

## Goals/Objectives

Chronic venous ulcers comprise approximately 70 to 80% of all lower limb ulcers. The pathophysiology of venous leg ulcers (VLUs) is associated with chronic venous insufficiency (CVI) (failure of the calf muscle pump, incompetent valves, and reflux in the venous system (1-2). Patients with delayed or non-healing VLUs often require nursing care for > 2 years, with incremental increases in costs and negative impact on quality of life (2). The purpose of this prospective evaluation was to evaluate the effects of a muscle pump activator (MPA) device (geko™) worn at the fibular head, stimulating the common peroneal nerve, improving Venous & Arterial volume/flow and Microcirculatory flux (3), on new or recurrent VLUs in a community setting. This was the first evaluation of the geko™ device to determine whether it could speed healing in new wounds in patients with CVI, where the average time to healing is 12-24 weeks for up to 62% of patients.

## Methods

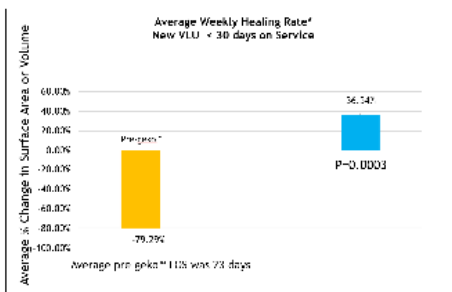
The evaluation was done in partnership with the Waterloo Wellington Local Health Integration Network (WW LHIN) Home and Community Care program. Up to 10 patients with Chronic Venous Insufficiency (CVI) and lower leg wounds on service less than 30 days could participate. Ethics approval was obtained from the Regional Centre for Excellence in Ethics, Homewood Health Centre, Guelph, Ontario.

The patients would be fitted with the geko™ devices, provided at no cost to the patient or the LHIN by Perfuse Medtec Inc. London, ON.

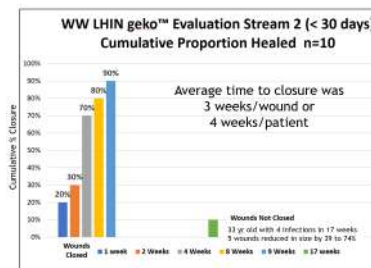
Outcomes would include percentage change in wound size pre- and with-geko™, time to healing, and impact on pain. If the patient's wounds were not healed at 8 weeks there would be an opportunity to continue with the devices for another 8 weeks.

## Results

Ten patients with 16 wounds enrolled. The average length of stay prior to implementation of the geko™ device was 23 days, by which time 5 more wounds had developed. The average weekly change in wound size prior to baseline was a 79% INCREASE in size. With the geko™ device, the average weekly change for all patients was a 36.54% reduction in Surface Area or Volume (range of 2.29 % to 100%). The difference in healing rates pre-and post-geko™ was highly statistically significant ( $p=0.0003$ ) (Image 1).



Sixteen wounds in 9 patients closed. The average healing time was 3.03 weeks per wound, or 4 weeks per patient (range of 5 days to 9 weeks). The cumulative healing rate was: twenty percent in 1 week, 30% at 2 weeks, 70% at 4 weeks, 80% at 8 weeks, 90% at 9 weeks (Image 2).



### Patient examples:

Case Study 1: On service x 7 days, unknown duration. 36.7% increase in wound size since admission



Case Study 2: 5 weeks on service; 0% healing. 15 year hx of recurrent VLUs; compliant with compression. Pain 5/10



## Implications

The average pre-MPA time on service of 23 days plus the average healing time of 21 days, the total was less than half that provided for healing in the OACCAC/ HSSO Venous Leg Ulcer Outcomes Based Pathway (14 weeks). These results seem to support earlier use of the MPA device as a first-line adjunctive therapy treatment from both an efficacy and economic perspective, and may prevent new patients from developing chronic, non-healing wounds.

## References:

1. Viva, A., Lev-Tov, H., Kirsner, R. S. Venous leg ulcers. *Annals of Internal Medicine*. 2016. 165(3): ITC17-ITC32. doi: 10. 7326/AITC201608020.
2. 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>
3. 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.

## Acknowledgements:

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