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Effect of a passive hip exoskeleton on walking distance in neurological patients

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ABSTRACT

Severe neurodegenerative diseases such as Parkinson's disease or multiple sclerosis and acute events like stroke, spinal cord injuries, or other related pathologies have been shown to negatively impact the central and peripheral nervous systems, thus causing severe impairments to mobility. The development and utilization of exoskeletons as rehabilitation devices have shown good potential for improving patients' gait function. Ten older adults (age: 68.9 ± 9.2 yrs; height: 1.65 ± 0.08 m; mass: 71.6 ± 11.0 kg) affected by neurological diseases impacting their gait function completed a 10-session gait training protocol where they walked for 10 minutes wearing a passive exoskeleton assisting hip flexion, namely, Exoband. Results showed that participants walked a significantly longer distance in the last session of training with respect to the first session (453.1 ± 178.8 m *vs* 392.4 ± 135.1 m, respectively). This study indicates the potential of Exoband as an effective tool for gait rehabilitation in patients with neurological diseases. Wearable, lightweight, and low-cost devices such as the one involved in this work have the potential to improve walking distance in patients.

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KEYWORDS
gait; neurological diseases; passive exoskeleton; rehabilitation

Introduction

The integrity and the interactions of sensory-motor neural networks at spinal and supra-spinal levels are fundamental to preserve a physiologically efficient gait pattern (Wall et al., 2015). Severe neurodegenerative diseases such as Parkinson's disease (PD) or multiple sclerosis (MS) and sudden events like stroke, spinal cord injuries, or other related pathologies have been shown to negatively impact the central and peripheral nervous systems, thus causing severe impairments to gait and mobility (Esquenazi et al., 2017). The resultant morbidity of people affected by these diseases is high and has been demonstrated to increase constantly (Chen et al., 2016). This leads to a reduction in independence and quality of life caused, among others, by the gait alterations associated with these diseases (Mahlknecht et al., 2013).

It is evident that the rehabilitation processes can play a fundamental role to improve gait in these patients both in the acute and the chronic phases. Indeed, evidence shows that intense repetitive task-specific training may favor motor plasticity enhancing functional restitution in patients with stroke or spinal cord injuries (Bowden et al., 2013; Chen et al., 2016; Wall et al., 2015). Similarly, in patients affected by MS, effective rehabilitation interventions are needed to reduce the effect of gait impairments as well as balance disorders (Afzal et al., 2020).

The employment of exoskeletons as rehabilitation devices is attracting the interest of physicians and therapists (Esquenazi et al., 2017; Federici et al., 2015). Thanks to growing popularity and technological advancements in the last decade (Sawicki et al., 2020), exoskeletons have been introduced in gait rehabilitation protocols showing promising effects in patients affected by MS (Afzal et al., 2020; Kozlowski et al., 2017; McGibbon et al., 2018) and stroke (Awad et al., 2017; Louie & Eng, 2016; Molteni et al., 2017). However, there are still several shortcomings limiting a wider adoption of these devices for rehabilitation purposes. These factors include cost (Chen et al., 2016; Gorgey, 2018), carriage weight (Chen et al., 2016; Young & Ferris, 2017), difficulty to wear and need of trained personnel to operate (Asbeck et al., 2014; Young & Ferris, 2017).

To overcome some of these limitations, research groups developed passive (operating without actuators and batteries) exoskeletons (Collins et al., 2015; Panizzolo, Bolgiani et al., 2019) to assist the user's gait by storing and releasing mechanical energy. Passive exoskeletons are lighter, cheaper and easier to wear than active ones (Sawicki et al., 2020). Hence, they could be more readily utilized both by medical staff in rehabilitation settings, and directly by the patients which could continue to exercise at home. Therefore, in the present study we aimed to investigate the effect of a passive exoskeleton assisting hip flexion on total walking distance (TWD) and rate of perceived exertion (RPE) during a 5-week training study in patients affected by neurological diseases.

Materials and Methods

Participants

Ten patients (5 males and 5 females; age: 68.9 ± 9.2 yrs; height: 1.65 ± 0.08 m; mass: 71.6 ± 11.0 kg) were recruited from a rehabilitation clinic (Centro Medico di Fisioterapia, Padova, Italy) after a clinical screening. Before undertaking the experimental protocol, the participants performed a 6-min Walk Test. They covered a distance of 238.4 ± 100.9 m which was

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~45 % lower than normative reference values for their age (Steffen, 2002). All participants presented with gait impairments attributed to different neurological diseases. Specifically, stroke occurred in four patients, two were affected by MS, two by PD, one by lumbar stenosis and one by cervical stenosis. All patients were considered to have stable clinical conditions and attended the rehabilitation clinic where the goal of their physical therapy was to maintain residual physical capacities enabling autonomy in activities of daily living. They started this maintenance activity at the clinic 6.3 ± 2.9 years before taking part in the present study. All participants walked independently at the time of the study, though four participants were aided by use of a walking cane and one participant used a rollator. During participant recruitment, members of the research team and the rehabilitation clinic informed patients about the aims of the study and the methods. Each patient gave written informed consent to participate in the study and were informed that they were free to withdraw at any stage. The research protocol met the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of the Department of Biomedical Sciences, University of Padova.

Experimental design

Patients involved in this study were diagnosed with their respective health conditions a long time before participation in the present study (7.2 ± 4.2 years). They already attended the rehabilitation clinic and followed the rehabilitation protocols regularly prescribed by their physicians. The experimental protocol in the present study involved the use of a passive hip flexion device, named Exoband (Moveo Walks, Cambridge, MA, USA). Participants attended the rehabilitation clinic twice per week. During each rehabilitation session, participants wore the Exoband while walking for 10 minutes back and forth along a 60-meter corridor. They were instructed to attempt to walk as far as possible (i.e. cover the longest possible walking distance) and were able to stop and rest within the walking session as needed. During the activity, participants were monitored by two physiotherapists. The protocol lasted 5 consecutive weeks, thus allowing each participant to complete 10 walking sessions of 10 minutes, wearing the Exoband. At the end of each walking session, physiotherapists reported the TWD in meters. In addition, RPE was recorded both at the beginning and at the end of each session using the Borg CR-10 scale (Borg, 1990). The mean value of these two measurements was considered for the analysis reported.

Exoband design and characterization

Exoband is a passive hip assistive device that can be worn by self-sufficient users independently in a couple of minutes. The device includes three main components: a waist belt and two thigh parts connected to the waist belt by means of two elastic elements, one for each leg (Figure 1). When the hip extends the elastic element stretches, thus storing elastic mechanical energy. When the leg starts to accelerate forward the elastic element initiates to shorten and applies a force in parallel with

Figure 1. Exoband worn by the patient during the data collection, picture, and schematic of the component of the device from different views.

the hip flexor muscles, ultimately assisting the user's gait. Varying the amount of preload (by means of changing the length of the ratchet strap), it is then possible to change the amount of force applied to the user. Exoband was presented in Panizzolo, Bolgiani et al. (2019) and the version used in the present study has slight differences from that used previously, which were implemented to increase its functionality and user comfort. First, the main textile used in the previous version was replaced to improve comfort and breathability. Second, the design of the thigh parts, including the elastic element, were modified to improve forces load path and overall comfort.

The mechanical characterization of the elastic element was obtained by means of a tensile test on a 858 MTS Mini Bionix II (MTS System Corporation, Eden Prairie, MN, USA). Briefly, the thigh part was clamped to the hydraulic actuator which stretched the elastic element at a constant speed of 1 mm/s. The force produced by the elastic element and its elongation were synchronously collected by a force transducer and a linear variable differential transformer, respectively (Figure 2a). This resulted in a relationship between force (F) and elongation (E) described by the following equation:

$$F = 1.2038 * E + 1.5042 \tag{1}$$

From this equation we obtained the stiffness of the elastic element: $K_{el} = 1.2038$ N/mm.

To estimate the elongation of the elastic element while the patients maintained a standing posture we used the following procedure. First, we estimated the femur length (La) of the participants using anthropometric data presented by Winter (2009). We then subtracted from this measurement the length of the waist belt including the ratchet strap (Lb), the length of the thigh part (Ld) and the set distance of the thigh part from the patella (Le). The length of the stretched elastic element during standing was obtained using the following equation:

$$Lc = La - (Le + Ld + Lb - Lr) \tag{2}$$

As the length Lb takes into account the entire length of the ratchet, to estimate the length of the stretched elastic element the overlap of the elastic element with the ratchet strap (Lr) was subtracted to Lb, based on the number of the ratchet steps engaged with the locking mechanism. Finally, the length of the resting elastic element ($L_0 = 85$ mm) was subtracted from Lc to estimate the elongation of the elastic element during standing. This resulted in an average elongation between the group of participants corresponded to 30.2 ± 20.3 mm and 31.1 ± 23.1 mm for the right and left leg, respectively. Replacing these lengths in the equation obtained with the mechanical characterization *(1)*, the estimated mean force applied in the upright standing was 37.9 ± 24.5 N and 39.0 ± 27.8 N for the right and left elastic element, respectively.

Statistical Analysis

Two-tail paired Student's t-test was employed to compare both TWD and the RPE between the first and tenth walking session. In addition, the time spent walking with the Exoband was correlated with the distance covered and TWD was correlated with RPE using Pearson's coefficient. Statistical significance was set to $p < .05$ for both paired Student's t-test and Pearson's coefficient (r). Pearson's coefficient was interpreted as weak ($r \le 0.35$), moderate ($0.36 \le r \le 0.67$), strong ($0.68 \le r \le 0.90$) or very strong ($r \ge 0.90$), according with the guidelines indicated by (Taylor, 1990). Effect size (ES) relative to the variables investigated (maximal distance covered and RPE) was calculated and interpreted as trivial (0.00–0.19), small (0.20–-0.59), moderate (0.60–1.19), large (1.20–1.99) or very large (>2.00) (Hopkins et al., 2009). Statistical analysis was performed with GraphPad Prism version 4.00 for Windows (GraphPad Software, San Diego California USA) and G*Power 3.1.5 software (Faul et al., 2007).

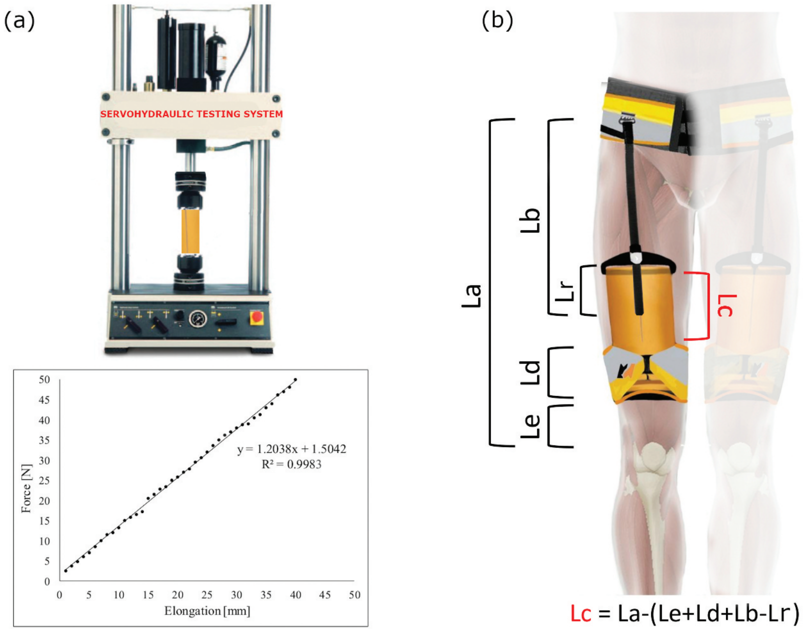

Figure 2. Mechanical characterization of the elastic element (a) and method for the estimation of the force applied by Exoband during the data collection (b).

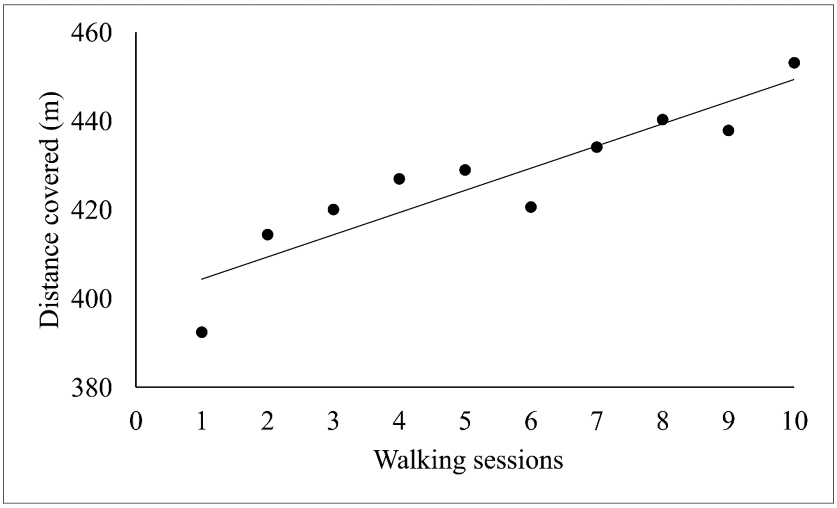

Figure 3. Correlation between walking sessions and the total walking distances (TWD). Black dots represent mean values of distance covered by the patients in each walking session.

Results

The participants walked farther in session 10 (453.1 ± 178.8 m; 95% CI: 325.2 to 581.0 m) than in session 1 (392.4 ± 135.1 m; 95% CI: 295.7 to 489.1). The difference resulted to be statistically significant ($p < .05$; ES: 0.38). Figure 3 illustrates the strong positive correlation between the sessions spent walking with the Exoband and meters covered (r = 0.9126; $p < .01$; 95% CI: 0.66 to 0.98). That is, participants walked farther the more they used Exoband. The RPE score was lower in session 10 (4.8 ± 2.8; 95% CI: 2.8 to 6.8) than in session 1 (5.1 ± 2.7; 95% CI: 3.2 to 7.0), although this difference did not reach the statistically significance threshold ($p > .05$; ES: 0.11). However, we found a statistically significant strong negative correlation (r = −0.8134; $p < .01$; 95% CI: −0.95 to −0.38) between the sessions spent walking with the Exoband and the correspondent RPE value (Figure 4): the more patients used Exoband, the lower their RPE at the completion of each session. TWD and RPE obtained during session 1 and 10 for each patient is reported in Table 1.

Discussion

The aim of the present study was to investigate the effect of a 5-week assistive gait training program with a passive exoskeleton in a group of patients affected by neurological diseases. Our work indicated that participants significantly increased the TWD by an average of 60.7 m from session 1 to session 10, thus improving walking capacity by ~15.5%. Furthermore, eight of ten patients showed an improvement in TWD at session 10 with respect to session 1, indicating that the Exoband had a positive effect at an individual level despite the different neurological pathologies.

Greater TWD indicated increased gait speed of participants across 5 weeks of gait training with Exoband. The increase in gait speed achieved during the training sessions (+0.101 m/s) fits into the range representing the minimal clinical significant difference [0.1–0.2 m/s (Bohannon & Glenney, 2014). Further, the gait speed reported by the patients in the last session of testing (0.75 ± 0.30 m/s) was ~14% higher than the gait speed reported by the patients during their initial 6-min Walk Test. This increase in gait speed, also obtained for a longer duration

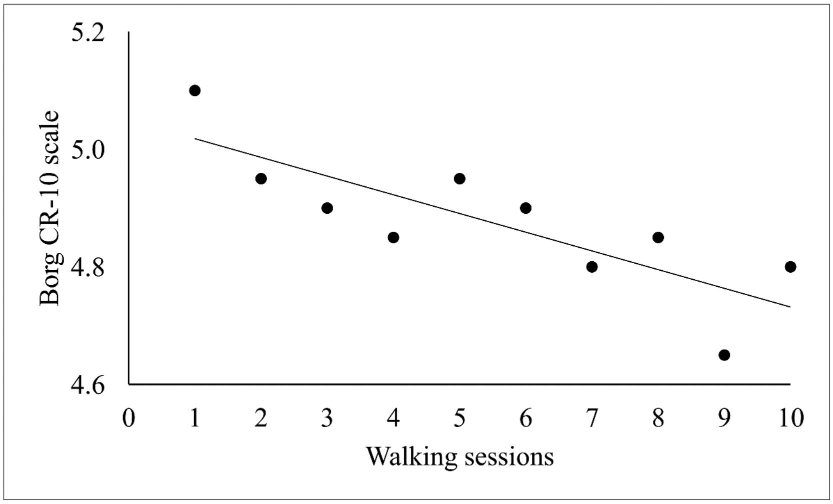

Figure 4. Correlation between walking sessions and RPE values. Black dots represent mean RPE values of patients in each walking session.

Table 1. Results of the total walking distance (TWD) and rate of perceived exertion (RPE) obtained by each patient in sessions 1 and 10.

		Total walking distance (m)		RPE (Borg CR-10)	
Patients	Pathology	Session 1	Session 10	Session 1	Session 10
P1	Stroke	300	358.5	5	5.5
P2	Parkinson	230	192	9	9.5
P3	Multiple sclerosis	322.5	361	4	3
P4	Stroke	317.5	285	7	6
P5	Stroke	567.5	660	5	5.5
P6	Multiple sclerosis	570	637.5	3	1
P7	Cervical stenosis	304	367	9.5	7.5
P8	Stroke	287.5	365	2.5	5.5
P9	Lumbar stenosis	445	617.5	4.5	4.5
P10	Parkinson	580	687.5	1.5	0

(6 min *vs* 10 min) could be translated into a small increased independence in daily tasks. This result represents one of the higher outcomes for this specific parameter compared to previous work with exoskeletons (Afzal et al., 2020) and indicates that Exoband intervention can be perceived by patients and can favor a change in their management. Other works involving the use of powered exoskeletons during post-stroke rehabilitation (Louie & Eng, 2016) reported changes in walking variables (i.e. gait speed, Timed Up and Go, 6-min Walk Test, and the Functional Ambulation Category) in both chronic and post-acute stroke. However, the variety of protocols applied in this scoping review, and the exoskeletons investigated, do not enable a direct comparison with the present study and the device involved in our work. Investigations specific to stroke patients, MS and PD also provide for indirect comparisons only. Awad et al. (2017) demonstrated reduced metabolic cost of walking in stroke patients, Afzal et al. (2020) showed improvements in walking speed and metabolic cost in MS and Sale et al. (2013) found positive changes in spatio-temporal parameters.

Although participants achieved longer distances at the end of the 5-week training, we found no significant differences in RPE comparing the first and last sessions. We also found a negative moderate correlation between session TWD and the correspondent RPE. It has been demonstrated that, while power output increases after aerobic training, RPE usually remains closed to pre-training levels (Heydari & Boutcher, 2013; Robertson, 2004). We speculate that aerobic adaptations may have occurred during gait training without altering participants' sense of exertion despite walking faster. Further, our previous work in a group of healthy elderly adults (Panizzolo et al., 2019) showed a reduced metabolic cost while walking with the Exoband. We also speculate that metabolic cost reductions likely occurred in this group of participants while using the Exoband, which may explain the invariance of the RPE associated with increasing TWD. Further, the between-session increment in TWD, together with lower RPE, could indicate a training effect with Exoband, as already demonstrated elsewhere for a soft exosuit (Panizzolo, Freisinger et al., 2019). To strengthen the results of the present study, further studies using larger sample sizes of patients with the same clinical presentation or health condition will be needed since the patients involved in the present study were affected by different neurological diseases.

The present study did not include a control group to enable comparison of Exoband-supported rehabilitation versus a simple 5-week walking intervention involving two bouts of 10 minutes of walking. Nevertheless, a review of the literature on this topic revealed improvements in TWD comparable to those of the present study in a group of MS patients achieved only with a much longer and more strenuous training protocol (8-weeks of training, involving four sessions per week, including both resistance and aerobic exercise training) (Sangelaji et al., 2016). Another study in stroke patients reported a lower increment in TWD (+8.6%) with respect to our present work after undergoing a 4-week training intervention involving 3 × 30 min of walking (Broderick et al., 2019). Further, a systematic review (Mehrholz et al., 2015) on the effect of treadmill training in Parkinson's disease reported a lack of improvement in TWD, thus highlighting the potential of Exoband to improve this measurement in this population.

Despite this study's limitations, it is the first to employ a passive exoskeleton for rehabilitation purposes. The findings of this work indicate that Exoband can be used as an effective gait training tool to increase TWD achieved by neurological patients within a few weeks of repeated use. Further, since Exoband can be worn autonomously by the users and it does not necessitate trained supervision or assistance, there is broad utility and applicability for remote rehabilitation in the home to improve gait function.

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