EKSO GT™ CLINICAL RESEARCH
SUMMARY OF FINDINGS
June 2018
Spinal Cord Injury Studies

2018

1. Cardiorespiratory demand and rate of perceived exertion during overground walking with a robotic exoskeleton in long-term manual wheelchair users with chronic spinal cord injury: A cross-sectional study

This study investigated wheelchair users engaged in a walking program using a robotic exoskeleton to observe the cardiorespiratory demands and determine if doing so provided moderate-intensity exercise, thus potentially avoiding the negative effects of prolonged sitting.

Thirteen long-term wheelchair users who had sustained a complete motor spinal cord injury participated in a walking program using the Ekso GT. The researchers measured cardiorespiratory changes and the perceived exertion using a portable gas analyzer system. The tests were conducted during sitting, standing, and 10 MWT using the Ekso GT. The participants showed an increase of 9-35% in cardiorespiratory measures just moving from a sitting to a standing position. When progressing from standing to walking in the Ekso, cardiorespiratory measures increased by 22-52%. The authors concluded that this group of long-term wheelchair users could attain health benefits from the use of the Ekso due to the moderate level of exercise that is provided standing and walking.


This study investigated the change in gait patterns and quality of life in patients with SCI who undergo adaptive training with the Ekso GT.

Eight persons with SCI underwent 3D Gait Analysis at baseline and after 20 training sessions that took place over 5 to 6 weeks. A participant satisfaction questionnaire, the 6MWT, 10MWT, the Borg Scale and the TUG Scale assessed the physical and qualitative changes that occurred after training. All subjects showed significant improvements in the TUG, 6MWT and 10MWT (p=0.008). The authors concluded that walking in the Ekso is safe and feasible in a heterogeneous group of SCI subjects and that spatio-temporal and kinematic parameters improved.


Participants with varying levels of motor incomplete spinal cord injuries were tested for cardiorespiratory and metabolic responses using different modes of overground bionic ambulation.

Four participants ranging in age from 24 to 48 years of age used the Ekso GT in fixed, adaptive, and maximal assist modes. There was a wide variation in cardiorespiratory and metabolic responses based on the modes and level of injury. In general, the fixed mode induced the highest response and was thought to be the optimal mode for cardiometabolic health benefits and overall improvements in fitness.
4. Locomotor training using an overground robotic exoskeleton in long-term manual wheelchair users with a chronic spinal cord injury living in the community: Lessons learned from a feasibility study in terms of recruitment, attendance, learnability, performance, and safety.
Gagnon DH et al. University of Montreal; Published in Journal of Neuroengineering and Rehabilitation, 2018;15:12

Outcomes in this study were rate of recruitment, attendance and completion as well as the ability to walk (progression) and safety.

Approximately 28% of the people with SCI who showed interest in the study actually enrolled and of the 14 individuals with complete motor SCI who started the program, 13 completed the 6 to 8-week program. Over the 18 sessions, standing, walking, and number of steps increased approximately 45%, 102%, and 249% respectively. Approximately 86% required only one therapist to assist them during walking and reached a walking speed of 0.25 m/sec. In terms of safety, one participant sustained a calcaneous fracture and was removed from the study and five participants reported pain and/or stiffness in the upper extremities during training. The authors concluded that use of the Ekso in complete motor SCI patients is safe and feasible but that larger studies are required. The authors also recommend pre-training to increase recruitment and better clinical guidelines to reduce the potential of fractures in those who use exoskeletons in the presence of complete motor SCI.
5. **Satisfaction and perceptions of long-term manual wheelchair users with a spinal cord injury upon completion of a locomotor training program with an overground robotic exoskeleton**


This study sought to quantify satisfaction and perception of the participants who engaged in an exoskeleton training program for 6-8 weeks.

Fourteen SCI subjects participated in a locomotor training program for 18 sessions, then completed an electronic questionnaire encompassing 41 statements about satisfaction, learnability, perceived health benefits and risks as well as motivation to engage in physical activity. Each statement used a visual analog scale of 0 to 100. The mean satisfaction with the robotic exoskeleton training program exceeded 95% and the positive feedback about the exoskeleton alone was around 82%. Attributes of the program were rated high (~85%) and ability to learn sit-to-stand and walking activities were rated close to 80%. Health benefits were perceived by 68%. The respondents (91%) also expressed motivation to engage in physical activity.

6. **How does wearable robotic exoskeleton affect overground walking performance measure with the 10-m and six-minute walk tests after a basic locomotor training in health individuals?**


This study explores the differences in gait patterns when walking in three different modes: without and exoskeleton, with the Ekso GT in ‘passive’ mode, and with the Ekso GT in ‘active’ mode.

After basic training with the Ekso GT, 17 healthy volunteers performed both the 10MWT (preferred and maximal speeds) and the 6MWT. The authors emphasized that the selection of walking tests should depend on the level of assistance provided by the WRE.

7. **Weight-bearing overground stepping in an exoskeleton with non-invasive spinal cord neuromodulation after motor complete paraplegia**


This is one of the first reports of spinal cord stimulation combined with the use of the Ekso GT exoskeleton.

Transcutaneous electrical stimulation, buspirone, and Ekso stepping were used in combination in an individual who had been completely paralyzed for more than 4 years. The study consisted of four phases: baseline, drug only, stimulation only, and drug plus stimulation. All phases were accomplished while using the Ekso GT for stepping practice. Three important points regarding the Ekso GT were made: 1) The Ekso provided weight-bearing walking with the assistance of only one person, 2) individuals use muscles in their arms, upper body, and trunk while walking, and 3) the patient has to actively use muscles for balance while walking. In addition, the authors found that long-term training resulted in improved synaptic connections that had long been dormant.
8. **Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics (Pan-Euro Study)**

Baunsgaard C et al. University of Copenhagen, Denmark. Published in *Spinal Cord* online at https://doi.org/10.1038/s41393-017-0013-7

*The Pan-Euro Study was conducted at 9 European Centers and measured safety, efficacy and quality of life in participants with complete or incomplete spinal cord injuries (recently injured or chronic) who trained in the Ekso or Ekso GT for 3x a week over 8 weeks.*

Fifty-two participants (mean age 35.8 yrs.) who sustained varying levels of acute or chronic injury to the spinal cord (AIS A through D) completed training and follow-up in this multicenter study. Walk modes used included Max, Fixed, and Adapt while training in the Ekso or Ekso GT for 24 one-hour sessions (3 times a week for 8 weeks). Heart rate, blood pressure, and the Rate of Perceived Exertion (RPE/Borg test) were measured at each training session. Though the median number of completed sessions was 21 (mean of 2.6 sessions per week), training was considered “complete” if participants walked for a minimum of 16 sessions. Results showed a significant increase in heart rate during the sessions with no significant change in blood pressure. RPE was significantly lower over time. Total up time, walk time, and number of steps increased significantly from the first training session to the last training session (p < 0.001) within all subgroups which included recently and chronically injured, paraplegia and tetraplegia and incomplete and complete injury. There was a significant increase in the number of participants who had gait function at baseline vs. at 12 weeks. There were no falls and no serious adverse events.


Baunsgaard C et al. University of Copenhagen, Denmark. Presented at the ISCOS Meeting in Dublin, Ireland, October 2017.

*The Pan-Euro Study also measured other qualitative factors such as pain, spasticity, range of motion, urinary and bowel function, independence, and quality of life in participants with complete or incomplete spinal cord injuries (recently injured or chronic) who trained in the Ekso or Ekso GT for 3x a week over 8 weeks.*

This presentation provided additional data that was not included in the recent publication (shown above). Researchers recorded baseline values of pain, spasticity (MAS), joint range of motion, urinary function, bowel function, spinal cord independence measures (SCIM III), and quality of life before training in the Ekso or Ekso GT for 24 one-hour sessions (3 times a week for 8 weeks). Tests that were performed at baseline were repeated at the midway (pain, spasticity), at the end of the 8 weeks, and finally at 4 weeks following the completion of training. There was a reduction in MAS pain scores before training compared to after training by week 4 and again at week 8. In 6 recently injured participants, there was more awareness in the need to defecate and all (N=25) within that group showed improvement in SCIM III scores whereas the chronically injured group (N=27) showed significant improvement on respiration and sphincter management. That same chronic group showed significant improvement in “satisfaction in life as a whole.” The authors concluded that the training was safe, well-tolerated and that participants would likely benefit more by training in the Ekso GT for a longer period of time.
10. **Exoskeleton Training May Improve Level of Physical Activity After Spinal Cord Injury: A Case Series.**


*This study examined whether exoskeleton training could improve levels of physical activity by increasing numbers of steps and walking time after SCI.*

The study explored whether exoskeleton training once a week for 10-15 weeks could improve levels of physical activity as determined by the duration of walking in persons with SCI. The main outcome measurements were walking time, standing time, ratio of walking to stand-up time and number of steps. Three men with chronic complete and one with incomplete SCI participated in the study. Walking time, stand-up time, number of steps, and ratio of walking to stand-up time increased in all participants. The maximum walking time increased from 12 to 57 minutes and the number of steps increased from 59 to 2,284 steps. By the conclusion of the study, all 4 participants were able to exercise for 26 to 59 minutes. The authors concluded that exoskeleton training for SCI persons may improve physical activity by increasing the number of steps and walking time as well as possibly increasing energy expenditure and improving body composition.

11. **Effect of short-term exoskeleton rehabilitation programme on central blood pressure and arterial wave reflection in patients with spinal cord injury.**


*SCI patients have been shown to have greater risk of cardiac disease. This study focused on the changes in cardiovascular markers after short-term (5 day) training in the Ekso GT.*

Six participants (age 30 +/- 13 yrs.) with various ASIA classifications and time since injury of 0.5 to 4.5 years underwent 60 minutes of standard physiotherapy before training in the Ekso GT for 90 minutes a day over 5 consecutive days. Prior to and after training, Pulse Wave Analysis was used to detect resting BP, arterial stiffness, and heart rate. The authors found that the training in Ekso GT reduced arterial stiffness and that larger, randomized trials are warranted due to the higher risk profile of the SCI patient.

12. **Effectiveness of exoskeleton training in SCI: preliminary study on metabolic and cardiac responses.**


*This study explored the metabolic and cardiac effects of SCI participants walking in the Ekso exoskeleton 3 times a week for a total of 20 sessions.*

Four participants engaged in the walking program where physiological changes in metabolic and cardiac markers were assessed at baseline and again at the end of training. Measurements included VO₂, HR, and MET (energy cost of physical activity). Gait speed and performance task load increased over time, but there was no significant change in VO₂ or metabolic activity. The authors concluded that these four SCI participants increased their speed and performance in the Ekso but without significantly increased metabolic demand.
13. **Bowel and bladder functions during and after robotic exoskeleton assisted walking overground training in SCI persons.**
Stampacchia, G. et al.: Pisa, Italy. Presented at the ISCOS Meeting in Dublin, Ireland, 24-26 October, 2017,

In this study of four participants (two paraplegic and two tetraplegic), bowel and bladder functions were assessed before and after walking in the Ekso exoskeleton.

This study focused on visceral improvement in the four participants with ASIA classification A, B, or C (subacute and chronic) who walked in the Ekso exoskeleton for 20 sessions and were tested again 3 months after the last session. All participants improved in neurogenic bowel function between baseline and end of study but most importantly, involuntary bladder leakage was reduced due to the reduction in bladder infections. The authors found that participants expressed an improved quality of life with improvements in pain and spasticity.

14. **Increased serum high-density lipoprotein after 36 exoskeleton-assisted walking sessions**

SCI patients have been shown to have lower high-density lipoprotein levels and are, therefore, at increased risk of cardiovascular disease. This study centered around the use of exoskeletons as a means to provide high-intensity exercise and measure the impact on HDL-c levels.

Fifteen participants trained for 36 one-hour sessions over 12 weeks using either Ekso GT or ReWalk. Serum HDL-c levels were measured at baseline and after the participant completed the 36 training sessions. A minimally clinically important difference (MCID) was considered to be a >2.0 mg/dl change in fasting serum levels. Results showed that more than half reached the MCID level and notably, those that did walked over 10,000 steps more than those participants who did not reach the MCID level. The authors concluded that walking with exoskeletons for 36 sessions lead to a favorable change in HDL-c levels.

15. **Patient-reported bladder management improvements after exoskeletal-assisted walking**
Hong E of the James J. Peters VA Medical Center in Bronx, NY. Published in *Journal of Spinal Cord Medicine* 2017;40(5) - ASCIP 2017 Conference Abstracts published 30 July 2017

This on-going study is a randomized, crossover design involving SCI patients that participated in exoskeleton walking sessions and usual activity sessions.

This interim analysis included ASIA A through D participants who were injured at least 6 months prior to enrollment. Bladder management was self-reported at baseline and after 12 weeks of usual activity and after 36 sessions of exoskeleton-assisted walking (EAW) using both the Ekso GT and ReWalk devices. The two groups either started with usual care followed by EAW or started with EAW followed by usual care. Results in 14 participants with a mean age of 42 years showed that 50% of the group showed clinical improvement after EAW vs. 14% after usual activity. In fact, 50% of the group showed negative changes after usual activity. The changes were statistically different between groups. After 36 sessions of exoskeleton walking, bladder management improved during sleep and created less concern in the participants.
16. Exoskeleton assisted walking (EAW) in acute rehab following spinal cord injury

This on-going Canadian Study is a single-arm study involving acute-injury SCI patients who participate in hour-long Ekso GT walking sessions 3x a week for up to 25 sessions.

The primary endpoint of this study is the change in vital signs. Safety endpoints include the number of falls and skin integrity issues, pain, and spasticity issues. Secondary endpoints related to efficacy include the 10MWT, 6 Min Walk Test and the Borg rating of perceived exertion. Data involving 8 participants with an average age of 37 and average time since injury of only 10.6 weeks demonstrated the safety and feasibility of exoskeleton walking after an acute spinal cord injury. Early data show that blood pressure trends were not inhibiting participation and there were no falls. Gait-related outcomes show dramatic improvement in all subjects who completed 13 or more sessions.

17. Neuromechanical adaptations during a robotic powered exoskeleton assisted walking session

This study analyzed the gait parameters and neuromuscular profiles in both able-bodied and SCI participants.

Four participants who had sustained a spinal cord injury (SCI) were compared to four able-bodied (AB) participants in this single-session, cross-sectional study using the Ekso exoskeleton under Max Assist settings. Data collected included temporal-spatial parameters, kinematics, walking velocity and electromyography results. As expected, AB individuals showed a significant reduction in walking velocity (P < 0.05) compared to their normal walk speed outside of the Ekso. However, when the AB individuals voluntarily assisted the Ekso, velocity increased to a “slow walk” speed. SCI individuals demonstrated a higher mean percent stance time but their walking velocity was still consistently lower than the AB group (P < 0.05). Muscle activation in the SCI group was demonstrated in several lower limb muscles. AB participants demonstrated some differences in phasing amplitudes of EMGs of lower limb muscle activation, primarily greater temporal-spatial response and neuromuscular phasic adaptions. Similarly, neuromuscular phasic adaptions while walking in the Ekso were shown in the SCI group and these were inconsistent to gait muscle activation outside of the Ekso.

18. Effect on Body Composition and Bone Mineral Density of Walking With a Robotic Exoskeleton in Adults With Chronic Spinal Cord Injury

This pilot study examined the physiological changes that occurred while training in the Ekso 3 times per week over a 6-week training period.

Five adults with chronic and complete SCI participated in the study. Baseline body composition was measured via dual energy X-ray absorptiometry and peripheral quantitative computed tomography. After 18 sessions of Ekso training (3 times a week for 6 weeks), participants were again measured using the same modalities. Investigators report a significant increase in lean leg and appendicular mass and a corresponding reduction in fat mass. Calf muscle diameter also increased significantly. Bone mineral density of the tibia increased by 14.5% and was considered to be clinically significant. The authors concluded that training with the exoskeleton appears to be associated with improvements in body composition and possibly bone health as well.
19. Training Response to Longitudinal Powered Exoskeleton Training for SCI

This study examined how exoskeleton training for 5 hours per week for 20 weeks changed gait parameters in chronic SCI participants.

Five SCI participants and two able-bodied controls trained in either the Ekso GT or the ReWalk exoskeleton for 5 hours per week over 20 weeks. The outcomes included gait parameters such as Center of Mass excursions, walking velocity, initial double stance time, single stance time, terminal double stance time, and swing time. Outcomes for spatial parameters included step length, step width and stride length. Exoskeleton training was shown to have a significant effect on walking velocity and increased stability. The authors concluded that the study supports the rationale for the increase in robotic exoskeleton velocity for SCI participants who completed their training.

20. Neurorehabilitation in paraplegic patients with an active powered exoskeleton (Ekso)

This study looked at both the physical and psychological improvements after training in Ekso 5 times per week over a 4-week training period

Thirteen men and women who had suffered either a complete (N=7) or incomplete (N=6) SCI participated in this study. Training was accomplished in all patients during a daily session lasting 45 to 60 minutes, 5 days a week for 4 weeks. The outcome measures included the 6 min walking test (6MWT), the Ashworth scale for spasticity, and various psychological tests (Beck Depression Inventory and Body Uneasiness Test-A). The incomplete SCI patients showed a statistically significant improvement in distance walked on the 6MWT P < 0.05. There were no statistically significant changes in the Ashworth Scale scores but all patients showed improvement in mood and body perception. The authors concluded that the exoskeleton shows promise in both motor and psychological recovery.

21. Trunk Muscle Activation Patterns During Walking With Robotic Exoskeletons in People with High Thoracic Motor Complete SCI
Alamro R, Chisholm A, Lam T. University of British Columbia, Vancouver, Canada; presented at the ASNR Meeting in November 2016

This study compared trunk muscle activity in 6 AIS A and AIS B Participants who used either Ekso, Ekso on a treadmill, or Lokomat.

Six participants with chronic injuries from levels C7 to T4 were included in this study. Each participant performed three walking modes at matched speeds (Ekso overground, Ekso with treadmill, and Lokomat) while trunk muscle activity was measured using surface EMG electrodes. Ekso under either condition was more effective than Lokomat in activating muscles below the level of injury in participants with motor complete SCI. The authors attributed this muscle activation to the need for lateral weight shifts while stepping in Ekso.

This study determined that taking a systematic, integrated approach to rehabilitation with robotic exoskeletons improved quality of care and provided an optimal research methodology to measure improved walking abilities in SCI patients.

The study explored ways to achieve optimal mobility outcomes through development and implementation of a clinical decision support and data management system that integrates key locomotor training principles to better meet individual patient needs. By proceeding systematically through the steps of examining the literature, collaborating internally, trying in practice, collecting data, studying and assessing – clinicians noticed improved walking ability in patients previously thought to have plateaued.

23. Optimizing Mobility Outcomes Across Locomotor Training Modalities: Clinical Reflection During Development of the PRIME Algorithm – A Case Series

This study explored an algorithmic approach to integrate optimal use of locomotor modalities including robotic exoskeletons.

The study explored and developed the Parkwood Program for Rehabilitation Innovation in Movement Enhancement (PRIME) system which is an algorithmic approach to the integrated, optimal use of available therapeutic modalities for locomotor training customized to patient’s situations and needs. Three participants who had previously plateaued were staged according to the Canadian SCI Standing and Walking Assessment tool (C-SWAT). An evolving clinical decision-making protocol was formed based on constant reassessment and participants underwent 8 months or more of outpatient therapy guided by the protocol. The protocol involved one or more robotic therapy tools. In all cases, participants used the Ekso GT at some point during their rehabilitation, and each improved in their C-SWAT stage.

24. Locomotor Training With Exoskeleton EKSO-GT in Patients With Motor Incomplete Spinal Cord Injury in a Hospital Setting- Preliminary Results

This study explored whether Ekso GT may assist in improvement of motor function and evaluated patient satisfaction.

The study explored how patients respond to rehabilitation training with Ekso GT. Twenty participants with motor incomplete SCI had rehabilitation cycles using Ekso GT, in addition to conventional treatment. Data was recorded at the beginning of the training, on the 12th session and on the 18th session. The 10-meter, 6-minutes, WISCI-II and SCIM-III tests were used to assess gait speed, mobility, kinetics, and endurance in the lower limb. The study also evaluated the degree of safety and tolerability of treatment, and reduction of pain and/or spasticity. Preliminary data showed significant improvement in SCIM Mobility, WISCI II, walking speed, endurance, and quality of life. In addition, the training proved safe and well tolerated, and all patients said they would recommend the use of Ekso in similar situations.
25. Powered Exoskeletons – and Their Implementation into the Therapeutic Approach of German SCI Centers
Bergner U. BGU Murnau, Germany; presented at the ISCoS Meeting in September 2016.

This study explored trends in German SCI centers using powered exoskeletons.

The study explored how powered exoskeletons are implemented in physiotherapy treatment settings of German SCI centers. In April 2016, a questionnaire was sent to 24 facilities using exoskeletons in German SCI acute care and rehab centers. The questionnaire surveyed clinical usage and therapy approaches to mobility training. Out of 22 hospitals that returned the survey, 8 of them have exoskeletons and treat an average of 13.5 patients with a powered exoskeleton per year.


This study explored how the Ekso Bionics exoskeleton may be useful in improving patient gait speed, step length and double limb support.

This study explored the effects of robotic gait training with Ekso GT on spatiotemporal gait parameters in spinal cord injured persons with gait disorders. The GAITRite® system, a portable gait analysis system was used to measure step length, gait speed, cadence, and double limb support. Two individuals with incomplete tetraplegia received overground gait training using Ekso GT for 8 weeks. Assessments were performed before and after the intervention and in a four week follow up with the GaitRite® system. Both participants showed improvement in gait speed, step length and double limb support.

27. A Study Exploring the Clinical Effects of a Short-Duration Exoskeleton Rehabilitation Programme on Key Physiological Markers in Spinal Cord Injury
Luard K, Martinelli L, Hobbs H, Faulkner J. Hobbs Rehabilitation Center, University of Winchester, United Kingdom; presented at the ISCoS Meeting in September 2016.

This study explored the use of the robotic Ekso Bionic exoskeleton in rehabilitation in patients with SCI.

This study explored the effect of a short duration Ekso Bionic exoskeleton rehabilitation program on several physiological outcomes. Four individuals with SCI and ASIA classifications A-C took part in a 5-day training program. Training consisted of daily 1 hour physiotherapy sessions, followed by 1.5 hours of gait training in the exoskeleton. Settings were used to progress the participants from passive (therapist activated) to active gait patterns. Prior to and following the training program, bladder and bowel function, ankle swelling, spasticity, gait parameters and vascular health were measured. All participants increased their walk time over the week, and improvements in bladder and bowel function along with a decrease in peripheral and central systolic blood pressure were observed.
Stampacchia G, Rustici A, Bigazzi S, Gerini A, Tombini T, Mazzoleni S. The Center for Spinal Cord Injured Persons, Pisa University Hospital, Pisa, Italy; Published in Neurorehabilitation 2016 DOI.10.3233/NRE-161358

This study explored the effects of walking with the Ekso exoskeleton on the reduction of pain and spasticity in spinal cord injured persons.

This study included 21 SCI participants who participated in a walking session assisted by a powered robotic exoskeleton. Prior to and after walking, pain and spasticity were assessed using a Numeric Rating Scale (NRS), the Modified Ashworth scale and the Penn scale. Positive and negative sensations were also evaluated using a questionnaire. The patient's global impression of change (PGIC) scale was administrated as well. The post-walking assessment showed a significant decrease in muscle spasticity and pain intensity. Questionnaires indicated a good acceptability of the robot-assisted walking. The authors concluded that "overground robot-assisted walking is well accepted by SCI persons and has positive effects in terms of spasticity and pain reduction."

29. Energy Expenditure and Cardiovascular Drift Effect During Extended Bionic Walking
Baunsgaard CB, Maher JL, Gerven JV, Palermo A, McMillian DW, Irwin RW, Biering-Sørensen F, Nash MS. The Miami Project to Cure Paralysis, and 2Department of Neurological Surgery and 3Rehabilitation Medicine, University of Miami Miller School of Medicine, Miami, FL; Presented at the American Spinal Injury Association (ASIA) annual conference 2016.

This pilot study observed changes in circulation during acute extended bionic walking with Ekso.

This study included 8 males with traumatic SCI and 5 non-injured controls. Testing was performed for 45 minutes under each of the following conditions; seated rest, standing, and indoor/outdoor bionic walking. VO₂ for all subjects was collected using a portable spirometer, perceived exertion rated (RPE) using the Borg 0-10 categorical-ratio scale, and the following obtained using wireless transthoracic impedance cardiograph (ZCG): Heart rate (HR), stroke volume (SV), and cardiac output (Q). %VO₂peak was computed for all timepoints (timepoints 0-1 min, 14-15 min, 29-30 min, 44-45 min). Comparable percentages of work were observed in subjects with SCI and CON when expressed as % of peak capacity. Increase in Q during bionic walking is explained by increased HR. SV decreased during standing in the exoskeleton, probably due to stasis venous pooling, although bionic walking maintains stable SV during extended walking.
30. Exploring the Psychosocial Impact of Ekso Bionics Technology

This is the first study in the United States that examines the psychosocial impact of walking in the Ekso GT.

Nine Veterans (mean age=47 yrs) with lower extremity weakness or paralysis and various levels of function participated in interviews about their daily activities and psychosocial status before and after walking in the Ekso GT. A total of 33 questions were asked and related to (1) change in function; (2) burdensomeness; (3) feasibility; and (4) psychosocial benefits. Preliminary results showed that walking in Ekso was meaningful and had benefits related to standing, walking, exercising and remaining eye-level with others with increasing levels of excitement and confidence expressed.

31. Effects on Mobility Training and De-adaptations in Subjects With Spinal Cord Injury Due to a Wearable Robot: A Preliminary Report
Sale P, Russo EF, Russo M, Masiero S, Piccione F, Calabrò RS, Filoni S. Department of Neurorehabilitation, Hospital Via Alberoni, Venice, Italy; Published in BMC Neurology 2016;16:12.

This is a pilot study examining the feasibility and acceptability of robot training for patients with spinal cord injury.

This pre-post design study enrolled three subjects with SCI and gait disorders. All subjects received walking sessions for 45 minutes 3 to 4 times a week for 20 sessions. All subjects showed improvement in gait based on spatiotemporal indexes, including velocity, step length, step width, and the six minute walk test. Participants also completed satisfaction questionnaires. Subjects expressed positive feelings during the training process and felt safe and comfortable with the robot at the end of the training period.
32. Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking
Kozlowski A, Bryce TN, Dijkers MP. Department of Rehabilitation Medicine, Icahn School of Medicine, Mount Sinai, NY. Published in Top Spinal Cord Inj Rehabil 2015;21(2):110–121. doi: 10.1310/sci2102-110

In this study, researchers explored whether individuals with motor complete and incomplete cervical injuries could learn to walk in an Ekso exoskeleton with little or no assistance and observed their perceptions of effort.

The goal of this study was to quantify the time and effort required by persons with SCI to learn to use the first-generation Ekso powered exoskeleton to walk. Participants were given up to 24 weekly sessions of instruction while collecting data on level of assistance, distance and speed, heart rate, perceived exertion, and adverse events. Using the number of sessions required for participants to stand up, walk for 30 minutes, and sit down, initially with minimal and subsequently with contact guard assistance, time and effort was calculated. Of the 7 participants (2 with tetraplegia and 5 with motor-complete injuries), 5 could stand, walk, and sit with contact guard or close supervision assistance, and 2 required minimal to moderate assistance. Walk times ranged from 28 to 94 minutes with average speeds ranging from 0.11 to 0.21 m/s. For all participants, heart rate changes and reported perceived exertion were consistent with light to moderate exercise. This study provides preliminary evidence that persons with neurological weakness due to SCI can learn to walk with little or no assistance and light to somewhat hard perceived exertion using a powered exoskeleton. Persons with different severities of injury, including those with motor complete C7 tetraplegia and motor incomplete C4 tetraplegia, may be able to learn to use this device.


This group of authors presents four case studies to compare the differences between conventional physical therapy and therapy using the exoskeleton.

Two groups of subjects (2 per group) with chronic incomplete spinal cord injury were randomly assigned to either conventional physical therapy (CPT) or robotic exoskeleton therapy (RET) with CPT. All subjects demonstrated improved outcomes in three measures. However, the RET/CPT demonstrated a greater degree of improvement over the CPT alone group.
2014

34. **Lower Limb Bionic Exoskeleton for Rehabilitation, Exercise or Mobility. Exploratory Case Series in Persons with Chronic, Complete Spinal Cord Injury.**

*This study explored reduction in pain and other responses to overground bionic ambulation in persons with complete spinal cord injury.*

Four participants between the ages of 26-38 years with complete SCI (AIS A) between the levels of T1-T10 for less than a year experienced over-ground bionic ambulation (OBA) three days a week for six weeks. Outcome measures were walking speeds and distances, energy expenditure, exercise conditioning effects, neuromuscular cortical activity patterns, and pain severity. Participants reported an average reduction in pain severity over the study period ranging between -1.3 and 1.7 on a 0 to 6 numerical rating scale. Significant changes in exercise conditioning, neuromuscular and cortical activities were not deemed significant. No adverse events were reported.

2013

35. **Evaluation of the Clinical Criteria for Safe and Efficient Use of Exoskeletons in Individuals with SCI**
Jayaraman A. Center for Bionic Medicine and Department of Physical Medicine and Rehabilitation at the Rehabilitation Institute of Chicago, Chicago, IL. Presented at the American Spinal Injury Association (ASIA) conference, 2013

12 patients were enrolled at the time of this presentation in a 12 week study, two visits per week. Some participants walked faster, but seemed to have less balance; others walked slower, but demonstrated better balance. Six-weeks of training seemed to be a stable point where training leveled off. Larger numbers were deemed needed to predict proficiency which includes different levels of injury, ROM, patient reported and performance-balanced tests.

36. **Safety and Feasibility of Using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury**

*This was a feasibility study wherein researchers evaluated the safety of the Ekso Bionics 1.0 prototype.*

Eight patients with complete T1 SCI or below, within two years of injury were included in this study of safety and feasibility. Patients participated in six weekly sessions with increasing time and decreasing assistance walking in the device. Blood pressure, pain level, spasticity, amount of assistance for don, doff, and transfer, time ambulating, walking time, and skin effects, among other measures were evaluated. Walking in Ekso was found safe for those with complete thoracic SCI in a controlled environment, in the presence of experts, and may eventually enhance mobility in those without volitional lower extremity function. There appeared to be a training effect in the device but further trials were deemed needed. Future studies of bionic exoskeletons as gait training devices are seen as warranted. Future studies of bionic exoskeletons as a clinical tool to alleviate secondary complications should be considered.
37. The Potential of the Ekso Exoskeleton for Affecting Long-Term Health and Well-Being in the SCI Population

This early study examined the feasibility of using Ekso in a variety of individuals with spinal cord injuries.

An evaluation of 13 patients (12 paraplegia, 1 tetraplegia) participated in the trials to determine the feasibility of innovative applications of technological advances for mobility after spinal cord injury. Dr. Forrest reported that walking and standing in Ekso is feasible for people with a range of spinal cord disorders, reporting it took a bit longer for higher injuries to learn how to use it. There were improvements in function with training using Ekso: Walking speed and distance, fluidity, gait, and balance all demonstrated improvements. Two individuals were evaluated for the potential benefits for heart, lungs, and circulation. Comparing an experienced walker (30 sessions) with a novice, there was evidence of training effects: the experienced user’s oxygen consumption, ventilation, and pulse returned to baseline resting values faster. There was also noted increased muscle firing in lower leg muscles, and it was suggested this will need to be studied further.
1. **Shaping neuroplasticity by using powered exoskeletons in patients with stroke: a randomized clinical trial.**

   This randomized controlled trial compared the effects of robotic exoskeletons with overground training versus overground training alone in improving specific gait functions related to the brain's neuroplasticity in chronic stroke patients.

   Forty participants aged 55 or older who had suffered a first-time ischemic supra-tentorial stroke were enrolled in this randomized, prospective study that tested baseline and post training performance in the following areas related to neuroplasticity: gait performance, gait cycle, muscle activation pattern, frontoparietal effective connectivity, corticospinal excitability, and sensory-motor integration. Randomization allocated the participants to all overground therapy or overground therapy plus the Ekso robotic exoskeleton training. All participants were trained for 60 minutes a day, 5 days a week for 8 weeks. The data at 8 weeks showed that Ekso participants not only met all of the primary outcome measures (whereas the overground only group did not), they did significantly better than the overground only group in multiple tests for neuroplasticity. These results led to the conclusion that Ekso can promote mobility in stroke patients and that combining Ekso training with overground training in stroke patients is promising.

2. **Automatic setting procedure for exoskeleton-assisted overground gait: proof of concept on stroke population.**

   This study focused on how to customize the gait rehabilitation of each individual stroke patient by defining muscular activation patterns and fine-tuning the exoskeleton with the goal of bringing the patient to a normal gait.

   Twenty participants (13 stroke patients and 7 healthy controls) were recruited to study the normal vs. abnormal timing and intensity of the lower limbs during walking. Muscle activation was seen as the key factor in reducing maladaptive neuroplasticity and leading to recovery of a more normal gait pattern. The exoskeleton was fine-tuned based on the capacity of the individual. EMG activity from various muscles was collected in both the neurologically impaired individuals and the healthy controls. The healthy controls served as the reference muscular activation pattern. Using a Gait Metric Index for each walking trial, gait parameters and settings on the exoskeleton could be changed to more closely match the normal controls.
3. **Wearable robotic exoskeleton for over-ground gait training in sub-acute and chronic hemiparetic stroke patients: preliminary results.**


This pre-post pilot study enrolled both sub-acute and chronic stroke patients to test the clinical effects of exoskeleton use during rehabilitation training.

Walking rehabilitation training using the Esko GT was conducted in 23 stroke patients, 12 of which were sub-acute and 11 were chronic. Training consisted of 12 one-hour sessions over 4 weeks. Clinical evaluations using the Ashworth Scale, Motricity Index, Trunk Control Test, Functional Ambulation Scale (FAC), 10-Meter Walk Test (10MWT), 6 Minute Walk Test (6MWT), and Walking Handicap Scale were performed at baseline, after the 6th session, and after the 12th session. Statistically significant improvements were demonstrated in both groups, specifically in the Motricity Index, FAC, 10MWT, and 6MWT. Both groups did not show a significant change between baseline and 12 weeks in the Ashworth scale. The sub-acute patients showed statistically significant improvement in the Walking Handicap Scale and Trunk Control Test from baseline to 12 weeks. The authors concluded that in both sub-acute and chronic stroke patients, improvement in ambulatory function is shown after 12 sessions of gait-training with the Ekso exoskeleton.

4. **Use of the Ekso Bionics Exoskeleton Robotic Assisted Mobility Device with Acute Rehabilitation Patients: Preliminary Results.** Flaherty V, Anderson C, Ball K, Furman K, Brady S; Marionjoy Rehabilitation Hospital, Wheaton, IL. Presented at the AMRPA in Chicago, IL, October 2017.

This prospective, non-randomized study utilized a pre-post design to evaluate functional changes in acute rehabilitation patients who used the Ekso GT.

Thirty-one participants were qualified for this study if they had paralysis or lower extremity weakness. Though SCI and TBI patients were included, the largest number of participants had experience a stroke (N=22). The mean number of treatments was 5.2 (range 3-11) over a time period ranging from 5 to 64 days. The 10 Meter Walk Test pre/post changes were significantly better (p = .001) and participants showed improved FIM scores (transfer and locomotion, p< 0001). With the significantly positive functional changes shown during this acute rehabilitation period, the authors concluded that the “up-time” and increased steps afforded by the use of the device had value in neuroplastic training and neuroplastic changes leading to ambulation recovery.
5. **Is a Structured Exoskeleton Overground Gait Training Program Superior to Traditional Care in Individuals Affected by Chronic, Severe Stroke?**

Hohl K, Deems-Dluhy S, Mummidisetty CK, Jayaraman A. Rehabilitation Institute of Chicago, Chicago, IL; Poster presented at AAP 2017.

*This study examines whether a high dose regimen in an exoskeleton produced better outcomes in stroke patients when compared to traditional gait therapy.*

Twenty-two chronic, severe stroke patients were divided into two parallel training groups that were matched based on gait speed at screening and gender. Twelve participants used the Ekso GT for overground gait training and ten performed standard overground gait training (SOC). Each group trained for one hour, three times a week for six weeks, then two times a week for a period of four weeks. The Esko group was approximately 8 years older on average, and chronicity was 50% longer compared to the SOC group. The authors noted that the first 9 visits (3 weeks) produced the greatest changes in outcomes. Both groups improved significantly in walking speed and balance. When the Ekso group was stratified based on low number of steps vs. high number of steps, there was no difference in outcomes. The authors concluded that walking in the exoskeleton can improve mobility in those chronically and severely impaired patients who have suffered a stroke.
6. **Exoskeleton Gait Training for Individuals Affected by Severe, Chronic Stroke**  
Knowlton MR, Deems-Dluhy SL, Jayaraman A, Scanlan K. Rehabilitation Institute of Chicago, Chicago, IL; Presented at APTA 2016.

This preliminary report of an ongoing study of subjects affected by severe, chronic stroke exploring the capacity to improve in speed and distance after gait training with the Ekso exoskeleton.

Ten out of a planned 60 subjects were enrolled at the time of this report. Training consists of one hour of overground walking with the Ekso GT three times per week for a total of 26 sessions. All subjects were at least 6-months post stroke and ambulating slower than 0.4 m/s. Assessments were performed at baseline and again after the 9th, 18th, and 26th sessions. Several subjects who completed the training have achieved clinically significant results in both the 6 min walk test distance and 10 m walk test speed but average scores across all subjects have not yet shown a clinically significant change in either outcome measure, possibly due to the small number of participants who have completed the trial at the time of this report. Enrollment is ongoing and is expected to be fulfilled in 2017.

7. **Neuromuscular pattern of the lower limbs of hemiparetic stroke patients during overground gait training: acute changes induced by a wearable exoskeleton**  
Molteni F. Villa Beretta Rehabilitation Center, Valduce Hospital (Costa Masnaga, LC) Italy; Presented at the Congregazione Delle Suore Infermiere Dell'Addolorata Ospedale Valduce 2016.

This study looks at the neuromuscular patterns and the changes that take place in acute and chronic stroke patients when they use an exoskeleton for overground training.

Fifty-one stroke patients (50% acute) were enrolled. The Oxfordshire Community Stroke Project (OCSP) Classification for cerebral infarction and Knutson’s Classification for neuromuscular patterns were used to classify each patient. A sEMG of muscles rectus femoris, hamstrings, tibialis anterior and soleus of both limbs was collected during over-ground walking both in standard condition and with Ekso; results of these tests are categorized and presented in this poster. The aggregate results show that Ekso used overground affects the time and intensity of the neuromuscular patterns in both acute and chronic stroke patients.
8. **Benefits of Ekso as a gait training device for post stroke patients during inpatient rehabilitation**
Nolan K. Kessler Institute for Rehabilitation, West Orange, NJ; Presented at AAP 2015.

**Utilization of a robotic exoskeleton to provide increased mass practice for gait training and its impact on discharge destination for individuals with acute stroke**

*This exploratory investigation of the use of the robotic exoskeleton to provide increased dosing of gait training.*

Fifteen participants with acute stroke underwent gait training with Ekso during inpatient rehabilitation in conjunction with traditional therapy. Participants ambulated over level surfaces with PT assistance. A matched sample of participants (n=15) was selected from a hospital database (matching criteria: length of stay, admission motor FIM, age, gender and affected side). The data was analyzed using independent sample and paired sample t-tests. Participants in the RE group walked an average distance of 212 feet in traditional PT where gait training was provided and 551 feet in RE sessions (p=.033). Discharge destination for the RE group: 10 home; 3 subacute; 2 nursing facility and for the matched sample: 13 home; 2 subacute. Motor FIM scores significantly increased from admission to discharge: RE group (p≤.001) and matched group (p≤.001). Motor FIM gain at discharge in the RE group significantly increased compared to the matched sample, 26.4±6.4 vs. 21.6±5.9, (p=0.044).
9. **Quantifying Gait Outcomes in Chronic Stroke using robotic training protocols**  
Angacian G; Presented as a Burke Summer Student Poster - 2014

This early feasibility study examined the effects of combining upper and lower extremity robotic training.

6 chronic stroke subjects (4 Ischemic and 2 Hemorrhagic, age range 53 to 83 years old) that presented some degree of gait dysfunction were allocated into one of two intervention groups: 1) combined therapy consisting of 1.5 hours of intensive repetitive exercise using the Ekso™ followed by 1 hour of upper arm robotic therapy, or 2) 1.5 hours of intensive repetitive exercise using the Ekso. Participants received robotic training 3 times per week for a total of 4-weeks. Outcome measures were recorded at baseline and post the 4 week training intervention. Both groups improved in all gait parameters tested, and there were statistically significant differences in two of the gait parameters: an increase in both stride length (p=0.03) and walking velocity while using the Ekso™ (p=0.04), as well as a positive trend in overground gait velocity and a decrease in double support phase percentage that were also noteworthy.

Meta-analysis and Review Papers


   This narrative review of the "state of the art" discusses the FDA-cleared exoskeleton devices and the challenge of both the developing regulatory science and industry standards. The authors searched PubMed, Clinicaltrials.gov, and the MAUDE database to look for adverse events as well as the prevailing inclusion and exclusion criteria for the various studies. Both the inclusion/ exclusion criteria and the adverse event reports were found to be very diverse. The authors then compared current regulations, regulatory procedures and standards for the medical device applications in the U.S., Europe and Japan. The authors advised increased awareness of the probable risks and the development of standards and regulations.


   This literature review provides a comparison of different exoskeletons (ReWalk, Indego, Ekso, Exo-H2, REX, HAL/HAL-3, ROBIN, Mina, WPAL, MindWalker) and discusses their development, key features and functionality. The authors describe variable assist software allows the therapist to adjust the level of assistance that the device provides to accommodate the requirements of the user. In addition, the authors point out that in recent conferences, data presented indicate improved walking speed, distance, gait, and balance of individuals with spinal cord injury. The authors discuss their personal experiences with the exoskeletons and predict their widespread use in the future after more long-term studies are completed.

3. Miller LE, Zimmerman AK, Herbert WG. **Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis.** Published in Medical Devices: Evidence and Research (2016);9:455–466.

   A review of 14 studies (8 using ReWalk™, 3 using Ekso™, 2 using Indego®, and one unspecified exoskeleton) amassing data in 111 patients were included. Training programs were set up three time a week for 60–120 minutes per session during a period of 1–24 weeks. The majority of studies used flat ground for training. Upon completion of training, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m and physiologic demand of powered
exoskeleton-assisted walking was 3.3 metabolic equivalents. The perceived exertion was 10 on the Borg 6–20 scale which is comparable to self-reported exertion of an able-bodied person walking at 3 miles per hour. Improvement in spasticity was reported in 38% and improvement in the regularity of bowel movements was reported in 61% of patients. There were no serious adverse events reported. The incidence of fall at any time during training (tethered) was 4.4%, and did not result in injury. Bone fractures during training occurred at a rate of 0.4%. Risks have since been mitigated with later generation exoskeletons and changes to patient eligibility criteria. The authors concluded that “exoskeletons allow patients with SCI to safely ambulate in real-world settings at a physical activity intensity conducive to prolonged use and known to yield health benefits.”


This systematic review of 8 powered exoskeletons (Bionic Leg, Ekso GT, HAL, Indego, ReWalk, WalkTrainer, WPAL) cited 22 studies that were analyzed based on their protocol design, subject demographics, study duration, and primary/secondary outcome measures for assessing the exoskeleton's performance in SCI subjects. The results showed that the level of injury varies across studies, with T10 injuries being represented in 45.4% of the studies. Outcome measures varied across studies, and none had measures spanning every category, making comparisons difficult. However, there was an emphasis on ambulatory-related primary outcome measures. The authors predict that the use of the exoskeleton in rehabilitation centers and at home will result in significant growth of the worldwide market.


Published abstract: Powered robotic exoskeletons are an emerging technology of wearable orthoses that can be used as an assistive device to enable non-ambulatory individuals with spinal cord injury (SCI) to walk, or as a rehabilitation tool to improve walking ability in ambulatory individuals with SCI. No studies to date have systematically reviewed the literature on the efficacy of powered exoskeletons on restoring walking function. Our objective was to systematically review the literature to determine the gait speed attained by individuals with SCI when using a powered exoskeleton to walk, factors influencing this speed, and characteristics of studies involving a powered exoskeleton (e.g. inclusion criteria, screening, and training processes). A systematic search in computerized databases was conducted to identify articles that reported on walking outcomes when using a powered exoskeleton. Individual gait speed data from each study was extracted. Pearson correlations were performed between gait speed and 1) age, 2) years post-injury, 3) injury level, and 4) number of training sessions. Fifteen articles met inclusion criteria, 14 of which investigated the powered exoskeleton as an assistive device for non-ambulatory individuals and one which used it as a training intervention for ambulatory individuals with SCI. The mean gait speed attained by non-ambulatory participants (n = 84) while wearing a powered exoskeleton was 0.26 m/s, with the majority having a thoracic-level motor-complete injury. Twelve articles reported individual data for the non-ambulatory participants, from which a positive correlation was found between gait speed and 1) age (r = 0.27, 95 % CI 0.02–0.48, p = 0.03, 63 participants), 2) injury level (r = 0.27, 95 % CI 0.02–0.48, p = 0.03, 63 participants), and 3) training sessions (r = 0.41, 95 % CI 0.16–0.61, p = 0.002, 55 participants). In conclusion, powered exoskeletons can provide non-ambulatory individuals with thoracic-level motor-complete SCI the ability to walk at modest speeds. This speed is related to level of injury as well as training time.


This chapter compares the current exoskeletons on the market, specifically Ekso, ReWalk, HAL, Honda Stride Management Assist, NASA-IHMC Mina, and REX. Notably, prolonged use in the complete-SCI population showed potential therapeutic benefits including the return of sensory and motor function in some study participants. The research on FES combined with Ekso is also discussed.

This presentation provided a comparison of 4 exoskeletons’ (Ekso, ReWalk, Indego, Rex) key features, their functioning, their maximum speed, and other variables. The study explored how the wearable robotic exoskeletons available for persons with SCI differ. PubMed, Medline, Google scholar and Wikipedia were reviewed to identify published and unpublished materials about exoskeletons. The study determined that each exoskeleton offers a variety of features for SCI users and can accommodate different levels of injuries.


The authors of this early systematic review that examined published articles from 2001 through 2014 concluded that the studies conducted to date were primarily an evaluation of safety of the devices and investigations into the physical and cognitive effort required to use the devices. In addition, the studies usually focused on the learning curve and gait enhancement. The authors stated that the studies confirmed the safety of HAL, Tibion Bionic Technologies, and Ekso devices when used in controlled environments. Due to the 2014 cutoff of this systematic review, it included details from earlier Ekso Bionics technologies such as the Human Universal Load Carrier (HULC) and eLegs, followed by a reference to one published clinical study (Kolakowsky-Hayner, 2013).

Many studies are too small to show statistical significance. Ekso Bionics™ does not make any claims about the potential benefits of the use of Ekso. ©2016 Ekso Bionics. All rights reserved. 0614BCRSU