Is it Time for a Paradigm Shift using an Adjunctive Therapy with Best Practices for Recalcitrant Venous Leg Ulcers?

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Background:
A complex interplay of factors contribute to chronic venous insufficiency (CVI) and venous hypertension, including deep vein thrombosis (DVT), incompetent venous valves, impaired calf muscle pump, and inactivity. Dermal changes associated with neuropathy caused by CVI[1] include hyperpigmentation; subcutaneous tissue fibrosis and eventual venous ulceration[2].

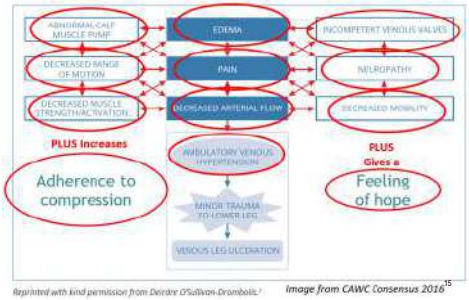
VLU Healing Times:
Some VLUs heal in 12 weeks or less[3], with early appropriate wound care and compression therapy. A 28.79% reduction in Surface Area in the first 4 weeks of therapy is considered a reliable predictor of closure at 24 weeks. Smaller, newer wounds heal faster[6,7]. However, the average time to healing is 12-24 weeks, with 62% of patients being healed at 24 weeks[4]. So, even with a "normal" healing trajectory, many patients will require more than the 14 weeks to heal found in the OACCAC Outcome-Based Pathways (OBP). Thirty percent of VLU patients will remain unhealed at one year, and 10-20% at 2 years, and some may never heal[8].

Costs and Quality of Life:
Non-healing Venous Leg Ulcers (VLUs) are a costly burden to the health care system, and negatively impact the patient with a reduced quality of life.

Treatment Options:
Experts recommend early aggressive treatment[4,9] with advanced or adjuvant therapies[4] for ulcers that fail to respond to care, are large, of long duration, or with slow healing after 3-4 weeks of optimal therapy[10].

The geko™ Wound Therapy Device:
A new technology, the geko™ neuromuscular electrostimulation (NMES) medical device (FirstKind Ltd, UK), appears to have great potential in overcoming the components of chronic venous insufficiency which cause venous ulcers and if not corrected, contribute to non-healing.
Worn just below the knee at the fibular head, it stimulates the common peroneal nerve, activating muscles in the lower leg, ankle and foot, and acts as a calf muscle pump[11,12]. This replicates at least 60% of the blood flow generated by walking, in a population where many walk < 200 meters per day.
It has been evaluated in 4 CCAC's[13,14] where 24 patients with non-healing, venous leg ulcers, and a combined 140+ year history of living with wounds, participated. Patients received usual best practices for VLUs PLUS the geko™ device, worn 6 hours per day, 5 days per week.

The geko™ device positively impacts Chronic Venous Insufficiency and the factors that lead to Venous Ulcerations:



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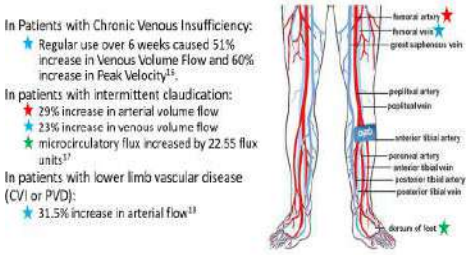
- Improves Arterial and Venous Flow and microcirculatory flux to the skin in the presence of venous and arterial disease



- Chronic edema reduction[16]
- Fibrinolytic effect[17]
- Near-isometric compression of the venous valve system[19], reducing the amount of sludge blood not effectively ejected with cardiac systole/diastole (p=0.0005)[20]
- Increased ability to flex and dorsiflex foot and ankle joints, with improved strength in legs and exercise tolerance[16]
- Up to 90% of patients with chronic VLUs report a marked reduction in pain with a subsequent reduction in narcotic use[21,22]; others report a reduction in symptoms of neuropathy[13]
- In 4 community evaluations, 26% of VLU patients were not in any/or therapeutic levels of compression; with the geko™ device, 100% went into therapeutic compression[13,14].

Impact on Healing:
Averaged over the 4 CCACs, the 17 patients who adhered to best practice treatment and use of the geko™ device had a reduction of Surface Area of 8.3% /week, or 25-32% over 3-4 weeks. This would be considered a "Normal" healing trajectory in newly admitted patients.

Implications for Practice:
Experts recommend aggressive treatment, alternative therapeutic measures, advanced or adjuvant therapies early for VLUs predicted to be hard to heal, that fail to respond to standard care, or for ulcers that are large, of long duration, or with slow healing after 3-4 weeks of optimal therapy. This new technology may present an important opportunity to change the course of healing in these patients by earlier intervention with an adjunctive therapy.

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