Powered Exoskeleton Published Research Summary

		Improved Physical Activity	Bowel/ Bladder	Pain	Spasticity	Body Composition	Mechanical Loading	Quality of Life	Device Safety & Feasibility	User Satisfaction
Chun et al. (2020)	Chun, A et al. "Changes in Bowel Function Following Exoskeletal-Assisted Walking in Persons with Spinal Cord Injury: An Observational Pilot Study." *Spinal Cord* 58.4 (2020): 459-66. Print.		✓							
Dijsseldonk et al. (2020)	van Dijsseldonk, R. B., et al. "Exoskeleton Home and Community Use in People with Complete Spinal Cord Injury." *Sci Rep* 10.1 (2020): 15600. Print.								✓	✓
Hong et al. (2020)	Hong, E.K. "Mobility Skills with Exoskeletal-Assisted Walking in Persons with Sci: Results from a Three Center Randomized Clinical Trial" Frontiers in Robotics and AI 7 (2020): 93. Print.								✓	
Shackleton et al. (2019)	Shackleton, Claire et al. "Effectiveness of over-ground robotic locomotor training in improving walking performance, cardiovascular demands, secondary complications and user-satisfaction in individuals with spinal cord injuries: A systematic review." Journal of rehabilitation medicine vol. 51,10 (2019): 723-733. doi:10.2340/16501977-2601	✓							✓	✓
Mekki et al. (2018)	Mekki, Marwa et al. "Robotic Rehabilitation and Spinal Cord Injury: a Narrative Review." Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics vol. 15,3 (2018): 604-617. doi:10.1007/s13311-018-0642-3	✓	✓	✓	✓			✓		
Holanda et al. (2017)	Holanda, Ledycnarf J et al. "Robotic assisted gait as a tool for rehabilitation of individuals with spinal cord injury: a systematic review." Journal of neuroengineering and rehabilitation vol. 14,1 126. 4 Dec. 2017, doi:10.1186/s12984-017-0338-7	✓		✓	✓	✓		✓		
Karelis et al. (2017)	Karelis, Antony D et al. "Effect on body composition and bone mineral density of walking with a robotic exoskeleton in adults with chronic spinal cord injury." Journal of rehabilitation medicine vol. 49,1 (2017): 84-87. doi:10.2340/16501977-2173					✓				
Miller et al. (2016)	Miller, Larry E et al. "Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis." Medical devices (Auckland, N.Z.) vol. 9 455-66. 22 Mar. 2016, doi:10.2147/MDER.S103102		✓						✓	
Raab et al. (2016)	Raab, Katharina, et al. "Effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury: a single case study." Spinal cord series and cases 2.1 (2016): 1-3.	✓	✓	✓				✓		
Stampacchia et al. (2016)	Stampacchia, Giulia, et al. "Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons." NeuroRehabilitation 39.2 (2016): 277-283.		✓	✓	✓					
Asselin et al. (2015)	Asselin, Pierre, et al. "Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia." Journal of rehabilitation research and development 52.2 (2015): 147.	✓								
Fineberg et al. (2013)	Fineberg, Drew B., et al. "Vertical ground reaction force-based analysis of powered exoskeleton-assisted walking in persons with motor-complete paraplegia." The journal of spinal cord medicine 36.4 (2013): 313-321.						✓			
Esquenazi et al. (2012)	Esquenazi, Alberto, et al. "The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury." American journal of physical medicine & rehabilitation 91.11 (2012): 911-921.		✓	✓	✓				✓	

Chun et al. (2020)

Chun, A., et al. "Changes in Bowel Function Following Exoskeletal-Assisted Walking in Persons with Spinal Cord Injury: An Observational Pilot Study." *Spinal Cord* 58.4 (2020): 459-66. Print.

The observational study explores the effects of exoskeleton-assisted walking (EAW) on bowel function in persons with spinal cord injury. Ten participants with T1 to T11 motor- complete paraplegia completed 25–63 sessions of EAW over a period of 12 to 14 weeks. Pre- and post-EAW training, participants were asked to report on various aspects of their bowel function as well as on their overall quality of life (QOL) as related to their bowel function. At least 5/10 participants reported improvements with frequency of bowel evacuations, less time spent on bowel management per day, fewer bowel accidents per month, reduced laxative and/or stool softener use, and improved overall satisfaction with their bowel program post-EAW training. Furthermore, 8/10 reported improved stool consistency and 7/10 reported improved bowel function related QOL. The authors noted that between 50 and 80% of the participants studied reported improvements in bowel function and/or management post-EAW training. They concluded that EAW training appeared to mitigate SCI-related bowel dysfunction.

Dijsseldonk et al. (2020)

van Dijsseldonk, R. B., et al. "Exoskeleton Home and Community Use in People with Complete Spinal Cord Injury." *Sci Rep* 10.1 (2020): 15600. Print.

The study assessed the amount, purpose, and location of exoskeleton use in the home and community environment, without any restrictions. After 8 weeks of training at a facility, 14 people with a complete SCI used the ReWalk exoskeleton at home and in the community. They used it for a median of 9 out of 16 days for an average of 3,226 steps. Participants kept a daily logbook, and completed two user experience questionnaires: Quebec User Evaluation of Satisfaction with assistive Technology (D-QUEST) and System Usability Scale (SUS). The exoskeleton was mostly used for exercise purposes (74%) and social interaction (20%). The main location of use was outdoors (48%). Overall, participants were satisfied with the exoskeleton (D-QUEST 3.7 ± 0.4) and its usability (SUS 72.5 [52.5–95.0]).

Hong et al. (2020)

Hong, E.K. "Mobility Skills with Exoskeletal-Assisted Walking in Persons with Sci: Results from a Three Center Randomized Clinical Trial" *Frontiers in Robotics and AI* 7 (2020): 93. Print.

A randomized clinical trial was conducted across three sites, in persons with chronic non-ambulatory SCI. The primary aim was to determine the number of sessions necessary to achieve adequate Exoskeleton Assisted Walking skills and velocity milestones. A total of 50 participants completed 36 sessions with ReWalk and Ekso devices. At 12 sessions 62%, 70%, and 72% of participants achieved the 10MWT, 6MWT, and TUG milestones, respectively. By 36 sessions 80%, 82%, and 84% achieved the 10MWT, 6MWT, and TUG milestones, respectively. The researchers concluded that it is feasible to train chronic non-ambulatory individuals with SCI in performance of Exoskeleton assisted walking sufficiently to achieve reasonable mobility skill outcome milestones.

Shackleton et al. (2019)

Shackleton, Claire et al. "Effectiveness of over-ground robotic locomotor training in improving walking performance, cardiovascular demands, secondary complications and user-satisfaction in individuals with spinal cord injuries: A systematic review." *Journal of rehabilitation medicine* vol. 51,10 (2019): 723-733. doi:10.2340/16501977-2601

A systematic review aiming to evaluate the effectiveness of over- ground robotic locomotor training in individuals with spinal cord injuries with regard to walking performance, cardiovascular demands, secondary health complications, and user-satisfaction. The review included 27 non-controlled studies representing 308 participants. Most studies showed decreases in exertion ratings, pain and spasticity, as well as reported positive well-being post-intervention. Seven studies were included in meta-analyses on walking performance, showing significant improvements post-intervention ($p<0.05$), with pooled effects for the 6-min walking test, 10-meter walking test, and The Timed Up and Go Test. The data suggests that exoskeleton ambulation allows patients with SCI to engage in physical activity at an intensity that provides health benefits, yet does not result in early fatigue. Authors concluded that robotic locomotor training shows promise as a tool for improving neurological rehabilitation however, there is limited evidence regarding its training benefits. Further high-powered, randomized controlled trials are suggested to enhance the evidence.

Mekki et al. (2018)

Mekki, Marwa et al. "Robotic Rehabilitation and Spinal Cord Injury: a Narrative Review." *Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics* vol. 15,3 (2018): 604-617. doi:10.1007/s13311-018-0642-3

A review on advances in robot-guided rehabilitation after SCI for the upper and lower extremities, as well as potential adjuncts to robotics. Authors recognize that the robotic devices in rehabilitation are used with 2 goals: to enhance recovery through repetitive, functional movement and increased neural plasticity and to act as a mobility aid beyond orthoses and wheelchairs. The authors organize the evidence of lower extremity exoskeleton research by the impact on spasticity, pain, cardiovascular system, change in metabolism, bowel function, quality of life, bone health, and ambulation.

Holanda et al. (2017)

Holanda, Ledycnarf J et al. "Robotic assisted gait as a tool for rehabilitation of individuals with spinal cord injury: a systematic review." *Journal of neuroengineering and rehabilitation* vol. 14,1 126. 4 Dec. 2017, doi:10.1186/s12984-017-0338-7

The purpose of this study was to compare robotic gait devices, and systematize the scientific evidences of these devices as a tool for rehabilitation of SCI individuals. Authors included 39 articles. The reviewed studies shows promising results regarding the reduction of pain and spasticity level; changes in proprioception, sensitivity to temperature, vibration, pressure, reflex behavior, electrical activity at muscular and cortical level, classification of the injury level. Some studies also show benefits of increase in walking speed, step length and distance traveled; improvements in sitting posture, intestinal, cardiorespiratory, metabolic, brain and psychological functions. This systematic review shows a significant progress in the area of robotic devices as “an innovative and effective therapy for the rehabilitation of individuals with SCI”.

Karelis et al. (2017)

Karelis, Antony D et al. “Effect on body composition and bone mineral density of walking with a robotic exoskeleton in adults with chronic spinal cord injury.” *Journal of rehabilitation medicine* vol. 49,1 (2017): 84-87. doi:10.2340/16501977-2173

The interventional study aimed to examine the effect on body composition and bone mineral density of locomotor training using a robotic exoskeleton in individuals with spinal cord injury. Five adults with a non-progressive traumatic complete spinal cord injury participated in a personalized 6-week progressive locomotor training using a robotic exoskeleton. Body composition measures were determined using dual energy X-ray absorptiometry and peripheral quantitative computed tomography. The intervention resulted in a significant increase in leg and appendicular lean body mass and a decrease in total, leg and appendicular fat mass. Furthermore, the calf muscle cross-sectional area increased significantly. Finally, although not statistically significant but may be clinically significant, there was an increase of 14.5% in bone mineral density of the tibia. A decrease of >5 % was also noted for subcutaneous adipose tissue and intramuscular adipose tissue. The researchers concluded that locomotor training using a robotic exoskeleton appears to be associated with improvements in body composition, and potentially, bone health.

Miller et al. (2016)

Miller, Larry E et al. “Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis.” *Medical devices (Auckland, N.Z.)* vol. 9 455-66. 22 Mar. 2016, doi:10.2147/MDER.S103102

A meta-analysis investigated the safety and efficacy of powered exoskeletons. It included 14 studies (8 ReWalk, 3 Ekso, 2 Indego® and 1 unspecified exoskeleton) with a total of 111 patients. Training programs were typically conducted three times per week, 60–120 minutes per session, for 1–24 weeks. Ten studies utilized flat indoor surfaces for training and four studies incorporated complex training including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. Following the exoskeleton training program, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m. The physiologic demand of powered exoskeleton-assisted walking was 3.3 metabolic equivalents and rating of 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. Improvements in spasticity and bowel movement regularity were reported in 38% and 61% of patients, respectively. No serious adverse events occurred. The incidence of fall at any

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time during training was 4.4%, all occurring while tethered using a first-generation exoskeleton and none resulting in injury. The incidence of bone fracture during training was 3.4%. These risks have since been mitigated with newer generation exoskeletons and refinements to patient eligibility criteria. The authors conclude that powered 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.

Raab et al. (2016)

Raab, Katharina, et al. "Effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury: a single case study." Spinal cord series and cases 2.1 (2016): 1-3.

This is a single case study investigating to what extent the quality of life (QoL) of patients with spinal cord injury can be influenced by training with an exoskeleton. One patient (male, 22 years), initially unable to walk independently after T11 traumatic spinal cord injury (ASIA Impairment Scale C), was recruited for this study 1 year after injury. The progress of his first 6 months of ReWalk training was documented and as primary outcome measure, the QoL was measured with SF-36 questionnaire. Secondary outcome measures were ASIA scale, Berg-Balance-Scale, and Dynamic Gait Index. After the 6-month training period, this patient reported increased scores in 6 out of 8 areas on the SF-36 (physical functioning, physical role function, physical pain, general health, vitality, and physical well-being). The ASIA motor score improved from segment L2 to L3. Sensory functions remained unchanged. The patient partly regained control for bowel and bladder functions. The Dynamic Gait Index improved from 0 to 18/21, and the Berg Balance Scale from 7 to 34/44. At the end of the study period the patient was able to walk independently supervised by one person. Quality of life, mobility, risk of falling, motor skills, and control of bladder and bowel functions were all improved. Overall, this demonstrated a positive effect of robot-assisted gait training on various areas of the patient’s life.

Stampacchia et al. (2016)

Stampacchia, Giulia, et al. "Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons." NeuroRehabilitation 39.2 (2016): 277-283.

The aim of this study was to investigate the acceptability of over ground robot-assisted walking and its effect on pain and spasticity. Twenty-one individuals with SCI participated in a walking session assisted by an Ekso GT powered robotic exoskeleton. Before and after the walking experience, both pain and spasticity were evaluated. Pain was assessed using a 0-10 Numeric Rating Scale (NRS) and muscle spasticity was assessed as subjective perception using the NRS scale as well as an objective assessment using both the Modified Ashworth Scale and the Penn Spasm Frequency Scale. Positive and negative sensations were investigated using a questionnaire. The patient’s global impression of change scale was administrated as well. The post-walking assessment demonstrated a significant decrease in muscle spasticity and pain intensity. Subjective questionnaires provided to participants indicated a good acceptability of the robot-assisted walking as seen in a global change after the walking session, high scores on the positive sensations, and low scores on the negative sensations. The authors concluded that over ground robot-assisted walking is well accepted by SCI persons and has positive effects in terms of spasticity and pain reduction.

Asselin et al. (2015)

Asselin, Pierre, et al. "Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia." Journal of rehabilitation research and development 52.2 (2015): 147.

The aim of this prospective, single-group observational study was to investigate energy expenditure and heart rate (HR) during powered exoskeletal-assisted use while participating in seated rest, exoskeleton-assisted standing, and exoskeleton-assisted walking. Oxygen uptake (VO2) while using the powered exoskeleton was compared to other reports that have investigated the use of passive gait orthotics in persons with paraplegia. In this study, 8 non-ambulatory participants with paraplegia were trained to ambulate with a powered exoskeleton. Measurements of oxygen uptake (VO2) and heart rate (HR) were recorded for 6 min while sitting, standing, and walking. The average value of VO2 during walking was significantly higher than for sitting and standing ($p < 0.001$). The HR response during walking was significantly greater than that of either sitting or standing ($p < 0.001$). On average, the participants reported RPEs ranging from very light (7) to somewhat hard (13), with an average RPE of very light to fairly light (10 ± 2). Research shows that use of an exoskeletal system that requires increased energy expenditure without requiring excessive effort is desirable. This study demonstrated that persons with paraplegia were able to ambulate efficiently using the powered exoskeleton for over ground ambulation, providing the potential for functional gain and improved fitness.

Fineberg et al. (2013)

Fineberg, Drew B., et al. "Vertical ground reaction force-based analysis of powered exoskeleton-assisted walking in persons with motor-complete paraplegia." The Journal of Spinal Cord Medicine 36.4 (2013): 313-321.

This is a cross-sectional study performed by the VA to analyze vertical Ground Reaction Forces (vGRF) during powered exoskeleton assisted walking using the ReWalk compared with vGRF of able-bodied gait. The aim was to show the magnitude and pattern of mechanical loading in persons with spinal cord injury (SCI) during powered exoskeleton-assisted walking. The study comprised 6 participants with motor complete SCI (T1–T11 AIS A/B) and three age, height, weight, and gender matched able-bodied volunteers. The participants were trained to ambulate over ground using a ReWalk exoskeleton and the vGRF was recorded using F-Scan sensors placed within the participants' shoes. Participants had to ambulate a minimum of 10 meters with the sensors in the shoes. Peak stance average (PSA) was computed from vGRF and normalized across all participants by percent body weight. Peak vGRF was determined for heel strike, mid-stance, and toe-off. Participants with motor-complete SCI, ambulating independently without hands on assistance, using a ReWalk demonstrated mechanical loading magnitudes and patterns similar to able-bodied gait. This suggests the potential for powered exoskeleton assisted walking to provide a mechanism for mechanical loading to the lower extremities.

Esquenazi et al. (2012)

Esquenazi, Alberto, et al. "The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury." American Journal of Physical Medicine & Rehabilitation 91.11 (2012): 911-921.

This open, non-comparative, non-randomized study was performed to assess the safety and performance of the ReWalk powered exoskeleton in enabling people with paraplegia to ambulate. This study comprised 12 subjects with paraplegia due to spinal cord injury who completed the active intervention. Subjects were trained for up to 24 sessions of 60- to 90-min duration over approximately 8 weeks. Near the completion of training, subjects had a performance evaluation visit that consisted of a 6-min walk test, a 10-m walk test, and a gait laboratory evaluation including three-dimensional motion capture and temporo-spatial data. After training, while using the ReWalk 10 of the 12 subjects were able to independently transfer and walk, without assistance, for at least 50 to 100 meters continuously, for a period of at least 5 to 10 mins continuously, and with velocities ranging from 0.03 to 0.45 m/sec. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk. Most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. The research shows that the ReWalk holds considerable potential as a safe ambulatory powered orthosis for patients with motor-complete thoracic-level SCI.

ReWalk does not make any claims about the potential benefits of the use of ReWalk.

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