Spasticity

Spasticity is assessed secondarily with exoskeleton use in 33 articles. The vast majority, 23 articles, examine patients with spinal cord injury (SCI) while six look at patients post-stroke. The most studied device in regards to spasticity is the Ekso1.1/GT/NR device, referred to as “Ekso” in this paper (18 articles), followed by the ReWalk (8 articles). Almost all of the articles looking at spasticity are either case studies or case series (22). Almost all (27) chose to measure spasticity using the Modified Ashworth Scale (MAS)/Ashworth scale. Spasticity is an important secondary health complication to study, as it appears frequently in patients with neurological impairment including up to 78% of those with spinal cord injury.[1]

Stroke (CVA)

For participants with stroke, there are mixed results in terms of exoskeleton walking affecting spasticity. Some studies showed no improvement after using an exoskeleton compared to controls.[2–5] However, these could be explained by lack of spasticity at baseline. In a sample of 46 patients, the median MAS at hip, knee, and ankle at baseline was 0, indicating that at least 50% of the sample had no spasticity in any joint of the lower extremity.[2] A similar baseline assessment was shown in a sample of 12 subacute participants with a median Ashworth scale scores at all joints being 0.[4] Of a sample of eight participants, two patients had improved spasticity while another two had worsening spasticity after 3 weeks of 5 Ekso sessions per week.[3] In 11 chronic patients, the median Ashworth score for knee extensors decreased from 2 to 1 after using Ekso for 12 sessions, though no change in median score was seen at the hip and an increase median score from 1 to 2 was seen at the ankle.[4]

Spinal Cord Injury (SCI)

Like patients with stoke, studies completed using participants with SCI show mixed results regarding how exoskeletons affect spasticity. While some studies showed no change in spasticity for participants, this could be explained by overall low to absent spasticity levels at baseline assessment.[6–8] Another suggestion for a reason why no or minimal change in spasticity was noted was because spasticity levels were only measured at baseline and completion of a multi-week intervention versus before and after each session, as it may be true that effects on spasticity are short-lasting.[9–12]

Comparing the end of a 26 session Indego gait training protocol completed by 45 participants, spasticity decreased from1.6±0.9 to 0.9±1.7.[13] MAS scores demonstrated that 26.7% of participants decreased spasticity while 62.2% of participants reported no change in spasticity from pre- to post- intervention.[13] Another study split participants into two groups: one with low spasticity at baseline (n=3) and one with higher spasticity at baseline (n=5). Those with higher spasticity levels showed no change over 12 week training with ReWalk, while the group with low spasticity at baseline experienced an initial increase then a decrease in spasticity.[14]

Some studies assessed the change in spasticity pre- to post- single exoskeleton session. One study demonstrated short-term spasticity improvements after exoskeleton walking, but did not note any long-term longitudinal change after 24 sessions of Ekso gait training.[15] During session 12 and 24, median spasticity decreased from pre- to post- training (Session 12: 4 (0–16) to 2 (0–10), session 24: 5 (0–14) to 2 (0–9)).[15] A second study evaluated 21 participants with SCI who completed a single session of Ekso gait training. Subjective reports of spasticity were assessed using a 10 point scale and the median decreased from 2.0 (0.0–4.5) to 0.0 (0.0–1.5) while objective data using the MAS confirmed the same decrease from 4.0 (0.0–10.7) to 2.0 (0.0–5.2).[16] A third study measured spasticity before and after each of 24 ReWalk sessions in 12 participants with complete SCI, and found, in total, spasticity improved 130 times and worsened 65 times, with 3 participants reporting overall improvement in spasticity throughout the study protocol.[17]

Multiple studies examined a combination of both exoskeleton usage and electrical stimulation. In a mixed intervention study including 20 sessions of FES cycling followed by 20 sessions of walking in Ekso, 7 participants with complete SCI decreased their MAS from 7.14±3.56 to 4.28±3.68 after FES cycling to 3.57±4.04 after Ekso walking.[18] In another Indego study that added peroneal nerve stimulation during the swing phase of walking, an increase in peak hip and knee flexion was seen but there was no effect on Ashworth scores noted.[19] A second study examining an integrated FES system with the Indego exoskeleton showed reduction in spasticity in three subjects when assessed immediately before and after walking session.[20] A paper examining spinal cord stimulation in conjunction with exoAtlet walking found that by using an anti-spastic mode of 67 pulses per second, individuals with severe spasticity were successful in walking with an exoskeleton.[21]

There is also one study that examined exoskeleton use as a personal device in the home and community. Fourteen individuals used the ReWalk device for two to three weeks and three of them (21.4%) reported a reduction in spasticity, though these results were reported subjectively.[22]

Multiple Sclerosis (MS)

Only two studies with a total of 14 participants are known to discuss subjects with Multiple Sclerosis and spasticity. The first is a case study discussing a 51-year-old female who utilized Ekso twice weekly for 15 sessions. There was no change in her spasticity.[23] A second study evaluated 13 people who used ReWalk 3 times a week for 8 weeks. While it was challenging to collect pre and post-session measurements, all but one post-session score were greater than one standard deviation lower than baseline measurement, indicating lowering of spasticity after the session.[24]

Acquired Brain Injury (ABI)

There is only one known study looking at participants with acquired brain injury (ABI) that assesses spasticity. This is a retrospective case-controlled study examining medical records of patients who utilized Ekso as part of their regular therapy. Twenty-nine patients were in the Ekso group and 20 in the control. There were no significant changes in MAS scores from admission to discharge in either group.[25]

Review Articles

There are seven known review articles that discuss spasticity and all but one focus on participants with SCI. One examines patients with CVA, though it focuses mostly on gait outcomes.[26] In total, 2940 patients are included in these reviews.

A meta-analysis of 11 articles demonstrated exoskeleton superiority with improving lower limb muscle tension when compared to conventional training, but noted that only two included studies discussed this topic.[27] Another review included 19 articles, with 6 overlapping from the previous meta-analysis. Four studies discussed spasticity but only two contained sufficient data to be included in meta-analysis. In these two articles, robotic-assisted gait training was inferior to conventional training for reducing spasticity, especially in the acute phase of SCI.[28] These results are directly conflicting. Both of these review articles focused heavily on studies utilizing the Lokomat or other body weight supported treadmill based exoskeletons.

The third review article is the only one that included both randomized and non-randomized trials. Because of this broader inclusion, this analysis consisted of 41 articles. Seven of the 41 studies looked at spasticity with Ekso and ReWalk being the most used devices. Significant spasticity reduction was seen in 3 of the 7 studies included in this review and another study demonstrated improvement in spasticity after a single session of exoskeleton walking.[29]

Another review article suggested that spasticity may be reduced after using exoskeletons, but noted that small sample size is a limitation of many of these studies.[1] Another limitation noted in a review was the significant variability in when assessments were completed in relation to length of the training period.[30] In a final review of 49 studies, of which 10 examined spasticity using 6 different devices, the exoskeletons were used to measure spasticity across joints, mostly by measuring the exoskeleton joint impedance.[31]

Conclusions

Spasticity is included as a secondary outcome in multiple published articles and shows mixed results. Limitations of this data include small sample sizes, a discrepancy of when spasticity is measured, and absence of spasticity at baseline. It is possible that using an exoskeleton decreases spasticity in subjects, especially over a single session.

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All know articles assessing spasticity in participants using an exoskeleton

Title	Authors	Journal	Device	Diagnosis
Retrospective case-control study to compare exoskeleton-assisted walking with standard care in subacute non-traumatic brain injury patients	Tosto-Mancuso J, Rozanski G, Patel N, Breyman E, Dewil S, Jumreornvong O, Putrino D, Tabacof L, Escalon M, Cortes M	NeuroRehabilitation. 2023;53(4):577-584	Ekso	ABI
The efficacy of exoskeleton robotic training on ambulation recovery in patients with spinal cord injury: A meta-analysis	Liu W, Chen JB	J Spinal Cord Med. 2023 Aug 3:1-10	Multiple – Review Article	SCI
Effectiveness of robotic-assisted gait training on cardiopulmonary fitness and exercise capacity for incomplete spinal cord injury: A systematic review and meta-analysis of randomized controlled trials	Li R, Ding M, Wang J, Pan H, Sun X, Huang L, Fu C, He C, Wei Q	Clin Rehabil. 2023 Mar;37(3):312-329	Ekso	SCI
Robotic locomotor training for spasticity, pain, and quality of life in individuals with chronic SCI: A pilot randomized controlled trial	Shackleton C, Evans R, West S, Derman W, Albertus Y	2023 Jan 30:4:1003360	Ekso	SCI
Effect of exoskeleton-assisted Body Weight-Supported Treadmill Training on gait function for patients with chronic stroke a scoping review	Yamamoto R, Sasaki S, Kuwahara W, Kawakami M, Kaneko F	2022 Dec 21;19(1):143	Multiple – Review Article	CVA
Improvement of quality of life after 2-month exoskeleton training in patients with chronic spinal cord injury	Van Nes IJW, van Dijsseldonk RB, van Herpen FHM, Rijken H, Geurts ACH, Keijsers NLW.	J Spinal Cord Med. 2022 Apr 4:1-7	ReWalk	SCI
Overground robotic training effects on walking and secondary health conditions in individuals with spinal cord injury: systematic review	Tamburella F, Lorusso M, Tramontano M, Fadlun S, Masciullo M, Scivoletto G	J Neuroeng Rehabil. 2022 Mar 15;19(1):27	Multiple – Review Article	SCI
Knowledge Gaps in Biophysical Changes After Powered Robotic Exoskeleton Walking by Individuals With Spinal Cord Injury-A Scoping Review	Yip CCH, Lam CY, Cheung KMC, Wong YW, Koljonen PA	Front Neurol. 2022 Mar 10:13:792295	Multiple – Review Article	SCI
Evaluation of safety and performance of the self balancing walking system Atalante in patients with complete motor spinal cord injury	Kerdraon J, Previnaire JG, Tucker M, Coignard P, Allegre W, Kanppen E, Ames A	Spinal Cord Ser Cases. 2021 Aug 4;7(1):71	Atalante	SCI

Title	Authors	Journal	Device	Diagnosis
Functional Gait Recovery after a Combination of Conventional Therapy and Overground Robot-Assisted Gait Training Is Not Associated with Significant Changes in Muscle Activation Pattern: An EMG Preliminary Study on Subjects Subacute Post Stroke	Infarinato F, Romano P, Goffredo M, Ottaviani M, Galafate D, Gison A, Petruccelli S, Pournajaf S, Franceschini M	Brain Sci. 2021 Apr 1;11(4):448.	Ekso	CVA
Enhancing quality of life in progressive multiple sclerosis with powered robotic exoskeleton	Wee SK, Ho CY, Tan SL, Ong CH	Mult Scler. 2021 Mar;27(3):483-487	Ekso	MS
Gait Recovery with an Overground Powered Exoskeleton: A Randomized Controlled Trial on Subacute Stroke Subjects	Molteni F, Guanziroli E, Goffredo M, Calabrò RS, Pournajaf S, Gaffuri M, Gasperini G, Filoni S, Baratta S, Galafate D, Le Pera D, Bramanti P, Franceschini M	Brain Sci. 2021 Jan 14;11(1):104	Ekso	CVA
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, Bigazzi M.	2021. NeuroRehabEXO.	Ekso	SCI
Exoskeleton home and community use in people with complete spinal cord injury	Van Dijsseldonk RB, van Nes IJW, Geurts ACH, Keijsers NLW	Sci Rep. 2020 Sep 24;10(1):15600	ReWalk	SCI
Feasibility of integrating robotic exoskeleton gait training in inpatient rehabilitation.	Swank C, Sikka S, Driver S, Bennett M, Callender L.	Disabil Rehabil Assist Technol. 2020 May;15(4):409-417	Ekso	CVA, SCI
Exoskeleton walk training in paralyzed individuals benefits from transcutaneous lumbar cord tonic electrical stimulation	Shapkova EY, Pismennaya EV, Emelyannikov DV, Ivanenko Y	Front Neurosci. 2020 May 25:14:416	ExoAtlet	SCI
Overground wearable powered exoskeleton for gait training in subacute stroke subjects: clinical and gait assessments.	Goffredo M, Guanziroli E, Pournajaf S, Gaffuri M, Gasperini G, Filoni S, Baratta S, Damiani C, Franceschini M, Molteni F	Eur J Phys Rehabil Med. 2019 Dec;55(6):710-721	Ekso	CVA
Retraining walking over ground in a powered exoskeleton after spinal cord injury: a prospective cohort study to examine functional gains and neuroplasticity	Khan AS, Livingstone DC, Hurd CL, Duchcherer J, Misiaszek JE, Gorassini MA, Manns PJ, Yang JF	J Neuroeng Rehabil. 2019 Nov 21;16(1):145	ReWalk	SCI

Title	Authors	Journal	Device	Diagnosis
Exoskeleton Gait Training After Spinal Cord Injury: An Exploratory Study on Secondary Health Conditions	Baunsgaard CB, Vig Nissen U, Brust AK, Frotzler A, Ribeill C, Kalke YB, León N, Gómez B, Samuelsson K, Antepohl W, Holmström U, Marklund N, Glott T, Opheim A, Penalva JB, Murillo N, Nachtegaal J, Faber W, Biering-Sørensen F	J Rehabil Med. 2018 Sep 28;50(9):806-813	Ekso	SCI
Examining the Effects of a Powered Exoskeleton on Quality of Life and Secondary Impairments in People Living with Spinal Cord Injury	Juszczak M, Galle E and Bushnik T	Top Spinal Cord Inj Rehabil. 2018 Fall;24(4):336-342	Indego	SCI
Robotic Rehabilitation and Spinal Cord Injury a Narrative Review	Mekki M, Delgado AD, Fry A, Putrino D, Huang V	Neurotherapeutics. 2018 Jul;15(3):604-617	Multiple – Review Article	SCI
FES coupled with a powered exoskeleton for cooperative muscle contribution in persons with paraplegia	Murray SA, Farris RJ, Goldfarb M, Hartigan C, Kandilakis C, Truex D	Annu Int Conf IEEE Eng Med Biol Soc. 2018 Jul:2018:2788-2792	Indego	SCI
Supplemental stimulation improves swing phase kinematics during exoskeleton assisted gait of SCI subjects with severe muscle spasticity	Ekelem A, Golfarb M	Front Neurosci. 2018 Jun 1:12:374	Indego	SCI
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.	Eur J Phys Rehabil Med. 2017 Oct;53(5):676-684	Ekso	CVA
Feasibility and Safety of a Powered Exoskeleton for Assisted Walking for Persons With Multiple Sclerosis: A Single-Group Preliminary Study	Kozlowski AJ, Fabian M, Lad D, Delgado AD.	Arch Phys Med Rehabil. 2017 Jul;98(7):1300-1307	ReWalk	MS
An integrated gait rehabilitation training based on Functional Electrical Stimulation cycling and overground robotic exoskeleton in complete spinal cord injury patients: preliminary results	Mazzoleni S, Battini E, Rustici A, Stampacchia G.	IEEE Int Conf Rehabil Robot. 2017 Jul:2017:289-293	Ekso	SCI
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	NeuroRehabilitation. 2016 Jun 27;39(2):277-83	Ekso	SCI

Title	Authors	Journal	Device	Diagnosis
Lower limb exoskeletons for individuals with chronic spinal cord injury: Findings from a feasibility study	Benson I, Hart K, van Middendorp JJ, Tussler D	Clin Rehabil. 2016 Jan;30(1):73-84.	ReWalk	CVA
Understanding Therapeutic Benefits of Overground Bionic Ambulation: 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	Arch Phys Med Rehabil. 2014 Oct;95(10):1878-1887.e4	Ekso	SCI
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	J Spine 2013, S4	Ekso	SCI
The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury	Esquenazi A, Talaty M, Packel A, Saulino M	Am J Phys Med Rehabil. 2012 Nov;91(11):911-21	ReWalk	SCI

CVA = stroke, SCI = spinal cord injury, MS = multiple sclerosis