What is your Approach to Recalcitrant Leg Ulcers….. Status Quo or Paradigm Shift Using New Technology to Achieve Healing?

Connie Harris RN, ET, IIWCC, MSc Wound Healing and Tissue Repair

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].

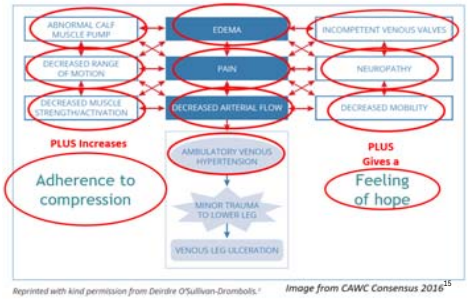
The geko™ Wound Therapy Device:

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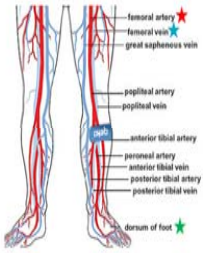
- Improves Arterial and Venous Flow and microcirculatory flux to the skin in the presence of venous and arterial disease

In Patients with Chronic Venous Insufficiency:
- Regular use over 6 weeks caused 51% increase in Venous Volume Flow and 60% increase in Peak Velocity[16].

In patients with intermittent claudication:
- 29% increase in arterial volume flow
- 23% increase in venous volume flow
- microcirculatory flux increased by 22.55 flux units[17]

In patients with lower limb vascular disease (CVI or PVD):
- 31.5% increase in arterial flow[18]



- 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 the 4 CCAC 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].

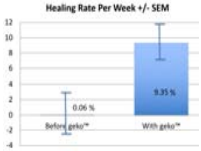
All 4 CCACs have either added the geko™ device to their formulary, or are in process.

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.

Pre- and With-geko™ Healing Rates:

In the 2 CCACs where the length of stay and initial wound measurements were available, the pre-geko™ device healing rate was 0.06% reduction in Surface Area (SA) per week, compared to a 9.35% reduction per week with the geko™ device for ALL patients[18], which is statistically significant (p<0.01)[13].



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Author contact information: Connie.Harris@perfusemedtec.com