Mechanised Orthosis for children with neurological disorders

Output N°3

Pilot of final exoskeleton and garment prototype.

Achieve TRL 5 for both mechanical and garment.

WP2: Evaluation of the prototypes
WP3: Feasibility of transfer of technology
Delivery date: 31/03/2023

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I. Introduction

MOTION project aimed developing an autonomous exoskeleton along with a smart garment system for children with gait disabilities caused by neurological disorders, in particular cerebral palsy (CP). The exoskeleton consists of a powered ankle foot orthosis (PAFO), a powered hip module and a powered exoskeleton for the lower limb. Pilot tests and feasibility measurements were performed with each prototype/module including the PAFO, the hip module and the lower limb exoskeleton with or without the smart garment. These measurements were conducted in engineering and clinical labs. This document provides a summary of the measurements and results that were obtained.

II. PAFO

II.1 Preparation and feasibility studies in Belgium

In preparation for the development and delivery of the exoskeletons, a few studies were set up to gather information and try out protocols.

1. Retrospective study on the effect of AFOs on gait in children with CP
   - Ethical approval: S64584 – 30/11/2020 (available on demand)
   - Clinical protocol is included in the ethical approval mentioned above
   - Resume of study: number of children tested and clinical results N = 170
   - Product: published paper in journal gait & posture Everaert et al., 2023
   - Deliverable: 2.1.1 - Define clinical specifications for the exoskeleton &
     2.1.5. - Pilot assessment of the exoskeleton with patients in the lab
2. Study on the effect of AFOs on the gross motor function of children with a neurological disorder
   - Ethical approval: S65042 – 31/03/2021
   - Clinical protocol is included in the ethical approval mentioned above
   - Resume of study: number of children tested and clinical results N = 30 children with neurological disorder
   - Product: oral presentation at ESMAC 2022, the paper submitted for this conference was published Everaert et al., 2023
   - Deliverable: 2.1.5. - Pilot assessment of the exoskeleton with patients in the lab
3. Creating reference databases:
   - Deliverable: D2.1.3 Normative laboratory tests on healthy subjects
     - Gathering data on healthy children and children with CP overground
       i. UK
       ii. Belgium
     - Gathering data on healthy children and children with CP for treadmill walking
     - Gathering data of children with CP for walking with their conventional AFOs
     - Data management
4. Repeatability study on children with CP walking in 4 conditions (overground, on the treadmill, with and without AFOs).
   - Ethical approval: S65337 – 25/06/2021
   - Protocol of the study is included in the ethical approval mentioned above
   - Resume of study: number of children tested and clinical results N = 8 children with CP
   - Product: master-thesis at KU Leuven (Bochmans et al. 2023)
5. Feasibility study on children with CP walking on the treadmill in 3 conditions (barefoot, with conventional AFO and with PAFO)

- Ethical approval:
- Protocol is included in the ethical approval mentioned above
- Resue of the study: gait measurements were performed with 8 CP children in the clinical gait lab
- Product: master thesis at KU Leuven (Holenarasipur Sadashivan et al. 2023)

II.2 Preparation and feasibility studies in the UK

1. Normative data collection
    - Ethical approval: 288842 from 21/07/2021
    - Protocol of the study is included in the ethical approval mentioned above
    - Product: report
2. Feasibility study
    - Ethical approval: 288842 from 23/08/2023
    - Protocol of the study is included in the ethical approval mentioned above

II.3 Testing report on children – feasibility study in Belgium

PAFO prototypes were tested for fitting, function and performance in the clinical gait lab following the protocol described in D 2.1.4.

Measurements were performed with 8 children with different degrees of gait disabilities due to neurological disorders (CP) described in D 3.2.2 and D 3.2.3.

II.3.1 Conclusion for the first 3 patients

Based on the literature, we hypothesized that with the conventional AFO first and second ankle rocker along with foot clearance would improve, but that the plantar flexion during push-off would decrease, leading to a smaller power generation. Further, we hypothesized that the provided power of the PAFO, in addition to the already existing benefits of the conventional AFO, would help improve the overall gait pattern of children with CP. Finally, we expected that these beneficial effects at the ankle would carry over to the knee and hip and eventually improve the overall gait pattern

Part of our first hypothesis can be confirmed. Overall, the AFO provided a better first ankle rocker and foot clearance at the cost of plantar flexion during push-off. However, an improvement in the second ankle rocker compared to barefoot walking was not seen. Also, the expected reduction in power generation at push-off was only seen in patients 2 and 3. Further benefits of the conventional AFO consisted of a restored internal dorsiflexion moment at loading response, decreased knee flexion in terminal stance and normal hip angles in stance and terminal swing in the drop foot pattern (patients 1&3). For the genu recurvatum pattern, additional benefits were a later and reduced knee hyperextension and small reductions in hip flexion during initial and terminal swing. By allowing some plantar flexion by using a hinged AFO and adding a power module, we hoped to improve the main weaknesses (reduced plantar flexion and power generation at push-off) of the conventional AFO.

With the use of the PAFO, the benefits of the AFO on the ankle kinematics were maintained and the weaknesses were addressed. The PAFO induced first, second and third ankle rocker and provided foot clearance, thereby restoring and approaching normal ankle kinematics. Along with providing the plantar flexion at push-off, the reduced power generation from the AFO in patient 2 and 3 was restored to barefoot walking values, or even exceeded these. Combining these two outcomes, the PAFO corrected the greatest weaknesses of the AFO.

Results from these measurements allow objective quantification of the immediate effects on gait and demonstrate the performance of the relevant parts of the technology in the clinical gait lab. Also, these results bring evidence that different technical concepts (control loop/assistance strategy) are adaptable and can perform the intended function. From an engineering perspective, performing the measurements with PAFO in the clinical gait lab with end users brings evidence of technology integration, functionality and performance. Also, it allows the identification and prioritization of technical updates, improvements and redesigns that must be performed before advancing the validation of the PAFO prototype from the clinical laboratory environment to a clinically relevant environment (such as a rehabilitation clinic).

TRL: 5 (CP children tested)

III. Hip

Ethical approval : is pending

Clinical protocol : see reference on PAFO

Resume of study : functional and engineering measurements with 1 healthy adult walking with the powered hip module in two conditions (over the ground and on the treadmill)

TRL : 5 (Adult tested)

IV. LowerLimb part

Ethical approval: pending

During July and August 2022, we had electrical and CEM tests performed by a notified body. We are waiting for the notifications concerning the safety of the 'lowerlimb part'. At the same time, with the help of a specialized society, we created all the reports designated to the Ethical committee. At the same time, PP15 is in touch with the local Ethical committee.

~~Clinical protocol: see reference (C1_Protocol Proof of concept exoskelet_ dd1503-2023_signed)~~

Resume of study: number of children tested and clinical results

Unfortunately, due to the delay of the Ethical committee we weren't able to test CP children in a clinical context.

We tested 1 CP child and 1 healthy child in France but not as an inclusion in the clinical study which will be held in NL.

IV.1 Testing report on children - France

Testing followed a strict procedure to be done.

Before testing on children, we tested the system on 3 healthy adults (see output 1).

Object of testing procedure: Validate the capacity of the structure to follow a pre-defined trajectory

on the one hand and to trigger the sequence of steps in automatic mode on the other without risk

for the user. It was a request of clinicians to have this validation to be able to provide a future clinical trial.

Population of children

1 CP children and 1 healthy child have been tested.

Range of weight [30-45Kg]; range of size [1,3-1,55m]

Conduction of tests

We ask person to sit down inside the structure (motor switch off), members are measured and the structure is adapted directly and adapts to the different parameters of the software.

We explain the different phases of the test: stand up, transfer of mass on one leg and automatic stepping, repeat during 10 steps. Balance and fall prevention were ensured by clinicians.

We ask the authorization to children and parents to film the test and to perform testing

Results

Volunteer 1: made 1 stage with the structure.

Volunteer 2: made 1 stage with the structure.

Conclusion of tests

Fit the child with the structure: adaptation to the size, fill the morphological parameters of the child's body in the system take approximately 5 min.

The time of adaptation for mass transfer was shorter for children in comparison to adults taking approximately 5 steps with the system!!!

For both children, the system follows the pre-programmed trajectory without any pain for the children.

Both children weren't afraid of using the system and said that they will be happy to test it again in the future.

TRL: 5

Video is available on demand only.

V. Garment

Resume of study:

Number of children tested: 1, One healthy child following the procedure: Stand and sit

Procedure:

While timing and with subject simply standing or sitting:

a. Start chrono

b. Put smart garment on

c. Power on

d. Start up software

e. Note donning time

f. Check incoming data visualisation during 15 sec

g. Send data collected to desktop and verify data set

h. Start chrono

i. Shut down software

j. Power off

k. Take off smart garment

l. Note doffing time

An analysis on experience by physical therapist as well as subject was done with a list of questions to ask (answers on visual analog scale 1 – 5):

It was easy to put the smart garment on

1 (= difficult) – 5 (= easy) => 4

It was easy to make sure that the sensors were well positioned

1 (= difficult) – 5 (= easy) => 3

The smart garment fitted well

1 (= bad) – 5 (= good) => 4

The smart garment is comfortable to wear

1 (= uncomfortable) – 5 (= comfortable) => 4

Data visualisation is easy to understand

1 (= difficult) – 5 (= easy) => 4

Software is easy to use

1 (= difficult) – 5 (= easy) => 4

It was easy to take the smart garment off

1 (= difficult) – 5 (= easy) => 4

We can see that all results concerning the garment are superior to 4, which means quite easy to use. Only the sensor position is a little bit difficult to estimate (score 3).

TRL5: tested on 1 healthy child: sitting and standing.

VI. Specific results

Specific results: validated clinical protocol for a limited group of children with neurological disability (2 or 3 patients by country, at least 10) within the conditions defined for TRL 5, support for therapist training and communication (see § C4.2) for feasibility of technology transfer.

We assume that TRL5 is reached for the different modules (Hip, PAFO, LowerLimb part, garment) attested by testing (see D3.2.6).

We assume that at least, PAFO module have been tested during clinical testing on 8 children with CP (see D2.1.5). We assume that from a cumulative point of view, gathering normative studies on gait analysis as well as stress analysis and clinical tests on PAFO, we reached at least 50 children with CP.

The data collected during the tests provide us with a significant opportunity to model and analyze the gait of children with cerebral palsy during walking, as well as assess stress and ensure the durability of the project's results for future applications or project follow-up, like our participation in the RE:HOME project.

VII. References

D 3.2.2 Pilot with children with neurological conditions

D3.2.3 Feasibility study with children with CP

D3.2.6 Achieve TRL5

D2.1.5 Pilot assessment of the exoskeleton with patients in the lab

D2.2.3 Pilot assessment with patients in the lab

NORMATIVE DATA COLLECTION.pdf

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Everaert, L., Papageorgiou, E., Van Campenhout, A., Labey, L., & Desloovere, K. (2023). The influence of ankle-foot orthoses on gait pathology in children with cerebral palsy: A retrospective study. Gait & Posture, 100, 149-156.

Holenarasipur Sadashivan, S., Desloovere, K., & Everaert, L. (2023). Evaluation of the working mechanism of a newly developed powered ankle-foot orthosis. KU Leuven. Faculteit Bewegings- en Revalidatiewetenschappen.