

Preliminary assessment of a robotic system for overground gait in children with cerebral palsy

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Conflict of interest statement:
The authors declare no conflict of interest.

Abstract

Purpose – Cerebral palsy is one of the leading causes of chronic disability in children. The current pilot study investigated (1) whether an exoskeleton system enables physiological gait patterns and (2) whether the system is user-friendly enough to envision its use in a clinical setting.

Design/methodology/approach – Participants included a convenience sample of six children with cerebral palsy. Following informed consent, study volunteers underwent baseline assessments, participated in eight sessions during which they used the exoskeleton system with the objective of achieving proficiency in use of the system, and underwent an end-of-study assessment of walking. Satisfaction and usability questionnaires were given to the family/caregiver.

Findings – All participants achieved a more regular gait pattern and improved their 6-Minute Walk Test scores. Overall satisfaction and usability were rated as good.

Practical implications – The exoskeleton system enabled physiological gait patterns, and the system was user-friendly enough to envision its use in a clinical setting.

Originality/value – There is potential for guiding treatment plans for individuals with cerebral palsy.

Keywords Cerebral palsy, Robotics, Rehabilitation

Paper type Research paper

Background

Cerebral palsy is one of the leading causes of chronic disability in children (Sah *et al.*, 2019). According to the current definition, cerebral palsy is a group of permanent, but not unchanging, disorders of movement and/or posture and of motor function, which are due to a non-progressive interference, lesion or abnormality of the developing/immature brain (Bax *et al.*, 2005; Cans *et al.*, 2007; Rosenbaum *et al.*, 2007). It is a life-long disorder that requires consistent and ongoing care.

Prevalence estimates of 1.7–3.2 per 1,000 cases have been reported (Gladstone, 2010; McGuire *et al.*, 2019; Oskoui *et al.*, 2013; Patel *et al.*, 2020; Pulgar *et al.*, 2019; Van Naarden Braun *et al.*, 2016), with estimates of 17,000,000 cases worldwide (Graham *et al.*, 2016). Research has shown that Medicaid costs for children with cerebral palsy are significantly higher than costs for all other children in the Medicaid database (e.g. \$22,383 vs \$1,358.) (Pulgar *et al.*, 2019). A recent systematic review of costs of cerebral palsy revealed that lifetime costs in the US are at \$921,000 per person (Shih *et al.*, 2018). In addition to healthcare costs, there are also costs to productivity and social costs (Kruse *et al.*, 2009).

Inadequate physical fitness is a major problem for individuals with cerebral palsy, ultimately impacting their health and function (Fowler *et al.*, 2007). Although there have been a number of

research studies looking at standing and walking after cerebral palsy, more rigorous research is needed to determine mode, intensity, frequency and duration (Fowler *et al.*, 2007). According to Eisenberg *et al.* (2009), standing improves muscle strength and postural control, visual, upper limb and oral motor skills and increases social communication. She also found that standing improved bowel function in her study of children with cerebral palsy exposed to a Hart Walker device. Another study showed that after an 8-week, 60-min, 4–5 time per week standing program, bone mineral density in the patella, tibial plateau and supracondylar femur significantly increased (Stuberg, 1992). Further, Fowler *et al.* (2007) suggested that lack of physical activity can contribute to chronic pain, fatigue and osteoporosis.

Current evidence: Research and clinical use of exoskeletons have increased dramatically in recent years. They have been used to rehabilitate lower extremities including ankles and knees (Bulea *et al.*, 2017; Lerner *et al.*, 2017a; Park *et al.*, 2020; Shideler *et al.*, 2020; Conner and Lerner, 2022; Conner *et al.*, 2020, 2021a), upper extremities including fingers and hands (McCall *et al.*, 2019; Butzer *et al.*, 2019; Dittli *et al.*, 2022; Kuo *et al.*, 2020; Lieber *et al.*, 2022), gross motor ability (Digiacoia *et al.*, 2020; Flores and Da Silva, 2019; Klobucká *et al.*, 2020; Weinberger *et al.*, 2019), spasticity (Cherni *et al.*, 2021), trunk control (Flores and Da Silva, 2019) and most often walking or gait (Attias *et al.*, 2016; Aycardi *et al.*, 2019; Chen *et al.*, 2021; Conner *et al.*, 2021b, 2022; Delgado *et al.*, 2021; Fang and Lerner, 2021; Fang *et al.*, 2022a, b; Harvey *et al.*, 2021; Kawasaki *et al.*, 2020a; Khamar *et al.*, 2022; Kim *et al.*, 2021; Kuroda *et al.*, 2020; Lerner *et al.*, 2016, 2017b, 2018, 2019; Orekhov *et al.*, 2020, 2021; Patane *et al.*, 2017; Rossi *et al.*, 2013; Ueno *et al.*, 2019; Wu *et al.*, 2017). Exoskeletons have been shown to be very effective with minimal adverse events (Bunge *et al.*, 2021). One systematic literature review suggested that, across 17 studies on 15 exoskeletons, gait is improved in individuals with cerebral palsy (Sarajchi *et al.*, 2021). A randomized cross-over control trial showed significant changes in hip flexion and extension angles and limb symmetry in individuals with cerebral palsy with the use of robotic-assisted gait training versus non-assisted gait training. There was also improvement in propulsion force of the affected limb with and after removing the robot, suggesting robot-assisted gait training may be effective for treating longer-term gait performance (Kawasaki *et al.*, 2020b). However, another randomized, parallel-controlled trial found that, while robot-assisted gait training can be safely performed and implemented in an inpatient setting for individuals with cerebral palsy, there were no significant clinically meaningful differences between the intervention and control groups on the primary outcome measure of the 10-meter walk test (Moll *et al.*, 2022).

Gap in the evidence: Does the Trexo Plus exoskeleton system enable physiological gait patterns? Is the system user-friendly to envision its use in the clinical setting?

How does this study fill this evidence gap?: The current pilot study investigated (1) whether the Trexo Plus exoskeleton system enables physiological gait patterns and (2) whether the system is user-friendly enough to envision its use in a clinical setting.

Implication of all the evidence: There is potential for guiding treatment plans for individuals with cerebral palsy.

Methods

Sample

Participants included a convenience sample of six children with cerebral palsy. Age ranges from 3–7 years with an average age of 4.3 years five of the six participants were Caucasian with one Hispanic participant. All were male. All but one caregiver was a mother; while the other was a grandmother with legal custody of the child. To be eligible to participate in the study, individuals met the following criteria: diagnosed with cerebral palsy; gross motor function classification system (GMFCS) levels III or IV; cleared by their treating physician for weight-bearing and use of the device; familiar with the use of a walker; have anthropometric characteristics compatible with the Trexo Plus system as follows (typically 2–10 years of age): Knee to Floor: 8.5" to 11.00"; Hip to

Floor: 17.25" to 21.5"; Maximum Thigh Girth: 16.50"; Maximum Shin Girth: 15.5" and Maximum Weight: 100 lbs. Exclusion criteria included: currently getting intensive gait training intervention; botulinum toxin injection in the lower limbs less than three months prior to enrollment in the study or planned during the duration of the study; major surgical procedures (e.g. selective dorsal rhizotomy) less than three months prior to enrollment in the study or planned during the duration of the study; change in spastic medication less than one month prior to enrollment in the study; uncontrolled seizures; any medical condition preventing active rehabilitation such as thromboembolic disease, progressive neurological disorder, cardiovascular or pulmonary contraindications, aggressive behavior, joint instabilities and compromised bone health, recent or non-consolidated fractures, osteoporosis; severe knee flexion contracture and knee valgus, severe spasticity (modified Ashworth scale score ≥ 3) and uncontrolled movements that interfere with the use of the device and skin lesions affecting the areas where the device straps will be attached to the body.

Equipment

The Trexo Plus (see [Figure 1](#)) is a wearable lower limb robotic device that is attached to a Rifton Pacer Gait Trainer. It allows children of any ability to utilize principles of using a powered lower limb robot to enhance gait training and locomotion training. The exoskeleton provides a highly repetitive and consistent gait pattern. Motors power the device joints at the hip and knee. Range of motion is set and controlled through a tablet interface operated by a Trexo-trained therapist. The exoskeleton allows the therapist to easily adjust gait pattern, speed of steps (cadence), amount of weight bearing and level of support provided. There are two modes: endurance and strength. The tablet allows the therapist to easily monitor the number of steps taken, initiation (whether the child is actively participating), time spent walking and speed of walking. The tablet stored the data by user so we could keep track of the individual participant's progress over the 10-week sessions.

Procedure

All study procedures were carried out in Good Shepherd's Pediatrics Department at the Hyland Center for Health and Technology. Prior to the first visit, we performed a phone screening using a brief questionnaire to determine the eligibility of prospective study volunteers. Individuals were informed that identifiable information could be recorded during the phone screening. If a subject was deemed eligible, identifiable information (e.g. name, how to contact the subject and his/her address) was collected. In addition, we asked the parents/guardians for permission to contact their

Figure 1 Trexo robotic exoskeleton



Source(s): Figure 1 is courtesy of Trexo Robotics

children's treating physician to get clearance for the use of the system. All participants were also reviewed for study participation by our pediatric physiatrist.

Following informed consent, study volunteers underwent baseline assessments (visit #1), participated in eight sessions during which they used the exoskeleton system with the objective of achieving proficiency of use of the system (visits #2–9) and underwent an end-of-study assessment of walking (visit #10). Other measures were collected during the visits (see Table 1). Satisfaction and usability questionnaires were given to the family/caregiver during visit #9 and collected during visits #10. Family/caregiver were also given the option of returning the filled-in questionnaires by email or mail.

During visit #1, we also collected video recordings while subjects ambulated using their own walker. At a later date, video raters examined the video recordings and assessed gait quality using the Edinburgh Visual Gait Score (EVGS) (Abe et al., 2022) scale. The EVGS scale is a reliable and validated tool for assessing gait quality in children with cerebral palsy (Del et al., 2016). The EVGS consists of 17 items to capture the severity of gait deviations. It is worth emphasizing that, as part of the consent process, all subjects were asked permission to be video recorded during the assessments.

Prior to each session, a member of the research team adjusted the mechanical and electronic settings of the system as required to accommodate the characteristics of each study volunteer (i.e. the subject's anthropometric characteristics and RoM at the hip, knee and ankle). The mechanical settings (e.g. length of the robotic exoskeleton segments) were adjusted manually. The electronic settings were adjusted using a tablet equipped with an app developed by the manufacturer of the system for this purpose.

Before positioning the subject in the system, a member of the study team performed a physical examination to check for skin integrity and to assess the subject's ability to proceed with the session. Then, subjects were positioned in the system. Subjects sat on the system's saddle, with their feet elevated above ground. The exoskeleton system was secured to the subject with two clip-in straps on each leg (at the shin and ankle), a chest prompt (if necessary for additional trunk support) and arm prompts if needed.

The system provided vertical support with adjustable weight-bearing support. The height of the frame was adjusted as needed during the session to modify the amount of weight support. The system is equipped with actuators at the hip and knee joints. The actuators were used to achieve a gait pattern with characteristics that were selected using the above-mentioned app on the accompanying tablet. Once subjects were positioned in the system, study staff ran the device in the "air gait" mode (i.e. without foot contact with the ground) to ensure that subjects were

Table 1 Research activities that will take place during each study visit									
	RoM	MAS	Prop	6MWT	EVGS (walker)	EVGS (Trexo)	Rest. HR	HR	Quest
Visit 1	X	X	X	X	X		X	X	
Visit 2						X		X	
Visit 3								X	
Visit 4								X	
Visit 5								X	
Visit 6								X	
Visit 7								X	
Visit 8								X	
Visit 9						X		X	
Visit 10	X	X		X	X		X	X	X
Note(s): RoM = Range of Motion; MAS = Modified Ashworth Scale; Prop = Proprioception; 6MWT = 6-Minute Walk Test; EVGS = Edinburgh Visual Gait Score; HR = Heart Rate and Quest = Quebec User Evaluation with Assistive Technology Source(s): Table by the authors									

comfortable and were properly strapped to the device. Then, study staff lowered the frame until subjects achieved ground contact with their feet. Each session consisted of up to approximately 30 min of walking. During the session, the speed, the level of assistance and the amount of unloading were adjusted as needed to maintain comfort during walking and maintain a physiological gait pattern. Subjects were allowed to take rest breaks if needed.

Gait sessions took place during visits #2 to #9 and were scheduled 2 to 4 times per week. These visits took place over a period of approximately four weeks. Each visit lasted approximately 45 min to 1 h. The gait session of each visit included 10–15 min to set up the system and 20–30 min of active walking. Study staff with clinical backgrounds adjusted the walking cadence to maximize speed without compromising the quality of gait patterns. Cadence ranged between 19 and 65 steps per minute. While subjects began each session with the system set in the “air gait” mode, the amount of unloading was gradually decreased as subjects became comfortable walking with the exoskeleton system. The settings of the system were logged by the app on the accompanying tablet. Also, the system logged the number of steps taken, the total duration of walking measured in minutes, and the cadence (steps/min) during each session.

Results

All participants achieved a more regular gait pattern and improved their 6MWT scores (see [Table 2](#)). To assess if the exoskeleton system facilitated achieving physiological gait patterns during robot-assisted overground walking (Aim 1), we derived descriptive statistics of the EVGS total scores generated via visual inspection of the gait patterns observed while children with cerebral palsy used the system with robotic assistance. In addition, we derived descriptive statistics of the heart rate data collected when children walk using the exoskeleton system. We used the heart rate data as a proxy for the level of exertion associated with the use of the system. No adverse effects or challenges were noted during Trexo sessions.

The parents/caregivers were asked a series of questions regarding usability (see [Table 3](#)). On a five-point Likert-type scale where 1 = Strongly Disagree and 5 = Strongly Agree. With regard to wearing/adjusting the system, the parents generally thought it was simple (mean = 3.7). Comfort

Table 2 Descriptive data

Patient	1	2	3	4	5	6
6MWT session 1 (feet)	0	25	186	352.4	29	20
6MWT session 10 (feet)	4	44	328	399	8	10
EVGS right session 1	8	16	9	19	NO	NO
EVGS right session 10	5	10	NO	10	NO	NO
EVGS left session 1	8	22	16	19	NO	NO
EVGS left session 10	6	16	NO	8	NO	NO
RHR session 1	106	80	80	90	80	78
RHR session 10	96	78	72	114	96	102
Average RHR	88.3	84.3	71.4	107.1	90.3	105
Steps taken session 2	691	507	850	669	738	1,075
Steps taken session 9	794	767	996	1,100	1,053	909
Average steps taken	733.4	811.9	974.1	1,122.6	1,091.6	1,035.6
Duration session 2	26	20	18	21	21	20
Duration session 9	25	22	20	22	30	20
Average duration	25.5	18.7	20.6	22.75	26.8	21.5
Cadence session 2	19	25	50	30	33	52
Cadence session 9	31	32.5	37	47	35	44
Average cadence	28.2	38.2	42.4	48	40.8	46.6

Note(s): 6MWT = 6-Minute Walk Test; EVGS = Edinburgh Visual Gait Score; RHR = Resting Heart Rate and NO = Not Obtained

Source(s): Table by the authors

Table 3 Usability responses

Patient number	1	2	3	4	5	6
<i>GS questionnaire</i>						
1. Wearing/adjusting	4	4	4	1	5	4
2. Comfortable using system	4	5	5	3	5	5
3. Comfortable using in clinic	5	5	5	4	5	5
4. Comfortable using system at home	4	5	4	2	5	5
5. Comfortable using system outdoors	4	5	3	4	5	5
6. Comfortable using system in community	4	5	4	3	4	4
7. Like system	10	9	8	1	10	10
8. Likely to use at home	10	10	8	1	10	10
<i>System usability scale</i>						
1. Use system frequently	5	5	5	1	5	5
2. System complex	1	3	3	5	2	2
3. System easy to use	4	4	3	2	4	4
4. Need support	2	3	5	4	3	2
5. Functions integrated	4	4	3	2	4	4
6. Inconsistency	2	3	3	5	2	2
7. Learn to use system quickly	4	4	3	1	3	3
8. Cumbersome	1	3	3	5	4	2
9. Confident using system	4	4	4	3	5	4
10. Need to learn things before get going	2	3	2	5		4
Source(s): Table by the authors						

level using the system after training was on average 4.5. Comfort level with using the exoskeleton in the clinic was 4.8 while at home it was 4.2. Similarly, comfort levels while using outdoors or in the community were 4.3 and 4, respectively. On a scale of 1–10 with 1 = I don't like at all and 10 = I like it a lot, parents/caregivers rated the exoskeleton an average of 8. Similarly, with 1 = Very Unlikely and 10 = Very Likely, parents/caregivers said they were likely to use the exoskeleton at home (Mean = 8.2).

The System Usability Scale (Bangor *et al.*, 2008) was also administered (see Table 3). Parents/caregivers endorsed that they would use the device frequently (Mean = 4.3). They did not find the system unnecessarily complex (Mean = 2.7) and thought it was easy to use (Mean = 3.5). On average they found the various functions on the exoskeleton were well integrated (Mean = 3.2). They did not think there was too much inconsistency in the system (Mean = 2.8) and thought that most people would learn to use the system very quickly (Mean = 3.0). However, they found the exoskeleton cumbersome to use (Mean = 3). While they felt confident using the exoskeleton (Mean = 4), they felt they needed further training before using the Trexo Plus (Mean = 3.2).

Overall, parents and caregivers were pleased with the results of the exoskeleton. One parent commented, "He tolerates the Trexo so much better than any other walker/gait trainer we've tried." Some suggestions offered by caregivers included increasing efficiency of starting the device, increasing the consistency of the device working (the company updated the system for ease of use several times), making the device affordable or able to be reimbursed through insurance, improving hip stability so less of a sensation to sit (harness rather than a seat) and redesigning the fasteners to be less cumbersome.

Discussion

The benefits of robotic-assisted gait training similar to the Trexo Plus have been well documented. We have been able to demonstrate in this small sample size improvements in gait, strength and endurance. Many qualitative and quantitative improvements were noted by caregivers that were not specifically measured during this study. Marked improvements in core strength and head control have been noted and are worth measuring specifically in future

studies. Families noted improvements in secretion management and increased vocalizations, which is another area that would benefit from more specific measurements. Given the many small areas of improvements in function and interaction within the home after the Trexo Plus trial, future research would benefit from including a quality of life survey before and after the treatment period.

Anecdotal reports from the caregivers of participants and speech-language pathologists treating patients who participated in the study reported changes in breath support, feeding and vocalization. For children classified as GMFCS levels I-III, measurements looking at gait quality and speed, improved physical fitness such as heart rate and blood pressure and measures looking at the child's activity such as self-care and participation such as in sports with peers should also be considered. With regard to children at other GMFCS levels, those at levels I and II would not need this level of assistance, and those at level V have significant physical impairments that may contraindicate device use (e.g. restricted voluntary muscle control; inability to control head and neck positioning).

Our study was limited with a small convenience sample and robust exclusion criteria. Future studies would benefit from a larger randomized sample including patients receiving botulinum toxin injections, as this is a standard of care for spasticity in the majority of individuals with cerebral palsy. Further, studies that compare botulinum toxin plus robotic gait training versus botulinum toxin alone or robotic gait training alone would be extremely helpful in guiding treatment plans for individuals with spastic cerebral palsy. Finally, there is a marked benefit physically for these patients with cerebral palsy getting up and walking with some frequency. There may be benefits comparing pulmonary function/endurance pre- and post-trial to demonstrate the health benefits of increasing weight bearing and ambulation as well.

This pilot study posed a number of challenges, of which the largest was the COVID-19 pandemic. Recruitment for the study started in December 2019 and progressed through August 2021. Recruitment was limited to current client caseloads and digital media advertisements (Facebook, etc.) due to decreased community engagement in local events due to the pandemic. Participants were limited based on the intensity of the study during the school year (requirement for an average of three sessions per week), caregiver's willingness to bring their child into the clinic during COVID-19 surges and strict exclusion criteria of no changes in spasticity management (injections) for three months before the study and other medical procedures.

Although recruitment was a concern during the study, those who used the device were safely treated and satisfied. Future studies should include efficacy, including assessment of trunk control and parent reports of quality of movement, sleep, bowel regimen and sleep hygiene. In addition, future recommendations would include outcome measure selection dependent on GMFCS level.

Lastly, while the current study investigated improvements in gait and endurance, we did not record observations of nor measure the impacts on other aspects of the children's motor skills or activities of daily living. Future investigations should include additional measures of motor skills and impacts on daily activities.

Conclusions

The Trexo Plus exoskeleton system enables physiological gait patterns, and the system is user-friendly enough to envision its use in a clinical setting.

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