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

2017

1. **Effect on Body Composition and Bone Mineral Density of Walking With a Robotic Exoskeleton in Adults With Chronic Spinal Cord Injury**
   Karelis A, Carvalho LP, Castillo MJ, Gagnon DH, and Aubertin-Leheudre M. University of Quebec at Montreal; published in the *Journal of Rehabilitation Medicine* 2017; 49: 84–87.

   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.

2016

2. **Neurorehabilitation in paraplegic patients with an active powered exoskeleton (Ekso)**
   Milia P, De Salvo F, Caserio M, Cope T, Weber P, Santella C, Fiorini S, Baldoni G, Bruschi R, Bigazzi B, Cencetti S, Da Campo M, Bigazzi P, and Bigazzi M. Neurorehabilitation and Robotic Area, Prosperius Institute, University of Perugia, Umbertide, Italy. *Digit Med* 2016;2:163-8.

   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.

3. **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.

4. **Development of a Clinical Decision Support System to Improve Locomotor Outcomes in Persons with Spinal Cord Injury**
Marrocco S, Aman S, Cornell S, Hsieh J, Fielding M, Wolfe D. 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.

5. **Exoskeleton Training and Physical Activity after Spinal Cord Injury - A Case Series.**
Gorgey A, Wade R, Villadelgado L, Khalil R, Lavis T. 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 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.

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6. **Optimizing Mobility Outcomes Across Locomotor Training Modalities: Clinical Reflection During Development of the PRIME Algorithm – A Case Series**
Cornell S, Hsieh J, Fielding M, Marrocco S, Wolfe D. 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 used the Ekso GT at some point during their rehabilitation, and each improved in their C-SWAT stage.

7. **Locomotor Training With Exoskeleton EKSO-GT in Patients With Motor Incomplete Spinal Cord Injury in a Hospital Setting- Preliminary Results**
Bonatti E, Baroncini I, Nalon, C, Giovannini T, Falcone R, Mazzoli N, Bonavita J; Montecatone Rehabilitation Institute, Imola, 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 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 s 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.

8. **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 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.

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9. **Effects of Overground Gait Training, Using the Robotic-Exoskeleton Ekso™ and Assessment of Gait Parameters Using the GAITRite®system. A Pilot Study.**
Arnell M, Svensson P, Nilsson H, Elmgren Frykberg G. 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.

10. **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 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.

11. **Safety and Efficacy of High-Dosage Use of Exoskeleton in Home Environment for Chronic SCI: A Pilot Study**
Strausser K. 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.

12. Walking With a Powered Robotic Exoskeleton: Subjective Experience, Spasticity and Pain in Spinal Cord Injured Persons

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 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."

13. 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 [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 (ASIA) 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). $\%VO_2peak$ 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.

14. Exploring the Psychosocial Impact of Ekso Bionics Technology

Brenner L. Rocky Mountain Mental Illness Research, Education, and Clinical Center, Denver, CO. Published in *Archives of Physical Medicine and Rehabilitation*, Vol. 97, Issue 10, e113. Presented at IBIA 2016.
Stearns- Yoder K, Dorsey-Holliman BA, Penzenik M E, Hadidi DA, Lange SM, Hebert JR, Brenner LA. Rocky Mountain Mental Illness Research, Education, and Clinical Center, Denver, CO. Presented at the ACRM Annual Conference, 2016. (Study update.)

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)

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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.

15. 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 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

16. 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 showed that individuals with motor complete 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. 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.

17. Improving Gait Performance After Spinal Cord Injury: A Comparison Between Conventional Physical Therapy and Therapy Using Exoskeletons

Kern M, Chang SH, Jennings J, Davis M, Francisco G. TIRR SCI Clinical Exoskeleton Group, Memorial Hermann, University of Texas Health. Presented at the ASIA 2015 and ISCoS 2015 annual conference.

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

18. Ekso Assisted Walking for Persons With SCI

Baeza-Dager JM, Firpi S, Tovar L, Voigt A, Kozlowski AJ. ICAHN School of Medicine, Mount Sinai, NY. Presented at the 2014 American Spinal Injury Association (ASIA) annual conference.

Two 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.

19. Exoskeleton Instead of a Wheelchair – Realistic Vision, or Wishful Thinking?

Nitschke J. BG Klinikum Bergmannstrost, Germany. 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, but one stood apart as an effective therapeutic training device (Ekso).

Two exoskeleton platforms were evaluated for their potential for a replacement for a wheelchair. Thirteen 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 how 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 with unanimously reported emotional benefits (ability to see the world eye-to-eye) and other 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.

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20. **Lower Limb Bionic Exoskeleton for Rehabilitation, Exercise or Mobility. Exploratory Case Series in Persons with Chronic, Complete Spinal Cord Injury.**
Kressler J Thomas CK, Field-Fote EC, Sanchez J, Widerström-Noga E, Cilien DC, Gant K, Ginnety K, Gonzalez H, Martinez A, Anderson KD, Nash MS. The Miami Project to Cure Paralysis, University of Miami, Miami, FL. Presented at the ASIA annual conference, San Antonio, TX, May 2014; published in *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. 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

21. **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

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.

22. **Safety and Feasibility of Using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury**
Kolakowsky-Hayner SA, Crew J, Moran S **,** Shah A. Santa Clara Valley Medical Center, San Jose, CA. 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

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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.

2012

23. **The Potential of the Ekso Exoskeleton for Affecting Long-Term Health and Well-Being in the SCI Population**
Forrest G. 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

2017

1. **Wearable robotic exoskeleton for over-ground gait training in sub-acute and chronic hemiparetic stroke patients: preliminary results.**
Molteni F, Gasperini G, Gaffuri M, Colombo M, Giovanzana C, Lorenzon C, Farina N, Cannaviello G, Scarano S, Proserpio D, Liberali D, Guanziroli E. Villa Beretta Rehabilitation Center, Valduce Hospital (Costa Masnaga, LC) Italy; Published in *Eur J Phys Rehabil Med* (2017); doi: 10.23736/S1973-9087.17.04591-9. [Epub ahead of print]

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.

2. **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.

3. **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; Poster presented at CSM 2017.

This study aimed to demonstrate changes in functional clinical outcomes of acute stroke and TBI patients who walked with the Ekso exoskeleton.

Six subjects ranging in ages 44 to 66 (mean age 55.6 yrs) and who had either suffered a stroke (N=4), TBI (N=1), or severe illness resulting in myopathy (N-1) were tested at baseline and again after a minimum of 4 sessions using the Ekso GT. The mean onset of illness to baseline was 16 days and the mean number of sessions was 7.33 sessions distributed over a period of 5 to 35 days. The mean number of steps in Ekso was 416 and mean up time was 30 minutes (range 18 to 45). Main outcome measures were FIM (transfers and locomotion) and Functional Reach Test. The mean 10MWT improved from 0.258 m/s to 0.443 m/s (p=0.035), mean FIM transfer scores changed from 3.5 to 4.8 (p=0.01), and mean FIM locomotion scores changed from 2.17 to 4.17 (p=0.012). Functional reach tests were marginally non-significant. As the authors predicted, as up time increased, the number of steps increased. The authors concluded that use of the Ekso in this acute patient population resulted in significantly positive functional and clinical changes and attribute these changes to neuroplastic retraining.

2016

4. **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 gives an early indication that subjects affected by severe, chronic stroke have 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.

5. **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.

2015-2016

6. **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
Russo A, Endersby K, Perret M, Kesten A, King M, Chervin K, Nolan KJ. Kessler Institute for Rehabilitation, West Orange, NJ; Presented at International Stroke Conference 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

7. **Quantifying Gait Outcomes in Chronic Stroke using robotic training protocols**
   Angacian G; 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

8. **Benefits of Variable Assist**
   Jayaraman A. 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.

Meta-analysis and Review Papers

1. 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 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 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."

2. 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.

3. Contreras-Vidal JL, Bhagat NA, Brantley J, Cruz-Garza JG, He Y, Manley Q, Nakagome S, Nathan K, Tan SH, Zhu F, Pons JL. **Powered Exoskeletons for bipedal locomotion after Spinal Cord Injury**, *J. Neural Eng* 13 (2016) 031001; http://iopscience.iop.org/article/10.1088/1741-2560/13/3/031001/pdf.

   This systematic review of 8 powered exoskeletons (Bionic Leg, Ekso GT, HAL, Indego, Kinesis, 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.

4. Esquenazi A, Talati M, Jayaraman A. **Powered Exoskeletons for Walking Assistance in Persons with Central Nervous System Injuries, A Narrative Review**. *PM&R* (2017); 9(1): 46–62; http://www.pmrjournal.org/article/S1934-1482(16)30879-6/abstract.

   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. One unique feature of Ekso that is discussed is the variable assist software. The authors describe how this new 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. Though most of the studies have been in this population, they expressed that the Ekso may help individuals who have suffered a stroke to stand longer and take more steps. The authors discuss their personal experiences with the exoskeletons and predict their widespread use in the future after more long-term studies are completed.

5. Jayaraman A, Burt S, Rymer WZ. **Using Robotic Exoskeletons for Over-Ground Locomotor Training,** a chapter in Neurorehabilitation Technology, Springer 2016: 493-511.

   This chapter compares the current exoskeletons on the market, specifically Ekso, ReWalk, HAL, Honda Stride Management Assist, NASA-IHMC Mina, and REX. At the time of publication, most of the reported benefits in Ekso were evident in either severely impaired individuals or in research and clinical facilities. Notably, prolonged use of the device in the complete-SCI population showed therapeutic benefits including the return of sensory and motor function in some study participants. The research on FES combined with Ekso is also discussed.

6. Gorgey A, Abdelrehim Z. **Exoskeletons and Rehabilitation after Spinal Cord Injury,** presented at the ISCoS Meeting in Vienna, Austria. September 2016.

   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.

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7. Federici S, Meloni F, Bracalenti M, De Filippis ML. **The Effectiveness of Powered, Active Lower Limb Exoskeletons in Neurorehabilitation: A Systematic Review.** *NeuroRehabilitation* 37 (2015) 321-340.

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).

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