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Human Factors Assessment of a Novel Pediatric Lower-Limb Exoskeleton

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Abstract: While several lower-limb exoskeletons have been designed for adult patients, there remains a lack of pediatric-oriented devices. This paper presented a human factor assessment of an adjustable pediatric lower-limb exoskeleton for childhood gait assistance. The hip and knee exoskeleton uses an adjustable frame for compatibility with children 6–11 years old. This assessment evaluates the device's comfort and ease of use through timed donning, doffing, and reconfiguration tasks. The able-bodied study participants donned the device in 6 min and 8 s, doffed it in 2 min and 29 s, and reconfigured it in 8 min and 23 s. The results of the timed trials suggest that the exoskeleton can be easily donned, doffed, and reconfigured to match the anthropometrics of pediatric users. A 6-min unpowered walking experiment was conducted while the child participant wore the exoskeletal device. Inspection of both the device and participant yielded no evidence of damage to either the device or wearer. Participant feedback on the device was positive with a system usability scale rating of 80/100. While minor improvements can be made to the adjustability indicators and padding placement, the results indicate the exoskeleton is suitable for further experimental evaluation through assistive control assessments.

Keywords: pediatrics; exoskeletons; human factors; wearable robotics

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1. Introduction

Medical lower-limb exoskeletons have been proposed as a supplementary technology to traditional physical therapy and body weight supported treadmill training (BWSTT) methods for dealing with gait impairment. Lower-limb exoskeletons can provide robotic assistive torques to the joints of the device wearer. The application of these devices in robotic assisted gait training (RAGT) can significantly reduce the muscle fatigue of the physical therapist overseeing the rehabilitation session, increase the controllability and accuracy of the wearer's walking motion, and allows for the exploration of various rehabilitative control strategies [1,2].

Several adult-oriented exoskeleton devices have been developed to assist individuals with gait impairment resulting from incidents such as stroke and spinal cord injury. Many exoskeleton devices such as the EksoNR by Ekso Bionics [3,4], the ReWalk Robotic exoskeletons [5], the Hybrid Assistive Limb by Cyberdyne [6], the Indego exoskeletons by Parker Hannifin [7], and the Rex Bionic exoskeleton [8] have even received FDA approval or CE Mark [9,10]. However, while the field of adult-oriented medical exoskeleton technology has been steadily expanding, there is significantly less development in the field of pediatric-oriented exoskeleton devices [11]. Pediatric individuals also deal with gait impairments which often stem from various genetic, neuromuscular, or neurological development disorders such as cerebral palsy [12,13], muscular dystrophy [14], or spina bifida [15]. The development and design of a pediatric-oriented exoskeleton for these individuals necessitates several additional design considerations relative to adult

devices. This includes the ability to accommodate and easily adjust to a larger range of possible anthropometric parameters, the ease at which a child can don and doff the device, a significant limitation on the acceptable device weight and size, and other desirable characteristics such as device mobility and usability. Several robotic walking devices such as the Lokomat [16,17] and the Walkbot-K [18] are attached to instrumented treadmill systems. Other exoskeleton devices such as the Trexo Home [19] and the CPWalker [20] are attached to external stability structures or devices. These additional structures limit the device's mobility in community settings and their ability to accomplish other activities of daily living outside of walking tasks. Other devices actuate only a single degree of freedom, such as the knee exoskeleton [21,22] and the ankle exoskeleton [23] developed by Lerner et al. The Marsi Bionics Atlas 2020 and 2030 exoskeletons lie on the other end of the actuation spectrum with 10 actuated degrees of freedom. However, this high degree of actuation results in a large device weight of 12 kg [24,25], representing a significant burden on a child wearer. The 2S-HAL by Cyberdyne shows great promise as a lightweight pediatric device [26,27], though the device's speed of adjustability, ease of use, and power capabilities remain underreported. The P-Legs device [28] by Eguren et al. is both mobile and lightweight. However, the need for customized 3D printed braces for each intended user ensures that the exoskeleton braces will need to be reprinted several times over the course of the wearer's growth. In situations where a single device must be used across multiple wearers, multiple braces must be prefabricated, and the device must be repeatedly disassembled and reassembled for each new wearer. This represents a significant increase in reconfiguration time, which plays a critical role in the average 30 to 60 min long physical therapy session [29]. Additionally, the need to pre-fabricate the customized braces for each individual can significantly inflate the cost of using the device. The anthropometrically parametrized exoskeleton by Laubscher et al. [30] suffers from similar limitations due to its customized 3D printed exoskeleton frame. To the authors' knowledge, there does not seem to be a suitable exoskeleton that addresses the needs of the pediatric population while remaining mobile, lightweight, quickly adjustable, and easy to don and doff.

This paper presented an evaluation and human factor assessment of an adjustable pediatric lower-limb exoskeleton. In previous work, the authors developed an exoskeleton joint actuator and tested its suitability for use in an exoskeleton system [31]. The authors also presented an initial exoskeleton frame design and created a walking simulation of a human–exoskeleton system under virtual constraint-based control [32]. Here, the design is finalized, and the exoskeleton is assembled at Cleveland State University. A preliminary human factor assessment is performed to validate the device's mobile and lightweight design, and to demonstrate the ease at which the exoskeleton can be adjusted, donned, and doffed. The results of the human factor assessment and the observations made by both the researchers and the study participants are presented in this manuscript. This paper serves to demonstrate that the newly developed exoskeleton device is appropriate for use with pediatric subjects in future gait assistance control experiments.

The remainder of this manuscript is organized as follows. Section 2 reviews the design of the exoskeleton system hardware. Section 3 details the procedure of the human factor assessment validating the exoskeleton design. Section 4 presents the results of the human factor assessment and the observations made by both the researchers and the study participants. Section 5 contains the conclusions and future work regarding the use of the adjustable pediatric lower-limb exoskeleton.

2. Adjustable Pediatric Lower-Limb Exoskeleton

A discussion on an earlier iteration of the exoskeleton frame is given in the authors' previous work [32]. The exoskeleton presented in this paper utilizes a newer version of the exoskeleton frame with minor changes in design with respect to the former. The height of the hip cradle was increased, and the torso wings were moved further to the side to better wrap around the hips. These changes provided greater fixation to the torso of the wearer during operation. Additionally, more space was provided at the hip joints to allow

for greater abduction and adduction motion in the legs. However, the range of adjustment that the exoskeleton can accommodate remains the same between the two iterations. A picture of the assembled exoskeleton without any straps, padding, or external electronics is shown in Figure 1.

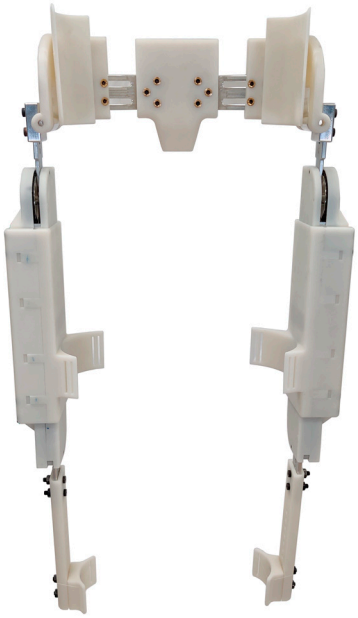

Figure 1. CSU Adjustable Pediatric Exoskeleton.

The exoskeleton is designed to fit the anthropometrics of children 6 to 11 years old based on recent census data [33]. This is accomplished by incorporating adjustable mechanisms within the frame. The exoskeleton frame consists of the hip cradle, thigh, and shank subassemblies which are shown in Figure 2a–c.

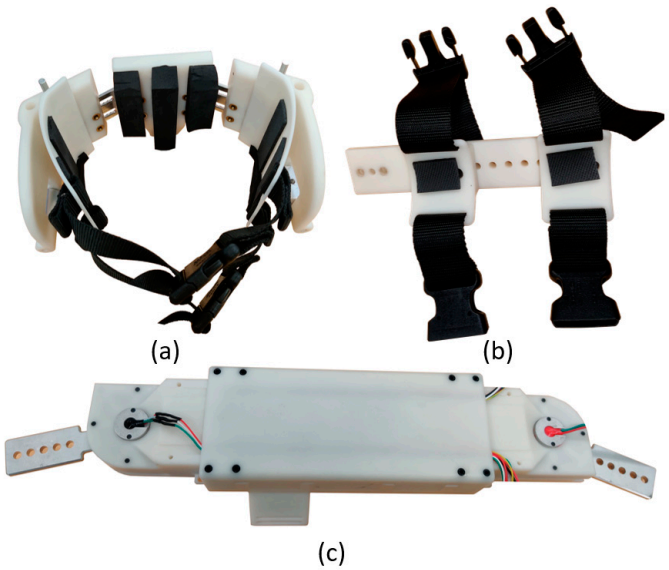

Figure 2. Pictures of the subassemblies which comprise the adjustable pediatric lower limb exoskeleton. (**a**) represents the hip cradle assembly (**b**) depicts the shank subassembly, and (**c**) shows the thigh subassembly.

These subassemblies can be reconfigured in a timely manner with a simple set of English unit Allen keys. The hip cradle can be widened by relocating the side arm plates

along the aluminum arms that stick out of the backplate. This is achieved through a system of socket head screws, threaded inserts imbedded into the hip side plates, and geometric features along the aluminum bars. The thigh subassembly can be extended or retracted to match the length of the wearer's thighs. This is accomplished by sliding the actuator housings along the major axis of the thigh tube shell and locking them in place at the desired length. The locking system utilizes a screw to raise or lower hex shaped spacers into channels that run along the length of the plastic actuator housing. The thigh subassembly can attach to the hip cradle through an adaptor plate that allows for free hip abduction and adduction. Finally, the shank subassembly consists of an actuator arm extension that attaches to the knee actuator in the thigh subassembly. Several modular cuffs can be attached to the actuator arm extension, which allows for fixation along various parts of the lower leg. The thigh and shank subassemblies combine to form an exoskeleton leg.

The exoskeleton provides actuation at both the hip and knee joints in the sagittal plane, similar to other hip and knee devices such as the Indego, Ekso Bionics, and ReWalk exoskeletons. The device was designed without an ankle foot orthosis (AFO) so that subjects with a preferred AFO device may use it in conjunction with this exoskeleton. The exoskeleton actuators are driven by a 144 W brushless DC motor, which exceeds the authors' 47.3 W estimate for the power requirements of nominal pediatric gait. A 20.4:1 hybrid belt and chain transmission is used to maintain low actuator friction and create an easily backdrivable actuator. The use of roller chains and sprockets at the output stage of the transmission also increases the actuator's resistance to unexpected impact loads in the event of falls. The resultant actuators, presented in greater detail in [31], are capable of delivering a continuous output torque of 5.9 Nm and theoretical peak torque of 46.9 Nm. For a greater discussion on the actuators design and specifications, see [31].

The plastic parts of the exoskeleton frame were printed from a polyacrylate-based plastic to help minimize device weight while maintaining rigidity and strength in the design. The metal parts are machined primarily from 7075 aluminum for similar reasons. This resulted in a total device weight of 4.72 kg excluding straps, padding, buckles, and external electronics such as batteries, servo amps, and microcontrollers.

3. Human Factor Assessment Procedure

The purpose of the human factor assessment presented in this manuscript was to evaluate whether the adjustable pediatric exoskeleton device displays the previously discussed device characteristics. This includes an easy to learn and use adjustability system, the ability to quickly don and doff the device, comfortability while in motion, and a lightweight design. These tests also verified that the device was suitable for further evaluation in future control experiments. The assessment involved a set of two volunteer participants. The first participant was an 11-year-old female able-bodied child. The second was the adult male parent/guardian of the child participant who accompanied the child for this experiment. The anthropometric parameters of the child participant were identified at the beginning of the testing session, and the researchers reconfigured the exoskeleton device to fit the child prior to the start of the timed tasks. The researchers demonstrated how to correctly don and doff the exoskeletal device to both participants. A small practice session of up to 15 min was offered wherein both the child and adult participants could practice donning and doffing the exoskeleton. The participants decided to proceed straight into the next part of the assessment without practice. There were four major tasks that the child and adult participants were asked to complete.

3.1. Exoskeleton Donning

In the first task, the exoskeleton was donned by the child participant with the assistance of the adult participant. At this stage, the adult participant was only responsible for assembling and affixing the device to the child. This timed task started with the exoskeleton disassembled into its three major components; the hip cradle, and the two legs which are each composed of a thigh and shank subassembly. The hip cradle is attached to the child's

torso first through the torso wings and a series of padded nylon straps. Once the hip is securely positioned, the left and right leg components can be attached to the hip cradle via the hip adaptor plate. The thigh and shank subassemblies can be fixed to the limbs of the child participant through the attached padded straps. All the relevant tools and connectors were given to the participants during the task, and a stool was provided for the child participant to sit on while the exoskeleton was assembled. The timer started when the adult first began handling the exoskeleton components and stopped when the child was able to stand with the exoskeleton properly affixed to their body. The results of this timed task provided insight on the device's ease of use and demonstrated how easy it is for a relatively unexperienced user or clinician to put the exoskeleton on a child participant.

3.2. Six Minute Walk Test

Once the child was wearing the exoskeletal device, they were tasked with walking on an instrumented treadmill for 6 min at a comfortable self-selected speed. An R-Mill instrumented treadmill (Motekforce Link, Amsterdam, The Netherlands) was used for these walking tasks. The treadmill included a parallel bar structure to assist with lateral balance and an optional overhead harness system to safely suspend the participant over the walking surface in the unlikely event of a fall. The experimental setup is shown in Figure 3. After the 6-min walking test, the researchers conducted an inspection of both the device and the child participant while under the parent/guardian's supervision. The purpose of this evaluation was to determine if continued and concurrent motion with the exoskeleton system would introduce any uncomfortable points of contact between the wearer and the device. The walking test also revealed if the exoskeletal frame would sustain any wear or damage during operation that would necessitate hardware adjustments.

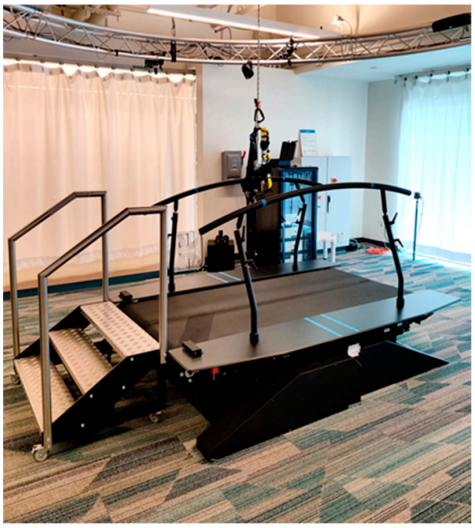

Figure 3. R-Mill instrumented treadmill.

3.3. Exoskeleton Doffing

Following the 6 min walking test, the researchers assisted the child back onto the stool. The adult participant was then tasked with removing the device from the child and disassembling the exoskeleton into its constituent components. This removal process represented another timed section of the experiment and began once the child was seated and the adult participant began to handle the exoskeleton components. The timed task ended once the exoskeleton had been properly disassembled into its three primary components. The results of this timed task demonstrated how easy it is for a relatively unexperienced user or clinician to take the exoskeleton off.

3.4. Exoskeleton Reconfiguration

Finally, the adult participant was tasked with making a configuration adjustment to the exoskeleton system, making the device one size larger in both the hip cradle and thigh length subassemblies. This timed trial served to assess the difficulty in adjusting the exoskeleton between users. The tasks also represented how the device might be adjusted in a clinical setting, or how a primary caregiver might need to make adjustments for a growing user. Before the timer started, researchers demonstrated to the adult participant how to reconfigure the exoskeleton system. An instruction manual with picture references was provided for them to utilize. The adult participant was then given a 30 min practice session. In this instance, the adult participant opted to proceed after practicing for less than five minutes. The timed task began when the adult participant first started their adjustments and ended when the exoskeleton was reconfigured as per the researchers' instructions.

At the end of these assessments, a small questionnaire was administered. This included an adjusted version of the system usability scale (SUS) [34] questionnaire set as well as a few additional questions asking both the adult and child participants their impression and observations about the system. Both participants collaboratively filled out the questionnaire and submitted their responses to the researchers.

4. Results

The volunteer participants were both informed of the motivations and purpose behind the conducted experiments and provided written consent in accordance with the Institutional Review Board at Cleveland State University. Written informed assent was given by the parent/guardian for the child's participation in this study.

The anthropometric parameters of the 11-year-old female volunteer participant were noted. The child volunteer subject weighed 30.8 kg and measured 149 cm in height. The participant's hip breadth was measured at around 23 cm, while the participant's thigh length measured at 36 cm. These parameters were within the exoskeleton's range of adjustment, and the child was capable of fitting comfortably within the exoskeleton after it was adjusted to the closest compatible configuration at 35.8 cm in thigh length and 24 cm in hip breadth. Padding was included at the hips and thighs to increase the child's comfort and ensure that the joint rotation centers of the exoskeleton roughly aligned with those of the child participant's body. Additionally padded straps were added over the shoulders to help keep the hip cradle in place and to prevent the exoskeleton from sliding down during operation. The child participant is shown wearing the exoskeleton in Figure 4.

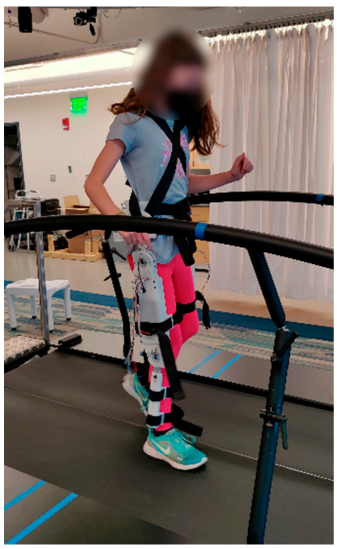

Figure 4. Pediatric participant walking on the instrumented treadmill while wearing the adjustable pediatric exoskeleton.

After the child and adult participants familiarized themselves with the exoskeleton hardware, the human factor assessment began. The amount of time elapsed for each task is shown in Table 1. The timed tasks were further broken down based on how long it took to address the hip cradle and the two different legs.

Table 1. Timed Trial Results.

	Donning (m:ss)	Doffing (m:ss)	Reconfiguration (m:ss)
Full Task Completion	6:08	2:29	8:23
Hip Cradle	0:00–1:20	–	0:00–1:52
Leg 1	1:20–3:15	–	1:52–5:21
Leg 2	3:15–4:45	–	5:21–8:23
Overhead Straps	4:45–6:08	–	**

–: Exoskeleton doffing time could not be split into discrete events. **: Not Applicable.

The child participant fully donned the exoskeleton in 6 min and 8 s without any intervention from the researchers, and they were able to doff the device in 2 min and 29 s. This represents a fast don/doff time considering the user's relative inexperience. Studies with the Indego exoskeleton indicate that after 8 training periods, it takes spinal cord injury (SCI) patients an average of around 9 min and 1 s to don the device, and an average of 2 min and 44 s to doff it [7]. The Ekso Generation 1 exoskeleton reported that SCI users took an average of 5–10 min to don the device, and less than 5 min to doff it after having completed up to 24 separate training sessions [35]. While the use of an able-bodied subject and the assistance of an able-bodied parent or guardian in our validation tests prevents the authors' from making direct comparisons in operative donning and doffing time, these preliminary results suggest that the exoskeleton is easy to use. The exoskeleton reconfiguration test was completed by the parent/guardian after 8 min and 23 s. The researchers did have to clarify for the participant how the locking mechanism of the thigh subassembly worked but did not have to physically intervene during this process. The successful reconfiguration indicates that the adjustment mechanisms for the exoskeleton frame were easy to learn and utilize.

All told, the donning, doffing, and reconfiguration of the exoskeleton amounted to roughly 17 min of elapsed time. While this does represent a significant proportion of the average time allotted for a physical therapy session, the amount of time that a user might spend to accomplish these tasks should be significantly lower. This test represented the first time that either the child or adult participants were exposed to the exoskeleton hardware. In addition, both participants opted to proceed directly into the timed tasks without using most of the allotted time given for training. The pediatric exoskeleton reconfiguration can also be performed prior to the start of the physical therapy session so long as the anthropometric parameters of the subject are measured or known beforehand.

During the 6-min walking test, the child participant initially walked with a rather stilted and unnatural gait. However, as the child developed more confidence in both the treadmill system and exoskeleton, the user eventually returned to what resembled a nominal gait profile. This demonstrated that the exoskeleton allowed for the full range of motion necessary to achieve normal human gait. While some pressure was noted at the hips, no pinch points, high friction contact points, or abrasions were observed due to the fixation of the exoskeleton to the wearer. An inspection of the exoskeleton itself produced no signs of device wear or exoskeleton frame damage.

Following the completion of the previous tasks, the participants filled out a questionnaire form and provided written feedback on the device's performance and their observations. Included in that questionnaire was a lightly adjusted SUS questionnaire, where the statement "I think that I would like to use this system frequently." was omitted and assigned an assumed neutral score. This was done as the participants were able-bodied and thus the question was not meaningfully applicable. The resultant SUS score was

80/100, which places the device in the acceptable range. This indicates that the exoskeleton design is ready for further assessment and use in future assistive control experiments. Outside of the SUS score, other points of feedback included the desire to include more strategic placement of padding to prevent the exoskeleton from resting too much weight on the torso wings. This would prevent the exoskeleton from digging into the hips over time. Recommendations were also made to add more visual indicators to the exoskeleton adjustability mechanisms to help clarify different configuration settings. This would also prevent any ambiguities in whether or not the reconfiguration is being performed properly. Further suggestions were made to increase the rigidity of the hip cradle adjustability mechanism to ease the reconfiguration process. However, based on the feedback given, there was no indication that the exoskeleton developed would require any major design'alterations.

5. Conclusions and Future Work

The adjustable pediatric exoskeleton and the human factor assessment presented in this paper aimed to demonstrate the device was lightweight, comfortable, easy to adjust, and simple to use. The results of the timed trials to don, doff, and adjust the exoskeleton by inexperienced operators demonstrated that the device is simple to understand, adopt and utilize. Clinicians or therapists with experience in using the exoskeleton may operate the system with higher speed and efficiency. The feedback from the walking tests and questionnaire suggests that only minor additions of padding are necessary to correct the minor discomfort that the users reported. The exoskeleton's SUS score indicates that the device is appropriate for further use and experimental evaluations.

Still, improvements can be made to future iterations of the exoskeleton frame. For one, creating faster adjustability mechanisms for the hip cradle and thigh subassembly could further reduce the device reconfiguration time. Future iterations of the adjustable frame should consider reducing the number of screws that the device user has to interface with. Additionally, the original design of the hip cradle rested a significant amount of weight on the user's hips. Future iterations of the hip cradle should consider the inclusion of an upper torso harness or other ways to distribute the device weight over a larger surface area.

Overall, the results yielded from this preliminary human factor assessment confirms that the device is easily adjustability and simple to use while maintaining a lightweight design. Only minor adjustments to padding placement and the inclusion of an overhead harness system were needed to ensure subject comfort while walking with the exoskeleton. The results of this preliminary human factor evaluation on the adjustable pediatric exoskeleton indicate that the device is ready for further device testing. Future evaluations of the exoskeletal device will investigate the ability for the system to provide meaningful gait assistance through exoskeleton gait guidance controllers in treadmill walking experiments.

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Informed Consent Statement: All subjects gave their informed consent for inclusion before they participated in this study. Informed assent was given by child participants and their parent/guardian for participation in this study.

Data Availability Statement: Not Applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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