Increased blood flow generates a **natural healing response**

geko™ wound therapy

Wound Therapy

Providing increased blood circulation to promote wound healing naturally from the inside

Supported by several peer reviewed papers and the recipient of multiple awards including best new product or service in Long Term Care by the Ontario Long Term Care Association.

Perfuse Medtec

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Innovative Technology

A paradigm shift in the management of wounds

The cause:

- Wounds, including venous, arterial and diabetic ulcers often have impaired blood flow[1,2]
- Impaired calf muscle pump function increases venous stasis and venous hypertension, and can negatively impact the severity of venous ulcerations[3,4,5,6]

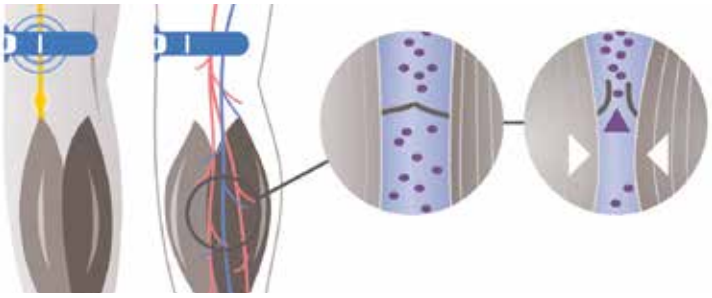
The treatment:

- Improved blood circulation results in enhanced wound closure[2,7], a natural healing response
- The geko™ device increases venous, arterial and microcirculatory blood flow in the lower limb in patients with chronic venous insufficiency[8,9] and intermittent claudication[10]. It also reduces edema[11, 12], augments the calf muscle pump[13] and maintains TCpO2 – promoting conditions suitable for wound healing[14, 17]

What is geko™ wound therapy?

Self-contained and wearable, the geko™ device:

- Low electrical current is required for nerve stimulation (versus the much higher power required to stimulate muscles) resulting in a pain-free experience
- Stimulates the common peroneal nerve, it activates the extensor muscles and stretches the antagonistic flexor muscles, acting as a calf muscle pump[13]
- Increases superficial femoral venous volume flow by 100%, femoral arterial volume flow by 75%[16] and microcirculatory flux to the skin on the dorsum of the foot[17] and thigh[18] by 400%
- Increases blood flow equal to 60% of that achieved when walking[15], so wearing it for 6 hours per day may give a physiological benefit comparable to over 3 hours of walking
- Benefits patients with chronic venous insufficiency over time[8,9]
- Is simple, easy to use, small and lightweight (just 10g) battery operated (no leads or wires), enabling the patient to be as mobile and independent as possible
- Is worn for 6 hours per day, 6 days per week
- Through gentle muscle contractions, provides feedback so that patients feel engaged in their care, and may have better adherence to treatment protocols

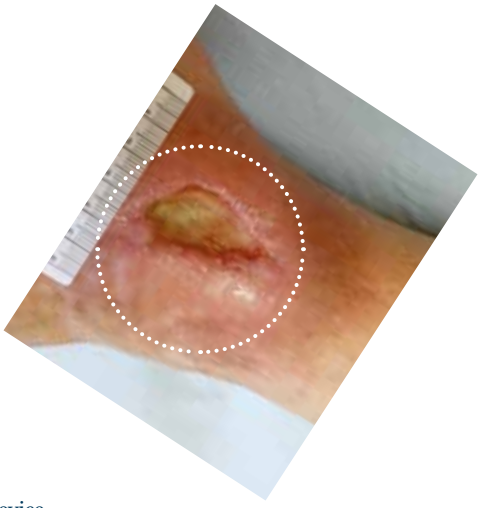


OnPulse™ TECHNOLOGY

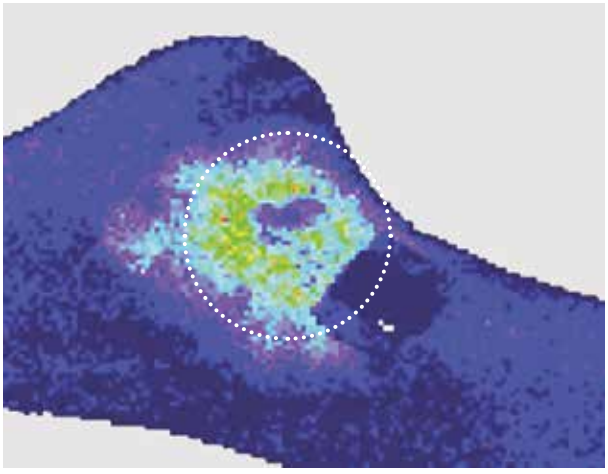
Speckle spectroscopy[19] – evaluation of a venous leg ulcer

As an example, when activated, the geko™ device caused a 225% increase in flux ($p<0.001$) in the wound bed and a 67% increase in flux ($p<0.001$) surrounding the peri-wound area[20]. Increases in flux corresponds to an increase in microcirculatory blood flow, which is clearly seen in the comparison below. This increase in blood flow results in an increase in red blood cells carrying oxygen and nutrients necessary for energy metabolism and healing.

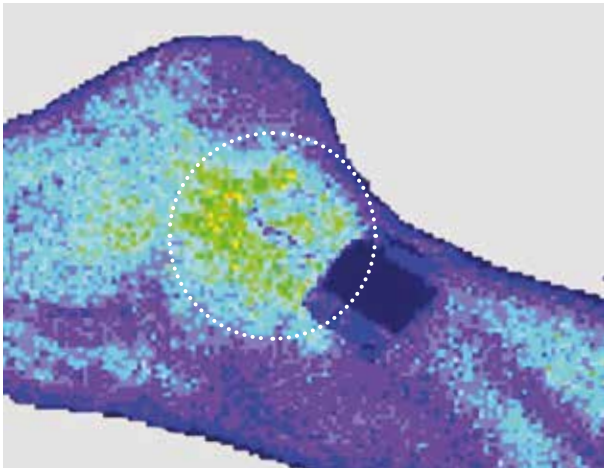
Further evidence can be reviewed at: www.gekowound.ca



Baseline speckle flow pattern



After activation of the geko™ device



Benefits of the geko™ device

The geko™ device increases venous and arterial blood flow while reducing pain[20] in individuals with lower leg ulcers.

In addition, consider the geko™ device[21]:

- In the management of lower leg edema that is contributing to reported pain
- In the management of stalled, chronic lower leg wounds that are not progressing along the expected healing trajectory (or wounds that can be predicted to be slow in healing from the onset)
- In conjunction with compression or when compression cannot be tolerated
- For patients with fixed ankle joints, those who are bedridden or those who have limited mobility

Preliminary evidence in an Ontario Home Care setting evaluation suggests this may be a first line treatment in conjunction with traditional therapy[22].

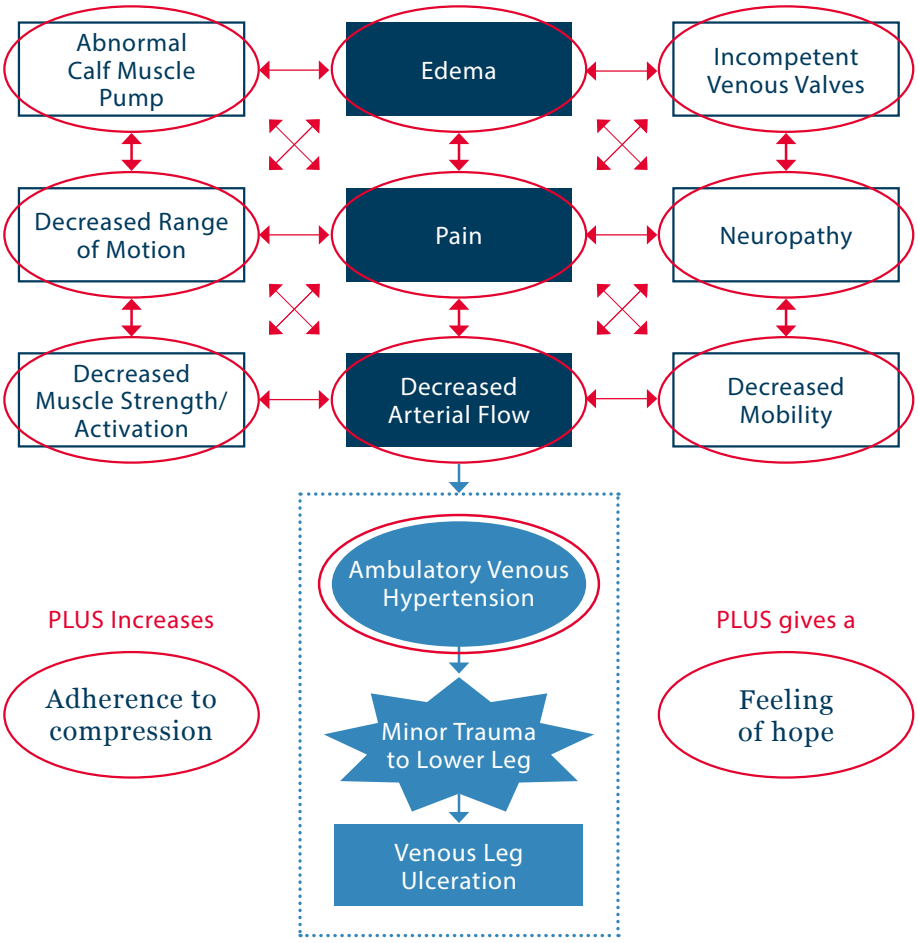
A recent consensus document from Wounds Canada articulated the benefits of low frequency nerve stimulation (geko™) in the management of venous leg ulcers[21]

The authors hypothesized that the management of such patients is complex. Many clinical and patient factors must be considered or influenced for successful patient management and healing. The pathway to success is shown in the adapted illustration below, demonstrating the areas where the geko™ device has an influence. The table **on the next page** provides further supporting evidence.

How does the geko™ device overcome venous leg ulceration?

The model below illustrates complex factors that contribute to chronic venous insufficiency (CVI) and venous leg ulceration. Various stages of the wound physiology such as edema, pain, venous hypertension and decreased arterial flow can be treated with the geko™ device, contributing to the healing of venous and other lower leg ulcers. **The geko™ device ends this cycle**.

The geko™ device has an effect on each of the areas circled in red



Original created by Dee O'Sullivan-Drombolis, modified with permission for illustrative purposes[21].

Research Evidence

The geko™ device has been the subject of scientific rigor to demonstrate its ability to increase blood circulation. The body of evidence continues to grow, targeting clinical issues such as CVI, in the management of lower leg wounds.

Clinical Issue with CVI	Device Effect
Abnormal Calf Muscle Pump	
• Non-healing venous ulcers correlate with impairment of the calf muscle pumps • 55% of patients with CVI have Calf Muscle Pump Dysfunction related to altered gait, causing venous hypertension[6]	• The device creates concentric contraction of the extensor muscles that cause dorsiflexion of the ankle joint and passive stretch of the calf flexor muscles. The passive motion of the flexor muscle acts as a calf muscle pump, which may enhance venous return by increasing intramuscular pressure[13] • This may be effective in reducing venous stasis and edema, influencing muscle oxygenation[13] • The results may indicate that the geko™ device effectively counteracts increases in muscle blood volume and deoxygenated hemoglobin during venous stasis[13]
Edema	
• Dependent edema begins in the peri-malleolar region and ascends the leg in early stages of CVI, changes over time to become fibrotic and indurated with Lipodermatosclerosis (LDS) due to changes in the fibrinolytic system[23] • It may develop into veno-lymphedema	• Case studies have shown that some patients with chronic and complex edema have had edema reductions with the geko™ device[11] • In a trial of the geko™ device with individuals with CVI, leg swelling reduced by 16% ($p<0.05$) in patients with venous disease [8,9] • Many patients with chronic venous ulcers who were not able to tolerate ANY compression therapy, or only tolerate minimal 10-15 mm Hg compression, have been able to either start or increase their level of compression therapy, leading to further edema reduction[24] • There is also a fibrinolytic effect[25] with the geko™ device which may reduce the fibrotic changes of LDS
Incompetent Venous Valves	
• 84% of people with VLUs have superficial vein valve failure[26] • Failure of the deep vein valves speeds venous disease[26] and increases the risk of venous ulcers • Both cause venous reflux and venous hypertension[26]	• The geko™ device reduces venous refilling and venous volume seen in venous stasis due to the activation of the muscle pumps[27] • It decreases the amount of "sludge" blood (erythrocytes seen as light gray in an ultrasound image) that is not effectively ejected forward through the valves with cardiac systole/ diastole[28] • When off, the Venous Sludge Index (VSI) was 53.5, when activated, the geko™ stimulation reduced the VSI to 7.6 ($p=0.0005$)[28]
Decreased Range of Motion, Decreased Muscle Strength and Activation	
• Decreased range of motion of the ankle can be related to nociceptive and neuropathic pain, woody fibrosis/LDS, edema, and fixed ankle joint related to CVI, over time develop decreased muscle strength and activation, and therefore decreased mobility[5,29]	• In case series studies, patients have reported an increased ability to flex and dorsiflex their foot and ankle[23], with increased strength in their legs with increased exercise tolerance[11]
Pain	
• People living with VLUs often report pain as 10/10 and are unable to tolerate compression therapy, which is one of the key interventions in treating CVI[24]	• Up to 90% of individuals with chronic long-standing VLUs using the geko™ device indicated a marked reduction in pain and a subsequent reduction in narcotic usage[20,30] • Patients who were unable to tolerate therapeutic levels of compression pre-geko™ were able to start and/or increase to therapeutic levels with the effect of the geko™ device[24]
Neuropathy	
• Neuropathy in individuals with CVI without Diabetes is related to perineural degeneration, edema, and collagen replacement and contributes to trophic skin changes and impaired healing[31] • Worse in proximal medial and lateral malleolus, proximal medial and lateral calf and thigh[31] • Maybe an unrecognized source of pain in this population[31]	• A study of a low frequency stimulation device to either the common peroneal or saphenous nerve[32,] depending on proximity to the ulcer, in conjunction with a four-layer compression bandaging system over 12 weeks, showed nearly four times greater improvement in the nerve sensation and two times the response to capascain applied topically, (both parameters reflecting improvement in C-fiber function)[32] • The improvement of C-fibre activation is also an indicator of the reversal of the neuropathy[21]
Decreased Arterial Flow	
• 15 to 30% of people with venous disease will also have peripheral arterial disease (PAD)[33]	• The geko™ device augments arterial, venous and microcirculatory volume flow in PAD patients and may prove a useful treatment adjunct in these patients[10,25]
Ambulatory Venous Hypertension	
• Unabated venous hypertension may result in dermal changes with hyperpigmentation; subcutaneous tissue fibrosis, termed "lipodermatosclerosis"; and eventual ulceration[26]	• The geko™ device was tested in 19 healthy volunteers using settings of 100 µs, 200 µs and 400 µs while volunteers were standing, sitting and lying. Mean Venous Transit Times (VTT) from the dorsal foot to the popliteal vein were measured along with ambulatory venous pressure and leg volume • The geko™ had a statistically significant impact, reducing VTT by up to 64%, Mean ambulatory pressure by up to 67% and leg volume by 17% ($P< 0.001$)[27]

Clinical evidence – evaluation of the geko™ device in the management of venous leg ulcers

Venous leg ulcer[a]

A 77 year-old female had a 10-year history of chronic ulcerations on the medial aspects of the lower legs, each episode lasting several months. She was concordant with high compression and had dressing changes 3 times a week. The geko™ device was used 5 days/week, 6 hours/day with time off. Pain reduced from 6/10 to 0/10 and the chronic wound gradually closed and she was fitted with compression stockings.

Prior to treatment – 10 year history

Closed at 10 months, 5 days

Painful leg ulcer[b]

A 41 year-old female with a BMI >33kg/m^2, spontaneous leg ulcers, 6 weeks prior; required IV and later oral antibiotics; still on oral x 5 days at baseline. ABPI: Left 1.0, Right 1.2; Pain 10/10 initially. As wounds closed she graduated from low to high compression as pain decreased to 0/10. She was fitted with compression stockings.

Prior to treatment – 6 week history

Closed at 18 weeks

Non-healing venous leg ulcer[a]

An 80 year-old female reported a 6.5 month history of VLU to the right medial malleolus, left medial malleolus and a pressure ulcer on her left heel. She was unable to tolerate compression due to pain and received nursing visits for wound care 3 times a week. geko™ therapy was increased from 2 hours/day to 4 hours/day. One wound closed in 18 days and the remaining in 2 ½ months. When pain was reduced she was fitted with compression. Her nurse commented on a change in her overall appearance and well-being.

Prior to treatment – 6.5 month history

Closed at 18 days

Unable to tolerate compression[a]

A 74 year-old male with 10-year history of left leg VLU closures and recurrences with several infections, bilateral knee replacements and a history of a severe burn to the area as a child. Pain was reported as 8/10 at baseline, he could not tolerate compression. But with geko™ pain reduced to 5/10 and he graduated from low to more moderate compression. He paused geko™ treatment periodically to manage dermatitis. The wound closed following 9 months of treatment and he was fitted with compression stockings.

Prior to treatment – 10 year history

Closed at 9 months

Clinical evidence – evaluation of the geko™ device in the management of other types of wounds

Non-healing surgical amputation[b]

A 77 year-old male, with CVI and diabetes, had a non-healing surgical amputation site of one toe on the right foot, 4.5 months in age, with previous bypass surgery to this leg 7 years prior. Angioplasty was performed 1 month before amputation of the toe. He also had a venous ulcer on the right shin, which had doubled in size over 3 months. He was in an inelastic Unna's paste boot dressing. His nursing visits went from every 2 days at baseline, to every 3 days by week 3. Both wounds closed at 5 weeks.

Prior to treatment – 4.5 month history

Closed at 5 weeks

Diabetic foot wound[c]

A female with type 2 diabetes and a non-healing second toe amputation; wedge resection and multiple plantar DFU which did not heal, following 1 year of wound care. She had 3+ peripheral edema below the knee. The geko™ therapy was 6 hours/day, 5 days/week. Edema reduced after 2 weeks and all wounds were closed following 4 weeks of geko™ treatment.

Prior to treatment – 1 year history

Closed at 4 weeks

Woody Fibrosis[b]

A 67 year-old male with type 1 diabetes a several year history of bilateral VLU and recurrent blisters. He had three hospitalizations in the year prior to the geko™ with cellulitis and sepsis from his legs requiring IV Antibiotics. geko™ was initiated for 6 hours/day 5 days/week and within 2 weeks his legs were getting softer and he had increased ankle mobility. The recurrent blisters decreased in frequency and duration. During the time of the evaluation he experienced only 1 course of oral antibiotics and no hospitalization.

Patient using the geko™ device – 14 month history

Some areas closed at 12 weeks; rest closed by 9 months

Pressure injury[d]

A 92 year-old female with Atrial fib, type 2 diabetes, benign hypertension, arthritis, glaucoma, and dementia. Wound etiology appeared to be pressure-related, and offloading and repositioning schedule in place. ABPI not available; suspected some arterial compromise. Right heel 0.9 x 0.6 cm, covered with scab. Left heel 2.1 x 1.7 cm, covered in eschar and dry scab, surrounded by hyperkeratotic skin. Wound duration of 4 months, healed in 3 months with the geko™ in combination with conservative sharp wound debridement and best practices.

Prior to treatment – 4 month history

Closed at 3 months

geko™
wound therapy

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