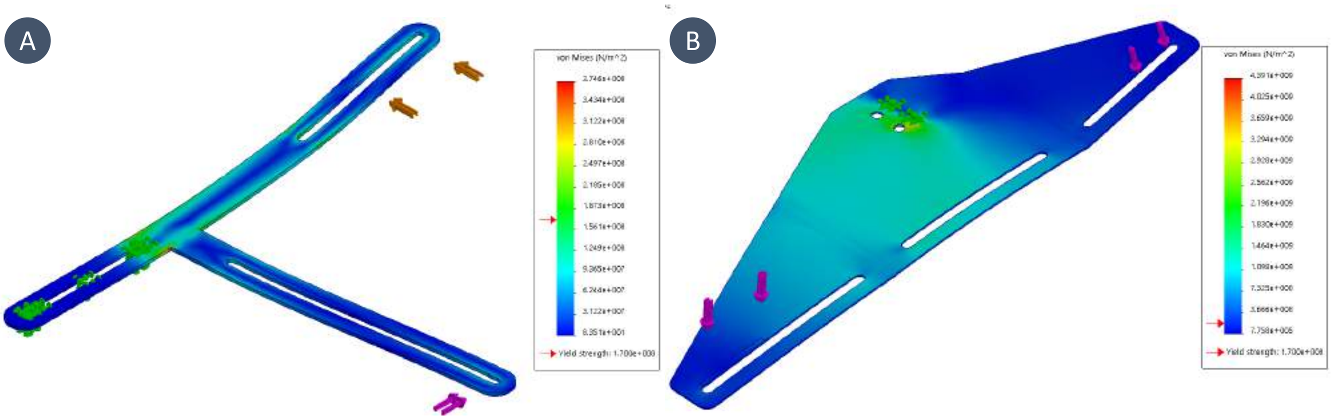


Figure 80: Stress analysis results of the (A) shank and (B) baseplate using 316L Stainless Steel (SS) sheet metal to showcase bending deformation of 2 mm thick parts with an applied load of 40 Newtons applied by the cylinder and 133 Newtons applied by the cyclist.

9.4 PNEUMATIC SYSTEM

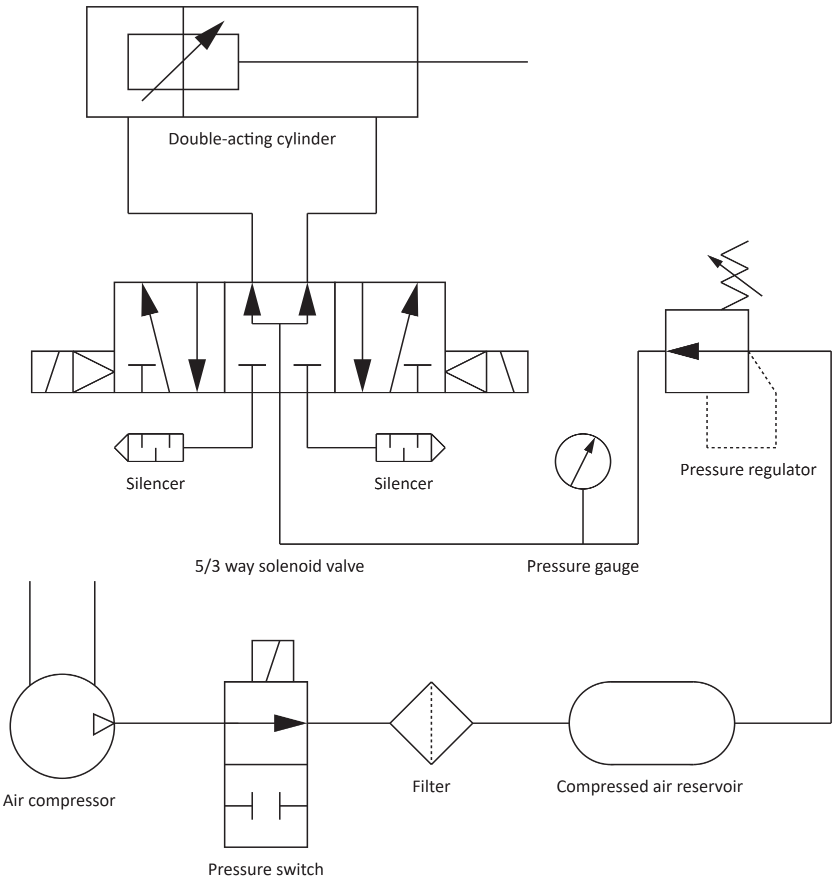


Figure 81: schematic pneumatic system for the proof-of-principle prototype

9.4.1 DOUBLE-ACTING PNEUMATIC CYLINDER

The most important design challenge of this part is to find a cohesion between cylinder properties and design geometry in such a way that one pneumatic cylinder is able to assist the necessary plantar- and dorsal flexion motion of the ankle for one lower leg. As discussed in Ch. 7.5.2. the double-acting pneumatic cylinder is the best suitable actuation modality for the ACO based on its performance and control characteristics and is therefore considered to be the main force control operator. Based on the expected function there are a few performance parameters that influence the obtained output force of the cylinder. For instance, air pressure and cylinder diameter are key parameters for defining the output force. To find a suitable configuration, multiple operational performance criteria are considered which are described by operating force, operating range of motion, operating speed and operating time.

Operating force:

1. Affects – assistance torque, together with torque-arm (requirement: torque ±25 Nm)
2. Defined by – [A] air pressure, and [B] cylinder diameter.
3. Variable with – differences in out-/in-stroke (i.e. respectfully plantar-/dorsal flexion motion).

Operating range of motion:

1. Affects – ankle range of motion (requirement: 30 degrees of which 10 degrees dorsal flexion and 20 degrees plantarflexion).
2. Defined by – [A] stroke length and [B] force-arm.
3. Variable with – anchor point positioning

Figure 82: Variations of compact SMC Pneumatic cylinder series C85 (www.pneumatiek.nl, 2017).

Operating speed:

1. Affects – pedal angular velocity or pedal frequency- i.e. cycling cadence (requirement: 1800 strokes/per minute)
2. Defined by – [A] air pressure (i.e. piston speed) and [B] stroke length
3. Variable with – input pressure and reaction force of the human muscle.

Operating time:

1. Affects – possible duration of exercise (requirement: 30 minutes).
2. Defined by – [A] cylinder diameter, [B] stroke length (i.e. A and B: volume of cylinder) and operating frequency [C].
3. Variable with – the volume of air supply (i.e. capacity of compressed air tank).

Hence, these functional properties define cylinder sizing and subsequently affect the overall weight, compactness, and compliance of the ACO. The main objective was to tune these parameters towards the desired values in order to find a lightweight and compact solution that meets these operational performance requirements. Firstly, a theoratical approach was followed to judge the feasibility of satisfying the required assistive torque of 25 Nm (i.e. 50% of the average torque around the ankle joint by healthy cyclist) with a compact cylinder.

As mentioned in Ch. 8.5 the force-arm (r_{rod}) is an important design parameter to define the required torque. According to the torque equation $T = F * r$. The first design consideration was to increase the distance between rod anchor point and the (artificial) joint (see fig. 83). By increasing r_{rod} a lower exertion force F_O and F_I is needed and subsequently lowers the operational performance requirements of the cylinder. Alongside this torque feature, another beneficial ancillary of an increased force-arm is observed concerning weight distribution of the orthosis. Namely, ideally an equilibrium around the pedal-axis is favourable to reduce additional loads on the lower leg as the majority of weight is located at the rear side of the orthosis. Thus, by moving the cylinder to the front, the mass of the cylinder will act as a counterweight to reduce these addition loads.

The second design consideration is the corresponding stroke length, because distance of the force-arm (r_{rod}) and stroke length (s_l) are defining the operating ROM (30 degrees). However, preferably the cylinder is as small as possible to minimize air consumption, weight, costs, and bulkiness. Hence, stroke length should be as short as possible while increasing the force-arm subsequently the stroke length needs to be increased to retain the operating ROM.

Within this design exercise an example unit of the SMC pneumatic cylinders C85 series (see fig. 82) was integrated into the 3D CAD model to optimize the geometry of the design regarding anchor point allocation and cylinder sizing. The corresponding datasheet (see Appendix L and M) was used to explore the possible cylinder sizes and properties, of which cylinder diameter (ranging from Ø8 - Ø25 mm), rod diameter (ranging from Ø4 – Ø10 mm) and stroke length (ranging from 10 – 300 mm), and operating pressure differential (ranging from 1 – 10 bar) are considered. In which cylinder sizes and stroke length were reviewed to check if prefabricated cylinders comply with the desired range-of-motion of the 3D CAD model.

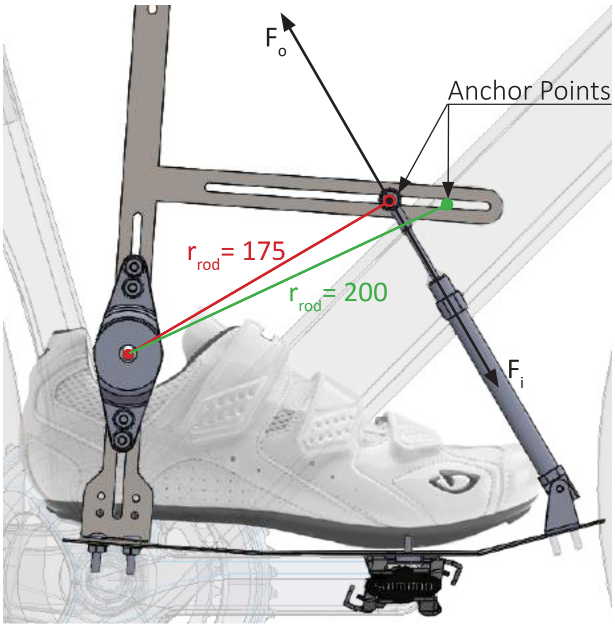


Figure 83: Contextual torque diagram for calculation of torque ($T = r_{rod} * F$) for allocation of anchor point positions, plus graphic representation of baseplate sandwich construction.

A minimal distance of r_{rod} = 143 mm was found with the largest cylinder available (CD85N-25-50; piston diameter: Ø25 mm, and rod diameter: Ø10 mm) to satisfy the required torque of 25 Nm with an operating pressure of 5 bar as can be seen in figure 84 and 85. Although, for the prototype a reasonable factor of safety is taken into account to avoid contractures during a first trial test. Therefore, a cylinder is selected that is able to exert around 15% of the required force (see fig. 85).

Furthermore, by changing the position of the anchor points while increasing r_{rod} between 175 – 200 mm (with corresponding cylinder stroke length of 80 mm) a torque range application is possible between 1,17 – 13,35 Nm for plantar flexion assist and between 0,98 – 11,22 Nm for dorsal flexion assist within pressure differential range (1 – 10 bar).

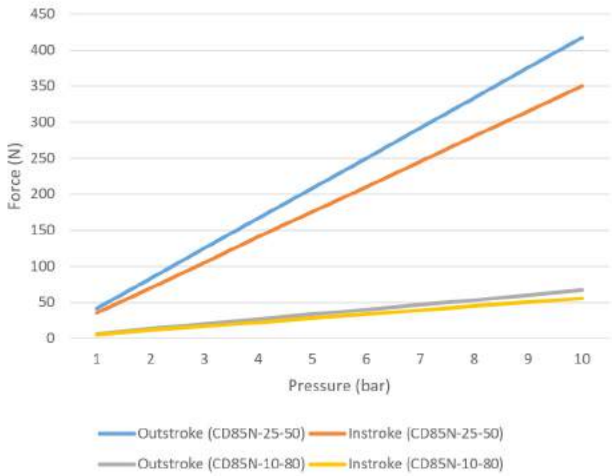


Figure 84: Force/Pressure diagram with CD85N-25-50; industrial design cylinder, and CD85N-10-80; functional prototype cylinder.

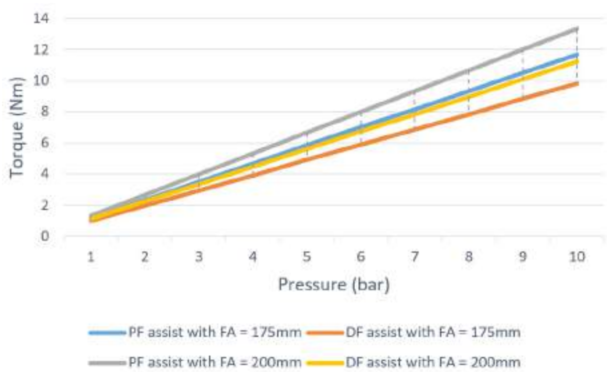


Figure 85: Torque/Pressure diagram with dorsal flexion (DF), plantar flexion (PF) and Force-arm (FA=r_{rod})

In addition, Hazem et al. (2009) proposed an interesting setup for the pneumatic actuator system (see fig. 86) and is therefore partly used in the schematic pneumatic system shown in figure 81. In which the fed air pressure can be controlled with a 5/3 solenoid valve to switch between operating pressure in each of the cylinder chambers. An optimization step for the final design could be made by implementation of the pressure sensors P1 and P2 (input variables) to accurately detect the pressure differential by the controller to correct the desired air pressure. Based on the output values gained from the position sensor the displacement of the shank (i.e. load) can be monitored an adjusted accordingly.

Cylinder air consumption

Another important property within the pneumatic system is the duration of rehabilitative cycling exercise which is, in essence, depended on the available air supply that is used during the cycling exercise. There are two options available to feed the cylinder with sufficient air. Namely, as previously mentioned in Ch. 9.2, a stationary air compressor or a portable compressed air tank. Wherein, cylinder diameter (i.e. effective area for out-/instroke), stroke length and frequency of operation are key variables. Even though, a portable compressed air tank is favourable, the decision was made to equip the prototype with a stationary air compressor (see fig. 87). Whereas the final design probably possesses a compressed air tank to create a compact and portable design solution. Consequently, the required volume of the compressed air tank was calculated to select an actuator that is suitable for both a stationary and a portable air supply. The calculations in Appendix M are showing that the compressed air tank (300 bar) of 0,45 L is containing sufficient air for a cycling exercises of approximately 30 minutes with 1800 strokes per minute (i.e. cadence of 60 RPM).

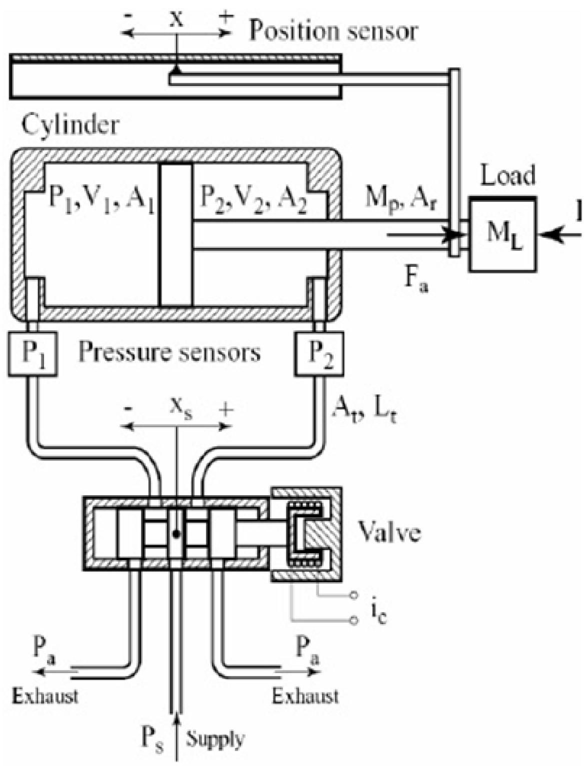


Figure 86: Schematic diagram of double-acting pneumatic actuator system (Hazem et al. 2009).

9.4.2 WORKSTATION DESIGN

In order to persue the designed pneumatic setup decribed by figure 81. A workstation is designed to assemble all the neccesary components at one place for operation of the pneumatic cylinder. The decision was made to mount the components on a cart to showcase the compatibility/compactness of a similar setup for implementation on the bike. For future operation at a rehabilitation centre (or comparable) to test with multiple patients a similar setup could be thought of. Besides, within this graduation project it was a cheap and efficient solution to carry everything from one place to the next.

In figure 87, the implemented components are highlighted and a brief explanation of component purpose for the pneumatic system is described.

After some try-outs were executed with the workstation and the functional prototype it was reasoned that several operational features were not possible to execute with the developed pneumatic system architecture. Although these components were adequate for a first Proof-Of-Concept (PoC) test to validate the envisioned working principle of the functional prototype. Furthermore, insights were gained to improve the system for future operation:

Manual pressure regulator
The manual pressure regulator can only be adjusted by hand. It was expected that this control method was adequate to discover the desired pressure level (i.e. level of assistance). However, for future purposes this component needs to enable electronic control so that the pressure level can be controlled according to the sensory information from the EMG surface sensors described in Ch. 9.6.

5/3 way solenoid valve
The 5/3 way solenoid valve is (without position sensor) generally used for absolute operation (i.e. full extension/retraction of the cylinder piston. However, with position sensor the 5/3 solenoid valve is able to reach limited midstroke positions. This is however not the envisioned functionality, the control valve should enable complex profiles with high accurate positioning of the cylinder piston. Thus, with recent insights it is reasoned that the most optimal solution would be to replace the 5/3 way solenoid valve with a 5/3 proportional control valve to increase the response time and linear proportionality of the cylinder piston.

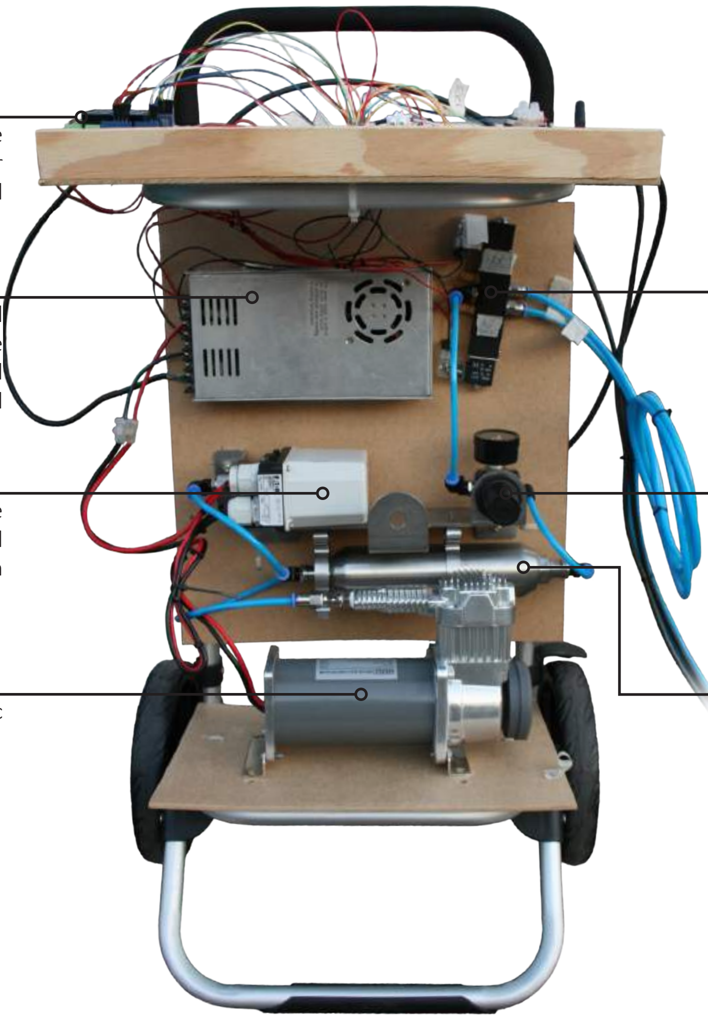


Figure 87: A portable workstation was developed for operation of the double-acting pneumatic cylinder. Besides, the workstation is intended to have a compact solution so that all the components can be carried at once for efficient installation on site and transport.

9.5 ELECTRICAL SYSTEM

The main design exercise for the electrical system was to integrate the selected sensors, such as rotary encoder, gyro sensor, position sensor and EMG surface sensors in the electrical part of the design. However, as mentioned previously in Ch. 9.5 some pneumatic components such as the pressure regulator and the 5/3 way solenoid valve were not implemented into the pneumatic system. Therefore, the position sensor and EMG sensors became useless and are withdrawn from electrical system for the functional prototype. Subsequently, signal processing variables changed according to figure 92. Nevertheless, within the signal processing (Ch. 9.5.1.) part of this chapter, the purpose of the above-mentioned sensors will be discussed to elaborate on the envisioned electrical system architecture.

In figure 88 and 89, the end-result of the functional prototype and electrical system is shown. This functional prototype possesses a 1024 P/R (incremental) rotary encoder; to measure the angle of the joint, and a BNO-055 (absolute orientation sensor) with built-in gyroscope; to measure the angle of the pedal (i.e. foot). These two sensors are connected to the Arduino board according to the electrical scheme which is shown in figure 88 and 91.

Leading up to this end-result, some difficulties were experienced with the programming of the rotary encoder with the Arduino (see Appendix O for the designed Arduino code). At first, a 24 P/R rotary encoder was implemented (see fig. 90). However, after extensively trying out the encoder, the decision was made to replace the 24 P/R rotary encoder with a 1024 P/R rotary encoder (see fig. 90). Because it was noticed that the 24 P/R rotary encoder was not suitable for measuring the angles of the joint seeing the sensitivity of the sensor relative to the restricted ROM of 30 degrees. Hence, the rotary encoder is able to only measure 2 steps in 30 degrees (i.e. 24 steps in 360 degrees). Consequently, it was not possible to capture the intended motion of the cyclist while moving between pedal phases, because it is for example not possible to identify the direction of the rotation.

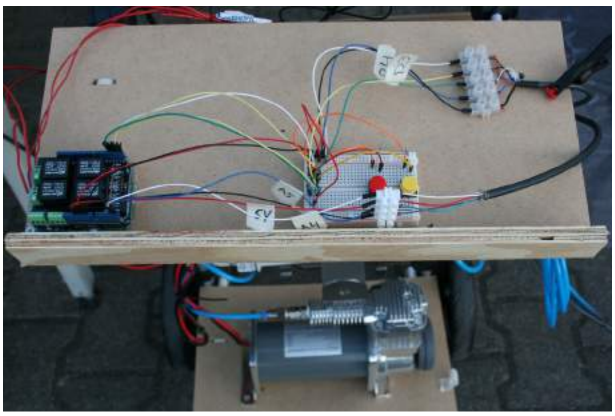


Figure 88: Arduino circuit board and wiring mounted on the workstation.

Figure 89: Final proof-of-principle prototype design.

9.5.1 SIGNAL PROCESSING

In table 6 of Appendix N, multiple sensors are listed that are detecting valuable information about the relative human and design components for signal processing. By means of these parameters, a suitable control strategy is sought for to drive the actuator with the desired level of assistance (i.e. force and positioning).

Alongside with figure 92 and 93, it is explained how the biomechanical data of the cyclist is acquired, processed and used within the design to correct the abnormal motion profile of the patient (see fig. 35 of Ch. 55).

Signal processing for assistive pedal movement:
In order to correct the abnormal motion profile of the patient it is important to firstly capture the kinematic state of the lower leg of the cyclist

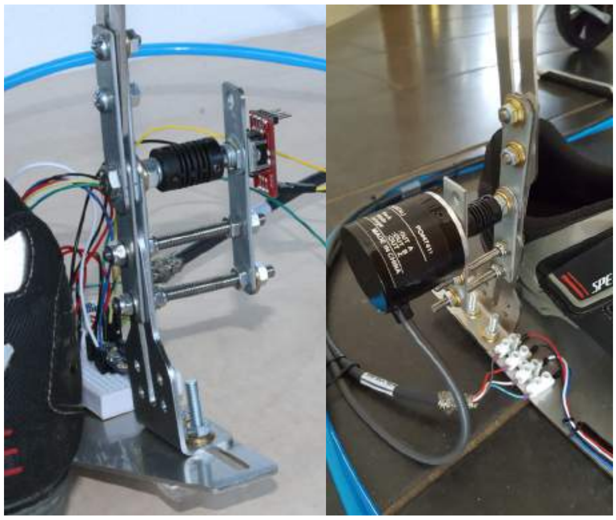


Figure 90: integrated 24 P/R rotary encoder at measuring the joint rotational motion (left) is replaced by a 1024 P/R incremental rotary encoder (right)

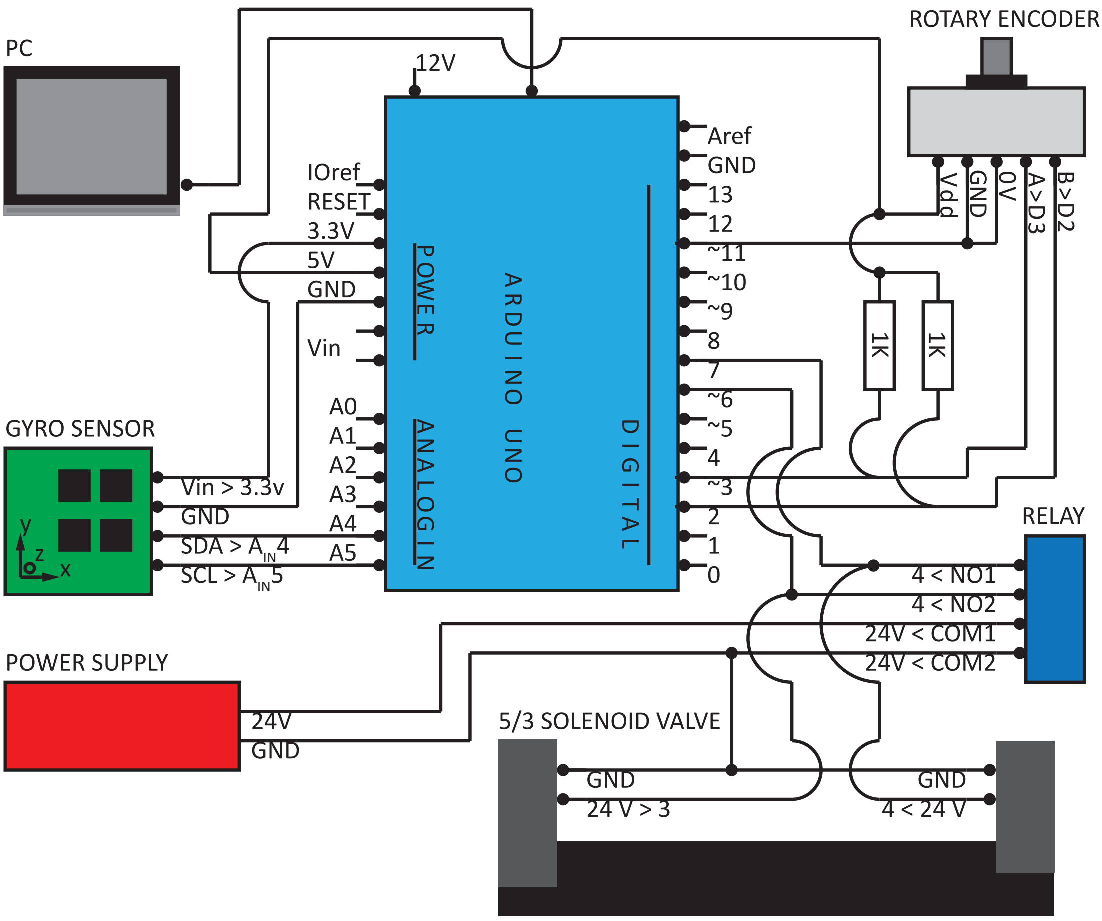


Figure 91: Schematic electrical circuit system of the developed proof-of-principle prototype .

by measuring the starting position of both the orientation of the pedal (i.e. position of the foot in space) and the corresponding joint angles (i.e. orientation of the shinbone in space). Hence, the starting position of the pedal and joint are revealing valuable information about the possible motion intention and their presence in a certain pedal phase. The parameters that are needed to feed the microcontroller with the required sensory information to create the desired motion profile of pedal and ankle joint are captured by means of a collaboration between gyro sensor (i.e. detects motion/position of the pedal) and the rotary encoder (i.e. detects motion/position of the joint). As shown in figure 88, the sensory information of both sensors are combined for processing to on the one hand, verify if the pedal is at a certain point in the pedal cycle (e.g. 10% of full pedal cycle) and on the other hand, predicts (with an algorithm) at which point the system should act upon the intended motion to either extend or retract the cylinder piston. Subsequently, the position sensor can be used to accurately verify the position of the cylinder piston.

Furthermore, it is possible to use the time variable at which peak angles occur to identify the pedal cadence. For instance, the frequency at which peak angles are occurring within a time domain tells us something about the pedal cadence as well as the angular velocity of the joint.

Thus, by acting accordingly concerning the timing of onset/offset for extension/retraction of the cylinder the cycling cadence of the cyclist can be retained.

The previously described sensors are all used to collect biomechanical data about the current kinematic state of the cyclist. So, based on these kinematic parameters (i.e. point at which the foot and joint are positioned) the microcontroller will send information (i.e. the range of extension or retraction) for positioning the cylinder piston. Therefore, the position sensor is used to control cylinder piston movement with the goal to retain the desired linear movement in varies positions. Which essentially determines the possible variations in ROM of the ankle joint.

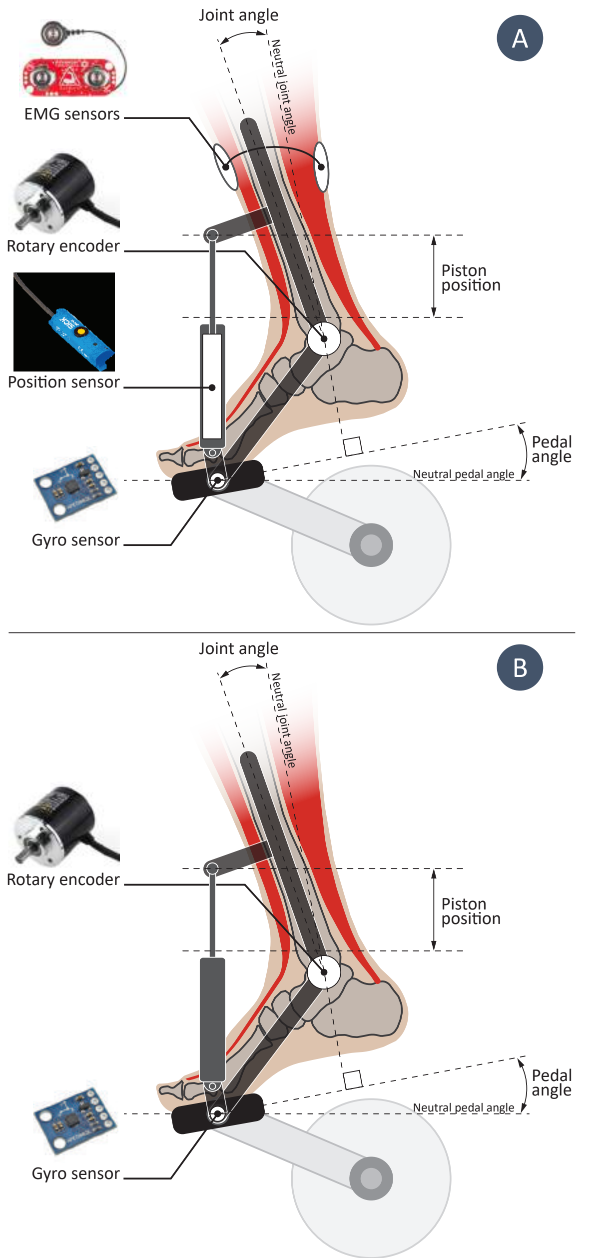


Figure 92: Sensor placement with corresponding parameters for signal processing, in which (A) is the composition of sensors for the desired/envision proof-of-principle prototype, and (B) is the composition of sensors for the developed functional prototype.

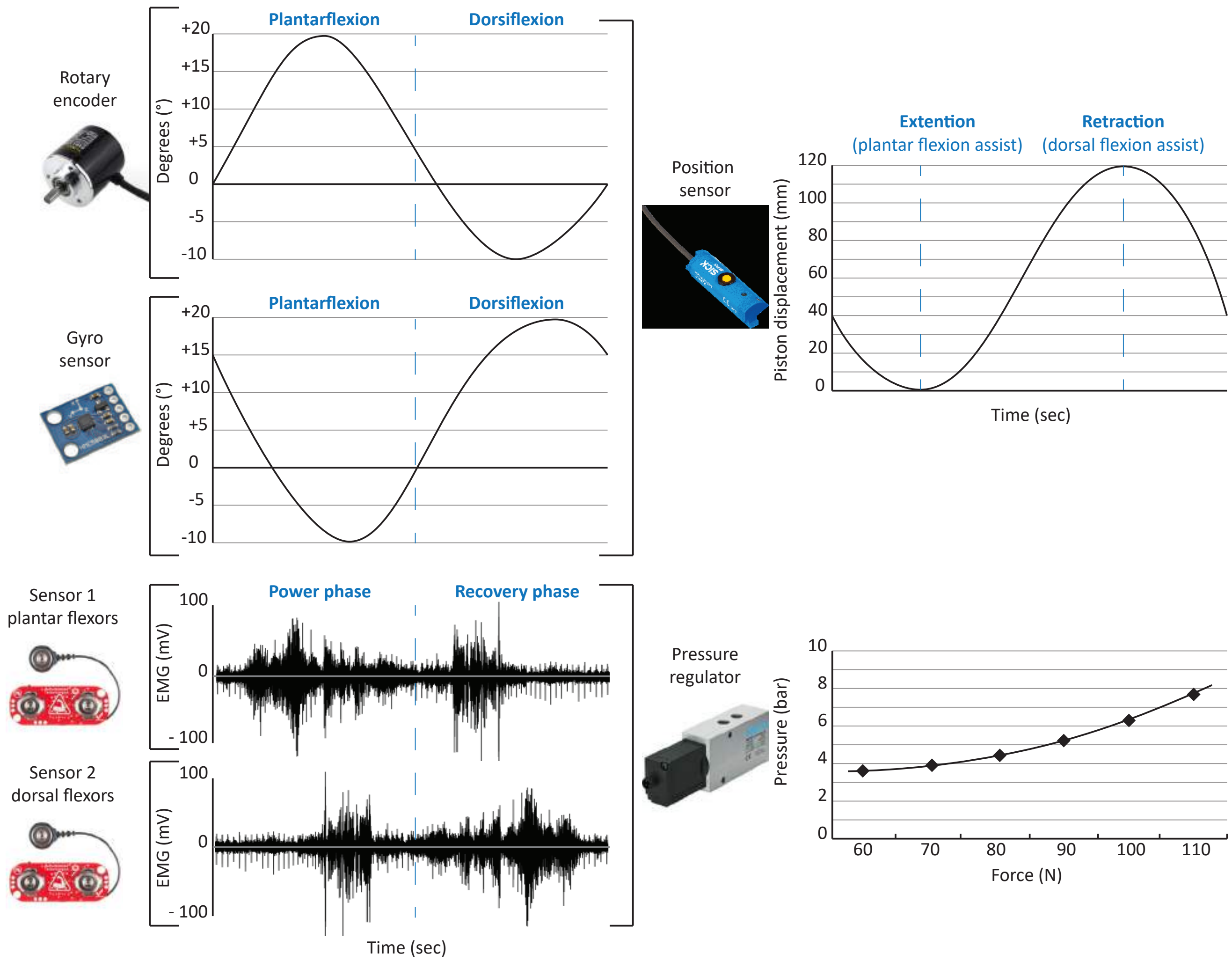


Figure 93: Signal processing diagram; sensors on the left side of the diagram are receiving biomechanical data (i.e. input variables) of the cyclist, whereas the right side of the diagram shows the the output variables after signal processing.

Signal processing for assistive pedal force:
The raw EMG signal that is detected with the surface EMG sensors follows out of the plantarflexion muscle contractions can be rectified and integrated in which the amplitude and time of the signal are indicating muscle strength, duration of innervation and on and offset values that can be translated into a pressure differential for the double-acting pneumatic cylinder. For example, during the power phase (i.e. from TDC to BDC) a cyclist will use their plantar flexor muscles (i.e. calf muscles) predominantly, the signals that are captured by the surface EMG sensors will be fed to the microcontroller. Subsequently, the microcontroller will process these signal (i.e. muscle effort) towards the desired force control (i.e. pressure differential assigned to the pressure regulator defines exerted force of the pneumatic cylinder) as shown in figure 93 to define the desired level of assistance. Hence, these forces can be expressed in a certain assistive torque around the ankle joint with the described force-arm of the shank (see Ch. 9.5).

POC TEST 10

In the Embodiment Design (Ch. 9) describes the preparations for a proof-of-principle prototype and the development of a functional prototype in the preparation for testing. Moreover, this chapter eloborates on proofing the working principle of the physical prototype which is the end-result of this report.

10.1 PROOF-OF-CONCEPT (POC) TESTING

10.1.1 RESEARCH OBJECTIVE

To study the impact of assistive torque on the kinematics of the ankle joint on a stationary race bike. The goal is to observe a possible change in the motion profile of the ankle joint after performing a full pedal cycle within two separate exercises: (1) without active assistance, and (2) with active assistance of the ACO prototype. The aim is to validate the applicability of active assistance on the cycling experience of the CMT patient during plantar flexion and dorsal flexion assistance.

Current motion profile: If the patient is pushing the pedal down during power phase (i.e. pedal at TDC towards BDC) without active assistive torque the heel "falls down" rapidly (i.e. the slope decreases rapidly – described by the green line in figure 95 of the user test) due to the lack of muscle strength in the calfs of the patient.

Desired motion profile: The dotted red line describes the preferred motion trajectory in which the abnormal ankle motion is corrected and assisted towards a smoother sinusoidal motion pattern.

Figure 94: Physical representation of the PoC test set-up.

It is expected that the position (i.e. specific angle) of the ankle will be corrected by applying assistive torque. Hence, the PoC test should provide an answer to the following questions;

- Is it possible to correct the unnatural angles of the ankle joint with active torque assistance?
- What is the influence of different pressure levels on the kinematic state of the joint?
- What is desired level of assistance for the patient?
- How does the patient experience the assistance?

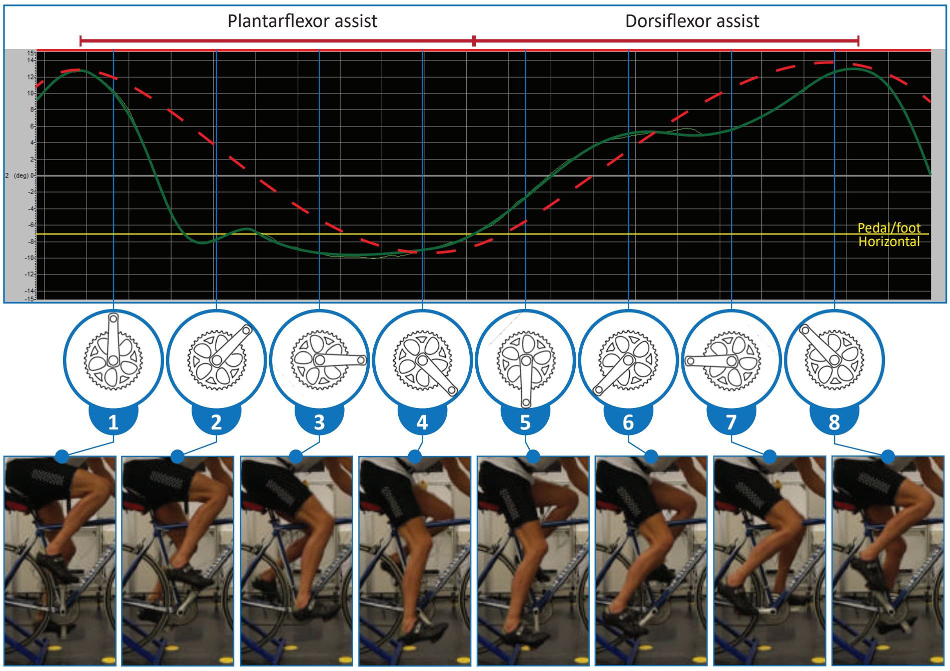


Figure 95: Reprint of the user test measurements concerning motion profile of the ankle joint; within the graph, the current motion profile (green line) and desired motion profile (dotted red line).

10.1.2 PROCEDURE

The Proof-of-Concept (PoC) test is held in two phases – a pilot phase and a trial phase – with the same participant (i.e. CMT patient) who performed the user test which was conducted in the analysis phase of the project (see Ch. 5).

The experimental set-up is similar to the user test (see fig. 96). Namely, during this PoC test, the pedal movement will be observed by means of a camera – capturing the kinematic posture of the cyclist (from a side view). Furthermore, the Biometrics goniometers are placed on the ankle and knee joint to capture the (angular) movements of the joints.

During the pilot phase, the participant will perform the tasks described in the roadmap (see Appendix O) to set the desired parameters for assistance and decide whether or not to proceed with the next phase in terms of safety. Moreover, the patient has to wear his standard passive AFO on his left leg in order to quickly respond in the case of an unwanted event and regain direct stability when stepping off the pedals. Hence, the passive AFO constrains ankle joint movability. Besides, it is expected that fixation of the ankle joint brings the primary focus of the patient to the performance of the ACO.

Within the trial phase two exercises will be performed;

<u>Exercise 1:</u> cycling without active assistance – to examine the motion profile of the ankle and knee joint while wearing the ACO and compare the data with the measurements of the user test.

<u>Exercise 2:</u> cycling with the active assistance of the ACO – constitutes an explorative study in which the influence of a variable level of assistance will be observed on the experience of the cyclist.

During these exercises several parameters will be adjusted to explore the possible influence on the

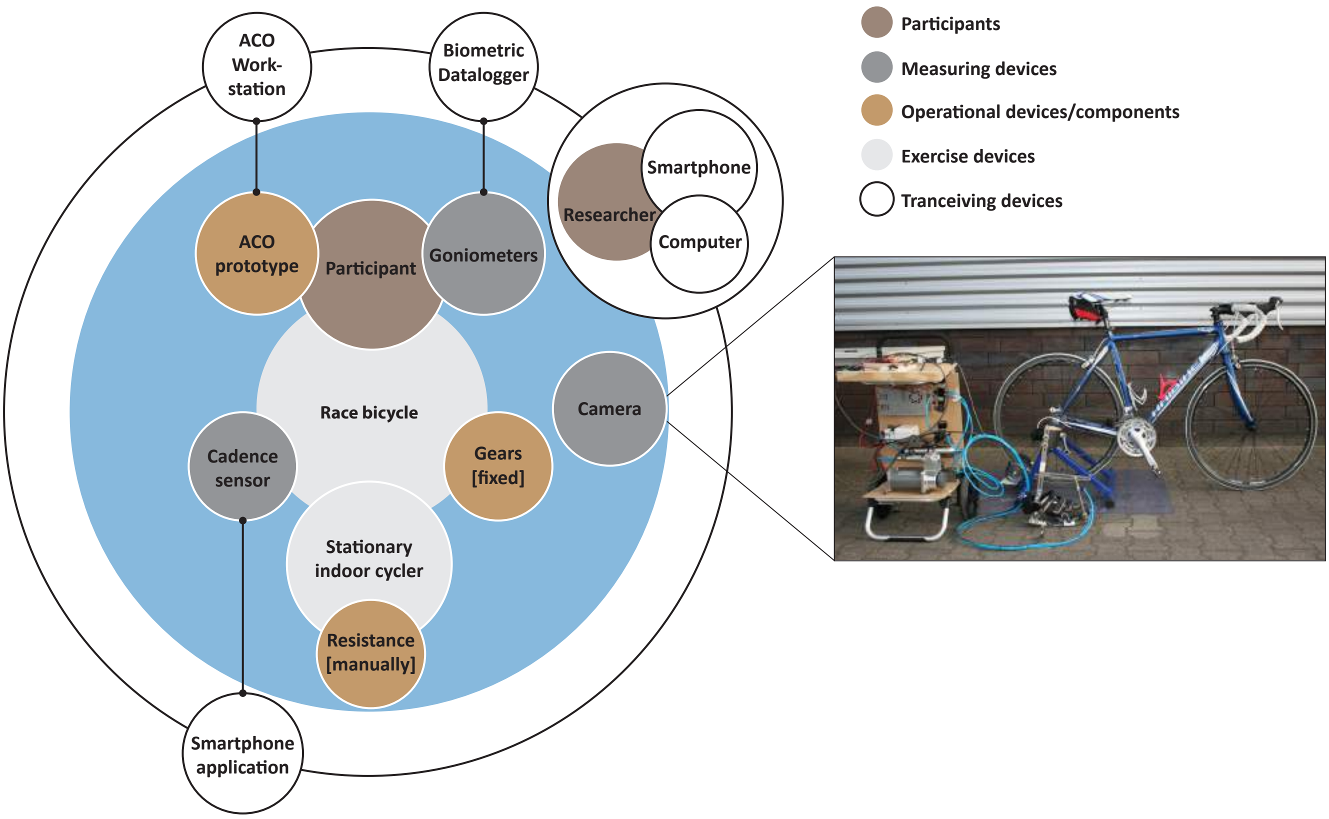


Figure 96: Schematic overview of the PoC test set-up

kinematic behaviour of the cyclist by tuning the following output variables:

Orthosis prototype:

- Pressure level (i.e. setting the pressure regulator between 0.5 – 10 bar)
- Onset/Offset values for extension and/or retraction of the cylinder piston.

Bike:

- Cadence (Max. 60 RPM)
- Level of cycling resistance (i.e. high or low resistance settings of the indoor cycler).

Within exercise 2, the ankle joint will be assisted by means of the orthosis prototype in which activation of the pneumatic cylinder concerns a step-function operation (i.e. fully extended/ retracted position of the cylinder) based on the position of the foot and position of the joint.

The allowable ROM of the joint for performing a pedal cycle is restricted (by the extension/ retraction range of the cylinder) to approximately 28 degrees of which 20 degrees plantarflexion and 8 degrees dorsiflexion is possible. The rotational movement of the joint is monitored by means of a 1024 P/R photoelectric rotary encoder (see fig. 98; point A) to ensure that the right posture of the lower leg is maintained throughout the whole pedal cycle. Thus, if the detected joint movement goes beyond the limited ROM values - the system will shut-off (i.e. cylinder is unpowered).

In addition, a gyro sensor (see fig. 98; point B) is attached to the baseplate of the orthosis which is tracking the position of the pedal (i.e. foot) in space to define the pedal phase (i.e. power phase or recovery phase). Subsequently, the position (i.e. degrees) and direction of rotation (i.e. clockwise or counter-clockwise direction) of the pedal is used for activation (i.e. onset and offset) of the cylinder.

Consequently, the onset for extension of the cylinder will be executed during power phase (between TDC and BDC of the pedal cycle) to assist the plantar flexor muscles of the patient when pedal angle is smaller then 0 degrees (i.e. horizontal reference point) and turning in a counter-clockwise direction (i.e. degrees become smaller). Likewise, the dorsal flexor muscles of the patient will experience assistance during the recovery phase (between BDC and TDC of the pedal cycle) when the pedal angle is greater than 5 degrees and turning in a clockwise direction (i.e.

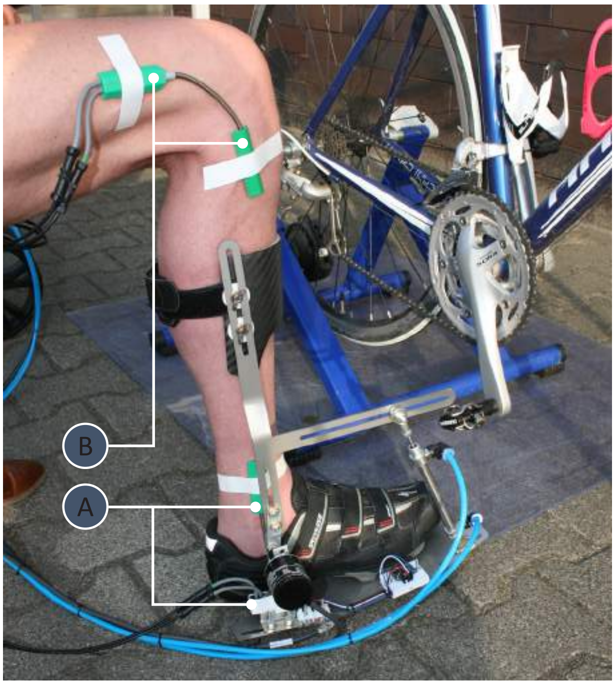


Figure 97: Illustrates the placement of goniometer while patient is wearing the ACO prototype; (A) ankle joint, and (B) knee joint.

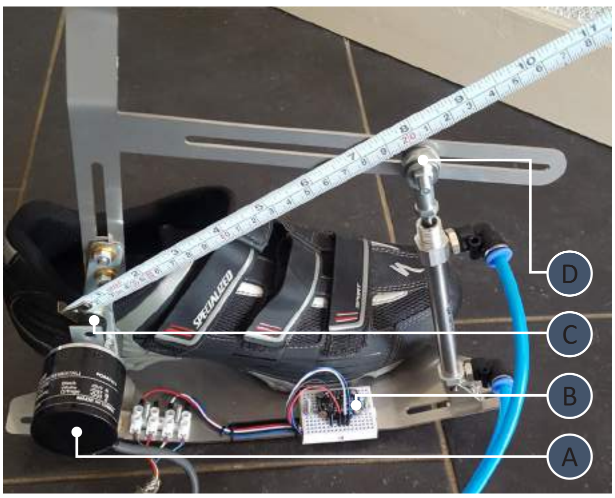


Figure 98: Allocation of (A) rotary encoder, (B) gyro sensor, (C) joint axis, and (D) cylinder piston anchor point.

degrees become greater). Although, these values are based on observing the preferred (theoretical) pedal cycle (see fig. 20) after which expected angles are defined for assistance activation. Thus, these values may change during execution of the PoC test when abnormal angles are perceived.

For torque range application the distance between piston anchor point and the joint is set to approximately 200 mm (see fig. 98; point C). whereby a change in pressure results in the following torque estimation shown in figure 99 based on the calculations described in Appendix M.

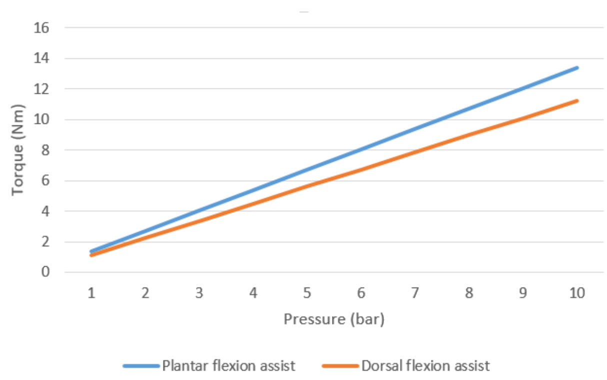


Figure 99: Torque range application of the cylinder for outstroke (i.e. plantar flexion assist) and outstroke (i.e. dorsal flexion assist) for different pressure levels.

10.2 RESULTS

As described in Ch. 10.2.3. the PoC test is executed in two phases – a pilot phase and a trial phase. Starting with the pilot phase, the patient was asked to think-out-loud what he was feeling while performing the tasks described in the roadmap (see Appendix O) these exercises are executed with low parameters for pressure level, cycling resistance, and cadence to ensure that no discomfort was experienced by the patient. After verification of a comfortable cycling experience, we proceeded with trial testing.

Although, during this pilot test it was difficult to communicate with the patient about his cycling experience and at the same time provide instructions about maintaining a certain cadence (preferably 60 RPM). Therefore, the patient was asked to maintain his own comfortable cycling pace throughout the exercises (which was fairly constant at around 40 RPM).

Starting with exercise 1, data was gathered from the angles of the ankle and knee without assistance while wearing the ACO at high cycling resistance. As shown in figure 100, the motion profile of the ankle and knee without assistance is almost identical to the measurements of the user test (see Ch. 5) – i.e. steep slope in power phase followed by a plateau while the knee is flexed (i.e. BDC) followed by lifting the heel rapidly during the recovery phase. Furthermore, it was noticed that the patient makes full use of the available ROM (i.e. approximately 30 degrees of limited ROM by the extension/retraction range of the cylinder).

Starting with exercise 2, the patient noticed no assistance with low-pressure settings while having a high bike resistance. Thus, step by step the pressure was turned up until the patient mentioned to feel a notable level of assistance at a pressure level of 6 bar (i.e. estimated torque of around 7 Nm). Simultaneously, caution was taken that the cylinder was performing the desired activation patterns. Because it was reasoned that the step-function operation would transfer the forces abruptly (i.e. full extension/retraction). Therefore, the timing of onset/offset values was the main point of attention. However, shortly after a few pedal strokes were made it became clear that the timing of the predefined values for the onset/offset of retraction was wrong. Thus, the main challenge at the start of exercise 2 was to find the correct timing for dorsal flexion assist by changing the predefined onset/offset values. Eventually, the correct timing (i.e. values) for dorsal flexion assist could not be found within the duration of this PoC test. In addition, the patient mentioned that the dorsal flexion assistance was unexpected, and caused an uncomfortable behavior of the ankle. This behavior was also visible in the measurements

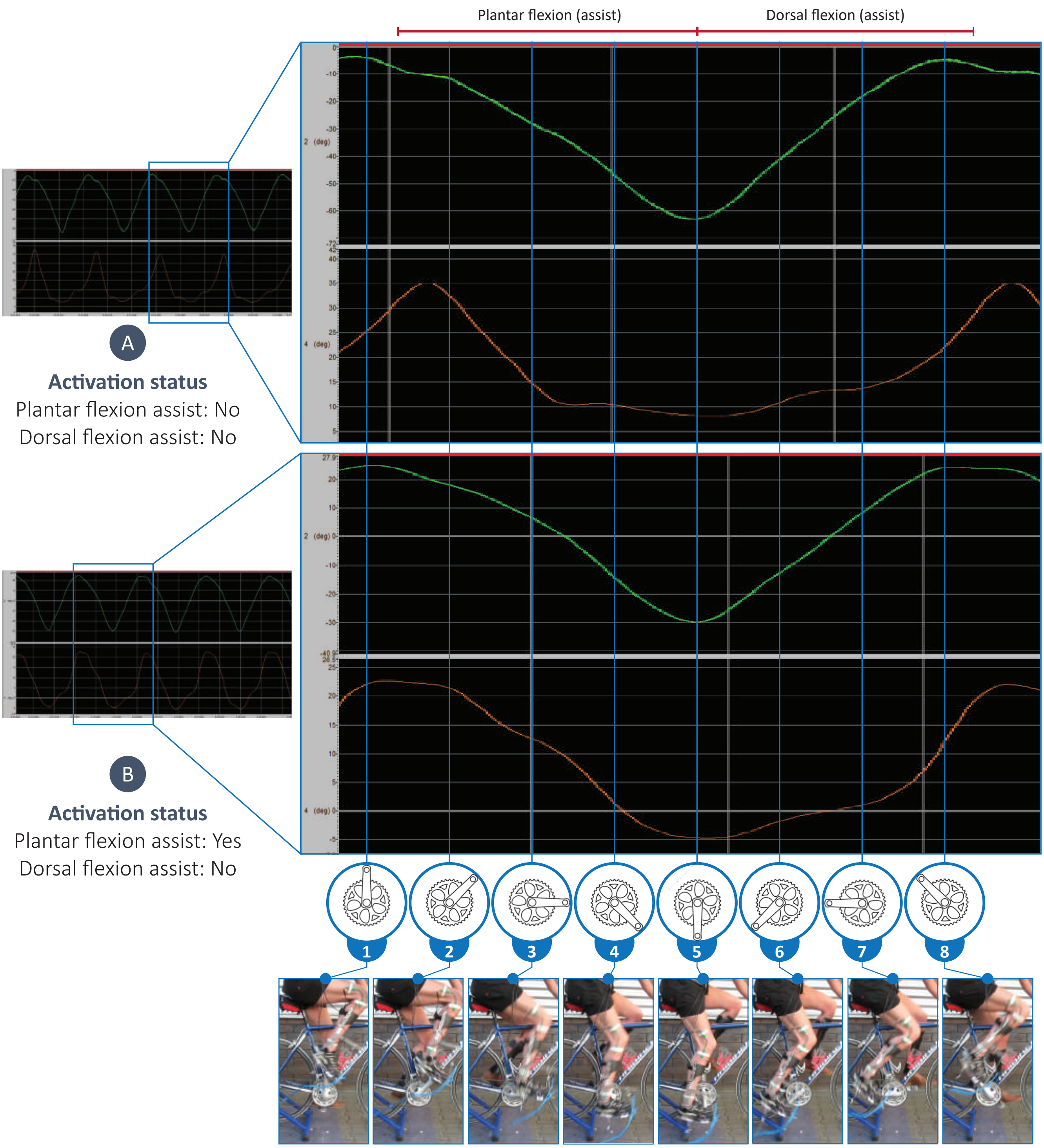


Figure 100: The graphs on the left are showing the motion profiles of four consecutive pedal cycles from (A) exercise 1; without active assistance, while wearing the ACO prototype, and (B) exercise 2; with active plantar flexion assistance with an estimated 10 Nm of assisted torque. From both graphs a single pedal stroke segment is captured, in which a notable difference can be observed between point 1 and 5 due to the applied pedal assistance. Besides, note that there is barely a difference in pedal stroke (i.e. angles) between point 5 and 8. Furthermore, the stop-motion camera footage (at the bottom of the figure) is capturing the posture of the patient while performing exercise B

as a second peak was captured that was caused by the abrupt retraction of the cylinder at the wrong timing (see figure 101). Thus, the decision was made to withdraw the dorsal flexion assistance and only provide plantar flexion assistance during exercise 2.

After evaluation of the measurements without dorsal flexion assistance different angles were observed compared to the angles of the ankle without assistance. It corroborated that the ACO prototype was working as expected as the angles (i.e. motion profile) of the ankle with plantar flexion assistance showed expected results. At an operating pressure of 8 bar the patient mentioned that he 'really felt the assistance' (i.e. estimated torque of around 10 Nm). This event was captured by the Biometric goniometers and is shown in figure 100. In order to synchronize the segments for a single pedal cycle for comparabe exercises, the angles of the knee are used as a reference point to identify the angle of the ankle at a specific position.. Comparing exercise 1 and 2 – it is clearly visible that the slope of the ankle joint angles is less steep between point 1 and 5 and after knee extension at point 5 the angles are almost identical to exercise 1..

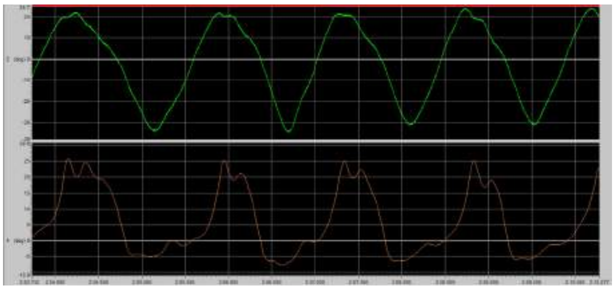


Figure 101: The motion profile of the ankle joint shows two peak moments in every single pedal cycle which is caused by wrong timing of dorsal flexion assistance activation.

10.3 DISCUSSION

The statement is justified that the muscle strength in the lower leg of the patient (i.e. participant) is virtually none after 12 years of carrying the CMT disease with corresponding sensory losses. Thus, it is reasoned that if the patient experiences assistance at around 6 bars of pressure (i.e. 7 Nm of torque assistance). It is therefore expected that, in general, CMT patients with considerable muscle strength in the lower legs are experiencing the assistance at lower levels of assistance torque. Hence, not only because the needed level of assistance is lower, but also because the sensory perception in the lower leg is affected by the CMT disease which implies that the threshold of perceiving assistance is expected to become lower.

The above-mentioned statement could also answer the question- why the patient makes full use of the available ROM without active assistance?- This may be because of the lack of muscle strength. Hence, the patient has no reference point during ambulation of the ankle in space. It is however not asked (because this happening was noticed while reviewing the results). But it could be that the patient is not aware of this behavior and uses the limited ROM as a reference point to take off from while proceeding with the next pedal stroke.

Furthermore, the patient mentioned that the orthosis created an undesired behavior of the ankle (on the right leg) during dorsal flexion assistance and that this assistance was distracting him from making the stroke with his left leg during while performing a power stroke.

At last, it was noticed that activation patterns (i.e. onset/offset concerning plantar/dorsal flexion assistance) are strongly dependent on saddle height and saddle distance from steering bar. Hence, these factors are influencing ambulation of the ankle and knee in a way that activation settings should be synchronized with the present set-up. For example, if the saddle height is set too high it is expected that the ankle angles for dorsal flexion become larger to perform a full pedal stroke. Subsequently, the heel of the patient will be pulled back rapidly when the patient tries to bring the foot towards TDC.

EVALUATION

11.1 CONCLUSIONS

Knowing that, at the end of every chapter in this report, the most important conclusions of that specific chapter are discussed. This chapter will focus on discussing the most important findings of PoC test and will provide an answer to the primary research questions and design challenges that are composed in the early stage of this assignment (see Ch. 1.7.1.). Namely;

Primary research question:

- What is the effect of an assistive cycling AFO on the cycling experience of CMT patients?

Secondary research question:

- How to achieve the optimal level of assistance?
- What is the desired level of assistance?
- How to enhance the cycling experience?

Even though the following statement is fairly subjective because the PoC test was executed with only one participant. Nevertheless, it is justified that the functionality of the envisioned ACO is proven. Namely, because the prototype showed the potential to yield the proposed working principle of the ACO by providing assistance torque while performing a full pedal cycle.

This statement is corroborated by examination of the measurements as well as the verbal feedback of the patient while he was executing the cycling exercises. The measurements in figure 100 are showing that the 'abnormal' (low) angles of the ankle (which are measured without assistance) are slightly lifted during the power phase between 0% (i.e. Top-Dead-Center; TDC) and 135% of the pedal cycle (with assistance). Comparing the exercise without assistance and the exercise with assistance, it can be observed that, without assistance, the foot of the patient reaches (the first) low peak angles earlier (around 90% of the pedal cycle), whereas low peak angles with assistance are reached around point 180% of the pedal cycle. It is therefore expected that the foot of the patient posses slightly earlier through neutral pedal position. Along with these findings, a less sharp peak at TDC is observed, this implies that there is a certain delay in ankle joint movement while the patient is pressing against the exerted forces of the ACO, otherwise, the angles would have changed more rapidly. Consequently, the angles between 315% and 45% of the pedal cycle are following a more smooth curvature.

Because the muscle strength of the patient is considered none. In this case, the assistance level can also be considered as resistance (level). As the muscles in the lower leg of the patient is incapable of applying forces on the pedal, the muscles of the upper leg should perform the pedal stroke. Therefore, if a patient with considerable muscle strength would perform the exercises the functional prototype is helping the patient in performing a pedal cycle because the needed assistance is lower.

Because of the aforementioned 'delay' in high angles at TDC and low angles at Bottom-Dead-Center (BDC) during the exercise with assistance, it is expected that joint angular velocities are also restrained since the assistance will partly take over the effort of the patient to perform a full pedal cycle.

There are a couple of ways to enhance the cycling experience by means of functional improvements. One of which is the implementation of a more powerful double-acting pneumatic cylinder. Because low pressure levels (i.e. smaller then 5 bar) were not effective. Whereas, higher pressure levels (i.e. greater then 6 bar) for plantarflexion was favorable during the PoC test. At an operating pressure of 8 out of 10 bars (i.e. estimated torque of around 10 Nm) the patient mentioned that he 'really felt the assistance'. Thus a more powerful cylinder will also enhance the ability to accurately determine the desired level of assistance. Even though notable assistance torque was perceived by the patient.

Based on the feedback of the patient, plantar flexion assist is predominant and enables high torque assistance levels, while dorsal flexion assistance is subordinate and should only be activated with a significantly lower level of assistance in the pullback phase of the pedal cycle. Especially when the primary focus is on the opposing leg and innervation of those muscles is low and sensory feedback is lacking it could distract the patient in performing the continuous motion cycle.

The preference of the patient for lower assistance levels during dorsal flexion assist was partly caused by uncontrolled activation of dorsal flexion assist. The cycling experience could be enhanced by enabling more accurate assistance operation control algorithms with corresponding components to enable highly accurate positioning of the cylinder piston to capture the right timing for activation of dorsal flexion assistance.

11.2 RECOMMENDATIONS

11.2.1 GENERAL IMPORTANCE

Market and society
CMT is one of the most common genetic diseases with an estimated prevalence of 1 in 2.500 people (Kenis-Coskun & Matthews, 2016). The ACO provides an intuitive rehabilitation/exercising tool for clinicians to experiment within a commonly known and very popular exercise activity. The demand for alternative treatment of neuro-muscular diseases like CMT and others is high. Among those assistive exercising, ankle joint mobilization, and potentially monitoring of muscle atrophy progression is favorable. It is therefore strongly recommended to further develop the ACO and create a personal rehabilitation program to provide valid mobility expectations for those who are uncertain about their physical capabilities. Furthermore, knowledge about the disease will be gathered that contributes to this relatively unknown disease among society and science. The obtained quantified medical data of multiple patients can be used by researchers/ doctors to expand the long-term knowledge about the CMT disease and prescribe an optimal AFO for ADL.

11.2.2 FUTURE RESEARCH

The functional prototype is designed to verify if the envisioned working principle is a potential solution for future of assistive orthosis technologies. This first step created valuable insights for future research. The recommendations are therefore primarily focused on the possible modifications that may be implemented to improve the ACO design concept and functional prototype.

Prototype design
The design of the functional prototype constitutes a relatively simple exoskeleton construction to enable adjustability of enhancing both - technical performance and ergonomic performance with a reasonable sense of safety. Therefore, several compromises are made within the design to ensure manufacturability.

The trajectory of the assistive force is slightly moved to the lateral side of the leg and causes torsion deformation of the shank. For future research, it is recommended to have the artificial pedal assistance aligned with the centerline of the foot to prevent torsion of the shank to ensure efficient exertion of forces onto the pedal.

Components & control
Unfortunately, one of the key design features for torque assistance could not be tested within

the current set-up of the prototype. Because a manually controlled pressure regulator is used for prototyping, EMG sensor implementation proved useless. Within this graduation project, there was no time and money left to replace the manually controlled pressure regulator with an electronically controllable pressure regulator or 5/3 proportional control valve. Therefore, the decision was made to manually mimic the pressure differential (i.e. level of assistance) by hand, which initially should have been detected by sensing the muscle effort of the patient by means of EMG surface sensors to define the desired level of assistance. Thus, it is recommended that further research will be executed by using them with the above-mentioned components.

Considering the potential risk of harm to the patient with high assistive forces a small cylinder size with low force exertion capabilities was chosen to test the working principle of the ACO. Even though a noticeable assistance was experienced by the patient, it is recommended that for future research a more powerful cylinder shall be used. On the one hand, to experience a greater difference in torque output and on the other hand, to more accurately define the desired level of assistance for plantar flexion and dorsal flexion.

Moreover, the torque application in the ACO prototype is according to a step-function operation (i.e. complete extension/retraction of the cylinder). Thus, to retain the desired ROM of the joints, the positioning of the anchor points was carefully selected to restrict the ROM of the ankle joint. For future research, it is therefore recommended to implement a Camber Axis Hinge to ensure restricted ROM at all time so that the stroke length of the cylinder is not a limiting factor for operational performances such as the requirement of a restricted ROM.

Operational communication (two legs)
The current ACO design is intended to operate on a single leg. Therefore, the composition and usage of sensors are designated to provide assistance of a single leg. However, most CMT patients are carrying the disease in both legs. Hence, it is preferred that both legs are assisted by the ACO while cycling. As described in Ch. 7.3.5. the opposing and continuous rotational motion of the crank-arm reveals valuable information about the pedal phase, which is currently solved by the mutual relation between the rotary encoder and gyro sensor to preserve stand-alone operation. Even though the crank-arm (among other bike components) should be untouched (seeing attached requirements), it is imaginable to use the gyro sensor on both legs to obtain accurate positioning of the pedals in space by (wireless) connecting the gyro sensor of the left leg with the right leg or vice versa. This control strategy is imaginable to have the capability of acting upon a variety of cycling scenarios. For example, by tracking mutual pedal direction and positioning, pedaling behavior of the cyclist can be captured so that assistance control is able to respond to stopping, backward pedaling, entering the bike, exiting the bike, and so forth.

Additionally, air pressure can be regulated between both orthoses. For example, if the left orthosis is exhausting the wasted air (stored in buffer tank) can be fed back into right orthosis for operation. This strategy will minimize air consumption and will increase the potential cycling duration .

Angular velocity
The aim of a future design is to correct the abnormal ankle motion and assist the ankle towards a smoother sinusoidal motion profile in which angular velocities of the joint should be as constant as possible for a given cadence. In order to create a constant angular velocity, the expected peak angular velocities of the ankle have to be reduced. Within the current stage of development, the prototype was not yet ready to measure the peak angular velocities of the joint to investigate at which point in the pedal cycle peak angular velocities are occurring. Hence, future developments could provide more insights on the angular velocity of the joint with the goal to create a smooth motion profile which will potentially enhance the cycling experience of the patient.

Final design
The end result of this graduation assignment can

be appointed by a functional prototype of the ACO that showcases the ability to correct an abnormal motion profile through a simple embodiment design and thereby enables the functional features of the envisioned ACO. Alongside, a (preliminary) industrial design is proposed which yet does not possesses the intended appearance and required instruments for an acceptable commercial product. Unfortunately, the following design improvements could not be carried out within this graduation project. Thus, aesthetics, user experience, durability, weight distribution and target group, the following design improvements are recommended to be considered:

Aesthetics
The industrial design is a first step in the proposal for a final design. Although the envisioned aesthetics of the ACO are not reached, the final design should strive for a significant level of elegance to attract future users.

User experience
With the ACO valuable data will be gathered about the physical performance of the CMT patient. This data shall be used by several users in the process of patient rehabilitation (e.g. physical therapist or rehabilitation doctor). For future research, it therefore is recommended to investigate what specific data is valuable for the primary users of the product to improve treatment.

Durability
The CMT patient mentioned during an interview in the analysis phase of the project that the durability of the regular passive AFO was fairly poor. Increasing complexity of a future active cycling orthosis will require an FMEA (Failure mode and effects analysis) to examine the reliability of the orthosis to help with the identification of the potential risk of failure.

Weight distribution
Ideally, the weight of the ACO is carried by the bike (i.e. pedal) itself and not resting against the lower leg of the cyclist. Although, no perfect solution could be found to let the pedal carry the total weight of the orthosis which is partly caused by displacement of the weight during shifting between pedal phases and geometry of the orthosis (i.e. skeleton design). Hence, it is therefore important to calculate the overall weight of the ACO to comply with the weight requirement (see Ch. 6.3.) and examine where the imbalance takes place in the system. In order to investigate 'if weight can be compensated by the actuator' (favorable) or 'if the weight will be carried by the cyclist' (not favourable).

In the industrial design it is observed that there are alternative options to minimize the additional loads for the cyclist. A plausible option would be to evenly distribute the weight of electrical and pneumatic component over the constructive/ support parts of the orthosis, such as, the shank and foot sole. However, the design freedom is limited due to the geometry of base components and their connective relationship (i.e. electrical and pneumatic). Therefore, the decision was made to build the prototype with a stationary air supply unit (i.e. air compressor) and not use a compressed air tank to feed the actuator as proposed in the industrial design. Furthermore, the electrical power supply and control board (e.g. Arduino) is mounted on the bike itself or on a separate workstation to minimize the additional load carried by the cyclist. A logical consequence of these decisions is that the prototype is not portable anymore. Although, these compromises on the requirements had to be made to comply with the comfort of wearing the orthosis. To examine how the weight is distributed in the prototype design it is recommended to have a clear understanding of the used components at the stage of development.

Target group
It was mentioned by the rehabilitation doctor within the conducted interview that the ACO has the potential to be applicable for a larger target group than just CMT patients. It is therefore recommended to investigate if the ACO is suitable for other types of disease in order to increase the demand for an active cycling orthosis.

ABBREVIATIONS

ABBREVIATIONS

General:

CMT	Charcot-Marie-Tooth
HMSN	Hereditary motor sensory neuropathy
AD	Autosomal dominant
AR	Autosomal recessive
AFO	Ankle-foot orthosis
AAFO	Active ankle-foot orthosis
PAFO	Passive ankle-foot orthosis
ACO	Assistive Cycling (ankle-foot) Orthosis
AAN	Assist As Needed
PT	Physical therapist (among which physiotherapist and occupational therapist)
OA	Orthopaedic advisor/specialist
OE	Orthopaedic expert
RD	Rehabilitation doctor
MD	Medical doctors (among which neurologists, geneticists, and orthopaedic surgeons)
GP	General Practitioner
P	Patient
C	Control (participant)
ADL	Activity daily living
QoL	Quality of life
EMG	Electromyography
NCS	Nerve conduction studies
DOF	Degrees of Freedom
ROM	Range of motion
RPM	Revolutions per minute
TDC	Top Dead Centre (bicycle crank position at 0 degrees)
BDC	Bottom Dead Centre (bicycle crank position at 180 degrees)
LOF	List of Features
SPD	Shimano’s clipless pedals

user test:

L60	Low resistance exercise with cadence of 60 RPM
L80	Low resistance exercise with cadence of 80 RPM
H60	High resistance exercise with cadence of 60 RPM
PL60	Patient low resistance exercise with cadence of 60 RPM
PL80	Patient low resistance exercise with cadence of 80 RPM
PH60	Patient high resistance exercise with cadence of 60 RPM
CL60	Control low resistance exercise with cadence of 60 RPM
CL80	Control low resistance exercise with cadence of 80 RPM
CH60	Control high resistance exercise with cadence of 60 RPM

Muscles:

GM	Gluteus Maximus
SM	Semimembranosus
BF	Bicep Femoris (long head)
VM	Vastus Medialis
RF	Rectus Femoris
VL	Vastus Lateralis
GM	Gastrocnemius Medialis
GL	Gastrocnemius Lateralis
SOL	Soleus
TA	Tibialis Anterior

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