

## Cardiovascular Effects

There are many articles in the literature that evaluate the use of robotic exoskeletons and their effect on cardiovascular outcome measures across a variety of diagnoses. Most of these publications cover the Ekso 1.1/GT/NR device (25), referred to as “Ekso” in this paper. Other devices used include ReWalk (9), Indego (6), HAL (5), ExoAtlet (2), and SuitX Phoenix (1), among others. The most widely studied diagnosis was Spinal Cord Injury (23), followed by CVA (1) and ABI (1). The most commonly reported outcome measures in regard to cardiovascular effects were Heart Rate (HR) (26), Blood Pressure (BP) (16),  $VO_2$  (15) and  $VCO_2$  (4).

### Spinal Cord Injury (SCI)

Several articles in the literature demonstrated that robotic exoskeleton usage in persons with SCI can induce positive cardiovascular effects and even exercise. In a 13 subject Ekso study in participants with SCI, it was found that cardiorespiratory measures including peak heart rate and oxygen uptake ( $HR_{peak}$  and  $VO_{2peak}$ ) increased from 9-35% from sitting to standing and further by 22-52% from standing to walking with the Ekso in a single session.<sup>1</sup> The authors concluded that walking in the Ekso allowed these users to achieve moderate intensity levels of exercise.<sup>1</sup> Walking was found to induce a higher average  $VO_2$  when compared to either sitting or standing in both individuals with SCI and healthy controls in another Ekso study.<sup>2</sup> An 8 subject ReWalk study in persons with SCI reported that average oxygen uptake and heart rate were found to be significantly higher for walking when compared to sitting or standing.<sup>3</sup> One participant from a four subject Ekso SCI study demonstrated an increase in oxygen uptake from 0.27 L/min during rest to 0.55 L/min during walking.<sup>4</sup> Another 4 subject Ekso study in persons with SCI reported a range of cardiorespiratory responses from low (24%  $VO_{2peak}$ ) in the least impaired individual to supramaximal (124%  $VO_{2peak}$ ) in the participant with the greatest impairment.<sup>5</sup> A smaller two subject Ekso SCI case study reported similar findings; exoskeleton walking was compared to overground walking without a device and it was found that the participant with a lower starting walking capacity had greater cardiorespiratory responses than the participant that started with a greater walking capacity.<sup>6</sup> An Indego study in persons with SCI that evaluated cardiorespiratory and metabolic responses at different walking speeds found that walking in the device resulted in % $VO_{2peak}$  range of 51.5 to 63.2% and metabolic cost ranged from 3.5 to 4.3 METs<sub>SCI</sub>.<sup>7</sup> Participants in an Ekso SCI study were able to achieve light to moderate levels of exercise based on reported heart rate changes.<sup>8</sup> A case study using a subject who ambulated with the Ekso found an increase in both heart rate and blood pressure when active voluntary effort was required (i.e. less device assistance).<sup>9</sup> A 52 subject multisite Ekso study in persons with SCI who completed a median of 21 sessions reported a significant increase in heart rate during the sessions and no change in blood pressure.<sup>10</sup> Data analysis in an 11 subject SCI Ekso study where participants used the device three times per week for up to 25 sessions revealed no significant differences over time for heart rate or blood pressure when looking at the study from beginning to end however, heart rate did increase 15-21% within the sessions while blood pressure remained unchanged.<sup>11</sup> Another single subject SCI case study found that walking in the Ekso in combination with spinal stimulation yielded an increase in cardiac response as measured by heart rate and blood pressure.<sup>12</sup> Two ReWalk SCI studies reported that average heart rate and blood pressure were found to be higher following a training session.<sup>13,14</sup> A third ReWalk study in six persons with SCI noted that average blood pressure went from 121/77 pre-



session to 129/83 post-session and average heart rate went from 68 pre-session to 92 post-session, indicating an exercise-like response.<sup>15</sup> Although inconsistency in  $VO_2$  measures was reported in a 3 subject SCI Ekso study, elevated heart rates were found in all participants when compared to seated rest.<sup>16</sup> In an SCI case study with 2 subjects it was found that the subjects reached peak HR at 53% and 60% of age predicted max after a single session with the Ekso.<sup>17</sup> Fifteen individuals with SCI used both Ekso and Lokomat and it was found that greater cardiovascular effort was required when using the Ekso.<sup>18</sup> A review of various devices found that gait training with robotic assistance improved peak oxygen consumption to a greater degree for subjects with chronic incomplete spinal cord injury.<sup>19</sup> Several of these studies reported significant increases in heart rate after using an exoskeleton in persons with SCI and some noted that users were able to achieve light to moderate levels of exercise.

Other studies focused on the evidence showing that exoskeletons were not overly taxing to use in regard to cardiovascular effects. One eight subject SCI Ekso study found no effects on  $VO_2$  after using the device two to three times per week for 12 weeks.<sup>20</sup> A ReWalk study in persons with SCI compared the device to a KAFO and found higher  $VO_2$  and  $VO_{2max}$  values for the KAFO in both the six minute walk test (6MWT) and 30 minute walk test (30MWT).<sup>21</sup> In a randomized 16 subject SCI study that compared Ekso to activity based therapy, it was found that the standing heart rate was significantly higher in the activity group when compared to the Ekso group at the end of the study.<sup>22</sup> However, it was noted in the same study that cardiovascular efficiency improved during the 6MWT for the Ekso group after 6 weeks and was maintained through the end of the 24 week study period.<sup>22</sup> These publications indicated that exoskeletons were no harder, and even easier in some cases, to use when compared to alternative therapies like KAFOs or activity based therapy.

Another interesting study in 12 non-randomized SCI participants compared Ekso with usual care physiotherapy and found a significant reduction in arterial wave reflection and mean arterial pressure which is notable because arterial wave reflection, which can be used to infer the degree of systemic arterial wave reflection, has been shown to predict future cardiovascular events and all-cause mortality independent of blood pressure.<sup>23</sup> Arterial wave reflection is the augmentation pressure expressed as a percentage of central pulse pressure.<sup>23</sup>

### Stroke (CVA)

The literature reporting on cardiovascular effects in persons with CVA who utilized a robotic exoskeleton is slim. A two subject Ekso study in persons with CVA found that the participants achieved 75-85% of the calculated max heart rates through 86-100% of the 30 training sessions, completed over a period of 10 weeks.<sup>24</sup>

### Acquired Brain Injury (ABI)

There is only one known publication evaluating the cardiovascular effect of robotic exoskeletons in persons with ABI. Ten subjects with ABI used the Ekso and it was reported that participants were in the light to very light range for HR during the  $10.4 \pm 4.8$  completed sessions.<sup>25</sup>



### Review Articles

One review examining both body weight supported treadmills (BWSTT) and overground exoskeletons concluded that walking in an exoskeleton led to improvements in cardiovascular endurance while BWSTT did not.<sup>26</sup> A review that examined studies using various devices (including gait trainer, Lokomat, Indego, HAL, and SMA, among others) in persons with CVA, SCI, and healthy subjects concluded that metabolic and cardiorespiratory outcome measures were lower during robot assisted gait when compared to walking without a device.<sup>27</sup> Another review that examined 31 articles using various devices in persons with SCI came to the conclusion that the use of such a wide range of metrics to measure cardiovascular outcomes made these studies too difficult to compare.<sup>28</sup> Use of several different devices in persons with SCI was evaluated in another review and while the authors acknowledged that significant increases in HR and oxygen consumption while transitioning from sitting to standing were reported in several different studies, they offered the explanation that this may be considered a normal response to maintaining blood pressure when changing position.<sup>29</sup>

### Conclusions

As mentioned in a review article<sup>28</sup> above, the wide variety of outcome measures reported in the literature make it challenging to draw an overall conclusion on the cardiovascular effect of robotic exoskeletons. In general, using the devices led to increases in outcome measures such as heart rate, blood pressure, and  $VO_2$ . Although these results did not necessarily correlate to high intensity exercise, these increases were seen as positive.

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## All known articles assessing cardiovascular effects in participants using an exoskeleton

<b>Title</b>	<b>Authors</b>	<b>Journal</b>	<b>Device</b>	<b>Diagnosis</b>
Feasibility of overground exoskeleton gait training during inpatient rehabilitation after severe acquired brain injury	Gillespie J, Trammell M, Ochoa C, Driver S, Callender L, Dubiel R, Swank C	Brain Inj. 2024 May 11;38(6):459-466.	Ekso	ABI
Intensity Modulated Exoskeleton Gait Training Post Stroke	Nolan KJ, Ames GR, Dandola CM, Breighner JE, Franco S, Karunakaran KK, Saleh S	Annu Int Conf IEEE Eng Med Biol Soc. 2023 Jul;2023:1-4.	Ekso	CVA
Intensity of overground robotic exoskeleton training in two persons with motor-complete tetraplegia: a case series	Bosteder KD, Moore A, Weeks A, Dawkins JD, Trammell M, Driver S, Hamilton R, Swank C	Spinal Cord Ser Cases. 2023 Jul 1;9(1):24.	Ekso	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.	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.	Multiple – Review Article	SCI
Gait robot-assisted rehabilitation in persons with spinal cord injury: A scoping review	Stampacchia G, Gazzotti V, Olivieri M, Andrenelli E, Bonaiuti D, Calabro RS, Carmignano SM, Cassio A, Fundaro C, Companini I, Mazzoli D, Cerulli S, Chisari C, Colombo V, Dalise S, Mazzoleni D, Melegari C, Merlo A, Boldrini P, Mazzoleni S, Posteraro F, Mazzucchelli M, Benanti P, Castelli E, Draicchio F, Falabella V, Galeri S, Gimigliano F, Grigioni M, Mazzon S, Molteni F, Morone G, Petrarca, Picelli A, Senatore M, Turchetti G, Bizzarrini E	NeuroRehabilitation. 2022;51(4):609-647.	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

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Exoskeleton Training and Trans-Spinal Stimulation for Physical Activity Enhancement After Spinal Cord Injury (EXTra-SCI): An Exploratory Study	Sutor TW, Ghatas MP, Goetz LL, Lavis TD, Gorgey AS	Front Rehabil Sci. 2022 Jan;2:789422.	Ekso	SCI
Robotic locomotor training leads to cardiovascular changes in individuals with incomplete spinal cord injury over a 24-week rehabilitation period: a randomized controlled pilot study	Evans RW, Shackleton C, West S, Derman W, Laurie Rauch HG, Baalbergen E, Albertus Y	Arch Phys Med Rehabil. 2021 Aug;102(8):1447-1456.	Ekso	SCI
Energy cost and psychological impact of robot-assisted gait training in people with spinal cord injury: effect of two types of devices	Corbianco S, Cavallini G, Dini M, Franzoni F, D'Avino C, Gerini A, Stampacchia G	Neurol Sci. 2021 Aug;42(8):3357-3366.	Ekso	SCI
Effects of robotic-assisted gait training on the central vascular health of individuals with spinal cord injury: A pilot study	Faulkner J, Martinelli L, Cook K, Stoner L, Ryan-Stewart H, Paine E, Hobbs H, Lambrick D	J Spinal Cord Med. 2021 Mar;44(2):299-305.	Ekso	SCI
Energy Efficiency and Patient Satisfaction of Gait With Knee-Ankle-Foot Orthosis and Robot (ReWalk)-Assisted in Patients With Spinal Cord Injury	Kwon SH, Lee BS, Lee HJ, Kim EJ, Lee JA, Yang SP, Kim TY, Pak HR, Kim HK, Kim HY, Jung JH, Oh SW	Ann Rehabil Med. 2020 Apr;44(2):131-141.	ReWalk	SCI
The safety and feasibility of exoskeletal assisted walking in acute rehabilitation following spinal cord injury	McIntosh K, Charbonneau R, Bensaada Y, Bhatiya U, Ho C	Arch Phys Med Rehabil. 2020 Jan;101(1):113-120.	Ekso	SCI
Differences in Acute Metabolic Responses to Bionics and Nonbionic Ambulation in Spinal Cord Injured Humans and Controls	Maher JL, Baunsgaard CB, van Gerven J, Palermo AE, Biering-Sorensen F, Mendez A, Irwin RW, Nash MS.	Arch Phys Med Rehabil. 2020 Jan;101(1):121-129.	Ekso	SCI

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Cardiorespiratory demand and rate of perceived exertion during overground walking with a robotic exoskeleton in long-term manual wheelchair users with chronic spinal cord injury: A cross-sectional study	Escalona MJ, Brosseau R, Vermette M, Comtois AS, Duclos C, Aubertin-Leheudre M, Gagnon DH.	Ann Phys Rehabil Med. 2018 Jul;61(4):215-223.	Ekso	SCI
Respiratory, Cardiovascular and Metabolic Responses during different modes of overground bionic ambulation in persons with motor-complete spinal cord injury: a case series	Kressler J, Wymer T, Domingo A.	J Rehabil Med. 2018 Feb 13;50(2):173-180.	Ekso	SCI
Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics	Bach Baunsgaard C, Vig Nissen U, Katrin Brust A, Frotzler A, Ribeill C, Kalke TB, León N, Gómez B, Samuelsson K, Antepohl W, Holmström U, Marklund N, Glott T, Opheim A, Benito J, Murillo N, Nachtegaal J, Faber W, Biering-Sørensen F	Spinal Cord. 2018 Feb;56(2):106-116.	Ekso	SCI
The immediate effects of robot-assistance on energy consumption and cardiorespiratory load during walking compared to walking without robot-assistance a systematic review	Lefeber N, Swinnen E, Kerckhofs E	Disabil Rehabil Assist Technol. 2017 Oct;12(7):657-671.	Multiple – Review Article	SCI, CVA
Exoskeleton Training May Improve Level of Physical Activity After Spinal Cord Injury: A Case Series	Gorgey AS, Wade R, Sumrell R, Villadelgado L, Khalil RE, Lavis T.	Top Spinal Cord Inj Rehabil. 2017 Summer;23(3):245-255.	Ekso	SCI
Weight Bearing Over-ground Stepping in an Exoskeleton with Non-invasive Spinal Cord Neuromodulation after Motor Complete Paraplegia	Gad P, Gerasimenko Y, Zdunowski S, Turner A, Sayenko D, Lu DC, Edgerton VR	Front Neurosci. 2017 Jun 8;11:333.	Ekso	SCI

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Lower limb exoskeletons for individuals with chronic spinal cord injury: Findings from a feasibility study	Benson I, Hart K, Tussler D, van Middendorp JJ	Clin Rehabil. 2016 Jan;30(1):73-84.	ReWalk	SCI
Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia	Asselin P, Knezevic S, Kornfeld S, Cirnigliaro C, Agranova-Breyter I, Bauman WA, Spungen AM	J Rehabil Res Dev. 2015;52(2):147-58.	ReWalk	SCI
Iron 'ElectriRx' man: Overground stepping in an exoskeleton combined with noninvasive spinal cord stimulation after paralysis	Gad PN, Gerasimenko YP, Zdunowski S, Sayenko D, Haakana P, Turner A, Lu D, Roy RR, Edgerton VR	Annu Int Conf IEEE Eng Med Biol Soc. 2015 Aug;2015:1124-7.	Ekso	SCI
Time and Effort Required by Persons with Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking	Kozlowski A, Bryce TN, Dijkers MP	Top Spinal Cord Inj Rehabil. 2015 Spring;21(2):110-21.	Ekso	SCI
Acute Cardiorespiratory and Metabolic Responses During Exoskeleton-Assisted Walking Overground Among Persons with Chronic Spinal Cord Injury	Evans N, Hartigan C, Kandilakis C, Pharo E, Clesson I	Top Spinal Cord Inj Rehabil. 2015 Spring;21(2):122-32.	Indego	SCI
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, Ginnetty K, Gonzalez H, Martinez A, Anderson KD, Nash MS	Arch Phys Med Rehabil. 2014 Oct;95(10):1878-1887.	Ekso	SCI
Safety and Feasibility of the Using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury	Kolakowsky-Hayner SA, Crew J, Moran S, Shah A.	J Spine. 2013	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

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ABI = acquired brain injury, CVA = stroke, SCI = spinal cord injury