

Goals:

Patients with delayed or non-healing VLU often require nursing care for > 2 years, with incremental increases in costs and negative impact on quality of life¹. This observational case study reports an evaluation of an innovative neuromuscular electrostimulation Muscle Pump Activator (MPA*) used as an adjunctive therapy with best practices for non-healing venous and mixed venous/arterial leg ulcers (VLUs). The objective was to determine whether the MPA device should be added to the medical supply formulary in 2 community home care programs.

Methodology:

Stimulating the common peroneal nerve (at the fibular head), this MPA device causes passive motion of the flexor muscles, acting as a calf muscle pump, increasing venous (101%)², arterial (75%)² and microcirculatory circulation (400%)³ in healthy volunteers. It is wearable, wrist-watch sized, easy to use, self-adhesive, and battery operated.



Ethics:

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

Results:

Twelve patients with 18 VLUs recalcitrant to treatment, consented to the evaluation and were followed for up to 20 weeks.

With the patient as their own control, the mean weekly healing rate with MPA for ALL patients was 9.35% (±SD 0.10) compared to pre-gekoTM 0.06% (±SD 0.10) (P <0.01). Forty-four percent of wounds healed. None of the patients with wounds which decreased in size but did not heal stayed on the MPA for the full evaluation, for a variety of health and personal reasons. One patient non-adherent with MPA and best practices had wound deterioration in 3 wounds. One patient, featured here, also had a non-healing toe amputation site, which healed rapidly after NMES was implemented.

Patient 1: VLU x 3 months; Surgical amputation of second toe X 4.5 months following angioplasty.



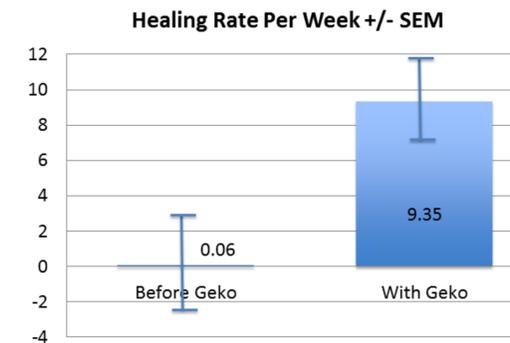
Baseline Ampt. Toe and VLU Both closed @ 5 weeks

Patient 2: Ulcers x 20 years

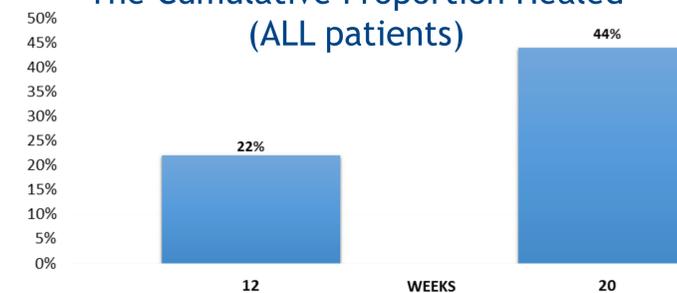


Baseline: Open areas SA 85cm,² covered in yellow fibrin. Pain 10/10; daily dressings for copious exudate, could not tolerate compression.
At 12 weeks: Open areas SA 12.1cm² stopped gekoTM at family request; pain 3/10, nursing visits every 3 days, in high compression bandages.

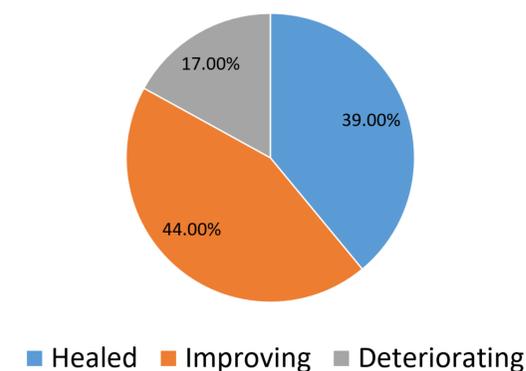
The pre-MPA device healing rate was 0.06% reduction in Surface Area (SA) per week, compare to 9.35% reduction (p<0.01) with the MPA device for ALL patients.



The Cumulative Proportion Healed (ALL patients)



All Patients with the MPA Device (Ulcer Healing through 20 weeks)



Three patients not in optimal therapy at baseline were able to increase the level of compression due to decreased pain, further enabling healing. Ninety-two percent of patients and families could be independent with the use of MPA, and were comfortable while wearing it.

Key Messages:

This small case series demonstrated a highly significant effectiveness of the MPA device in these hard-to-heal VLUs. With the MPA there was a 9.35% (±SD 0.10) reduction in SA compared to pre-MPA 0.06% (±SD 0.10) (P <0.01). Further evaluations to determine dose and criteria for patient selection are underway.

References:

This material will appear in: Harris, C¹, Duong, R², van der Heyden, G³, Byrnes, B⁴, Cattryse, R⁵, Orr, A⁶, Keast, D.⁷ Evaluation of an exciting neuromuscular electrostimulation device for chronic, non-healing venous leg ulcers . IWJ 2017 (in press).

1. Tennvall RJ, Hjelmgren J, Öien R. The cost of treating hard-to-heal venous leg ulcers: results from a Swedish survey. *World Wide Wounds* 2006. Available at: <http://www.worldwidewounds.com/2006/november/Tennvall/Cost-of-treating-hard-to-heal-venous-leg-ulcers.html>
2. Tucker AT, Maass A, Bain DS, 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.
3. 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.

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