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# Over-ground robotic lower limb exoskeleton in neurological gait rehabilitation: User experiences and effects on walking ability

## Abstract

**BACKGROUND:** Over-ground robotic lower limb exoskeletons are safe and feasible in rehabilitation with individuals with spinal cord injury (SCI) and stroke. Information about effects on stroke rehabilitees is scarce and descriptions of learning process and user experience is lacking.

**OBJECTIVE:** The objectives of this study were to describe how rehabilitees learn exoskeleton use, to study effects of exoskeleton assisted walking (EAW) training, and to study rehabilitees' user experiences.

**METHODS:** One-group pre-test post-test pre-experimental study involved five rehabilitees with stroke or traumatic brain injury (TBI). Participants in chronic phase underwent twice a week an 8-week training intervention with Indego exoskeleton. Process of learning to walk and the level of assistance were documented. Outcome measurements were conducted with 6-minute and 10-meter walk tests (6MWT, 10mWT). User experience was assessed with a satisfaction questionnaire.

**RESULTS:** Rehabilitees learnt to walk using the exoskeleton with the assistance from 2-3 therapists within two sessions and progressed individually. Three participants improved their results in 10mWT, four in 6MWT. The rehabilitees felt comfortable and safe when using and exercising with the device.

**CONCLUSION:** Indego exoskeleton may be beneficial to gait rehabilitation with chronic stroke or TBI rehabilitees. The rehabilitees were satisfied with the exoskeleton as a rehabilitation device.

Keywords: Exoskeleton, neurological rehabilitation, gait, robotics, stroke, traumatic brain injury

## 1 Introduction

Gait training in rehabilitation has developed from bodyweight supported treadmill training to robot-assisted gait training (RAGT) on treadmill or exoskeleton assisted over-ground gait training [1]. Wearable powered lower limb exoskeletons, with upper body support of assistive gait aid, provide a person a possibility to perform reciprocal stepping. Many devices are seen in the market for use in rehabilitation and community settings. [2] A recent review summarizes that exoskeletons appears promising as a tool for rehabilitation with individuals with spinal cord injury (SCI) improving walking performance, health outcomes and psychological well-being [3]. Individuals with SCI have achieved walking ability with Indego exoskeleton without physical assistance and speeds close to speeds that are required in household ambulation.

Some studies have described learning processes of exoskeleton gait training. They have shown that during five training sessions individuals with SCI have learned to walk over 10 meters with exoskeletons with minimal or moderate assistance by a physiotherapist and crutches or walker. Within five sessions some have also walked outside, through ramps or grass. [4] [5]

User satisfaction with wearable exoskeletons has also been studied in few studies. A recent review concluded that individuals with SCI felt safe and comfortable using the device and they had tendencies towards strong positive statements about acceptability and emotional or health benefits of exoskeleton assisted walking (EAW). [3] Participants with SCI have also reported not having considerable pain caused by using the device and not having breathing difficulties while training [5] [6] [7].

Benefits in stroke rehabilitation have also been shown in few studies [8] [9] but far less literature is available compared to SCI. Stroke rehabilitees in subacute phase of recovery have shown to improve their walking ability during EAW based on the 10 meter walk test (10mWT) and 6 minute walk test (6MWT) [9] [10]. Also, chronic stroke rehabilitees have been shown to benefit from EAW measured with the 10mWT [8], 6MWT and Functional Ambulation Classification (FAC) [11]. Information about stroke patients' learning process and user satisfaction is missing. Studies with traumatic brain injury (TBI) rehabilitees, to our knowledge, have not been published so far.

The high prevalence of stroke (According to the World Health Organization, 15 million people suffer stroke worldwide each year) [12] and promising result from previous studies underlines the need for further researching the potential benefits of exoskeletons in stroke rehabilitation.

The device used in this study is Indego exoskeleton [13]. Indego is a wearable powered lower limb exoskeleton, which consists of hip part, two upper leg parts and two lower leg parts. Battery and electronics are in hip part. Upper legs contain powered joints in knees and hips, lower legs are integrated ankle foot orthoses. The device has different programs for individuals, who have limited walking ability (Therapy +) and who have no voluntary movements in lower limbs (Motion+) (Table 1). Adjustments are set through Indego App with iOS device. See the picture of Indego in Figure 1. The device was selected while all the exoskeletons used in Finland are currently Indego exoskeletons and Parker Hannifin corporation has authorized dealer in Finland. In Europe, the device is used with stroke and TBI patients, but no research on Indego is published.

We have not been able to locate any recent studies of stroke rehabilitees using Indego exoskeleton. One study of development of the device have concerned stroke rehabilitation. [14] Though other exoskeletons have been shown to be safe and feasible with stroke rehabilitees [8] [11], the user experience has not been studied. Also, the impact of EAW on functional ability, has not been widely studied. In hospital setting subacute stroke rehabilitees have gained better results in modified Barthel Index after exoskeleton training [9] [10] Otherwise, outcome measures of functional ability have not been reported.

The purpose of this study was to provide information about usability, feasibility and impacts of EAW with different neurological diagnoses. Another purpose was to study the rehabilitees' user experience which is especially important as exoskeletons are also available as personal models (assistive aids). Further studies of exoskeletons supporting independent living are needed but are out of scope of this paper. [15]

## 2 Methods and materials

### 2.1 Study Design

The study was a pre-experimental one-group pre-test post-test study. Tests were conducted before and after the EAW training intervention. Training was implemented in rehabilitation centers or physiotherapy clinics in Satakunta district in Finland. The places were selected based on suitable rehabilitees and their physiotherapy places. The results, study methods and implementation of this pre-experimental study are used or revised in the next study, which is already on-going.

Ethical approval granted from ethical board of human sciences in universities of Satakunta. The study followed the responsible conduct of research (RCR guidelines), formulated by the Finnish advisory board on research integrity (TENK) [16]. All the necessary approvals were obtained in each center. All rehabilitees received oral and written information about the study, data collection and data management. Participants gave their written consent. General Data Protection Regulation (EU GDPR) was obeyed and the data was anonymized. The gathered data was saved under password in researcher's personal file in the database of Satakunta University of Applied Sciences (SAMK). The anonymized data is stored in SAMK's database and is available for further use by permission of SAMK.

## 2.2 Participants

The convenient sampling was carried out for individuals with stroke, SCI or TBI. Adult (18 years or over) and committed rehabilitees, who met the criteria shown in Table 2, were phone screened via neurological physiotherapists in the clinics and centers in the Satakunta area. Only rehabilitees in the subacute or chronic phase were included due to the unpredictable spontaneous recovery and commitment challenges in the acute phase. Previous experience of EAW was not accepted.

Rehabilitee's own physiotherapist performed preliminary assessments of suitable individuals.

Researchers conducted the last control of suitability, e.g. joint movements, spasticity and fitting into the device. A written approval from the medical doctor (specialized in neurology) was required whether the participant was suitable for Indego use based on inclusion and exclusion criteria for safety using (Table 2). Due to detailed criteria, physiotherapists managed to evaluate their patients and select only suitable

rehabilitees to get EAW as a part of their physiotherapy. Thereby, no possible candidates were excluded. Only one suitable rehabilitee could not participate, but the reason was the small size of torso padding, which is not mentioned in criteria for safe using.

### 2.3 Training protocol

The training intervention lasted 8 weeks, involving two 60min sessions per week. The training was integrated into the rehabilitees' rehabilitation program. The length and frequency of the sessions were based on the rehabilitees' financial coverage based on referral document. Participants' other therapies continued as before.

The Intervention protocol followed the progress used in earlier Indego study [17]. After necessary measurement for fitting the device, rehabilitees were informed and familiarized of using Indego exoskeleton. After being able to perform safely sit-to-stand, standing and stand-to-sit, rehabilitees trained ambulation indoors on smooth surfaces. With progress and proficiency in using the device, the training included more difficult activities, such as walking on different surfaces or carpets and managing doors (Table 3.). Due to minus degrees (Celsius), walking outdoor was not possible. The sessions were led by researchers, who are physiotherapists trained for using Indego.

Adjustments in the device were set individually. Motion+ program (M+) was used with participants who did not have enough voluntary strength in both lower limbs. Therapy+ program (T+) was used when a rehabilitee was able to initiate the steps by hip flexion. (Table 1)

## 2.4 Outcome measurements

The outcome measurements in our study were selected according to components of functioning in The International Classification of Functioning, Disability and Health (ICF) [18]. Body functions were acknowledged by measuring heart rate (HR), blood pressure (BP), feeling of fatigue (scale 0-10), pain (scale 0-10) and checking skin condition according to measure the suitability and ensuring the safety in the sessions. Body structures were measured for assessing the suitability and inclusion criteria. Walking tests and satisfaction questionnaire were related to activities and participation. Contextual factors were taken into account as environmental factors when documenting the process of training: confronting thresholds and different surfaces.

### 2.4.1 Learning and assistance

The process of learning to walk with Indego was documented during the intervention. Activities like sit-to-stand or stand-to-sit, standing balance, walking on different surfaces and performing tasks while standing were written down. The number of sessions, when the achievement was successfully performed was documented. Progress of learning has been studied with SCI rehabilitees in earlier studies [4] [5]. The level of assistance was documented by terms of maximal, moderate or minimal assistance or supervision and as a number of needed therapists [4] [19]. Rated perceived exertion (RPE) after each session provided information of how exhausting the training is. The scale in Borg's RPE is from 6 to 20, from no exertion at all to absolute maximum and it has been used in earlier Indego study [17].

### 2.4.2 Walking ability

Walking tests were conducted in the beginning (t0), in the middle (t1) and in the end (t2). T0 and t2 were done with and without the device, t1 was done without the device. 10mWT and 6MWT were



performed according to instructions [20][21]. Tests with the device were first conducted when a rehabilitee was able to walk over 10m (10mWT) and over 6min without a pause (6MWT). The FAC (Table 4) with six levels of walking ability (from category 0: nonfunctional ambulation to category 5: independent ambulation) [22] was documented based on discussions with participant and his / her physiotherapist at t0 and t2.

#### 2.4.3 User satisfaction with Indego exoskeleton

Users' satisfaction was measured by a questionnaire, used in earlier studies [5] [6] [7] in the end of intervention. Rehabilitees' opinions were documented for ten statements concerning the easiness and safety of using the device and whether they felt improvements in spasticity, pain, bowel movement or fatigue. Subjective answers were given by a Likert scale: 1) strongly disagree, 2) disagree, 3) somewhat disagree, 4) agree and 5) strongly agree. In addition to earlier studies the rehabilitees were asked, if they would use the device as a rehabilitation device or assistive device in the future.

#### 2.5 Data analysis

In this study, descriptive data-analysis was carried out in order to answer the research questions. With a small group of participants, it is not meaningful and reasonable to make deep statistical analysis, while relationships and correlations between values might not be trustworthy. Data interpretation is in the descriptive level to find out tendencies of similarities and differences. Based on EU standard GDPR (General data protection regulation) we can't describe cases in more detailed in order to avoid revealing their identity.

Interval and ratio values of achievements and walking tests were analyzed as univariate data by calculating quantities in frequencies and percentages. Results of the satisfaction questionnaire are in ordinal scale. Despite of that, they are reported as mean values and standard deviation, like that done in earlier studies [5] [6] [7].

## 3 Results

### 3.1 Participants

Six rehabilitees gave their consent to participate and they were measured for fitting the device. One of them was not suitable because the torso pad did not reach around. Characteristics of the included participants are shown in Table 5. All the rehabilitees had over one year since their injury and were in the chronic phase. They had no fractures or experience of EAW over-ground.

They were out-patients and Indego training replaces four rehabilitees' conventional physiotherapy. One rehabilitee had financial coverage for robotic assisted gait training using Lokomat and Indego training replaced that, while the rehabilitee still had her conventional physiotherapy and pool therapy. No dropouts or absence due to sickness occurred. Based on participant's financial coverage based on referral their number of sessions were 8 (n=1), 12 (n=1) or 15 (n=3) times.

### 3.2 Learning and assistance

In the first session, everyone (N=5) succeeded to stand up and sit down. Four rehabilitees were able to walk 4-23m during the first session. One had difficulties with spasticity and ankle position in the device

and was unable to take steps. Setting the device took more time compared to the others. The training was started with M+ (trajectory-based program) with every rehabilitee, rehabilitees R2 and R4 were able to change it to T+ (program, in which the rehabilitee initiates steps). Individually considered assistive devices during the intervention were walkers, platform walker, Wheellator (walker-wheelchair), crutch and cane.

In the first or second session, every rehabilitee (N=5) walked all at once at least 10m using the Indego and assisted by two or three therapists (Table 6). Three rehabilitees (R1, R2, R4) were able to walk all at once over 100m without a pause during the intervention. All the rehabilitees (N=5) managed to walk altogether over 100m within a session, R2 and R4 in the second session, rest of the rehabilitees in the fifth.

All the rehabilitees (N=5) succeeded to walk altogether over 200m in a single session during the intervention. R5 had big difficulties after 9<sup>th</sup> session of 15 session period. The walked distances reduced, and the level of assistance remained maximal to moderate from three therapists. Four participants achieved minimal level of assistance from two assistants and R4 even supervision assistance. Two of these rehabilitees required moderate assistance over ten sessions.

Three rehabilitees (R1, R2, R4) walked over different surfaces, carpets and small thresholds. They also did upper limb coordination exercises while leaning the device against a table. One of those participants took an elevator upstairs and downstairs in her fifth session. She needed supervision assistance and help to keep the door open long enough to enter in and out.

No clear trend of increasing or decreasing in RPE was found. The scores at the end of each session varied among participants from very very light (score of 7) to very very hard (score of 19). Three participants' mean value was somewhat hard (13) or lower, two participants' hard (15) or higher. RPE differed session by session based on the effort required due to set assistance or support of the device.

While investigating the achievements and progressing of the rehabilitees the researcher observed and documented many issues that effected on the process of learning to walk with exoskeleton. Challenges were seen with paretic arm and hand, and in postural control. Occurred challenges and solutions are shown in Table 7.

### 3.3 Walking ability

Participants' speed with the device according to the 10mWT improved (n=3), stayed in the same level (n=1) or got worse (n=1) (Figure 2). Three participants improved their speed without the device progressively, while one participant gained worse results at t2 compared to t0.

According to the 6MWT four participants' walking distances improved with the device. One participant gained shorter distance at t2 compared to t0 (Figure 3). Without the device four participants improved their distances, while one participant's result decreased.

At t0 participants' (N=5) mean value in FAC was 2,4 ( $\pm 0,9$ ) and increased into 3,4 ( $\pm 0,9$ ) at t2. Three rehabilitees' classification improved by one or two categories, with R3 and R4 remained in the same level.

### 3.4 User satisfaction with Indego exoskeleton

After the training period, all the rehabilitees (N=5) felt comfortable using the device (agreed or strongly agreed) and exercising with it (strongly agreed, agreed or somewhat agreed) (Table 8). They also felt safe using it. All participants that had spasticity (n=4) felt that the exoskeleton training reduced spasticity (strongly agreed, agreed or somewhat agreed).

Four out of five participants were willing to use the device as a rehabilitation tool in the future (Table 8). None of the five participants could imagine using the exoskeleton as an assistive walking aid at home.

### 3.5 Adverse events

Severe adverse event did not happen during the intervention. On four occasions, small dint and two times light redness occurred in rehabilitees' skin. These problems were solved by using better padding. Two participants experienced pain in their feet during walking, but pain disappeared immediately after taking the device off. Participants mentioned occasionally having pain in their back, knee, wrist or big toe. These were eased by adjusting the device and / or having breaks.

The results of body functions; HR, BP, pain and fatigue measured for safety reasons during every session, did not show relevant variation. The results did not cause interruptions or prevention of training with any participant.

## 4 Discussion

This study aimed to provide information about usability, feasibility and impacts of EAW with different neurological diagnoses, added with user experience. The main findings were that rehabilitees with stroke or TBI progressed differently but were able to learn to walk using Indego exoskeleton with assistance from one, two or three physiotherapists. Four out of five participants improved their walking ability, but one did not benefit from EAW. Rehabilitees felt that it was safe and comfortable to use and exercise with the device. They would like to use Indego as a rehabilitation device but could not imagine it as an assistive walking aid.

The results of this study cannot be directly compared to results of studies with SCI rehabilitees. The disease status of participants in this study was different as well as way of functioning with or despite of impairments. The possibilities and hindrances of using an exoskeleton are different; an individual with SCI might not have any impairment in functions of upper extremity whereas an individual with stroke always has problems in body control and upper extremity. That sets requirements for assistive aid and challenges for rehabilitee to handle the device.

## 4.1 Achievements, feasibility and usability

Rehabilitees in our study learnt to sit-to-stand, stand-to-sit, standing balance and walking 10m within two sessions. The need of assistance during the training period varied from supervision from one or two therapists to maximal or moderate assistance from three therapists. Three rehabilitees succeeded to walk over carpets and thresholds etc. In earlier studies of individuals with SCI, participants have achieved above mentioned tasks within 5 sessions [4] [5] but used the device individually or with minimal to moderate assistance by one physiotherapist. Participants' achievements or level of assistance have not been reported in earlier studies with strokes. However, we found the requirement for two assistive therapists due to challenges of holding with the paretic hand.

When considering contextual factors affecting the ICF domain of activities and participation, environmental factors can create barriers which the exoskeleton cannot cross. Small thresholds can be stepped over but bigger steps not, cold weather or snow prevents rehabilitees to access outdoor living. That means, even though a rehabilitee can achieve a skill, he or she might not be able to utilize it for participation.

Based on study results there was no clear reason for why one participant did not progress. Questions rose about possible overload, difficulties with adjustment settings, cold weather increasing the spasticity when arriving to therapy or poorly slept nights. Difficulties in training have not been reported in earlier studies.

In our study settings, it was not appropriate to have more than two sessions per week with home living chronic outpatient rehabilitees. The majority of rehabilitees (n=4) had no other physiotherapy than

exoskeleton training. Rehabilitees (n=4) still gained benefits, though frequency was lower than in earlier studies [9] [10] [17]. It would be beneficial to evaluate, how much more effective the training would be with subacute rehabilitees, when the plasticity of brains is higher.

The attendance in training sessions of our study was high, but participants' recruitment in the first place was challenging. In earlier studies with stroke rehabilitees, recruitment rates have not been reported.

#### 4.2 Impact on walking ability

The results in this study showed positive signs in improving walking ability, which is included in mobility domain of the ICF activities and participation. The majority of the rehabilitees improved their results in the 10mWT and 6MWT in our study. Also, in earlier studies chronic stroke rehabilitees have improved their walking ability [8] [11]. Significance of the changes was not reasonable to calculate in such a small population, but results are aligned compared to earlier findings.

The improvements in FAC in our study were consistent with earlier studies [9] [10], where subacute stroke patients gained significant improvements. In this study mean value of FAC at t0 was 2,4 ( $\pm 0,9$ ) and at t2 it was 3,4 ( $\pm 0,9$ ). In the study of Platz et al. (2016) the results with subacute stroke patients were 2,5 ( $\pm 1,48$ ) at the beginning and 4,0 ( $\pm 0,0$ ) at the end [10].



### 4.3 User satisfaction with exoskeleton

Items in satisfaction questionnaire covers many issues in ICF. The basic meaning of user satisfaction can though be considered to refer to activities and participation and good scores in results might indicate better managing in that domain. Based on the satisfaction questionnaire of this study, participants felt comfortable using the device and did not have breathing difficulties while training. That was consistent with satisfaction results in earlier studies [5] [6] [7]. In our study, participants felt almost as safe as participants in above mentioned studies (average value in this study was 3,8, in earlier studies it was 4 or higher). The lowest value in our study was related to bowel function, which also was one of the lowest in an earlier study [5].

Despite of willingness to use Indego exoskeleton as a rehabilitation tool, rehabilitees in our study could not imagine it as an assistive device in the home setting. In our study, the participants needed assistance to EAW from at least 1-2 therapists, which decreased their independence. They also had difficulties with finding a proper assistive device like walkers due to paretic upper limb. These issues might cause problems in home settings, too.

### 4.4 Limitations of this study

The small size and lack of control group limited our ability to make comprehensive conclusions. Participants also had different diagnoses, but all had hemiparesis as a symptom. Small sample and heterogeneity though allow us to describe results in more detail and widen the perspective of exoskeleton users. The absence of Indego studies with stroke and TBI rehabilitees increases the need for additional studies with exoskeletons, and other rehabilitees than SCI.

In this study the outcomes of gait rehabilitation were measured with validated tests, which showed specific effects on walking ability. The effects on functioning would be important to measure, but no reliable objective tools have yet been established to measure the effects in rehabilitees' active daily living.

User experience was studied with the satisfaction questionnaire that is not validated. It was though conducted by the author (TJ) in a reliable way as other measurements. The results of this study should be interpreted as preliminary results and experience, which can guide the direction of future studies.

## 5 Conclusions

This study showed that Indego exoskeleton training may provide benefits to chronic stroke and TBI rehabilitees but is not suitable for everyone. Exoskeleton is a safe and comfortable tool in gait training but requires individually tailored settings and assistance with different diagnoses and individuals. In future studies with larger samples, it would be beneficial to find the correlations and arguments to whom the training is most beneficial and what are the benefits compared to other rehabilitation methods. In practice the decision of who uses the exoskeleton in rehabilitation and in what phase, should be considered thoroughly.

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## References

[1] Mikolajczyk M, Ciobanu I, Badea DI, Iliescu A, Pizzamiglio S, Schauer T et al. Advanced technology for gait rehabilitation: An overview. *Advances in Mechanical Engineering*. 2018; 10(7): 1-9.

doi10.1177/1687814018783627.

[2] Palermo AE, Maher JL, Baunsgaard CB, Nash MS. Clinician-Focused overview of bionic exoskeleton use after spinal cord injury. *Topics in Spinal Cord Injury Rehabilitation*. 2017; 23(3): 234-244.

doi10.1310/sci2303-234.

[3] Shackleton C, Evans R, Shamley D, West S, Albertus Y. Effectiveness of over-ground robotic locomotor training in improving walking performance, cardiovascular demands, secondary complications and user-satisfaction in individuals with spinal cord injuries: a systematic review. *Journal of Rehabilitation Medicine*. 2019; 51: 723-733. doi10.2340/16501977-2601.

[4] Hartigan C, Kandilakis C, Dalley S, Clausen M, Wilson E, Morrison S et al. Mobility outcomes following five training sessions with a powered exoskeleton. *Topics of Spinal Cord Injury and Rehabilitation*. 2015; 21(2): 93-99. doi10.1310/aci2102-93.

[5] Platz T, Gillner A, Borgwaldt N, Kroll S, Roscka S. Clinical study. Device-training for individuals with thoracic and lumbar spinal cord injury using powered exoskeleton for technically assisted mobility: achievement and user satisfaction. *BioMed Research International*. 2016; Article ID 8459018. doi10.1155/2016/8459018.

[6] Zeilig G, Weingarden H, Zwecker M, Dudkiewicz I, Bloch A, Esquenazi A. Safety and tolerance of the ReWalk exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study. *The Journal of Spinal Cord Medicine*. 2012; 35(2): 96-101. doi10.1179/2045772312Y.0000000003.

[7] Sale P, Russo EF, Scarton A, Calabrò RS, Masiero S, Filoni S. Training for mobility with exoskeleton robot in spinal cord injury patients: a pilot study. *European Journal of Physical and Rehabilitation Medicine*. 2018; 54(5): 745-751. doi10.23736/S1973-9087.18.04819-0.

[8] Calabrò RS, Naro A, Russo M, Bramanti P, Carioti L, Balletta T et al. Shaping neuroplasticity by using powered exoskeletons in patients with stroke: a randomized clinical trial. *Journal of NeuroEngineering and Rehabilitation*. 2018; 15: 35. doi10.1186/s12984-018-0377-8.

[9] Goffredo M, Guanziroli E, Pournajaf S, Gaffuri M, Gasperini G, Filoni S et al. Overground wearable powered exoskeleton for gait training in subacute stroke subjects: clinical and gait assessments. *European Journal of Physical and Rehabilitation Medicine*. 2019. doi10.23736/S1973-9087.19.05574-6.

[10] Goffredo M, Iacovelli C, Russo E, Pournajaf S, Di Blasi C, Galafate D et al. Stroke gait rehabilitation: a comparison of end-effector, overground exoskeleton, and conventional gait training. *Applied Sciences*. 2019, 9. doi 10.3390/app9132627.

[11] 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. *European Journal of Physical Rehabilitation Medicine*. 2017; 53(5): 676-684. doi 10.23736/S1973-9087.17.04591-9.

[12] The Internet Stroke Center [homepage on the internet]. The internet stroke center - an independent web resource for information about stroke care and research. [updated 2020; cited 2020 May 25] Available from: [www.strokecenter.org/patients/about-stroke/stroke-statistics/](http://www.strokecenter.org/patients/about-stroke/stroke-statistics/).

[13] Parker Hannifin Corporation [homepage on the internet]. Indego. [updated 2020; cited 2020 March 8] Available from: [www.indego.com](http://www.indego.com).

[14] Murray SA, Ha KH, Goldfarb M. An assistive controller for a lower-limb exoskeleton for rehabilitation after stroke, and preliminary assessment thereof. *Conf Proc IEEE Eng Med Biol Soc*. 2015. doi 10.1109/EMBC.2014.6944521.

[15] Tefertiller C, Hays K, Jones J, Jayaraman A, Hartigan C, Bushnik T, et al. Initial outcomes from a multicenter study utilizing the Indego powered exoskeleton in spinal cord injury. *Topics of Spinal Cord Injury in Rehabilitation*. 2018; 24(1): 78-85. doi 10.1310/sci17-00014.

[16] Finnish Advisory Board on Research Integrity. Responsible conduct of research and procedures for handling allegations of misconduct in Finland. Guidelines of the Finnish Advisory Board on Research Integrity 2012. [Online, Cited 2019 March 28] Available from: <https://www.tenk.fi>.

[17] Juszczak M, Gallo E, Bushnik T. Examining the effects of a powered exoskeleton on quality of life and secondary impairments in people living with spinal cord injury. *Topics of Spinal Cord Injury Rehabilitation*. 2018; 24(4): 336-342. doi 10.1310/sci17-00055.

[18] World Health Organization. How to use the ICF: A practical manual for using the International Classification of Functioning, Disability and Health (ICF). Exposure draft for comment. [Online, Cited: 2020 April 18] Available from <https://www.who.int/>.

[19] Kozlowski AJ, Bryce TN, Dijkers MP. Time and effort required by persons with spinal cord injury to learn to use a powered exoskeleton for assisted walking. Topics of Spinal Cord Injury Rehabilitation. 2015; 21(2); 110-121. doi 10.1310/sci2102-110.

[20] Shirley Ryan Ability Lab [homepage on the internet]. Rehabilitation Measures Database, 10 meter walk test. [updated 2014 January 22; cited 2020 March 8]. Available from: <https://www.sralab.org/rehabilitation-measures/10-meter-walk-test>.

[21] Shirley Ryan Ability Lab [homepage on the internet]. Rehabilitation Measure Database, 6-minute walk test. [updated 2013 April 26; cited 2020 March 8]. Available from: <https://www.sralab.org/rehabilitation-measures/6-minute-walk-test>.

[22] Shirley Ryan Ability Lab [homepage on the internet]. Rehabilitation Measures Database, Functional ambulation category. [updated 2012 January 19; cited 2020 March 8]. Available from: <https://www.sralab.org/rehabilitation-measures/functional-ambulation-category>.

Tables

Table 1. Indego software suites

<b>Software</b>	<b>steps</b>	<b>trajectory</b>	<b>assist</b>
<b>Motion+</b>	postural changes trigger steps (forward lean)	predetermined step through app	full or variable robotic assist while moving joints
<b>Therapy+</b>	hip flexion initiates steps	determined by the user	adjustable levels of assist during stance / swing

Table 2. Eligibility for this study and inclusion and exclusion criteria by Parker Hannifin Corporation

<p style="border: 1px solid black; border-radius: 5px; padding: 2px; margin-bottom: 10px;">Eligibility for this study:</p> <ul style="list-style-type: none"> <li>•SCI, stroke or TBI</li> <li>•Subacute or chronic phase</li> <li>•Not independently ambulatory</li> <li>•Current physiotherapy period paid by Kela, insurance company, primary health care, rehabilitee himself or some other</li> <li>•No previous experience of using Indego exoskeleton</li> </ul>
<p style="border: 1px solid black; border-radius: 5px; padding: 2px; margin-bottom: 10px;">Inclusion criteria for safety using:</p> <ul style="list-style-type: none"> <li>•Sufficient upper extremity strength to manage approved stability aids</li> <li>•Passive range of motion at their hips, knees and ankles to neutral or better</li> <li>•Healthy bone density</li> <li>•Tolerance for being fully up-right without being symptomatic</li> <li>•Height 150cm – 190cm (5,1” – 6,3”)</li> <li>•Weight not exceeding 113kg (250lbs)</li> <li>•Seated hip width not exceeding 42,2cm (16,6”)</li> <li>•Femur lengths 35,5 – 47cm (14 – 18,5”)</li> <li>•Intact skin where person would come in direct contact the Indego device</li> <li>•Spasticity level 3 or less on the Modified Ashworth Scale (MAS)</li> <li>•Stable cardiovascular health</li> </ul>
<p style="border: 1px solid black; border-radius: 5px; padding: 2px; margin-bottom: 10px;">Exclusion criteria for safety using:</p> <ul style="list-style-type: none"> <li>•Severe vascular disorders of the lower limbs (e.g. unresolved deep vein thrombosis)</li> <li>•Diminished standing tolerance (caused by, e.g. orthostatic hypotension)</li> <li>•Poor bone health that places the user at an increased risk for fracture during ambulation</li> <li>•Contractures at the hips, knees and ankles</li> <li>•Uncontrolled autonomic dysreflexia</li> <li>•Uncontrolled hypertension or hypotension</li> <li>•Poor skin integrity in areas in contact with the device</li> <li>•Heterotopic ossification that would limit joint range of motion</li> <li>•Cognitive impairments resulting in inability to follow directions</li> <li>•Visual impairments which would make ambulation unsafe</li> <li>•Lower limb prosthesis</li> <li>•Any condition which in the opinion of a medical doctor prevents the user from using device</li> </ul>

Table 3. Training procedure.

The number of sessions	Activities
1.	- Complete necessary measurements - Information and familiarization of using the device - Trying the device on
1.- 3.	- Sit-to-stand, standing, stand-to-sit - Walking a few steps
4.- to the end	Walking on different surfaces, individual progress based on participants skills and proficiency

Table 4. Functional Ambulation Classification (FAC).

0:	Patient cannot walk, or needs help from 2 or more persons
1:	Patient needs firm continuous support from 1 person who helps carrying weight and with balance
2:	Patient needs continuous or intermittent support of one person to help with balance and coordination
3:	Patient requires verbal supervision or stand-by help from one person without physical contact
4:	Patient can walk independently on level ground, but requires help on stairs, slopes or uneven surfaces
5:	Patient can walk independently anywhere

Table 5. Characteristics of the rehabilitees

Gender	60% female, 40% male
Age (MD, years)	62 (range of variation 30-69)
Dg	1 stroke / haemorrhage, left paretic, 2 stroke / infarction, left paretic, 1 stroke / infarction, right paretic, 1 TBI, left paretic
Time since injury (MD, years)	7 (range of variation 2,5-32)



Table 6. Rehabilitees' (N=5) achievements and number of sessions, when a milestone achieved presented as medians

	<b>MD</b>	<b>Range of variation</b>
<b>Sessions</b>	15	8-15
<b>Longest walked distance in a session altogether (meters)</b>	245	220-354
<b>Longest walked distance all at once (meters)</b>	109	80-164
<b>10m at once (number of session)</b>	2	1-2
<b>100m in a session (number of session)</b>	5	2-5
<b>Only 2 assistants (number of session)</b>	3,5 (4 rehabilitees)	2-8
<b>Minimal assistance achieved (number of session)</b>	7 (4 rehabilitees)	2-14
<b>Contact guard assistance achieved (number of session)</b>	9 (1 rehabilitee)	9
<b>Change to T+* (number of session)</b>	4,5 (2 rehabilitees)	2-7
<b>Crossing carpets and small thresholds or training with upper limbs (number of session)</b>	6 (3 rehabilitees)	4-10
<b>RPE** (mean values, SD)</b>	13,87 ±0,74	12,00 ±0,93 - 16,83 ±1,53

T+\* = Therapy+ program, \*\*RPE = Rated Perceived exertion

Table 7. Challenges in rehabilitees (N=5) learning process and solutions.

<b>ID</b>	<b>Challenges</b>	<b>Solution</b>
R1	Spasticity provoked in the ankles when wearing exoskeleton	Use of own orthoses while wearing the exoskeleton
	Problems in taking a grip because of spasticity and pain	trying several assistive devices but the best was platform walker
R2	Stance phase with healthy lower limb due to tight hamstring muscles and 10 degree limit in extension of the knee	Use of Therapy+ mode
	Pain in paretic stiff upper limb	Use of one crutch
R3	Pusher syndrome provoked by exoskeleton training	Alteration of training in the beginning very close to a wall next to R3's healthy side
	Difficulties in taking a grip due to inactivation of paralyzed upper limb	Use of platform walker
R4	Difficulties in initiating stepping in Therapy+ mode	Manual facilitation in the beginning to help to move the paretic lower limb
	Minor problems in taking a grip due inactivation of paretic hand	Physiotherapists assist of assistive device
R5	Poor awareness of posture in upper body and difficulties in weight sifting to paretic side	Using a mirror in front of the rehabilitee, giving cues by touching the arm
	Difficulties in leaning on the paretic upper limb	Trying several assistive devices, the best were platform walker and Parker Hannifin's walker with high arm support

Table 8. Results of satisfaction questionnaire and additional questions as mean values and standard deviation (SD).

Questions	Mean (SD)
1) Training / learning to use the device is not complicated	3,2 (±0,9)
2) Wearing / adjusting the device is relatively simple	3,0 (±0,7)
3) It was comfortable to exercise with the device	4,2 (±0,8)
4) The usage of the device did not cause considerable pain	3,2 (±0,8)
5) I did not feel excessive fatigue while exercising with the device	3,8 (±0,8)
6) After completing the training period, I felt comfortable using the device	4,2 (±0,5)
7) Training with the device diminishes the spasticity in my legs	3,8 (±1,0)
8) I did not have breathing difficulties while training with the device	4 (±1,2)
9) I felt improvement in my bowel movement during the training program	2,4 (±1,1)
10) After completing the training, I felt safe using the device	3,8 (±0,5)
I could imagine using the device as an assistive walking aid at home	2 (±0,0)
I would use the device as a rehabilitation device in the future	4 (±1,7)

Answers in scale 1. Strongly disagree, 2. Disagree, 3. Somewhat agree, 4. Agree, 5. Strongly agree.

#### Figure captions

Figure 1. Picture of Indego exoskeleton

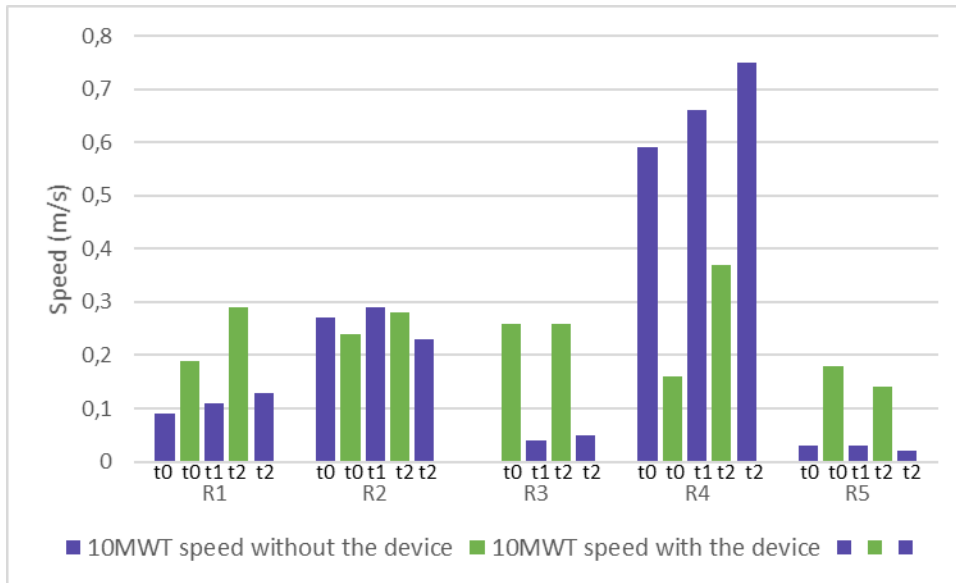
Figure 2. 10-meter walk test (10mWT)

Figure 3. 6-min walk test (6MWT)

#### Figures



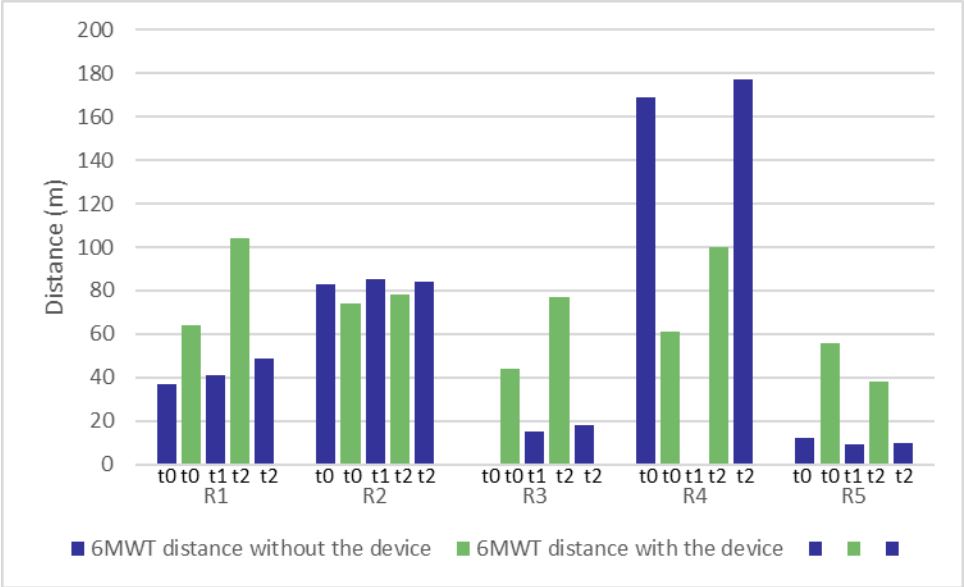
Figure 1. Picture of Indego exoskeleton (Parker Hannifin Corporation)



T0 = test at the beginning, t1 = test in the middle, t2 = test at the end of intervention

Participants' IDs: R1, R2, R3, R4

Figure 2. Results of 10-meter walk test (10mWT)



T0 = test at the beginning, t1 = test in the middle, t2 = test at the end of intervention

Participants' IDs: R1, R2, R3, R4

Figure 3. Results of 6-min walk test (6MWT)