

Design of a Lower Limb Exoskeleton for Neuromuscularly Impaired Children

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Abstract -

Neuromuscular impairments in children can cause difficulties in their mobility and independence. In this paper, we present the feedback and outcomes of the design of an exoskeleton for the lower limbs of children with neuromuscular impairments. The exoskeleton aims to provide assistance to the children's lower limbs to help them walk more efficiently and independently. The exoskeleton design includes considerations for the children's anthropometry, range of motion, and gait characteristics. The proposed exoskeleton has the potential to significantly improve the quality of life of children with neuromuscular impairments.

Keywords: children, design, exoskeleton, lower limb, neuromuscular impairment.

I. INTRODUCTION

According to Beckhung [1], 30% of children with Cerebral Palsy (CP) is not able to walk at 5 years of age and 16% of the CP children need assistive devices to walk. This means that 46% of the CP children, approximatively 6500 children in Europe, might benefit from innovative technology like lower limb exoskeletons to promote walking. Exoskeletons have the potential to provide more significant assistance to the lower limbs and improve the mobility and independence of children with neuromuscular impairments [2]. The exoskeleton INES aims to provide assistance to the children's lower limbs to help them walk more efficiently and independently. Although robotic assistive walking devices already exist, they need specific development for children [3],[4]. This paper presents the feedback and outcomes of the design a full lower limb automated exoskeleton, to allow the rehabilitation of CP children..

II. PROJECT CONSIDERATIONS

It seems important to us to consider how to approach a project that brings together different scientific and human cultures before starting the development. Issues are different for doctors, engineers, and users when it comes to the design of a lower limb exoskeleton for children with neurological disabilities.

A. Human, financial, and technical factors

1) Financial factor

For doctors: Financial issues are related to the cost of medical equipment such as exoskeletons for CP children. They must ensure that the cost of this equipment is justified

by the benefits it brings to patients. They must also negotiate with insurance companies to obtain reimbursement for this equipment for their patients.

For engineers: Financial issues are related to the design, manufacture, and commercialization of medical equipment such as exoskeletons. Engineers must ensure that the costs of design and manufacture are justified by the benefits that the exoskeleton brings to patients and that they can sell the exoskeleton at a price that covers these costs while making a reasonable profit.

For users: Financial issues are related to the cost of the exoskeleton and the availability of insurance to cover the costs. Users must ensure that they have the necessary financial resources to purchase or rent the exoskeleton. They may also need help negotiating with insurance companies to obtain reimbursement for the exoskeleton.

We must therefore demonstrate that the system brings a benefit to the patient, a better use of hospital resources, which will ensure its coverage by health insurance. The additional costs associated with the procedures required to launch a medical device on the market must therefore be counterbalanced by the volume of sales for the manufacturer.

In conclusion, the project must begin by defining the road to the market.

2) Human factor

For doctors: Human issues are related to improving the quality of life of patients. Doctors must ensure that the exoskeleton meets the needs of patients and improves their mobility and independence. Doctors must also ensure that the use of the exoskeleton is safe and does not present any risks to the health of patients.

For engineers: Human issues are related to the design and manufacture of the exoskeleton. Engineers must ensure that the exoskeleton is designed to meet the needs of patients and that it is safe and reliable. Engineers must also ensure that the exoskeleton is easy to use and does not present any risks to the health of patients.

For users: Human issues are related to improving their quality of life. Users must ensure that the exoskeleton meets their needs and improves their mobility and independence. Users must also ensure that the exoskeleton is easy to use and does not present any risks to their health. We must demonstrate that the system matches with patient and clinicians requirements without giving false expectations.

3) Technical factor

For doctors: Technical issues are related to understanding the functioning of the exoskeleton and the ability to use it effectively to help patients. Doctors must also ensure that the exoskeleton is compatible with other medical equipment used by patients.

For engineers: Technical issues are related to the design and manufacture of the exoskeleton, including issues related to materials, power supply, control systems, and sensors. Engineers must ensure that the exoskeleton is reliable and safe, and that it meets the needs of patients.

For users: Technical issues are related to the ease of use of the exoskeleton and the ability to control it effectively. Users must also ensure that the exoskeleton is compatible with their physical abilities and does not present any risks to their health.

There are several other technical considerations that need to be addressed during the design process of such a lower limb exoskeleton for CP children.

-Comfort: The exoskeleton should be designed with comfort in mind to ensure that the child can wear it for time without experiencing discomfort or pain.

-Adjustability: The exoskeleton should be adjustable to accommodate the child's growth and changes in their physical condition over time.

-Durability: The exoskeleton should be durable and able to withstand the wear and tear of daily use.

-Weight: The exoskeleton should be lightweight to minimize the burden on the child and avoid fatigue.

-Battery life: The battery life should correspond to the use.

-Safety features: The exoskeleton should be equipped with safety features such as emergency stop buttons and automatic shut-off mechanisms in case of malfunction.

By considering these technical factors, engineers can design an exoskeleton that meets the needs of both doctors and users while also being financially viable and affordable.

4) Temporal issues

It is important to establish a rigorous project management method that coordinates the different stakeholders (users, doctors, and engineers) and ensures that deadlines are met. Here are some key steps to take to meet the time constraints.

-Identify the specific time constraints of each stakeholder. Engineers may have constraints related to manufacturing or material availability, while users may have constraints related to their schedule or immediate need. Doctors may have constraints related to appointments or scheduled surgical interventions. This schedule should also include key stages such as design, manufacturing, testing, and commissioning.

- Prioritizing and identify independent tasks to plan activities for each stakeholder based on their schedule and

specific constraints in a way that allows for effective coordination between stakeholders and ensure smooth progress towards achieving the desired outcome. The most urgent tasks and independent ones should be addressed first to meet the immediate needs of users and developers (Fig. 1).

-Monitor progress and communicate with partners regularly to ensure that deadlines are met or to report any potential delays or issues that may affect deadlines.

By using this method, time constraints can be effectively considered, allowing engineers to meet deadlines while addressing the immediate needs of users and working in collaboration with doctors to ensure safe and effective use of lower limb exoskeletons for children with CP.

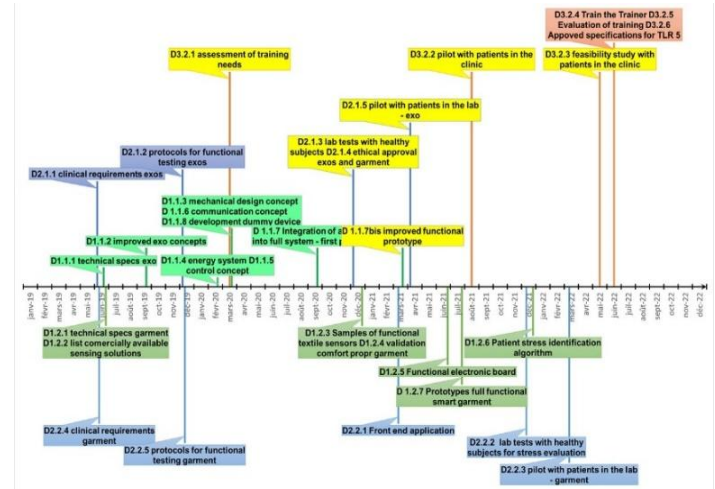


Figure 1. Timeline management of the project

5) Managing human and technical issues

In the design of a lower limb exoskeleton for children with neurological impairments, addressing both technological and human challenges is crucial. First, the design process requires a multidisciplinary and complementary team, including engineers, medical professionals, and users, to ensure that all aspects of the exoskeleton are addressed (Fig. 2).

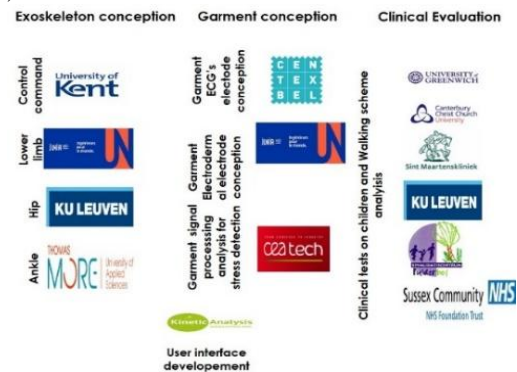


Figure 2. Co-creation and team skills

This collaboration requires a common language and shared objectives to ensure that everyone involved is working towards the same goals. Additionally, it is crucial to ensure that the clinical and technical requirements of the exoskeleton align (Fig. 3).

To achieve this, protocols for clinical testing must be defined to accurately measure the effectiveness of the exoskeleton for its intended purpose.

| Technical point | Clinical point | Match | Improve technical matching | Improve clinical matching |
|---------------------------------|---|------------------|---|---|
| Rigid structure | Strong muscle spasm | NO | Adapt as best as possible the mechanical properties of the exoskeleton. Analyse EMG to predict spasms. | Inclusion criteria • Use of specific drug (Botox...)? • Define : Frequency, time span, time table of the spasms... |
| Joint structure | Accommodate a child's contractors or reduced ranges of comfortable movement | YES And NO | Adapt mechanical limits and software limits | Inclusion criteria • Angular capacity of joints... • Maximum amplitude of muscle contractors |
| Adaptativ structure | AFO be separate from the exoskeleton so that it can be altered as necessary for growth or comfort | YES | Fine tune definition of the mechanical interface to ensure the most adaptativ structure | Inclusion criteria • Test on selected population to ensure an acceptable variation of the AFO dimensions |
| Balance & tracking trajectories | Strong muscle spasm & Accommodate a child's contractors or reduced ranges of comfortable movement | NO | Develop scenarii to manage the risk. - Define speed of motion, duration... Set the maximum reaction time of the system. | Fine tune definition of conditions of use of the exoskeleton Number of steps, sitting-standing phase, chose the best time table, sense of balance for those children.... |

Figure 3. Matching technical and clinical points

Furthermore, the duration of the ethical committee review must be balanced with other project tasks to ensure that deadlines are met without sacrificing quality or safety. From a user perspective, it is important to minimize the time spent on adjustments to the exoskeleton in the presence of children. Providing quantifiable elements for patients, children, medical professionals, and associations can help to ensure that the exoskeleton meets their specific needs and expectations. It is also essential to provide quantifiable elements for the scientific community to further advance the field of lower limb exoskeletons, this could be done by means of simulation software. Finally, managing expectations and avoiding disappointments is critical to ensure that the exoskeleton provides real benefits for users and their families. Once the tasks and roles are well defined, each person can work independently as long as the input and output data for each task or deliverable are clearly defined by using flow chart (Fig. 4-5).

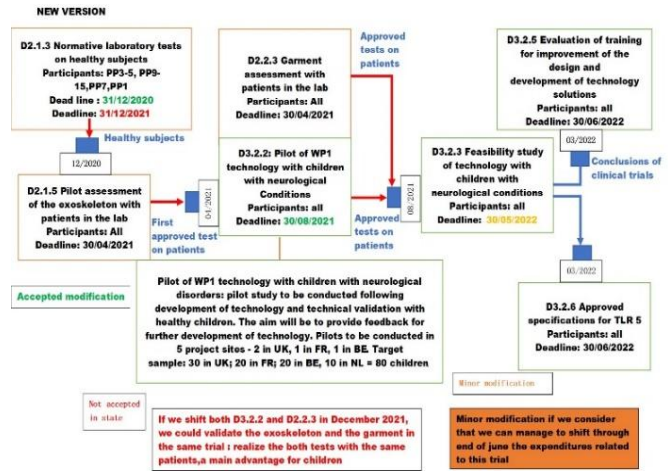


Figure 4. Flow chart with date of availabilities

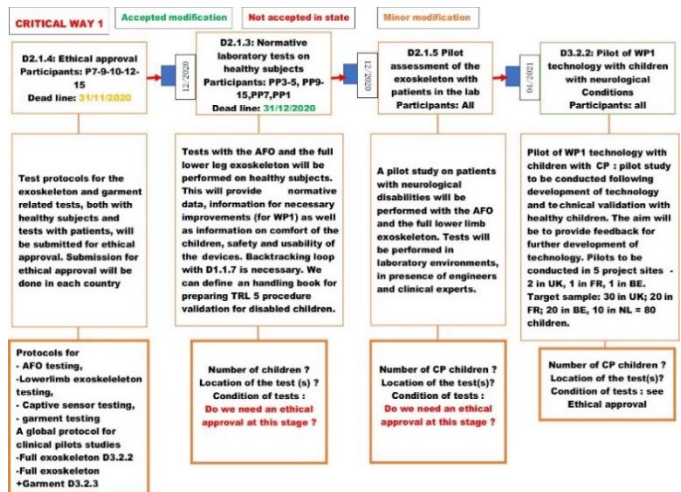


Figure 5. Identify critical way and mitigate it

III. DESIGN CONSIDERATIONS

In the design of a lower limb exoskeleton for children with neurological impairments, the user is a central figure. The user, in this case, is the child who will be using the exoskeleton. The design process must take into account the specific needs and limitations of the user, such as their age, weight, height, and range of motion. It is important to consider the child's comfort and safety during use, as well as their ability to interact with the exoskeleton and engage in various activities. Furthermore, the design must take into account the child's rehabilitation goals, which may vary depending on the specific neurological condition they have. Involving the user and their family in the design process is crucial to ensure that the exoskeleton meets their needs and expectations and facilitates their rehabilitation process. The exoskeleton design must consider the anthropometry of the children who will use it. The exoskeleton must fit the children's legs comfortably and

securely without restricting their movements. The exoskeleton's height, width, and depth must be adjustable to accommodate different leg lengths, widths, and circumferences. The exoskeleton design must allow for the natural range of motion of the children's lower limbs. The exoskeleton must not restrict or impede the children's movements, but rather assist and enhance them. The exoskeleton's joints must be designed to allow for the natural flexion and extension of the children's joints during walking. The exoskeleton design must consider the children's gait characteristics. The exoskeleton must provide assistance to the children's lower limbs during the gait cycle, which includes the stance phase, where the foot is in contact with the ground, and swing phase, where the foot is lifted off the ground.

IV. EXOSKELETON DESIGN

The reader will find in [5] and [6] all the necessary scientific considerations for fine-tune technical investigation. We developed a numerical model of the structure to validate the system before starting the manufacturing (Fig. 6). The proposed exoskeleton design consists in 6 actuated joints (2 at each hip, and 1 at each knee). The structure of the exoskeleton uses aluminum, carbo fiber, 3D-Printing materials for saving weight. Easy size-adjustment mechanism is designed for adapting to children from 6 to 12 years old. Hip joint alignment mechanism is implemented for joint compliance.

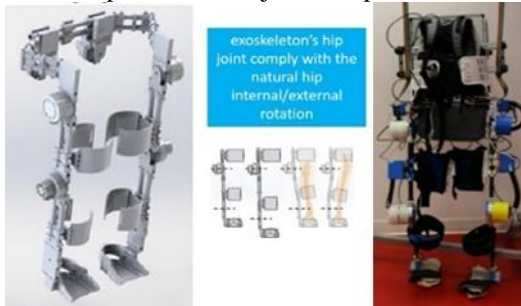


Figure 6. Numerical model vs real Ines's exoskeleton

Table 1 defines the power requirements of the actuation unit based on a database of gait analyses from typically developed children with a weight in the range [25-55Kg].

| | Rate Pow. (W) | Reduction ratio | Max. Tor. (Nm) | Max. Vel. (deg/s) |
|-----------|---------------|-----------------|----------------|-------------------|
| Hip(F/E) | 220 | 100:1 | 110 | 300 |
| Hip(A/A) | 150 | 80:1 | 87 | 450 |
| Knee(F/E) | 150 | 50:1 | 70 | 720 |

Table I: Actuator specifications

According to article 2 and 9 of Regulation UE 2017/745, INES is a class II a medical device. Thanks to a risk analysis we dealt at an early stage the safety and quality management for the system elaboration. We consider mechanical and software limits as well as current limitation to avoid torques and joint limits overflow. Approved companies performed electrical and electromagnetic tests on the structure.

The general control architecture is shown in Fig. 7. It consists in a Speed Unit target machine to serve as the on-board control PC with an EtherCAT master that operates the system at a frequency of 1kHz. It also allow us to develop the control software with MATLAB Simulink and collect all the data during testing

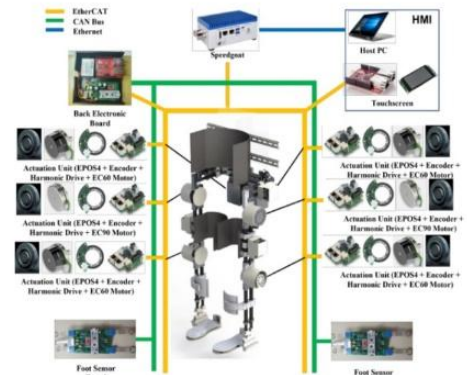


Figure 7. Control architecture

We provide two Human Interface machines, a PC-based UI for controlling for application engineer to tune and monitor the exoskeleton and monitor the states of exoskeleton in real-time and a reduced touchscreen-based UI for therapists to control the exoskeleton during the rehabilitation session(Fig. 8).

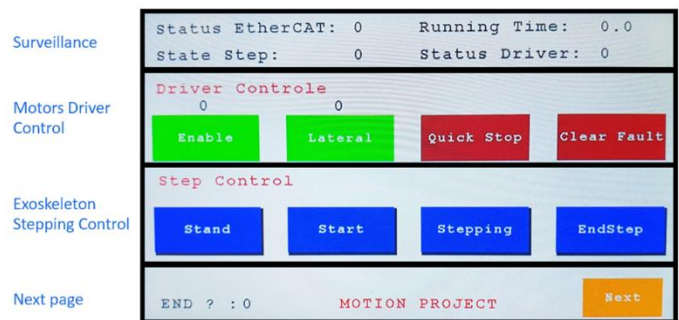


Figure 8. Stand alone application

In order to let the patient easily shift their Center Of Mass (COM) between two feet, a Finite State Machine (FSM) model is proposed in which the COM shifts during the double-stand phase. If the exoskeleton detects the weight transfer is successfully done, the actions for stepping will be automatically triggered. The Actions A1, A3, and A6 are for

transferring the weight on the stand foot while both feet are on the ground (Fig. 9). If the exoskeleton detects the weight transfer is successfully done, the actions for stepping (A2, A4, A5, A7, A8) will be automatically triggered.

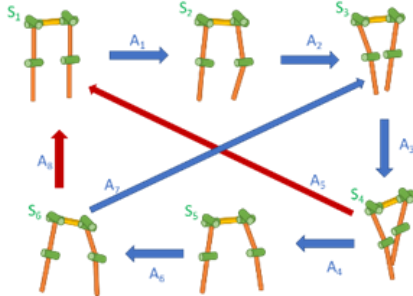


Figure 9. Step controlling

V. RESULTS

We defined a user guideline and performed tests on three healthy adults with anthropometric characteristics in the range of the structure as represented in Table2.

| Volunteer | Height (cm) | Weight (kg) | Thigh Length (cm) | Shank Length (cm) | Number of stages |
|-----------|-------------|-------------|-------------------|-------------------|------------------|
| 1 | 156 | 45 | 40 | 42 | 3 |
| 2 | 157 | 52 | 40 | 41 | 3 |
| 3 | 151 | 50 | 40 | 40 | 4 |

Table2 : Anthropometric characteristic

The object of testing procedure was to 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. This was a request of clinicians to be able to provide a future clinical protocol for children. Testing started by an explanation of the different phases of the test: stand up, transfer of mass on one leg and automatic stepping, repeat during 10 steps. To improve the system after each stage in relation with the clinicians, volunteers gave their feedback. All the testing with adults were satisfying in terms of security for the user and for the capacity of the structure to follow a programmed trajectory of walking with an automatic trigger. The user need a training period to understand the way of COP transfer to ensure an automated stepping. Reader will find in [6] the detailed technical data. The analysis of stress in relation with comfort is evaluated using a smart garment designed during this project too [7]. Videos [8] are available on the YouTube channel of MOTION and reader will find in the official website [9] all the detailed of the project.

CONCLUSION AND PERSPECTIVES

This paper presents the feedback and outcomes from MOTION Project. During this project, we develop a mobile exoskeleton for children with CP. By using management project and communication methods, we showed that it is

possible to propose a new system adapted for children with CP despite the delays due to covid19 crisis. Time line for ethical approval is the break point of this kind of project. We suggest collaborating with specialized companies to be able to deliver all the documentation in compliance with regulation rules for clinical test of prototypes. We plan to perform tests on CP children in Netherlands in May 2023 and to reach a level of innovation of 6.

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REFERENCES

- [1] Beckung E, White-Koning M, Marcelli M, McManus V, Michelsen S, Parkes J, Parkinson K, Thyen U, Arnaud C, Fauconnier J, Colver A. Health status of children with cerebral palsy living in Europe: a multi-centre study. *Child Care Health Dev.* 2008 Nov;34(6):806-14. doi: 10.1111/j.1365-2214.2008.00877.x. PMID: 18959578.
- [2] E. Delgado, C. Cumplido, J. Ramos, E. Garcés, G. Puyuelo, A. Plaza, M. Hernández et al, "ATLAS2030 Pediatric Gait Exoskeleton: Changes on Range of Motion, Strength and Spasticity in ChildrenWith Cerebral Palsy. A Case Series Study," *Frontiers in pediatrics*, vol.9, pp.753226, 2021.
- [3] S. Nakagawa, H. Mutsuzaki, Y. Mataka, Y. Endo, M. Matsuda, K. Yoshikawa, H. Kamada and M. Yamazaki, "Newly developed hybrid assistive limb for pediatric patients with cerebral palsy: a case report," *Journal of Physical Therapy Science*, vol. 31, no. 8, pp, 702-707, 2019.
- [4] LokomatPro Pediatric Module (2022). [Online]. Available: www.hocoma.com/us/solutions/lokomat/modules/#Pediatric-Module.
- [5] Zhang, Y., De Groof, S., Peyrodie, L., & Labey, L. 'Mechanical design of an exoskeleton with joint-aligning mechanism for children with cerebral palsy'. *International Conference for Biomedical Robotics and Biomechatronics (BioRob 2020)* (pp. 106-111).
- [6] Zhang, Y., Bressel, M., De Groof, S., Dominé, F., Labey, L., & Peyrodie, L. (2023). Design and Control of a Size-Adjustable Pediatric Lower-Limb Exoskeleton Based on Weight Shift. *Ieee Access*, 11, 6372-6384.
- [7] V. Nivitha Varghees, H. Cao, and L. Peyrodie, "Variational Mode Decomposition Based Simultaneous R Peak Detection and Noise Suppression for Automatic ECG Analysis," in *IEEE Sensors Journal*, doi: 10.1109/JSEN.2023.3257332.
- [8] Ines Youtube Channel (2023). [Online]. Available at <https://www.youtube.com/channel/UCnfxbSzPpq3GKG8xIrTnRSw>
- [9] Official MOTION website [OnLine]. Available at <https://www.motion-interreg.eu/>