Evaluating a Neuromuscular Electrostimulation (NMES) device as part of the treatment pathway for patients with non-healing venous leg ulcers – A case series

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Introduction

Despite best efforts, some wounds are hard to heal and some risk never healing.[1] A chronic (hard to heal) wound is defined as a wound that does not heal in the orderly stages of the healing process, or is 40–50% unhealed after four weeks of appropriate treatment.[2] For venous leg ulcers (VLUs) in particular, over 50% fail to heal in 12 months and many recur.[3] For those wounds that are not responding to good standard of care, the use of adjunctive therapies should be considered.[4]

The NMES device is a small, self-adhesive, wearable device that is applied to the surface of the skin on the lateral aspect of the leg just below the knee, over the head of the fibula. It delivers a charge-balanced electrical pulse once per second to the common peroneal nerve which passes through this site, eliciting a muscular twitch of the foot, so activating the calf and foot muscle pumps, and thus increasing venous, arterial, and microvascular flow.[5,6] The device has several stimulation levels to ensure a dorsiflexion is achieved whilst being comfortable for the patient.

Our institution had used this device as part of a recently published randomised self-controlled trial (RCT).[7] This trial compared the rate of wound margin advance (WMA) for VLUs receiving the NMES device as an adjunct to standard of care (multi-layered compression) and compared outcomes to patients receiving standard of care alone. Following this trial's success, the Tissue Viability team decided to take a more pragmatic approach in evaluating the addition of the NMES device to standard of care, in the real-world setting.

The following case series reports on the use of the NMES device as an adjunctive therapy in 5 patients who were deemed to have chronic non-healing venous leg ulcers.

The use of the device was at the discretion of the Tissue Viability team who tracked the healing trajectory of each wound until closure was achieved in line with the local primary care pathway.

Method

The trust pathway approach for venous leg ulcers is to ensure patients receive gold-standard management by having compression therapy for a minimum of 4 weeks. If a patient's wound is on a positive healing trajectory, then they would continue with this regimen alone. If, however, a patient's wound was showing no signs of improvement in the rate of healing, then an NMES device would be commenced as an adjunct therapy to standard care for a 4-week period.

There was no inclusion or exclusion criteria and patients were selected if they had lower limb wounds that were not following a positive healing trajectory.

Patients were given full instructions of how to apply and remove the device. All 5 patients wore the NMES device for 12 hours per day, 7 days per week. Patients continued with standard of care during the evaluation period.

Patients were evaluated by a specialist nurse. The rate of wound healing was calculated on day 28 and day 56 as part of the normal clinical review process. This was a standard clinical assessment (aligned to the patient pathway). Patients were asked to verbally report levels of wound related pain using a numerical rating scale of 0-10, both prior to, and during treatment with NMES. Patient acceptance of and ability to self-manage the device was also recorded.

Table 1 - Patient details

Patient ID	Sex	Age	Wound Location	Baseline Wound Status
1	Female	72	Dorsum of foot	Static
2	Female	68	Gaiter area	Increasing in size
3	Female	67	Lateral malleolus	Static
4	Male	59	Gaiter area	Static
5	Male	60	Medial malleolus	Static

References
1.National Wound Care Strategy Programme. Preventing and improving care of chronic lower limb wounds. Available at: https://www.nationalwoundcarestrategy.net/nwcsp-publications-and-resources/. Accessed: November 2023.
2.Atkin, L.; Bucko, Z.; Conde Montero, E.; Cutting, K.; Moffatt, C.; Probst, A.; Romanelli, M.; Schultz, G.S.; Tettelbach, W. Implementing TIMERS: The race against hard-to-heal wounds. J. Wound Care. 2019, 28, 1–49
3.Guest, J.F., Fuller, G.W. and Vowden, P., 2018. Venous leg ulcer management in clinical practice in the UK: costs and outcomes. International wound journal, 15(1), pp.29-37
4.Vowden, K. and Vowden, P., 2021. Integrating adjunctive therapy into practice: recognising 'hard-to-heal' wounds. Journal of Community Nursing, 35(6).
5.Das SK, Dhoonmoon L, Chhabra S. Neuromuscular stimulation of the common peroneal nerve increases arterial and venous velocity in patients with venous leg ulcers. Int Wound J. 2021; 18(2): 187-193.
6.Bosanquet DC, Ivins N, Jones N, Harding KG. Microcirculatory flux and Pulsatility in arterial leg ulcers is increased by intermittent neuromuscular electrostimulation of the common peroneal nerve. Ann Vasc Surg. 2021; 71: 308-314.
7.Bull, R.H., Clements, D., Collarte, A.J. and Harding, K.G., 2023. The impact of a new intervention for venous leg ulcers: A within-patient controlled trial. International Wound Journal.

Results/Discussion

Patients' 1 and 2 wounds had fully healed at the end of 1 cycle (28 days) of treatment with the NMES device. Patients' 3, 4 and 5 wounds had all healed by the end of 2 cycles (56 days) of treatment with the device.

All 5 patients were concordant with use of the NMES device and reported that they found it easy to apply and remove. No adverse events were reported during the evaluation period for any patients wearing the NMES device.

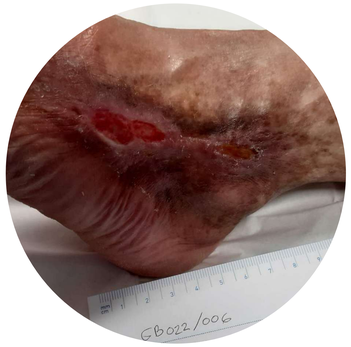
2 patients reported pain at baseline assessment. Both patients reported a reduction in pain with the use of the NMES device.

Table 2 - Results

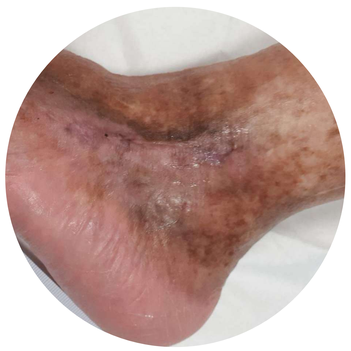
Pt	Baseline wound location	Baseline wound length (cm)	Baseline wound width (cm)	Baseline wound area (cm2)	Review 1 28 days Wound length (cm)	Review 1 28 days Wound width (cm)	Review 1 28 days Wound area (cm2)	Review 2 56 days Wound area (cm2)	Maximum NMES therapy	No. of NMES cycles completed	Healed
1	Dorsal foot	2.7	1	2.7	0	0	0	N/A	28	1	Y
2	Gaiter	1.8	1.5	2.7	0	0	0	N/A	28	1	Y
3	Lateral malleolus	1.8	1.6	2.88	1	0.7	0.7	0	56	2	Y
4	Gaiter	2.5	2	5	2.5	1.5	3.75	0	56	2	Y
5	Medial malleolus	3	1.7	5.1	0.8	1	0.8	0	56	2	Y

Patient 1

- 72-year-old female
- PMH – varicose veins, fatty liver, hypertension
- Ulcer duration – 6 weeks
- Pain score at baseline – 0
- Wound care regimen – DACC primary dressing, short stretch compression bandaging
- NMES device discontinued at 4-week review as wound fully healed



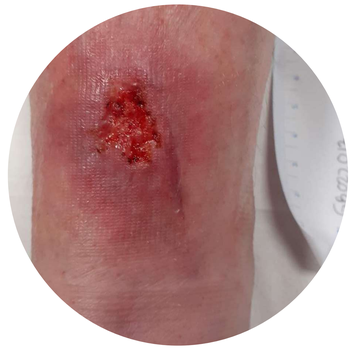
25th April - baseline



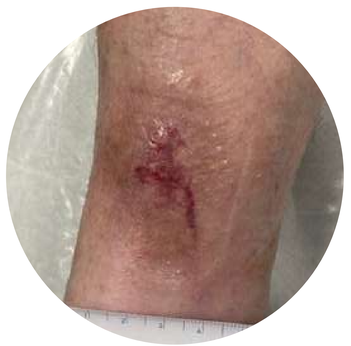
24th May - 1st follow up

Patient 2

- 62-year-old female
- PMH – hypertension, asthma
- Ulcer duration – 11 weeks
- Pain score reported by patient – 0
- Wound care regimen – silicone foam primary dressing, short stretch compression bandaging
- NMES device discontinued at 4-week review as wound fully healed



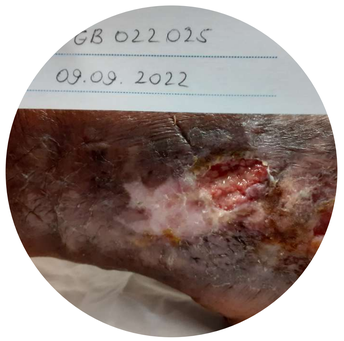
17th May - baseline



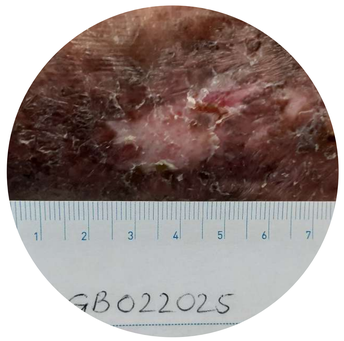
14th June - 1st follow up

Patient 3

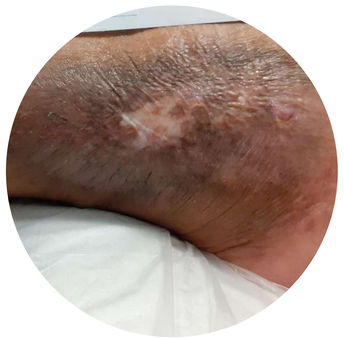
- 67-year-old female
- PMH - osteoarthritis, epilepsy, left ventricular hypertrophy, alpha thalassaemia, historic DVT
- Ulcer duration – 14 weeks
- Pain score reported by patient – 10 (pain score 4 after one week; pain score 1 after four weeks of NMES)
- Wound care regimen – Cadexomer Iodine primary dressing, compression bandaging
- NMES device discontinued at 8-week review as wound fully healed



9th Sept - baseline



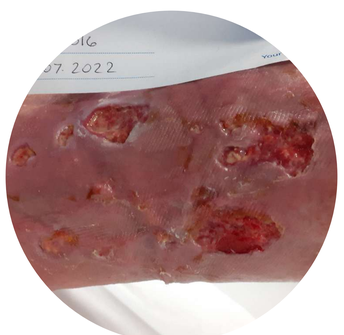
7th Oct - 1st review



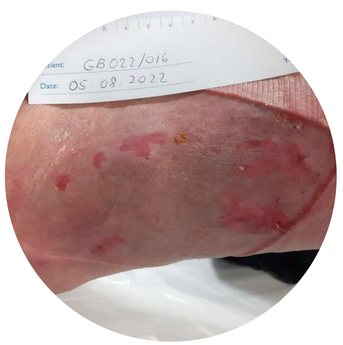
4th Nov - 2nd review closeup

Patient 4

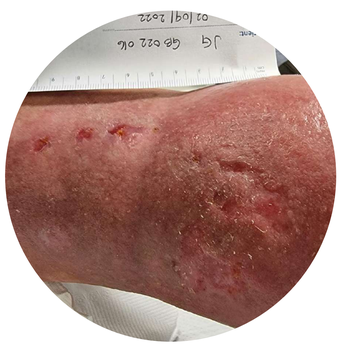
- 59-year-old male
- PMH - type II diabetes, gout
- Ulcer duration – 6 weeks
- Pain score reported by patient at baseline – 4 (no further pain scores reported)
- Wound care regimen – Silver foam primary dressing, compression bandaging
- NMES device discontinued at 8-week review as wound fully healed (wound had healed at week 5 but patient continued with NMES device until review)



8th July - baseline



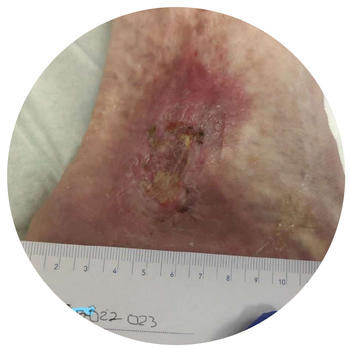
5th Aug - 1st review



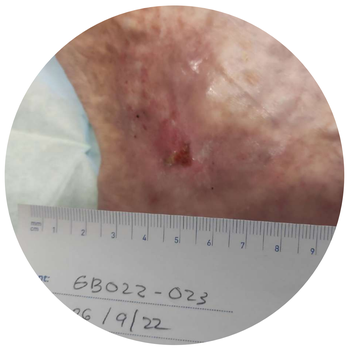
2nd Sept - 2nd review

Patient 5

- 60-year-old male
- PMH - COPD, alcohol dependence, depressive disorder
- Ulcer duration – 9 weeks
- Pain score reported by patient at baseline – 0
- Wound care regimen – Silver foam primary dressing, compression bandaging
- NMES device discontinued at 8-week review as wound fully healed



25th Aug - baseline



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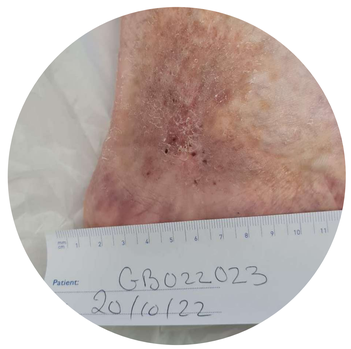

20th Oct - 2nd review

The favorable results observed in this case series reflect those highlighted in the aforementioned RCT. In that RCT, the incorporation of NMES alongside standard care resulted in over a twofold increase in the healing rate for patients with venous leg ulcers when compared to those receiving standard care alone.

Conclusion

This reported case series demonstrates how the NMES device was used to manage a group of patients with non-healing, chronic venous leg ulcers in a real-world clinical setting. The results of this evaluation emphasise the advantage of integrating the NMES device into the leg ulcer treatment regimen which demonstrated improved healing and health economic outcomes for patient with VLUs that were not previously responding to standard of care protocols.