Evaluation of a muscle pump-activating device for non-healing venous leg ulcers

Harris, C\textsuperscript{1,2}, Duong, R\textsuperscript{3}, Vanderheyden, G\textsuperscript{4}, Byrnes, B\textsuperscript{5}, Cattrysse, R\textsuperscript{5}, Orr, A\textsuperscript{6}, Keast, D\textsuperscript{7}

AUTHORS AFFILIATION: CarePartners (formerly), Perfuse Medtec Inc. London, Canada\textsuperscript{1}, Hamilton Niagara Halimand Brant (HNHB) Community Care Access Centre, Hamilton, ON Canada\textsuperscript{2}, Mississauga Halton Community Care Access Centre, Mississauga, ON Canada\textsuperscript{3}, South West Community Care Access Centre, London, ON Canada\textsuperscript{4}, CarePartners, South West Division, Tillsonburg, ON Canada\textsuperscript{5}, CarePartners, Mississauga Halton Division, Mississauga, ON Canada\textsuperscript{6}, Parkwood Institute, Western University, London, ON Canada\textsuperscript{7}

Abstract

Objectives
This evaluation involves an innovative muscle pump-activating device (geko\textsuperscript{TM}) as an adjunctive therapy with best practices for non-healing venous leg ulcers (VLUs). Stimulating the common peroneal nerve (at the fibular head), the geko\textsuperscript{TM} device creates a response that acts as foot and calf muscle pumps, increasing venous, arterial and microcirculatory flow.

Aims
The aim was to evaluate and determine if the geko\textsuperscript{TM} is effective in this population and if it should be added to the medical supply formulary.

Methods
In all, 12 patients with 18 recalcitrant VLUs (defined as less than 30% reduction in wound size in 30 days with best practices) in two community settings in Ontario consented to the evaluation and were treated with the geko\textsuperscript{TM} for up to 20 weeks.

Results
A total of 44% of wounds healed, and 39% decreased in size. One patient non-adherent with the geko\textsuperscript{TM} and best practices had deterioration in his or her wounds. With the patients as their own control, the mean weekly healing rate with the geko\textsuperscript{TM} was 9.35\% (±SD 0.10) compared to 0.06\% (±SD 0.10) prior to baseline, which was statistically significant ($P < 0.01$). Three patients not in optimal therapy increased compression due to decreased pain, further enabling healing. This study was not a randomised investigation, although the patients acted as their own controls. A pragmatic evaluation reflects the reality of the community sector; in spite of best practices or evidence-based care, therapy is not uniformly applied, with some participants unable to tolerate or indeed comply with optimal compression therapy. Rash occurred under the devices in 7 of 12 (58\%) patients. One patient stopped the device due to rash, while another had to take breaks from using the device. Subsequently, the manufacturer (Firstkind Ltd) has developed a new device and protocol specific to the requirements of wound therapy to minimise this response.

Conclusions
This small case series demonstrated the highly significant effectiveness of the geko\textsuperscript{TM} device in these hard-to-heal VLUs. Further evaluations to determine dose and patient selection criteria are underway.