The Cloud Walker

Performance of a novel prototype of a passive gait orthosis tested by healthy people.

T. J. van Hengel

The Cloud Walker

TU Delft Delft University of Technology

Delft Department of Biomedical Engineering

The Cloud Walker

Performance of a novel prototype of a passive gait orthosis tested by healthy people.

For the degree of Master of Science in Musculoskeletal Biomechanics at Delft University of Technology

T. J. van Hengel

4235959

July 10, 2022

Graduation Committee members:
Dr. ir. G. Smit
Prof. dr. F.C.T. van der Helm
Prof. dr. ir. J. Harlaar

Faculty of Mechanical, Maritime and Materials Engineering (3mE) · Delft University of Technology

Abstract

Goal: Build and evaluate the first prototype of the Cloud Walker, a passive assistive gait orthosis.
Method: The Cloud Walker uses muscles of the upper body to store energy in the springs at the back of the Cloud Walker. This energy can than be used to swing the legs forward. The Cloud Walker was evaluated by 9 healthy participants walking on a treadmill. The participants walked at different speeds with and without the Cloud Walker. Finishing speed, EMG, heart rate, stride length and questionnaires are used to obtain insight on the performance of the Cloud Walker.
Results: 3 out of 9 participants finished the test at the maximum speed of 4 km/h. The muscle activity of the measured upper leg muscles was higher with the Cloud Walker than without it. The heart rate increased more when walking with the Cloud Walker than walking without the Cloud Walker. The stride length at a slower pace was larger with the Cloud Walker. The stride length was smaller at a higher pace with the Cloud Walker than without it. The questionnaires showed that the Cloud Walker is a little uncomfortable and that walking with it takes a lot of effort.
Discussion: It is expected that SCI patients are able to walk in the Cloud Walker since the device is comparable to other orthotic devices such as the ARGO. The Cloud Walker can obtain a higher speed and costs less effort than comparable devices.

Preface

During my master Biomedical Engineering at the Delft University of Technology, I had a lecture about orthosis and how people with paraplegia are able to walk small distances. The course, where every week different speakers would give a lecture, was given by Gerwin Smit. The guest lecture about walking with paraplegia was given by Frans van der Helm. During the lecture the honest question came up why orthosis are mostly still the same as 30 years ago. After the lecture we set up a meeting to see if we could make a Master Thesis of this subject. When we paved the path for this thesis project we started to gather experts and information on different aspects to make this project become a success.

Acknowledgements

The Cloud Walker project is a collaboration project between the Delft University of Technology, Erasmus Medical Centre and Rijndam Rehabilitation Centre. The project was made possible together by Open Mind Call 2021. This is a convergence project where projects with multiple disciplines like the Cloud Walker could request a funding. With both Gerwin Smit and Frans van der Helm as my supervisors together with Rutger Osterthun of the Erasmus Medical Center and Rijndam Rehabilitation Center we have a team of professionals from all the different disciplines. I would like to thank them all for the guidance and opportunities they have given me along the way.

Delft, University of Technology T. J. van Hengel
July 10, 2022

Chapter 1

Introduction

1-1 Background

According to the WHO there are between 250.000 and 500.000 people who suffer from spinal chord injury (SCI). The severity of the injury determines the symptoms. This can be partial or complete loss in sensory or motor function. The higher the level of SCI the less function remains [WHO, 2013].
A few weeks after a SCI, the muscles already start to change. Muscle cross sectional areas are decreasing and the amount of intramuscular fat is increasing. The latter is less noticeable but contributes to the decrease in muscle strength [Gorgey and Dudley, 2007, Castro et al., 1999]. Keeping these muscles active while they are not functional helps the overall fitness of the body.
Orthotic devices can help to keep the muscles healthy. Walking with orthotic devices would decrease physical and mental problems. According to a study by J Eng et al., patients perceive improvements in their overall health. Digestion, blood circulation, bowel and bladder function increase with the use of a walking device [Eng et al., 2001].

1-2 State of the art

In order to make SCI patients walk, orthotic devices are used as support to stand and assist to walk. According to Appendix A-13 there are three categories of orthotic devices; passive, hybrid and active orthotic devices.

- Passive devices use no external sources to mobilize the legs.
- Hybrid systems use electrical stimulated muscles to mobilize the legs.
- Active devices use electrical motors to mobilize the legs.

The Cloud Walker is a passive assistive device where the upper body muscles are used to store energy which can be used to walk. In Figure 1-1 one of the participants is wearing the Cloud Walker. For safety reasons, there has to be someone near in case the user is about to fall due to balancing issues. When the user is using crutches, the balance is better since there are always three points of contact with the ground and the center of gravity is between these points.

Figure 1-1: The Cloud Walker is worn by the participant on the left. For safety reasons, there should always be someone near in case the user is about to fall.

1-3 Problem definition

Orthotic devices are able to make people with SCI walk again. However the passive devices had little development the last few decades. Active devices are becoming more interesting since it has potentially more functions and is less energy consuming than current passive devices. However the active devices available on the market are more expensive than a passive orthosis and therefore not likely affordable for SCI patients since it won't be covered by any assurance. The weight of an active device is almost three times as high as a passive orthosis. With both devices, there should be a person to assist the patient because of the risk to fall. It would be harder for the person to lift a fallen patient with a 25-30 kg exoskeleton on his legs than a patient with a mechanical orthosis of 7-10 kg. The active exoskeleton uses heavy batteries to power the system, where a passive, mechanical orthosis uses own body muscles and conservation of energy to make patients walk.
Since this research is about the first prototype, the base performance will be evaluated by comparing normal walking of healthy people to walking with the Cloud Walker with the same healthy people. This will be done with healthy people instead of SCI patients because it would be safer to do and more data can be accomplished that could indicate the usability of the Cloud Walker with SCI patients.
The research question of this paper will thus be;

What is the performance of the passive gait orthosis, the Cloud Walker, in terms of obtainable speed, leg muscle activity, used effort and walking motion when used by healthy people compared to normal walking with the same healthy people?

1-4 Objectives

The research question can be divided in objectives. The overall aim is to perform better than other passive, hybrid or active devices. There are objectives created about the design of the Cloud Walker and about the knowledge that needs to be obtained.

Design objectives:

- Design and create a prototype that will keep functioning over a testing period testing multiple participants.
- Design and create a light weight prototype compared to other assistive gait devices.
- Design and create a prototype low in production cost comparing to other assistive gait devices.

Knowledge objectives:

- Evaluate if users of the prototype are using hip flexion and extension muscles.
- Evaluate if the prototype is low in energy cost compared with other devices.
- Evaluate if the prototype is comfortable to walk in on normal walking pace.

1-5 Structure

This report will elaborate on the Cloud Walker. The first upcoming chapter will describe the functionality and design process of the Cloud Walker.
The second chapter will describe the tests done to meet the objectives.
The third chapter will show the results of the testing period with the Cloud Walker.
In the fourth chapter the results will be discussed.
In the fifth chapter recommendations will be made.
The conclusion on the objectives will be the concluding chapter of this thesis.

Chapter 2

Design Process

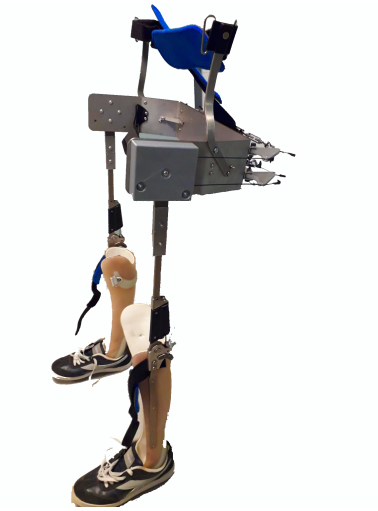


Figure 2-1: The complete side view of the final first prototype of the Cloud Walker. The leg parts and waist fixation are from an ARGO. The hip frame is self designed.

2-1 Working principle

The legs of humans are made for walking and in a very efficient way. To make SCI patients walk, there are a lot of muscles needed to replace these efficient leg muscles. The Cloud Walker is therefore based on moving the legs using the muscles of the upper body. In Figure 2-1 The Cloud Walker prototype can be seen.

The back and abdominal muscles are used to put tension in the springs at the back of the hip frame. The arm and shoulders muscles are used in combination with crutches to stabilise the user. When the user is extending the upper body as in Figure 2-2 the hip joint will rotate and will tension the upper spring at the back of the hip frame. The tension can be released by the user by shifting the weight from both legs to one leg. By shifting the weight, one leg will come of the ground. The tension will be transferred to flex the hip of the lifted leg to make the leg swing forward.
When the user is flexing the upper body as in Figure 2-3, the hip joint will rotate and will tension the lower spring at the back of the hip frame. The tension will be transferred to extend the hip of the standing leg, creating a larger step.
The entire theoretical way of walking should then be to extend the upper body, lift one leg, swing the leg with the upper spring force, flex the upper body during the swing phase, extend the step with the lower spring force, place the foot. The crutches can assist in keeping balance and even to give a little push forward during swing. When continuously doing these motions, walking should be possible by using the muscles in the upper body.

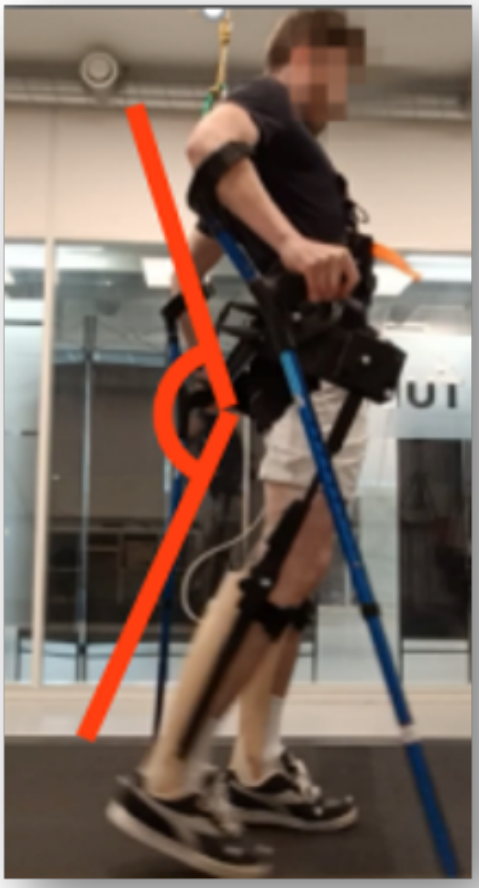


Figure 2-2: Extending the upper body will put tension in the upper spring at the back of the Cloud Walker. When lifting a leg the tension in the spring will swing the leg forward.

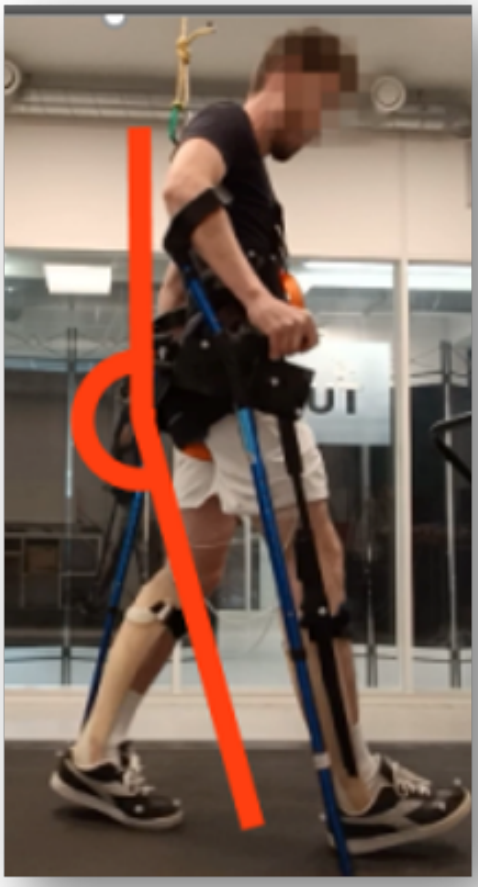
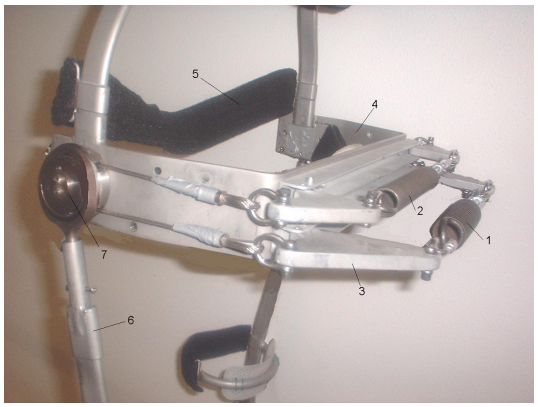


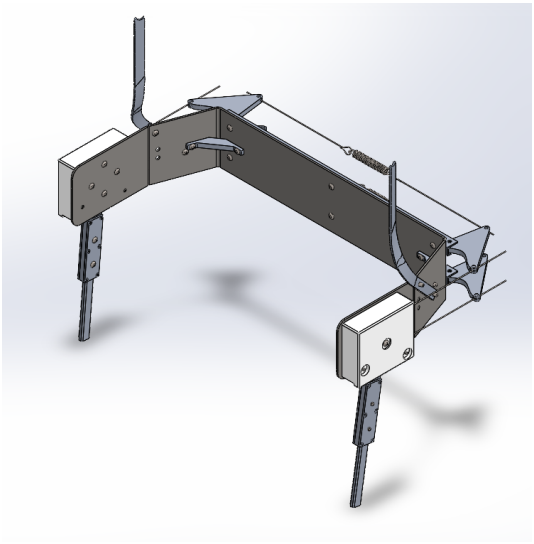
Figure 2-3: Flexing the upper body will put tension in the lower spring at the back of the Cloud Walker. The tension will extend the hip of the standing leg, creating a larger step.

2-2 Creating a 3D model

The idea of a new type of mechanical orthosis started with an unfinished PHD project at the University of Twente named the Caddy [Sanders, 2006]. The unfinished project came with some patent drawings and one photo. At the start of the project, only the photo was available to start designing the prototype (Figure 2-4a).
The hip structure seen in Figure 2-4b is the result of the combination of the Caddy project and an old ARGO. Some of the parts of an old ARGO were available to work in this prototype. The padding, leg parts and torso fixation were reused for the prototype of the Cloud Walker. The parts available from the ARGO are used to scale the image of Figure 2-4a into a 3D model in SOLIDWORKS. Parts like the springs, cables, cable clamps, buffers and bearings that are bought also determine some of the choices in the design.
The springs determine the strength needed in the cable, but the cable also needs to be flexible enough to loop around the hip joint. The diameter of the cable determines the size of the cable clamps which also need to be fixated around the hip joint.



(a) The Caddy project. This prototype was made in 2003. The Caddy project was never finished.



(b) 3D model of the hip frame of the Cloud Walker.

Figure 2-4: Hip frames of both the Caddy project and the Cloud Walker project

2-3 Materials

The materials are chosen to be mostly light weight. The parts are made of stainless steel, aluminium or printed in 3D with PLA filament.
The hip plate (Figure 2-5) is made from stainless steel because the plate had to be bent. The first choice was to use aluminium for this as the same as the other parts. However, bending aluminium makes it a lot weaker and it might even break while bending. Therefore a stainless steel plate of 3 mm has been laser cut and bent afterwards.
Most of the other parts are water cut from aluminium plates to make the design as light

weighted as possible while having enough stiffness to handle the moments produced while walking. Only the axis of the joints could not be made from plates (Figure 2-6). The axis are made on a metal lathe and are also from aluminium. The production of the axis and post processing of all other parts were all done by myself in the workshop of the faculty of 3ME. The caps over the hip joint of the

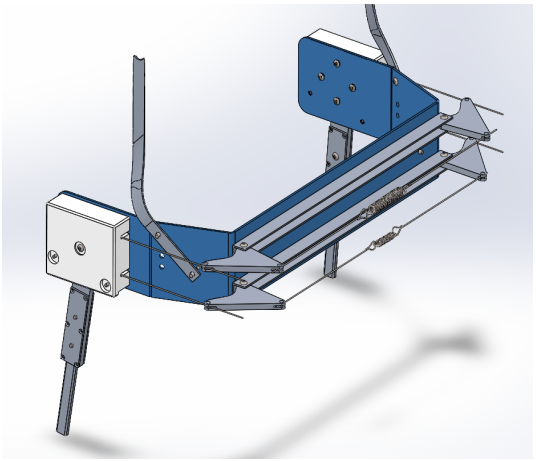


Figure 2-5: In blue: Stainless steel hip plate functioning as a base for all other parts.

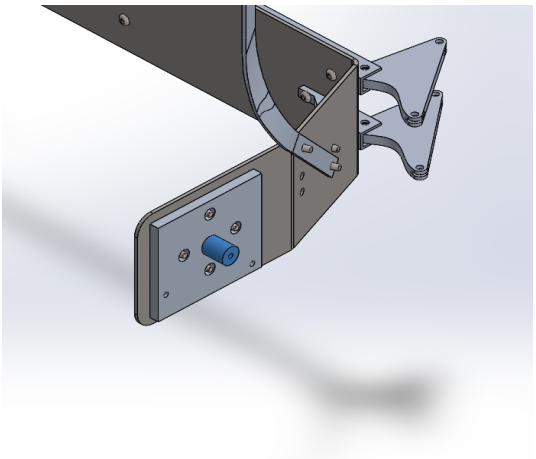


Figure 2-6: In blue: The aluminium axis of the hip joint created on the metal lathe.

design are made from PLA filament (Figure 2-7). 3D printing is a fast and easy way to produce 3D structures. Because the caps do not have any load on them. The caps should only cover the rotating parts underneath to prevent clothing or skin from damaging. Another benefit of PLA is that the caps are a bit softer and less sharp than the other parts. This is beneficial since the hands and arms are swinging close to hip frame, so if a hand hits the cap it would not hurt or cause damage to the skin.

The stiffness springs at the back of the hip

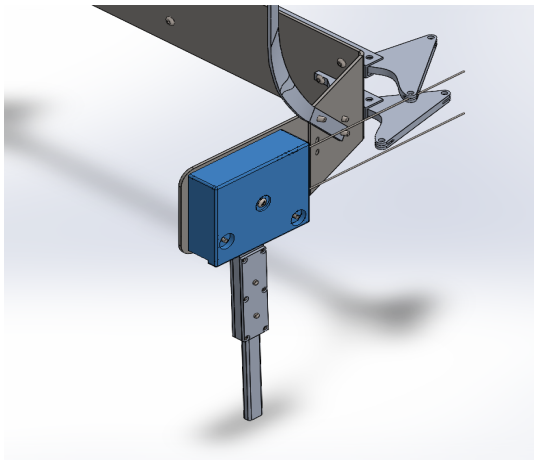


Figure 2-7: In blue: PLA printed cap covering the rotating parts of the hip joint.

frame are estimated based on the springs used in the Caddy project. The flexion and extension springs used in the Caddy project had a stiffness of about 2.6 N/mm and 20 N/mm respectively. Comparing different springs, the springs for the Cloud Walker were set on 10 N/mm and 15 N/mm for flexion en extension springs respectively. The springs are made at a specialised company Tevema with serial numbers T42842 and T42810 respectively.
The flexion spring has a higher stiffness compared to the 2.6 N/mm of the Caddy because with the 2.6 N/mm the leg of the Cloud Walker was not able to swing the leg forward. An even higher stiffness was also tried but caused pain in the lower back. The extension spring is compensated a bit for the increase in stiffness for the same reason that it would be too intense for the lower back muscles.
The cables and cable clamps are selected to

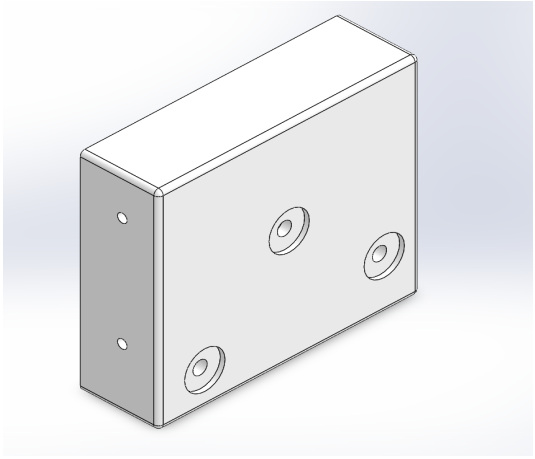
withstand at least the force the springs could generate.
The bearings used in the system are polymer sliding bearings. This is sufficient since the max load on the bearings is relatively low as it is the weight of the upper body and the amount of revolutions is about 60 per minute, a normal walking pace.
There are buffers installed in the hip joint to make sure the force unleashed by the springs would not cause the leg to swing too far. The buffers were set to let the leg swing 25 degrees to the front and extend the leg 35 degrees at the back.
The screws used in the system are all socket button head screws M5 (ISO 7380). The button head is always at the inner side of the hip frame, since these screws have no sharp edges that could damage skin or clothing.

2-4 Production

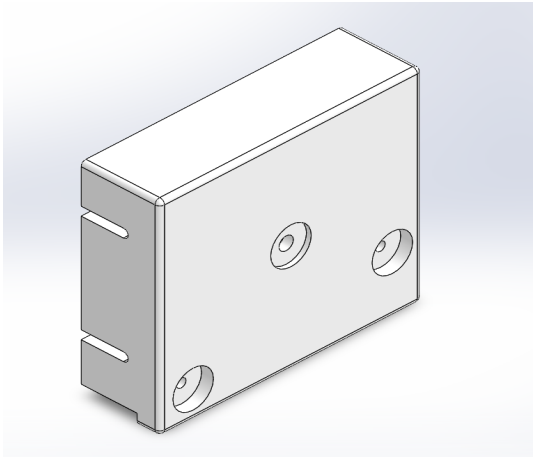
The design is created so most parts could be cut with a laser or water cutting machine. The use of plates makes the production easier, significantly shorter and lower in costs than the production of 3D parts from aluminium blocks. The down side is that all plates have to be connected by screws which makes the design heavier, but time and cost where considered more important than the weight.
The thickness of the plates where chosen due to limitation of the available thicknesses.
8 mm Aluminium is the thickest plate to cut by the water cutter. Some plates are made thinner where it was clear there would not be much load on it. For example the joint cover plates only need to hold the upper leg bar in place. A 3 mm aluminium plate is sufficed to do this.

2-5 Assembly

The well designed 3D model had the right tolerances that there was just enough space that everything would fit perfectly. Even the parts of the old ARGO that had some wear and tear fitted perfectly on the produced hip Frame. One belt is replaced with a new one since it was too short to fit around the waist.
The caps on the joints where redesigned during the assembly phase. The cap needs to guide the cable from inside the cap to the outside at the back. However, as shown in Figure 2-8a, this was difficult because the cable had to go through the holes on the side. Tensioning of the cable around the joint difficult was difficult. The new design in Figure 2-8b was designed with slots instead of holes on the side. This made it possible to put the cap on the joint after the cable was put around the joint.
In the assembly there are button head screws used to connect the parts. This is done since these types of screws have no raised sharp edges which might damage the skin or clothing of the user. In Appendix A-1 all the parts are shown in the assembly of the model together with their material, production method and post processing.



(a) first version of the cap with small holes at the side to guide the cables.



(b) latest version of the cap with slots at the side, which still guide the cables, but also makes it easier to assemble and disassemble.

Figure 2-8: Designs of the hip cap

Chapter 3

Method

3-1 Objective expectations

In order to fulfill the objectives, a test is created to obtain data to validate our goals.
The prototype needs to be continuously checked for safety reasons. It is expected that there will be some wear in the bearing of the hip joint. Also screws are expected to get loose. It is not expected that the prototype will endure such damage that the test need to be stopped.
SCI patients with a T8-T12 level of injury are not able to use their legs. The participants are therefore asked to use their leg muscles as less as possible but instead use the abdominal and lower back muscles to use the Cloud Walker as it is meant to. To validate if the leg muscles are used or in what range they are used, the muscle activity of the quadriceps and hamstrings will be measured with EMG sensors. These muscles are both used for flexing and extending the hips. The expectation is that there is less muscle activity in the upper legs when walking with the Cloud Walker compared to normal walking.
It is expected that walking with the Cloud Walker will cost more energy than normal walking. This because walking with the legs is considered more efficient than walking with the muscles of the upper body. It is expected that the Cloud Walker will be less energy demanding than other passive orthotic devices, but more than active devices since the movement there is powered with electric motors. To verify this, a heart rate monitor will give an indication of the amount of effort it takes to walk.
To validate the motion of walking, several markers are placed on the participants for the tracking system to track. The stride length will be used to describe the motion of walking. The stride length will be calculated to see if the length differs between normal walking and walking with the Cloud Walker. The expectation is that there will be a difference between the stride lengths. Because the Cloud Walker has no knee or ankle joints, the stride length could be shorter if the participants are not walking as described in the earlier Section 2-1. However, if the upper body is extending and flexing as described, the stride length might be even bigger especially with low speeds.

3-2 Participants

The test mentioned in Appendix A-4 is prepared for 10 participants. The group consists of 2 males and 8 females, most of them were students. On forehand, it was desirable to have 5 male and 5 female subjects. It was tougher to find men to do the test because of the limitations of the device. The Cloud Walker uses old parts of the ARGO, which include the shoes. The maximum shoe size of the participants was size 41 (EURO size).

Other limitations were the hip height, waist circumference and calve circumference. The hip of the participant should be in range of the hip joint of the Cloud Walker, the waist should be fitting in the belt around the hip and the calves should be placed in the leg shells. The last mentioned was found as limitation during the test trials. Participant four did not fit the calves in the leg shells and had to be withdrawn from the study. The test is done by 9 participants in 5 days time. Unfortunately during the test of the first participant, the motion tracking and and EMG signal got lost. The entire EMG data of this participant is not taken into calculation.

3-3 Materials

The test has been done on a treadmill. The treadmill is wider than a standard treadmill. This made it possible to walk on the treadmill with crutches. The treadmill can increase speed with steps of 0.1 km/h, which was sufficient for the test. It has an emergency button to directly stop the treadmill in case of emergency.
During the test, the participants got 3 types of measurement equipment on them.
The EMG sensors measured the muscle activity of the muscles in the upper leg, namely the quadriceps and the hamstring muscles. The EMG equipment used in the test is the TMSi Mobi8 EMG with wired electrodes with a sample frequency of 2048 Hz.
A heart rate monitor was strapped around the chest and measured the heart rate to measure the amount of effort it took to walk with and without the Cloud Walker. The monitor used in this test is the Polar H10 heart rate sensor with a sample frequency of 1 Hz.
Tracking markers are placed on the participants and on the Cloud Walker based on the CAST marker model created by Cappozzo et al. [Cappozzo, 1995] and seen in Figure 3-1. Tracking cameras have followed the tracks of the participants. The tracking system used in the test is the Qualisys motion capture system with 8 cameras with a sample frequency of 100 Hz.

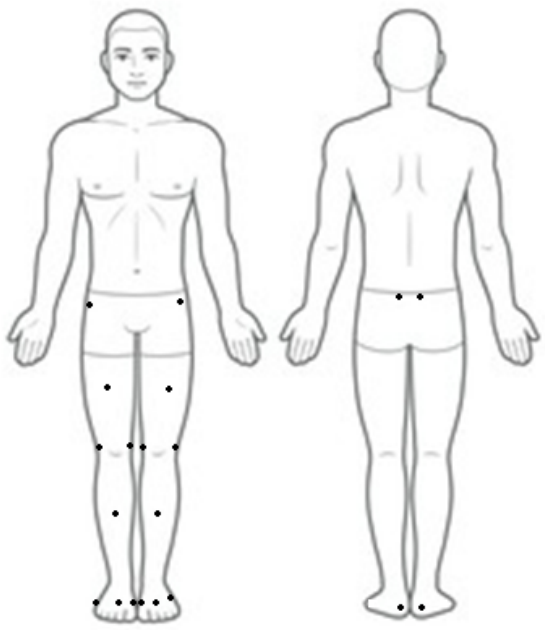


Figure 3-1: The black dots are the markers placed over the lower body. The dots on the center front of the upper and lower leg became marker clusters in the actual test.

3-4 Test protocol

The test consists of two parts. The first part is walking without the Cloud Walker at different speeds on a treadmill. The second part consist of walking with the Cloud Walker at different speeds on a treadmill. Participants could always take a brake or stop the test when they feel uncomfortable.
At the beginning of the test, some body parts of the participants were measured. This should give more insight in the type of person fitting the Cloud Walker. The participant placed the heart rate monitor just below the chest. The EMG electrodes are placed on the legs and the wires are guided to the monitor box. The

markers for the tracking system are placed on the upper and lower legs and the feet of the participants as can be seen in Figure 3-1.
The first part is used to gather reference data. The participant has to walk for at least a minute at the same set speed on the treadmill. The minutes of data can then easily be compared. The treadmill starts at 0.5 km/h and will then increase with steps of 0.5 km/h up to 4 km/h. Normal walking tends to be about 4 km/h.
In Appendix A-13, it is found that the overall walking speed with an orthotic device or exoskeleton is slower than normal walking. It would therefore not be safe to go over 4 km/h.

After the first part of the test the participant has a break and gets explained how the Cloud Walker is working and how to make walking the easiest. They also are asked to use their leg muscles as little as possible. After about 10 meters of walking on normal ground, the participant can start the second part, walking on the treadmill.
The second part has the same build up as the first part, starting at 0.5 km/h and increasing with steps of 0.5 km/h. Whenever the participant felt uncomfortable to go to a faster speed or they walked at 4 km/h for at least a minute, the test ended.
After the test the participant is asked to fill in a questionnaire about the fitting and feeling about the Cloud Walker.

3-5 Safety

During the test, the participant is always strapped in a harness which is attached to the ceiling. In case of a fall, the participant will be caught by the harness to avoid falling on the ground.
The participants had to walk with crutches on the treadmill. Though walking without is also possible for healthy subjects, the test had to come as close as possible to testing with SCI patients. Crutches make it easier to keep your balance when walking with stiff legs such as the Cloud Walker has.
The test were done during the Covid-19 pandemic. The whole set up and equipment needed to be cleaned and disinfected after the test. All participants could sustain the requested protocol.

3-6 Approval

To validate the prototype and the test, the entire study had to receive an approval. The study is done on healthy subjects to gather a lot of data. Also testing on healthy subject instead of SCI patients can tell a lot more on the feeling and comfort of walking. To receive the approval of the Human Research Ethics Committee (HREC) of the University, there where multiple documents that needed to be filled in:

- The data processing and storage is written down in the Data Management Plan (DMP), see Appendix A-2).
- The device is safety approved in the Device Report, see Appendix A-3.
- The test protocol can be found in Appendix A-4.
- The participant information can be found in Appendix A-5.
- The checklist has been filled in in Appendix A-6.

After these files were sent to the HREC, the letter of approval was given under ID2061, see Appendix A-7.

Chapter 4

Results

4-1 Test results

The test results consists of four categories looking at the relative differences between walking with the Cloud Walker and without the Cloud Walker. The four categories are; the speed obtained on the treadmill, the muscle activity in the quadriceps and hamstrings, the effort using the heart rate and the stride length looking at the walking pattern.

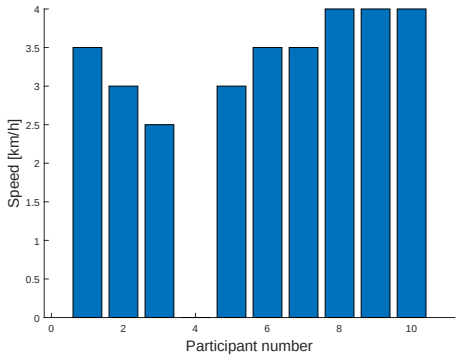


Figure 4-1: Completed speed per participant. Participant #4 had to step out beforehand.

4-1-1 Speed

The treadmill started at a speed of 0.5 km/h. From there the participants had to walk at least a minute in order to proceed to a speed of 0.5 km/h faster. All the participants were able to walk 3 km/h, but only 8 of the 9 participants completed this speed. The results can be seen in Figure 4-1. Note that participant #4 has not been able to fit the Cloud Walker and therefore will not be taken into account in the rest of the results.

4-1-2 EMG

The EMG signal is measured during the entire test. EMG data from walking without the Cloud Walker is used as reference to see in which scenario the upper leg muscles are more used. In Figure 4-2 a small piece of the raw EMG data can be seen. The walking pattern is clearly seen in this piece with activity alternating on the left and right leg. The ground sensor of participant #1 got loose during the second part of the test. The data of this participant are not used to calculate results.

In Appendix A-8 all the data of every participant walking without the Cloud Walker can be seen. This shows the spread of the activity of the muscles. The 2048 Hz EMG data is filtered using a second order Butterworth filter with low pass of 300 Hz and a high pass of 30 Hz. Next, the values have been made absolute and then smoothed with a moving mean filter of 2048 Hz. This corresponds with one second of the original signal, since it was found that at higher speeds there were around one stride per second.

In Appendix A-9 all the data of every par-

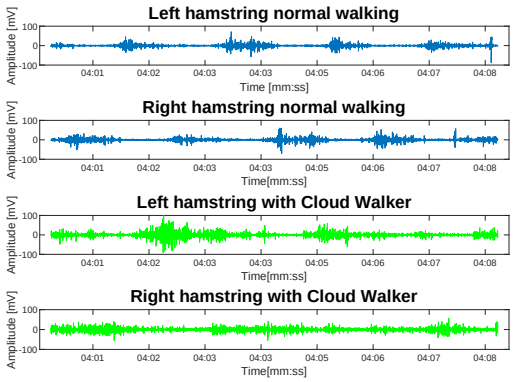


Figure 4-2: A zoom in on an example piece of a participant walking with and without the Cloud Walker. The alternating placement and push off from the foot are visible as the peaking signals.

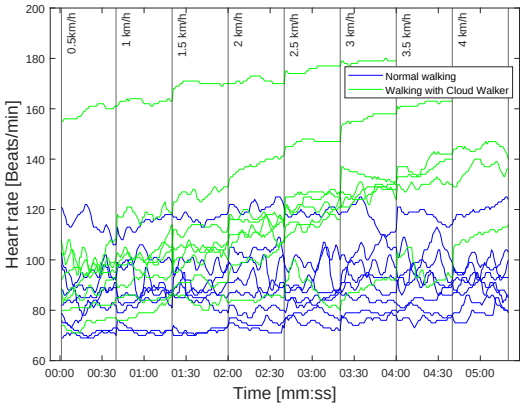


Figure 4-3: Heart rate data of all the participants per speed slot. There is barely an increase over time during normal walking opposed to walking with the Cloud Walker.

ticipant walking with the Cloud Walker can be seen. Though it was wanted to achieve one minute of data per speed, there were a lot of slots just a bit less. To make sure the data is comparable the time slots are set on 40 seconds. This data has been filtered and smoothed the same way. There is an increase of muscle activity over time while increasing the speed. In the higher speed ranges there is less data because not all participants finished the test up to 4 km/h. The quality of the data is overall less than the data of walking without the Cloud Walker.
In Appendix A-10 the data of all participants is averaged per muscle. Also the difference between walking with and without the Cloud Walker is plotted. Here can be seen that walking with the Cloud Walker actually uses more muscle activity than walking without the Cloud Walker.

4-1-3 Heart rate

The heart rate is measured during the entire test. The data of the heart rate from walking without the Cloud Walker is again used as reference to see which scenario is taking more effort.

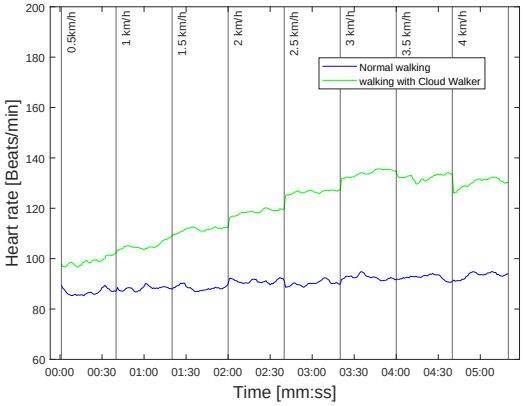


Figure 4-4: The average heart rate during walking with and without the Cloud Walker

Heart rate is a good guideline to see how much effort an activity costs. This was also found during the literature review, see Appendix A-13, where multiple test were done with the heart rate as measure of effort.

In Figure 4-3 all the data can be seen during the 40 second time slots per speed. In Figure 4-4 are the averages plotted of walking with and without the Cloud Walker. The heart rate increases more when walking with the Cloud Walker than walking without the Cloud Walker. During the higher speeds the average of walking with the Cloud Walker goes down.

This is because some participants that had a high heart rate stopped earlier than the 4 km/h finish.

4-1-4 Stride length

A marker tracking system is used to look into the walking movement of the participants with and without the Cloud Walker. The stride length is used as an indication of the walking pattern. In Figure 4-5 the average stride length per speed slot can be seen during walking without the Cloud Walker. In Figure 4-6 the average stride length per speed slot can be seen during walking with the Cloud Walker. With the lower speed slots, the stride lengths of walking with the Cloud Walker is larger and more deviating compared to normal walking. The stride length of walking without the Cloud Walker approaches a length of 700 mm. The stride length of walking with the Cloud Walker approaches 600 mm, but spikes at the 4 km/h to an average above 750 mm.

4-2 Prototype analysis

4-2-1 Wear of the prototype

The Cloud Walker prototype endured the entire week of testing with 9 different participants. The prototype was checked after every test on loose screws, cable slip, tension of the springs and other small checks. In the entire time of testing there were no corrections or fixes needed. Only during the last few tests, there was a squeaking sound in the hip joints, pointing at plastic on metal friction.
The wear and tear did caused some damage, though this was not considered dangerous or in need of a quick fix. In Figure 4-7 there are multiple places that show damage. In Figure 4-7a and Figure 4-7c can be seen that the inside of the cap has some serious damage. The damage is caused by the cable clamps scraping the inside of the caps. In Figure 4-7b can be seen that 2 of the screws went loose during the last test. They were still in the joint, but not tightened anymore. In both Figure 4-7b and Figure 4-7d there is also wear on the joint due to the cables. The edge of the joint is at some places flattened.

4-2-2 Questionnaires

Before starting the test, the participants had to fill in a introduction form (see Appendix A-11). In the form were questions about the gender, age, shoe size and weight as well as some body measurements which needed to be taken. The results of this introduction form can be seen in Figure 4-8.

The average age of the participating group is 26 years old. 7 of those are female, just 2 are male. This due to the restricted body sizes of the possible users of the Cloud Walker. The average shoe size of 40 lies in that same line of restrictions since 41 is the maximum shoe size. The average weight is 66 kg, which caused no visible complications wearing the Cloud Walker.
The average leg length, measured from the ground to the the greater trochanter of the hip, is 95 cm. Above the 95 cm, the hip joint of the participant came a bit above the hip joint of the Cloud Walker and the lowest strap came below the hip joint of the participant. It was observed that this influences the amount of angle changes in the hip joint of the Cloud Walker.
The average calve circumference is 35 cm. There where two participants with a circumference of 40+ cm. One could not fit in the leg shell of the Cloud Walker. The other could barely fit in. After the test, there was some skin damage and some serious pressure marks on the participant that could barely fit, see Figure 4-9.
The average waist circumference is 84 cm. There were no limitations found up to the maximum of 103 cm in this participant group. The belt was difficult to tighten with larger circumfer-

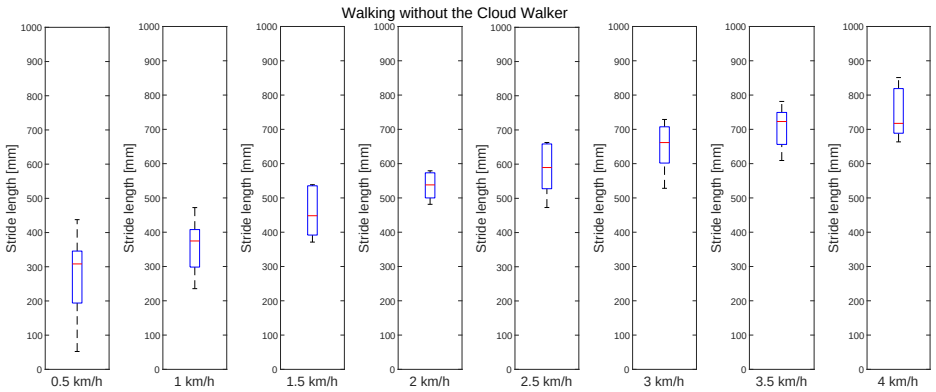


Figure 4-5: Average stride length per speed slot during walking without the Cloud Walker

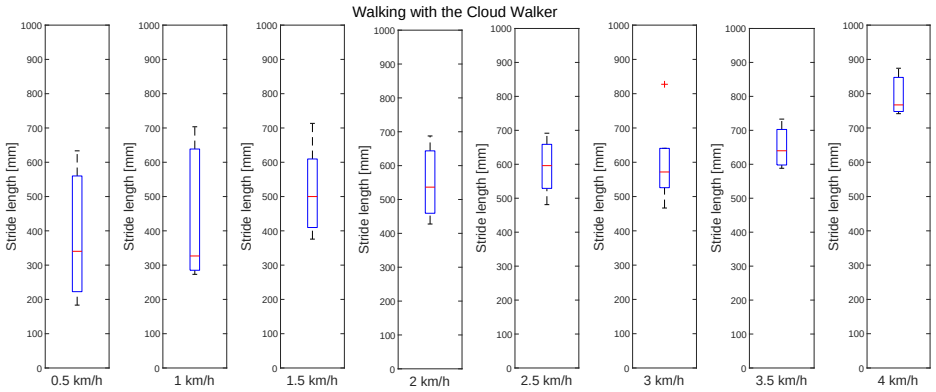
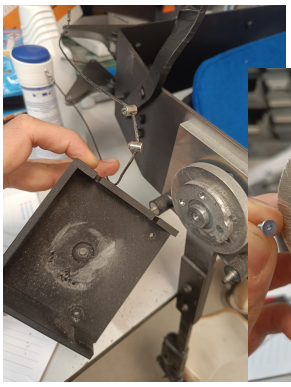
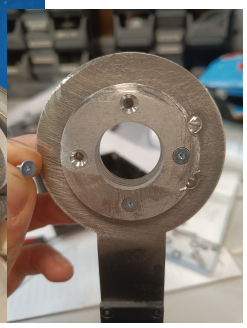


Figure 4-6: Average stride length per speed slot during walking with the Cloud Walker



(a) Left hip; Damage in the cap caused by the cable and cable clamps.



(b) Left joint; loose screws and smoothed edges caused by cable friction.

(c) Right hip; Damage in the cap caused by the cable and cable clamps.

(d) Right joint;Smoothed edges caused by cable friction.

Figure 4-7: Damage in the parts of the hip joint.

ences.
After every test, the participants are asked to fill in a evaluation form (see Appendix A-12). The results can be seen in Figure 4-10.
The test costs above average in effort and can therefor not be seen as a normal walk in the park. Walking with the Cloud Walker was seen as a hard exercise. Within the participant group there were multiple participants that were sweating during the test. Since the second part of the test took about 10 minutes, this was quite a exercise to keep on walking.
The Cloud Walker is considered not comfortable nor painful for healthy people. Most participants feel pressure in the legs or the shoes. People elaborate on the comfort with areas of pressure in the plastic leg shells with marks like in Figure 4-9. Also the feet were found uncomfortable because the plastic leg shell continues underneath the foot. As a result the damping of the shoe is gone and made walking less shock absorbing.
Luckily no one got injured badly. There were some cramps in the foot, areas of pressure and a small scrape on a hand that hit the hip joint cap. There were no falls or other situation which would have stopped the tests.

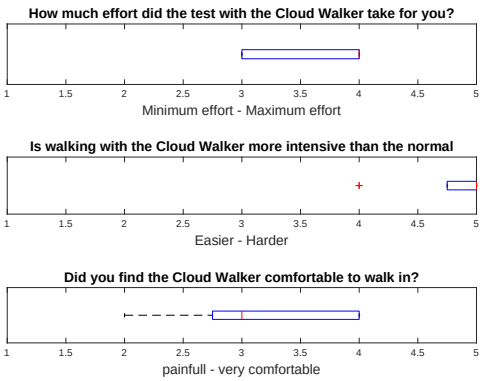


Figure 4-10: Results of the evaluation questionnaire. The test was found to take quite some effort. It was definitely more intensive than normal walking. The Cloud Walker felt uncomfortable to walk in.

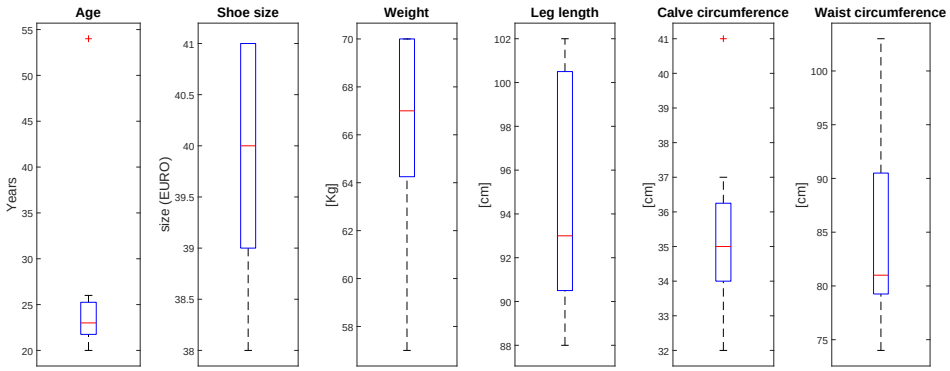


Figure 4-8: Results of the introduction questionnaire. The most of the participants were fellow students and most fit in the Cloud Walker. Only one did not fit the Cloud Walker due to a too big calve circumference.

Figure 4-9: Pressure marks on the calve of participant due to the hard leg shells.

Chapter 5

Discussion

5-1 Objectives

In order to achieve the objectives there had to be multiple test outputs. Not every result is a clear answer to one of the objectives. Together however, the results will give a good insight on how the Cloud Walker prototype is performing. With these results as a baseline, the prototype will be redesigned and evaluated in further studies.

5-2 Test results

5-2-1 Speed

The fact that participants could not or barely complete the speed of 4 km/h shows that walking at higher speeds becomes very hard. This can be due to limited movement in the Cloud Walker because of the stiff knees and ankles or that it takes to much effort to use the other muscles instead of the leg muscles for walking.

5-2-2 EMG

Looking at the quality of the signal it can be seen that the data from the left leg is better than the data of the right leg, especially the right quadriceps. This can be explained by the placement of the sensors together with the equipment. The EMG system used is a wired system. The sensors are wired up to a connector box which then sends the signal to the computer wireless. The connector box was placed at the left of the body and the wires are guided with to their sensors using tape to prevent the wires from swinging a lot. The swinging of the cable can cause the sensors to rotate a bit which may cause extra noise in the signal. The right side sensor wires were more difficult to tape down to make then swing as little as possible. Still the difference between the right quadriceps and right hamstring are also visible. An explanation could be that the sensor input for the connector box might have been a bit looser. Though this is harder to confirm it can clearly be seen that the data of the right quadriceps has more noise with all participants. Looking into the EMG signals of walking with the Cloud Walker, it is interesting to see that the data of the right quadriceps is actually one of the better, though the wires of the sensors are still the same as before. No explanation has been found on why this data is better than the right quadriceps when walking without the Cloud Walker since the sensors were kept in place in both scenarios.
It is seen in Appendix A-10 that there is more muscle activity of the muscles while walking with the Cloud Walker opposed to walking without the Cloud Walker. This is against the objectives set in Section 1-4. There are three explanations why there is more muscle

activity in walking with the Cloud Walker.
Firstly, with normal walking all the muscles in the leg have a small contribution making the walking pace. Walking in the Cloud Walker fixes the foot, ankle and calves. This means that the upper legs might be used subconsciously more than with normal walking.
Secondly, the fixation of the lower legs, especially the ankles, causes the participants to have less feeling of balance. Together with the moving of the upper body to empower the Cloud Walker, this makes keeping balance even harder. The crutches might help the participant to keep balance. The walking movement of walking with the Cloud Walker is different than normal walking, this might influence the feeling of balance more than expected.
Thirdly, the fixation and hard leg shells of the Cloud Walker can cause a less damped foot placement. This might cause a cocontraction of the muscles in the leg to absorb the reaction force when the foot is placed on the ground.

5-2-3 Heart rate

At the beginning of the test of walking with the Cloud Walker the heart rate is already higher than the start of the beginning of walking without the Cloud Walker. This might be because of the stress due to not exactly knowing of what will happen or because of the introduction and first few steps of the Cloud Walker when not yet on the treadmill. Nevertheless, the assumption can definitely made that walking with the Cloud Walker costs more effort that normal walking. This can be explained by something mentioned earlier. The legs are made for walking in a very efficient way. Walking with the muscles of the upper body is way less efficient and will therefore take cost more effort.

5-2-4 Stride length

The spread in the box plots of the participants in Figure 4-6 shows there are different kinds of techniques to walk with the Cloud Walker. Some participants preferred less steps and therefore longer stride lengths during the slower speed slots. Others preferred more steps and shorter stride lengths. This is something to look into to figure out what the less effort taking technique is.

5-3 Prototype analysis

5-3-1 Prototype check

It was better than expected that the Cloud Walker functioned this well over the entire testing period. There were no complications during the testing period and no parts needed to be replaced. The wear observed after testing is mostly caused by the cables sliding over the materials in the hip joint. This is probably because the hip joints are parallel and that the hip frame is too wide. There is some freedom in the joint so the feet of the participants can be placed more towards another. This puts the parallel hip joints under an angle and therefore slightly misalign the cables, which cause the cables to cause damage to the hip joint itself. The cables themselves were not damaged.

5-3-2 Questionnaires

Looking into Figure 4-10, the participants thought the Cloud Walker was uncomfortable to walk in. This is explainable due to the custom fit of the old ARGO parts. These parts were especially made for one specific person. For most people the fit will therefore not be perfect and sometimes even uncomfortable. The fit and feeling of comfort can in a way effect the walking performance. A better fit can convert the effort used by the participant into

energy in the springs. The cramps and small injuries experienced by the participants have also their effect on the walking motion. If the ideal walking motion is not obtainable, this can seriously affect the results.

5-3-3 Observations during testing period

During the testing period there are multiple observations made that can be used to improve the prototype. the observations will be summed up and discussed briefly:

- The width of the hip frame results in too much space in the tightness of the belts; therefore the transmission of movement is limited.
- The handlebars on the crutches are at the same height as the widest point of the hip frame, next to the joint caps. This makes it difficult to place the crutches without bumping to the caps, especially with smaller users.
- While walking the feet are sometimes dragged over the ground. This hinders the smoothness of the walking motion. Foot clearance is needed to maintain the smooth walking walking movement.
- At higher speeds it was observed as easier to maintain walking pace and correct crutch placement. At lower speed, it was more difficult to stay balanced.

5-4 Performance compared to other devices

During the research of the literature review (see Appendix A-13), the data of different types of orthotic devices is compared. Looking at Appendix A-13 Table 3-1, The data of mechanical orthotic devices are shown. The average walking speed is 0.22 m/s (0.792 km/h) and the average heart rate is 135 beats/min. Looking at the data from the Cloud Walker we see a that the average speed is 3.44 km/h and an average heart rate of 119 beats/min. At the better comparable speed of 1 km/h the average heart rate with the Cloud Walker is 106 beats/min. This is relatively low compared to the average of the data found in Table 3-1.
Even comparing the results of the Cloud Walker to the results of the literature review for the hybrid (Table 4-1) and active orthotic devices(Table 5-1), the Cloud Walker has a promising result. The hybrid devices have an average speed of 0.26 m/s (0.93 km/h) and average heart rate of 132 beats/min.
The active devices have an average speed of 0.32 m/s (1.14 km/h) and an average heart rate of 113 beats/min.

5-5 Usability for SCI patients

The Cloud Walker is designed for SCI patients, though it is tested on healthy participants. It is expected that SCI patients are able to walk in the Cloud Walker since the device is comparable to other orthotic devices such as the ARGO. The mechanism is thought to be effective for SCI patients with a low level of injury similar to the users of the ARGO (T8-T12).
The use of the mechanism and keeping balance at the same time can cause trouble, but is expected to work with proper training and guidance. The Cloud Walker can therefore be used as a training device at first, since it takes quite the effort to walk.
A new version of the prototype with a better fit and more foot clearance can already be a huge step to an actual training device.

Chapter 6

Recommendations

6-1 Test results

6-1-1 Test Protocol

The test protocol was made to gather a lot of data on multiple participants to set a baseline. This also meant that the participants had no experience with the Cloud Walker at the beginning of the test. Using one or a few participants that can train with the device over a longer period of time would be very interesting to research.
Testing on an actual SCI patient is the next goal. The process might be a bit more difficult, but since this is the eventual target, it would be of great interest.

6-1-2 EMG

The EMG system used gave some noisy data on the right quadriceps. There are other systems available with wireless sensors that might give better results. Only two muscles were measured, though there are a lot of other muscles that healthy people use to walk and stabilize the body that SCI patients can not use anymore. It is recommended to look more into those muscles.

6-1-3 Speed

Testing to find out how long someone can walk on their most comfortable speed would give a better insight on how long the device can be used. It would be good to know if someone can walk to for example the supermarket or only from the chair to the kitchen.

6-1-4 Heart rate

The heart rate monitor has a sample frequency of only 1 Hz. Since the heart rate increase is quite slow this is sufficient, but for more detailed data a higher sample frequency would be needed.

6-1-5 Stride length

The stride length is calculated to give insight in the walking pattern. This showed that there are multiple techniques to walk with the Cloud Walker. It might be interesting to measure the angle variation between the legs and the upper body as a measure on how much energy is added to the system. This would require more markers on the participants, but the same system can be used for that.

6-2 Prototype analysis

For a new version of prototype there are a couple of things that can be improved.
Firstly, there is the fit of the Cloud Walker. A more covering fit and more comfortable materials are expected to increase performance.

Secondly, foot clearance is expected to improve the walking motion. This can be accomplished by creating a hinging knee and/or ankle joint. It is important that balance issues and fall risks are still limited to a bare minimum.
Thirdly, the design can be more light weight and less bulky appearing. A load study can help determining how much material is needed to support and mobilize the user of the Cloud Walker. At last, the hip joint needs to be improved to prevent the wear which is shown in Figure 4-7.

Chapter 7

Conclusion

The research question of this thesis was:

What is the performance of the passive gait orthosis, the Cloud Walker, in terms of obtainable speed, leg muscle activity, used effort and walking motion when used by healthy people compared to normal walking with the same healthy people?

The answer to this research question is:

- A speed of up to 4 km/h can be achieved with the Cloud Walker.
- The leg activity of walking with the Cloud Walker is higher than walking without it.
- It takes more effort to walk with the Cloud Walker than without it.
- The stride length varies at low speeds with the Cloud Walker. The stride length is smaller at higher speeds with the Cloud Walker than without it.

The design objectives are all met:

- The Cloud walker endured the entire testing period without major issues.
- The design is light weight as it weighs about 7 kg.
- The costs are low, though this is also because there are parts from an old ARGO used.

The knowledge objectives are not entirely met:

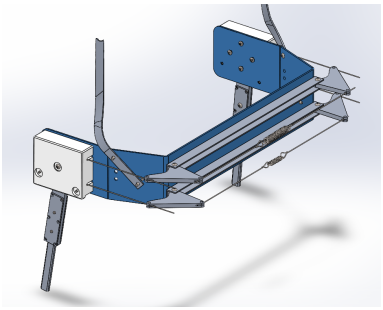
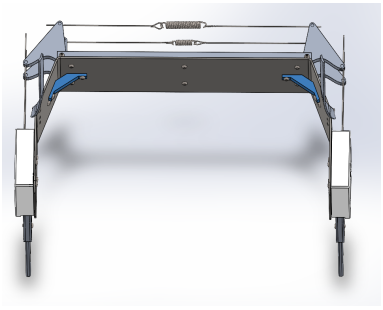
- It is expected, but not confirmed that an SCI patient can walk in the Cloud Walker. There were no falls during the use of the Cloud Walker. There were some balance issues though especially with lower speed.
- The prototype is low in energy cost compared to other orthotic devices, though the Cloud Walker is tested on healthy participants and the other devices are tested with SCI patients. Walking with the Cloud Walker costs more effort than walking without.
- The Cloud Walker does feel slightly uncomfortable when walking on a normal walking pace due to the stiff material of the leg shells.

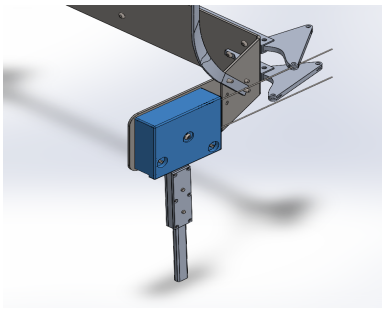
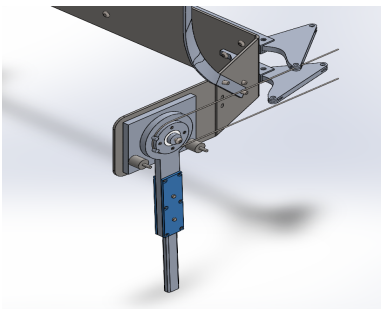
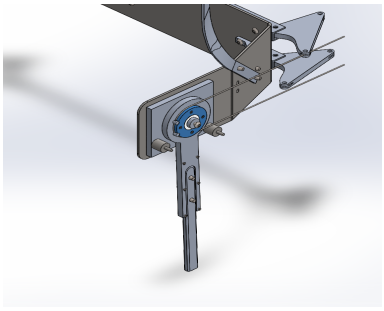
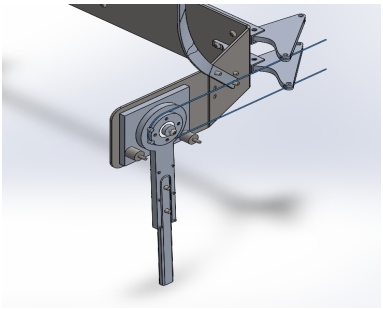
Appendix A

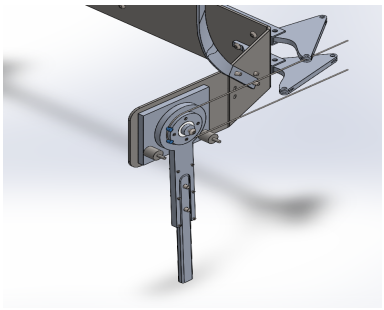
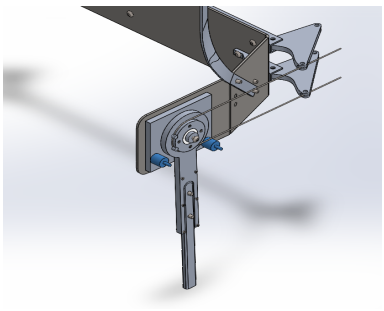
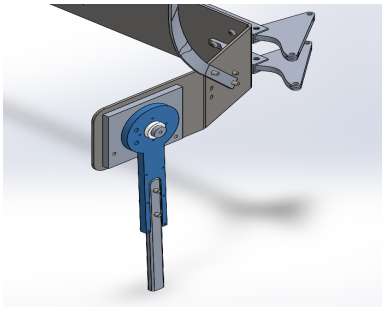
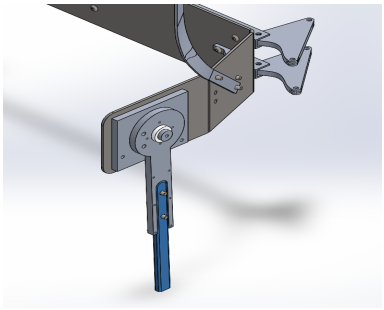
Appendices

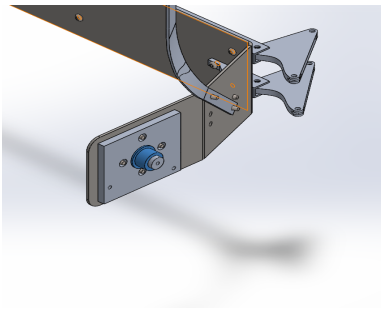
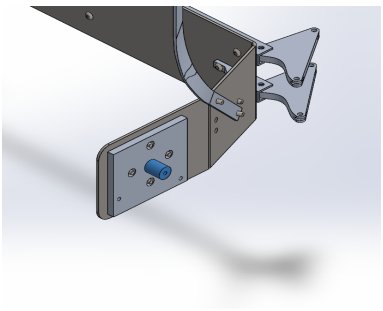
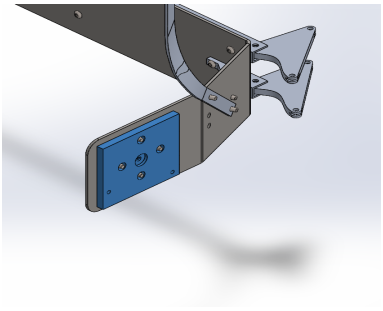
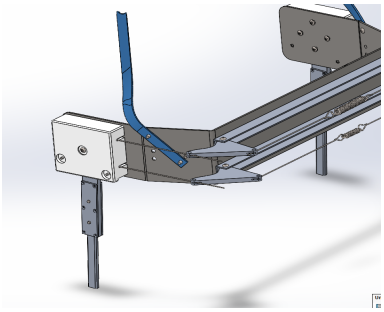
A-1 Parts

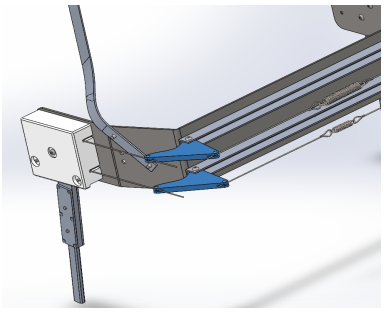
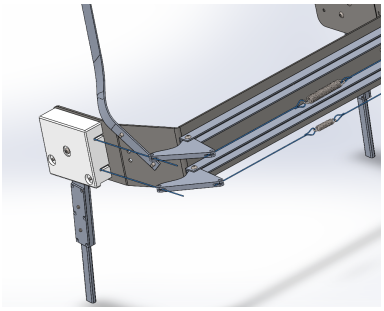
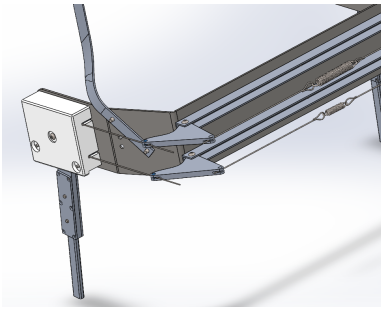
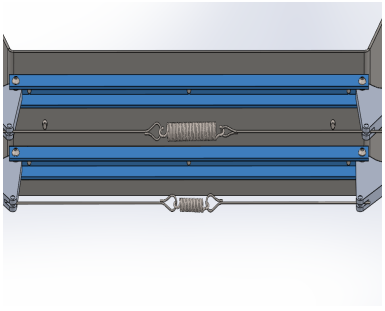
.

	Hip frame Material: 3mm stainless steel Production method: laser cutting Post processing: Sanding, Bending
	Hip frame support Material: 8mm aluminium plate Production method: water cutting Post processing: Sanding, Drilling holes

	Hip Joint Cap Material: PLA Filament Production method: 3D printing Post processing: Sanding
	Joint cover plates Material: 3mm aluminium plate Production method: water cutting Post processing: Sanding, drill center holes
	Joint cable plate Material: 5mm aluminium plate Production method: water cutting Post processing: Sanding, drill center holes
	Cable Material: 1.5mm stainless steel Store bought Post processing: cutting, shielding ends with ferrules

	Cable clamps Material: stainless steel Store bought Post processing: -
	Buffers Material: stainless steel & rubber Store bought Post processing: -
	Hip joint Material: 8mm aluminium plate water cutting Post processing: sanding, drilling
	Upper leg bar Material: aluminium reused from ARGO Post processing: -

	Sliding bearing Material: polymer Store bought Post processing: -
	Joint axis Material: aluminium rod Production method: metal lathe Post processing: drilling
	Joint base Material: 8mm aluminium plate Production method: water cutting Post processing: sanding, drilling
	Torso fixator Material: aluminium reused from ARGO Post processing: -

	Triangles Material: 8mm aluminium plate Production method: water cutting Post processing: sanding, drilling
	Cables Material: 1.5mm stainless steel Store bought Post processing: cutting, shielding ends with ferrules
	Cable clamps Material: stainless steel Store bought Post processing: -
	Fixation rail Material: aluminium profile Store bought Post processing: sanding, drilling

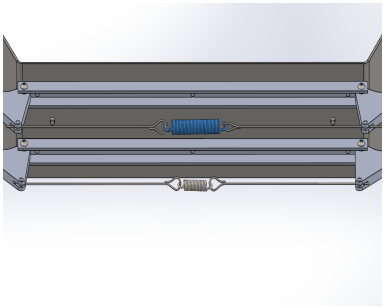
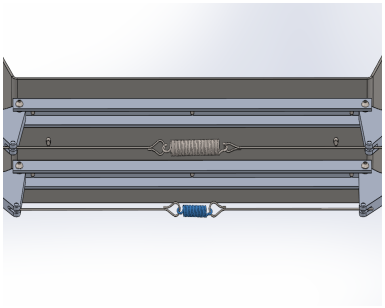
	Flexion spring Material: stainless steel Store bought Post processing: -
	Extension spring Material: stainless steel Store bought Post processing: -

Table A-1: Part summary

A-2 Data Management Plan

Walking assistance for paraplegia patients

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

My faculty data steward, Yasemin Türkyilmaz-van der Velden, has reviewed this DMP on 19-01-2022

2. Date of consultation with support staff.

2022-01-19

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
pseudonymised data on current age, gender, weight and body sizes	.csv	questionnaire	calculating fitness and fitting of prototype	onedrive and Project Drive	The PI and 2 guiding professors
pseudonymised data on heartrate and muscle activity	.csv	heart rate monitor and EMG sensors	measure muscle activity	onedrive and Project Drive	The PI and 2 guiding professors
anonymised video and photo footage of test by blurring the faces	.MP4	camera	motion analysis	onedrive and Project Drive	The PI and 2 guiding professors
feedback on prototype	.csv	questionnaire	development of the prototype	onedrive and Project Drive	The PI and 2 guiding professors

4. How much data storage will you require during the project lifetime?

- 250 GB - 5 TB

II. Documentation and data quality

5. What documentation will accompany data?

- README file or other documentation explaining how data is organised

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- OneDrive
- Project Storage at TU Delft

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects or 3rd party datasets collected from human participants?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, ask your Faculty Data Steward for

advice. You can also check with the privacy website or contact the privacy team: privacy-tud@tudelft.nl

- Yes

I will use current age, gender and body sizes as personal data. This data will be pseudonymised by using participant numbers without writing any names to the data. The document linking the name to the participant number will be stored with the informed consent forms.

8B. Will you work with any types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question. If this is not the case, you can use the example below.

The datasets underlying the published papers will be publicly released following the TU Delft Research Data Framework Policy. During the active phase of research, the project leader from TU Delft will oversee the access rights to data (and other outputs), as well as any requests for access from external parties. They will be released publicly no later than at the time of publication of corresponding research papers.

10. Which personal data will you process? Tick all that apply

- Data collected in Informed Consent form (names and email addresses)
- Signed consent forms
- Special categories of personal data (specify which): race, ethnicity, criminal offence data, political beliefs, union membership, religion, sex life, health data, biometric or genetic data
- Photographs, video materials, performance appraisals or student results
- Gender, date of birth and/or age

all personal data will be pseudonymised. Faces in video footage will be blurred if any are identifiable.

11. Please list the categories of data subjects

Categories of data subjects that might partake include healthy students, or other adults with a base fitness since they have to walk on a treadmill.

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

16. Please describe the informed consent procedure you will follow:

All study participants will be asked for their written consent for taking part in the study and for data processing before the start of the study.

17. Where will you store the signed consent forms?

- Other - please explain below

The informed consent will be collected hard copy and stored in a locked office space.

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA).
In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).
If two or more of the options listed below apply, you will have to complete the DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.
If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.
If you have any additional comments, please add them in the box below.

- Sensitive personal data

For the study I will collect video and photos and blur the faces I also will monitor the heart rate and pseudonymize it.

19. Did the privacy team advise you to perform a DPIA?

- No

22. What will happen with personal research data after the end of the research project?

- Personal research data will be destroyed after the end of the research project
- Anonymised or aggregated data will be shared with others

The form which can match participant numbers with names will be destroyed at the end of the research project.

23. How long will (pseudonymised) personal data be stored for?

- 10 years or more, in accordance with the TU Delft Research Data Framework Policy

24. What is the purpose of sharing personal data?

- For research purposes, which are in-line with the original research purpose for which data have been collected

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what you will do with data from participants who did not consent to data sharing

Participants who do not sign the consent form will be excluded from the research.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- All other non-personal data (and code) produced in the project

29. How will you share research data (and code), including the one mentioned in question 22?

- All anonymised or aggregated data, and/or all other non-personal data will be uploaded to 4TU.ResearchData with public access

30. How much of your data will be shared in a research data repository?

- 100 GB - 1 TB

31. When will the data (or code) be shared?

- As soon as corresponding results (papers, theses, reports) are published

Data will be shared in the thesis itself

32. Under what licence will be the data/code released?

- CC0

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, leading the collaboration

The leading institute is TU Delft. Other institutes involved are Erasmus University, Erasmus Medical Center and Rijndam Rehabilitation Center

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

Gerwin Smit (G.Smit@tudelft.nl), my supervisor.

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

4TU.ResearchData is able to archive 1TB of data per researcher per year free of charge for all TU Delft researchers. We do not expect to exceed this and therefore there are no additional costs of long term preservation.

A-3 Device Report

Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION WITH HUMAN SUBJECT RESEARCH

This report should be completed for every experimental device that is to be used in interaction with humans and that is not CE certified or used in a setting where the CE certification no longer applies[1].

The first part of the report has to be completed by the researcher and/or a responsible technician.

Then, the safety officer (Heath, Security and Environment advisor) of the faculty responsible for the device has to inspect the device and fill in the second part of this form. An actual list of safety-officers is provided on this webpage.

Note that in addition to this, all experiments that involve human subjects have to be approved by the Human Research Ethics Committee of TU Delft. Information on ethics topics, including the application process, is provided on the HREC website.

Device identification (name, location): Cloud Walker, TU Delft

Configurations inspected[2]: NA

Type of experiment to be carried out on the device:[3] Walking

Name(s) of applicants(s): Gerwin Smit

Job title(s) of applicants(s): Assistant Professor, supervisor

(Please note that the inspection report should be filled in by a TU Delft employee. In case of a BSc/MSc thesis project, the responsible supervisor has to fill in and sign the inspection report.)

Date: 02/03/2022

Signature(s):

1 Modified, altered, used for a purpose not reasonably foreseen in the CE certification

2 If the devices can be used in multiple configurations, otherwise insert NA

3 e.g. driving, flying, VR navigation, physical exercise, ...

1

Setup summary

Please provide a brief description of the experimental device (functions and components) and the setup in which context it supposed to be used. Please document with pictures where necessary.

More elaborate descriptions should be added as an appendix (see below).

I am developing a prototype to mechanically assist paraplegia patient in walking. This leg orthosis will be fully mechanical without the use of any electronics. The prototype consists of the following components:

Hipframe; where all other parts are attached and what the participant will 'wear'. It is made of stainless steel

Hipjoints; axis from the hipframe with a rotational coupling which go to the legs. The joint is driven by cables which go to the Energy storage. It is made of aluminium and sealed off with a plastic cap.

Energy storage; At the back of the hipframe there are two springs which are connected through cables to the hipjoints.

Leg parts: The leg parts are from an old ARGO system(Leg orthoses) and are attached to the joints. They are strapped to the legs and makes them stiff.

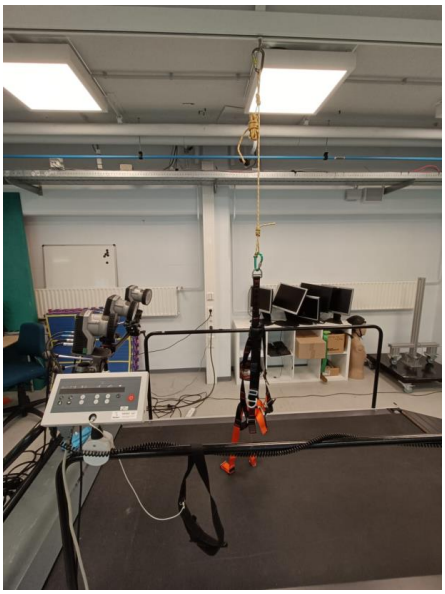
Shoes: There are shoes at the end of the leg parts to secure the participants feet

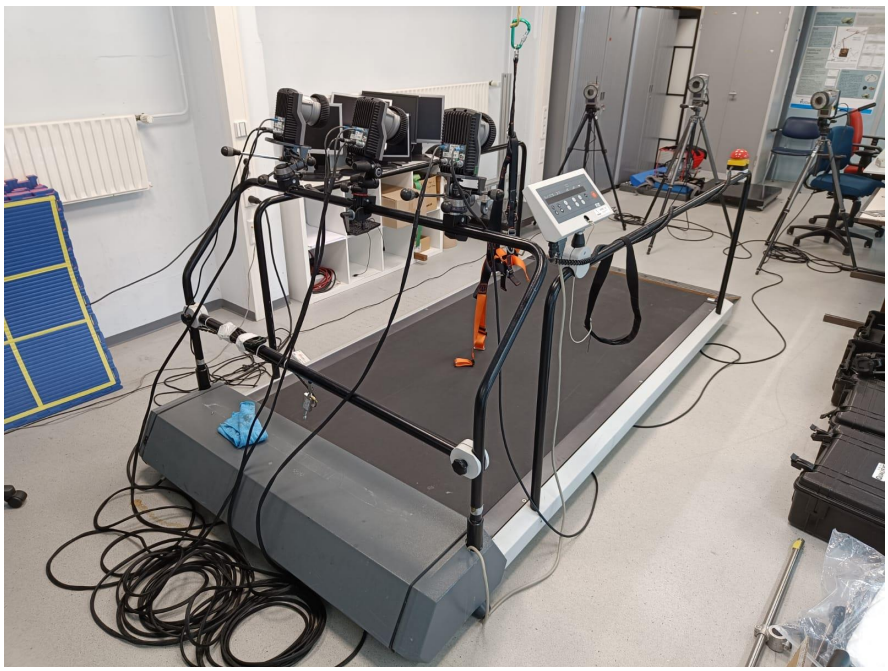
Straps: there are straps to secure the participant to the Cloud Walker. There are straps at waist level, hip level and lower leg level. The straps are made of nylon and Velcro.

Cable connectors: These triangles are used to transfer the stored energy into the joint to make the leg swing. The triangles can rotate over an axis attached to the hip frame. The cables are clamped in these triangles using screw rope clamps.

Cables: The cables are steel cables normally used as break cables on mountain bikes. The cables are clamped by screw rope clamps and the ends are provided with end caps.

The Cloud Walker will be tested on a treadmill while the participant is secured in a security harness which is attached to the ceiling. In case the participant falls, the rope will prevent falling on the ground.





Risk checklist

Please fill in the following checklist and consider these hazards that are typically present in many research setups. If a hazard is present, please describe how it is dealt with.

Also, mention any other hazards that are present.

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	x	Sharp edges, rotating parts and steel cables	Sharp edges are not in direct contact with the body due to Velcro straps. Rotating parts are covered with a plastic cap. Cable ends are provided with end caps.
Electrical	-		
Structural failure	-		
Touch Temperature	-		
Electromagnetic radiation	-		
Ionizing radiation	-		
(Near-)optical radiation (lasers, IR-, UV-, bright visible light sources)	-		
Noise exposure	-		
Materials (flammability, offgassing, etc.)	-		
Chemical processes	-		
Fall risk	X	Since the legs are strapped stiff to the Cloud Walker, one might feel frightened to fall.	Executing researcher must stay near when walking. Crutches are provided. During tests the participants are using a safety harness.
Other:			
Other:			
Other:			

Appendices

Here, you may add one or more appendices describing more detailed aspects of your setup or the research procedures.

Photos:

Figure 1 Cloud Walker front view.

Tork floor stand is used to keep the Cloud Walker standing

Figure 2 Cloud Walker side view

Figure 3 Cloud Walker Top view

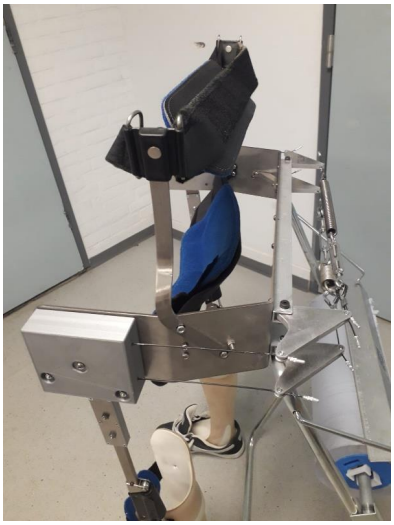


Figure 4 Close up hip frame

Figure 5 Close up Cable connections

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name:

Peter Kohne

Faculty:

3ME

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

Date: 02/03/2022

Signature: 

Inspection valid until[4]:

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

4 Indicate validity of the inspection, with a maximum of 3 years

A-4 Test Protocol

Background of the research

Background of the research The device is designed to help people with paraplegia to walk small distances. Before testing the Cloud Walker on paraplegia patients, the Cloud Walker will be tested on healthy subjects first to receive feedback from a more accessible group of participants. The Cloud Walker prototype needs to be fitted to the legs and lower trunk and will have stiff legs. In Figure 1 you can see the Cloud Walker.

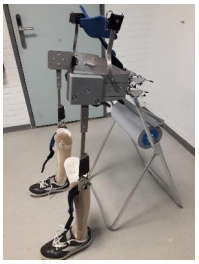


Figure 1 The Cloud Walker

Research Question

What is the physical effort, stride length and muscle activity of healthy subjects while walking compared to walking with the Cloud Walker when walking on a treadmill?

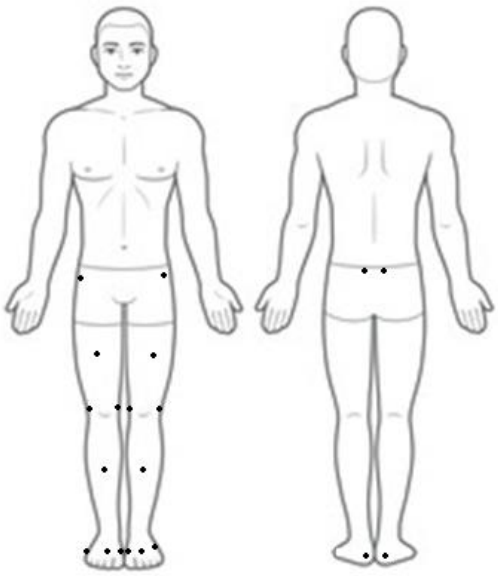
To be measured:

- Body sizes: upper and lower leg length, shoe size, waist size
- Muscle activity: the upper leg
- Motion tracking: to calculate the stride length. Markers can be placed on the Cloud Walker.
- Heart rate monitor: to calculate physical effort

Placement sensors

The EMG will be placed on both quadriceps(rector Femoris) and both hamstrings(semitendinosus)

The markers for motion tracking will be placed as follows:



Expected results:

The test should indicate what muscles and how much activity the subjects use for walking with and without the Cloud Walker. This could indicate if a person with paraplegia would be able to walk in the Cloud Walker. Exhaustion will be measured to give an estimate of how exhausting walking in the Cloud Walker can be. Stride length and speed will give an estimate on how close walking with a Cloud walker will be compared to normal walking. Body sizes are only used for fitting the prototype.

Protocol

Healthy subjects will be put on a treadmill. Firstly without the Cloud Walker to collect reference data. Secondly with the Cloud Walker to collect data on different walking speeds. In between the subject will have a small instruction on how to walk with the Cloud Walker.

Stage	With or without CW	Walking speed	Time
Introduction and Placing sensors			15 min
#1	Without	0.5 km/h	1 min
#2	Without	1 km/h	1 min
#3	Without	1.5 km/h	1 min
#4	Without	2 km/h	1 min
#5	Without	2.5 km/h	1 min
#6	Without	3 km/h	1 min
#7	Without	3.5 km/h	1 min
#8	Without	4 km/h	1 min
5 min break and 10 min introduction CW			15 min
#9	With	0.5 km/h	1 min
#10	With	1 km/h	1 min
#11	With	1.5 km/h	1 min
#12	With	2 km/h	1 min
#13	With	2.5 km/h	1 min
#14	With	3 km/h	1 min
#15	With	3.5 km/h	1 min
#16	With	4 km/h	1 min
Total			46 min

A-5 Participant Information

Cloud Walker: Walking assistance for paraplegia patients

Participation information

Date 20-04-2022

The prototype of the Cloud Walker is about to be tested. In this letter you will find information about the research. For any questions you can contact the researchers listed at the bottom of this form.

Background of the research

The device is designed to help people with paraplegia to walk small distances. Before testing the Cloud Walker on paraplegia patients, the Cloud Walker will be tested on healthy subjects first to receive feedback from a more accessible group of participants. The Cloud Walker prototype needs to be fitted to the legs and lower trunk and will have stiff legs. Participants will be guided with all steps by the executing researcher. In Figure 1 you can see the Cloud Walker.

Figure 1: the Cloud Walker

Preparation

In preparation of the study the participant will need to wear **sport clothing**. EMG sensors will be stuck to the skin of the legs of the participants. The participant is requested to wear shorts, so the sensors can be placed easily on the skin. The participant needs to wear shoes in which he/she can walk for a longer period.

Procedure of the study

The study exists of five stages and will take about an hour to complete.

Stage 1: Questionnaire and measuring body sizes

Before the study the participant is asked to fill in a questionnaire which will ask for some body measures such as leg and waist size. The executing researcher has to come close to the participant in order to measure these body measurements.

Stage 2: Measuring regular muscle activity

The participant will be walking on a treadmill at different walking speed. Heartrate and muscle activity will be measured as control data by the use of heart rate monitor and EMG sensors. Be aware that the executing researcher has to come close to the participant to place sensors on the skin and help with the fitting of the Cloud Walker.

Stage 3: Putting on the Cloud Walker

The participant will be donning the Cloud Walker. The executive researcher will help where necessary and might take pictures for research or development purposes.

Stage 4: Walking with the Cloud Walker

During the test the participant will wear a heartrate tracker and EMG sensors. The heartrate will measure the effort needed to walk with the Cloud Walker. The EMG sensors will measure leg muscle activity. The participant has to use their legs as minimal as possible as if they are paraplegia patients.

Stage 5: Feedback

As last stage, the participant has to fill in a questionnaire about the experience with the Cloud Walker. This data will be used for research and development. After completing the study you will get a small thank you from the executing researcher.

Risks of participating

The study will be carried out as save as possible. The Cloud Walker has been inspected by a TU Delft specialist and the procedure has been approved by the Human Research Ethics Committee.

As measurements against Covid, the executing participant will wear a face mask the entire time of the study. The participant is asked to do the same unless walking on the treadmill. The Cloud Walker itself will be disinfected before and after each new user.

During the study wearing the device, there might be a fear of falling since the legs are tied stiff to the Cloud Walker. The participant will be guided by the executing researcher towards the treadmill and/ or can use crutches. On the treadmill the participant will be strapped in a harness which is attached to the ceiling to prevent the user from falling. The emergence button will shut down the treadmill instant if necessary.

Procedure of withdraw

The participant can withdraw from the study at any moment if they feel the need to. When the participant withdraws from the study, all data and footage will be deleted as if the participant never took part in the study in the first place. The reason the withdraw from the study might be noted if the participant withdraws due to physical injury by the Cloud Walker or the study itself.

Personal information and privacy

The participant will be asked for their current age, gender, weight and body sizes. This is for research purposes and fitting of the Cloud Walker. The participant can get access to their personal information and ask for rectification or erasure of personal information. All personal information and gathered data will be anonymised and stored safely with the executing researcher for the time the thesis project is running. Data will only be available to the executing researcher and supervising researcher.

Contact information

Participants can contact the executing researcher by all times;

Thomas van Hengel
T.J.vanHengel@student.tudelft.nl
0642123473

For urgent matters or complains, the participant can contact the supervising researcher;

Gerwin Smit
G.Smit@tudelft.nl

A-6 Checklist HREC

Delft University of Technology
ETHICS REVIEW CHECKLIST FOR HUMAN RESEARCH
(Version 15.11.2021)

IMPORTANT NOTES ON PREPARING THIS CHECKLIST

1. An HREC application should be submitted for every research study that involves human participants (as "Research Subjects") carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as Faculty Data Stewards, Faculty HSE advisors, the TU Delft Privacy Team or external Medical research partners.
6. You can find more guidance on completing your HREC application (including tips for completing this checklist) here
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments here

I. Applicant Information

PROJECT TITLE:	**Walking assistance for paraplegia patients**
Research period: *Over what period of time will this specific part of the research take place*	**February 7th - March 18th 2022**
Faculty:	**3ME**
Department:	**BME**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master thesis**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**EU, Erasmus MC & TUD**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Thomas van Hengel**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	**T.J.vanHengel@student.tudelft.nl**
Position of Corresponding Researcher: *(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)*	**Masters**
Name of Responsible Researcher: ***Note:** all student work must have a named Responsible Researcher to approve, sign and submit this application*	**Gerwin Smit**
E-mail of Responsible Researcher: *Please ensure that an institutional email address (**no Gmail, Yahoo, etc.**) is used for all project documentation/ communications including Informed Consent materials*	**G.Smit@tudelft.nl**
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**Assistant Professor**

II. Research Overview

NOTE:** You can find more guidance on completing your HREC application (including tips for completing this checklist) **here

a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

Add your text here – (please avoid jargon and abbrevations)
I am developing a prototype to mechanically assist paraplegia patient in walking. This leg orthosis will be fully mechanical without the use of any electronics. The project is done in collaboration with the Erasmus MC. For this study, the prototype will be tested by a group of healthy subjects (n=10). In a later study it might be tested on paraplegia patients. The healthy subjects will be recruited within the TU Delft population (students or employees) and selected on body size which fit the prototype. The test consists of the subject walking in the prototoype on a treadmill when anchored in a harness attached to the ceiling. In the test the donn/doff time will be measured. The walking speed and heartrate will be measured as a measure of the effort. The EMG of the legs will be measured as a control that the participants are not using their leg muscles and therefore behave as if they were paraplegia patients.

b) **If your application is an extension, amendment or additional project** related to an existing HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

Add your text here – (please avoid jargon and abbrevations)
n/a

III. Risk Assessment and Mitigation Plan

NOTE: *You can find more guidance on completing your HREC application (including tips for completing this checklist)* ***here***

Please complete the following table in full for all points to which your answer is "yes". Bear in mind that the vast majority of projects involving human participants as "Research Subjects" also involve the collection of **Personally Identifiable Information (PII)** and/or **Personally Identifiable Research Data (PIRD)** which may pose potential risks to participants as detailed in Section G: Data Processing and Privacy below.

To ensure alignment between your risk assessment, data management and what you agree with your "Research Subjects" you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – **but this is not compulsory**.

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT**	**MITIGATION PLAN**	**DMP**	**ICF**
A: Partners and collaboration						
1. Will the research be carried out in collaboration with additional organisational partners such as: • One or more collaborating research and/or commercial organisations • Either a research, or a work experience internship provider[1] [1] *If yes, please include the graduation agreement in this application*	x		**The research is a TU Delftmaster graduation project that takes place at the TU Delft. The project is part of the Cloud Walker project which is a collaboration between the TU Delft and Erasmus Medical center, Erasmus University and Rijndam Rehabilitating Center.** **The collaboration does not bring risks.**			
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? *If yes please provide a copy of the signed DTA/DPA*		x				
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? *If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below*		x				
B: Location						
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		x				
5. Will the research take place in a country or countries outside the EU?		x				
6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?		x				
C: Participants						

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT**	**MITIGATION PLAN**	**DMP**	**ICF**
7. Will the study involve participants who **may** be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).		x				
8. Will the study involve participants who **may** be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents?		x				
9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)? *It is essential that you safeguard against possible adverse consequences of this situation (such as allowing a student's failure to participate to your satisfaction to affect your evaluation of their coursework).*		x				
10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study?		x				
D: Recruiting Participants						
11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups		x				
12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children; a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)		x				
13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party data-gathering service, such as a survey platform?		x				
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?	x		Participants will receive a gift card of 15 euros.	This will not be mentioned on forehand and therefore not result to bias.		
E: Subject Matter *Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.*						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and *In Vitro Diagnostic Medical* Devices Research		x				
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?		x				

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT**	**MITIGATION PLAN**	**DMP**	**ICF**
If yes see here to determine whether medical ethical approval is required						
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*		x				
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?	x		**The subject might feel a fear to fall**	**The use of a harness attached to the ceiling should prevent such a fall**		
19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups) *Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.*		x				
20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)		x				
21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? *If yes please attach the advice/ approval from the Privacy Team to this application*		x				
22. Does your research investigate causes or areas of conflict? *If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.*		x				
23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences *If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.*		x				
F: Research Methods						
24. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		x				
25. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		x				
26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?		x	With a normal leg orthose, there is a risk of falling. In our study we prevent falling by using a safety harness.			
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*	x		The prototype is not certified			

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT**	**MITIGATION PLAN**	**DMP**	**ICF**
• Was the device built in-house?	x					
• Was it inspected by a safety expert at TU Delft? *If yes, please provide a signed **device report***	x					
• If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *If yes, please provide records of the inspection*		x				
28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	x		**I need to be close to the subject to adjust and put on the prototype. When the subject is not in the harness I need to stay close to the subject to guide him/her from and to a chair.**	**I will wear a face mask the entire time. And make sure the hands and prototype are disinfected before/after use.**		
29. Will your research involve **either:** a) "big data", combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants **and/or** b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?		x				
G: Data Processing and Privacy						
30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)		x				
31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc	X		Photo and video footage will be collected. Gender, age and body sizes will be collected.	I will try not to film faces. If there are faces in the videos they will be blurred. Other personal data will be anonymized.		
32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants		x				
33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?	x		The research finding will be published in the master thesis and a conference and journal publication in the future.			
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?	x		The research data will be archived in the 4TU database of the TU Delft.			

H: More on Informed Consent and Data Management

NOTE: *You can find more guidance on completing your HREC application (including tips for preparing your Informed Consent materials)* ***here***

Your research involves human participants as "Research Subjects" if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

Got a comment on this checklist or the HREC process? You can leave your comments here

IV. Signature/s

Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.

Name of Corresponding Researcher (if different from the Responsible Researcher) (print)
Thomas van Hengel

Signature of Corresponding Researcher: 

Date: 27-01-2022

Name of Responsible Researcher (print)
Gerwin Smit

Signature (or upload consent by mail) Responsible Researcher: 

Date: 02-03-2022

V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

Required:

- **Always:** This completed HREC checklist
- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

Please also attach any of the following, if relevant to your research:

Document or approval	Contact/s
Full Research Ethics Application	After the assessment of your initial application **HREC will let you know if and when you need to submit additional information**
Signed, valid Device Report	Your Faculty HSE advisor
Ethics approval from an external Medical Committee	TU Delft Policy Advisor, Medical (Devices) Research
Ethics approval from an external Research Ethics Committee	Please append, if possible, with your submission
Approved Data Transfer or Data Processing Agreement	Your Faculty Data Steward and/or TU Delft Privacy Team
Approved Graduation Agreement	Your Master's thesis supervisor
Data Processing Impact Assessment (DPIA)	TU Delft Privacy Team
Other specific requirement	Please reference/explain in your checklist and append with your submission

A-7 Letter of approval ID2061

Date 18-Mar-2022
Contact person Dr. Cath Cotton, Policy Advisor Academic Integrity
E-mail c.m.cotton@tudelft.nl

Human Research Ethics Committee
TU Delft
(http://hrec.tudelft.nl/)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: Cloud Walker: Walking assistance for paraplegia patients
Applicant: Hengel, Thomas van

Dear Thomas van Hengel,

It is a pleasure to inform you that your application mentioned above has been approved.

Please note that this approval is subject to your ensuring that the following conditions are fulfilled:

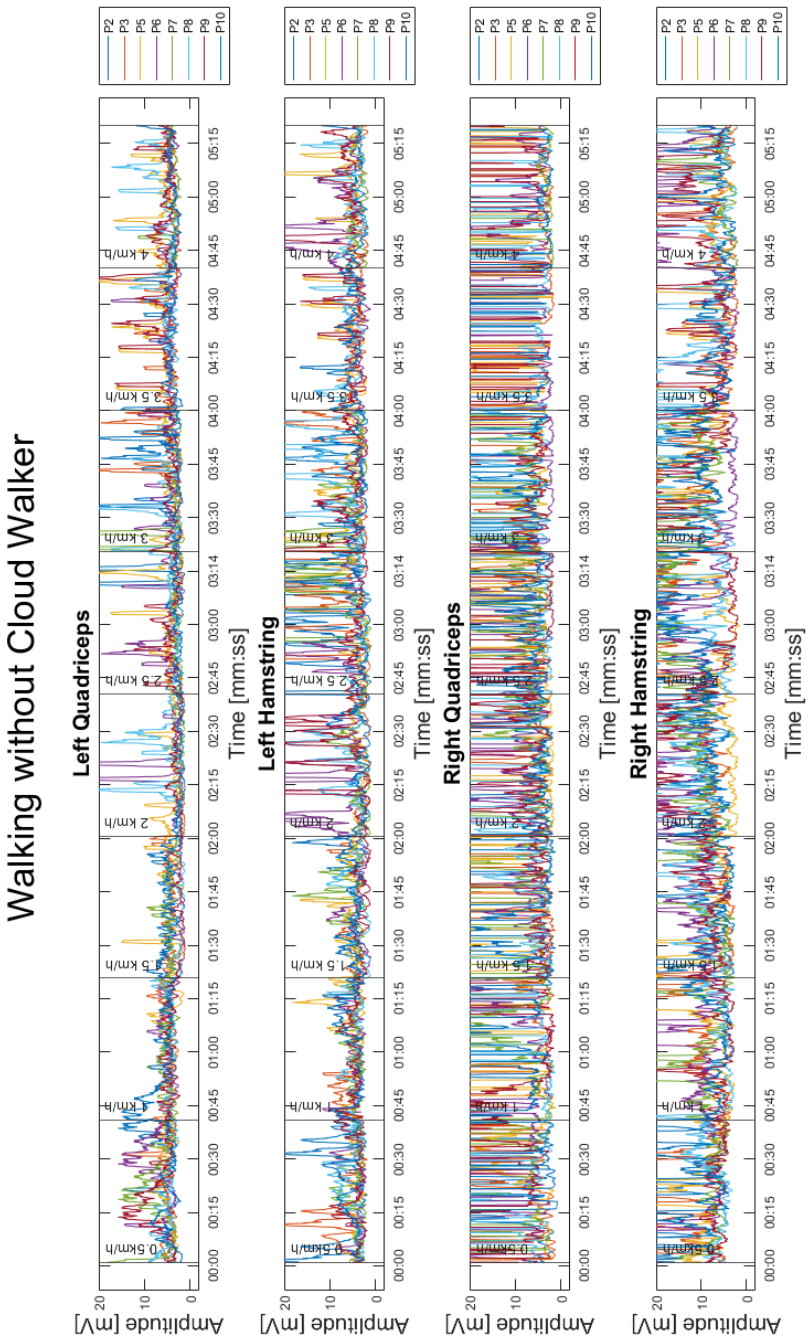
1) Any future changes or amendments to the research project are checked with the HREC;
2) HSE and Legal Services are consulted on the issues of liability and insurance;
3) The Informed Consent form clearly communicates to participants what PII and PIRD are collected in the experiment.

Good luck with your research!

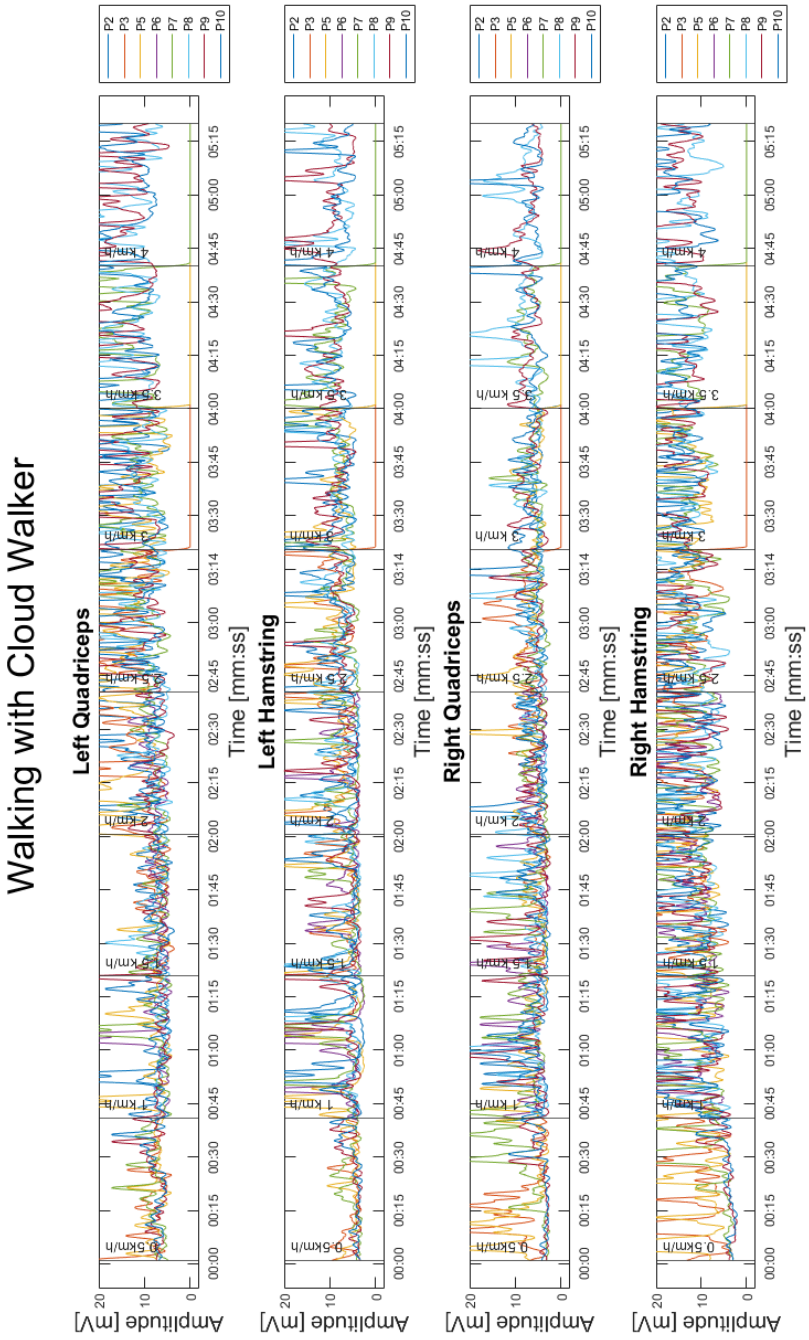
Sincerely,

Dr. Ir. U. Pesch
Chair HREC
Faculty of Technology, Policy and Management

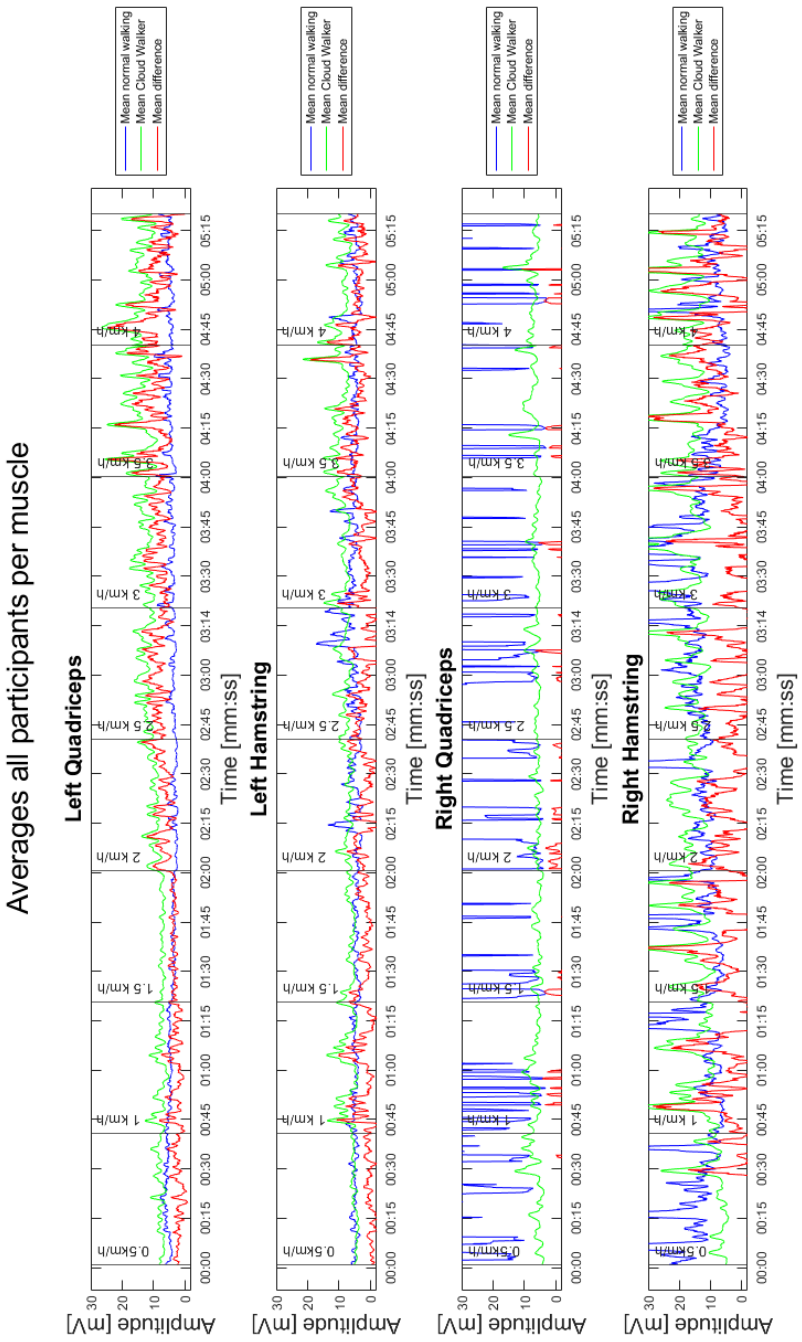
A-8 EMG of all participants walking without the Cloud Walker



A-9 EMG of all participants walking with the Cloud Walker



A-10 EMG the average of all participants per muscle



A-11 Introduction Questionnaire

Introduction form

* Required

1. What is your participant number? (ask researcher)

_____

2. What is your current age? *

_____

3. How would you describe your gender? *

Mark only one oval.

- ◯ Male
- ◯ Female
- ◯ Prefer not to say
- ◯ Other: _____

4. What is your shoe size?

Mark only one oval.

- ◯ 38
- ◯ 39
- ◯ 40
- ◯ 41

Body sizes

I will measure some of you body sizes. If you are not comfortable with this, please leave blank and notify the researcher

5. What is your current weight?

_____

6. Leg length (measure ankle to hipjoint)

_____

7. Calve circumference (measure calve)

_____

8. Waist circumference (measure waist)

_____

A-12 Evaluation Questionnaire

30-06-2022 14:27 Evaluation From

Evaluation From

* Required

1. What is your participant number? *

2. How much effort did the test with the Cloud Walker take for you? *

Mark only one oval.

	1	2	3	4	5	
like a walk in the park	◯	◯	◯	◯	◯	like climbing a mountain

3. Was walking with the Cloud walker more intensive than the normal walking *

Mark only one oval.

	1	2	3	4	5	
Easier	◯	◯	◯	◯	◯	Harder

4. Did you find the Cloud Walker comfortable to walk in? *

Mark only one oval.

	1	2	3	4	5	
It was painfull	◯	◯	◯	◯	◯	It was very comfortable

https://docs.google.com/forms/d/1PGR15FvyFfgy2vrS2GtqZpeDXQu_cFpkGUYrjzBcgZ8/edit 1/3

5. Can you elaborate on the comfortability?

6. What muscles did you use during the test? *

Check all that apply.

- [ ] Abdominal muscles
- [ ] Arm muscles (pushing with crutches)
- [ ] Back muscles
- [ ] Leg muscles
- [ ] Other: _____

7. Do you have any soar places or areas of pain? *

8. Do you have any remarks about the test or the device? *

A-13 Lower limb orthotic devices: A literature review

Lower limb orthotic devices: A literature review

T. J. van Hengel

Literature Review

TU Delft Delft University of Technology

Delft Department of Biomedical Engineering

Lower limb orthotic devices: A literature review

Literature Review

T. J. van Hengel

4235959

June 2, 2022

Faculty of Mechanical, Maritime and Materials Engineering (3mE) · Delft University of Technology

Abstract

The goal of this review is to describe the different kinds of orthosis for patients with SCI below the cortical level. Basic mechanics, type of orthosis, gait performance and user experience and community integration will be compared to find the best type orthosis for different patients. Devices with mechanical support are cheap and quite simple to control. Nevertheless, these devices are difficult to don/doff independently and very demanding for the upper body.
Devices controlled with electrical stimulated muscles is a very light weighted solution which also stimulates the muscles and can increase muscle mass. However these devices work best with implanted electrodes which have to be placed in surgery. These implanted electrodes are not for all patients available. Using the FES system only is very demanding, recommended is to use a mechanical or powered orthosis to give more stability and security.
Devices powered by external electrical actuators are still in heavily development. These heavy and expensive devices have the highest gait speed of all orthosis. This review shows the data of test done with multiple kinds of orthosis though quite some data on energy cost is missing and there is little comparability between the tests.
The conclusion of this review is that not all patients are suitable for one of the three categories of devices. Most devices are difficult to don/doff independently or is takes quite the time. Gait speed is less than half of the gait speed of able-bodied and energy expenditure is still very high for the data that is available.

Preface and Acknowledgment

During my master Biomedical Engineering at the Delft University of Technology, I had a lecture about orthosis and how people with paraplegia are able to walk small distances. The course, where every week different speakers would give a lecture, was given by Gerwin Smit. The guest lecture about walking with paraplegia was given by Frans van der Helm. During the lecture the honest question came up why orthosis are mostly still the same as 30 years ago. After the lecture we set up a meeting to see if we could make a Master Thesis of this subject. With both Gerwin and Frans as my supervisors and this review with the state-of-the-art of orthosis I will be going to work on a prototype for a new type of reciprocating gait orthosis. Together with the Erasmus Medical Center and Rijndam Rehabilitation Center we have a team of professionals from all the different aspects of making this project to become a success.

Chapter 1

Introduction

1-1 Background

According to the WHO there are between 250.000 and 500.000 people who suffer from spinal chord injury (SCI). The severity of the injury determines the symptoms. This can be partial or complete loss in sensory or motor function. The higher the level of SCI the less function remains [WHO, 2013].
Orthotic devices can change the life of a paraplegic patient, whether this is in the case of a rehabilitating or a permanent disabled patient. The need to walk for paraplegia patients would decrease some physical and mental discomfort or even diseases. Only a few weeks after the SCI the muscles already start to change. Muscle cross sectional areas are decreasing and the amount of intramuscular fat is increasing. The latter is less noticeable but contributes to the decrease in muscle strength [Gorgey and Dudley, 2007, Castro et al., 1999]. Keeping these muscles active while they are not functional helps the overall fitness of the body. According to a study by J Eng et al. patients perceive improvements in their overall health. Digestion, blood circulation, bowel and bladder function increase with the use of a walking device [Eng et al., 2001]. There are multiple different types of orthosis to do this, which will be discussed in this review.

1-2 Problem definition

There is a lot of research done in this field of interest. The last review on the subject is by M. Arazpour in 2015. Arazpour compares different types of devices by energy expenditure. He concludes that development of hybrid and powered orthoses is essential and that energy expenditure studies can find a solution to reduce energy costs [Arazpour et al., 2015]. The problem is that there is no overview of the state-of-the-art of orthosis describing the mechanics, the performances and the usability of all the different types of orthosis and which are available for different kinds of patients. Also since Arazpour in 2015, there has been a great development in powered exoskeletons which will be described in this review.

1-3 Objectives

The goal of this review is to describe the different kinds of orthosis for patients with SCI below the cortical level. Basic mechanics, type of orthosis, gait performance and user experience and community integration will be compared to find the best type orthosis for different kind of patients.

The research of Arazpour from 2015 is set as a base of this research and is completed with more data and the developments from 2015

to the present. This review is taking the next step which would be clear recommendations on different kinds of orthoses, which will be summarized and combined to find the most beneficial course of action.

1-4 Structure

In this review three different types of categories are distinguished in three chapters; Devices with mechanical support, devices powered by electrical stimulated muscles and devices powered by external electrical actuators.

Devices with mechanical support are powered only by the upper body without the use of any electrodes nor external actuators. Devices powered by electrical stimulated muscles use functional electrical stimulation (FES) to activate leg muscles to activate gait. Devices powered by external actuators are mostly robotic exoskeletons. The exoskeleton can walk by the use of batteries and motorized joints.
Every chapter is further divided in sections about the basic mechanics, the type of systems, the gait performance and the user experience and community integration. All the different devices that have some characteristics in common are grouped. Every chapter ends with the most important remarks.
The discussion, conclusion and recommendations advice which device should be used for different patients and how these devices could be improved.

Chapter 2

Search Process

2-1 Search query

By the use of a Population Intervention Comparison Outcome (PICO) analysis, a Boolean search query was formed with keywords. as follows;

Long-leg AND ("reciprocating gait Orthosis" OR HKAFO OR RGO OR "Powered Orthosis" OR Functional Electrical Stimulation) AND (gait) AND ("energy consumption" OR "energy expenditure") AND (paraplegia OR "Spinal cord injury")

2-2 Selection

Papers were selected on the following criteria:

- The level of paraplegia must cover the (lower) trunk and legs
- Test results of at least one of the categories should be given
- Test results had to include either a comparable walking speed, energy expenditure or distance per minute in order to compare the tests with the devices.
- Papers which involve detailed descriptions on the devices were also selected.

Papers were excluded when one of the following criteria was met:

- Test with patient which have just paraplegia patients with an incomplete SCI.
- Papers must be written in English.
- Papers not available via the TU Delft.
- Data is only used when the original source is available.

Figure 2-1: Prisma flowchart

2-3 Results

A web search is performed in Google Scholar, Web of Science and Scopus. The search query in these search engines resulted in 395 papers. After removing duplicates 173 results remained. On base of the title, abstract, conclusion and figures and tables the results are filtered. After the selecting process 43 papers remained. The last web search using the search query was completed on the 13th of august 2021. While reading the papers, some more papers were added from the references of these selected papers. This puts the total on 58 selected papers.

Chapter 3

Devices equipped with mechanical support

3-1 Mechanics

Mechanically powered orthoses are passive systems without using any external electrical actuator. The devices are made out of stiff metal beams along the legs, hips and sometimes even the trunk, depending on the level of injury. There are two types of mechanically powered orthosis.
The mechanical braces are long leg braces with some additional hinges or springs to supply some degree of freedom during gait.
The reciprocating gait devices are capable to transfer movement from one leg to the other and make walking more smoothly and natural appealing.

Figure 3-1: The HKAFO is a long leg brace with hinges that allow small movements

3-2 Types of systems

3-2-1 Mechanical braces

The Hip-Knee-Ankle-Foot-Orthoses (**HKAFO**) is a kind of long legged orthosis. It consists of a metal beam along both lateral sides of the legs with fixation bands. The long legged caliper, which is this basic type of HKAFO, would be the predecessor of the modern HKAFO. The modern HKAFO is provided with knee and hip joints to allow small movements to make the gait a bit more natural appealing.

The **Walkabout** is a device where two KAFOs are joined medially by a single axis hip joint [Harvey et al., 1997]. The hip joint restricts mediolateral movement and rotational movement of the hips. The joint can easily removed from the KAFOs. The system uses a gravity principle to swing the leg to the front so it is not mechanically assisted as in the RGOs. Though the Walkabout has no corset, it can still be used by patient with paraplegia below the level of T3. [Step-on, 1993]

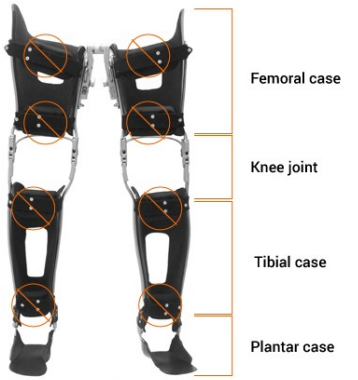


Figure 3-2: The Walkabout has a hinge between the legs

The Hip Energy Storage Walking Orthosis (**HESWO**) is a hip orthosis which uses a spring on the pelvic shell to store energy and use it to elevate the hip into swing phase. The system consists of two KAFOs joint by a pelvic shell, which holds two springs around the hip joint, one anterior and one posterior [Yang et al., 2017].

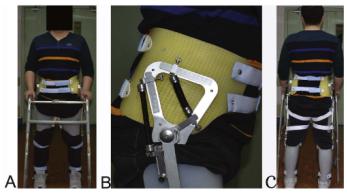


Figure 3-3: The HESWO has two springs lateral of each hip to store energy

The **ParaWalker** is a kind of Hip Guidance Orthosis (**HGO**). The rigid body brace is supplied with a free rotational hip joint incorporates a limited range of flexion and extension of the hip. When the swing leg is elevated from the ground, gravity makes the leg swing forward. The straight leg swings in front of the patient. To "push" the body over the stance leg, the patient has to raise the trunk forward and upwards by using its crutches or walker. The Parawalker introduced in the beginning of the eighties is later upgraded with a FES system, which makes it less demanding for the upper body to perform gait [Patrick and McClelland, 1985, Stallard et al., 1986].

Figure 3-4: The Parawalker uses gravity to swing the leg to the front

3-2-2 Reciprocating gait devices

The Reciprocating Gait Orthosis(**RGO**) uses two cables to help flex of the hip of the swing leg when the hip of the stance leg is extending. While the legs remain stiff, the hip can tilt to move the body weight on one leg at the time. When the user shifts his or her weight to one leg, the other leg can swing to the front by leaning the upper body into the system. [Leung et al., 2009]. The Isocentric Reciprocating Gait Orthosis (**IRGO**) is a RGO which has an rotating beam with an isocentric point of rotation medial posterior of the hips. This beam connects the hips as a rotating hinge and converts hip movement into leg movement [Samadian et al., 2015].

Figure 3-5: The Reciprocating Gait Orthosis uses two cables to convert movement from one leg to the other

Figure 3-6: The IRGO has a rotating beam that transfers hip movement into leg movement

Figure 3-7: The ARGO uses only one cable to couple the hips and their movement

The Advanced Reciprocating Gait Orthosis (**ARGO**) is a RGO which has a single cable that couples the hips posterior of the hips. The cable transfers torque from the left hip to the right. If the patient lifts one leg and leans back, the extension of the hip of the stance leg will result in a flexion of the hip of the swing leg. this guiding mechanism results in a lower energy consumption compared to calipers or HKAFOs [Jaspers et al., 1997, Kawashima et al., 2006].
The Weight Bearing Control Orthosis (**WBC**) is tested by Kawashima et al.. It reduces energy costs by gas powered footplates. These footplates supplied with gas powered pistons from a C02 tank on the user's back. This orthosis has reciprocal guide assistance to facilitate leg swing and movable foot plates to make better clearance from the floor [Kawashima et al., 2003]. Though this orthosis is gas powered, in the literature it is compared with the other RGO systems since it has a reciprocating system as leading system.

3-3 Gait performance

Table 3-1 shows the gait performance of the devices with mechanical support. Subjects walking with these passive devices have an average gait speed of 0.22 m/s. Yang et al. compare the IRGO with the HESWO which they developed. Subjects liked the HESWO better due to its function to automatically initiate the swing phase as soon as the hip is elevated. This improved the walking pattern and the gait speed. Also the energy expenditure was less than with the use of the IRGO.
In the research of Harvey et al. a comparison is made between the IRGO and the Walka-

bout. The patients using the IRGO are faster and require less assistance than the Walkabout users. the IRGO users need more assistance in standing up. The users had trouble with unlocking the hips, less movement in the hips and the weight of the IRGO(6kg). Yang et al. conclude that the IRGO is quicker and makes the user more independent, while the Walkabout is easier to stand up with.
The WBC developed by Kawashima et al. is less energy demanding than other systems. However the system is only tested with 4 patients where 1 has an incomplete SCI. Unfortunately, this gives better values than studies with only complete SCI patients. The use of the WBC therefore has to be further investigated.

3-4 User experience and community integration

In a follow up study by Hawran et al. 40 patients were questioned who had left the clinic with calipers(HKAFO) to use at home [Hawran and Biering-Sørensen, 1996].
The study took place in 1993-1994 after the patients had been discharged in the period of 1973-1982. At the follow up interview only 3 patients still used their long leg calipers at home and 7 used them for over 5 years. The main reasons patients won't use their calipers anymore are mostly due to trouble with donning and doffing, a fear of falling or the fact that it is impractical since they don't have their hands available.
Another follow up study done by Jaspers et al. questioned 14 patients about their experiences with the ARGO and if they still use the orthosis [Jaspers et al., 1997]. After at least 1 year, 12 out of the 14 patients were still using the Argo on a regular basis for therapeutic reasons. The patients gave as reasons why they are not using the ARGO for other purposes that the ARGO is too heavy and cumbersome and the walking speed is too low. Half of the patients used the ARGO fully independent. Others needed help donning and standing up.
Merati et al. did a follow up study after 4 years since the beginning of their own study [Merati et al., 2000]. Of the four subjects using the Parawalker, three abandoned their orthosis because donning and doffing was too difficult or it cost too much energy to ambulate. The fourth patient was not available for comments. From the six subjects using the RGO, three were still using the RGO, two abandoned their orthosis. the sixth was not available for comments. The main difficulty with the system is that it is too bulky when in use.
Sykes et al. investigated the nonusage in RGOs over the period of 1986-1993 [Sykes et al., 1995]. Of the 85 questioned patients, only 35 responded. Twenty patients stopped using the RGO. Different reasons were given for the nonusage. eleven patients stopped using the RGO because of surgical or medical reasons. Others found the RGO uncomfortable, difficult to donn/doff or fit poorly. Also the energy costs of walking was said to be a reason.

Table 3-1: Test results of different types of mechanically driven orthoses

Research	Level of SCI	Amount of subject	Orthosis	Gait speed [m/s]	Heart rate [Beats/min]	Energy cost [J/kg/m]	Energy consumption [J/kg/s]
[Bernardi et al., 1999]	Abled-people	18	none	1.28	112.9	3.53	4.52
Mechanical braces							
[Harvey et al., 1997]	T9-T12	10	Walkabout	0.14	-	-	-
[Yang et al., 2017]	T5-T12	12	HESWO	0.19	114.3	-	-
[Merati et al., 2000]	C7-T10	4	Parawalker	0.16	150	-	-
[Nene and Jennings, 1992]	T3-T12	16	Parawalker	0.28	134	-	-
[Nene and Patrick, 1989]	T4-T9	10	Parawalker	0.21	-	14.48	3.1
[Nene and Patrick, 1990]	T4-T7	5	Parawalker	0.23	-	11.22	2.59
Reciprocating gait devices							
[Hirokawa et al., 1996]	T1-T10	6	RGO	0.21	-	21	4.18
[Winchester et al., 1993]	T5-T10	4	RGO	0.23	-	19.44	4.37
[Bernardi et al., 1995]	T4-T12	10	RGO	0.21	-	20	4.3
[Merati et al., 2000]	T3-T11	6	RGO	0.19	131	24.87	4.64
[Yang et al., 2017]	T5-T12	12	RGO	0.16	120.6	-	-
[Bernardi et al., 1999]	-*	11	RGO	0.17	180.2	27.2	-
[Felici et al., 1997]	T5-L1	6	RGO&ARGO	0.26	-	32.3	8.26
[Harvey et al., 1997]	T9-T12	10	IRGO	0.34	-	-	-
[Samadian et al., 2015]	T9-T12	6	IRGO	0.29	-	-	-
[Kawashima et al., 2006]	T5-T12	10	ARGO	0.33	133	20.12	6.11
[Massucci et al., 1998]	T3-T12	6	ARGO	0.16	-	29	4.64
[Ijzerman et al., 1999]	T4-T12	10	ARGO	0.21	-	28.2	5.92
[Arazpour et al., 2016]	T8-T12	4	ARGO	0.24	109.8	-	-
[Kawashima et al., 2003]	T8-T12	4	WBC	0.32	147.3	17.12	5.41

* no level is known, but all patients have a complete SCI

3-5 Concluding remarks

The devices with mechanical support are a simple and relatively cheap option for subjects to perceive walking. There are two kinds of mechanical support:

- Mechanical braces are stiff which makes it very demanding for the upper body to swing the legs into gait.
- Reciprocating gait devices make walking a bit more smooth and natural appealing, though the upper body still has to do the work.

Chapter 4

Devices powered by electrical stimulated muscles

4-1 Mechanics

Functional electrical stimulation(**FES**), also called Functional Neuromuscular Stimulation (FNS), can activate the muscle even though the motor function of the patient is limited or even absent. When programmed the right way, patients can walk using their electrically activated muscles. Over longer periods of stimulation fatigue in the muscles limits the distance that can be walked. Therefore, FES can be combined with a mechanical device (RGO, HKAFO) or even a robotic device to reduce energy cost.
With the use of transcutaneous or percutaneous electrodes, selected muscles can be activated by electrical impulses. Transcutaneous electrodes are electrodes attached to the skin without puncturing the skin, so with sticky markers. Percutaneous electrodes are puncturing the skin or implanted in the muscle for deep muscle stimulation.

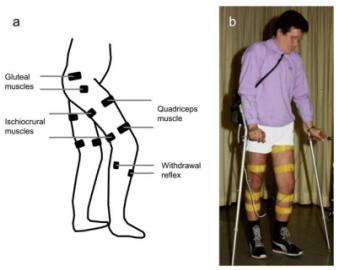


Figure 4-1: With Functional Electrical Stimulation(FES) electrodes placed on the legs stimulate the muscles

Sigmedics, producer of the **Parastep**, made a protocol on calibrating the Parastep before the training period can start. After the device is attached to the patient, the system has to be calibrated to the patients body reactions. To calibrate the strength of the quadriceps, the patient is lying on their back on a low bed with the knees over the edge so the feet are on the floor. The minimum stimulation needed to extend the knees is recorded. After that, small amounts of extra weight is then added to the ankles at each contraction and the intensity of the stimulus is recorded as well. This can be done up to a certain amount of kilo's which is considered as safe for the patient. This could leap up to 10 kg [Brissot et al., 2000, Gallien et al., 1995]. A lot of researchers using the Parastep or even another form of FES system use this protocol as a standard.

4-2 Types of systems

4-2-1 Transcutaneous electrodes

The first FES systems from 1963 used surface electrodes to stimulate the muscles. Kantrowitz et al. and Kralj et al. used these superficial electrodes to stimulate the lower extremity. Later in 1972, Kralj et al. tested the superficial FES system on a large group of 50 patients so they could stand up [Kralj and Grobelnik, 1973]. These superficial electrodes need to be placed every single time a subject wants to walk. Superficial electrodes are effective, though deeper stimulation give better result and less skin problems [Kantrowitz, 1960, Kralj and Grobelnik, 1973, Shimada et al., 1996].

The controlled-Brake Orthosis (**CBO**) developed by Goldfarb et al. combines a FES system of surface electrode with a computer controlled braking system. This hybrid system gives more stability and reduces muscle fatigue compared with FES-only systems [Goldfarb et al., 2003].

The **Parastep** (Sigmedics, Inc., Northfield, IL) is a FES device based on the alternate activation of the quadriceps muscle and the withdrawal reflex [Brissot et al., 2000, Gallien et al., 1995]. The four-channel device is controlled by a microcomputer in the walker. The device can be complemented by two additional channels. The Parastep delivers a transcutaneous monophasic symmetrical pulse. The pulse width is 300 μs and has a constant current between 0-300 mA at 24 Hz. The four channels activate both quadriceps and the withdrawal reflex. The two additional channels can be used to activate the gluteus or both lumbar muscles. The battery provides 2,5 hour of continuous use. The weight of the system is about 500 g excluding the weight of an AFO,KAFO or HKAFO.

The hybrid neuroprosthesis(**HNP**) combines FES with external mechanical components. The bracing provides stability without hindering movement and the FES system provides the forward progression. For the mechanical part the HNP consists of a TKHAFO. The FES part consists of 16 channels stimulating 8 different muscles from the trunk to the calves [Kobetic et al., 2009, To, 2010]. Although Kobetic et al. tested the HNP with an SCI patient, no usable data can be derived from their study. The study provides data for able-bodied subjects and incomparable data for the SCI patient.

Figure 4-2: The electrodes of the Parastep© by Sigmedics are controlled by the controller in the walker

The **RGO generation II** is a reciprocating gait orthosis with functional electrical stimulation. It is a kind of HNP designed in Louisiana State University Medical Center.n The RGO II includes a RGO combined with a FES system which gives the benefits of both systems; stability and reduced muscle fatigue [Thoumie et al., 1995].

4-2-2 Percutaneous Electrodes

Percutaneous electrodes are hard to work with. Shimada et al. review that a lot of these percutaneous electrodes break and have to be replaced. Up to 30% failed within the year. Since the transcutaneous electrodes are becoming more advanced and wireless implanted electrodes are in development, the use of percutaneous electrodes would decrease [Shimada

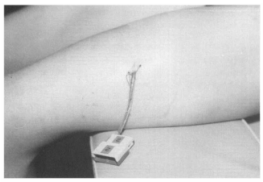


Figure 4-3: The percutaneous electrodes are implanted in the body and connected to the external power unit with wires

et al., 1996].

The Case Western Reserve University/Veterans Affairs(**CWRU/VA**) implanted standing neuroprosthesis is an implanted FES system that is connected via radio waves. The system consists of 8 implanted stimulators. An external control unit (ECU) provides power and command signals to the implanted stimulators and can operate over 4 hours consecutively on full charge. The ECU records commands which can be received and interpreted on a laptop with specialised software [Forrest et al., 2012].

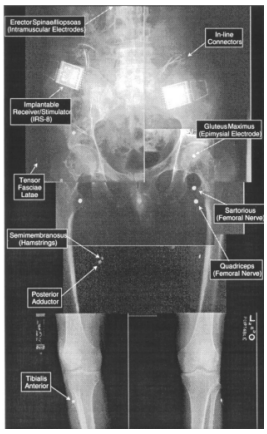


Figure 4-4: The white dots are implanted electrodes of the CWRU/VA implanted standing neuroprosthesis and can stimulate when a wireless signal is sent.

4-3 Gait performance

Table 4-1 shows the gait performance when paraplegia patients use the the FES only, the Parastep and a combination of some kind of a reciprocating device and FES. The average gait speed is calculated to be 0.25m/s, which makes the devices with electrical stimulation faster than the average gait speed of the devices with mechanical support (0.22 m/s).
Though there is not much data on energy cost and consumption, multiple researchers write about how demanding walking with a FES system is. Becker et al. states already in 1985 that FES is usable in sitting and standing to reduce spasticity in paraplegia. However walking for more than 15 minutes is too energy consuming. The subjects had a 6 month training prior to this study [Becker et al., 1985].
Beillot et al. used a RGO with FES on 14 subjects to measure energy consumption of locomotion. In two training periods of at least 6 weeks Beillot et al. had to conclude that the training periods were not intense enough to see improvement in the physical fitness [Beillot et al., 1996].
Popovic et al. used two eight-channel stimulators for different walking speeds on their subjects and compared their findings with the measurements from able-bodied subjects. The lowest energy costs was achieved in fast walking, which is still twice as costly for a speed of only 60% of the able-bodied subjects.
The stimulation of the muscles increases the muscle force. Brissot et al. used the Parastep for their research. Brissot et al. measured an average maximum force of about 3.4 kg in the quadriceps in order for the patients to stand up. At the end of the training period the quadriceps had a average maximum force of 7.5 kg and an increase of 5 cm of the thigh circumference [Brissot et al., 2000]. Gallien et al. used the same protocol as Brissot et al. to research gait improvement using the Parastep. The initial maximum force measurement in the quadriceps is 4.2 kg. At dis-

charge this is 6.9 kg. After the training period the thigh circumference has increased with an average of 5 cm [Gallien et al., 1995].

4-4 User experience and community integration

The high muscle fatigue is a major issue according to the subjects. Kobetic and Marsolais et al. wrote a review in 1991 about different types of orthoses, FES and hybrid systems. Small FES systems of only 4-6 channels can give stability in standing and even a bit of walking when combined with a orthosis. Systems with 48 channels can achieve swing and stance phases and gives stability to the trunk, hip, knee and ankle. Speeds up to 1 meter per second can be reached. However the energy costs are way too high and the system is difficult to don/doff [Marsolais et al., 1991]. In later research Kobetic and Marsolais et al. tried different setups in hybrid orthosis. They varied different mechanical orthosis with different amount of electrodes. Their conclusion is that patient with FES and no or simple mechanical orthosis can achieve higher speeds, however patients feel imbalance and cannot achieve a upright posture. More stable orthosis however made the patients slower [Marsolais et al., 2014]
The 13 out of 15 patients remaining from the research of Brissot et al. [Brissot et al., 2000] could stand up with the Parastep after generally two sessions. Walking between bars occurred during an average of five sessions. Patients could walk independently with the help of a walker after 14 sessions during one month. The evaluation shows that five out of 13 patient use their Parastep at home and three use it even outside. However all patients use the Parastep for physical fitness only and not for functional ambulation or social gatherings.
Gallien et al. performed research on thirteen patients with the Parastep [Gallien et al., 1995]. Most of the patients could stand up with the Parastep within two sessions. The first steps with the Parastep took place around the tenth session. Adverse effects included back pain, ankle sprain, a calcaneum fracture, and one patient with a broken sacrum due to a fall. 8 out of the 13 patients where questioned after 15 months for a follow up research. Four patients are using the Parastep regularly at home. However, the device is only used to exercise. Self esteem and confidence appear to be increased greatly, but the device was considered too difficult to don/doff and too high in energy costs [Merati et al., 2000]
The follow-up study of Forrest et al. evaluates the CWRU/VA implanted standing neuroprosthesis. Of the 11 subjects, 9 use the system for exercising multiple times per week. It also helps them with daily activities according to 6 subjects. All the users were very satisfied with the ease of the system and found the system very safe and reliable, though the surgery is very intense [Yang et al., 2017].

4-5 Concluding remarks

The devices powered by electrical stimulated muscles can be have different types of electrodes:

- Transcutaneous electrodes are in small amounts easy to don/doff but a larger amount takes a long time. It has to be done every time a patient wants to walk.
- Percutaneous wired electrodes break easy and are therefore less used. The implanted electrodes with wireless stimulation can stimulate the muscle on a even deeper level and are less likely to break.

Both two types are physically demanding, but they can help subjects to regain their mobility if not permanently paralysed. Though the system itself is very light, a combination of FES with some kind of mechanical device

Table 4-1: Test results of different types of devices with electrical stimulation

Research	Level of SCI	Amount of subject	Type of orthosis	Gait speed [m/s]	Heart rate [Beats/min]	Energy cost [J/kg/m]	Energy consumption [J/kg/s]
[Bernardi et al., 1999]	Abled-people	18	none	1.28	112.9	3.53	4.52
Transcutaneous electrodes							
[Becker et al., 1985]	T5-T8	3	FES	0.16	-	-	-
[Isakov et al., 1986]	C7-T9	4	FES	0.10	-	-	-
[Popovic et al., 2003]	T8-T10	6	FES	0.50	105	-	-
[Goldfarb et al., 2003]	T6-T8	4	CBO	0.06	-	-	-
[Brissot et al., 2000]	T3-T11	13	Parastep	0.15	168.3	69.9	-
[Gallien et al., 1995]	T4-T10	13	Parastep	0.20	105	-	-
[Spadone et al., 2003]	T5	1	Parastep	0.06	124	-	-
[Winchester et al., 1994]	T4-T12	5	Parastep	0.21	-	-	-
[Hsieh et al., 2009]	L1	1	RGO+FES	0.17	-	-	-
[Isakov et al., 1992]	T4	1	RGO+FES	0.42	-	-	-
[Merati et al., 2000]	C7-T10	4	RGO+FES	0.16	155	-	-
[Sykes et al., 1996]	C2-T6	5	RGO+FES	0.22	-	13.7	2.6
[Beillot et al., 1996]	T2-T12	14	RGOII	0.23	-	-	-
[Thoumie et al., 1995]	C8-T12	26	RGOII	0.20	-	-	-
[Spadone et al., 2003]	T5	1	ARGO+FES	0.01	108	-	-
Percutaneous electrodes							
[Forrest et al., 2012]	T6	1	CWRU/VA	0.1	-	-	-

would give more stability and security to the subjects.

Chapter 5

Devices powered by external electrical actuators

5-1 Mechanics

Gorgey et al. did not find any evidence that ambulation with an active system will increase skeletal muscle size or lean mass during or after their research training. He recommends that active systems still have to work with some kind of electrical stimulation of the muscles to improve the metabolic profile of a SCI patient [Gorgey et al., 2017]. Nowadays there are multiple powered systems which also have an integrated FES system so muscles can be trained as well.

5-2 Types of systems

5-2-1 External electrical powered devices without FES

The **ReWalk** is a battery powered exoskeleton remotely controlled by a wrist pad controller developed in 2006 in Marlborough. The ReWalk can be controlled by subtle trunk motion and changes in the center of gravity. the ReWalk is applicable for patients with SCI below the level of T4. The ReWalk has no FES build into it and is controllable with an arm watch to perform sitting, standing and walking. [Gorgey et al., 2019, Esquenazi et al., 2017]

Figure 5-1: The ReWalk powered orthosis is controlled by hip movements

The **EKSO** is an exoskeleton with sensors that automatically detect if the patient is leaning forward or backward to initiate walking. The Ekso is developed to offer gait training in paraplegia patients with a range of features in their gait-training mode. Patients with an SCI below the level of C6 can make use of the Ekso. [Gorgey et al., 2017] The **REX bionics** is an exoskeleton where patients do not need crutches or walkers in order to keep balance and to help mobilizing the patient. Since REX stabilizes everything below the trunk, patients with a SCI high in the cervical area can still be applicable. The exoskeleton is with 38 kg the heaviest of the current available exoskeletons. There is still no further research done unfortunately. [Gorgey et al., 2019]

Figure 5-2: The EKSO has different gait training modes

Figure 5-4: The Indego exoskeleton has also an implemented FES system

Figure 5-3: With the REX the patients have no more need for a walker or crutches

5-2-2 External electrical powered devices with FES

The **Indego** is designed at the Vanderbilt University in Macedonia. It has one motor in each knee and hip and is constructed on top of a ankle-foot-orthosis(AFO). Including the lithium battery, the exoskeleton weighs only 12 kg, which is at least twice as low as other powered orthosis. The Indego is applicable for patients with SCI below T4. The build in FES system, makes this powered orthosis an powered hybrid orthosis. [Hartigan et al., 2015] **HAL** (Hybrid Assistive Limb) is said to be the worlds first wearable cyborg. This Japanese exoskeleton allows voluntary machine support by amplifying minimal bio-electrical signals from the hip and knee flexors and extensors. The device is only usable for patients with weakened gait mobility since the system amplifies neurological signals, which are unable to provide for patients with a complete SCI [Aach et al., 2014].

Figure 5-5: The Hybrid Assistive Limb (HAL) is controlled by amplified signals from the joints of the patient

The Motor Assisted Hybrid Neuroprosthesis (**MAHNP**) is developed by Nandor et al.. This new type of exoskeleton is attached on top of two AFOs. The battery in a small backpack powers 4 motors in the hip and knee joints and the implanted FES system. Though there is much yet unknown, the system is tested on two SCI patient; one with level T4 SCI and the other is unknown [Nandor et al., 2021]. Though the system is tested there is no further data on energy cost or muscle fatigue.

5-3 Gait performance

Table 5-1 shows the gait performance of the external electrical powered devices. On first sight can be seen that there are no measurements for the energy cost and energy consumption. Also just a few measurements of heart rate. This might be due to the fact that walking is not so demanding for people with paraplegia since the powered orthosis is doing all the work. This also would explain why the heart rates are relatively low. Only with the research of Evens et al. a significantly higher heart rate is shown. This could be explained because the Indego system uses FES and therefore triggers muscle fatigue.
The average gait speed is quite faster than of those of the systems with electrical stimulation and the mechanically driven systems (0.30 m/s vs 0.25 m/s and 0.22 ms respectively). However, there should be noted that in this category subjects were less disabled. Not all subject had complete SCI or had a low level of SCI.

5-4 User experience and community integration

Orthosis with external electrical actuators are said to have great potential. Since the development of these powered exoskeletons about twenty years ago, a lot of improvements are already made. After training with the HAL, Aach et al. measured an increase of muscle circumference between 5 and 50 mm in a 3 month training process, while also gaining an increase in gait speed up to 0.5 m/s, a third of average walking speed in healthy subjects. Subjects from the training from Kozlowski et al. report some extra benefits after the training. They report improvement in balance, posture, bowel movement, reduction of back pain and even better sleeping [Kozlowski et al., 2015]. Also was mentioned that patients with spasticity experience a reduce in spasticity, which is mentioned as an improvement by users of any kind of orthosis as well. The externally electrical powered devices still have issues such as fall risk, slow walking speed, the don/doff time and in most of the devices, the need of a walker or crutches or even a physical therapist to help them. In a lot of the training sessions a physical therapist is needed to be close to the patient to reduce fall risk. Though this just might be needed for mental support for the patient, these patients are still dependent on support. Even with a powered exoskeleton, there is still a need for personal guidance. Hartigan et al. followed the training of 16 paraplegia patient to walk with the Indego. The level of injury ranged from C5 til L1. Though the tetraplegia patients(C5-C7) could not don/doff the Indego by themselves, the most patients in the level range of T9-L1 could do this without the help of the physical therapist within a time range of 2:30 and 13 minutes [Gorgey et al., 2017, Hartigan et al., 2015].

5-5 Concluding remarks

The devices powered by external electrical actuators are relatively new orthoses. The devices can be categorised into two categories:

- External electrical powered devices without FES can be used by permanently paralysed subject. Less disabled subject would not gain an increase in muscle since the device is doing all the work.
- External electrical powered devices with FES make gait training less demanding for the upper body while the muscles in the lower extremities are stimulated.

These devices are very expensive and are still quite slow. With an average of 0.30 m/s it is considered the fastest of the orthosis, though it is still only a quarter (in the best a third) of the gait speed of able-bodied patients.

Table 5-1: Gait performance of devices powered by external electrical actuators

Research	Level of SCI	Amount of subject	Type of orthosis	Gait speed [m/s]	Heart rate [Beats/min]	Energy cost [J/kg/m]	Energy consumption [J/kg/s]
[Bernardi et al., 1999]	Abled-people	18	none	1.28	112.9	3.53	4.53
External electrical powered devices without FES							
[Zeilig et al., 2012]	T5-T12	6	ReWalk	0.21	92	-	-
[Asselin et al., 2015]	T2-T11	8	ReWalk	0.22	118	-	-
[Kozlowski et al., 2015]	C4-L1	7*	EKSO	0.15	104	-	-
[Gorgey et al., 2017]	C5-T4	4	EKSO	0.44	-	-	-
External electrical powered devices with FES							
[Evans et al., 2015]	T6-T12	5	Indego	0.27	142	-	-
[Hartigan et al., 2015]	T9-L1	8	Indego	0.45	-	-	-
[Aach et al., 2014]	T7-L3	8*	HAL	0.50	-	-	-
[Tsukahara et al., 2011]	T10	1	HAL	0.11	-	-	-
[Nandor et al., 2021]	T4-?	2	MAHNP	0.31	-	-	-

* not all subject have a complete SCI

Chapter 6

Discussion

6-1 Mechanics

The passive devices are the most simple and cheapest devices for paraplegia patients to stand up and even walk for short distances. The devices are sometimes hard to don/doff, though of all the different categories there are many that are more difficult to wear. Because the lack of muscle use in the legs, all the energy to walk has to come from the upper body which is too energy demanding.
The devices with electrical stimulation are only available for some patients. Patients with epilepsy, pregnancy, other electronic devices such as a pacemaker, open wounds, deep vein thrombosis, skin problems, obesity and likely even more criteria are not or less suitable for FES. According to an estimation of Jaeger et al., the population which could account for electrical stimulation is only between 4.7% and 11.25% of the paraplegia patients in the USA. SCI patients with lesions above T4 or below T12 are also not appropriate for FES training and the patient should be fit enough to compensate for the high energy costs of walking. [Jaeger et al., 1990].

6-2 Gait performance

6-2-1 Gait speed

The highest gait speed for devices with mechanical support is acquired with the WBC, IRGO and ARGO (0.32 m/s, 0.33m/s 0.34 m/s), though these are also the devices with a relative high energy cost. Since these devices are all devices with a reciprocating mechanism, this would be the the best performing orthosis without any electrical components.
Since the development of the FES a lot of combinations are made between the electrical stimulation and a mechanical or sometimes even powered orthosis. This would give the patients more stability and security, though patients using only FES are said to achieve faster gait [Marsolais et al., 2014]. The data confirms this with 0.50 m/s as the highest gait speed of all the devices with electrical stimulation. The next highest is a combination of RGO and FES with 0.42 m/s, but since this is only one subject it can be seen as an extreme. The rest of the combinations are indeed performing less in gait speed. More research should be done on why and how mechanical orthosis are limiting the gait speed.

6-2-2 Energy demand

To compare the amount of energy needed for ambulation the heart rate, energy cost and en-

ergy consumption can be compared with each other. A lot of research papers miss this kind of data which makes it hard to compare. The data that is available might also not be comparable since the measurements were collected in different training processes or the levels of SCI are different. With the development of FES, Sigmedics made a standard protocol for calibrating the system which is a first step. In the more current day research the test protocol is standardised with a 6 minute walking test and a 10 meter walking test. If more research is done with different kinds of orthosis following these tests, a much easier to compare review can be made. With the information available from this review there are outcomes that can be compared, however firm conclusions are hard to make.
Devices with external electrical actuators can make people stand up and walk with the least amount of effort. The devices are still heavily in development though. Subjects are still not able to walk distances without the use of crutches or walkers and some even require a physical therapist helping them. The REX is said to be able to make patients walk independent. However, no data is available which makes it difficult to say if this device will be advantageous on the other powered exoskeletons. An argument could be made that the device performs all the walking so the patients have no energy cost what so ever, but that would not hold for the devices using the FES system.

6-3 User experience and community integration

The devices with mechanical support do have the most follow-up studies. Concluding from those studies, a lot of patients stopped using their orthosis. This is due to medical reasons, but also because of energy cost of the actual gait and don/doff difficulties. The ARGO has the most success after a year of usage. However the ARGO, and the other mechanical orthosis as well, are mostly used for exercise purposes, barely for in home walking and not for community integration. This is mostly due to the energy cost, but also because of the slow gait speed. A short walk would still take a lot of time and energy.
The mechanical orthosis are said to be difficult to don/doff and are energy demanding. This problem stays with the introduction of FES systems. transcutaneous electrodes are clearly visible and hard to don/doff every single time of use. Implanted electrodes are considered the most effective and patients are quite happy with them. Though these need to be surgically placed, which is not considered an option for all SCI patient, the don/doff time is the lowest of all devices.
There are quite some positive aspects about the use of devices with external electrical actuators. Overall physical well being increases and the highest gait speed of all orthosis. The don/doff time however is still an issue. Some patients could not do this independently and for others who could do this independently it took quite the time.

Chapter 7

Conclusion

This review describes many different types of orthosis for different kinds of patients. There are different advantages and disadvantages for each system. Devices with mechanical support are the cheapest and most simple option for patients with SCI to experience walking most of the patients can wear these. Weight support is limited as in all the different devices, so patients with obesity might not be qualified. Most of these devices give support to the trunk which makes these devices available for patients with higher levels of SCI. As long as they are able to use their arms. Reciprocating devices are slightly less demanding than mechanical braces, which make them available for a larger group that might not be as fit to walk with mechanical braces.
For patients who would like to use electrical stimulation, the combination of FES with a mechanical or powered device is probably the best option. If implanted electrodes are an option, it would be the most effective and easy to don/doff. However the higher the level of SCI the more muscles have to be stimulated in order to minimally give balance. This makes FES only available for fit patients with a level of SCI between T4 and T12. Patients with epilepsy, pregnancy, other electronic devices such as a pacemaker, open wounds, deep vein thrombosis, skin problems, obesity and maybe even more are not suitable for FES. In the USA, this makes the group that can use FES only between 4.7% and 11.25% of the paraplegia.
The powered exoskeletons are at the moment very expensive and are not at the point yet where patients can walk independently. This makes the devices with external electrical actuators available for only limited amount of patients. Since the trunk is stabilised with most powered exoskeletons, patients with higher level of SCI can still use them.

The conclusion of this review is that not all patients are suitable for one of the three categories. Crutches, walkers or other support options are still needed in order to walk. Only some devices can be donned or doffed without extra help, which is essential for independent walking alongside the time and difficulty to don/doff the orthosis. Gait speed is still very low for all three categories. The best is about 0,5 m/s which is still not even half the speed of normal walking for able-bodied. In all known cases the energy costs are still high, which makes it hard to walk long distances.

Chapter 8

Recommendations

The devices with reciprocating support are in text less energy demanding, though this is not clearly visible in the data. Further research should be done, if possible in such a way that the tests are comparable such as the 6 minute or 10 meter walking tests. Since the first mechanical orthosis, engineering has changed a lot. Complicated mechanism and other ways of manufacturing might improve the mechanical orthosis.
The devices with electrical stimulation need more data on energy expenditure. For these tests it would be an improvement if the data is comparable with other systems. If electrodes can be implanted with minimal invasive surgery this might make the FES system a better approachable option.
The devices with external electrical actuators are still heavily in development there is limited data available and the only comparable data is the gait speed. Since the new technology of exoskeletons, it is recommended to develop a cheaper version of the powered orthosis, so it would be more accessible for patients all over the world. Until that is realistic, the cheaper mechanical orthosis and FES systems should keep developing with modern day production techniques such as 3D printing. 3D printing is perfectly suitable for custom made parts. Since every patient has a slightly different body structure, orthosis have to be fitted perfectly in order to make walking as comfortable and effective as possible.

Bibliography

[Aach et al., 2014] Aach, M., Cruciger, O., Sczesny-Kaiser, M., Höffken, O., Meindl, R., Tegenthoff, M., Schwenkreis, P., Sankai, Y., and Schildhauer, T. A. (2014). Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord injury: a pilot study. *Spine J*, 14(12):2847–53.

[Arazpour et al., 2016] Arazpour, M., Samadian, M., Bahramizadeh, M., Bani, M. A., Gharib, M., Hosseini, S. A., Hutchins, S. W., and Mardani, M. A. (2016). The effect of trunk extension on physiological cost index in spinal cord injury patients when using the advanced reciprocating gait orthosis: A pilot study. *Prosthetics and Orthotics International*, 40(6):696–702.

[Arazpour et al., 2015] Arazpour, M., Samadian, M., Bahramizadeh, M., Joghtaei, M., Maleki, M., Bani, M. A., and Hutchins, S. (2015). The efficiency of orthotic interventions on energy consumption in paraplegic patients: a literature review. *Spinal Cord*, 53(3):168–175.

[Asselin et al., 2015] Asselin, P., Knezevic, S., Kornfeld, S., Cirnigliaro, C., Agranova-Breyter, I., Bauman, W. A., and Spungen, A. M. (2015). Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia. *Journal of Rehabilitation Research and Development*, 52(2):147–158.

[Becker et al., 1985] Becker, E., Najenson, T., and et al. (1985). p: Nepo; y cost and physiological reactions to effort during acryation op paraplegics by functional electrical stimulation. *Scand J Rehab Med*, 12:102–107.

[Beillot et al., 1996] Beillot, J., Carre, F., Le Claire, G., Thoumie, P., Perruoin-Verbe, B., Cormerais, A., Courtillon, A., Tanguy, E., Nadeau, G., and Rochcongar, P. (1996). Energy consumption of paraplegic locomotion using reciprocating gait orthosis. *European journal of applied physiology and occupational physiology*, 73(3):376–381.

[Bernardi et al., 1995] Bernardi, M., Canale, I., Castellano, V., Difilippo, L., Felici, F., and Marchetti, M. (1995). The efficiency of walking of paraplegic patients using a reciprocating gait orthosis. *Paraplegia*, 33(7):409–415.

[Bernardi et al., 1999] Bernardi, M., Macaluso, A., Sproviero, E., Castellano, V., Coratella, D., Felici, F., Rodio, A., Piacentini, M. F., Marchetti, M., and Ditunno Jr, J. (1999). Cost of walking and locomotor impairment. *Journal of electromyography and kinesiology*, 9(2):149–157.

[Brissot et al., 2000] Brissot, R., Gallien, P., Le Bot, M.-P., Beaubras, A., Laisné, D., Beillot, J., and Dassonville, J. (2000). Clinical experience with functional electrical stimulation-assisted gait with parastep in spinal cord–injured patients. *Spine*, 25(4):501–508.

[Castro et al., 1999] Castro, M. J., Apple Jr, D. F., Hillegass, E. A., and Dudley, G. A.

(1999). Influence of complete spinal cord injury on skeletal muscle cross-sectional area within the first 6 months of injury. *European journal of applied physiology and occupational physiology*, 80(4):373–378.

[Eng et al., 2001] Eng, J. J., Levins, S. M., Townson, A. F., Mah-Jones, D., Bremner, J., and Huston, G. (2001). Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*, 81(8):1392–9.

[Esquenazi et al., 2017] Esquenazi, A., Talaty, M., and Jayaraman, A. (2017). Powered exoskeletons for walking assistance in persons with central nervous system injuries: A narrative review. *Pm&R*, 9(1):46–62.

[Evans et al., 2015] Evans, N., Hartigan, C., Kandilakis, C., Pharo, E., and Clesson, I. (2015). Acute cardiorespiratory and metabolic responses during exoskeleton-assisted walking overground among persons with chronic spinal cord injury. *Topics in Spinal Cord Injury Rehabilitation*, 21(2):122–132.

[Felici et al., 1997] Felici, F., Bernardi, M., Rodio, A., Marchettoni, P., Castellano, V., and Macaluso, A. (1997). Rehabilitation of walking for paraplegic patients by means of a treadmill. *Spinal Cord*, 35(6):383–385.

[Forrest et al., 2012] Forrest, G. P., Smith, T. C., Triolo, R. J., Gagnon, J., DiRisio, D., Miller, M. E., and Rhodi, L. (2012). Use of the case western reserve/veterans administration neuroprosthesis for exercise, standing and transfers by a paraplegic subject. *Disability and Rehabilitation: Assistive Technology*, 7(4):340–344.

[Gallien et al., 1995] Gallien, P., Brissot, R., Eyssette, M., Tell, L., Barat, M., Wiart, L., and Petit, K. (1995). Restoration of gait by functional electrical stimulation for spinal cord injured patients. *Spinal Cord*, 33(11):660–664.

[Goldfarb et al., 2003] Goldfarb, M., Korkowski, K., Harrold, B., and Durfee, W. (2003). Preliminary evaluation of a controlled-brake orthosis for fes-aided gait. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 11(3):241–248.

[Gorgey and Dudley, 2007] Gorgey, A. S. and Dudley, G. A. (2007). Skeletal muscle atrophy and increased intramuscular fat after incomplete spinal cord injury. *Spinal Cord*, 45(4):304–309.

[Gorgey et al., 2019] Gorgey, A. S., Sumrell, R., and Goetz, L. L. (2019). Exoskeletal assisted rehabilitation after spinal cord injury. *Atlas of Orthoses and Assistive Devices*, pages 440–447. e2.

[Gorgey et al., 2017] Gorgey, A. S., Wade, R., Sumrell, R., Villadelgado, L., Khalil, R. E., and Lavis, T. (2017). Exoskeleton training may improve level of physical activity after spinal cord injury: a case series. *Topics in spinal cord injury rehabilitation*, 23(3):245–255.

[Hartigan et al., 2015] Hartigan, C., Kandilakis, C., Dalley, S., Clausen, M., Wilson, E., Morrison, S., Etheridge, S., and Farris, R. (2015). Mobility outcomes following five training sessions with a powered exoskeleton. *Top Spinal Cord Inj Rehabil*, 21(2):93–9.

[Harvey et al., 1997] Harvey, L. A., Smith, M. B., Davis, G. M., and Engel, S. (1997). Functional outcomes attained by t9-12 paraplegic patients with the walkabout and the isocentric reciprocal gait orthoses. *Archives of Physical Medicine and Rehabilitation*, 78(7):706–711.

[Hawran and Biering-Sørensen, 1996] Hawran, S. and Biering-Sørensen, F. (1996). The use of long leg calipers for paraplegic patients: a follow-up study of patients discharged 1973–82. *Spinal Cord*, 34(11):666–668.

[Hirokawa et al., 1996] Hirokawa, S., Solomonow, M., Baratta, R., and D'Ambrosia, R. (1996). Energy expenditure and fatiguability in paraplegic ambulation using reciprocating gait orthosis and electric stimulation. *Disabil Rehabil*, 18(3):115–22. Hirokawa, S Solomonow, M Baratta, R D'Ambrosia, R Comparative Study Journal Article England Disabil Rehabil. 1996 Mar;18(3):115-22. doi: 10.3109/09638289609166028.

[Hsieh et al., 2009] Hsieh, J.-C., Chen, S.-C., Chen, C.-C., Chen, Y.-L., Chang, W.-H., Li, Y.-C., and Shih, Y.-Y. (2009). Paraplegic using a reciprocating gait orthosis (rgo) with functional electrical stimulation. In *World Congress on Medical Physics and Biomedical Engineering, September 7-12, 2009, Munich, Germany*, pages 5–8. Springer.

[Ijzerman et al., 1999] Ijzerman, M. J., Baardman, G., van't Hof, M. A., Boom, H. B., Hermens, H. J., and Veltink, P. H. (1999). Validity and reproducibility of crutch force and heart rate measurements to assess energy expenditure of paraplegic gait. *Archives of physical medicine and rehabilitation*, 80(9):1017–1023.

[Isakov et al., 1992] Isakov, E., Douglas, R., and Berns, P. (1992). Ambulation using the reciprocating gait orthosis and functional electrical stimulation. *Spinal Cord*, 30(4):239–245.

[Isakov et al., 1986] Isakov, E., Mizrahi, J., and Najenson, T. (1986). Biomechanical and physiological evaluation of fes-activated paraplegic patients. *J Rehabil Res Dev*, 23(3):9–19.

[Jaeger et al., 1990] Jaeger, R. J., Yarkony, G. M., Roth, E. J., and Lovell, L. (1990). Estimating the user population of a simple electrical stimulation system for standing. *Spinal Cord*, 28(8):505–511.

[Jaspers et al., 1997] Jaspers, P., Peeraer, L., Van Petegem, W., and Van der Perre, G. (1997). The use of an advanced reciprocating gait orthosis by paraplegic individuals: a follow-up study. *Spinal Cord*, 35(9):585–589.

[Kantrowitz, 1960] Kantrowitz, A. (1960). Electronix physiologic aids: A report of the maimonides hospital.

[Kawashima et al., 2003] Kawashima, N., Sone, Y., Nakazawa, K., Akai, M., and Yano, H. (2003). Energy expenditure during walking with weight-bearing control (wbc) orthosis in thoracic level of paraplegic patients. *Spinal Cord*, 41(9):506–510.

[Kawashima et al., 2006] Kawashima, N., Taguchi, D., Nakazawa, K., and Akai, M. (2006). Effect of lesion level on the orthotic gait performance in individuals with complete paraplegia. *Spinal Cord*, 44(8):487–494.

[Kobetic et al., 2009] Kobetic, R., To, C. S., Schnellenberger, J. R., Audu, M. L., Bulea, T. C., Gaudio, R., Pinault, G., Tashman, S., and Triolo, R. J. (2009). Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury. *Journal of Rehabilitation Research & Development*, 46(3).

[Kozlowski et al., 2015] Kozlowski, A., Bryce, T., and Dijkers, M. (2015). Time and effort required by persons with spinal cord injury to learn to use a powered exoskeleton for assisted walking. *Topics in spinal cord injury rehabilitation*, 21(2):110–121.

[Kralj and Grobelnik, 1973] Kralj, A. and Grobelnik, S. (1973). Functional electrical stimulation - a new hope for paraplegic patients. *Bulletin of prosthetics research*, pages 75–102.

[Leung et al., 2009] Leung, A., Wong, A., Wong, E., and Hutchins, S. (2009). The physiological cost index of walking with an isocentric reciprocating gait orthosis among patients with t12-l1 spinal cord injury. *Prosthetics and Orthotics International*, 33(1):61–68.

[Marsolais et al., 2014] Marsolais, E., Kobetic, R., Gaudio, R., Tashman, S., Nandurkar, S., Triolo, R., and Lehneis, H. (2014). Effect of multi-channel hybrid orthosis configuration on walking in paraplegia. In *IFESS 2002 Annual Conference*.

[Marsolais et al., 1991] Marsolais, E. B., Kobetic, M. P. R., Chizeck, H. J., and Jacobs, J. L. (1991). for walking in complete paraplegia. *Neurorehabilitation and Neural Repair*.

[Massucci et al., 1998] Massucci, M., Brunetti, G., Piperno, R., Betti, L., and Franceschini, M. (1998). Walking with the advanced reciprocating gait orthosis (argo) in thoracic paraplegic patients: energy expenditure and cardiorespiratory performance. *Spinal Cord*, 36(4):223–227.

[Merati et al., 2000] Merati, G., Sarchi, P., Ferrarin, M., Pedotti, A., and Veicsteinas, A. (2000). Paraplegic adaptation to assisted-walking: energy expenditure during wheelchair versus orthosis use. *Spinal Cord*, 38(1):37–44.

[Nandor et al., 2021] Nandor, M., Kobetic, R., Audu, M., Triolo, R., and Quinn, R. (2021). A muscle-first, electromechanical hybrid gait restoration system in people with spinal cord injury. *Frontiers in Robotics and AI*, 8.

[Nene and Jennings, 1992] Nene, A. and Jennings, S. (1992). Physiological cost index of paraplegic locomotion using the orlau parawalker. *Spinal Cord*, 30(4):246–252.

[Nene and Patrick, 1989] Nene, A. and Patrick, J. (1989). Energy cost of paraplegic locomotion with the orlau parawalker. *Spinal Cord*, 27(1):5–18.

[Nene and Patrick, 1990] Nene, A. and Patrick, J. (1990). Energy cost of paraplegic locomotion using the parawalker–electrical stimulation" hybrid" orthosis. *Archives of physical medicine and rehabilitation*, 71(2):116–120.

[Patrick and McClelland, 1985] Patrick, J. H. and McClelland, M. R. (1985). Low energy cost reciprocal walking for the adult paraplegic. *Spinal Cord*, 23(2):113–117.

[Popovic et al., 2003] Popovic, D., Radulovic, M., Schwirtlich, L., and Jaukovic, N. (2003). Automatic vs hand-controlled walking of paraplegics. *Medical Engineering & Physics*, 25(1):63–73.

[Samadian et al., 2015] Samadian, M., Arazpour, M., Bani, M. A., Pouyan, A., Bahramizadeh, M., and Hutchins, S. W. (2015). The influence of orthotic gait training with an isocentric reciprocating gait orthosis on the walking ability of paraplegic patients: a pilot study. *Spinal Cord*, 53(10):754–757.

[Shimada et al., 1996] Shimada, Y., Sato, K., Abe, E., Kagaya, H., Ebata, K., Oba, M., and Sato, M. (1996). Clinical experience of functional electrical stimulation in complete paraplegia. *Spinal Cord*, 34(10):615–619.

[Spadone et al., 2003] Spadone, R., Merati, G., Bertocchi, E., Mevio, E., Veicsteinas, A., Pedotti, A., and Ferrarin, M. (2003). Energy consumption of locomotion with orthosis versus parastep-assisted gait: a single case study. *Spinal cord*, 41(2):97–104.

[Stallard et al., 1986] Stallard, J., Major, R., Poiner, R., Farmer, I., and Jones, N. (1986). Engineering design considerations of the orlau parawalker and fes hybrid system. *Engineering in medicine*, 15(3):123–129.

[Step-on, 1993] Step-on (1993). Walkabout system.

[Sykes et al., 1996] Sykes, L., Campbell, I., Powell, E., Ross, E., and Edwards, J. (1996). Energy expenditure of walking for adult patients with spinal cord lesions using the reciprocating gait orthosis and functional electrical stimulation. *Spinal Cord*, 34(11):659–665.

[Sykes et al., 1995] Sykes, L., Edwards, J., Powell, E. S., and Ross, E. R. S. (1995). The reciprocating gait orthosis: long-term usage patterns. *Archives of physical medicine and rehabilitation*, 76(8):779–783.

[Thoumie et al., 1995] Thoumie, P., Perrouin-Verbe, B., Le Claire, G., Bedoiseau, M., Busnel, M., Cormerais, A., Courtillon, A., Mathe, J., Moutet, F., and Nadeau, G. (1995). Restoration of functional gait in paraplegic patients with the rgo-ii hybrid orthosis. a multicentre controlled study. i. clinical evaluation. *Spinal Cord*, 33(11):647–653.

[To, 2010] To, C. S.-H. (2010). *Closed-loop control and variable constraint mechanisms of a hybrid neuroprosthesis to restore gait after spinal cord injury*. Thesis, Case Western Reserve University.

[Tsukahara et al., 2011] Tsukahara, A., Hasegawa, Y., and Sankai, Y. (2011). Gait support for complete spinal cord injury patient by synchronized leg-swing with hal. In *2011 IEEE/RSJ International Conference on Intelligent Robots and Systems*, pages 1737–1742. IEEE.

[WHO, 2013] WHO (2013). Spinal chord injury.

[Winchester et al., 1994] Winchester, P., Carollo, J., and Habasevich, R. (1994). Physiologic costs of reciprocal gait in fes assisted walking. *Spinal Cord*, 32(10):680–686.

[Winchester et al., 1993] Winchester, P. K., Carollo, J. J., Parekh, R. N., Lutz, L. M., and Aston, J. W., J. (1993). A comparison of paraplegic gait performance using two types of reciprocating gait orthoses. *Prosthet Orthot Int*, 17(2):101–6. Winchester, P K Carollo, J J Parekh, R N Lutz, L M Aston, J W Jr Comparative Study Journal Article Research Support, Non-U.S. Gov't France Prosthet Orthot Int. 1993 Aug;17(2):101-6. doi: 10.3109/03093649309164364.

[Yang et al., 2017] Yang, M. L., Li, J. J., Guan, X. Y., Gao, L. J., Gao, F., Du, L. J., Zhao, H. M., Yang, D. G., Yu, Y., Wang, Q. M., Wang, R. C., and Ji, L. H. (2017). Effectiveness of an innovative hip energy storage walking orthosis for improving paraplegic walking: A pilot randomized controlled study. *Gait & Posture*, 57:91–96.

[Zeilig et al., 2012] Zeilig, G., Weingarden, H., Zwecker, M., Dudkiewicz, I., Bloch, A., and Esquenazi, A. (2012). Safety and tolerance of the rewalk™ exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study. *J Spinal Cord Med*, 35(2):96–101.

[WHO, 2013] WHO (2013). Spinal chord injury.

Bibliography

[Cappozzo, 1995] Cappozzo, A. e. a. (1995). Position and orientation in space of bones during movement: anatomical frame definition and determination. *Clinical Biomechanics*, 10(4):171–178.

[Castro et al., 1999] Castro, M. J., Apple Jr, D. F., Hillegass, E. A., and Dudley, G. A. (1999). Influence of complete spinal cord injury on skeletal muscle cross-sectional area within the first 6 months of injury. *European journal of applied physiology and occupational physiology*, 80(4):373–378.

[Eng et al., 2001] Eng, J. J., Levins, S. M., Townson, A. F., Mah-Jones, D., Bremner, J., and Huston, G. (2001). Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*, 81(8):1392–9.

[Gorgey and Dudley, 2007] Gorgey, A. S. and Dudley, G. A. (2007). Skeletal muscle atrophy and increased intramuscular fat after incomplete spinal cord injury. *Spinal Cord*, 45(4):304–309.

[Sanders, 2006] Sanders, A. (2006). Splint for teaching paraplegics how to walk, comprises bracket with hinge parts in hip joint regions connected to supports and to each other via coupling mechanism. *Dutch Patent NL1027993C2*.