European Journal of Physical and Rehabilitation Medicine 2017 October;53(5):676-84
DOI: 10.23736/S1973-9087.17.04591-9

ORIGINAL ARTICLE

Wearable robotic exoskeleton for overground gait training in sub-acute and chronic hemiparetic stroke patients: preliminary results

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ABSTRACT

BACKGROUND: Recovery of therapeutic or functional ambulatory capacity in post-stroke patients is a primary goal of rehabilitation. Wearable powered exoskeletons allow patients with gait dysfunctions to perform over-ground gait training, even immediately after the acute event.
AIM: To investigate the feasibility and the clinical effects of an over-ground walking training with a wearable powered exoskeleton in sub-acute and chronic stroke patients.
DESIGN: Prospective, pilot pre-post, open label, non-randomized experimental study.
SETTING: A single neurological rehabilitation center for inpatients and outpatients.
POPULATION: Twenty-three post-stroke patients were enrolled: 12 sub-acute (mean age: 43.8±13.3 years, 5 male and 7 female, 7 right hemiparesis and 5 left hemiparesis) and 11 chronic (mean age: 55.5±15.9 years, 7 male and 4 female, 4 right hemiparesis and 7 left hemiparesis) patients.
METHODS: Patients underwent 12 sessions (60 min/session, 3 times/week) of walking rehabilitation training using Ekso™, a wearable bionic suit that enables individuals with lower extremity disabilities and minimal forearm strength to stand up, sit down and walk over a flat hard surface with a full weight-bearing reciprocal gait. Clinical evaluations were performed at the beginning of the training period (t0), after 6 sessions (t1) and after 12 sessions (t2) and were based on the Ashworth scale, Motricity Index, Trunk Control Test, Functional Ambulation Scale, 10-Meter Walking Test, 6-Minute Walking Test, and Walking Handicap Scale. Wilcoxon's test ($P<0.05$) was used to detect significant changes.
RESULTS: Statistically significant improvements were observed at the three assessment periods for both groups in Motricity Index, Functional Ambulation Scale, 10-meter walking test, and 6-minute walking test. Sub-acute patients achieved statistically significant improvement in Trunk Control Test and Walking Handicap Scale at t0-t2. Sub-acute and chronic patient did not achieve significant improvement in Ashworth scale at t0-t2.
CONCLUSIONS: Twelve sessions of over-ground gait training using a powered wearable robotic exoskeleton improved ambulatory functions in sub-acute and chronic post-stroke patients. Large, randomized multicenter studies are needed to confirm these preliminary data.
CLINICAL REHABILITATION IMPACT: To plan a completely new individual tailored robotic rehabilitation strategy after stroke, including task-oriented over-ground gait training.

(*Cite this article as:* Molteni F, Gasperini G, Gaffuri M, Colombo M, Giovanzana C, Lorenzon C, *et al.* Wearable robotic exoskeleton for overground gait training in sub-acute and chronic hemiparetic stroke patients: preliminary results. Eur J Phys Rehabil Med 2017;53:676-84. DOI: 10.23736/S1973-9087.17.04591-9)

Key words: Stroke - Rehabilitation - Exoskeleton device - Neurologic gait disorders.

Stroke is a leading cause of acquired disability in adults worldwide.[1] Hemiparesis, with loss of coordination in upper and lower limb joints, is one of the most disabling consequences. Post stroke locomotor impairments are often associated with abnormal timing and intensity in recruitment of lower limb muscles,

thereby affecting muscle coordination and walking ability.[2-5] Literature reports indicate that 30-40% of stroke survivors have limited or no walking ability even after rehabilitation;[6, 7] for this reason there is an ongoing need to advance the efficacy of gait rehabilitation for stroke survivors.[8]

Recent evidence demonstrates that the central nervous system (CNS) can reorganize after injury and that reorganization in a functional meaningful way depends on motor activity during rehabilitative training.[9, 10] There is growing evidence that a high number of task-oriented, repetitive movements based on the principles of motor learning can improve muscular strength, movement coordination and functions in neurological patients.[11, 12] Task-specific training exoskeletons with body weight supported treadmill training have been developed for gait rehabilitation after stroke. These technologies can provide higher number of repetitions for walking practice than conventional gait training, avoiding additional strain on therapists. However, there is conflicting evidence regarding the efficacy of treadmill-based robotics for gait training compared to conventional therapy.[8]

In a literature review of electromechanical devices for gait rehabilitation in stroke patients,[13] authors concluded that patients who receive treadmill robotic-assisted gait training in combination with physiotherapy after stroke are more likely to achieve independent walking than patients who receive gait training without these devices. Other systematic reviews report no difference in gait speed and endurance when comparing conventional therapy and electromechanical treadmill-based robotics involving equal intensity and duration of training.[14] However, restricting patients to training on a treadmill does not allow the patient to practice real-world gait scenarios, such as walking over non-smooth surfaces, stepping over objects, and practicing standing up and sitting down. Moreover, during treadmill robotic training with body weight support, patients could have less control [15] over the initiation of each single step and a lack of variability in visual spatial flow.[16] These features represent an essential challenge for reaching functional overground walking.

Wearable powered exoskeletons are a recent technological development allowing individuals with lower limbs pathologies and/or weakness to walk on a hard, flat surface.[17] The devices incorporate actuators that move the patient's legs through the gait cycle in the sagittal plane. The robotic device guides the legs through pre-programmed physiological gait patterns while the subject experiences near-normal proprioceptive input during limb loading. The pre-programmed walking pattern is quite similar to a normal gait and it includes gait cycle timing, interlimb and interjoint coordination, appropriate limb loading and afferent signals.[18]

Wearable powered exoskeletons are in accord with modern principles of overground gait rehabilitation. In particular, these device should maximize loading of the lower limbs instead of the upper extremities during training, promote hip extension and limb unloading synchronization with simultaneous loading of the contralateral lower limb to promote swing initiation, and promote step initiation from a stride position to allow weight transfer from an extended and loaded limb forward to the unloaded limb.[19-22] The powered exoskeleton's kinematic chain maps the human limb anatomy and the control emulates human neuromotor control; thus, it is a promising new tool for gait rehabilitation and challenges the way in which neurological rehabilitation training should be provided.

Initially, wearable powered exoskeletons were designed as assistive devices that allowed complete spinal cord injury (SCI) patients' safe ambulation.[23, 24]

There is a paucity of published data on powered robotic exoskeletons for gait rehabilitation in post-stroke patients. The aim of this study was to investigate the feasibility and the clinical effects of overground walking training with a wearable powered exoskeleton (Ekso™, Ekso Bionics, Richmond, CA, USA) in sub-acute and chronic stroke patients.

Materials and methods

A total of 23 stroke patients were referred to and enrolled for study at Villa Beretta Rehabilitation Center (Costa Masnaga, Lecco, Italy) from December 2013 to December 2014. Time from the acute event ranged from 25 days to 2350 days and included sub-acute (<180 days from acute event) and chronic (>180 days from acute event) patients. Characteristics of the 12 sub-acute and 11 chronic patients are presented in Table I.

Patients were screened by a board-certified physiatrist, who was experienced in the biomechanics of gait and the use of robotic device technology and who screened potential study participants for eligibility.

TABLE I.—*Characteristics of sub-acute and chronic patients.*

Characteristics	Sub-acute patients (N.=12)	Chronic patients (N.=11)
Mean age, years	43.8±13.3	55.5±15.9
Gender, N.		
Male	5	4
Female	7	4
Hemiparesis, N.		
Left	5	7
Right	7	4
Etiology		
Ischemia	7	6
Hemorrhagia	4	5
Mean time from acute event, days (range)	66.4 (25-180)	597.5 (181-2350)

The inclusion criteria were: hemiparesis secondary to a single onset unilateral stroke, no significant lower extremity joint pain, no major sensory deficits, no significant lower limb contractures, and stable cardiovascular and respiratory conditions. The exclusion criteria were: any orthopedic or neurologic conditions in addition to stroke, any significant musculoskeletal problem that could limit hip and knee extension or ankle plantar flexion, and incapacity to understand instructions and give written formal consent.

Written informed consent was obtained from each subject. Ethical approval of the treatment and of the evaluation protocol was granted by the joint local Ethics Committee for the provinces of Lecco, Como and Sondrio (protocol no. 0040564/15U, issued on 30/09/2015).

Intervention: a robotic device for overground gait training

Ekso is a wearable bionic suit: it enables individuals with lower limb disabilities and minimal forearm strength to stand, sit and walk over a flat hard surface with a full weight-bearing reciprocal gait under the supervision of a physical therapist. Ekso is intended for non-ambulatory and ambulatory post-stroke patients, spinal cord complete and incomplete injury patients with different etiology, and traumatic brain injury patients. It can also be used as a therapeutic device in patients who must re-learn walking with a proper step pattern and functional weight shift by moving the patient's legs through a customizable predefined patient-tailored kinematic pattern.

Ekso weighs 23 kg and can be used by individuals who weigh up to 100 kg and range from 160 to 190 cm of height. Patients must have a standing hip width at maximum of 43 cm. Ekso is equipped with 4 battery-powered motors at the hips and knees, which are designed to support or replace deficient neuromuscular function.

Ekso setting definitions: trigger and assistance

There are four types of actuation for each patient step: FirstStep™, by which a physical therapist actuates steps with a button push; ActiveStep™, by which the patient takes control of actuating steps via buttons on the crutches or walker; ProStep™, by which the patient achieves the next step by moving body weight laterally and then forward; ProStep Plus™, by which steps are triggered by the user's lateral weight shift. The amount of power contribution to one or both legs during walking can be tuned with three types of assistance for each single step. The first is Bilateral Max Assist, in which Ekso provides full power to both legs. No strength is required from the patient: only proper balance and weight shifts are required to achieve walking. The second is Adaptive Assist, in which patients with any amount of lower extremity strength contribute to their walking efforts; Ekso dynamically adjusts to produce a smooth, consistent gait. The third is Fixed Assist, whereby Ekso legs provide a fixed amount of prespecified power to help patients to complete steps in a specified amount of time.

Study design

This was a prospective, pilot pre-post, open label, non-randomized experimental study. Enrolled patients underwent 12 sessions (60 min/session for 3 times a week) of walking rehabilitation training using the powered wearable robotic device. ProStep Plus™ and Bilateral Max Assist were used as the default settings in this study. Before the start of the training period, the gait cycle kinematic parameters of the exoskeleton were fine-tuned using surface electromyography (sEMG). The sEMG of tibialis anterior, soleus, rectus femoris, and hamstring muscles was collected bilaterally. Different exoskeleton parameters were set for each patient and sEMG was collected. The choice of the best configuration was defined on the basis of the best muscles activa-

TABLE II.—*Clinical Scale for activities ICF domain in sub-acute patients.*

ICF domain	Period		
	t_0	t_1	t_2
Ashworth Scale			
Hip abductors	0 (0-1)	0 (0-1)	0 (0-1)
Knee extensors	0 (0-3)	0 (0-1)	0 (0-1)
Ankle plantar flexors	0 (0-3)	1.5 (0-3)	1 (0-3)
Motricity Index			
Total	33.5 (1-65)	43.5 (10-65)	59 (19-100)
Hip	14 (0-25)	19 (9-25)	19 (9-33)
Knee	16.5 (0-25)	19 (0-25)	22 (9-33)
Ankle	4.5 (0-14)	9 (0-19)	14 (0-33)

Data are presented as median (range).
ICF: International Classification of Functioning, Disability and Health; t_0: beginning of training period; t_1: after 6 sessions; t_2: after 12 sessions.

tion timing according to clinical practice; in this way, a customized and tailored robotic treatment was defined.

Sub-acute patients underwent robotic training in conjunction with conventional physiotherapy training, whereas chronic patients underwent only overground robotic gait training. A clinical evaluation based on the International Classification of Functioning, Disability and Health (ICF),[25] was undertaken at three points in the overall training period: at the beginning of the training period (t_0), after 6 sessions (t_1) and after 12 sessions of the training period (t_2).

For the body function and structure ICF domain, we adopted the Ashworth (Ash) scale to evaluate hip adductor, knee extensor, and ankle plantar flexor muscles spasticity [26] and the Motricity Index (MI) to measure strength in the lower extremities.[27] For the activities ICF domain, the Trunk Control Test (TCT) was used to evaluate trunk control, not only during the maintenance of the sitting position, but also during "dynamic conditions." [28] The Functional Ambulation Scale (FAC) was used to evaluate basic motor skills necessary for functional ambulation.[29] For the activities ICF domain, we also used the 10-Meter Walking Test (10mWT) to evaluate walking speed over a short distance [30] and the 6-Minute Walking Test (6minWT) as a sub-maximal test of aerobic capacity/endurance to assess distance walked during 6 minutes.[31] For the participation ICF domain, the Walking Handicap Scale (WHS) was used to assess quantitatively a person's customary level of walking ability at home and in the community.[32]

TABLE III.—*Clinical scale for activities and participation ICF domains for sub-acute patients.*

ICF domain	Period		
	t_0	t_1	t_2
Trunk Control Test	61 (12-74)	61 (24-74)	61 (24-100)
Functional Ambulation Scale	0.5 (0-3)	2.5 (0-4)	3 (0-4)
10mWT, s	27.8±12.8	29.4±21.1	29.2±25.4
10mWT, steps	18.4±12.4	16.5±8.4	15.7±7.5
10mWT, m/s	0.46±0.29	0.49±0.28	0.56±0.33
6minWT, m	157.6±77.6	192.1±103.7	205.1±113.2
Walking Handicap Scale	1 (1-3)	1.5 (1-4)	2 (1-4)

Data are presented as median (range) or as mean±SD.
ICF: International Classification of Functioning, Disability and Health; 10mWT: 10-Meter Walk Test; 6minWT: 6-Minute Walk Test.

Statistical analysis

The Friedman test, useful to make non-parametric multiple comparisons, and then a *post-hoc* analysis with Wilcoxon and Bonferroni correction of P values was performed. Wilcoxon test, a non-parametric test that compares two paired groups, was employed to detect significant changes between data at baseline (t_0), after 6 sessions (t_1), and at the end of 12 sessions of the training period (t_2). Statistical analyses were performed with SPSS Statistics (IBM Corporation, Armonk, NY, USA); statistical significance was set at 0.05.

Results

Sub-acute patients

Twelve sub-acute patients were evaluated at t_o, t_1, and t_2. In Table II, the median and range of values of Ashworth and motricity index scales for sub-acute patients are reported. The Ashworth scale, measured at hip adductor muscles ($P_{t0\text{-}t1}$=0.99, $P_{t0\text{-}t2}$=0.99), at knee extensor muscles ($P_{t0\text{-}t1}$=0.63, $P_{t0\text{-}t2}$=0.99), and at ankle plantar flexor muscles ($P_{t0\text{-}t1}$=0.25, $P_{t0\text{-}t2}$=0.50), did not reveal statistical differences. The total score of Motricity Index showed significant improvements at t_0-t_1 (P=0.002), t_1-t_2 (P=0.0078), and t_0-t_2 (P=0.001). The partial scores of the MI revealed significant improvements at hip level at t_0-t_1 (P=0.0078) and t_0-t_2 (P=0.002). MI evaluated at knee level evidenced significant change at t_0-t_1 (P=0.0313) and t_0-t_2 (P=0.0078). MI evaluated at ankle level also revealed significant improvement at t_0-t_2 (P=0.0156).

TABLE IV.—*Clinical scale for body function and structure ICF domain for chronic patients.*

ICF domain	Period		
	t_0	t_1	t_2
Ashworth Scale			
Hip abductors	0 (0-3)	0 (0-3)	0 (0-3)
Knee extensors	2 (0-3)	1 (0-3)	1 (0-3)
Ankle plantar flexors	1 (0-3)	1 (0-3)	2 (0-3)
Motricity Index			
Total	34 (1-48)	38 (1-54)	38 (1-54)
Hip	9 (0-19)	14 (0-19)	14 (0-25)
Knee	14 (0-25)	14 (0-25)	14 (0-25)
Ankle	9 (0-19)	9 (0-25)	9 (0-25)

Data are presented as median (range).
ICF: International Classification of Functioning, Disability and Health; t_0: beginning of training period; t_1: after 6 sessions; t_2: after 12 sessions.

TABLE V.—*Clinical scale for activities and participation ICF domains for chronic patients.*

ICF domain	Period		
	t_0	t_1	t_2
Trunk Control Test	61 (0-74)	61 (0-74)	61 (0-74)
Functional Ambulation Scale	1 (0-3)	2 (0-4)	2 (0-4)
10mWT, s	83.8±78.4	56.0±38.5	55.0±34.4
10mWT, steps	23.8±11.3	18.8±5.6	19.0±5.7
10mWT, m/s	0.20±0.12	0.24±0.13	0.25±0.16
6minWT, m	79.5±46.8	88.0±43.3	92.0±59.3
Walking Handicap Scale	2 (1-3)	2 (1-3)	2 (1-3)

Data are presented as median (range) or as mean±SD.
ICF: International Classification of Functioning, Disability and Health; 10mWT: 10-Meter Walk Test; 6minWT: 6-Minute Walk Test.

In Table III, the median values of TCT and FAC and the mean values of 10mWT and 6minWT are reported. TCT showed significant change at t_1-t_2 (P=0.0078) and t_0-t_2 (P=0.0039). There also was significant change in FAC at t_0-t_1 (P=0.001) and t_0-t_2 (P=0.001). At the beginning of the training period, 5 of the sub-acute patients were able to walk and they performed the 10mWT and 6minWT. At t_1 2 additional patients regained ambulation, and at t_2 a total of 9 patients were able to walk. For the 10mWT, there was no significant difference in time ($P_{t0\text{-}t1}$=0.63, $P_{t0\text{-}t2}$=0.46) or in the number of steps ($P_{t0\text{-}t1}$=0.81, $p_{t0\text{-}t2}$=0.38). Significant improvement in walking velocity was achieved at t_1-t_2 (P=0.0234) and t_0-t_2 (P=0.0078). The 6minWT showed a statistically significant change at t_0-t_1 (P=0.0156), t_1-t_2 (P=0.0195), and t_0-t_2 (P=0.0039). Last in Table III, WHS improved significantly from t_0-t_2 (P=0.0156).

Chronic patients

Eleven chronic patients were evaluated at t_0, t_1, and t_2. In Table IV, the Ashworth and Motricity Index scales for chronic patients are reported. The Ashworth Scale, measured at hip adductor muscles ($P_{t0\text{-}t1}$=0.99, $P_{t0\text{-}t2}$=0.99), at knee extensor muscles ($P_{t0\text{-}t1}$=0.50, $P_{t0\text{-}t2}$=0.25), and at ankle plantar flexor muscles ($P_{t0\text{-}t1}$=0.99, $P_{t0\text{-}t2}$=0.25) did not reveal significant differences at any of the time periods (t_0-t_1, t_0-t_2) The total score of MI showed significant improvement at the following periods: t_0-t_1 (P=0.0156), and at t_0-t_2 (P=0.0078). The partial scores of the MI revealed significant improvement at hip level at t_0-t_1 (P=0.0156) and t_0-t_2 (P=0.0156); at knee level ($P_{t0\text{-}t1}$=0.50, $P_{t0\text{-}t2}$=0.99) and at ankle level ($P_{t0\text{-}t1}$=0.25, $P_{t0\text{-}t2}$=0.25), there were no significant differences.

Table V lists TCT, FAC, 10mWT, 6 minWT, and WHS values. TCT did not differ significantly between assessment periods. However, there was significant change in FAC at t_0-t_2 (P=0.0313). At the beginning of the training period, 4 of the 11 chronic patients were able to walk and to perform 10mWT and 6minWT. At t_1, 2 patients regained this activity, and at t_2, 7 patients were able to walk. In the 10mWT, there was no significant change in time ($P_{t0\text{-}t1}$=0.99, $P_{t0\text{-}t2}$=0.94) or in the number of steps ($P_{t0\text{-}t1}$=0.99, $P_{t0\text{-}t2}$=0.61); the walking velocity improved significantly at t_1-t_2 (P=0.0156) and at t_0-t_2 (P=0.0156). The 6minWT evidenced a significant improvement at t_1-t_2 (P=0.0156), and t_0-t_2 (P=0.0313). There was no improvement in WHS at any of the assessment periods.

Discussion

We performed this study to evaluate changes in clinical outcomes induced by overground gait training with Ekso in sub-acute and chronic hemiparetic stroke patients using clinical scales defined by ICF classification, as suggested by Geroin *et al.*[25] Recovery of independent ambulation after stroke is a major goal of rehabilitation. However, it is very difficult to choose the best treatment for each individual, and decisions currently are made on a subjective basis.[31] Literature evidence regarding the use of wearable powered exoskeletons for overground training of stroke patients is very poor. In a recent review [8] of wearable powered exoskeletons for stroke

patients, the authors reported that only four different types of powered exoskeletons had been studied in a small number of stroke patients and the published data were controversial. The authors commented on the need to research the clinical usefulness of other commercial wearable powered exoskeletons to stroke patients. This study is the first to describe the use of Ekso as a gait rehabilitation tool in stroke patients.

Sub-acute patients

In sub-acute patients, the Ashworth scale did not show a significant difference between the conditions analyzed; no changes in value were observed at hip and knee level whereas an increase in value was observed in plantar flexor muscles (t_0=0, t_2=1). It is noteworthy that in this small group of patients, high-intensity gait rehabilitation training with the wearable overground device did not increase spasticity.

Total and partial scores of Motricity Index showed a positive increase in value; literature reports [33-36] of other "stationary devices" confirm these findings. MI evaluated at knee and hip level confirmed that, at the end of the training period (t_2) with Ekso, patients fully restored a complete active range of motion against gravity. Specifically, the median value of MI at hip level was 14 at the beginning of the training period (t_0) and reached 19 at t_2; the median value of MI at knee level was evaluated as 16.6 at t_0 and reached 22 at t_2. A statistically significant change also was measured at ankle level with a partial but incomplete recovery of active movement (median value t_0=4.5, t_2=14). This finding may be reflected by the fact that, when the patient wears Ekso, the ankle joint position is fixed.

Statistical differences were found for TCT, FAC, 10mWT walking velocity and 6minWT walking endurance. No changes in median TCT values were observed between t_0, t_1, and t_2, even when observing a modification in the distribution of single values and in the range of measures. An improvement in the median FAC, from non-functional walking (t_0=1.5) to walking with only supervision and without physical contact (t_2=3), was measured. Mehrholz *et al*. found that FAC score can predict independent community ambulation 6 months after stroke with high sensitivity and specificity.[13] These findings confirm the literature data from "stationary devices," [33, 34, 37-41] in which a major positive change in FAC value was registered in patients treated with body weight treadmill robotic devices compared to traditional overground treatment.

Mean velocity during spontaneous walking in the 10mWT increased from 0.46 m/s before robotic training to 0.56 m/s at the end of the training sessions. This pre-post difference of 0.10 m/s is lower than the Minimally Clinically Important Difference (MCID) for stroke patients of 0.16 m/s.[25] In the sub-acute group, the number of patients able to walk at t_0 was 5, at t_1 2 additional patients regained the walking ability and, at t_2, 9 of the 12 patients achieved ambulation. An analysis of single subjects' values between the three assessments shows that the difference from t_0 to t_2 is more than MCID for 6 out of the 12 (50%) patients. Reports from the literature [33-44] demonstrate improvement in patients' walking velocity after treadmill body-weight support robotic training even if no significant changes occurred from conventional to robotic training.

Similar considerations can be made for the distance covered in 6minWT. The mean distance increases from 157.6 m at t_0 to 205.1 m at t_2. In 6minWT, MCID is set at 50 m, and 8 out of 12 (67%) patients achieved a pre-post difference of >50 m.[25]

An improvement in WHS was observed at the end of the training period (from 1 at t_0 to 2 at t_2), indicating recovery of household ambulation as described by Perry.[31] In the small group of sub-acute patients, an increase of the measures of activity in ICF domain was accompanied by an increase in the measure of participation.

Two studies of wearable powered exoskeletons in sub-acute stroke patients reported improved walking independence after wearable robotic walking training for non-ambulatory stroke patients.[45, 46] This finding agrees with the results of the present study and are similar to those reported in systematic reviews on the use of treadmill robotic training in non-ambulatory patients early after stroke.[13, 14]

Wong *et al.* described a wearable robotic knee orthosis and reported significant improvement in walking speed for sub-acute stroke patients who had some residual movement and less improvement in patients without voluntary control.[47] In contrast in our study, we observed improvements for both ambulant and for non-ambulant patients. In our study, sub-acute patients performed not only robotic training, but also conventional

physiotherapy training. Due to the study design, we were not able to demonstrate if modification in walking abilities resulted from spontaneous recovery, robotic training, conventional treatment, or the integration of all of these factors.

Chronic patients

In chronic patients, there were no significant changes in Ashworth scale, whereas some differences in MI total score and at hip level were observed. The median MI value at hip level was 9 at t_0 and 14 at t_2, with partial recovery of active range of motion; no changes in values were observed at knee or ankle levels.

In the activity domain of the ICF, there was no significant change over time in TCT, whereas significant improvement occurred in FAC with an increase from 1 at t_0 to 2 at t_2. Significant changes in speed and distance were observed. Mean velocity increased from 0.20 m/s at t_0 to 0.25 m/s at t_2, and distance covered in 6 minutes increased from 79.5 to 92 m over the total evaluation period. The improvements in velocity and distance were less than the MCID for stroke patients (0.16 m/s for velocity, 50 m for distance). However, the number of patients performing the 6minWT and 10mWT was different at each assessment period. Four chronic stroke patients were able to walk at t_0, 6 at t_1, and 7 at t_2. For 3 subjects, the pre-post differences in velocity and distance were greater than those of the MCID.

Among several studies, results of spontaneous walking velocity in chronic patients before and after treadmill body-weight supported robotic treatment disagree.[40, 45, 48, 49] In our study, chronic patients only underwent robotic overground gait training; for this reason, their improvements in FAC, 10mWT, and 6minWT are due to the robotic treatment.

Until the present study, literature reports on chronic stroke patients were conducted on ambulant patients.[8] In our study, we considered ambulant as well as non-ambulant chronic stroke patients and we observed improvements in clinical scales for both types of patients.

Louie and Eng also reported that chronic stroke patients do not respond as positively to exoskeletal gait training as do sub-acute patients.[8] In our study, a statistical improvement in functional ability was observed for sub-acute and for chronic stroke patients.

Overwhelmingly, the literature reports that significantly positive results, in terms of recovery of functional and independent ambulation, can be reached using repetitive, intensive, and task-oriented exercises based on motor learning. Louie and Eng have questioned the hypothesis that treadmill robotic gait training, characterized by sagittal movement of the legs without movement of the body into the space, can induce a functional result.[8] Overground exoskeletons require that the patient actively interfaces with the exoskeleton. With powered wearable exoskeleton Ekso, the patient is responsible for maintaining trunk and balance control and for navigating over different surfaces. Contribution of visual spatial and vestibular components, as well as patient engagement, is required.

Consequently, overground gait training with a wearable powered exoskeleton should stimulate motor control and be a good tool for walking rehabilitation in stroke patients. Our findings contrast with literature evidence that reports that a "passive exercise," in which external motors provide the full power of both legs, could potentially reduce the effort of the patient during training at high passive guidance.[50] However, our results agree with those of Louie and Eng.[8]

Limitations of the study

This was an open-label study with a small number of recruited stroke patients who had different clinical conditions; there was no control group, and there was no long-term follow-up evaluation. For these reasons, it is not possible to generalize the results of this study even if this work could represent a first attempt to describe the effects provided by a powered wearable robotic device on sub-acute and chronic stroke subjects.

Conclusions

This study suggests that it is possible to modify clinical outcome measures in sub-acute and chronic post stroke patients after 12 sessions of gait training with a powered wearable robotic exoskeleton after fine-tuning the kinematic gait cycle parameters. It is possible to plan a new individually tailored rehabilitation strategy (including task-oriented gait training) after stroke. Large multicenter randomized controlled trials comparing standard and robotic overground gait training, are warranted to verify the findings of this preliminary study.

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Authors' contributions.—Franco Molteni participated in the design and coordination of the study, data collection, and data analyses, and drafted the manuscript. Giulio Gasperini and Marina Gaffuri participated in the design of the study, enrollment and the data analyses and drafted the manuscript. Maria Colombo, Chiara Giovanzana, Chiara Lorenzon, and Nico Farina participated in the design of the study, patients enrollment, and the data analyses. Giovanni Cannaviello participated in the design of the study, data collection, data analyses, and drafted the manuscript. Stefano Scarano participated in the data collection and analyses. Davide Proserpio and Davide Liberali participated in administration of patients' training. Eleonora Guanziroli participated in the design of the study, data collection, data analyses, and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Article first published online: January 24, 2017. - Manuscript accepted: January 23, 2017. - Manuscript revised: January 17, 2017. - Manuscript received: November 30, 2016.