EKSO GT™ CLINICAL RESEARCH

SUMMARY OF 2016 ISCoS Poster Presentations

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Ekso Bionics

ISCoS 2016 Poster Presentations Summary

Several clinical trials, including multi-center trials, are underway in Europe and North America to study the effects of using the Ekso GT robotic exoskeleton in participants with spinal cord injury (SCI). These studies include those with paraplegia and tetraplegia, both complete and incomplete, ranging from acute to chronic in recovery. Having thus far enrolled a total of 125 participants, they show the feasibility of clinical use and gait progression, as well as improvements in secondary complications resulting from the injury. A large multi-center trial of 52 participants known as the PanEuro study, showed a statistically significant increase in the time up, time walking, and number of steps taken during a session in both complete and incomplete SCI after training in Ekso GT 3x/week for 8 weeks.[1] It also showed that the walking time becomes an increasing percentage of up time over 8 weeks of training, with greater improvement in the first 4 weeks.[1] Gorgey et al.[2] showed modest to impressive progression in these same areas with only one training session per week for 10-15 weeks in three participants with complete SCI and one participant with incomplete SCI. Stampacchia et al.[3] demonstrated that Ekso GT training for 20 sessions, 3x/week, resulted in statistically significant improvements during formal, timed gait and balance assessments (10 Meter Walk Test, 6 Minute Walk Test, and Timed Up & Go) in eleven users with a complete SCI. Furthermore, preliminary results from Bonatti et al.[4] demonstrated that Ekso GT training for 18 sessions resulted in statistically significant improvements in functional assessments (10 Meter Walk Test while using the device, 6 Minute Walk Test, Spinal Cord Independence Measure, and the Walking Index for Spinal Cord Injury-II) as well as quality of life in 20 participants with incomplete SCI. Optimal frequency, duration, and intensity of sessions for acute and chronic SCI rehabilitation outcomes remain unknown, but these studies provide a strong basis for future trials.

The Ekso GT must provide sufficient support for a weak, unconditioned user to particpate in a full session, while allowing the physical therapist to challenge those who are more functional. A study by Baunsgaard et al.[5] demonstrated through cardiovascular, oxygen consumption (VO_2), and participants' perceived exertion measures that even for 8 participants with very chronic and severe injuries, *standing* in Ekso GT required very little cardiorespiratory work (~20% max VO_2) with perceived effort at or near resting level (1 out of 10 on the Borg Scale). However, they showed that *walking* in Ekso GT for 45 minutes in one session required increased work (~40% max VO_2), improved circulation through increased heart rate and cardiac output, and was still only perceived as light effort (2 out of 10). The amount of work and the perceived effort were similar to those of five participants without SCI who walked outside of Ekso GT at a self-selected pace.[5] While the speed in Ekso GT was slower compared to the speed of those without SCI, participants with SCI demonstrated the possibility of walking long distances without fatigue while obtaining the physiological benefits of improved circulation. Faber et al.[6] collected % peak VO2 and HR data in 10 participants with SCI and 10 without SCI as they walked 1) outside Ekso GT, 2) in Ekso GT with full support, and 3) in Ekso GT with partial support. These researchers found increasing

oxygen consumption and heart rate with each testing conditioning, respectively, stating that walking in the Ekso could "induce high physical strain". Thus, Ekso GT can challenge the user's strength and/or endurance, particularly the proximal hip and knee joint muscles. These muscle groups were determined to have an increased motor output compared to the distal muscles in those with SCI while walking in the Ekso GT and compared to those without SCI walking at their own pace.[6] Stampacchia et al.[7] compared the oxygen consumption and metabolic equivalent (MET) of eight participants walking in Ekso GT with walking in the Lokomat. One MET is the amount of oxygen a person consumes at rest for 1 minute. Walking in Ekso GT was measured at an average of 2.6 METs, comparable to walking at 2.0 mph for a person without SCI. Walking in the Lokomat was measured at an average of 1.5 METs, just above a resting level. They also showed statistically significant higher VO_2 walking in Ekso GT (about 3x resting VO_2), compared to walking in the Lokomat (about 2x resting VO_2).[7]

In addition to increased respiration and circulation, other secondary benefits of training in Ekso GT included statistically significantly decreases in spasticity on both a formal exam and a self-report by the participants after 20 sessions.[3] Further, Luard et al.[8] reported improvements in four participants' bowel and bladder function, blood pressure, and self-reported spasticity after only five training sessions. At the other extreme, Strausser[9] showed long-term use (12 to 24 months) in the home improved bowel and bladder function with reduced medications in three participants, improved lower extremity strength and reduced pain and pain medication in one participant with incomplete SCI, and statistically improved bone density in the other two participants with complete SCI who had DEXA performed. The other two participants' pain reports remained relatively unaffected. Quality of life increased in the two participants with lower starting scores. Bonatti et al.[4] also showed statistically significant improvements in quality of life in their 20 participants.

Exoskeleton use in neurorehabilitation is expanding and becoming integrated into the clinic. Bergner[10] found that half of 22 clinics surveyed in Germany owned exoskeletons, six of which owned Ekso GT. A Canadian group[11,12] recently created locomotor training decision-making software for their clinic that is based on the functional classification of the patient. The software recommends assessments and then uses the results to provide recommended gait training interventions, one of which is Ekso GT. Resulting longitudinal reports of three clients show and physical therapists state they have seen "improved walking ability in patients previously thought to have plateaued". As with any intervention, however, use of Ekso GT has its limits. Arnell et al.[13] showed only small changes in gait parameters (speed, stride length, and cadence) in two participants with high functioning tetraplegia and relatively fast walking speeds, one of them near normal (0.7 m/s and 0.9 m/s). These two participants are likely at a higher classification level and walking speed where the current version of Ekso GT may not be the most advantageous device to use to improve these outcomes.

Current research has shown that training in Ekso GT is safe and progression in the device is feasible. These early data demonstrate that this training improves walking and functional outcomes, both in and out of the device. While these outcomes continue to be collected, upcoming trials will look to determine these improvements at different time points in recovery (acute vs. chronic), the optimal dosage of training (frequency, intensity, and total number of sessions), and the characteristics of those who respond best to the training. The PanEuro study[1] results have already shown that level of injury had an effect on outcomes, while time since injury and severity of injury (AIS classification) did not. These current trials are stepping stones to better individualize training and efficiently achieve the best outcomes during rehabilitation and eventually in the home.

References

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