

Skin Integrity

There are only a few articles that examine skin integrity beyond reporting that some adverse events are skin related. All of these articles look at subjects with spinal cord injuries (SCI). The majority of these studies utilized the Ekso1.1/EksoGT/EksoNR, referred to as “Ekso” in this paper. The second most used device was the ReWalk. All studies utilized visual inspection of the skin.

While there are other studies not included in this paper that reported on skin issues resulting from use of an exoskeleton device, these articles did not set out to identify these issues, whereas the studies that are included here had skin evaluation as a predetermined outcome measure before initiation of the study.

Spinal Cord Injury (SCI)

There are five studies that examine skin as an outcome measure. All of these were safety and/or feasibility studies for persons with acute or chronic SCI. One study of 11 participants who sustained a SCI between 3 and 15 weeks prior to beginning walking in Ekso three times per week for up to 25 total sessions examined a range of functional and safety outcomes.¹ Two participants experienced skin integrity issues including a heel wound, which was attributed to trauma experienced outside of the study, and a superficial scrape on the low back.¹ Both participants were able to continue with the study.¹ Seven subjects between 65 and 578 days post SCI walked in Ekso once per week for 6 weeks and showed no major skin effects from using the device.² There was an unspecified number of skin changes, but all were superficial and found to be stage 1.² The most common locations of redness were over the anterior tibia, greater trochanter, sacrum, abdomen, and dorsum of the foot.² Another study that included 25 participants within one year post injury and 27 with chronic SCI showed 9 skin issues throughout the duration of walking in Ekso 3 times per week for 8 weeks.³ These skin issues were subcategorized into blanching erythema or non-blanching category I pressure ulcer (n=5) at the thigh, tibia, instep of foot, or heel, and category 2 pressure ulcers (n=4) at the shoulder, thigh, or instep of the foot.³ These skin issues were not separated by those with acute or chronic injuries.

In those with chronic injuries, a study enrolled 10 participants all greater than 1 year post injury (range: 1 year, 3 months to 21 years, 9 months) who walked in the ReWalk for up to 20 sessions. Two participants dropped out of the study due to recurrent skin breakdown.⁴ Throughout the study, there were 5 grade 1 skin aberrations in 3 participants, and 10 grade 2 in 5 subjects that were device related.⁴ There were an additional two non-device related skin problems, while five of the 10 participants did not experience any skin issues.⁴ Another study using the ReWalk for up to 24 sessions recruited participants who were injured for at least 1 year and reported only one skin abrasion in an area in contact with the device.⁵

Conclusion

While skin integrity isn't typically an outcome measure examined in a study beyond a safety and/or feasibility trial, results demonstrate that skin integrity issues are possible with use of an exoskeleton. However, these issues tended to be minor and not impact participation in these



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studies. It is also important to remember that all of the studies discussed here are older, published at least 4 years ago, and it is likely that device manufacturers have changed device design and clinical training in that time.

References

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2. Kolakowsky-Hayner SA. Safety and Feasibility of using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury. *J Spine*. Published online 2013. doi:10.4172/2165-7939.S4-003
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5. Esquenazi A, Talaty M, Packel A, Saulino M. The ReWalk Powered Exoskeleton to Restore Ambulatory Function to Individuals with Thoracic-Level Motor-Complete Spinal Cord Injury. *American Journal of Physical Medicine & Rehabilitation*. 2012;91(11):911-921. doi:10.1097/PHM.0b013e318269d9a3

All known articles assessing skin integrity in participants using an exoskeleton

Title	Authors	Journal	Device	Diagnosis
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	Spinal Cord 58, 787–794 (2020)	Ekso	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
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 YB, 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
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
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

SCI = spinal cord injury