European Journal of Physical and Rehabilitation Medicine
EDIZIONI MINERVA MEDICA

Training for mobility with exoskeleton robot in Person with Spinal Cord Injury: A pilot study.

Patrizio SALE, Emanuele Francesco RUSSO, Stefano MASIERO, Alessandra SCARTON, Rocco Salvatore CALABRò, Serena FILONI

European Journal of Physical and Rehabilitation Medicine 2018 Mar 07
DOI: 10.23736/S1973-9087.18.04819-0

Article type: Original Article

Article first published online: March 7, 2018
Manuscript accepted: March 6, 2018
Manuscript revised: February 16, 2018
Manuscript received: May 15, 2017

Author information page:

Training for mobility with exoskeleton robot in Person with Spinal Cord Injury: A pilot study.

Patrizio Sale[1]*, Emanuele Francesco Russo[2]*, Alessandra Scarton[3], Rocco Salvatore Calabrò[4] Stefano Masiero*[1] and Serena Filoni*[2].

[1] Rehabilitation Unit, Department of Neuroscience, University of Padua, Via Giustiniani 2, Padua 35128, Italy.

[2] Fondazione Centri di Riabilitazione Padre Pio Onlus, Viale Cappuccini 77, 71013 San Giovanni Rotondo, Italy.

[3] Invictus Rehabilitation Center, Viale del Lavoro, 14 35020 Ponte San Nicolò (PD), Italy.

[4] IRCCS Centro, Neurolesi "Bonino-Pulejo", Messina, Italy.

* The authors contributed equally to this work.

Correspondence:

Patrizio Sale

Rehabilitation Unit,

Department of Neuroscience,

University of Padua,

Via Giustiniani 2, Padua 35128, Italy.

Title pages:

Training for mobility in Spinal Cord Injury: a preliminary report.

Running title:

Wearable Robot and Spinal Cord Injury.

Number of tables: 3

Key words: Spinal Cord Injury, Mobility, Gait Analysis, Lower limb, Robot.

Abstract:

BACKGROUND: Wearable robots are people-oriented robots designed to be worn all day, thus helping in the daily activities. They can assist in walking, running, jumping higher or even lifting objects too heavy in normal conditions.

AIM: The aim of this report was thus to investigate the change in gait pattern trough 3D gait analysis subjects with Spinal Cord Injury (PwSCI) that underwent an adaptive training with a wearable Exoskeletal Device (ESD). The change in the quality of life was also investigate together with the possibility to wear these devices all day, to improve the mobility.

DESIGN: Prospective quasi-experimental study, pre- and post-design.

SETTING: Outpatient PwSCI.

POPULATION: Eight volunteer PwSCI who had never used any ESD device before, were recruited.

METHODS: Subjects underwent a 3D Gait Analysis (GA) while wearing the ESD at baseline (inclusion) (T0) and after 20 sessions of training over an expected average of 5/6 weeks (T1). The secondary outcome measures were: Participant Satisfaction Questionnaire, 6 minutes walking test (6MWT), Borg Scale (the test was administered in indoor and outdoor conditions) and Timed Up and Go test (TUG). Spatiotemporal and kinematic parameters were assessed and their change from the beginning to the end of the training was the secondary outcome.

RESULTS: No dropouts were recorded during the training and all subjects were able to terminate the protocol (compliant subjects: n=8). After the training, all person showed some significant improvements for TUG, 6MWT and 10 MWT ($Z=-2.521$ $p=0.008$) and for the spatio-temporal and kinematics parameters.

CONCLUSIONS: This paper confirms that the adaptive training with ESD is safe and feasible in a heterogeneous sample of persons with SCI, especially in ameliorating the interaction between the patients and the device with an improvement of spatio-temporal and kinematics parameters.

CLINICAL REHABILITATION IMPACT: Since the training has been proven safe and the hypothesis that the subjects with spinal cord injury improving their performance over time and being able to adapt at the use of device in full autonomy at home during all the activities of the daily living has strengthened.

Keywords: Spinal cord injury, gait analysis, rehabilitation, Exoskeleton, wearable robotics, Mobility.

Introduction

A Spinal Cord Injury (SCI) is a damage to any part of the spinal cord that results in loss of functions such as mobility or feeling, below the site of the injury (1)-(2) . The most common causes of SCI are automobile crashes and falls, followed by gunshot wounds, motorcycle crashes, diving incidents, and medical/surgical complications (3). Person with SCI (PwSCI) can thus be of any age and the changes they experience in the motor, autonomic and sensory function are either temporary or permanent (4). Clinically, SCI creates a "multi-systems failure" that involve various systems: respiratory, nervous, endocrine, immune, gastrointestinal, genitourinary, cardiovascular, metabolic, musculoskeletal, psychiatric, skin and reproductive (5). In addition, SCI increases the risk for several secondary medical consequences of paralysis such as osteoporosis, muscle atrophy and pressure ulcers (6).

Since the situation can be really compromised, the rehabilitation of PwSCI focuses on recovering the highest possible level of autonomy. Mobility limitations are a key factor contributing to reduced function and health and thus to the life satisfaction of the PwSCI (7)(1). The recovery of ambulation has potential benefits in these subjects: being unable to walk affects psychological well-being and can increase the risk of depression and reduce the quality of life (8). Gait recovery is thus an integral part of rehabilitation and often influences whether a subject can return home or to work (9,10).

In the past decade the application of robotic technologies such as exoskeletons to recover lower limb function has grown rapidly in the rehabilitative practice (7). Exoskeletons can be classified in three main types: rehabilitation exoskeletons, exoskeletons for partial assistance and exoskeletons for full support assistance (11). The first kind of devices focuses on gait rehabilitation. They are used to relieve physical therapist from the strenuous and non-ergonomic burden of manual body weight support typical of the traditional physical therapy. Their use can indeed help speeding up the recovery time freeing the patient from the need to rely on pre-determined hours set forth by a physical therapist (7). The therapy could thus be personalized on the capacity of the subject. This should imply a faster recovery and improvement of gait ability and parameters (12).

The second application of exoskeletons is aimed at enhancing the physical abilities of able-bodied humans (i.e. human strength augmentation) (6). Eventually, the third application is for human locomotion assistance, which is targeted at paralyzed subjects who have completely lost motor and sensor function in their lower limbs as the PwSCI (7,13). These robotics devices that fit closely and operate in parallel with the human legs, could augment the human performance.

Furthermore, they also allow to walk repetitively in an environment which reproduces the over-ground gait with the correct proprioceptive and exteroceptive feedback: this is a key point for gait recovery.

Recently, a new definition of robotic devices has been introduced: the wearable robot (1,12). Wearable robots are people-oriented robots designed to be worn all day, thus helping in the daily activities(14). They can assist in walking, running, jumping higher or even lifting objects too heavy in normal conditions. Wearable exoskeletons are hoped to be used not only for military purposes but also for medical assistance. This because robotic gait training has been observed to improve gait speed, walking capacity and stride length and to reduce fatigue in neurological subjects (1,15–17). However, while multiple studies have shown beneficial effects of robotic interventions for some pathologies, the evidence is less for others.

The aim of this report was thus to investigate the change in gait pattern trough 3D gait analysis of SCI subjects that underwent an adaptive training with an Exoskeletal Device (ESD). ESD is a wearable bionic suit, which enables individuals with lower extremity disabilities to stand up and walk over ground with a natural, full weight bearing, reciprocal gait. Walking is achieved by the user's weight shifts activating sensors in the device, which initiate steps. Battery-powered motors drive the legs, replacing deficient neuromuscular function. ESD provides functional based rehabilitation, over ground gait training, and upright, weight bearing exercise unlike any other. The change in the quality of life was also investigate together with the possibility to wear these devices all day, to definitely improve the mobility.

Methods:

This was prospective quasi-experimental study, pre- and post-design. Eight volunteer subjects who had never used the Ekso^{TM} device or any other exoskeleton before, were recruited. Each subject was informed about the study procedure and aims and then, after a period of discussion and reflection either enrolled voluntarily and provided written informed consent or declined to participate. All procedures conformed to the World Medical Association declaration of Helsinki (2016).

A preliminary medical examination including a physical and a neurological assessment were conducted.

The following inclusion criteria were identified:

a) chronic motor complete or incomplete cervical, thoracic and lumbar (C7-L2) spinal cord injury;

b) skin integrity;

c) adequate hip, knee and ankle range of motion;

d) spasticity level of 3 or less (Ashworth scale);

e) ability to physically fit into the exoskeletal device;

f) ability to tolerate upright standing for a minimum of 30 minutes;

g) joint range of motion within normal functional limits for ambulation;

h) sufficient upper body strength to balance themselves using the walker while wearing the exoskeleton.

The following exclusion criteria were identified:

i) Heart or respiratory comorbidity;

j) Hemodynamic instability;

k) Presence of unhealed fractures;

l) Presence of heterotopic ossification that may impede walking;

m) Presence of osteoporosis;

n) Height below 62 inches or above 74 inches;

o) Weight above 220 lbs;

p) Cognitive and/or communicative disability (e.g. due to brain injury).

Subjects were required to be able to follow directions and to demonstrate learning capability.

Subjects underwent a 3D Gait Analysis (GA) and all assessments while wearing the ESD at baseline (inclusion) (T0) and after 20 sessions of adaptive training over an expected average of 5/6 weeks (T1) (1).

The primary outcome measures were:

1. 6 minutes walking test (6MWT) and Borg Scale (the test was administered in indoor and outdoor conditions)(18);
2. Timed Up and Go test (TUG)(19)

The secondary outcome measures were:

1. Visual Analog Scale for Pain for pain and fatigue(1).
2. Participant Satisfaction Questionnaire (10 questions were asked to each subject during and upon the completion of the active participation phase of the treatment) (T1)(4);

3. Spatiotemporal and kinematic parameters assessed trough 3D-Gait Analysis.

All clinical and instrumental data were collected as the subjects walked using the front rolling walker and the ESD suit.

Before, during and after the training sessions subjects performed standardized assessments and complete the questionnaires to evaluate the functional and psychological effects of the exoskeleton (subject's workload and satisfaction). Trained professionals, who were not involved in the research project, performed all instrumental and clinical assessments.

Training with the ESD.

Each enrolled subject was asked to perform 20 sessions (5/4 days a week for 4/5 weeks) of ESD training. Heart rate and blood pressure were monitored at the beginning and at the end of each session. During the training, the therapist followed the treatment standing near the patient, to help if necessary.

The practice included a robot-assisted walking training, at variable speeds, for 45 minutes. After 45 minutes the session was stopped.

The subjects were trained using the FirstStep mode for up to 3 sessions of 30 minutes before T0, to keep familiarity with the device. In this setting, the therapist initiates movement with a button. The user moves from the up and down movement of the walker to the gait even after the first session. Following, the subject used the ProStep Plus™ mode. In this adaptive modality, the steps are triggered by the patient's load and the forward motion of the limb. In ProStep Plus™, the steps are triggered by the user's weight shift plus the initiation of forward leg movement. In particular subject initiates swing limb advancement after reaching lateral target and ESD assists swing completion as programmed. Subject are guided through proper lateral shift and lifting foot off the ground to release pressure from forefoot sensors. The leg moves consistently through swing and is less susceptible to the subject's interaction. This assist mode is best used for people with a complete SCI level of injury without lower extremity motor strength. During the use, the patient puts in as much force as he or she can, the device automatically detects and adds the missing strength, resulting in patient's gait being fluid. The therapist receives feedback about the strength with which the device supports the patient so that he / she can perform the step within a specified time. The parameters of the treatment were noted for each session, and the steps taken during the simulated walking were converted into the distance covered, based on the step length

previously chosen. Adjustments of training parameters were done every day by the physical therapist based on the quality of walking (adequate step height during swing phase and adequate knee stability during stance phase), current physical condition (observation of breathing rate and degree of transpiration), and motivation (as verbally indicated by the participant). All changes were made in agreement with the participant and reflect the improvement in interaction between the patients and the device. During training sessions, rest intervals were introduced if required by the participant or suggested by the therapist.

Experimental Procedures for 3D-Gait Analysis

The 3d GA was conducted using a 6-camera optoelectronic system (SMART 300 DX, BTS, Italy, sampling frequency 120Hz) with 2 TV camera Video systems (BTS, Italy) synchronized with the force platform systems (Kistler 9286A).

After the collection of some anthropometric measures (height, weight, distance between the anterior-superior iliac spine and the medial malleolus, distance between the femoral condyles or diameter of the knee, distance between the malleoli or diameter of the ankle, distance between the anterior iliac spines and thickness of the pelvis), passive markers were positioned according to the Helen Hayes marker-set on specific anatomical landmarks (AL)(20–22). In case the ALs were hidden by the exoskeleton, markers were placed on its structure since the system was rigidly bound to the legs of the PWSCI.

Subjects were asked to walk with ESD with a front rolling walker at their own natural pace (self-selected and comfortable speed), along a 10-meter walkway.

In order to assure reproducibility and repeatability, the same experienced operator collected a minimum of 6 trials for each session. At least 4 steps for each examination were recorded and among them two subsequent strides (one for the right and one for the left side) were considered for the computation of the time/distance parameters and the joint angles values (SmartAnalyzer, BTS, Italy). To assess the subject at the steady state walking condition, the selected strides were those in the centre of the lab. All the data obtained from GA were normalized as % of the gait cycle.

Dependent Variables

In this analysis, only spatiotemporal parameters and kinematic data were considered. Although ground reaction forces were acquired during the study, they are not included in the present

analysis and are not discussed in this paper. This choice was made also considering that taking into account the weight of the ESD and the use of the walker in the analysis would have required a complex kinetic model.

The following parameters were considered:

- Mean velocity: mean velocity of progression, computed as the average instantaneous speed of the marker placed on sacrum;
- Cadence (steps/min): number of steps in a time unit;
- Stride length: longitudinal distance between successive points of heel contact of the same foot;
- Stance phase (as % of the gait cycle): % of the gait cycle when both feet are on the ground.
- Swing phase (as % of the gait cycle): % of the gait cycle when foot swings forward between one episode of ground contact and the next.
- Double support (as % of the gait cycle): the duration of the phase of support on both feet as percentage of gait cycle
- Pelvis tilt initial contact (degrees)
- ROM pelvis tilt (degrees)
- ROM hip flexion-extension (degrees)
- ROM Knee flexion-extension (degrees)
- Knee Initial Contact (KIC)
- ROM Ankle dorsi-plantar flexion (degrees)

Statistical analysis

All the previously defined parameters were computed for each participant. Mean values and standard deviations of all indexes were calculated. Kolomogorov–Smirnov tests were used to verify if the parameters were normally distributed. As this was not the case, the Wilcoxon's test was used to detect significant changes between data at baseline (T0) and endpoint (T1). Statistical significance was set at $p<0.05$.

RESULTS:

No dropouts were recorded during the training and all subjects were able to terminate the protocol (compliant subjects: n=8). Demographic and clinical data of the 8 PwSCI are shown in table 1. After the training, all subjects showed some significant improvements for TUG, 6MWT and

10 MWT (Z=-2.521 p=0.008) (table 2). The averaged results of Participant Satisfaction Questionnaire for acceptability are reported in table 3. Moreover, a statistical change was found in the answer 6 (Z=-2.449 p=0.031), 9 (Z=-2.449 p=0.031) and 10 (Z=-2.414 p=0.016) at T1. The mean values of the spatiotemporal parameters and kinematic parameters for all subjects are summarized in table 4. The statistical analysis of the spatiotemporal parameters showed an improvement in term of velocity, cadence and length of stride (Z=-2.524 p=0.008) (table 2). At T1, the kinematic data showed changes in the knee flexion at the initial contact (Z=-2.100 p=0.039), an improvement of hip ROM (Z=-2.103 p=0.039), a decrement of first minimum value of dorsi-plantarflexion (Z=-2.033 p=0.047) and an improvement of ankle ROM (Z=-2.527 p=0.008). The gait in Ekso ™ was fundamentally symmetric. Graphic data were generated for both sides (but not presented here for brevity). As such, we conduct our analysis by looking at a single leg.

DISCUSSION:

The main aim of our research was to assess the benefits in terms of mobility and satisfaction of a new robotic adaptive training in subject with PWSCI using a commercial wearable robotic device.

Difficulty in walking is a major feature of neurological disease but is also an activity of daily living on which subjects place the greatest value. As a consequence, restoring ambulation is an important goal for subjects with acute SCI. Walking ability, important for quality of life and participation in social and economic life, can be adversely affected in SCI in terms of balance, resistance and speed.

To assess the gait performance the most famous and reliable clinical test were used: the TUG, the 10MWT and the 6MWT (18,23).

After the 5 to 6 weeks of training, all the subjects showed an average decrease of 28 seconds in the performance of the TUG test. This demonstrate an improvement in the person's mobility and in both static and dynamic balance after the training with the ESD.

Furthermore, the average improvement in the 6MWT, both in external and internal environment, suggests an amelioration in all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism (24).

After the training, the 10MWT was performed with an average decrease of 31 seconds, which proves an increment of the gait speed. This is an important result when considering the role of the velocity of gait in the daily life activities. Eventually, the results of the BORG test indicate a

decrease of the effort required to perform all the examination and thus a general effective amelioration of the gait ability and performance. This is consistent with what reported in a previous study (1)(7).

Exercising with ESD has been proven effective in improvement the interaction between the patients and the device with improving time-space parameters and joint kinematics during the gait when the subject wearing the exoskeleton. It has also decreased the level of spasticity and regularized the intestinal transit in subjects with neurological bowel.

Furthermore, the training has been proven safe since no dropouts were recorded during the study. This strengthens the hypothesis that the subjects will be able to use the exoskeletons in full autonomy in a home version and in the everyday life. The fact that practice lasted only 5 to 6 weeks may indicate that this result can be achieved in short times.

Other robotic devices are available for gait training, one of the most famous being the ReWalk.

The comparison of the kinematic graphs of the gait pattern of the PWSCI wearing the EksoTM with those obtained in the work of Talaty (25) about PWSCI who use ReWalk, shows a lower rate of progression; at the hip level an increased ROM with greater flexion; at the knee level an higher flexion at the initial contact and a greater ROM in the swing phase oscillation. No difference at the ankle (dorsiflexion pattern) is observed. This comparison seems to indicate that our ESD allow a more physiological pattern of hip and knee angle during gait. With regard to the spatio-temporal parameters, subjects using ReWalk have a higher speed. This can be due to the weight of the exoskeleton and to the way it is programmed. Moreover, this paper reports for the first time until now, a preliminary analysis into how the walking kinematics differed across the heterogeneous sample of persons with SCI - as a first step to understand the possible contribution to the velocity range and determine if the subjects who did not walk as well could be taught to improve by mimicking the better walkers.

LIMITS:

Limitations of this study come from the use of the Helen-Hayes marker-set for the GA. Some of the ALs were in fact hidden by the exoskeleton and thus placed on the exoskeleton. However, considering that the lower limbs of the subjects were paralyzed, the assumption of a rigid bound between them and the exoskeleton can be accepted. Furthermore, the kinetic was not considered in the evaluation given the use of the walker during the gait trial. The knowledge of how the forces

are distributed in the joints could be useful to prevent bones fractures and thus the analysis will be added as in a future development.

CONCLUSION:

This paper confirms that the adaptive training with ESD is effective, especially in ameliorating clinical outcomes, spatiotemporal and kinematics parameters. Since the training has been proven safe and the hypothesis that the subjects with spinal cord injury improving their performance over time and being able to adapt at the use of device in full autonomy at home during all the activities of the daily living has strengthened.

Competing interest: The authors declare that they have no competing interests and that there are no conflicts of interest or financial disclosures.

1. Sale P, Russo EF, Russo M, Masiero S, Piccione F, Calabrò RS, et al. Effects on mobility training and de-adaptations in subjects with Spinal Cord Injury due to a Wearable Robot: a preliminary report. BMC Neurol [Internet]. 2016 Dec 28;16(1):12. Available from: http://dx.doi.org/10.1186/s12883-016-0536-0
2. Sale P, Mazzarella F, Pagliacci MC, Aito S, Agosti M, Franceschini M. Sport, free time and hobbies in people with spinal cord injury. Spinal Cord. 2012;50(6).
3. Chen Y, Tang Y, Vogel LC, DeVivo MJ. Causes of Spinal Cord Injury. Top Spinal Cord Inj Rehabil. 2013;19(1):1–8.
4. Zeilig G, Weingarden H, Zwecker M, Dudkiewicz I, Bloch AE. Safety and tolerance of the ReWalk[TM] exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study. J Spinal Cord Med [Internet]. 2012;35(2):96–101 6p. Available from: http://search.ebscohost.com/login.aspx?direct=true&db=cin20&AN=104546547&site=ehost-live
5. Sun X, Jones ZB, Chen X-M, Zhou L, So K-F, Ren Y. Multiple organ dysfunction and systemic inflammation after spinal cord injury: a complex relationship. J Neuroinflammation [Internet]. 2016 Dec 6 [cited 2016 Nov 3];13(1):260. Available from: http://jneuroinflammation.biomedcentral.com/articles/10.1186/s12974-016-0736-y
6. Chen B, Ma H, Qin L-Y, Gao F, Chan K-M, Law S-W, et al. Recent developments and challenges of lower extremity exoskeletons. J Orthop Transl. 2016;5:26–37.

7. Sale P, Franceschini M, Waldner A, Hesse S. Use of the robot assisted gait therapy in rehabilitation of patients with stroke and spinal cord injury. Eur J Phys Rehabil Med. 2012;48(1).
8. Louie DR, Eng JJ, Lam T. Gait speed using powered robotic exoskeletons after spinal cord injury: a systematic review and correlational study. J Neuroeng Rehabil. 2015 Oct;12.
9. Schmidt H, Werner C, Bernhardt R, Hesse S, Krüger J. Gait rehabilitation machines based on programmable footplates. J Neuroeng Rehabil [Internet]. 2007 [cited 2017 Jan 4];4(1):2. Available from: http://jneuroengrehab.biomedcentral.com/articles/10.1186/1743-0003-4-2
10. Dietz V, Colombo G, Jensen L, Hesse S, Krüger J, Carr J, et al. Locomotor activity in spinal man. Lancet [Internet]. 1994 Nov [cited 2017 Jan 4];344(8932):1260–3. Available from: http://linkinghub.elsevier.com/retrieve/pii/S014067369490751X
11. Contreras-Vidal JL, A Bhagat N, Brantley J, Cruz-Garza JG, He Y, Manley Q, et al. Powered exoskeletons for bipedal locomotion after spinal cord injury. J Neural Eng [Internet]. 2016 Jun 1 [cited 2017 Jan 4];13(3):31001. Available from: http://iopscience.iop.org/1741-2552/13/3/031001
12. Miller L, Zimmermann A, Herbert W. Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis. Med Devices Evid Res [Internet]. 2016 Mar;9:455. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27042146%5Cnhttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC4809334
13. Semprini R, Sale P, Foti C, Fini M, Franceschini M, Semprini, Roberta; Sale, Patrizio; Foti, Calogero; Fini, Massimo; Franceschini M. Gait impairement in neurological disorders: a new technological approach. Funct Neurol. 2009;24(4):179–83.
14. Singh B, Ashish R, Gurvinder S, Virk S. Lower Limb Exoskeletons : A Brief Review Lower Limb Exoskeletons : A Brief Review. 2016;(January):18–24.
15. Androwis GJ, Nolan KJ. Evaluation of a Robotic Exoskeleton for Gait Training in Acute Stroke: A Case Study. In Springer International Publishing; 2017 [cited 2016 Nov 3]. p. 9–13. Available from: http://link.springer.com/10.1007/978-3-319-46532-6_2
16. Kleiner A, Galli M, Gaglione M, Hildebrand D, Sale P, Albertini G, et al. The Parkinsonian Gait Spatiotemporal Parameters Quantified by a Single Inertial Sensor before and after Automated Mechanical Peripheral Stimulation Treatment. Parkinsons Dis. 2015;2015.
17. Sale P, Stocchi F, Galafate D, De Pandis MF, Le Pera D, Sova I, et al. Effects of robot assisted

gait training in progressive supranuclear palsy (PSP): A preliminary report. Front Hum Neurosci. 2014;8(1 APR).

18. Amatachaya S, Naewla S, Srisim K, Arrayawichanon P, Siritaratiwat W. Concurrent validity of the 10-meter walk test as compared with the 6-minute walk test in patients with spinal cord injury at various levels of ability. Spinal Cord. 2014 Apr;52(4):333–6.
19. Bovolenta F, Sale P, Dall'Armi V, Clerici P, Franceschini M. Robot-aided therapy for upper limbs in patients with stroke-related lesions. Brief report of a clinical experience. J Neuroeng Rehabil [Internet]. 2011;8(1):18. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3086823&tool=pmcentrez&rendertype=abstract
20. Davis RB, Õunpuu S, Tyburski D, Gage JR. A gait analysis data collection and reduction technique. Hum Mov Sci. 1991;10(5):575–87.
21. Kadaba MP, Ramakrishnan HK, Wootten ME, Gainey J, Gorton G, Cochran GVB. Repeatability of kinematic, kinetic, and electromyographic data in normal adult gait. J Orthop Res [Internet]. 1989 Nov [cited 2017 Jan 4];7(6):849–60. Available from: http://doi.wiley.com/10.1002/jor.1100070611
22. Kadaba MP, Ramakrishnan HK, Wootten ME. Measurement of Lower Extremity Kinematics During Level Walking. J Orthop Res Orthop Res Soc. 1990;8383.
23. Hedel HJ van, Wirz M, Dietz V. Assessing walking ability in subjects with spinal cord injury: Validity and reliability of 3 walking tests. Arch Phys Med Rehabil. 2005 Feb;86(2):190–6.
24. Brooks D, Solway S, Gibbons WJ. ATS statement on six-minute walk test. Am J Respir Crit Care Med. 2003 May;167(9):1287.
25. Talaty M, Esquenazi A, Briceno JE. Differentiating ability in users of the ReWalkTM powered exoskeleton: An analysis of walking kinematics. IEEE Int Conf Rehabil Robot. 2013;

	Age	Gender	Level of lesion	ASIA
Subject 1	50	M	D10	A
Subject 2	37	M	D7	B
Subject 3	21	F	L1	A
Subject 4	67	M	D12	B
Subject 5	41	M	D1	B
Subject 6	38	M	T1	A
Subject 7	42	F	L2	C
Subject 8	50	M	L1	B

Table 1. Clinical characteristics of all subjects.

	T0 Mean± SD	T1 Mean± SD	P
TUG (s)	86,83±28,64	58,06±12,7	0,008
VAS FATIGUE	3,00±2,39	1,75±1,91	n.s.
VAS PAIN	1,00±2,83	0,88±2,47	n.s.
6MWT Indoor (m)	62,31±21,86	98,38±17,80	0,008
BORG Indoor	1,50±1,07	1,63±1,41	n.s.
6MWT Outdoor (m)	73,21±26,90	99,13±20,10	0,008
BORG Outdoor	2,38±1,60	1,75±1,28	n.s.
10 mWT (m/s)	0,17±0,06	0,31±0,05	0,008

Table 2: Observed mean ± standard deviation for all clinical tests.

Questions:	T0 Mean ± SD	T1 Mean ± SD
Training/learning to use the device is not complicated	3,88±0.99	4,38±0,74
Wearing/adjusting the device is relatively simple	3,75±0,89	4,13±1,13
It was comfortable to exercise with the device	4±0,76	4,63±0,52
The usage of the device did not cause considerable pain	4,5±0,76	4,88±0,35
I did not feel excessive fatigue while excessive with the device	3,5±1,2	3,75±1,28
After completing the training period I felt comfortable using the device	4±0,76	4,75±0,46
Training with the device diminishes the spasticity in my legs	5.00±0.00	5.00±0.00
I did not have breathing difficulties while training with the device	4,5±1,07	5.00±0.00
I felt improvement in my bowel movement during the training program	3,38±1,06	4,13±1,13
After completing the training I felt safe using the device	2,88±1,13	4,5±0,53

TABLE 3. Participants satisfaction questionnaire of the training. (observed mean ± standard deviation at T0 and T1).

	Velocity (%h/s)		Cadence (step/min)		Stride length (%h) RX		Stride length (%h) LX	
	T0	T1	T0	T1	T0	T1	TO	T1
Mean	10,55	15,06	36,90	44,73	33,67	40,81	33,87	40,70
SD	2,86	2,76	5,50	4,73	5,18	4,43	4,87	4,56
P values	0,008	0,008	0,008	0,008	0,008	0,008	0,008	0,008
	Stance time (% cycle gait) RX		Stance time (% cycle gait) LX		Double support (% cycle gait) RX		Double support (% cycle gait) LX	
	T0	T1	T0	T1	T0	T1	TO	T1
Mean	79,71	79,43	79,34	78,53	29,29	27,74	29,61	29,92
Sd	2,57	2,13	2,14	3,02	4,02	3,46	3,31	3,43
P values	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

Table 4: Observed mean ± standard deviation of 3D Gait Analysis .