Received: 15 July 2024 | Revised: 19 August 2024 | Accepted: 19 August 2024
DOI: 10.1111/iwj.70040

REVIEW ARTICLE

IWJ WILEY

Continuous muscle pump activation by neuromuscular electrical stimulation of the common peroneal nerve in the treatment of patients with venous leg ulcers: A position paper

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Abstract
The standard treatment for patients with confirmed Venous Leg Ulcers (VLUs) is compression therapy to improve the function of the calf muscle pump. There is a significant cohort of patients who are unable to tolerate optimal compression therapy or indeed any level of compression therapy. In addition, there is a cohort of patients who can tolerate compression whose ulcers show little or no evidence of healing. There is a need for ways to further improve calf muscle pump function and to improve venous ulcer healing in these patients. Published data were reviewed on the use of Muscle Pump Activation (MPA) using common peroneal nerve neuromuscular electrical stimulation (NMES) to improve calf muscle pump function. There is physiological evidence that MPA can improve calf muscle pump function and venous return in both control subjects and in patients with venous disease. The use of MPA has also been shown to improve venous flow volume and venous flow velocity on ultrasound scanning in patients with venous disease. MPA has been shown to improve microcirculation in the skin using Laser Doppler and laser Doppler Speckle Contrast Imaging, in both normal subjects as well as in patients with venous disease and VLU. A recent randomized controlled trial of MPA plus compression therapy compared with compression therapy alone, found significantly faster rates of healing with the use of MPA in addition to compression therapy. There are indications for the use of MPA as an adjunctive treatment to enhance calf muscle pump function in patients with VLU:

- who cannot tolerate compression therapy
- who can only tolerate suboptimal, low-level compression

- whose ulcer healing remains slow or stalled with optimal compression.

KEYWORDS

compression bandages, muscle pump function, venous return, venous ulcer, wound healing

Key Messages

The Muscle Pump Activation device improves venous return in normal subjects and in patients with venous leg ulcers.The Muscle Pump Activator device can be used

- as an adjunct to standard of care compression therapy to accelerate venous leg ulcer healing in patients whose ulcer healing remains slow or stalled
- as an adjunct to suboptimal therapy in patients who cannot tolerate optimal compression therapy in order the improve calf muscle pump function and venous leg ulcer healing
- in patients who cannot tolerate any compression therapy to improve calf muscle pump function, to help facilitate some level of compression therapy and to potentially improve venous leg ulcer healing.

1 | INTRODUCTION

Chronic venous leg ulceration (VLU) typically occurs on the lower leg anywhere from the ankle to the knee, and the underlying cause has been identified as an abnormal calf muscle pump function.[1] Venous insufficiency alone is not sufficient to cause ulceration; however, when it results in a deficiency in the calf muscle pump function, VLU is more likely to occur.[2] Abnormal calf muscle pump function might be contributed to by changes in the deep veins, the superficial veins, the calf muscle function itself or an immobile or fixed ankle joint.[3] The venous changes may result from a prior deep vein thrombosis causing secondary incompetence or obstruction, from primary incompetence of the valves or from a genetic abnormality in the veins.[3]

In the normal physiological response, when subjects are sitting or standing, venous pressure in the legs is high and that high pressure results in fluid and protein leaking into the interstitial tissues.[4] With exercise, pressure reduces in the veins and as a result the efflux of fluid and protein is reduced, which enables fluid and protein to return to the intravascular compartment. With chronic venous disease (CVD), the venous pressure with exercise reduces to a lesser extent depending on the severity of the venous disease.[2,4–6] This is termed ambulatory venous hypertension and can cause the following changes: microcirculatory changes in the skin, reduced tissue oxygenation, lipodermatoscelosis (woody fibrosis due to fibrin deposits) with pigmentation (due to haemorrhage of red blood cells with deposits of melanin and hemosiderin) and scarring in the dermis and subcutaneous tissue, and pitting edema in the leg (often first present around the medial malleolus where the greater saphenous vein is superficial). These changes result in an impaired healing process and potential development of VLU. Patients may report symptoms of leg heaviness, fatigue, cramping, aching or other painful sensations, skin itch and restless legs.

The standard treatment for patients with confirmed VLU is to use optimal compression therapy (30–40 mm Hg) to improve calf muscle pump function. This has the effect of improving venous return, reducing ambulatory venous hypertension and reducing edema.[7,8] With compression therapy, the expelled venous volume increases and the ambulatory venous hypertension reduces. This enables the venous return of fluid and protein resulting in improved wound healing. The venous return and ambulatory venous hypertension are improved with patients wearing compression during exercise. However, when patients stand or sit for prolonged periods, some benefits of compression are lost, but it does continue to have some impact on the control of oedema. There are different types of compression therapy that include elastic and inelastic systems. These could include multilayer compression wraps, mechanical forms of compression, compression stockings and adjustable wraps with hook and loop fasteners. While there are debates on optimal compression therapy types, there is consensus that improving calf muscle pump function enables VLUs to heal or to heal at a faster rate with compression than without compression.[9–11]

Supervised exercise programmes have also been utilized in patients with venous leg ulcers (VLUs) to help improve calf muscle pump function, to improve patients' venous ejection fraction[12,13] and to significantly improve VLU healing when it is added as an adjunct to VLU compression therapy.[14] Although beneficial, supervised exercise programmes are not always accessible for patients with VLUs and may not be suitable for patients with limited mobility.

There is a significant cohort of patients who are unable to tolerate optimal compression therapy or indeed any level of compression therapy and who are unable to participate in a supervised exercise programmes. A review of concordance with compression therapy in VLUs found that in the treatment of active VLUs, non-concordance was the lowest in randomized controlled trials at rates of 2% to 4%, while in real world studies, the rates of non-concordance were between 10% and 80%.[15] In the Canadian Bandaging Trial that evaluated two different compression bandaging systems, the number of patients who either refused the compression system or who had to cease treatment due to problems with the compression system was 16.0%.[11] In that study, when all causes for ceasing compression were considered, this represented 23.8% of patients in the study. In these patients, clinicians may use no compression, or a lower level of compression therapy in the hope that with time patients may be able to tolerate optimal compression therapy. There is no effective method to improve the calf muscle pump function in patients who have little or no compression. In some centres, these patients are categorized as receiving maintenance therapy for their VLUs and may also be regarded as unhealable without the use of compression therapy.

In addition, there is a cohort of patients who can tolerate compression whose ulcers show little or no evidence of healing. In the Canadian Bandaging Trial,[11] 24.3% of patients had unhealed ulcers after 24 weeks of treatment and 12.0% after 36 weeks of treatment. Clinicians have traditionally not had other readily available options to improve calf muscle pump function and hence to improve the rate of wound healing in these patients. They may at times try different types of compression to see if that will have an effect, but these patients often remain slow to heal. Non-healing or slow to heal ulcers impact quality of life for the patients and result in excessive costs to the healthcare system.

There is therefore a place for other methods to improve calf muscle pump function in patients with VLU that can act as an adjunct to compression therapy and supervised exercise programmes. Activation of the calf muscle pump using neuromuscular electrical stimulation (NMES) is an option to improve the calf muscle pump as an adjunct to compression therapy. There have been a number of methods to achieve this which have included direct stimulation of muscles in the lower leg by electrodes applied over different calf muscles[16]; applying electrical stimulation over the common peroneal nerve to achieve activation of the muscles in the anterior and lateral compartments of the lower leg,[17] and the use of a footplate to stimulate muscles in the foot and the leg.[18] Direct stimulation of the muscles of the posterior compartment can impact both motor and sensory nerves and is recommended for use for up to 30-min periods only.[16] The foot plate device requires direct contact with the skin of the foot; hence, it is not able to be used concurrently with compression bandages or stockings and is normally recommended for up to 30 minutes per day.[18] Electrical stimulation of the common peroneal nerve using the MPA device (geko™, Firstkind Ltd, UK) is able to be delivered continuously and is recommended for use for 12 hours per day for patients with VLU.[19] By activating the muscles of the anterior and lateral compartments of the lower leg, the flexor muscles of the calf are passively stretched and this passive motion acts as a calf muscle pump.[20] This has the advantage of providing continuous improvement of calf muscle pump function when patients are at lying, sitting or standing. The benefits of improved calf muscle pump function have been shown to reverse when the device is not actively being used[17]; hence, the use of the continuously applied MPA device has optimal benefits of improving calf muscle pump function in patients with VLU and therefore improving healing.

There are cohorts of patients with VLU who need assistance beyond compression and exercise programmes to improve their calf muscle pump function. These cohorts include patients with VLU who cannot exercise or tolerate any compression; patients who can only tolerate low level compression; and patients who can tolerate optimal compression, but whose ulcer healing remains slow or stalled.

2 | METHODS

The published literature on the impact of activation of the calf muscle pump by NMES of the common peroneal nerve was evaluated. From the literature, the goal was to determine the impact of NMES of the common peroneal nerve on venous return and microcirculation in normal subjects, in patients with venous disease and in patients with VLUs. In particular, the goal was to review literature on the continuous use of NMES of the common peroneal nerve using the MPA device (geko™). The objective was to summarize the data on the impact of MPA on the venous physiology and on improving VLU healing.

The search of published literature was conducted using combinations of search terms to identify papers that reported the impact on venous function in both

TABLE 1 Summary of literature search.

Primary search phrases	Secondary search phrases
(a) Summary of search terms used for identification of published literature	
Neuromuscular electrical stimulation of the common peroneal nerve	*Venous return*
Neuromuscular electrostimulation of the common peroneal nerve	*Lower limb blood flow*
	Venous ulceration
	Wound healing
(b) Summary of identified articles	
Articles identified	112
Articles excluded after review of title, abstract and or full article	90
Articles identified	22

volunteers and patients with venous disease and that reported the impact on ulcer healing. The search terms are summarized in Table 1a with the primary terms being using in conjunction with the secondary terms. These searches incorporated databases including Medline, CINAHL, Web of Science, Cochrane database and Google Scholar. Further papers were assessed from the references listed in papers that were identified from the searches. The objective was to include only published papers that had utilized NMES of the common peroneal nerve and that had assessed its impact on venous return or on the healing of venous ulcers. Book chapters, theses for higher degrees and conference presentations and posters were excluded. Table 1b summarizes the papers that were identified and screened and the number that were found to have met the criteria and to have evaluated the impact on venous physiology or on VLU healing.

3 | RESULTS

3.1 | Improvement of calf muscle pump function and skin microcirculation with the use of MPA

There was evidence of improvement in calf muscle pump function in healthy volunteers by using electrodes placed over the common peroneal nerve and connecting those to an electrical stimulation device. There was evidence a significant increase in both flow velocity and flow volume, as assessed by ultrasound evaluation in both the femoral vein and the popliteal vein[21–23] (Table 2).

Continuous stimulation using the MPA device has also been used in healthy volunteers (Table 2). Flow velocity was improved in all studies.[17,24–29] Only three studies measured flow volume, and in two, there was significant improvement compared with baseline.[17,28] In one, there was significant improvement compared with intermittent pneumatic compression but a non-significant increase compared with baseline.[24] One study calculated ejection volume which did not significantly improve.[25]

There were two studies using the MPA device in patients with venous disease, and there was improvement in flow velocity in both studies[30,31] (Table 3). In one study, there was a significant improvement in flow volume in patients with superficial venous disease and those with deep vein reflux, but not those with deep vein obstruction.[30] In the other study, there was a non-significant increase in flow volume.[31]

MPA in healthy volunteers has also demonstrated significant improvement in microcirculation in the skin using both Laser Doppler assessment on the foot and leg,[17,24,32] and Laser Doppler Speckle Contrast Imaging in the thigh[33] (Table 4). In assessment of microcirculation of the skin in patients with venous disease (Table 5) there was a significant improvement in microcirculation as assessed by Laser Doppler flux on the foot in patients with superficial venous disease and with deep vein obstruction, but not with deep venous insufficiency.[30] In patients with active VLUs, there was significant improvement using Laser Speckle Contrast Imaging in both flux and pulsatility, in both the ulcer base and in the peri-ulcer surrounding skin.[34]

3.2 | Improvement of venous ulcer healing with MPA

Data from case series[35–40] and a recent randomized controlled trial[19] have demonstrated that the use of MPA can improve the healing rates of VLUs. The case studies include observational patient cohort studies with difficult to heal venous ulcers that provide consistent indications of improved healing with MPA with and without compression therapy.[35–40] An amalgamation of case series of patients from the community found that 30 of 70 patients achieved complete healing after an average of 9 weeks of MPA application.[40] A randomized controlled trial of MPA plus compression therapy compared with compression therapy alone documented significantly faster rates of VLU healing with the use of MPA device in addition to compression therapy.[19]

TABLE 2 Impact of neuromuscular electrical stimulation (NMES) of the common peroneal nerve on venous physiology in subjects without venous disease.

Paper	NMES device	Subject number	Subjects	Study design	Venous flow assessment	Ultrasound comparisons			
Tucker[21]	Electrodes at CPN nerve 5-min stimulation	30	Healthy	Single-arm within-subject comparisons	Ultrasound femoral vein during stimulation	Flow velocity		Flow volume	
						% increase from baseline		% Increase from baseline	
						200–360%*		225–375%*	
Martinez-Rodriguez[22]	Electrodes At CPN nerve 1 min stimulation	24	Healthy	Single-arm within-subject comparisons	Ultrasound popliteal vein during stimulation	Flow velocity[a]		Flow Volume[a]	
						Baseline	Stimulation	Baseline	Stimulation
						13.1 (9.9–17.6)	48.9 (120.1–251.2)*	75.1 (55.5 –114.7)	174.0 (120.1–251.2)*
Izumi[23]	Electrodes at CPN nerve. Also IPC and muscle stimulation	10	Healthy	Single-arm within-subject comparisons	Ultrasound popliteal vein	Flow velocity[c]		Flow volume[c]	
						Baseline	Stimulation	Baseline	Stimulation
						26 (19–38)	102 (49–148)*	69 (41–118)	185 (105–355)*
Williams[17]	Geko T-1 for 20 mins Also IPC	10	Healthy	Single-arm within-subject comparisons	Ultrasound femoral vein during stimulation	Flow velocity		Flow Volume	
						% increased from Baseline		%Increase from baseline	
						103%*	Flow volume	101%*	
Jawad[24]	Geko T-1 for 30 mins Also IPC	10	Healthy	Single-arm within-subject comparisons	Ultrasound femoral vein during stimulation	Flow velocity[a]		Flow volume[a]	
						Baseline	Stimulation	Baseline	Stimulation
						13.8 (5.4)	38.3 (10.35)***	123.5 (73.4)	163 (105.3)***
						Increase 174%***		Increase 33%	
Avazzedah[25]	Geko T-1 for 4 mins & direct soleus muscle stimulation	12	Healthy	Single-arm within-subject comparisons	Ultrasound popliteal vein during stimulation	Flow velocity[b]		Ejection Volume (Flow volume X duration of pulse	
						Baseline	Stimulation	Baseline	Stimulation
						17.54 (4.1)	46.34 (18.3)*	16.62 (9.1)	19.76 (10.6)
Warwick[26]	Geko For 5 mins With and without plaster cast	10	Healthy	Single-arm within-subject comparisons	Ultrasound femoral vein during stimulation	Flow velocity[b]			
						Supine		Standing non weight bearing	
						Baseline	Stimulation	Baseline	Stimulation
						15.3 (1.6)	21.6 (2.2)**	11.8 (1.0)	26.8 (3.1)*
						No difference with or without plaster cast			
						Not significant with leg elevation or standing weight bearing w/o cast			

(Continues)

TABLE 2 (Continued)

Paper	NMES device	Subject number	Subjects	Study design	Venous flow assessment	Ultrasound comparisons				
Yilmaz[27]	Geko For 1 hour in every 4 hours in bed post procedure	30	Post Total knee replacement patients	RCT to Geko & stockings v no Geko & stockings	Ultrasound femoral vein after removing NMES and stockings	Flow velocity[b]				
							Geko		No Geko	
							Preop	Postop	Preop	Postop
							10.40 (1.75)	17.46 (2.86)*	10.24 (1.16)	13.84 (3.58)
Griffin[28]	Geko Applied for 5 min or more	18	Healthy	Single-arm within-subject comparisons	Ultrasound of peroneal, posterior tibial and gastrocnemius veins during stimulation	Flow velocity[b]			Flow volume[b]	
							Baseline	Stimulation	Baseline	Stimulation
						Per	6.51 (1.12)	20.58 (7.91)*	19.82 (15.39)	26.91 (21.34)**
						PT	7.31 (1.35)	15.48 (4.49)*	18.74 (9.65)	23.40 (12.21)**
						Gastroc	7.86 (2.06)	18.63 (6.18)*	14.86 (6.31)	17.45 (7.71)**
Calbiyik[29]	Geko continuous for 6 days	64	Post total hip surgery	RCT to Geko or no Geko Postop	Ultrasound femoral vein during stimulation	Flow velocity[2]				
						Geko		No Geko		
						Preop	Postop	Preop	Postop	
						8.86 (1.55)	15.59 (2.08)*	9.02 (2.68)	10.78 (3.48)	

Note: Flow volume, mL/min, flow velocity, cm/s.

Abbreviations: CPN, common peroneal nerve; IPC, intermittent pneumatic compression; Per, peroneal vein; PT, posterior tibial vein; Gastroc, gastrocnemius vein.

[a]Median (IQR).

[b]Mean (SD).

[c]Median (range).

*$p < 0.01$; **$p < 0.05$; ***$p < 0.01$ compared with IPC;

TABLE 3 Impact of neuromuscular electrical stimulation (NMES) of the common peroneal nerve on venous physiology in subjects with venous disease.

Paper	NMES device	Subject number	Subjects	Study design	Venous flow assessment	Ultrasound comparisons				
Williams[30]	Geko T-1 4–6 h/day, 5 days/ week, for 6 weeks	40	10 healthy 10 Venous Disease Superficial 10 Deep vein insufficiency 10 Deep vein obstruction	Four group comparative study	Ultrasound femoral vein during stimulation	% change from baseline[a]				
							Flow velocity		Flow volume	
						Healthy	34.8 (−4–81)*		22.5 (−10–40)	
						VD superficial	62.8 (25–138)*		37.5 (−10-172)**	
						VD deep insufficiency	9.0 (−10–84)***		17.4 (1–49)**	
						VD Deep obstruction	14.8 (−8–51)***		5.9 (−11–21)***	
Das[31]	Geko T-2 and R-2	14	Patients with active venous ulceration	Single-arm within-subject comparisons	Ultrasound of popliteal vein seated and recumbent		Flow velocity[b]		Flow volume[b]	
							Base	Stim	Base	Stim
						Seated	10	33*	Non-significant increase	
						Recumbent	14	47*	Non-significant increase	

Note: flow volume mL/min; flow velocity cm/s.
[a]Median (IQR).
[b]Mean.
*$p < 0.01$; **$p < 0.05$; ***Not significant.

4 | DISCUSSION

Clinicians have long been challenged with VLU patient treatment options when patients cannot for multiple reasons tolerate compression therapy. This review has identified that there is good evidence that the use of MPA can improve calf muscle pump function in normal subjects and in patients with venous disease.

Flow velocity in the veins in the leg has been consistently demonstrated to significantly improve with the use of MPA in normal subjects and in patients with venous disease. One of the studies in patients with venous disease demonstrated that the improvement was significant in patients with superficial venous disease, but it was not significant in patients with deep venous disease.

Flow velocity in the lower limb veins in response to MPA was not assessed in all of the studies on normal subjects; however, in those in which it was assessed, improvement was significant in all except one study. In patients with venous disease, one study showed that flow volume improved significantly in patients with superficial and deep vein insufficiency, but the improvement was not significant in patients with deep vein obstruction. One further study showed that the improvement was not significant.

Microcirculation had significant improvement with the use of MPA in both normal subjects and in patients with venous disease. In subjects with venous disease, there was significant improvement in patients with superficial venous disease and in those with deep venous obstruction, but not in those with deep venous insufficiency.

There is consistent evidence of improvement of venous flow velocity and venous flow volume and in microcirculation in both normal subjects and in patients with venous disease. In some of the studied cohorts the improvements were not statistically significant which could in part be related to the small sizes of the cohorts of subjects in the different studies.

There is growing evidence that the use of MPA in addition to the standard care that patients are able to tolerate does improve VLU wound healing. The study that demonstrated improvement of VLU healing with MPA in combination with compression therapy, compared with compression therapy alone, highlights the improvement in wound healing that that MPA brings to these patients by improving calf muscle pump function. A key contribution to that improvement in wound healing in patients with venous ulcers is that MPA provides continuous improvement in calf muscle pump function, whether the patient is walking or resting. The calf muscle function improvement with compression occurs only when patients are exercising the calf muscle.

TABLE 4 Impact of neuromuscular electrical stimulation (NMES) of the common peroneal nerve on microcirculation in subjects without venous disease.

Paper	NMES device	Subject number	Subjects	Study design	Measurement location	Microcirculation improvements
Tucker[21]	Electrodes at CPN 5-min stimulation	30	Healthy	Single-arm within-subject comparisons	Laser Doppler Dorsum of foot	% Increase in flux from Baseline 525%–2100%*
Williams[17]	Geko T-1 for 20 mins Also IPC	10	Healthy	Single-arm within-subject comparisons	Laser Doppler Leg	% Increase in flux from baseline 251.8%*
Jawad[24]	Geko T-1 for 30 mins Also IPC	10	Healthy	Single-arm within-subject comparisons	Laser Doppler Dorsum of foot	Baseline[a] 9.45 (7.46); Stimulation[a] 35.46 (24.26)* 394% Increase from baseline*
Warwick[32]	Geko T-1	10	Healthy	Single-arm within-subject comparisons	Laser Doppler Dorsum of foot	% Increase in flux[c] from baseline mean of all four positions with and without a plaster cast 141% (70–212)*
Bahadori[33]	Geko Also IPC	10	Healthy	Single-arm within-subject comparisons	Laser Speckle Contrast Imaging thigh	Baseline[b] 165.2 (86.7); Stimulation[b] 605.7 (321.4)* Mean % increase from baseline—399.8 (210.1)*

Abbreviation: CPN, common peroneal nerve.
[a]Flux units, median (interquartile range).
[b]Flux units, mean (standard deviation).
[c]Mean (confidence intervals).
*$p < 0.01$.

TABLE 5 Impact of neuromuscular electrical stimulation (NMES) of the common peroneal nerve on venous microcirculation in subjects with venous disease.

Paper	NMES device	Subject number	Subjects	Study design	Venous flow assessment	Ultrasound comparisons		
Williams[30]	Geko T-1 4–6 h/day, 5 days/week, for 6 weeks	40	10 healthy 10 venous disease superficial 10 feep vein insufficiency 10 deep vein obstruction	Four-group comparative study	Laser Doppler on the foot during stimulation	% change in flux from baseline[a]		
						Healthy	274.8 (279)*	
						VD superficial	264.9 (283)**	
						VD deep insufficiency	69.3 (126)	
						VD deep obstruction	46.9 (50)**	
Das[34]	Geko	16	Patients with VLU	Single-arm within-subject	Laser Speckle Contrast Imaging of ulcer		% increase flux %	% increase pulsatility
						Ulcer	27%**	170%*
						Peri-wound	34%*	173%*

[a]Mean (SD).
*$p < 0.01$; **$p < 0.05$.

Clinicians do now have an option with the use of MPA as an adjunct therapy to improve calf muscle pump function in patients with VLU who cannot tolerate optimal compression therapy and in those patients whose VLUs are not healing adequately on optimal compression therapy. There is consistent evidence that MPA does improve calf muscle pump function and wound healing and is therefore indicated for these patients. Further larger studies on the use of MPA in these patients is needed to confirm these benefits.

5 | SUMMARY

There is a clear indication from published studies for the use of MPA to enhance calf muscle pump function as an adjunct treatment to improve wound healing in the following patient groups with VLU

- patients who cannot tolerate compression therapy
- patients who can only tolerate suboptimal low-level compression
- patients whose ulcers healing remains slow or stalled with the use of optimal compression

ACKNOWLEDGEMENTS

The authors would like to thank Connie Harris who has maintained a compilation of the published literature on the MPA device.

CONFLICT OF INTEREST STATEMENT

Dr Michael C. Stacey and Dr. R. Gary Sibbald have consultancy agreements with Perfuse Medtec Inc to provide advice on the clinical areas where the use of the MPA device may be prioritized. Dr Stacey and Dr Sibbald have been in receipt of speaker's fees from Perfuse Medtec Inc.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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How to cite this article: Stacey MC, Sibbald RG, Evans R. Continuous muscle pump activation by neuromuscular electrical stimulation of the common peroneal nerve in the treatment of patients with venous leg ulcers: A position paper. *Int Wound J*. 2024;21(9):e70040. doi:10.1111/iwj.70040