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The effectiveness of a passive hip exoskeleton in improving walking ability during the rehabilitation of patients with neurological conditions

Sara Liguori[1,2], Claudio Semplicini[3], Adriana Gerardi[4], Giuseppe Marcolin[5], Fausto Antonio Panizzolo[3], Francesca Gimigliano[2]

[1]Department of Medical and Surgical Specialties and Dentistry, University of Campania Luigi Vanvitelli, Naples, Italy
[2]Department of Mental and Physical Health and Preventive Medicine, University of Campania Luigi Vanvitelli, Naples, Italy
[3]Moveo Srl, None, Padova, Italy
[4]Synlab Cemes, None, Padova, Italy
[5]Department of Biomedical Sciences, University of Padova, Padova, Italy

Abstract

Objectives: This study aims to evaluate the effectiveness of the ExoBand, a passive hip orthosis, in improving walking speed as part of a rehabilitation program for patients with neurological gait impairments.

Patients and methods: Between March 2022 and December 2022, a total of 25 adults with chronic neurological diseases affecting gait were included. The patients were assigned to either the intervention group (n = 13, Group A), who trained with the ExoBand, or the control group (n = 12, Group B). Both groups underwent 10 rehabilitation sessions over two or three weeks, including gait training on a treadmill and functional exercises. Gait speed was assessed pre- (T0) and post-intervention (T1) using the Walker View system.

Results: Of a total of 25 patients included in the study, 12 were male and 13 were female. The mean age was 57.2 ± 12.6 years in Group A and 56.1 ± 12.1 years in Group B, indicating no significant difference ($p = 0.8$). Both groups showed significant improvements in gait speed; however, the intervention group demonstrated a significantly greater increase (+14.2% *vs.* +8.6%, $p < 0.05$). No adverse events were reported. Additionally, 77% of ExoBand users expressed willingness to use it daily, while 100% would recommend it to other individuals.

Conclusion: The present study provides preliminary evidence supporting the use of the soft exoskeleton ExoBand as a potential effective rehabilitation tool for individuals with neurological disorders affecting gait. Our findings demonstrate that incorporating the ExoBand into a structured rehabilitation program leads to notable improvements in walking speed, aligning with the minimal clinically important difference for functional mobility enhancement. These results highlight the potential of passive wearable hip orthoses as a cost-effective and accessible alternative to more complex robotic-assisted gait rehabilitation methods.

Keywords: Exoskeleton, gait, neurological disorder, orthosis, rehabilitation.

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Correspondence: Sara Liguori, MD. Department of Medical and Surgical Specialties and Dentistry, University of Campania Luigi Vanvitelli, Naples, 80138 Italy.

E-mail: sara.liguori@unicampania.it

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Neurological disorders, which encompass a range of conditions such as cerebrovascular accidents, neurodegenerative diseases, and autoimmune diseases, are significant contributors to global morbidity, disability, and mortality rates.[1] Among the various complications associated with these disorders, gait disturbances are particularly prevalent. These impairments not only increase the risk of falls, but also adversely affect individuals' physical and mental well-being, ultimately reducing overall independence.[1]

The wide range of gait abnormalities, including hemiplegic, spastic diplegic, neuropathic, myopathic, Parkinsonian, choreiform, ataxic (cerebellar), and sensory gaits, highlights the necessity for accurate walking evaluation and tailored rehabilitation strategies.[2] In terms of impairment, the involvement of proximal hip muscle strength in walking has been commonly observed in several neurological disorders. To illustrate, in individuals with mild Parkinson's disease (PD), hip muscle weakness and bradykinesia significantly affect walking speed primarily over longer distances.[3] Similarly, in those with multiple sclerosis (MS), hip flexor muscle weakness is commonly observed in those with more severe mobility impairments.[4] Engaging these muscles in regular exercise has been shown to enhance daily activity, cardiovascular fitness, muscle strength, and reduce fatigue in individuals with MS.[5] In this context, technology has played a pivotal role, in developing wearable devices designed to assist individuals with mobility and support locomotion rehabilitation. Lower limb exoskeletons are emerging as a revolutionary technology for robotic gait rehabilitation, demonstrating significant potential for improving gait function.[6-9] Active exoskeletons are showing promising results in gait rehabilitation by providing dynamic walking assistance. While these devices offer greater support, they tend to be more complex and costly.[10] In contrast, passive exoskeleton systems are simpler and more affordable, but provide lower levels of assistance. Among passive devices, hip exoskeletons have shown effectiveness in reducing the energy cost of walking in healthy elders and in improving walking distance in individuals with neurological diseases in non-rehabilitative setting.[11,12]

In the light of these findings, passive hip orthoses may be a promising new wearable lower limb exoskeleton for gait rehabilitation. In the present study, we aimed to evaluate the effectiveness of passive hip orthoses in improving walking speed as a rehabilitation device for individuals with neurological disorders and gait disturbances.

PATIENTS AND METHODS

This quasi-experimental study was conducted at the Rehabilitation Center (CEMES, Synlab) and the Department of Physical and Rehabilitation Medicine at the University Hospital "Luigi Vanvitelli" between March 2022 and December 2022. The study was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.[13] Consecutive individuals older than 18 years old with neurological disease and presenting walking impairment, referring to a rehabilitation center (CEMES, Synlab, Padova, IT) where ExoBand (Moveo, Padova, Italy) is in use as the standard of care for walking rehabilitation were screened. Inclusion criteria were as follows: patients diagnosed with neurological disease in a chronic stage; gait abnormalities clinically defined (waddling gait, instability, fatigability) or proximal muscle weakness (4+/5 on hip flexion or below measured with manual muscle testing scored with Medical Research Council [MRC] scale); being able to walk at least 10 m; not having received any training sessions in the previous three months; who have never used the device before. Exclusion criteria were as follows: those with severe cognitive impairment, other factors modifying the clinical course during the treatment period or in the previous three months (e.g., treatment changes or concomitant illnesses). Finally, a total of 25 adults diagnosed with neurological disorders impairing gait function, including PD (n = 4), MS (n = 10), and post-stroke conditions (n = 11) were included. A written informed consent was obtained from each patient. The study protocol was approved by the University of Campania "Luigi Vanvitelli" Ethics Committee

(Date: 31.03.2022, No: 0021756/2022). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Intervention

The patients were consecutively assigned either to the intervention (n = 13, Group A) or the control group (n = 12, Group B). Both groups underwent 10 training sessions, conducted over a period of two to three weeks, following the standard of care of rehabilitation programs for each individual and pathology.

Every training session lasted 60 min followed a standardized two-part structure. The first part included a gait training (20 min) on a treadmill (Walker View system, TecnoBody, Bergamo, Italy). All patients walked at a constant speed determined during an initial familiarization session. The second part provided a personalized program (40 min) including passive and active stretching, joint mobilization, strengthening exercises, and balance training on unstable surfaces. Specific attention was given to heel-toe exercises and lengthening the posterior kinetic chain to improve motor control. During the gait training session subjects were asked to walk for 20 min on the treadmill at the speed identified in the first session of familiarization, and only group A participants were requested to wear the soft exoskeleton ExoBand. The ExoBand functions as a passive wearable apparatus, operating as a walking brace (Figure 1); it is engineered with a mechanism designed to store energy generated during the initial phase of the gait cycle, subsequently releasing it in the following phase. This mechanism augments hip flexor thrust, thereby resulting in an enhancement of functional walking.

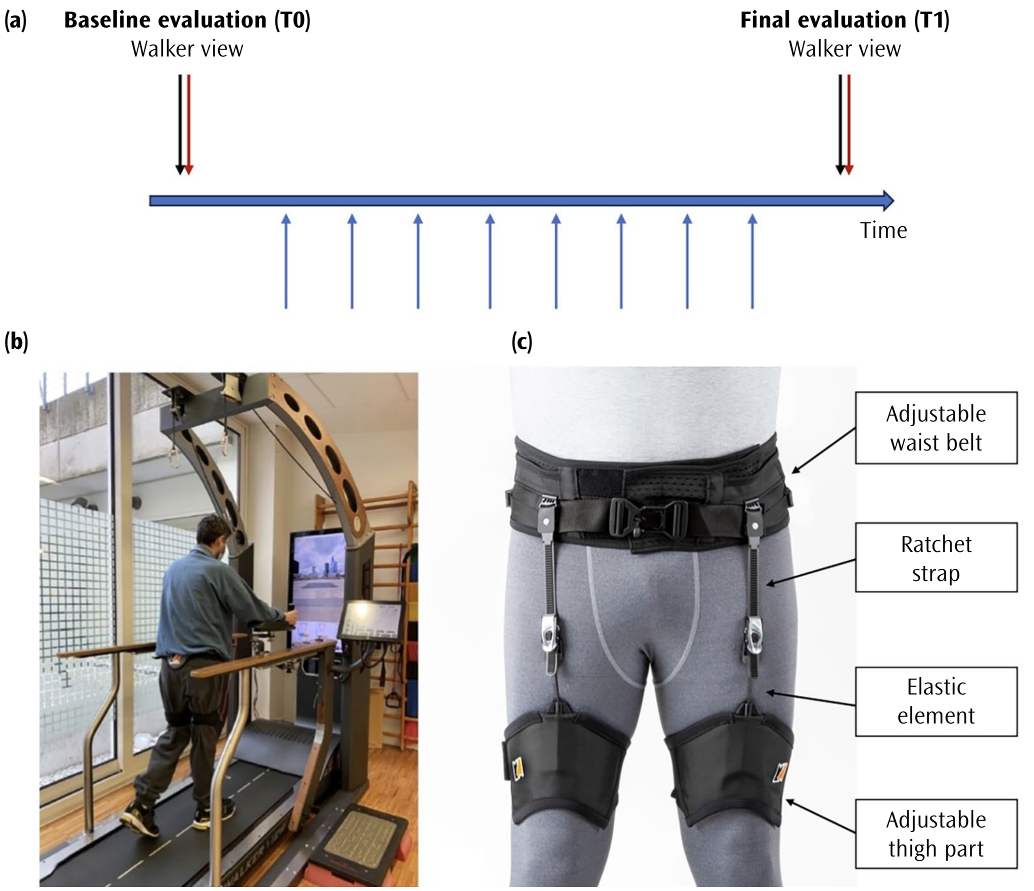

Figure 1. (a) Graphical synthesis of the study protocol; **(b)** Treadmill used for the gait training; **(c)** Biomechanical components and structural description of the passive hip orthosis.

Table 1. Population characteristics, demographic, clinical conditions, baseline preferred speed

	Intervention group		Control group		
	n	Mean ± SD	n	Mean ± SD	*p*
Age (years)		57.2 ± 12.6		56.1 ± 12.1	> 0.05
Height (cm)		169.5 ± 9.7		169.1 ± 6.6	> 0.05
Weight (kg)		72.5 1 ± 5.0		67.8 ± 12.4	> 0.05
Preferred baseline walking speed (m/s)		0.71 ± 0.20		0.61 ± 0.20	> 0.05
Disease					
Stroke	6		5		
PD	3		1		
MS	4		6		
Walking aids					
None	9		9		
Cane	3		1		
Rollator	1		2		

SD, standard deviation; PD, Parkinson's disease; MS, multiple sclerosis.

Each individual program was set up by a qualified physiotherapist, according to good clinical practice and standard of care.

Outcomes

Demographic, anthropometric and clinical data were collected. At the baseline (T0) and at the end of treatment (T1), gait speed was evaluated through Walker View system. At the end of the rehabilitation program, the participants trained with ExoBand were given a questionnaire, asking whether they would use the ExoBand in daily life and whether they would recommend the device to other individuals (closed-ended question: Yes/No/It depends).

Statistical analysis

Study power analysis and sample size calculation were performed using the G*Power version 3.1.9.2 software (Heinrich Heine University Düsseldorf, Düsseldorf, Germany). Accordingly, a total of 24 participants were required for the study with a study power of 80%.

Statistical analysis was performed using the JASP version 0.18.3.0 software (JASP Team, Amsterdam, The Netherlands). Normality of distribution of variables was checked using the Shapiro-Wilk test, while the equality of variances for walking speeds was confirmed via the Levene's test. A 2 × 2 repeated measures analysis of variance (ANOVA) was used to assess the effects of the treatment (within-subjects factor: T0 *vs.* T1), the differences between groups (between-subjects factor: Group A *vs.* Group B), and the significance of their interaction. The independent samples t-test was conducted to compare the relative percentage increase in walking speed between the two groups. A *p* value of < 0.05 was considered statistically significant.

RESULTS

Of a total of 25 patients included in the study, 12 were male and 13 were female. The mean age was 57.2 ± 12.6 years in Group A and 56.1 ± 12.1 years in Group B, indicating no significant difference ($p = 0.8$) (Table 1).

The beneficial effects of training sessions on gait characteristics were confirmed in both groups, as demonstrated by a significant increase in walking speed at the conclusion of the training period, (0.71 to 0.81 m/sec in Group A, from 0.55 to 0.61 m/sec in Group B, $p < 0.05$) (Figure 2a, b). The increase was significantly higher in subjects trained with ExoBand (+14.2% *vs.* +8.6%, $p < 0.05$, Figure 2c). No adverse events derived using the ExoBand were reported.

The intervention group was also asked to rate the ExoBand by answering three Yes/No questions. A total of 77% of them would wear the device in their daily activity outside the rehabilitation context, 61% found it easy to wear unaided, and 100% would recommend the device to other individuals with gait disorders (Figure 3).

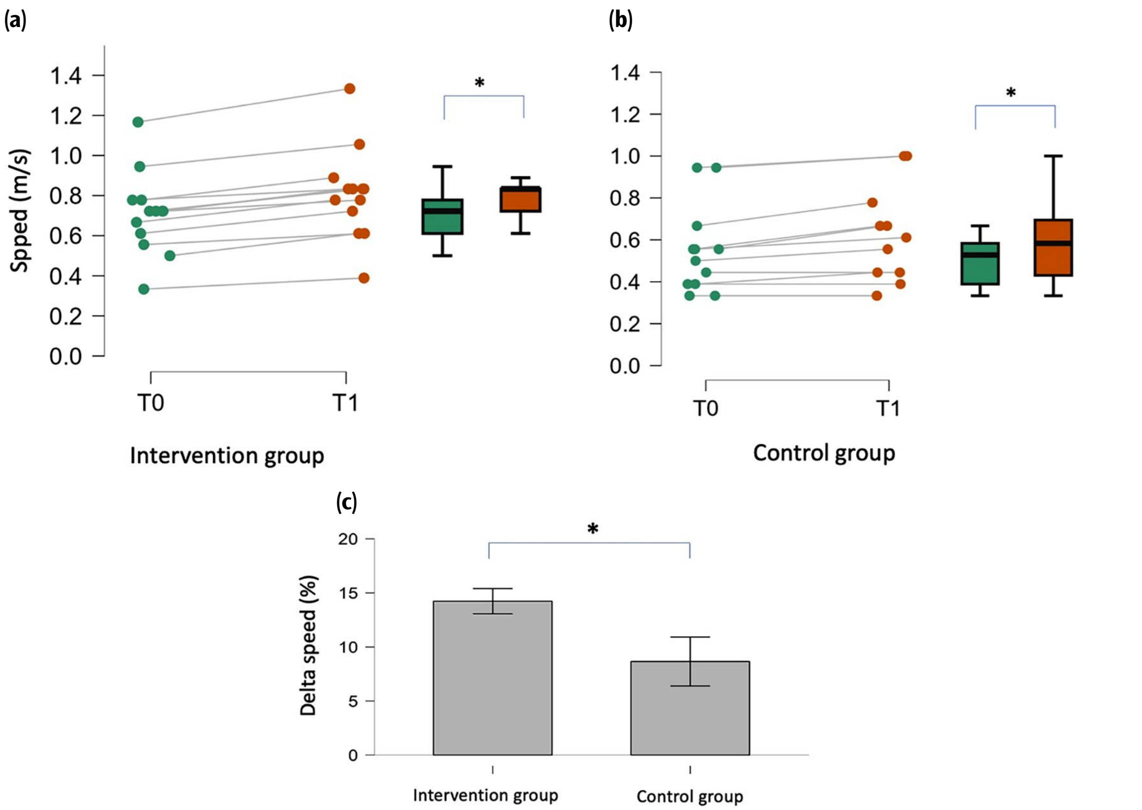

Figure 2. Changes in walking speed following the gait training program in **(a)** Group A, **(b)** Group B and **(c)** Delta speed among groups.

DISCUSSION

In the present study, we evaluated the effectiveness of passive hip orthoses in improving walking speed as a rehabilitation device for individuals with neurological disorders and gait disturbances. Our study results suggest the potential of a specific type of external support, namely the soft exoskeleton ExoBand, as a promising instrument for gait rehabilitation in individuals suffering from neurological diseases. The device, which is currently deployed in various centers as a rehabilitation tool, has already been proven to diminish the energy expenditure in elderly and to ameliorate gait characteristics in individuals affected by different neurological disorders.[11,12]

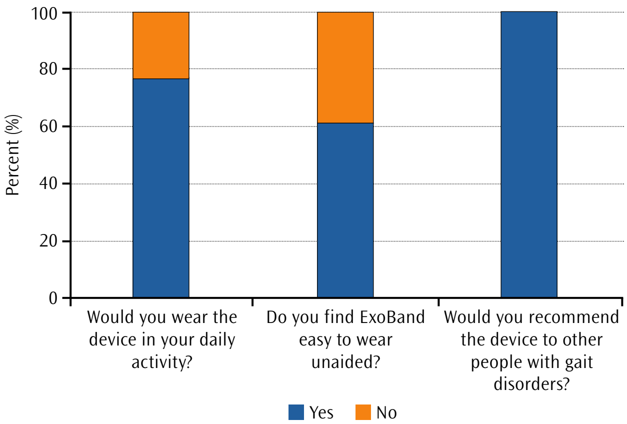

Figure 3. Patient satisfaction and usability assessment of the passive exoskeleton.

In the current study, we observed a positive trend of ExoBand within a tailored rehabilitation protocol on individuals with neurological diseases impairing their walking capabilities. The observed enhancement in gait speed, achieved after the training sessions in intervention group (+0.1 m/sec) aligns with the minimal clinically significant difference (0.1-0.2 m/sec).[14] These results are in line with prior research conducted with an earlier version of the device in a similar neurological cohort,[12] and are supported by a control group.

The device has also demonstrated its ability to store energy during the initial phase of the gait cycle and release it in the subsequent phase, thus facilitating hip propulsion and reducing the fatigue perceived by patients.

Walking speed is a valuable indicator for monitoring progress and health across diverse populations, as it reflects overall well-being and the ability to perform daily activities. This measure serves as an essential tool for assessing both general health and functional capabilities.[15] The present study indicates the feasibility of a passive hip wearable device in enhancing gait performance among older adults afflicted with neurological diseases, specifically in terms of improved speed. This achievement stands out as one of the most significant results observed for this specific metric with this device, comparable to those achieved by more advanced exoskeletons.[16] However, while interventions like robot-assisted gait training (RAGT) rely on a rigid structure capable of supporting the individual's weight and providing substantial assistance, such an approach may not always be necessary to restore normal gait function in individuals who retain the ability to walk after a neurological injury, such as those with mild MS or PD. In this context, preliminary evidence suggests that the ExoBand intervention is perceived favorably by individuals and may contribute to meaningful improvements in their mobility management in a more lightweight and cost-effective manner.[17] One of the key strengths of this device is its flexible structure, which does not restrict the wearer's mobility. It enhances comfort, helps reduce metabolic cost, and makes it easier to put on and take off. Its low-profile design makes it suitable for daily use, contributing to improvements in gait balance, functional mobility, and gait parameters. Additionally, it promotes social participation, increases trunk stability, and reduces the risk of falls in individuals with neurological diseases and mild disabilities.[18] Another important aspect is the safety and acceptability of the device. Similarly, no adverse events related to the use of ExoBand were reported in our study, confirming its clinical safety. The high acceptability and ease of use of the device represent crucial factors in promoting adherence to long-term rehabilitation programs.

The psychological aspect is also significant, encompassing both the increase in self-sufficiency and improved motor abilities, as well as the overall user experience of the device; these factors positively impact the patient's mental well-being, boosting self-esteem and overall quality of life.[19] However, the low actuation torques of these devices may limit their effectiveness for individuals with severe motor impairments, particularly non-ambulatory ones.[20] Therefore, the ExoBand is best suited for ambulatory individuals with mild to moderate impairments.

Although our findings supporting the benefits of the ExoBand in improving walking speed are limited by the brief duration of the intervention and the small heterogeneous sample size, these preliminary data provide a relevant foundation for larger randomized-controlled trials. These findings also pave the way for further exploration of additional gait metrics to fully assess the ExoBand's potential across a range of rehabilitative applications.

In conclusion, the present study provides preliminary evidence supporting the use of the soft exoskeleton ExoBand as a potential effective rehabilitation tool for individuals with neurological disorders affecting gait. Our findings demonstrate that incorporating the ExoBand into a structured rehabilitation program leads to notable improvements in walking speed, aligning with the minimal clinically important difference for functional mobility enhancement. These results highlight the potential of passive wearable hip orthoses as a cost-effective and accessible alternative to more complex robotic-assisted gait rehabilitation methods. While these findings are promising, inherent limitations, including the quasi-experimental design, short intervention duration, and small, heterogeneous sample size, highlight the need for larger, randomized-controlled trials to further investigate the effectiveness of ExoBand. Taken together, future research should explore additional gait parameters and long-term outcomes to comprehensively assess the device's rehabilitative potential. Nonetheless, this study contributes to the groundwork for integrating passive exoskeletons into clinical practice, offering a practical and innovative approach to improving mobility in individuals with neurological disorders.

Declaration of Conflicting Interests

A patent has been filed describing the ExoBand components documented in this manuscript; F.A.P. was author of this patent and is employed by Moveo srl, the entity that manufactures the ExoBand. C.S. holds employment with by Moveo srl. Beyond these disclosures, there are no further competing interests to declare.

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Author Contributions

S.L., C.S., F.A.P., F.G.: Conceived the study idea and conceptualized the project; C.S., G.M., F.A.P.: Were responsible for the methodological design; F.A.P., F.G.: Provided overall control and supervision, critically reviewed the manuscript; S.L., C.S., A.G., G.M., F.A.P., F.G.: Data collection and processing were performed; C.S., G.M., F.A.P.: Data analysis and interpretation were carried out; S.L., C.S.: Conducted the literature review, compiled the references, and managed the funding, drafted the original manuscript; F.A.P., F.G.: Critically reviewed the manuscript; C.S., A.G., G.M., F.A.P.: Materials and resources were provided. All authors approved the final version of the article.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

AI Disclosure

The authors declare that artificial intelligence (AI) tools were not used, or were used solely for language editing, and had no role in data analysis, interpretation, or the formulation of conclusions. All scientific content, data interpretation, and conclusions are the sole responsibility of the authors. The authors further confirm that AI tools were not used to generate, fabricate, or 'hallucinate' references, and that all references have been carefully verified for accuracy.

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