Pain

The research regarding use of exoskeletons is largely neutral to positive towards improving pain. Publications utilized multiple types of exoskeleton devices, though the majority utilized the Ekso1.1/EksoGT/EksoNR, referred to as “Ekso” in this paper. Articles looking at pain improvements are almost exclusively related to the spinal cord injury population. This makes sense as pain is a common complication for those with SCI, affecting an estimated 65-85% of this population.[1] The majority of articles utilized a visual analog scale or numeric pain rating to assess pain. Pain was often a secondary outcome measure utilized in the study as a way to measure adverse events or comfort of device wearing.

Stroke (CVA)

In the only known study assessing pain in participants post stroke, 42 participants utilized the Indego device twice a week for two weeks and none experienced pain due to the device during any session.[2]

Multiple Sclerosis (MS)

The single known study assessing participants with MS is a case study in which the participant did not experience any pain before or after an Ekso session.[3]

Spinal Cord Injury (SCI)

There is more robust research on participants with spinal cord injury and their secondary health outcomes. These show a range of results.

Some studies show positive results in regards to pain after using an exoskeleton. One study that included participants with any level SCI found that by using the ReWalk, their pain decreased after exoskeleton walking as compared to before the session.[4] This pain change was assessed for each session, but no meaningful change over the whole 12 week intervention was noted.[4] Another unique study looked at pain levels both before and after a single session walking in the Ekso in 21 participants with SCI utilized a 10 point numeric pain rating scale and on initial evaluation, showed a non-significant decrease from 4.0 to 0.0.[5] However, when only participants who had pain initially were analyzed (12 out of 21) a significant decrease from 6.0 to 2.0 was noted.[5] A smaller sample of 3 participants who underwent treatment with Ekso for 18 sessions reported lower pain severity at the end of intervention versus at the start.[6] A small study with 8 subjects showed slight decrease in pain levels from pre-Ekso intervention to post 20 sessions, though this was nonsignificant from 1.00 +/- 2.83 to 0.88 +/- 2.47 on visual analog scale.[7] In a smaller sample of 3 participants using the Ekso 20 times, there was a 9% reduction in pain.[8] A study of 12 subjects utilizing ReWalk up to 26 times showed that five of the subjects reported a combined total of 28 sessions where pain was notably reduced, compared to only one participant who reported an increase in pain after any session.[9] This one participant had the same increased pain with a standing frame and therefore the increased pain was attributed to standing and not to the device itself.[9] While not statistically significant, a study where participants first completed 20 sessions of FES cycling followed by 20 sessions of Ekso walking saw reductions in pain during FES cycling that continued to decrease with Ekso walking.[10]

Other studies are more neutral, reporting no or non-significant changes in pain during an intervention with an exoskeleton. Twelve participants with thoracic level injuries utilized the Atalante exoskeleton with no difference in pain between pre- and post-intervention.[11] When examining the percentage of participants experiencing pain prior to, after, and at two time points during a 24 session intervention with Ekso, no meaningful changes were noted with 40% of participants reporting pain at all time points and 31% of participants experiencing no pain at any time point.[12] In a study using the Indego exoskeleton for 26 sessions each with 45 participants with chronic SCI, there was no significant change in self-reported pain from the start of the intervention (1.1 +/- 1.7) to the conclusion of the intervention (0.9 +/- 1.6) measured on a numerical pain rating scale from 0-10.[13] Six individuals completed weekly Ekso sessions for 6 weeks and were assessed for pain before and after sessions. Overall, there were minimal pain results, with the most common area of pain being in the upper extremities, likely from overuse of the arms on the assistive device.[14] A ten-point visual analogue scale was used with 10 participants who utilized the ReWalk for up to 20 sessions. There were minimal changes in terms of pain perception before and after sessions.[15] Another 6 participants who walked in ReWalk between 7 and 24 times had an average pain of 1.77 on the VAS scale prior to training and 1.71 post training.[16] Pain levels in a study using Ekso demonstrated that the average increase in pain was 1mm, significantly below the known minimum clinically significant difference of 12mm when using an 100mm visual analog scale.[17] A study of 40 subjects who used the Phoenix device for 20 sessions had no significant difference in pain between pre and post session.[18]

One known study noted an increase in pain resulting from using an exoskeleton. A randomized controlled trial of participants with tetraplegia who received either activity-based training or robotic locomotor training with Ekso over 24 weeks showed an increase in pain levels for both groups with no significant difference between groups.[19]

Another study tracked pain as an adverse event. Of the 24 participants who totaled 12 sessions in Able each, 27.2% of adverse events were related to pain, with another 11.1% being related to neuropathic pain.[20]

Personal Use

One known study specifically examined exoskeletons for personal use at home and in the community. Fourteen individuals and their support persons utilized the ReWalk device at home during a 2-3 week period. One participant reported a reduction in neuropathic pain, while four others reported muscle or joint pain as a result of using the exoskeleton.[21] Two of those four participants reported pain in the shoulder which resulted in them stopping use of the ReWalk for either 1 day or the remainder of the study.[21]

Reviews

A few review articles have examined pain in relation to exoskeleton use. All of these review articles also look at other effects from exoskeletons, so pain is a small subset of the total number of articles and results that the authors examined. Out of six studies, five showed a trend in pain reduction in subjects with subacute or chronic SCI.[22] Two reviews commented on a few small-scale case series that indicated a potential positive effect of exoskeleton walking on neuropathic pain.[23,24] Yip et al comments also on how floor effects could be contributing to

studies that demonstrated no effect on pain, because self-reported pain in participants at baseline was low.[24]

Conclusion

Overall, research focused on pain associated with exoskeleton use is always a secondary outcome measure and shows varied results, even with similar dosage and study design. Pain is a challenging outcome to track because, while many persons with SCI exhibit some sort of pain post injury, there are many types of pain and pain is a subjective experience. While some studies showed that using an exoskeleton decreased pain, other studies show it increases pain, which may be due to exertion or utilizing muscles that aren't normally taxed. It is also worth noting that a number of studies report pain in the upper extremities after using an exoskeleton, which is likely due to the use of an assistive device (e.g. walker) in combination with the exoskeleton. Other articles do not specify body part that experienced the pain.

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All known articles assessing pain in participants using an exoskeleton

Title	Authors	Journal	Device	Diagnosis
Multicentric investigation on the safety, feasibility and usability of the ABLE lower-limb robotic exoskeleton for individuals with spinal cord injury: a framework towards the standardisation of clinical evaluations	Wright MA, Herzog F, Mas-Vinyals A, Carnicero-Carmona A, Lobo-Prat J, Hensel C, Franz S, Weidner N, Vidal J, Opisso E, Rupp R	J Neuroeng Rehabil. 2023 Apr 12;20(1):45.	Able	SCI
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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
Utilization of Robotic Exoskeleton for Overground Walking in Acute and Chronic Stroke	Nolan KJ, Karunakaran KK, Roberts P, Tefertiller C, Walter AM, Zhang J, Leslie D, Jayaraman A and Francisco GE	Front Neurorobot. 2021 Sep 1:15:689363.	Indego	CVA
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Training for mobility with exoskeleton robot in person with Spinal Cord Injury: a pilot study.	Sale P, Russo EF, Scarton A, Calabrò RS, Masiero S, Filoni S	Eur J Phys Rehabil Med. 2018 Oct;54(5):745-751.	Ekso	SCI
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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
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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
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Safety and tolerance of the ReWalk™ exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study	Zeilig G, Weingarden H, Zwecker M, Dudkiewicz I, Bloch A, Esquenazi A.	J Spinal Cord Med. 2012 Mar;35(2):96-101.	ReWalk	SCI

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