FOR THE HUMAN ENDEAVOR

EKSO™ CLINICAL RESEARCH
SUMMARY OF FINDINGS

The following pages include brief summaries of the known research in chronological order which has been presented in the form of abstracts, posters, or public presentations on the use of Ekso robotic exoskeletons for individuals recovering from such neurological conditions as spinal cord injury and stroke.

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1. **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.

2. **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.

   This was a feasibility study wherein researchers evaluated the safety of the emerging technology.

   Bionic exoskeletons such as Ekso are 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.

3. **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, (2013) J Spine S4:003

   This was a feasibility study wherein researchers evaluated the safety of the emerging technology.

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.

4. **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

The Rehabilitation Institute of Chicago's Center for Bionic Medicine and Department of Physical Medicine and Rehabilitation presented preliminary results of their ongoing research. Their goals were to identify the clinical criteria for safe and efficient use of exoskeletons in individuals with SCI, develop training strategies for independent over-ground ambulation of individuals with SCI in a clinical setting, and develop training strategies to allow independent ambulation of individuals with SCI at home and in the community.

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.

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

Kressler, Jochen, Ph.D. et al., The Miami Project to Cure Paralysis, presented at the American Spinal Injury Association annual conference, San Antonio, TX, May 2014.

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 overground 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.

6. **Exoskeleton Instead of a Wheelchair – Realistic Vision, or Wishful Thinking?**
Jane Nitschke, BG Klinikum Bergmannstrost , presented at the OTWorld 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. 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.

7. **Adaptation of Exoskeleton-Assisted Walking for Non Ambulatory Spinal Cord Injury: Preliminary Results**
E.M. Johnsen, A. Ramanujam, E. Garbarini, R. Lamb, G. Forrest; Kessler Foundation, presented at the World Congress of Biomechanics, July 2014.
With practice, Ekso users were able to achieve increased muscle activation per gait cycle with training and became more similar to able-bodied walking.

Researchers at the Kessler Foundation studied Ekso's impact on functional, neural, and loading capacity for walking and gait adaptions for motor incomplete and complete SCI patients in both the acute (<6 sessions) and chronic phases (>20 sessions) of training. With practice, Ekso users were able to actively increase step swing time, stride length and hip extension after walking with an Ekso robotic exoskeleton and most notably, muscle

activation per gait cycle increased with training and became more similar to able-bodied walking.

8. **Simulation of Muscle Work During Hip/Knee Exoskeleton-Assisted Gait**

P. J. Barrance, A. Ramanujam, E. Johnsen, G. Forrest; Kessler Foundation Research Center, presented at the World Congress of Biomechanics, July 2014.

Study focused on mathematically simulating human and exoskeleton interactions to deepen understanding results of on-going studies of intensive exoskeleton training.

Researchers at Kessler wanted to assess the therapeutic effect on motor recovery, as a means of evaluating muscular contributions to ambulation. In this preliminary investigation, they studied changes in muscle power estimations when functional hip or knee assistance was simulated in an idealized model of exoskeletally-assisted gait.

Knee extensor work during mid-late stance was reduced to 47-58% of baseline in case 1. Hip flexor work during swing was reduced to 18-54% of baseline in case 2. Changes in work done also occurred in other functional groups: for example, knee flexor power in mid-late stance increased in case 1 (119-136% baseline), and net negative knee extensor work during swing decreased in case 2 (62-74% baseline).

These changes to simulated muscle forces were generally consistent with researchers' expectations. This approach might be used to simulate robotically assisted gait based on measured exoskeletal torques, as well as kinematics and ground reaction forces.

9. **Gait Training of Stroke Patients using a Robotic Exoskeleton during Inpatient Rehabilitation: Feasibility Study**

Karen J. Nolan, PhD, Kessler Foundation, presented at International Workshop of Wearable Robotics in Baiona, Pontevedra, Spain September 17, 2014

Ekso GT proved to be a safe device to use for gait training of stroke survivors in an inpatient rehabilitation environment, and in fact, especially benefited individuals who were less functionally independent ambulators. At the conclusion of the study, all patients were standing up longer and taking more steps, with approximate standing and walking times with the Ekso GT of 35 and 18 minutes, respectively, per session.

Eight stroke patients who were prescribed gait training during inpatient rehabilitation training, safely increased their cadence (steps per minute) after six weeks of rehabilitation with the assistance of the Ekso™ GT robotic exoskeleton. The patients were gait trained using the Ekso device for 25% of their total physical therapy time. Average cadence with the Ekso robotic exoskeleton was 17.1 at initial session, which increased to 27.67 by the final session.