



## Quality of Life (QOL)

The research regarding the use of exoskeletons and its impact on Quality of Life (QOL) is overall positive. Publications evaluated multiple types of exoskeleton devices, though the majority utilized the Ekso1.1/EksoGT/EksoNR, referred to as “Ekso” in this paper. Quality of life when using an exoskeleton has been assessed in multiple diagnostic groups including SCI, CVA, MS, and general neurological diagnoses. The majority of articles utilized the SF-36 or SF-12 to assess QOL and the Beck Depression Inventory to assess mood.

### General Neurological Disorders

In patients with general neurological diagnoses, a review article analysis of 31 studies which utilized 11 different exoskeleton devices was completed that examined both pre-post and randomized control trials.<sup>1</sup> Intervention using an exoskeleton was compared to conventional therapy in randomized control trials. Significant improvements in the quality of life from both a mental health quality of life and a physical health quality of life perspective were seen for participants who were randomized to utilize robotic training.<sup>1</sup> In pre-post studies, a significant effect from using an exoskeleton was found on quality of life in both realms as well.<sup>1</sup> No significant decrease in depression was noted from either study type.<sup>1</sup>

### Spinal Cord Injury (SCI)

There are multiple articles looking at participants with spinal cord injuries. Pre-post studies showed significant improvements in QOL and mood, while randomized control trials (RCTs) only sometimes showed superiority of the exoskeleton treated group and otherwise noted improvements in both groups.

In one study examining acute SCI, the Beck Depression Inventory (BDI) was given to participants of an Ekso program during rehabilitation before and after a four week training period. The BDI includes 21 questions where takers select an answer from 0 to 3 for each question and a sum is computed to get a score between 0 and 63, with higher scores indicating greater depression. All patients improved their BDI score from an average of 18.2 (borderline clinical depression) at admission to an average of 14 (mild mood disturbance) after training.<sup>2</sup> A notable finding was on item two, where scores post-intervention for almost all participants improved to 0, revealing that the patients had a positive vision about their future after intervention using the exoskeleton.<sup>2</sup> Another study that looked at acute patients with SCI enrolled 42 patients and randomized them to receive Ekso or conventional gait training for a total of 40 sessions over 8 weeks. The Ekso group had more significant improvements on total quality of life and mood scores per the SF-12 and Beck Depression Inventory, but the effect size was categorized as low to moderate.<sup>3</sup>

In participants who have chronic SCI, both pre-post studies and randomized control trials were found in the literature with results similar to the acute subject groups. Most pre-post studies showed improvement in QOL from using an exoskeleton. One such study examined satisfaction with life as a whole and was shown in a group of 27 chronically injured participants to increase from beginning to end of treatment with Ekso, but also at follow up 4 weeks after final training.<sup>4</sup> A case study examining a participant with chronic SCI who trained with the ReWalk exoskeleton



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improved on most subscales of the SF-36 through the training period.<sup>5</sup> A larger study using the ReWalk three times a week for eight weeks in 21 participants with chronic SCI demonstrated a significant improvement in QOL (SF-36 sum score improvement from  $571 \pm 133$  to  $621 \pm 90$ ).<sup>6</sup> Four of the eight subscales (bodily pain, social functioning, mental health, and general health perception) improved significantly with  $p < 0.05$ .<sup>6</sup> A third article using ReWalk demonstrated a four point improvement on the quality of life subscale of the Assistive Technology Device Predisposition Assessment (ATD-PA).<sup>7</sup> Seven individuals with an average SCI duration of 11.4 years who used ReWalk daily for four to five weeks showed a significant improvement in the SF-12 domain role physical.<sup>8</sup> One pre-post study, however, did not show a difference in QOL; forty five participants who utilized Indego for 24-32 sessions saw no significant change in quality of life when measured with the Satisfaction with Life Scale.<sup>9</sup>

Randomized trials comparing an exoskeleton to conventional treatment in participants with chronic SCI showed mixed results. Sixteen participants were randomized into either a 24 week Ekso program or an Activity Based Training (ABT) regimen of the same length. The group who received treatments with robotics had increased ( $p = 0.03$ ) perceptions of general, physical, and psychological QOL with changes of 27%, 23% and 3% from pre to post intervention, respectively.<sup>10</sup> Comparatively, the ABT group had non-significant increases of 10%, 9% and 8% for the three domains, respectively.<sup>10</sup> In a sample of 110 patients randomized to receive robotic exoskeleton treatment ( $n = 79$ ) or conventional therapy ( $n = 31$ ) in addition to psychological treatment for two 3-week cycles, the severity of the state anxiety and general depression symptoms and all the depression factors were significantly decreased after the 7-week rehabilitation program, compared with the first measurement, regardless of the type of rehabilitation.<sup>11</sup> A different randomized controlled trial compared exoskeleton versus usual activity in the home and community. Proportion of successes in QOL measures between groups showed no statistically significant differences, though this may have been confounded by low exoskeleton usage.<sup>12</sup>

There was a small pre-post study with subjects who demonstrated gait disturbance due to spinal root dysfunction who had undergone spinal surgery and were treated with the ExoAtlet for 2-3 times a week over 4 or 8 weeks. Participants were given the modified geriatric depression scale. Participants who were demonstrating weakness for only 1 month ( $n = 2$ ) both improved their score by three points, while those that were chronic in nature ( $n = 2$ , weakness for 26 and 38 weeks) improved by four and two points.<sup>13</sup>

Review articles focusing on patients with SCI often commented on QOL as one component of secondary health. One such article drew parallels between reduction of physical health complications like spasticity and pressure ulcers and subsequent improvement of QOL.<sup>14</sup> It also mentioned that social integration is essential to improving quality of life and how it is necessary to be active and carry out activities to do so.<sup>10</sup> Another article highlighted how challenging it is to make comparisons between articles due to many different metrics being used to measure QOL; eight measures were used in the 11 articles that this review examined.<sup>15</sup> Another 12 articles examined QOL, but it is notable that only 5 of these used a validated scale with a trend towards improvements in health related QOL.<sup>16</sup> Of the studies using non-validated scales, these showed a trend towards improved emotional, physical and psychological benefits.<sup>16</sup>



### Stroke (CVA)

For participants with stroke, results varied between those with acute and chronic diagnoses. For patients with acute stroke (average days since = 39), 36 patients were randomly assigned to receive exoskeleton training or usual care and no significant differences were found regarding quality of life.<sup>17</sup>

Patients with chronic stroke (n=32) received conventional physical therapy for 8 weeks with gait training either by way of the Lokomat or ExoAtlet device. After the treatment, there was a statistically significant difference in the parameters of vitality, mental health, bodily pain, and general health perception, all favoring treatment with the ExoAtlet.<sup>18</sup> Another study looking at patients post stroke randomized 30 patients with chronic stroke to either receive Ekso treatment or conventional physical therapy three times per week for eight weeks. Using the COPE inventory, the Ekso group significantly improved scores from pre to post intervention on four of the five subscales, whereas the conventional treatment group only improved on one subscale.<sup>19</sup> Mood and global quality of life also increased more so in the Ekso group.<sup>19</sup>

A large meta-analysis of 34 randomized controlled trials including 1166 participants concluded that only 5 of those studies looked at the participation of stroke patients and only one measurement, the EuroQOL-5 Dimension Questionnaire (EQ-5D), could be further analyzed showing superior results of using an exoskeleton over conventional rehabilitation.<sup>20</sup>

### Multiple Sclerosis (MS)

While participants with MS using exoskeletons are not as largely studied as patients with SCI and CVA, the studies that do exist often examine quality of life. A review of seven randomized control trials specifically looked at mental health, demonstrating that use of a stationary or an overground exoskeleton has positive effects on non-physical QOL and a slight positive impact on depression.<sup>21</sup> A case study of a 51 year old woman who underwent 15 sessions of Ekso gait training had her most meaningful significant change in quality of life, where her EQ-5D score improved from 0.358 to 0.549.<sup>22</sup> Another case study looked at a 71 year old male who utilized the Uan.Go device for 10 sessions with significant improvements noted in multiple sections of the SF-36; emotional role scoring (+33 points), pain detected (-24 points), social functioning (+16 points), and general health (+10 points).<sup>23</sup> A retrospective study with a control group of matched participants who did not receive treatment using the Ekso showed that the Ekso group had a higher perception of mental well-being (an improvement of 16.3 versus 1.6 in the control group) measured by the Multiple Sclerosis Quality of Life-54 (MS-QOL).<sup>24</sup> Mixed results regarding quality of life were seen in a small sample size of eight participants who walked three times a week over eight weeks in the ReWalk.<sup>25</sup>

### Broader Technology Program

Two known studies examined rehabilitation technology as a whole and its impact on QOL. One broader study utilizing a breadth of robotic and virtual reality equipment in a rehabilitation center for participants with MS found that using innovative technologies can help motivate patients during the rehabilitation process, noting significant pre- to post- treatment differences in both physical and mental quality of life (median physical QOL improved by 18.3 points while median mental QOL improved by 17.4 points).<sup>26</sup> Another study looked at a similar high-intensity



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technology-assisted training program for patients in the subacute or chronic phase of stroke found improvement relating to quality of life visible on the Stroke Impact Scale.<sup>27</sup>

### Conclusion

This literature is largely positive, demonstrating that use of an exoskeleton can improve the quality of life of its users. When comparing to conventional rehabilitation, most studies agree that exoskeletons are superior for improving QOL. Pre-post studies mostly agree that when QOL was measured both before and after exoskeleton training, the post assessment of QOL shows improvement.

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## All known articles assessing quality of life (QOL) in participants using an exoskeleton

Title	Authors	Journal	Device	Diagnosis
Exoskeletal-Assisted Walking in Veterans With Paralysis: A Randomized Clinical Trial	Spungen AM, Dematt EJ, Biswas K, Jones KM, Mi Z, Snodgrass AJ, Morin K, Asselin PK, Cirnigliaro CM, Kirshblum S, Gorman PH, Goetz LL, Stenson K, White KT, Hon A, Sabharwal S, Kiratli BJ, Ota D, Bennett B, Berman JE, Castillo D, Lee KK, Eddy BW, Henzel MK, Trbovich M, Holmes SA, Skelton F, Priebe M, Kornfeld SL, Huang GC, Bauman WA	JAMA Netw Open. 2024 Sep 3;7(9):e2431501	Rewalk	SCI
Effect of robotic exoskeleton training on lower limb function, activity and participation in stroke patients: a systematic review and meta-analysis of randomized controlled trials	Yang J, Zhu Y, Li H, Wang K, Li D, Qi Q	Front Neurol. 2024 Aug 13:15:1453781	Multiple – Review Article	CVA
Robotic assisted and exoskeleton gait training effect in mental health and fatigue of multiple sclerosis patients. A systematic review and a meta-analysis	Christodoulou VN, Varvarousis DN, Ntritsos G, Dimopoulos D, Giannakeas N, Vasileiadis GI, Korompilias A, Ploumis A	Disabil Rehabil. 2024 Apr 14:1-12	Multiple – Review Article	MS
Effects of robotic-assisted gait training on physical capacity, and quality of life among chronic stroke patients: A randomized controlled study	Bodur BE, Erdoğanoğlu Y, Sel SA	J Clin Neurosci. 2024 Jan 18:120:129-137.	ExoAtlet, lokomat	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.	Digital Medicine. 2023 Dec Vol 9, Issue 4	Ekso	SCI
Impact of Robotic-Assisted Gait Therapy on Depression and Anxiety Symptoms in Patients with Subacute Spinal Cord Injuries (SCIs)—A Prospective Clinical Study	Widuch-Spodyniuk A, Tarnacka B, Korczyński B, Wiśniewska J	J Clin Med. 2023 Nov 17;12(22):7153.	Ekso, Lokomat	SCI
Effect of robot-assisted gait training on quality of life and depression in neurological impairment: A systematic review and meta-analysis	den Brave M, Beaudart C, Maertens de Noordhout B, Gillot V, Kaux JF	Clin Rehabil. 2023 Jul;37(7):876-890.	Multiple – Review Article	Multiple – Review Article

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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	Front Rehabil Sci. 2023 Jan 30;4:1003360.	Ekso	SCI
Clinical efficacy of overground powered exoskeleton for gait training in patients with subacute stroke: A randomized controlled pilot trial	Yoo HJ, Bae CR, Jeong H, Ko MH, Kang YK, Pyun SB	Medicine (Baltimore). 2023 Jan 27;102(4):e32761.	ExoAtlet	CVA
The Outcomes of Robotic Rehabilitation Assisted Devices Following Spinal Cord Injury and the Prevention of Secondary Associated Complications	Nistor-Cseppento CD, Gherle A, Negrut N, Bungau SG, Sabau AM, Radu AF, Bungau AF, Tit DM, Uivaraseanu B, Ghitea TC, Uivarosan D	Medicina (Kaunas). 2022 Oct 13;58(10):1447	Multiple – Review Article	SCI
Feasibility and cost description of highly intensive rehabilitation involving new technologies in patients with post-acute stroke	Schuster-Amft C, Kool J, Moller JC, Schweinfurter R, Ernst MJ, Reicherzer L, Ziller C, Schwab ME, Wieser S, Wirz M	Pilot Feasibility Stud. 2022 Jul 5;8(1):139	Multiple – Review Article	CVA
Exoskeleton-assisted Gait Training in Spinal Disease With Gait Disturbance	Jang TG, Choi SH, Yu SH, Kim DH, Han IH, Nam KH.	Korean J Neurotrauma. 2022 May 2;18(2):316-323	ExoAtlet	SCI
Body Representation in Patients with Severe Spinal Cord Injury: A Pilot Study on the Promising Role of Powered Exoskeleton for Gait Training	Maggio MG, Naro A, De Luca R, Latella D, Balletta T, Caccamo L, Pioggia G, Bruschetta D, Calabrò RS	J Pers Med. 2022 Apr 11;12(4):619.	Ekso	SCI
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
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
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	Neuroeng Rehabil. 2022 Mar 15;19(1):27	Multiple – Review Article	SCI
Efficacy of an exoskeleton-based physical therapy program for non-ambulatory patients during subacute stroke rehabilitation: a randomized controlled trial	Louie DR, Mortenson WB, Durocher M, Schneeberg A, Teasell R, Yao J, Eng JJ	J Neuroeng Rehabil. 2021 Oct 10;18(1):149.	Ekso	CVA

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Walking with UAN.GO Exoskeleton: Training and Compliance in a Multiple Sclerosis Patient	Sesenna G, Calzolari C, Gruppi MP, Ciardi G.	Neurol Int. 2021 Aug 23;13(3):428-438	Uan.Go	MS
Wearable Robotic Gait Training in Persons with Multiple Sclerosis: A Satisfaction Study	Fernández-Vázquez D, Cano-de-la-Cuerda R, Gor-García-Fogeda MD, Molina-Rueda F	Sensors (Basel). 2021 Jul 20;21(14):4940.	Ekso	MS
Can powered exoskeletons improve gait and balance in multiple sclerosis? A retrospective study	Russo M, Grazia Maggio M, Naro A, Portaro S, Porcari B, Balletta T, De Luca R, Raciti L, Calabrò RS	Int J Rehabil Res. 2021 Jun 1;44(2):126-130.	Ekso	MS
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
Does overground robotic gait training improve non-motor outcomes in patients with chronic stroke? Findings from a pilot study	De Luca R, Maresca G, Balletta T, Cannavò A, Leonardi S, Latella D, Maggio MG, Portaro S, Naro A, Calabrò RS	J Clin Neurosci. 2020 Nov;81:240-245.	Ekso	CVA
Patients' perspective and usability of innovation technology in a new rehabilitation pathway: An exploratory study in patients with multiple sclerosis	Manuli A, Maggio MG, Tripoli D, Guillì M, Cannavo A, La Rosa G, Sciarrone F, Avena G, Calabro RS	Mult Scler Relat Disord. 2020 Sep;44:102312	Lokomat, Ekso, GEO	MS
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
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
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
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

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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	SCI
Effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury: a single case study	Raab K, Krakow K, Tripp F and Jung M	Spinal Cord Ser Cases. 2016 Jan 7;2:15025.	ReWalk	SCI
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	SCI

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