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Feasibility of Using Autonomous Ankle Exoskeletons to Augment Community Walking in Cerebral Palsy

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ABSTRACT *Objective:* This pilot study investigated the feasibility and efficacy of using autonomous ankle exoskeletons in community settings among individuals with cerebral palsy (CP). Five participants completed two structured community walking protocols: a week-long ankle exoskeleton acclimation and training intervention, and a dose-matched Sham intervention of unassisted walking. *Results:* Results demonstrated significant improvements in acclimatized walking performance with the ankle exoskeleton, including increased speed and stride length. Participants also reported increased enjoyment and perceived benefits of using the exoskeleton. While ankle exoskeleton training did not lead to significant improvements in unassisted walking, this study demonstrates the feasibility of using ankle exoskeletons in the real world by people with CP. *Conclusions:* This study highlights the potential of wearable exoskeletons to augment community walking performance in CP, laying a foundation for further exploration in real-world environments.

INDEX TERMS Cerebral palsy (CP), exoskeleton, robotic gait intervention.

IMPACT STATEMENT The findings underscore the potential of wearable exoskeletons to improve real-world walking performance for individuals with cerebral palsy, with implications for improving mobility and quality of life in this population.

I. INTRODUCTION

Cerebral palsy (CP) is the most prevalent child-onset movement disorder worldwide [1], [2]. It disrupts neuromotor control and development, leading to slower, metabolically inefficient, and pathological gait [3], [4], [5]. These deficiencies can lead to decreased physical activity, impaired mobility, and a reduced quality of life [2], [6], [7]. To enhance mobility in individuals with CP, researchers and clinicians have developed wearable walking aids, primarily focusing on the ankle due to its pivotal role in efficient walking and the prevalent decrease in neuromuscular function at this joint [3], [8]. Ankle-foot orthoses (AFOs) are commonly prescribed to prevent foot drop, maintain foot clearance, and provide ankle stability [9], [10], [11], [12]. However, AFOs restrict ankle motion, hindering the engagement of plantar flexor muscles and reducing push-off power [9].

Recently, wearable robotic ankle exoskeletons have emerged as an alternative to improve mobility in CP. These devices can improve gait efficiency and endurance by increasing propulsive ankle push-off power, leading to increased stride length and gait speed [13], [14], [15], [16], [17]. These are noteworthy outcomes as ankle joint power, walking speed, and stride length are important contributors to mobility and are lower in individuals with CP [8], [18], [19]. Despite their potential, exoskeletons have been predominantly tested in laboratory or clinical settings under researcher supervision [20]. There is limited evidence regarding their feasibility, enjoyment, or effectiveness in free-living environments such as homes and communities.

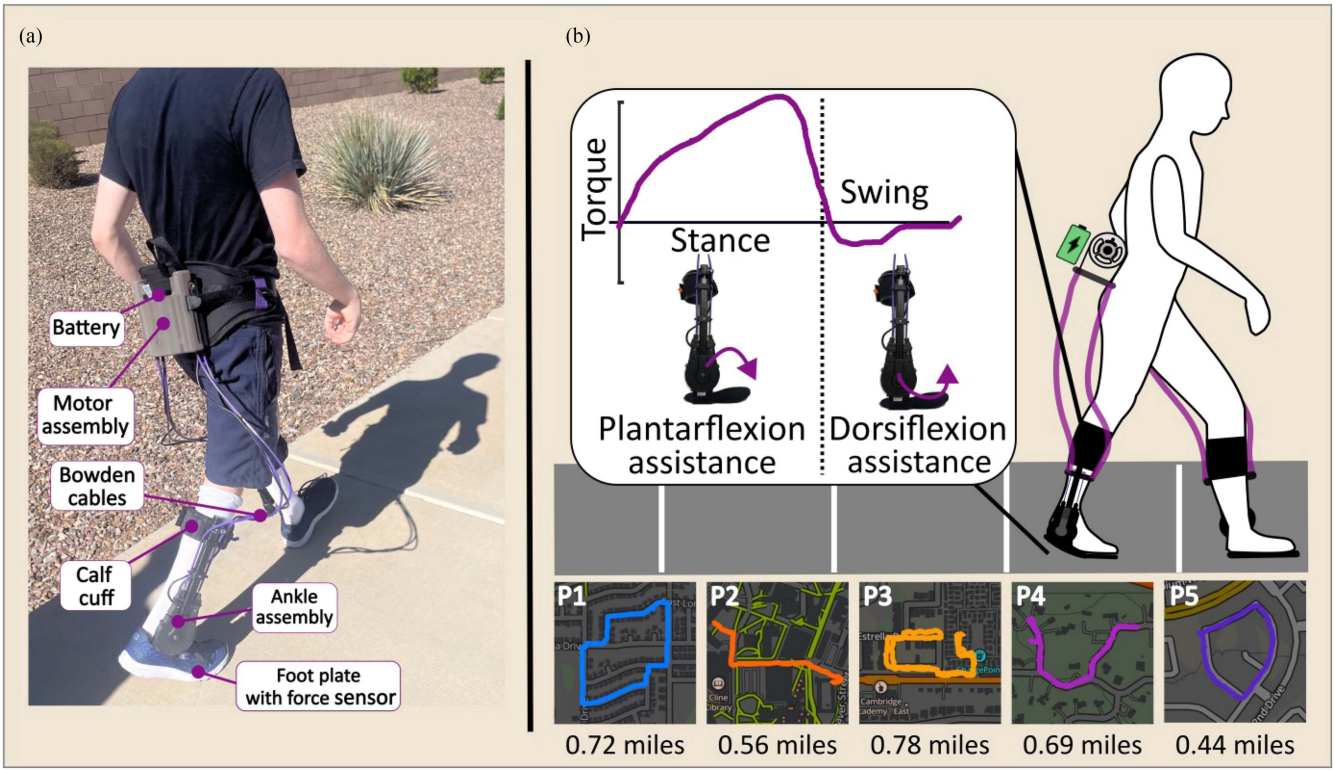

FIGURE 1. **(a) The ankle exoskeleton with its main components labeled. The battery motor assembly and microcontroller are housed in the waist assembly. The device was attached to the user at the shank and delivers assistance ankle torque through the pulley and boden cables which attach to the motors. The force sensors beneath each foot provide input into the system. (b) Top is an illustration of how the ankle exoskeleton proved plantarflexion assistive torque during the stance phase of walking and dorsiflexion assistive torque during the swing phase of walking. Bottom shows the community walking route used for each participant during the assessments and interventions. P$^{\#}$ refers to participants 1–5.**

The purpose of this pilot study was to investigate the feasibility of using autonomous ankle exoskeletons in community settings among individuals with CP. Our primary objective was to explore the potential for a wearable exoskeleton to improve mobility during walking in real-world neighborhood settings (Fig. 1). We hypothesized that (a) participants with CP would be able to don and operate the device without researcher intervention, and (b) walking with the Exo would result in a preferred walking experience and facilitate faster walking with longer and fewer strides when compared to walking without the device. Our secondary objective was to determine if daily self-administered gait training with the Exo would result in improved functional (unassisted) walking performance more than a sham intervention involving equivalent gait training without the device. We hypothesized that community-based Exo training would result in improvements in unassisted walking performance and that the improvements would be greater than those resulting from the Sham intervention. To test our hypotheses, we enrolled 5 individuals with hemi- or diplegic CP between the ages of 14-to-40 years old for participation in our cross-over design study. We block randomized completion of week-long Exo or Sham walking interventions, separated by a ∼1 month wash-out period. For each assessment and training session, participants walked around the same route within their neighborhood community. We conducted pre- and post-walking assessments before and after each intervention.

II. RESULTS

A. EFFECTS OF EXO ASSISTANCE ON WALKING PERFORMANCE

1) PRE-ACCLIMATED EXO WALKING PERFORMANCE

There were no significant differences in walking performance between pre-acclimatized Exo and pre-acclimatized shod walking (Supplemental Material; Table I). However, trends showed a 10% decrease in strides ($p = .051$) and a 9.7% increase in stride length ($p = .057$) with the Exo.

2) ACCLIMATED EXO WALKING PERFORMANCE

Post-acclimation, Exo walking performance improved significantly compared to pre-acclimatized shod walking. Participants took 10.0% fewer strides, had 12.4% longer strides, and completed the walk 18.7% faster ($p = .026$; .029; .042). Walking speed also trended higher, with an 18.8% increase ($p = .056$). Comparing acclimated Exo to acclimated shod walking, participants took 7.5% fewer strides, walked 7.5% faster, and had 11.8% longer strides ($p = .009$; .014; .013; Fig. 2 panel a).

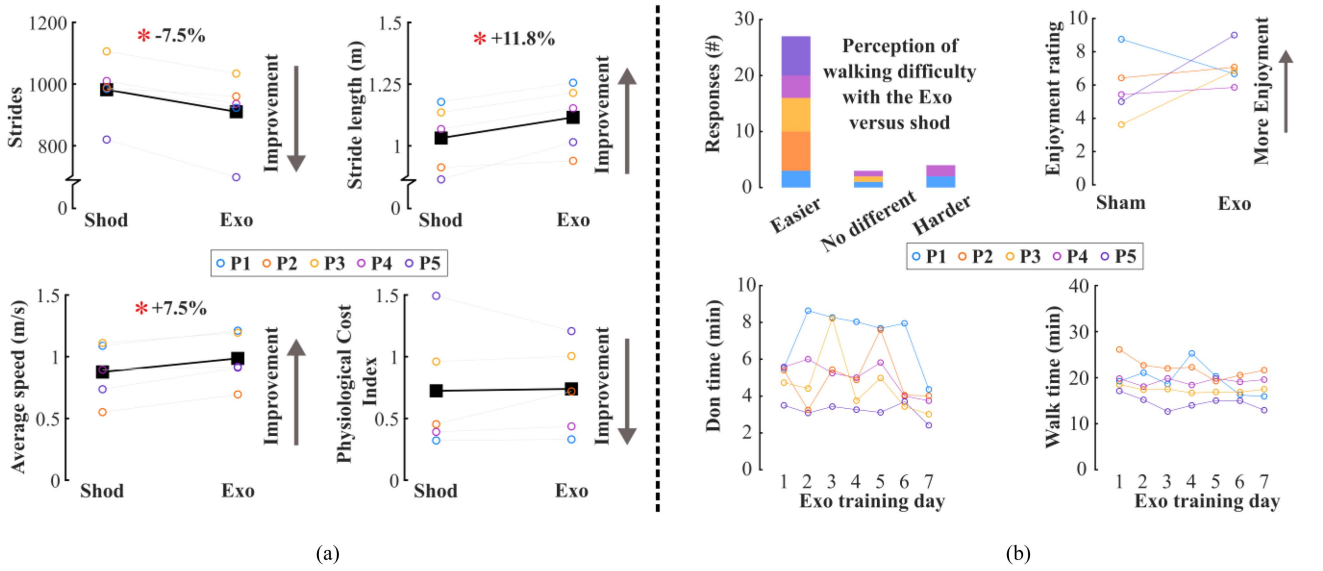

FIGURE 2. **(a) Participants' individual values, displayed with open circles, and group average values, in filled squares, during post-acclimatized shod walking and post-acclimatized exo walking. Exo walking after training resulted in 7.5% fewer strides, 11.8% longer strides, and 7.5% faster walking speed when compared to shod walking after training. ∗ Denotes significant at $p < .05$. (b) Participants' perceived benefit response during ankle exoskeleton (Exo) training (top left). Participants' enjoyment rating during sham and exo training (top right). Time of exo don time (bottom left) and walking time (bottom right) during the Exo training intervention.**

B. EFFECTS OF THE EXO TRAINING INTERVENTION

1) EXO TRAINING INTERVENTION EFFECTS ON EXO WALKING

After the Exo intervention, Exo walking speed increased by 10.6% ($p = .030$), and walking time decreased by 12.8% ($p = .036$). (Supplemental Material; Table II).

2) EXO AND SHAM INTERVENTION EFFECTS ON SHOD WALKING

Unassisted walking performance remained unchanged after both the Exo and Sham interventions (Supplemental Material; Table II).

C. FEASIBILITY

Donning the device took an average of 5.02 ± 1.21 minutes, and participants walked for about 18.70 ± 1.72 minutes during Exo training and 19.99 ± 1.52 minutes during Sham training. Enjoyment was 18.5% higher during Exo training (6.98 ± 1.5) compared to Sham training (5.85 ± 0.66). Participants felt the Exo made walking easier 77% of the time, harder 14%, and no different 8% (Fig. 2 panel b). The system usability scale (SUS) [21] score averaged 77.6 ± 22.7, with three participants scoring 90 or higher and one scoring 37.5. No falls were reported during the study.

III. DISCUSSION

The purpose of this pilot study was to investigate the performance and feasibility of using an ankle exoskeleton to improve walking performance in free-living community settings among individuals with CP. In support of our primary hypothesis, participants demonstrated improved walking performance with the Exo, having faster speeds and longer strides compared to walking shod. Further, Exo walking performance improved after the acclimation period. We also found favorable usability outcomes as assessed through participant enjoyment, donning time, and perceived benefit. Contrary to our secondary hypothesis, one week of community-based Exo training did not lead to significant improvements in shod walking performance.

To our knowledge, this is the first study to explore the autonomous use of a powered ankle exoskeleton in the community by individuals with CP. We chose daily Exo use to simulate habitual usage, and the one-week duration was dictated by practical considerations. (device sharing, family commitment, etc.) for a first-of-its-kind feasibility study. With these promising results, we plan to conduct studies of much longer duration (e.g., months).

As indicated by a recent review, previous studies have investigated the potential of wearable exoskeletons for gait training among a variety of patient populations [21]. However, only 3 of the 87 studies included in the review tested wearable exoskeletons among people with CP [22], [23], [24] and only one of the 87 tested was conducted outside a laboratory environment [25]. This highlights the importance of work in conducting real-world, cognitively engaging training environments, which is believed to lead to improved outcomes in motor rehabilitation [26], [27].

A. PERFORMANCE DURING EXO WALKING

Walking performance improved with the Exo compared to shod following acclimation. Participants walked faster and

with fewer and longer strides. This increase in speed is clinically relevant, as individuals with CP typically walk slower than non-disable peers [28], [29], and walking speed has been correlated with physical function and other cognitive and social status among individuals with CP [30]. We observed these improvements after only one week of acclimation, and we suspect further improvements with additional use. Participants expended the same energy (PCI) in Exo and shod walking, indicating they used the Exo to walk faster without extra effort instead of walking at the same speed with lower energy.

B. CHANGES IN UNASSISTED WALKING

Contrary to our hypothesis, and other evidence in the literature from controlled laboratory settings, unassisted (shod) walking performance did not improve after Exo training. A recent case study found 12 robot-assisted gait training sessions over 4 weeks to improve walking speed by 33% and step length by 13.2% among individuals with CP [24]. While the length of the training session was comparable between that study and ours, the number of sessions in that study was about 66% more than in our study. Utilizing more training sessions in our study design may have resulted in significant improvements in unassisted walking performance. It was reassuring, however, that Exo training did not hinder the shod walking performance of the participants, indicating device dependence. This may be related to how our device was controlled, requiring users to voluntarily initiate the walking pattern, and only then will the Exo assist. Other systems that passively move individuals' lower limbs through predetermined kinematic patterns of gait do not require user effort and therefore may weaken motor learning and muscle recruitment [32].

C. DEVICE FEASIBILITY AND PERCEPTIONS

User perception of usability and benefit is critical to the adoption of mobility and rehabilitation solutions. We assessed device usability using the SUS questionnaire. The average rating was 77.6/100. For comparison, individuals with spinal cord injuries scored the commercially-available ReWalk Personal 6.0, a hip and knee-powered device, a 72.5 on the SUS after a 2–3-week intervention [33]. While one participant in our study did not find our device to be very useable, providing a score of 37.5, the remaining participants found our device to be more user-friendly (ratings of 67.5–97.5). User feedback indicated a desire for improvements to the mobile app, a "headless" operation mode, a pause feature, and an improved waist belt adjustor for easier donning.

Further, participants typically found walking with the Exo to be more enjoyable than walking without the device, as evidenced by an average enjoyment level of 6.98/10 during the Exo intervention compared to 5.85/10 during the Sham intervention. Participants also overwhelmingly perceived that the Exo device made walking easier. This would likely be a positive factor influencing the compliance of at-home- or community-based gait training, which would be a noteworthy feature of having a wearable exoskeleton in the home.

D. LIMITATIONS

Carefully thought about the design of this community-based feasibility study was essential to ensure feasibility and meaningful results. This pilot study was intended to demonstrate feasibility before investing in a larger sample size and a longer duration invention. Similar to other first-of-their-kind multi-visit studies in CP [34], [35], this study involved a relatively small sample size (six enrolled, five completing the protocol). As such, we encourage cautious interpretation of our results given the small sample size. While efforts were made to ensure diversity in participant characteristics, including age, gender, and CP severity, the generalizability of the findings may be limited. Further, a longer intervention period may provide a more comprehensive understanding of the long-term effects. Still, the intervention used in this study was long enough to observe a significant difference in Exo walking versus shod walking. Additionally, our focus was primarily on objective walking measures. Including metrics like muscle activation and energy expenditure in future studies could provide a more comprehensive assessment of Exo efficacy.

E. CONCLUSION

Our findings suggest that the Exo can improve aspects of community walking performance compared to unassisted walking, particularly walking speed and stride length. However, contrary to expectations, Exo training did not lead to significant improvements in unassisted walking performance. Nevertheless, the feasibility of ankle exoskeleton use in community settings was evident, as indicated by participant enjoyment, donning time, and perceived benefits. Importantly, this study contributes to the limited body of research on the use of powered exoskeletons in the real world for individuals with CP. Enhancements to the device's usability, as suggested by participant feedback, hold promise for improving overall user experience and compliance with gait training.

IV. MATERIALS AND METHODS

The Northern Arizona University Institutional Review Board approved the study protocol (#2137424). We registered this study at ClinicalTrials.gov (NCT06244901). Inclusion criteria included a diagnosis of hemi- or diplegic CP, the ability to walk with the device without knee hyperextension, the ability to walk for at least 20 minutes, and a Gross Motor Function Classification System level I–III. We excluded participants who had orthopedic surgery within six months of participation or who had the presence of any condition(s) that would preclude safe participation. Adult participants provided written consent. Minors provided verbal and written consent alongside written consent from a parent. Five participants with CP completed the study (Table 1). A sixth male participant enrolled but was unable to complete the protocol due to a device malfunction.

The ankle exoskeleton device [16], [36] used in this study was designed and developed in our lab, and manufactured by a spin-off company (Biomotum, Portland, USA). The device

TABLE 1. Participant Demographics

ID	Age (yr.)	Height (cm)	Weight (kg)	Sex	GMFCS	Order of Intervention
P1	40	180	73	M	II	Exo; Sham
P2	30	155	62	F	III	Sham; Exo
P3	14	149	47	M	II	Sham; Exo
P4	22	152	19	F	III	Exo; Sham
P5	18	170	57	M	II	Sham; Exo

GMFS; Gross motor function classification system score,
Exo; ankle exoskeleton

provided assistive ankle torque during the stance and swing phase of walking (Fig. 1). During stance phase, we used a proportional joint moment controller to provide instantaneously adaptive torque [36], [37]. More details can be found in the supplementary materials.

A. EXPERIMENTAL PROCEDURE

We traveled to each participant's home after their enrollment where we obtained informed consent and measured a walking route based on each participant's walking ability and availability around the home and community. We targeted approximately 20 minutes for each participant to complete their route at their self-selected comfortable pace and participants used this route for all walking trials. Participants were then enrolled in both the Exo training and Sham intervention using block randomization (Fig. 3). The study implemented a washout period (∼one month) between the interventions to mitigate the order effect. We conducted the pre and post-walking assessments before and after each intervention. More details about the assessments are in the supplemental materials.

During the Exo training intervention, participants walked once per day for 6–7 days with the exoskeleton, recording their session details in an Exo training log (Supplemental Material; Table III) after each training walk. For the Sham intervention, participants walked without the device for 6–7 days and completed a post-Sham questionnaire (Supplemental Material; Table IV).

B. DEVICE FAMILIARIZATION

We trained participants and their families on device use, troubleshooting, and maintenance during the first home visit. These procedures were also provided to the participants by way of a simple operating manual. Once trained, participants independently donned, powered on, and operated the device without any verbal or physical assistance for any subsequent trial or evaluation. Assistance from a parent or living partner was allowed (e.g., tying shoes or fastening the waist belt). Once the device was operating, the participant performed a short walk, about 5 minutes, to determine the participant-specific level of assistance. This level of assistance was tuned by the researcher and based on the participant's preference, feedback, and gross walking performance. For example, if

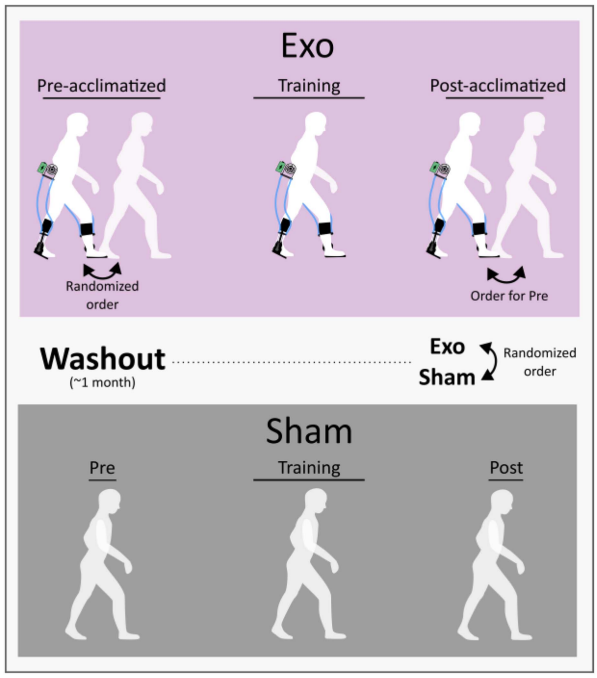

FIGURE 3. A depiction of the experimental protocol. Participants were enrolled by way of block randomization into the ankle exoskeleton (Exo) intervention and the Sham intervention with a washout period in between. Walking assessments were conducted before and after each intervention. During the intervention, the participants trained daily by walking in an outdoor neighborhood setting following a set route. Each intervention lasted for ∼ one week. The participants walked with the device during the exo intervention, and without the device during the Sham intervention. For the Exo walking assessments, the order of condition, exo or shod, was block randomized during the pre-acclimated walking assessment and kept the same for the post acclimatized walking assessment between each participant. During the Exo intervention, participants trained for 6–7 days with the Exo. During the Sham intervention, participants walked 6–7 days without the exo. The order of the interventions was block randomized.

the participant indicated that they thought the level of assistance was too high, which led to discomfort and an unsteady pattern of gait, the level of assistance was decreased and again evaluated. If the participant and researcher could not perceive or visualize a measurable benefit from the device, the researcher would increase the level of assistance and evaluate again. Participant-specific level of assistance is provided in the Supplemental Material, Table V.

C. PRE AND POST WALKING ASSESSMENTS

1) EXO ASSESSMENTS

The Exo walking assessments were used to quantify participants' community walking mobility with and without Exo assistance and the feasibility of using the device at home. Pre-acclimatized shod and Exo walks were performed before Exo training, and post-acclimatized walks were done after training. The walks were block-randomized between participants and performed on the predetermined walking route. Sufficient rest, lasting at least 20 minutes, was provided between each walk. Participants were also permitted to take a break during the walk for fatigue, if necessary, which was included in the

walking time. Participants completed the system usability scale [20] to quantify their perception of the usability of the device on a scale of 0–100 after the Exo training intervention.

2) SHAM ASSESSMENT

The Sham walking assessment was used to determine if potential unassisted walking improvement after the Exo intervention would be greater than following a matched amount of unassisted structured daily walking. Before and after the Sham intervention, participants completed one walk without the Exo (pre/post-Sham shod walking assessment).

D. DATA AND STATISTICAL ANALYSES

The primary performance outcome variables of interest included stride count, stride length, walking speed, elapsed walking time, and physiological cost index (PCI) [38] during the pre and post-walking assessments. Stride length was calculated by dividing the distance of the walking route, determined by GPS, by the number of strides. We calculated walking speed as the walking route distance divided by walking time. Physiological cost index is calculated as working heart rate subtracted by resting heart rate which is then divided by walking speed. Heart rate was measured using a pulse oximeter. We used two-tailed paired-sample t-tests to determine if differences in mean outcome variables between the interventions and between pre and post-walking assessments were statistically significant; the alpha level was set to 0.05.

1) WALKING PERFORMANCE COMPARISONS WITH THE EXO

We performed several a priori comparisons when assessing the effectiveness of the Exo. To determine if the Exo provided immediate improvements in walking performance, we compared pre-acclimatized shod and Exo walking assessments. To determine acclimated effects, we compared post-acclimatized shod and Exo walking assessments. This within-assessment comparison was used to minimize potential differences across assessments (e.g., weather, participant fatigue, etc.). We also compared pre-acclimatized shod and post-acclimatized Exo walking assessments because there was a potential training effect on the shod condition. Theoretically, the participants could have improved their baseline walking performance over the weeklong study.

2) EFFECTS OF GAIT TRAINING

To determine if acclimation to the Exo improved walking performance when using the Exo, we analyzed performance differences between pre-and post-acclimatized Exo walks. To determine if Exo training led to improvements in unassisted (i.e., normal) walking, we analyzed performance differences between pre- and post-acclimatized shod walks. We also compared post-acclimatized shod and post-Sham shod walks to determine the intervention's impact.

E. FEASIBILITY

To evaluate the feasibility and perceptions of using the Exo at home and in the community, we measured enjoyment levels during the two training interventions (Exo and Sham). We also recorded participants' perceived benefit, donning operation time, walk time, and SUS score when using the Exo after the Exo intervention. P1 was unable to receive their usual donning assistance on Exo training day five, thus the donning time (34.8 minutes), walk time (25.4 minutes), enjoyment rating (2), and perceived benefit (harder) were removed.

SUPPLEMENTARY MATERIALS

Supplementary Materials are available for download and include details about the ankle exoskeleton used for this study and more details about the ankle exoskeleton and Sham training intervention used in this study. Supplemental tables which contain the results of the statistical are also included.

CONFLICT OF INTEREST

ZL is a co-founder with shareholder interest in Biomotum, Inc., a spinoff company from his laboratory that is seeking to commercialize the device used in this study. He also has intellectual property inventorship rights covering aspects of the design and control of the device used in this study.

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