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Design Considerations for the Development of Lower Limb Pediatric Exoskeletons a Literature Review

Amandine Gesta, Sofiane Achiche, *Member, IEEE* and Abolfazl Mohebbi, *Member, IEEE*

***Abstract*— Cerebral Palsy is the most prevalent cause of gait disorder in childhood, affecting the range of motion, power, and joint torques of children. Several treatments are available, ranging from physical therapy to surgery. However, these treatments are usually complex, costly, and long. Robotic exoskeletons could provide longer, more frequent, and personalized training sessions with quantified data on the gait characteristics. Unfortunately, very few pediatric exoskeletons are available compared to those for adults. Therefore, design guidelines are needed for the development of pediatric exoskeletons to facilitate market entry. This article proposes design considerations through an in-depth review of the available pediatric lower-limb exoskeletons. This research has identified nine exoskeletons with at least one actuated joint at the ankle level and discussed their clinical, mechanical, and control characteristics. Although all the identified exoskeletons use electric motors to reduce their weight, improvements must be made to further minimize it. In addition, these exoskeletons need to be more easily adaptable to the user's morphology. Impedance control methods are commonly used, which ensures the interaction safety. However, they should be more personalized to the specific neurological deficiencies. Furthermore, stronger validation of these exoskeletons is required through clinical trials.**

***Index Terms*— Cerebral Palsy, Exoskeleton, Rehabilitation robotics, Wearable robotics**

I. Introduction

An exoskeleton is a mechatronic device that acts as an external supporting skeleton to enable the movement of the limbs of the human body [1]. This technology can improve, recover from, maintain, or assist an individual's motor abilities in various domains (military field, construction workers, medical field) [2].

Exoskeletons can be classified as either untethered or tethered. Tethered exoskeletons are limited to research or clinical use due to their bulky size. Untethered exoskeletons allow us to overcome this problem by having all the components onboard with the patient, enabling wider use (at home for example). The fact that the exoskeleton can be used at any time and in any place allows for the diversification of training with different terrain types (smooth, gravel, stairs ...). This also allows for an extended period of training time to complement the physical therapies, e.g., on a daily basis, at any place. However, this imposes new limitations, particularly regarding the exoskeleton's size, weight, and autonomy.

Because it is a more complicated design task, we will focus on portable exoskeletons in this paper in order to propose suitable design steps. This paper will support engineers in the task of conceptual design and component selection for each subsystem of an exoskeleton according to the desired application and requirements. The goal is to provide design guidance to speed up the process of developing and releasing this kind of technology onto the market while avoiding overlooking critical requirements that would delay this process. These indications will be demonstrated with reference to the creation of ankle exoskeletons for children with cerebral palsy (CP). A study of the relevant literature has been done for this purpose, enabling us to pinpoint each design's strong points as well as any potential weak areas or elements that have been omitted. Different modes of actuation, design and control strategies adopted by these exoskeletons will be compared.

The rest of this article is organized as follows: in Section II, the specificities of cerebral palsy will be presented in order to identify the clinical needs for such technology. In Section III, we comprehensively discuss design considerations for pediatric exoskeletons, covering constraints applicable to medical devices and exoskeletons in general, along with the specific requirements of pediatric users. Section IV provides both the systematic methodology used for the literature study, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), and the results of the review on pediatric ankle exoskeletons developed within the last 10 years. Finally, the findings are summarized and discussed in Section V. The concluding remarks are presented in Section VI.

II. Cerebral Palsy

Before delving into the specifics of exoskeleton design, it is essential to understand how it can benefit children with CP.

Cerebral palsy is a neurological condition that affects movement, posture and coordination and is characterized by difficulties in controlling voluntary movements, lack of coordination, muscle spasticity and tremors. These symptoms are caused by damage or abnormalities in the developing brain, typically occurring before birth, during birth or in early childhood. It is the most common cause of motor disorders in childhood (2.11 per 1000 children worldwide [3]). It is not a progressive condition, meaning brain damage does not worsen over time, but the symptoms, such as gait disorders, can change and vary in severity among individuals. *The Gross Motor Function Classification System* (GMFCS) is used to measure the degree of severity of gait disorders. In addition to having motor difficulties, children with CP grow differently than typical children. Therefore, growth curves specific to these children have been developed [4].

There are three different types of CP based on the type of symptoms (Figure 1). Spastic CP is the most prevalent type and accounts for 80% of all CP cases [5]. These disorders can significantly impact the walking patterns, and specific classifications have been proposed for spastic hemiplegia (Winters et al., 1987) and spastic diplegia (Sutherland and

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Davids, 1993) [6]. For instance, spastic diplegia can be categorized into true equinus, jump knee, apparent equinus, and crouch gait, each characterized by distinct gait patterns involving ankle, knee, and hip movements (Figure 2). A true equinus gait pattern is characterized by a drop foot in the swing phase and a permanent plantarflexion of the ankle in the stance phase with knee and hip in extension. For the jump knee disorder, knee and hip are in flexion while there is an equinus at the ankle. This can occur with or without knee stiffness. The third type, the apparent equinus, presents an excessive flexion of the knee and hip but with a normal dorsiflexion at the ankle. A crouch gait pattern is also defined by an excessive flexion at the knee and hip but also a dorsiflexion at the ankle [6].

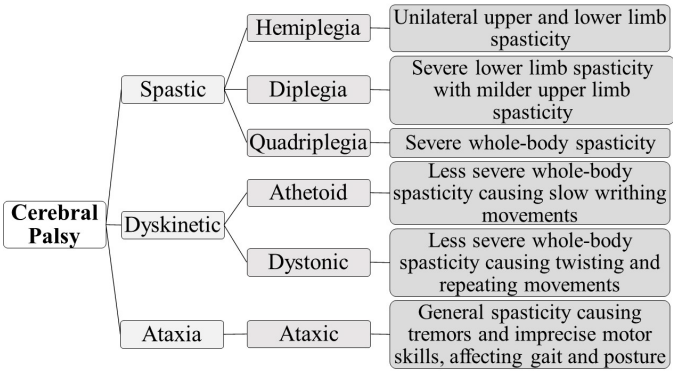


Figure 1: Types of Cerebral Palsy [5]

Physiotherapists follow these children as early as possible to prevent the worsening of their motor disorders. For mild cases, they recommend walking rehabilitation sessions and passive orthoses, while more severe cases require Botulinium Neurotoxin-A injections and surgery [7]. The lifetime cost of care for an individual is estimated at around US$1 million [8]. Despite the costs involved, most of these children still risk losing their ability to walk gradually. Therefore, additional assistive devices becomes essential to improve mobility and prevent a decline in walking ability [9], [10].

Hence, exoskeletons for the lower limbs have the potential to enhance therapy effectiveness. Research studies have shown that using exoskeletons during walking for patients with locomotor impairments can improve their gait pattern by assisting with dorsiflexion and plantarflexion, resulting in lower metabolic cost and fatigue [9], [10]. Moreover, it can increase the duration and frequency of gait training, reduce manual assistance from therapists, and even enable for daily use at home with portable exoskeletons, leading to faster improvement in the child's health, quality of life, and a decrease in related medical expenses. However, these innovation face greater challenges in the validation and commercialization than technologies developed for adults [11]. This can be attributed to the wide range of physical specifications among pediatric patients, which change according to growth and impose restrictive weight constraints. Recent studies on neuroplasticity have provided strong evidence that providing early assistance to children with motor deficits can slow down the progression [12], [13]. This may result in less severe impairments in adulthood, compared to those who did not receive rehabilitation in their childhood, ultimately lowering the cost of future treatments.

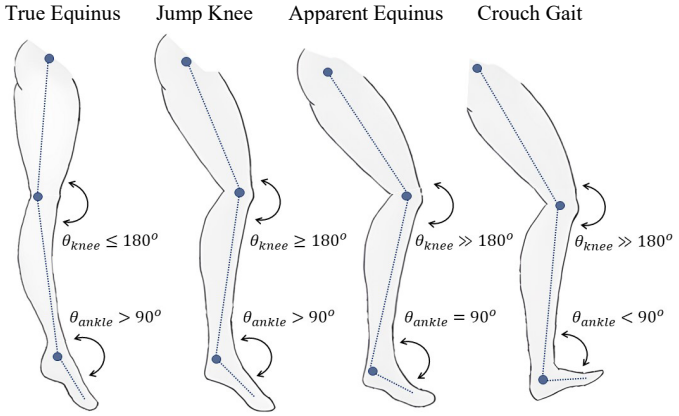


Figure 2: Gait impairments in spastic diplegia CP [7]

III. Design Considerations for Pediatric Exoskeletons

Exoskeletons are complex and relatively new devices. Despite extensive research, the field of exoskeleton development has progressed slowly, with many projects stalling before reaching commercialization [14]. Developing an exoskeleton is a challenging endeavor, requiring skills in mechanical, electrical and control engineering. Furthermore, the design of exoskeletons for children entails additional constraints due to their ongoing growth and development. Moreover, the low dexterity exhibited by pediatric users, combined with the challenges of conducting clinical trials, complicates the development process. To validate a prototype, a set of requirements must be fulfilled. The following sections outline a set of criteria that should be considered in the design of pediatric exoskeletons. These requirements can be specific to medical devices in general, to exoskeletons in particular, or more precisely to pediatric exoskeletons.

A. User Requirements

Human-centered design is crucial for developing pediatric exoskeletons that meet the user's specific needs, capabilities, and comfort - a key requirement in rehabilitation robotics. MedTech devices face common constraints such as "safety", "comfort", "inclusiveness", and "ethical and social considerations" [15]. Pediatric users require special ethical protocols due to their vulnerability and limited informed consent capacity. These protocols involve getting consent from both the child and their legal guardians. Therapists may also stress the need for exoskeletons to be "easy to use and install". Useful devices may be rejected if they are too complex to set up. Moreover, exoskeletons often have costly components, so making them "affordable" is a major challenge. Lower costs enable more access and feasibility for families and healthcare systems to provide updated exoskeletons as children grow.

B. Structural Characteristics

The user requirements impact the design of the structural characteristics of the exoskeleton. The exoskeleton must be "durable" for any target population since it may involve complex processes and costly components. Moreover, the exoskeleton's joints should be "aligned with the human joints" to enable smooth motion and prevent injury [16].

For a pediatric population, certain criteria become even more stringent, such as "weight" and "inertia". The findings suggest

that adding a 4 kg-mass to the foot increases the net metabolic rate by 36% [17]. This indicates that reducing the weight added to distal parts could improve the subject's gait efficiency. Children have a lower weight-bearing capacity compared to adults, so the "location of the added mass" is critical. Placing most of the mass near the center of gravity can lessen the load on the child.

The device must also be "adjustable" to accommodate the changing anatomy of growing children, which enhances its durability. For personal use, this aspect is not necessarily applicable to adult users as their physical characteristics show less variability compared to children. Moreover, as children with CP have different growth patterns compared to typically developing children (TDC), specific growth curves have been established based on their severity on the GMFCS scale [4]. In the case of children in level II, ranging from 5 to 14 years old, their height typically falls within the range of approximately 95 cm to 150 cm [4]. Using the anthropomorphic model developed by Winter et al. (2009) [18], the length of the shank segment is found to exhibit variability within the range of 23 cm to 37 cm. The optimal position for the ankle joint is estimated to be situated approximately 3.7 cm to 5.85 cm above the base of the foot. Furthermore, the foot dimensions are expected to span between 14.4 cm and 22.8 cm in length. A trade-off is often required between the adjustability of the device to fit a range of subjects and the "customization" to fit one specific subject and increase comfort. The objective is to achieve seamless integration between the device and the user; thus, customization is sought after. As previously stated in the introduction, CP can manifest in various forms, affecting the gait pattern of either multiple lower limb joints or a single joint. For this reason, the exoskeleton should also be "modular" to meet the individual needs of various users by actuating the hip, knee, or ankle.

C. Static Properties of Gait

To provide the best assistance to the users and enhance their walking ability, information about the "kinematic" parameters of both TDC and children with CP is necessary. This information will enable us to identify the necessary type, timing, and amount of assistance, improving the assistance strategy while keeping the user engaged in their walking process. The static properties will aid in determining the actuation sizing and control strategy. The required kinematics information includes the "range of motion" (ROM), "gait maturation", relevant "degrees of freedom", and "spaciotemporal parameters" (such as step length and cadence) [14], [19]. TDC generally has a range of motion between -25° in plantarflexion and 15° in dorsiflexion. Additionally, there is a notable correlation between spatiotemporal parameters and gait maturation. Studies have shown a linear relationship between step length and leg length in the developmental phase from age 1 to 7, as well as a direct correlation between age and walking speed [20]. The influence of walking speed on kinematics and kinetics parameters for TDC emphasizes the importance of determining the targeted gait speed to appropriately size the actuation system [21]. In the case of children with CP, their self-selected speed is estimated to vary between 0.7 m/s and 1.2 m/s, depending on their age and GMFCS level [22].

D. Dynamic Properties of Gait

It is also important to consider the "dynamic properties of gait", such as "velocity" for the proper sizing of actuation [19]. These characteristics are hard to find even for adult subjects. Joint velocity changes according to the walking speed. In [23], lower limb joint velocities are computed for adults and for different gait speeds. This data can be used to have an idea and adapted to children. The ankle joint maximum velocity goes from -100 deg/s (plantarflexion) to 80 deg/s (dorsiflexion) for a slow walking speed (0.4 m/s to 0.59 m/s) and from -300 deg/s to 200 deg/s for a fast walking speed (1.4 m/s to 1.6 m/s) [23]. Properly sizing motors and developing the control strategy requires an understanding of the "kinetics", including the "torque" and "power" generated at the targeted joint. These data can be obtained from open access databases, such as the normalized curves provided by Winter et al. (2009) [18]. As an example, the study presented in [24] establishes that the maximum normalized torque of children during dorsiflexion is around 0.45 Nm/kg and 1.1 Nm/kg in plantarflexion. Regarding power generation and absorption they are generally set -0.2 W/kg in plantarflexion and 3 W/kg in dorsiflexion [25]. The actuation system doesn't need to provide that amount of torque or power depending on the user's impairments. An assistance rate can, for instance, be set to 20% of the biological torque, which corresponds to an actuation peak torque and power of 0.09 Nm/kg and 0.6 W/kg in dorsiflexion and 0.22 Nm/kg and -0.04 W/kg in plantarflexion.

E. Actuation System Specifications

Regarding the actuation system, the first step is to determine the "number of joints" to be actuated. Next, we must consider the "type of actuation" we will be using [14]. The three main options for active actuation are hydraulic, pneumatic, and electric actuators [2], [26]. Hydraulic actuators offer considerable power output but are afflicted by high cost and bulkiness, thereby limiting their practicality and portability [27]. Pneumatic actuators, although lighter, exhibit lower power capacity and pose challenges in control and precision [27]. Conversely, electric actuators provide precise controllability, along with their lightweight nature and ease of portability. Consequently, the majority of developed exoskeletons opt for electric actuators [27]. In the context of pediatric exoskeletons, this preference is even more pronounced due to the stricter weight constraints as shown in Section IV. These active actuators can be utilized with mechanical mechanisms to create hybrid actuators. For example, Orekhov et al. (2022) combined a parallel spring and an electric motor in the design of an ankle exoskeleton [28]. This integration enables reductions in motor size, energy consumption, and overall weight of the design.

Additionally, we want the actuation system to be "compliant", which can be achieved through the control strategy or by using Series Elastic Actuators (SEAs) in the actuation system. As mentioned previously, the "assistive rate" must also be defined based on the static and dynamic properties of gait, allowing for the selection of an actuation system capable of generating the appropriate range of motion and torque. We need to identify the technique for "transmitting the movement" that can be linked to the "compliant" criterion [14]. Electric actuators offer various options for motion transmission,

including cables, mechanisms (such as pulleys, belts, and springs), and gearboxes (such as planetary gears and harmonic drive gears). In adult exoskeletons development, cable-driven actuation systems are widely employed to relocate the actuation system, typically to the user's backpack, thereby freeing the distal joint [1].

F. Control Strategy

The control architecture for portable exoskeletons is designed in three levels. The top level sets the overall behavior for the device, the middle level regulates the commands based on sensor data, and the low-level controller executes the desired behavior directly at the actuator level [29]. According to the findings presented in [29], the desired control mode for an exoskeleton can be manually configured using interfaces such as buttons or user interfaces, or it can be automated through techniques like Brain-Computer Interfaces or movement recognition. In terms of the mid-level controller, options include, for example, using Machine Learning algorithms or Finite State Machines (FSMs) to determine the user's gait phase or state. Based on the timing of the gait, commands are then transmitted to low-level controllers. In most cases, these commands are generated by impedance controllers or based on torque/position profiles. Commonly employed as low-level controllers are feedback or feedforward controllers based on position, velocity or torque commands as in [30]. These controllers are not limited to these examples, but they are the most used, especially in the pediatric field.

The control system's goal should be to mimic a natural walking experience, making it crucial to prioritize "transparency" in the mechatronic system when evaluating different options. To achieve a natural walking experience, the control strategy should be carefully chosen. This requires us to identify the necessary sensors and select them based on their "sensitivity" or "accuracy". To handle sensor information and implement the control algorithm, we must choose an embedded system with efficient "processing power and time". When selecting the electronic components, we must consider the "required voltage" and find a battery that provides the necessary power. There is a current issue with battery capacity, as the available autonomy for portable exoskeletons is limited to approximately 30 minutes [31].

G. Risks and Regulations Considerations

Regulations and standards are crucial in the development process of medical devices, like pediatric exoskeletons, to ensure safety, efficacy, and quality. Failure to adhere to these rules can lead to a commercialization failure. To access the US market, the device needs to comply with FDA regulations, including the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Code of Federal Regulations (CFR). To provide accurate requirements depending on the application, the FDA has established a device classification based on risks: Class I (low-risk), Class II (moderate-risk), and Class III (high-risk). Pediatric exoskeletons are classified as Class II, thus, according to the 21 CFR 890.3480, exoskeletons should pass general and eight specific controls [32], [33]. Specific controls are related to biocompatibility (ISO 10993-1:2009), electromagnetic compatibility, device safety and efficiency regarding the electromechanical components. Non-clinical and clinical validation as well as documentation requirements are also provided. In addition, international standards play a significant role, such as ISO 14971 for risk management or IEC 60601-1:2005 for electrical safety [32]. Pediatric exoskeleton developers should establish a robust Quality Management System (QMS) adhering to ISO 13485, implement Good Manufacturing Practice (GMP) as per 21 CFR Part 820, ensure compliance with electromagnetic compatibility standards like IEC 60601-1-2, and follow software standards like IEC 62304. General Principles of Software Validation are also given by the FDA. Standards like TC 62/SC 62D/JWG 36, ISO 13482, ANSI/AAMI HA60601-1-11:2015 and ASTM F48 Exoskeletons and Exosuits provide guidelines for the design, testing and safety of exoskeletons [32].

H. Validation Metrics

The requirements established previously are interdependent. For example, a trade-off must be made between "adjustability" and "customization", between "weight" and "comfort" or "durability". To enhance "durability", stronger and typically heavier materials are often required, but the "weight" constraint must still be respected. To ensure that none of the criteria are neglected, "metrics" must be established to evaluate the satisfaction of the set specifications. These metrics can be both objective and subjective, including objective metrics such as Single-Port Pressure Magnitude or Pressure Duration, which are measured using resistive or capacitive sensors, and subjective metrics that are based on user feedback regarding discomfort or pain experienced [34].

IV. Exoskeletons for Children with Cerebral Palsy

Despite its crucial role in walking dynamics, balance control, and shock absorption, the ankle joint is often overlooked in many exoskeleton development projects [35]–[37]. In fact, there are more exoskeletons designed to assist the hip, the knee joint or both, than the ankle joint [36]. As a result, a comprehensive literature review was conducted on exoskeletons that incorporate the ankle joint actuation specifically in the context of pediatric rehabilitation. This review will help demonstrate how the development considerations have been addressed and whether the current prototype meets these requirements.

A. Literature Review Methodology

For that reason, a comprehensive literature review was conducted using a systematic methodology for reproducibility and ease of updating. The PRISMA tool was utilized to ensure no steps were missed. The article search was conducted in seven databases, namely: Engineering Village (Compendex & Inspec), ProQuest, PubMed, Web of Science, IEEE Xplore, Science direct and SpringerLink. The search query employed the following common formulation: *(Exoskeleton* OR Exosuit* OR "Active orthosis" OR "Powered orthosis") AND (Ankle OR "Ankle foot") AND (Pediatric* OR Paediatric* OR Child* OR "Cerebral Palsy").* The search resulted in 127 articles, but after removal of duplicates and sorting based on exclusive criteria, only 33 articles were used for the literature review (Figure 3). Our database was expanded using related articles found in the references of the articles studied. The

database was expanded by including related studies found in the references of the examined articles.

These findings also confirm the recent increase in research on the topic, as the number of published papers on single or multi-joint exoskeletons with at least ankle joint actuation has more than tripled since 2018.

These articles can be categorized based on the focus of the research laboratory developing the exoskeletons. To date, eight different exoskeletons have been identified. The information collected about these exoskeletons will be useful in illustrating the design considerations discussed later. The research laboratories identified in this study have developed various other exoskeletons, including knee or hip exoskeletons [38], [39]. However, since the ankle joint is not actuated, these exoskeletons have been excluded from the analysis.

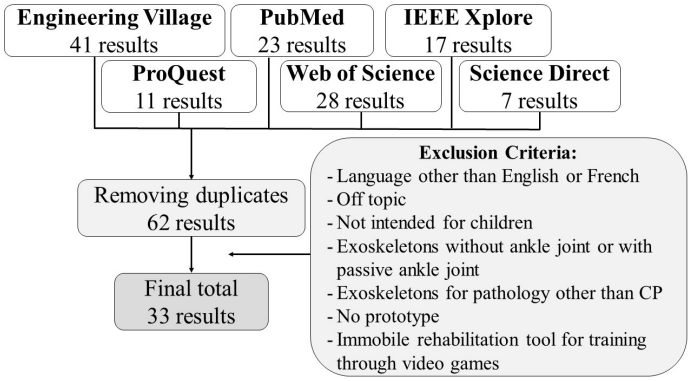


Figure 3: Steps for the selection of articles

B. *Ankle-Foot exoskeleton*

Regarding ankle exoskeletons, only one prototype has been identified.

1) *Biomotum SPARK / NAU Biomechanics Lab*

Out of the 33 articles collected in the literature review, 23 were published by the team at the North Arizona University's biomechanics lab. These studies led to the creation of the Biomotum start-up and the launch of their first exoskeleton, NAU-Biomotum SPARK, in September 2021 [40]. This exoskeleton is designed for research, rehabilitation clinics, and daily use, but is currently only available for use in a research setting and has not yet been approved by the FDA [40].

This portable exoskeleton provides actuation on the ankle joint in both dorsiflexion and plantarflexion (Figure 5.a). It has been tested on subjects aged from 5 years old to 35 years old with spasticity (diplegic or hemiplegic) with GMFCS levels between I and III [41], [42]. These studies have shown that patients using the exoskeleton have a reduction in metabolic cost while walking [9], [10], [41]–[45]. The complete (bilateral) exoskeleton weighs between 2.4 kg and 2.6 kg depending on the size of the patient - and therefore on the dimensioning of the different components. To limit the weight at the patient's extremities, most of the components are located at the patient's waist: batteries and actuation system (motors and custom Printed Circuit Board (PCB) with microcontrollers and drivers for the motors) [44]. This would represent between 50% and 65% of the total weight of the exoskeleton. To transmit the movement at the ankle, Bowden cables and pulleys are used. The structure is mainly composed of carbon fibers to minimize the weight of the exoskeleton frame (foot platform, calf link ...). Considerable effort has been dedicated to minimizing the weight of the exoskeleton and optimizing its weight distribution.

The concept of housing the motor within a backpack may reduce the impact of adding mass on the user; however, this arrangement would introduce complexities to the control algorithm due to the extra motion transmission it entails. Moreover, having cables extending from the user's back to their ankles may risk entanglement with objects in their surroundings.

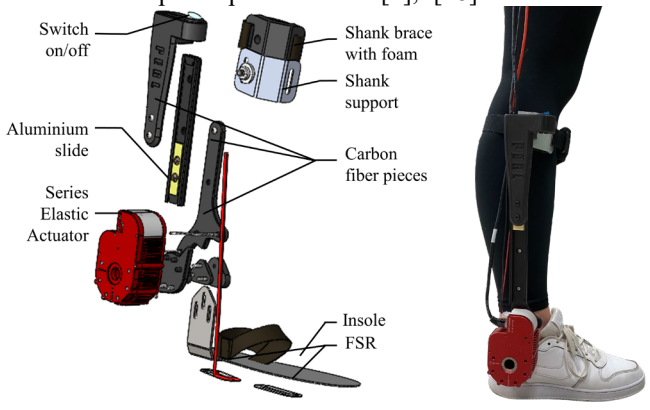
Regarding the components, the drive system consists of an electric motor (EC4-Pole 90 W, Maxon) with a planetary gearbox (89:1 GP 22HP, Maxon). The battery is a Li-Ion (KamPing) of 2000 mAh and 24V for an estimated autonomy of 20-35 minutes of maximum use. The PCB consists of a microcontroller (Teensy 3.6, PJRC), a driver for the motors (ESCON Module 50/8, Maxon), a Bluetooth module, voltage regulators for the battery and signal acquisition systems (INA125P, Texas Instruments). The pulley used at the ankle to transmit the motion has a diameter of 80 mm and a reduction ratio of 5:1. As for the sensors, a force-sensitive resistor (FSR, FLexiforce A502, Tekscan) is placed in the foot platform at toe level and a force sensor was prototyped with 7075-651 aluminum and Wheatstone Bridge mounted strain gauges [44].

In the case of a 5-year-old child with level II impairments, weighing approximately 17 kg, it is important to highlight that the weight of the exoskeleton, which accounts for roughly 14% of their body weight, is non-negligible.

2) *Pediatric Exoskeleton for Rehabilitation of Lower limbs (PERL)*

After conducting this literature review and gathering the relevant design criteria, our research laboratory, POLAR (Polytechnique Laboratory for Assistive and Rehabilitation technologies), at Polytechnique Montréal, developed an ankle exoskeleton for children with CP (level I-II), named “Pediatric Exoskeleton for Rehabilitation of Lower Limb (PERL)” (Figure 4). PERL is intended for dorsiflexion and plantarflexion of children between 5 years old and 14 years old, weighing between 15 kg and 45 kg and having a height varying between 95 cm and 140 cm.

The overall design is anthropomorphic, and the structure has been dimensioned using growth curves specific to children with CP and anthropomorphic models [4], [18]. To reduce the



(a) (b)

Figure 4 : a) CAD model and b) prototype of PERL exoskeleton

prototype's weight, the structure is made of aluminum and carbon fibers. To further minimize the impact of added mass, most of the electronic components (embedded system, battery…) are relocated in a backpack near the center of gravity, with only the actuator remaining at the ankle level. Foam has been incorporated to prevent skin abrasions and increase comfort. Lateral slides are used to fit different sizes of tibia and to align the actuator axis with the ankle axis. A customizable insole made of foam and high-density polyethylene (HDPE) can be replaced as needed to ensure a proper fit and maximum comfort for the user.

The ankle joint is actuated by a SEA from *Hebi Robotics* which is composed of a BLDC motor, a geartrain and a spring. The design also integrates the control electronics and a wide range of sensors such as angular position (multi turn absolute encoder) and velocity sensors, a 3-axis accelerometer, a current sensor, and a torque sensor. The actuation system only weighs 475g. It can provide a peak torque of 20 Nm and a continuous torque of 8 Nm. An adaptive impedance controller with an inner torque controller will be implemented on PERL. To implement this controller, the insoles also incorporate FSRs. In the future, electromyographic (EMG) sensors will be added to the design. Throughout the prototyping stage, we made every effort to ensure that all the criteria mentioned in this article were respected.

C. Knee Ankle-Foot exoskeleton

The only known prototype of an exoskeleton incorporating both the knee and ankle joints is the WAKE-Up exoskeleton.

1) WAKE-Up exoskeleton

The WAKE-Up exoskeleton (Wearable Ankle Knee Exoskeleton) is a modular knee and ankle exoskeleton providing one Degree of Freedom (DoF) to each of the joints it actuates (Figure 5.b). Its modular design allows for the option of using one or both modules, providing two DoFs per leg. This exoskeleton is an upgraded version of an alpha prototype developed in Italy in 2014 and is designed to assist children between 5 years old and 13 years old with neurological conditions such as cerebral palsy, who weigh between 10 kg and 25 kg [46], [47].

Its modular design plays a crucial role as it increases the versatility of the exoskeleton, making it possible to accommodate a larger number of users. However, it is important to keep in mind that the design should be easily installable to minimize the time spent changing the modules.

To actuate the WAKE-Up joints, a Rotary Series Elastic Actuator (RSEA) is used with a belt pulley having a ratio of 2/3. The RSEA is composed of a servomotor (RE-MAX motor, Maxon) with a PID type position and speed controller (Dynamixel EX-106+, Trossen Robotics, IL, USA) and a torsion spring capable of transmitting a nominal torque of 3.5 Nm [47]. The elastic component of this actuator should offer a more compliant motion transmission compared to typical BLDC motors, although the control may be more complex.

The information on motor position, spring deformation, gait cycle dynamics is obtained with an absolute 14-bit magnetic encoder (MA3, US Digital, WA, USA) directly incorporated in the spring to measure the angular position of the spring. This is also made possible by a 9-axis IMU with accelerometer, gyroscope, and magnetometer (MPU-9350, InvenSense, USA) and six footswitches in the foot platforms. The Range of Motion for the two actuated joints is between 45° and 100°. The assisting torque is up to 5.2 Nm, which is approximately 15% of the maximum net moment at the knee and ankle during walking in TDC. [47].

Regarding the control strategy, Patané et al. (2017) have chosen to use a master/slave structure, i.e., there is only one master module to control several slave modules. The master module is a MyRio controller (National instruments, TX, USA) with an ARM Cortex-A9. These modules are therefore programmed in LabVIEW RT (National Instruments, TX, USA). A GUI is also implemented in the master module and is accessible from a remote monitor via a wifi connection. This interface allows one to control the exoskeleton and to configure some parameters. As for the slave nodes, they are formed by the RSEA actuation system but also by a 32-bit microcontroller (PIC32MX440F512H, Microchip, USA) and all the sensors mentioned above. A PID controller is implemented locally to process the information from the slave nodes [47].

D. Hip Knee Ankle-Foot exoskeletons

Moving on to the category of more comprehensive exoskeletons, which are equipped with actuated hip, knee, and ankle joints, we have identified four different prototypes.

1) P-LEGS

The Houston-based research team developed the P-LEGS in 2019 (Figure 5.f). This exoskeleton is designed as a rehabilitation tool for children with walking disorders resulting from conditions such as cerebral palsy, spina bifida, or spinal cord injury. Clinical testing was conducted on children aged 4 to 8, weighing between 16 kg and 28 kg, and having standing heights between 1m and 1m23. Each leg has three actuated joints (hip, knee, and ankle) resulting in six active DoFs in the sagittal plane and two passive DoFs in the frontal plane for the hip joints, making a total of eight DoFs [48]. The device weighs 2.5 kg which is extremely lightweight for this type of exoskeleton.

The P-LEGS is attached to the patient using 3D printed shin and thigh pieces that are customized from 3D scans of the children. The joints are powered by 24V Maxon electric motors coupled to ball bearings and gearboxes with a 161:1 ratio. Each joint contains an ARM Cortex M-4 MCU, the actuator and its driver, a 9-axis IMU, acquisition systems for signals from the FSRs located in the soles and various sensors. Among these sensors, we find temperature, voltage and current sensors, a rotary encoder and a Wheatstone bridge composed of torque sensors. This system, using a CAN bus communication protocol, makes each joint independent from the others, which makes the exoskeleton modular [48].

The control strategy adopted here is the Assist-As-Needed (AAN) principle, which aims to involve the patient during walking with the exoskeleton rather than completely replacing their motor function. This is achieved through adaptive impedance control with a PD position controller (specific to each joint) [48].

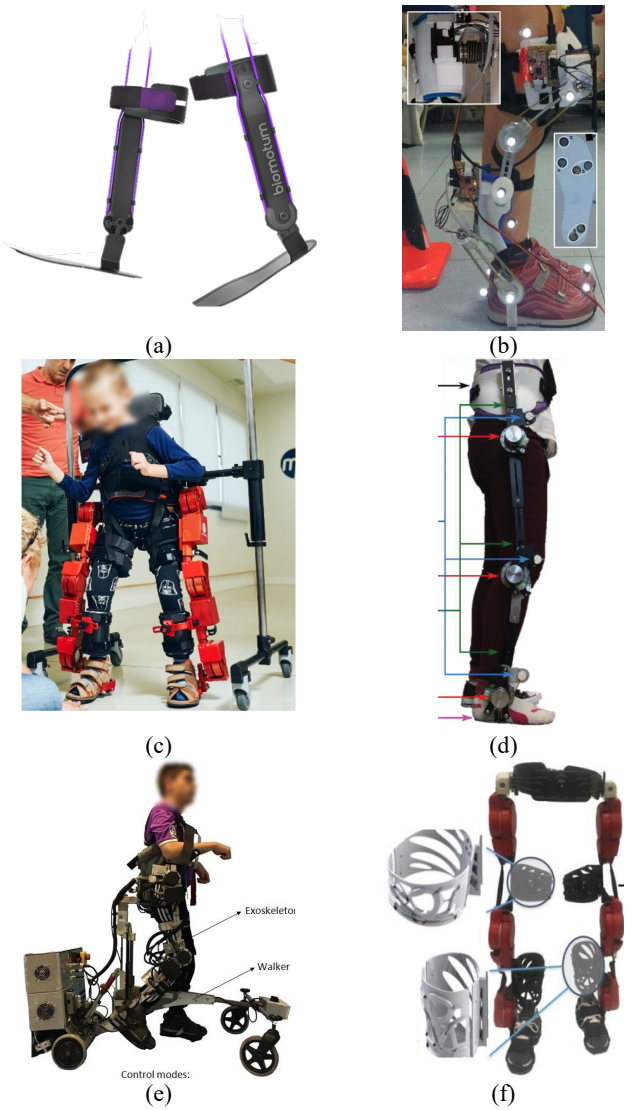
2) Pediatric EK - National Polytechnic Institute of Mexico

The National Polytechnic Institute of Mexico research team developed a pediatric exoskeleton in 2021, suitable for children

weighing between 30 kg and 66 kg and measuring between 1m36 and 1m68. The exoskeleton provides motion to all three joints of each leg in the sagittal plane, giving it a total of six DoFs. This exoskeleton is attached to a walker that has three DoFs [49].

The exoskeleton and walker are constructed of aluminum, while covers made of polylactic acid (PLA) have been added to protect the user's feet, shins, and thighs from the metal structure. Regarding the actuation system, six robust linear actuators are used for each joint. Each actuator has a rotatory resistance sensor that provides information on the angular position of each joint. The motors are controlled by Pololu VNH3SP30 drivers. The whole device, i.e., exoskeleton and walker, is moved by two DC motors. This robotic device has a static load of 228.79 kg and a dynamic load of 11.33 kg which is still heavy [49].

To control this system, a TIVA C Series TM4C1294 microprocessor with an ARM Cortex-M4 120 Mhz nucleus is used. EMG sensors (MyoWare muscle sensors) are also placed on the patient to record muscle activation in the legs. Once processed, these data allow the controller to identify the beginning of a new gait cycle and thus control the exoskeleton accordingly [49]. The integration of EMG sensors enables the control system to mimic the timing of human gait, leading to a more transparent overall system. However, the reliability of EMG data and the ease and speed of installation may be questionable.



(a) (b) (c) (d) (e) (f)

Figure 5 : a) NAU-Biomotum Spark [44], b) Wake Up Exoskeleton [35], c) Atlas 2030 [52], d) ExoRoboWalker [51], e) CPWalker [55] and f) P LEGs [48]

3) HKAF exoskeleton - Canela et al. (2013)

The exoskeleton developed by Canela in 2013 is an adaptation of an adult model. It is designed for use by children aged 7 to 17. Each joint is powered by a BLDC electric motor (EC-45 70W 24V) coupled with 160:1 ratio gearbox. This is the only information available about the design and control of this exoskeleton [35], [50].

4) ExoRoboWalker

The ExoRoboWalker, developed in 2019 by Andrade et al. (2019) has a total weight of 6.57 kg which is 2.6 times the P-LEGs' weight (Figure 5.d) [51].

Each joint is driven by a BLDC electric motor (EC 45 flat, 70 W, Maxon) coupled to a 160:1 ratio harmonic drive gearbox (CSD-20-160-2a, Harmonic Drive). Each motor has a Hall effect sensor to measure the output speed of the motor and a potentiometer to measure the angle of each joint. Strain gauges are used to quantify the interaction between the exoskeleton and the user. This would make the system more transparent and reduce the risk of significant force impacts, leading to improved safety. Pressure sensors placed in the sole allow the controller to determine the phase of the gait cycle in which the user is. An impedance controller with a PD torque controller is implemented [51]. In the future, this team would like to refine the controller parameterization, perform clinical tests on healthy patients and develop a user-robot interface by adding EMG and EEG sensors [51].

E. Trunk Hip Knee Ankle-Foot Exoskeletons

In the category of exoskeletons that provide additional DoFs to the waist for improved balance, two prototypes were identified.

1) ATLAS 2030, Marsi Bionics & Spanish National Research Council

The Atlas 2030 is a modular exoskeleton of the lower limbs that can be adjusted for children between the ages of 3 and 14 with a weight limit of 40 kg (Figure 5.c). It is available in three different sizes (S, M, and L) and has a safety frame to maintain the child's balance while walking [52]. Having different sizes available can provide a balance between adjustability and customization, preventing the use of over or under-dimensioned motors. This exoskeleton weighs 14 kg and has between 8 and 12 active DoFs, depending on the chosen modules. It is an improved version of the ATLAS 2020, which had 10 active and 2 passive DoFs and weighed 14 kg [53]. It recently received CE approval for commercial use. For each of its joints, two types of movement must be performed: one in the sagittal plane and the other in the frontal plane. A rotary and linear actuator will be used respectively. For the actuation of each joint in the sagittal plane, a BLDC electric motor (70 W BLDC motor) with quadrature encoder and Hall effect sensor is coupled to a 160:1 ratio gearbox. The maximum torque that this actuator can provide is 60 Nm. For the actuation system in frontal plane, the same type of motor will be used but it will be coupled to a 3:1 gearbox and then to a 10x3 ball spindle output. A patent has

been filed for the actuators of the four joints (trunk, hip, knee, ankle). To power all this, six batteries are used [54]. The autonomy is 2.5 hours in continuous use.

The high-level control system uses a National Instrument board (MyRio) with a real-time processor. The signals are transmitted by the controller according to the data from the various positions, force, and pressure sensors via an I2C serial line to the local actuators. The low-level control is enabled by an ATMEL microcontroller. Three low-level control modules are required per leg. Thanks to all these modules, the ATLAS allows the user to go forward and backward and has two control modes: an automatic mode where the trajectory is predefined and based on the walking pattern of a healthy individual and an active mode where the exoskeleton is paused during the swing phase. The ATLAS 2030 is also equipped with an automatic balance control. All control parameters are programmable from a mobile app connected via Wi-Fi to the device [54].

2) CPWalker, Bayon et al.

The CPWalker is an exoskeleton with an integrated smart walker created by Bayón et al. in 2016 (Figure 5.e). It offers a total of six DoFs for the exoskeleton and four DoFs for the walker. The technology has been tested on children aged 11 to 18 years, with a maximum weight of 75 kg and ranging in GMFCS levels from I to IV [55].

The intelligent walker is driven by two gearmotors (Kelvin K80 63.105) coupled to rear wheels, which allows a translational movement. The speed of the walker is controlled by encoders on each motor. This walker is said to be intelligent because it allows the support of a percentage of the patient's weight which can be customized according to their deficit. As for the exoskeleton, each actuator consists of a BLDC electric motor (EC-60 flat 408057, Maxon) with a Harmonic Drive gearbox with a ratio of 1:160 [55]. The control of the exoskeleton is enabled by data collected by potentiometers, force sensors and pressure sensors in the sole (FSR 400 30-73258). The user-technology interaction is done via a Multimodal Human Robot Interface (MHRI) composed of several units: an EEG unit, an EMG unit, an IMU and a Laser Range Finder (LRF) [55], which enhances the precision, transparency, and safety of the controller and the exoskeleton.

V. Discussion

In this article, design considerations for exoskeletons, more specifically pediatric exoskeletons, have been presented and are summarized in Figure 6. The literature review illustrates how researchers account for these constraints for their design. Eight exoskeletons with an actuated ankle were listed and the exoskeleton PERL has been introduced.

The number of actuated joints and the GMFCS level of the targeted population are correlated. The fewer the number of joints actuated, the more the child should be able to maintain balance and walk. The CPWalker doesn't follow this rule. It actuates hip, knee and ankle joints and integrates a walker, but it only assists children of level II and III. This design could be useful for children with low mobility capacity like level IV or V which is perhaps envisioned by the research group.

TABLE I
PEDIATRIC EXOSKELETONS CHARACTERISTICS

Exoskeletons	Joints	Target population	Actuators	Dynamic properties	Control strategy	Sensors	Weight
NAU-Biomotum SPARK [44]	AF[1]	5 – 35 yo GMFCS I-III SD[5]/SH[6]	BLDC[10] motors – Maxon, Maxon gearbox – 89 :1, Pulley –5 :1	24 V, 90 W, max torque: 12 Nm	Assist-as-Needed, FSM, Torque control – PID	FSR, torque sensor, strain gauges	2.4 to 2.6kg
WAKE-Up [47]	KAF[2]	5 – 13 yo, SH[6]	RSEA – servomotors – Maxon, Gearbox: 2/3	max torque: 5.2 Nm	FSM, Position control – PID	FSR, IMU, absolute 14-bit magnetic encoder	-
P-LEGS [48]	HKAF[4]	4 – 8 yo	BLDC[10] motors – Maxon, Gearbox: 161:1	24 V, max torque: 76 Nm	Adaptive Impedance Control, Assist-as-Needed, Position control – PD	FSR, IMU, temperature/ voltage/current sensors, rotary encoder, torque sensor	2.5 kg
Pediatric EK – Mexico [49]	HKAF[4]	-	DC[9] motors	-	-	EMG, resistance rotatory sensor	228.79 kg (static load) 11.33 kg (dynamic load)
HKAF - Canela et al. [35], [50]	HKAF[4]	-	BLDC[10] motors, Gearbox: 160:1	24 V, 70 W, max torque: 34.3 Nm	-	-	-
ExoRoboWalker [51]	HKAF[4]	-	BLDC[10] motors – Maxon, Harmonic Drive gearbox: 160:1	70 W	Impedance Control, FSM, Torque control – PD	FSR, potentiometer, strain gauges, Hall effect sensors	6.57 kg
ATLAS 2030 [37], [54]	THKAF[5]	3 – 14 yo, SMA[7] - type II, CP - GMFCS III-V, SDT[8] Limits: 40 kg, 100-150 cm	BLDC[10] motors, Gearbox: 160:1	70 W, max torque: 60 Nm, walking speed: 0.5 m/s	Impedance Control, Position control – PID	FSR, IMU, encoder	14 kg
CPWalker [55]	THKAF[5]	12 – 17 yo GMFCS II-III	BLDC[10] motors – Maxon, Harmonic Drive gearbox: 160:1	-	Impedance Control, Position control – PID	FSR, EEG, EMG, IMU, LRF, potentiometer	-

[1]AF: Ankle Foot, [2]KAF: Knee Ankle Foot, [3]HKAF: Hip Knee Ankle Foot, [4]THKAF: Trunk Hip Knee Ankle Foot, [5]SD: spastic diplegia, [6]SH: spastic hemiplegia, [7]SMA: Spinal Muscular Atrophy, [8]SDT: Spastic / dystonic tetraparesis, [9]DC: Direct Current, [10]BLDC: BrushLess Direct Current

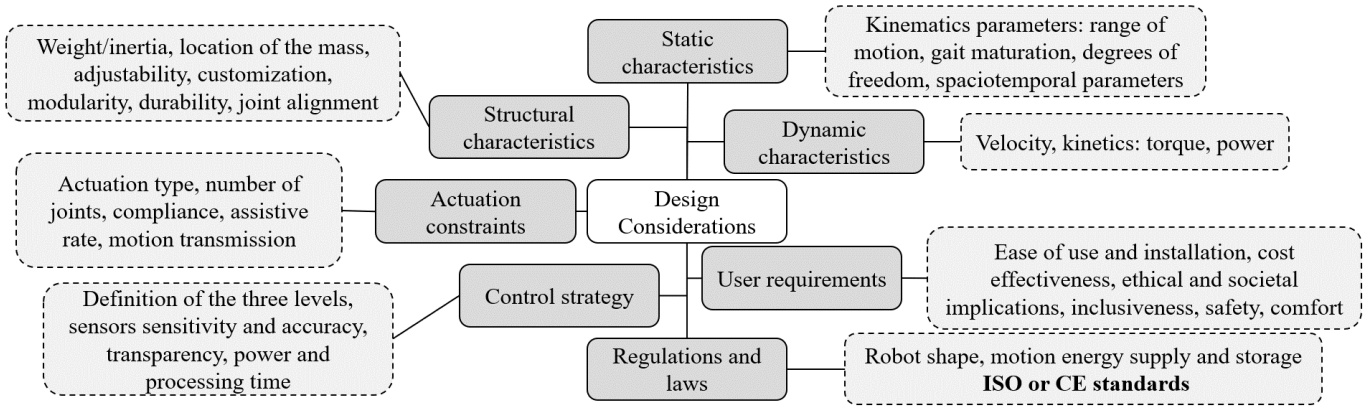


Figure 6 : Summary of design considerations for the development of an exoskeleton

Focusing on pediatric users means being able to cope with a huge variability of size. A child's growth can represent an increase of 50% of its size, like going from 1m to 1m50. The exoskeletons' ability to follow this growth is one of the most challenging tasks for the researchers both in terms of the mechanical structure (strength, adaptability...) and the actuators dimensioning (power, strength...). Slides and Velcro straps are commonly used. Offering different model sizes like the ATLAS 2030 can be an alternative to under or over-dimensional designs. However, it implies changing the exoskeleton at least once which can raise questions of affordability. Exoskeleton rental or recycling should be considered. Actuation requirements increase with the patient's weight. This aspect is one of the main technological limitations. It involves making a trade-off between choosing powerful actuators able to assist adolescents and choosing lightweight actuators that can be borne by young children. The torque capacity of the actuation system also depends on the level of assistance needed. Prof. Lerner's research team has chosen to assist at 21% of the biological torque [45]. If, on the other hand, one wants to be able to fully support the ankle's rotational movement, it will be necessary to opt for a much higher torque, as is the case with the ATLAS 2030 with 60 Nm of maximum torque [56]. Nonetheless, more powerful actuators can be heavier and require bigger batteries which increase the overall weight. For the same number of actuated joints, the ExoRoboWalker is 2.6 times heavier than the P-LEGs. This significant difference can be explained by the material used or by the actuation system of the ExoRoboWalker that requires more energy.

Regarding the mechanical properties of the actuators, three main forms of energy were identified to set each joint in motion: pneumatic, hydraulic, and electrical energy. No pediatric exoskeleton in this review uses pneumatic or hydraulic energy. One reason for this choice is the weight and cost characteristics of these actuators. Most of the chosen motors are small to make the design compact which reduces their capacity to provide an important output torque. For this reason, all the proposed designs integrate a gear ratio to increase the output torque and provide the required force to actuate the joint. Also, among electric motors, there is a preference for brushless motors. Brushless motors are an alternative to brushed motors and have many advantages. They allow for higher starting torque with better efficiency. They are often more precise and efficient and offer a longer service life. However, these motors are more expensive and require more external components than conventional motors with brushes. Only the WAKE-Up exoskeleton and PERL exoskeleton integrate SEA actuator in their design. SEAs offer a more compliant output transmission, which can enhance user interaction and make it more natural. This type of actuator should be further investigated for exoskeleton use.

The control of the exoskeleton is enabled through an interface for interaction with the user via sensors. The chosen control strategy will directly define the sensor requirements. As listed in Table I, all known high-level controllers are based on human-machine interaction, i.e., they consider the interaction forces to avoid injuring the patient. Indeed, the strategies used are either impedance control or admittance control. Moreover, this assistance can be applied permanently or intermittently to involve the patients more in their rehabilitation process and avoid losing the motor functions he already has. "Assist-As-Needed" control is the approach of assisting a patient only in a phase of his gait cycle that is known to have a motor deficit, which seems to be the right approach to optimize the child's progress. In low-level controllers, we find classical controllers such as PID or PD controllers of position or torque. As mentioned in the design requirements section, a multitude of complex control strategies have been developed for adult users using Machine Learning algorithms, motion recognition or prediction, advanced control techniques or feedforward low-level controllers. The strategies implemented for pediatric users are not as developed as those for adult users. Research is more advanced for adult subjects which explains this gap. Plus, the complexity of the targeted population with unpredictable and unstable gait pattern is another obstacle. Research should focus on improving control strategies and providing more adaptive control laws. Control strategies should take advantage of the high neuroplasticity of children, compared to adults, to assist more efficiently their gait and increase their progress.

These control modalities require information on the phase of the gait cycle, on the position of the joint or on the torque/force applied at the joint. The majority of exoskeletons are equipped with force sensors placed under the foot platform, which allows them to identify the phase of walking according to whether the heel, the toes, or both, are in contact with the ground. Heel strike is the beginning of the stance phase and toes off is the beginning of the swing phase. This gait detection can work for TDC. However, children with CP do not always have a stance phase starting with a heel strike which can affect the gait phase detection. It may also be possible to integrate EMG or EEG sensors to make the control more complex by performing movement prediction. From the data of electrical stimulation at

the level of the muscles or the brain, it is possible to determine the intentions of movement of the user. This method is highly interesting and could add precision and reactivity to the exoskeleton to finally make it more transparent.

There is scarce information in the design (mechanical and control system) regarding adherence to international standards, although it is very important. This can be attributed to the fact that only a few pediatric exoskeletons have been FDA or CE approved thus far.

As the interest in exoskeletons for children with CP has emerged recently, few studies have been conducted to measure their impact and effectiveness on a patient's gait pattern. Indeed, among the nine exoskeletons listed, only three have been clinically tested: NAU-Biomotum SPARK, WAKE-Up exoskeleton and the CPWalker. In total, these studies included 69 participants, 59 for the NAU-Biomotum SPARK, three for the WAKE-up and seven for the CP-Walker [35]. Further trials are needed to demonstrate the benefits of assistive technologies on gait dynamics and metabolic cost. Of the total number of participants with known cerebral palsy severity, 30 were GMFCS I, 22 were GMFCS II and 13 were GMFCS III [35]. The studies are rather well distributed between these three levels. However, the absence of GMFCS IV or V subjects underlines the difficulty of assisting the most severe levels due to their lack of mobility and balance. Moreover, these exoskeletons were tested on children suffering from spastic disorders with spastic diplegia (12) or spastic hemiplegia (9) [35].

This state of the art focuses on ankle exoskeletons specifically for children with CP. This research could be extended to other types of locomotor disorders such as deficits due to lesions in the spine. Techniques used for other pathologies could be adapted to subjects with CP. Moreover, only pediatric exoskeletons are studied here. It could be interesting to explore in more detail the design and control choices made for adult exoskeletons and briefly mentioned in the design considerations section of this article. Given the number of adult exoskeletons currently being developed and marketed, more studies have surely been conducted. It would be useful to see the results to get an idea of what is to be preferred or avoided in terms of actuators or control strategy. Finally, it should be noted that among the exoskeletons presented, only one, to my knowledge, has been commercialized and three have been tested. The effectiveness of each exoskeleton has not been proven, even if some design choices seem better than others, they should, in the future, be compared based on the effect on the subject's gait.

VI. Conclusion

To conclude, walking therapies for children suffering from locomotor disorders such as Cerebral Palsy could be improved with the use of lower limb exoskeletons. Beyond the fact that they would allow to optimize the rehabilitation sessions by making them longer and more personalized through collection of quantitative data of the progress and deficits of walking of the children, a daily use at home could be attainable with portable exoskeletons. Currently, most exoskeletons are designed for adult population, which creates a large gap in the pediatric exoskeleton market. Moreover, these technologies are extremely expensive, which also represents a real challenge. This article provides a comprehensive list of design considerations that should be considered during the development process.

The current advancements in the design of pediatric exoskeletons with actuated ankle joints showcase the various decisions made regarding the structure, actuation, and control strategy to fulfill previously stated requirements. We reviewed nine exoskeletons among which: two include actuation of the ankle, one includes actuation of the knee and the ankle, four include actuation of the hip, knee, and ankle, and finally, two include actuation of the trunk, hip, knee, and ankle. Different properties were analyzed, such as the target population, joint actuation types, and the control strategy. In summary, this type of technology seems to be adapted for children between 5 years old and 13 years old whose CP level of severity varies according to the number of actuated joints. These joints are mostly activated by DC electric motors, mainly because of their lightness and efficiency. Yet, the weight of such devices needs to be minimized. Proposed solutions include sliding mechanisms or offering various sizes of the device. Concerning the control strategy, to allow for better compliance of the exoskeleton, force controls are adopted which also lower the risk of injuring the user. Nevertheless, these control strategies should be even smarter by adapting in real time the control law to the patient deficits. Finally, very few clinical trials have been undertaken to prove the effectiveness of these exoskeletons.

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