

Goals:

This observational case study series reports the first evaluation of a novel neuromuscular electrostimulation muscle pump activator (MPA)* as an adjunctive therapy in healing in patients with chronic non-healing Venous Leg Ulcers (VLUs), in 2 home care communities. The purpose was to learn how the self-contained, easy to use, and wearable * could contribute to healing with this patient population, and if positive, to add the product to the Medical Supply and Equipment formularies.

Methodology:

When the MPA device is applied to the common peroneal nerve, it can increase the venous flow by 100%¹, arterial flow by 75%¹ and microcirculatory flow by 400%.² Patients whose VLUs had failed to heal within 24 weeks of standard therapy were identified and consented to the product evaluation, with physician agreement.



Ethics:

Ethics review was obtained from The Regional Centre for Excellence in Ethics, Homewood Health Centre, Guelph, Ontario.

Results:

Eleven patients consented to the evaluation with a combined 107-year history of recalcitrant venous leg ulcers. The pre-MPA healing rates were unknown.

The average weekly % change in surface area (SA) for the 28 measured wounds with the gekoTM was a 4.5% reduction (range of -3% to 40%). Two circumferential leg wounds in one patient were never measured. Six patients (54%) with 16 wounds were adherent to gekoTM and best practice wound care had a 7% reduction in SA per week. One patient who was adherent to care was likely not healable, having been offered amputation prior to the evaluation. Without her, the average weekly percentage change in SA for adherent, healable patients increases to 7.6%.

Patient 1:



Baseline



@ 26 weeks



@ 32 weeks

Patient 2:



Severe infection
@ 27 weeks



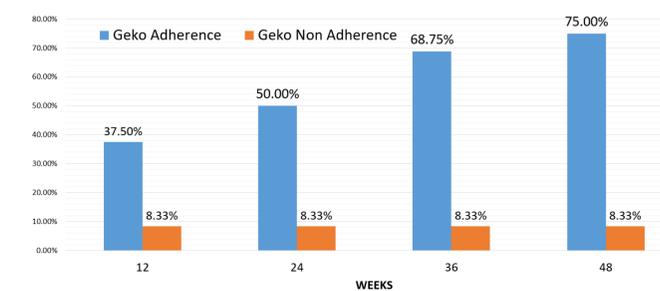
Rt. Leg
@ 39 weeks



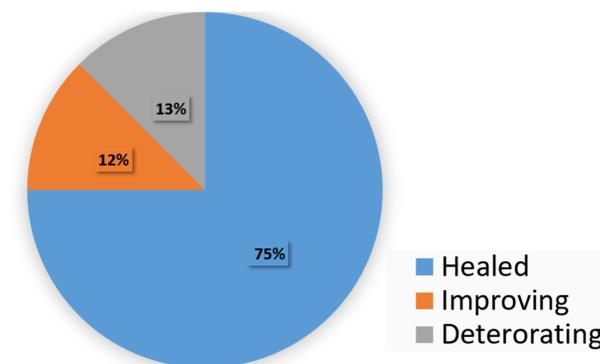
Left leg
@ 50 weeks

By comparison, the average weekly percentage change for wounds in the 5 (46%) patients non-adherent with the wound care plan and/or MPA with 12 measurable wounds was 1.82% (reduction).

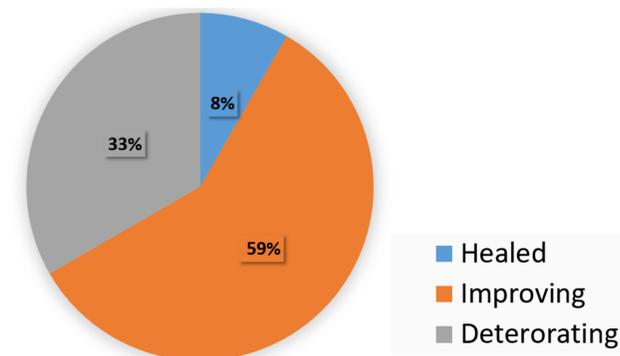
Cumulative Proportion Healed with the MPA Device and Best Practices



Outcome Proportion of Wounds for Patients Adherent to MPA &/or Best Practices



Outcome Proportion of Wounds for Patients Non-Adherent to MPA &/or Best Practices



A very positive result was pain reduction. Three patients who were not in optimal or any compression either started or increased to a therapeutic level of compression therapy, key in treating CVI. The MPA device has been added to the medical supply formulary in one center; pending in the other.

Key Messages:

In this evaluation, the MPA device reduced pain, assisted patients in tolerating compression therapy and achieved a rate of healing of 7% reduction in SA per week for recalcitrant, non-healing VLUs. This is comparable to the rate seen in NEW venous leg ulcers (28.79% at four weeks) that should heal within 24 weeks³. It is a promising start to what may well be a valuable adjunct to best-practice care.

References:

- This material will appear in: Harris, C, Loney, A, Brooke, J, Charlebois, A, Coppola, L, Mehta, S, Flett, N- Refractory Venous Leg Ulcers: Observational Evaluation of Innovative New Technology. *Int Wound J.* 2017 (in press).
1. Tucker AT, et al. Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. *Int J Angiol* 2010;19:e31-e37.
 2. Jawad H, et al. The effectiveness of a novel neuromuscular electrostimulation method versus intermittent pneumatic compression in enhancing lower limb blood flow. *J Vasc Surg: Venous Lymphat Disord.* 2014;2(2):160-5.
 3. Kantor J, Margolis DJ. A multicenter study of percentage change in venous leg ulcer area as a prognostic index of healing at 24 weeks. *Br J Dermatol.* 2000;142:960-4.

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