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