

Research Evidence

The geko™ device has been the subject of scientific rigor to demonstrate its ability to increase blood circulation. The body of evidence continues to grow, targeting clinical issues such as CVI, in the management of lower leg wounds.

Clinical Issue	Device Effect
<p>Abnormal Calf Muscle Pump</p> <ul style="list-style-type: none"> • Non-healing VLU correlate with impairment of the calf muscle pumps. • 55% of patients with CVI have Calf Muscle Pump Dysfunction related to altered gait, causing venous hypertension.¹ 	<ul style="list-style-type: none"> • The geko™ device creates concentric contraction of the extensor muscles that cause dorsiflexion of the ankle and passive stretch of the calf flexor muscles. This acts as a calf muscle pump, which may enhance venous return by increasing intramuscular pressure.² • This may be effective in reducing venous stasis and edema, influencing muscle oxygenation.² • The results may indicate that the geko™ device effectively counteracts increases in muscle blood volume and deoxygenated hemoglobin during venous stasis.²
<p>Edema</p> <ul style="list-style-type: none"> • Dependent edema begins in the perimalleolar region and ascends the leg in early stages of CVI, changes over time to become fibrotic and indurated with Lipodermatosclerosis (LDS) due to changes in the fibrinolytic system.³ • It may develop into lymphedema. • Edema results in a palpable swelling in the lower extremity caused by fluid accumulation in the interstitium. • Calf muscle pump dysfunction contributes to lower limb edema impeding wound healing.⁹ 	<ul style="list-style-type: none"> • Case studies have shown that some patients with chronic and complex edema have had edema reductions with the geko™ device.⁴ • In a trial of the geko™ device in individuals with CVI, leg swelling reduced by 16% ($p < 0.05$) in patients with venous disease.^{5,6} • Many patients with chronic VLU who were unable to tolerate ANY compression therapy, or who only tolerated minimal 10-15 mm Hg compression were able to start or increase their level of compression, leading to further edema reduction.⁷ • There is also a fibrinolytic effect⁸ with the geko™ device which may reduce the fibrotic changes of LDS. • With a stimulation rate of once per second, the geko™ device simultaneously activates a series of muscles including the tibialis, peroneus longus and lateral gastrocnemius. Collectively these muscle contractions elongate and compress the venous system, efficiently moving blood from the deep veins of the calf. This generates blood flow equivalent to about 60% of continuous walking.⁹
<p>Incompetent Venous Valves</p> <ul style="list-style-type: none"> • 84% of people with VLUs have superficial vein valve failure.¹⁰ • Failure of the deep vein valves speeds venous disease⁹ and increases the risk of venous ulcers. • Both cause venous reflux and venous hypertension.¹⁰ 	<ul style="list-style-type: none"> • The geko™ device reduces venous refilling and venous volume seen in venous stasis due to the activation of the muscle pumps.¹¹ • It decreases the amount of "sludge" blood (erythrocytes seen as light gray in an ultrasound image) that is not effectively ejected forward through the valves.¹² • When off, the Venous Sludge Index (VSI) was 53.5, when activated, the geko™ device stimulation reduced the VSI to 7.6 ($p = 0.0005$).¹²
<p>Decreased Range of Motion, Decreased Muscle Strength and Activation, Decreased Mobility</p> <ul style="list-style-type: none"> • Decreased ROM can be related to nociceptive and neuropathic pain, woody fibrosis/lipodermatosclerosis, edema, and fixed ankle joint related to CVI, over time develop decreased muscle strength and activation, and decreased mobility.^{18, 13} 	<ul style="list-style-type: none"> • In case series studies, patients have reported an increased ability to flex and dorsiflex their foot and ankle,³ with increased strength in their legs with increased exercise tolerance.⁴
<p>Pain</p> <ul style="list-style-type: none"> • People living with VLUs often report pain as 10/10 and are unable to tolerate compression therapy, a key intervention in treating CVI.⁷ 	<ul style="list-style-type: none"> • Up to 90% of individuals with chronic VLUs using the geko™ device indicated a marked reduction in pain.^{14, 22} • Patients unable to tolerate compression pre-geko™ were able to start and/or increase to therapeutic levels with the effect of the geko™ device.⁷
<p>Neuropathy</p> <ul style="list-style-type: none"> • Neuropathy in individuals with CVI without Diabetes is related to perineural degeneration, edema, collagen replacement and contributes to trophic skin changes and impaired healing.¹⁵ • Worse in proximal medial and lateral malleolus, proximal medial and lateral calf and thigh.¹⁵ • Maybe an unrecognized source of pain.¹⁵ 	<ul style="list-style-type: none"> • A pre-geko™ study of a low frequency stimulation device to either the common peroneal or saphenous nerve,¹⁶ depending on proximity to the ulcer, in conjunction with a four-layer compression bandaging system over 12 weeks, showed nearly 4x greater improvement in the nerve sensation and 2x the response to capsaicin applied topically, (both parameters reflecting improvement in C-fibre function).¹⁶ • The improvement of C-fibre activation is also an indicator of the reversal of the neuropathy.¹⁹

Decreased Arterial Flow

- 15 to 30% of people with CVI will also have peripheral arterial disease (PAD).¹⁷
- The geko™ device augments arterial, venous and microcirculatory volume flow in peripheral arterial disease patients and may prove a useful treatment adjunct.^{20, 8}
- The geko™ device applied to the common peroneal nerve substantially and immediately increases microcirculatory blood flow to the wound bed and edge in patients with ischemic lower limb wounds. These data may provide mechanistic insight into the clinical efficacy of NMES in healing wounds.²³
- Activation of lower limb muscle pumps by 1 Hz intermittent neuromuscular stimulation of the common peroneal nerve provides substantial augmentation of venous and arterial flow in the lower limb of patients with venous leg ulcers. This has important implications in the management of patients with venous leg ulcers.²⁴

Ambulatory Venous Hypertension

- Unabated venous hypertension may result in dermal changes with hyperpigmentation, subcutaneous tissue fibrosis, termed "lipodermatosclerosis", and eventual ulceration.¹⁰
- The geko™ device was tested in 19 healthy volunteers, using settings of 100 µs, 200 µs and 400 µs while volunteers were standing, sitting and lying. Mean Venous Transit Times (VTT) from the dorsal foot to the popliteal vein were measured along with ambulatory venous pressure and leg volume.
- The geko™ device had a statistically significant impact, reducing VTT by up to 64%, Mean ambulatory pressure by up to 67% and leg volume by 17% (P< 0.001).¹¹

References:

1. Williams KJ, Ayekoloye O, Moore HM, Davies AH. The calf muscle pump revisited. *J Vasc Surg Venous Lymphat Disord.* 2014;2(3):329-34. doi: 10.1016/j.jvsv.2013.10.053. Epub 2014 Jan 28
2. Zhang Q, Styf J, Ekström L, Holm AK. Effects of electrical nerve stimulation on force generation, oxygenation and blood volume in muscles of the immobilized human leg. *Scand J Clin Lab Invest.* 2014 Aug;74(5):369-77
3. Vivas A, Lev-Tov H, Kirsner RS. In the Clinic: Venous Leg Ulcers. *Ann Intern Med.* 2016;165(3):ITC17-ITC32
4. Ingves MV, Power AH. Two Cases of Transcutaneous Electrical Nerve Stimulation of the Common Peroneal Nerve Successfully Treating Refractory, Multifactorial Leg Edema. *Journal of Investigative Medicine High Impact Case Reports.* October- December 2014. 1-4. Available at: <http://journals.sagepub.com/doi/abs/10.1177/2324709614559839>
5. Williams KJ, Babber A, Ravikumar R, Ellis M, Davies AH. Pilot Trial of neuromuscular stimulation in the management of chronic venous disease. 2 Posters from VEINS Conference, UK. 2014
6. Williams KJ, Davies AH. Pilot trial of neuromuscular stimulation in the management of chronic venous disease. *British Journal of Surgery.* 2015;102:20
7. Harris C, Duong R, Vanderheyden G, Byrnes B, Cattrysse R, Orr A, Keast D. Evaluation of a muscle pump activating device for non-healing venous leg ulcers. *Int Wound J* 2017; 14:1189-1198
8. Barnes R, Madden LA, Chetter IC. Fibrinolytic effects of peroneal nerve stimulation in patients with lower limb vascular disease. *Blood Coagulation and Fibrinolysis.* 2016; 27:275-280
9. Burrows, C., Rabley-Koch, C.A., Ramage, D., Evans, R., The Role of the geko™ device in the Prevention and Treatment of Leg Edema (2020) <https://www.gekodevices.com/wp-content/uploads/2021/04/Leg-edema-White-Paper-FINAL-1.pdf>
10. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Contemporary reviews in cardiovascular medicine circulation.* 2014;130:333-346. <http://circ.ahajournals.org/content/130/4/333>
11. Khanbhai M, Hansrani V, Sultan J, Burke J, McCollum CN. The effect of neuromuscular electrostimulation on lower limb venous physiology. Academic Surgery Unit, Institute of Cardiovascular Sciences, Manchester Academic Health Science Centre. Society of Academic & Research Surgery, VASCULAR 1 Wednesday 7 January 2015 09.45-11.20 <http://www.surgicalresearch.org.uk/sars-2015/>
12. Lattimer C, Azzam M, Kalodiki E. Common peroneal nerve stimulation reduces blood sludging in the popliteal vein standing and lying. 2016. http://www.gekodevices.com/media/128135/acp_2016_geko.pdf
13. Back TL, Padberg FT, Jr, Araki CT, Thompson PN & Hobson RW, 2nd. Limited range of motion is a significant factor in venous ulceration. *J Vasc Surg* 1995; 22(5):519-23
14. Brooke J. Loney A. The geko™ a neuromuscular electrostimulation (NEMS) device and its healing effect on diabetic foot and venous leg ulcers. CAET/WOCN Conference, May 2015
15. Padberg FT, Maniker AH, Carmel G, Pappas PJ, Silva MB, and Hobson RW. Sensory impairment: A feature of chronic venous insufficiency. *J Vasc Surg* 1999;30:836-43
16. Ogrin R, Darzins P, Khalil Z. The use of sensory nerve stimulation and compression bandaging to improve sensory nerve function and healing of chronic venous leg ulcers. *Current Aging Science.* 2009;2(1):72-80
17. Marston W. Mixed Arterial and Venous Ulcers. *Wounds.* 2011;23(12):351-356
18. O'Brien JA, Edwards HE, Finlayson KJ & Kerr G. Understanding the relationships between the calf muscle pump, ankle range of motion and healing for adults with venous leg ulcers: A review of the literature [online]. *Wound Practice & Research: Journal of the Australian Wound Management Association, Vol. 20, No. 2, Jun 2012: 80-85*
19. Orsted HL, O'Sullivan-Drombolis D, Haley J, LeBlanc K, Parsons L. The effects of low frequency nerve stimulation to support the healing of venous leg ulcers. *Canadian Association of Wound Care Consensus Paper – Nov 2016*
20. Barnes R, Shahin Y, Tucker AT, Chetter IC. Haemodynamic efficacy of the geko™ electrical neuromuscular stimulation device in claudicants. Oral presentation at Society of Academic & Research Surgery, 2014 Annual Meeting (January 8/9, 2014), Cambridge University, England. http://www.surgicalresearch.org.uk/wp-content/uploads/2013/10/1A_Vascular_Surgery_1.pdf
21. Harding KG. A New Innovation in Wound Treatment. Presenting at CAWD Conference 2016.
22. Harris C, Rabley-Koch C, Carol, Ramage D, Cattrysse, R Case Study, Debilitating chronic veno-lymphoedema: using a muscle pump activator medical device to heal wounds and improve skin integrity
23. Bosanquet D, Ivins N, Jones N, Harding K G, Microcirculatory Flux and Pulsatility in Arterial Leg Ulcers is Increased by Intermittent Neuromuscular Electrostimulation of the Common Peroneal Nerve. Elsevier: *Clinical Research* 2020 <https://pubmed.ncbi.nlm.nih.gov/32768540/>
24. Das SK, Dhooonmoon L, Chhabra S. Neuromuscular stimulation of the common peroneal nerve increases arterial and venous velocity in patients with venous leg ulcers. *Int Wound J.* 2020;1-7. <https://pubmed.ncbi.nlm.nih.gov/33236847/>

Distributed in Canada by:



Orders: info@perfusedmedtec.com

© Firstkind and Perfuse 2021
geko™ is a registered trade mark of Sky Medical Technology Limited
OnPulse™ is a registered trade mark of Sky Medical Technology Limited

MPLW04090V2