# EKSO GT™ CLINICAL RESEARCH

**SUMMARY OF FINDINGS**

**November 30, 2016**

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**Spinal Cord Injury Studies**

**2016**

1. **Trunk Muscle Activation Patterns During Walking With Robotic Exoskeletons in People with High Thoracic Motor Complete SCI**
   Raed Alamro, Amanda Chisholm,Tania Lam, 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.

2. **Development of a Clinical Decision Support System to Improve Locomotor Outcomes in Persons with Spinal Cord Injury**
   S. Marrocco, S. Aman, S. Cornell, J. Hsieh, M. Fielding, D. Wolfe, Parkwood Institute, Western University, Canada; presented at the ISCOS Meeting in September 2016.

   *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.

3. **Exoskeletons and Rehabilitation after Spinal Cord Injury**
   A. Gorgey, Z. Abdelrehim, the Spinal Cord Injury & Disorders Center of Excellence, Hunter Holmes McGuire Veterans Health Administration; Virginia Commonwealth University, United States; presented at the ISCOS Meeting in September 2016.

   *This study provided a comparison of 4 exoskeletons (Ekso, ReWalk, Indego, Rex): key features, functioning, maximum speed, etc.*

   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. Four brands were identified, including Ekso. The study determined that each exoskeleton offers a variety of features for SCI users and accommodate different levels of injuries.

4. **Exoskeleton Training and Physical Activity after Spinal Cord Injury. A Case Series.**
A. Gorgey, R. Wade, L. Villadelgado, R. Khalil, T. Lavis, the Spinal Cord Injury & Disorders Center of Excellence, Hunter Holmes McGuire Veterans Health Administration; Virginia Commonwealth University, United States; presented at the ISCOS Meeting in September 2016.

*This study demonstrated how exoskeleton training improves level 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 energy expenditure of one participant was also measured during use of Ekso and compared to resting conditions. The main outcome measurements were walking time, standing time, ratio of walking to stand-up time and number of steps. Four men with chronic complete and 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. On average, number of steps increased by 6.5 and walking time exceeded 38 minutes.

5. **Optimizing mobility outcomes across locomotor training modalities: Clinical reflection during development of the PRIME algorithm – A case series**
S. Cornell, J. Hsieh, M. Fielding, S. Marrocco, D. Wolfe, Parkwood Institute, Canada; presented at the ISCOS Meeting in September 2016.

*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 improved in their C-SWAT stage.

6. **Locomotor Training With Exoskeleton EKSO-GT in Patients With Motor Incomplete Spinal Cord Injury in a Hospital Setting- Preliminary Results**
E. Bonatti, Montecatone Rehabilitation Institute, Italy; presented at the ISCOS Meeting in September 2016.

*This study demonstrated how Ekso GT may assist in improvement of motor function and that patients were overall satisfied with the training and would recommend it.*

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 12$^{th}$ session and on the 18$^{th}$ session. The 10-meter, 6-minutes, WISCI-II and SCIM-III tests were used to assess motor function in the lower limb, kinetic characteristics and locomotion endurance. The study also evaluated the degree of safety and tolerability of treatment, reduction of pain and/or

spasticity. Preliminary data showed an improvement in motor function, the training proved safe and well tolerated and all patients said they would recommend the use of Ekso in similar situations.

7. **Powered Exoskeletons – and their implementation into the Therapeutic Approach of German SCI centers**
U. Bergner, BGU Murnau, Germany; presented at the ISCOS Meeting in September 2016.

*This study demonstrated the trend that more and more German SCI Centers are 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.

8. **Effects of overground gait training, using the robotic-exoskeleton Ekso™ and assessment of gait parameters using the GAITRite®system. A pilot study.**
Arnell, Svensson, Nilsson, Frykberg, Uppsala University Hospital; presented at ISCOS Meeting in September 2016.

*This study demonstrated 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.

9. **A series of case studies exploring the effect of a short-duration Ekso Bionic exoskeleton rehabilitation programme on bladder and bowl function, spasticity, ankle swelling, gait parameters and vascular health in patients with SCI**
K Luard, Hobbs Rehabilitation Center, University of Winchester, United Kingdom; presented at the ISCOS Meeting in September 2016.

*This study demonstrated that the robotic Ekso Bionic exoskeleton may be a useful adjunct to 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.

10. **Safety and efficacy of high-dosage use of exoskeleton in home environment for chronic SCI: a pilot study**
Katherine Strausser, Ekso Bionics; presented at the ISCoS Meeting in September 16, 2016.

*This pilot study showed that long-term home use of the Ekso exoskeleton led to physiological improvements.*

Three participants used the exoskeleton at home for 1-2 years. Two of the three showed an increased quality of life, and all three reported improved bowel and bladder function along with reduction in medication usage. One participant with incomplete SCI showed improved lower extremity strength, reduced pain, and reduction in pain medication. Objectively measured bone density statistically improved in two participants with complete SCI.

11. **Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons**
Giulia Stampacchia; The Center for Spinal Cord Injured Persons, Pisa University Hospital, Pisa, Italy; Published in *Neurorehabilition* 2016 DOI.10.3233/NRE-161358

*This study demonstrated that walking with the Ekso exoskeleton reduced 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."

12. **Energy Expenditure and Cardiovascular Drift Effect during Extended Bionic Walking**
Carsten B. Baunsgaard; M.D. [1]The Miami Project to Cure Paralysis, and [2]Department of Neurological Surgery and [3]Rehabilitation Medicine, University of Miami Miller School of Medicine, Miami, FL; Presented at the American Spinal Injury Association annual conference 2016.

*This pilot study confirmed that Increased circulation occurs 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. $VO_2$ 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). %$VO_2$peak 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.

13. **Effects on Mobility Training and De-adaptations in Subjects With Spinal Cord Injury Due to a Wearable Robot: a preliminary report**
Patrizio Sale, Department of Neurorehabilitation, Hospital Via Alberoni, Venice, Italy; Published in *BMC Neurology* 2016;16:12.

*This is a pilot study demonstrating 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.

**2015**

14. **Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking**
Allen Kozlowski, 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 showed that individuals with motor completed and incomplete cervical injuries could learn to walk in an Ekso exoskeleton with little or no assistance and their perceptions of effort were light to moderate.*

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. Seven male participants (2 with tetraplegia and 5 with motor-complete injuries) had complete data. Of these, 5 participants 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

15. **Recovery Outcomes for Incomplete SCI**
Marcie Kern TIRR Memorial Hermann, University of Texas Health. Presented at the American Spinal Injury Association annual conference 2015.

*4 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**

16. **Ekso Assisted walking for persons with SCI**
JM Baeza-Dager, ICAHN School of Medicine, Mount Sinai, NY Presented at the American Spinal Injury Association annual conference 2014.

*2 case studies to demonstrate feasibility and safety of exoskeletons for Cervical SCI; Results were positive but larger studies are needed.*

Two males, ages 27 and 37 with sub-acute injury at C8 and chronic injury at C4 respectively were able to make progress safely over a period of 25-37 weeks. Authors concluded that use of the Ekso Exoskeleton offer a new strategy for walking after cervical spine injuries.

17. **Exoskeleton Instead of a Wheelchair – Realistic Vision, or Wishful Thinking?**
Jane Nitschke, BG Klinikum Bergmannstrost , presented at the OT World International World Congress, Leipzig, Germany, May 2014.

*Two robotic exoskeletons were evaluated as a mobility alternative for a wheelchair. Positive results such as reduction in pain and spasticity were reported, as well as improvements in overall well-being and quality of life. Neither exoskeleton was currently considered a viable alternative to a wheelchair, and one stood apart as an effective therapeutic training device (Ekso).*

Two exoskeleton platforms were evaluated for their potential for a replacement for a wheelchair. 13 patients tried one exoskeleton and 4 participants evaluated both. Level of lesions ranged from sub T3 to sub L1 (AIS A). The length of SCI varied from 29 years to 6 months. All patients relied on a manual wheelchair for daily mobility. Participants were queried on the impact walking in an exoskeleton impacted their well-being, quality of life and their general opinion on the use of this technology. Both exoskeletons elicited positive feedback in this regard. In spite of the unanimously reported emotional benefits of being able to see the "incredible" ability to see the world eye-to-eye and the other evidenced positive effects such as reduction of spasticity and pain, all patients reported they would only use an exoskeleton as a therapeutic device and under clinical supervision of a trained therapist: Only one exoskeleton was seen as effective for these purposes.

18. **Lower Limb Bionic Exoskeleton for Rehabilitation, Exercise or Mobility. Exploratory Case Series in Persons with Chronic, Complete Spinal Cord Injury.**
Jochen Kressler, Ph.D. et al., The Miami Project to Cure Paralysis, Three cases presented at the American Spinal Injury Association annual conference, San Antonio, TX, May 2014. 'Four cases published in the *Archives of Physical Medicine and Rehabilitation* 2014, Oct;95(10):1878-1887.

*Reduction in pain in persons with complete spinal cord injury was the most notable finding in this study exploring the multifaceted responses to overground bionic ambulation.*

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. In order to evaluate various responses to OBA including neuromuscular activation, exercise conditioning, capacity for mobility and impact on neuropathic pain, 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 activity were not deemed significant. No adverse events were reported.

**2013**

19. **Evaluation of the Clinical Criteria for Safe and Efficient Use of Exoskeletons in Individuals with SCI**
Arun Jayaraman, PT, PhD, et. al, Center for Bionic Medicine and Department of Physical Medicine and Rehabilitation at the Rehabilitation Institute of Chicago, presented at of the at the 2013 American Spinal Injury Association (ASIA) conference, 2013

*These preliminary results on 12 subjects outlined the training strategies for independent over-ground ambulation as well as the safe and efficient use of exoskeletons for community ambulation.*

12 patients were enrolled at the time of this presentation (C6-L4, complete) in 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.

**2012**

20. **Safety and Feasibility of Using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury**
Stephanie A Kolakowsky-Hayner, et al., Santa Clara Valley Medical Center, presented at the Paralyzed Veterans of America conference and at the annual scientific meeting of the International Spinal Cord Society in London, Aug. 2012. Published in *Spine* (2013) S4:003

*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.

21. **The Potential of the Ekso Exoskeleton for Affecting Long-Term Health and Well-Being in the SCI Population**
Gail Forrest, PhD., et. al, Kessler Foundation, presented at the Academy of Spinal Cord Injury Professionals (ASCIP), Sept. 2012

*Using Ekso as a platform for full weight bearing, over ground ambulation in SCI patients is feasible for a wide range of patients and produces improvements in walking speed and distance, fluidity, gait and balance. There also appears to be a training effect and increased muscle firing which requires further study.*

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.

**Stroke Studies**

**2016**

1. **Exoskeleton Gait Training for Individuals Affected by Severe, Chronic Stroke**
MR Knowlton et al. Rehabilitation Institute of Chicago, IL; Presented at APTA 2016 and CSM 2016

This study is ongoing and there is a plan to enroll 60 subjects. Ten subjects were enrolled at the time of this report. Several subjects achieved clinically significant results in both the 6 min walk test distance and10 m walk test speed but average scores across all subjects did not yet represent a clinically significant change with either outcome measure; enrollment is to continue.

2. **Neuromuscular pattern of the lower limbs of hemiparetic stroke patients during overground gait training: acute changes induced by a wearable exoskeleton**
F. Molteni, 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.

**2015**

3. **Benefits of Ekso as a gait training device for post stroke patients during inpatient rehabilitation**
   Karen Nolan, Kessler Institute for Rehabilitation, West Orange, NJ; Presented at AAP 2015
   Anthony Russo, Kessler Institute for Rehabilitation, West Orange, NJ; Presented at AHA 2016

   *This exploratory investigation demonstrated the robotic exoskeleton provides increased dosing of gait training. Improvement of motor FIM scores in the exoskeleton group demonstrated the impact of mass practice provided by the exoskeleton.*

   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 facilty 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).

**2014**

4. **Quantifying Gait Outcomes in Chronic Stroke using robotic training protocols**
   G Angacian; Presented as a Burke Summer Student Poster - 2014

   *Chronic Stroke patients that had some degree of gait dysfunction benefited from 4 weeks of gain training with Ekso. Upper limb robotic training can be combined with robotic gait training, and maintain observable gait improvement.*

   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 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

**2012**

5. **Benefits of Variable Assist**
   Arun Jayaraman, PT, PhD, et. al, Center for Bionic Medicine and Department of Physical Medicine and Rehabilitation at the Rehabilitation Institute of Chicago - 2012

*Three sub-acute subjects with left CVA (right hemiparesis) were enrolled in the study. 2 subjects were non-ambulatory and one subject was ambulatory with R AFO and Hemi-walker. Subjects completed 3-4 sessions with Ekso.*

All subjects were able to walk in the exoskeleton on the first session. All three subjects increased their distance for a 6-minute walk test (2 from unable previous). Testing shows ability to increase steps with less exertion from the therapists. Ekso was able to work with all abilities, including one subject who was unable to walk previously due to pushing syndrome.

*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.*



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**Meta-analysis and Review Papers**

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.** *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 majoring 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 f 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 of3.4%. 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."

Louie DR, Eng JJ, Lam T and Spinal Cord Injury Research Evidence (SCIRE) Research Team. **Gait speed using powered robotic exoskeletons after spinal cord injury: a systematic review and correlational study.** Journal of NeuroEngineering and Rehabilitation (2015) 12:82.

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.