Adjunctive application of a muscle pump activator to improve blood flow in patients with lower limb ulcerations related to chronic venous insufficiency

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Introductioon
The calf muscle pump generates high pressures that assist in venous blood return against the force of gravity.[1, 2] Neuro muscular electro-stimulation (NMES) to the common peroneal nerve activates the calf and foot muscle pumps. This in turn increases venous, arterial and microcirculatory blood flow in the lower limb[3], reduces edema and promotes conditions to support wound healing. The effect of applying electrical muscle pump activation on wound healing in patients with chronic venous insufficiency and delayed wound healing beyond expected trajectories despite optimized graduated compression therapy and best practice wound management is examined.

Procedure/Method
The muscle pump activator device was applied to three ambulatory wound clinic patients with mixed etiology lower extremity wounds and a history chronic venous insufficiency. The device was applied to both legs over the common peroneal nerve for 6 hours per day; 5 days per week. The devices were applied by the patient during a time of their daily period of greatest inactivity. This was done until wound closure was achieved and for up to one month following to help ensure a more robust healing after closure.

Findings/Results
Wound healing outcomes were found to be improved over standard care with all wounds attaining full closure. Each patient demonstrated an individualized pattern of wound healing; however, healing times were expedited compared to baseline, once the muscle pump activation system was initiated. All patients remained healed one month after the device trial was completed. Secondary findings included a reduced lower leg edema, improvement in subjective pain, a softening of woody fibrosis and an improvement in skin color.

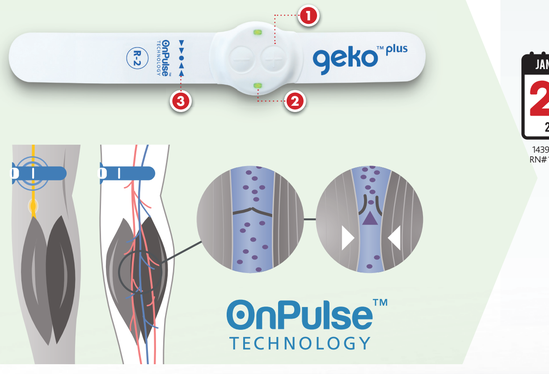
Implications/Applications
The development of adjunctive technologies provides the opportunity to better address health concerns and promote positive patient outcomes. Lower extremity wounds are a challenge to the patients' who live with them and to the health care teams developing a treatment plan. Use of a NMES provides another valuable tool in the wound healing toolbox.

References
1. Meagher, H. et al. (September 2012). An experimental study of prescribed walking in the management of venous leg ulcers. Journal of Wound Care. 21(9).
2. Davies, J., et al (2008). Improving the calf pump using home-based exercises for patients with chronic venous disease. Wounds UK. 4(3).
3. Williams, KJ et al. (Poster) Vascular Society Annual Scientific Meeting. Glasgow November 2014

The geko™ Device

Wearable, non-invasive, easy-to-use technology that heals from the inside-out. It delivers a tiny electrical charge that activates the body's "muscle pumps" to send blood flow to the wound. It weighs 10 grams is the size of a wrist watch and is self-contained.

1. Two switches (+/-) for adjusting the 8 stimulation levels
2. LED Lights
3. Indicator line to assist with device placement



Case 1

50 year old woman with extensive chronic venous insufficiency. History of recurrent leg ulcerations and intermittent infection/cellulits for over 8 years. Her right leg was especially problematic and has required skin grafting twice with eventual ulcer reoccurence each time despite 30-40 mmHg compression stockings. While she is a smoker, she had no other significant medical history.

In February 2015 the patient developed reulceration over several areas of her right leg. She experienced recurrent local infection with intermittent wound improvement and deterioration despite best practice wound care, maintenance debridement and wrapped graduated compression. Adjuctive therapy with Pentoxifylline 400mg po TID was added in May 2015. ABPI's (R) 1.31 (L) 1.31.

Call Procedure:
geko™ muscle pump activator device initated December 15th 2015. The patient applied the circulation stimulation device to each leg, 5 days a week, 6 hours per day with only minor skin irritation beneath the device. This was managed successfully with low dose topical steroid cream. Best practice wound care, maintenance debridement and compression wrapping were continued.

Findings:
After 10 months of non-healing, the patient progressed quickly to full closure in 5 weeks. She continued utilizing the geko™ device one month after healing and was transitioned into a velcro compression device. The patient's leg became softer and more pliable to touch with less brawny edema and a fading of her hemosiderin staining to a lighter brown. Subjectively the patient was very pleased to have finally healed this very difficult to manage wound.

DECEMBER 15 2015
1546HR MST
RN#424 ID

DECEMBER 28 2015
1511HR MST
RN# 1423 HM

JANUARY 22 2016
1439HR MST
RN# 1423 HM

Case 2

58 year old woman with history of mild chronic venous insufficiency and surgical removal of bilateral ingrown great toe nails September 23rd, 2015. She developed infection and cellulitis with the wounds being non-healing. She was diagnosed with osteomyelitis one month later and underwent treatment with appropriate IV antibiotics for 6 weeks. During that time the wounds to both nail beds remained non-healing with moderate bilateral lower leg and foot edema. ABPIs: (R) 1.16 (L) 1.14 Monfilament testing 10/10 bilaterally.

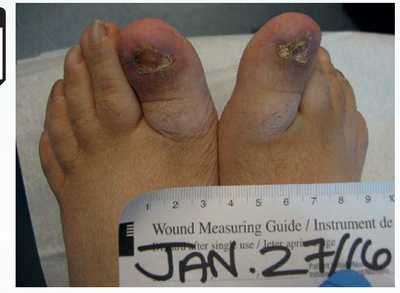
Call Procedure:
geko™ muscle pump activator device was initiated December 15th. This was initiated 2 1/2 weeks into treatment for osteomyelitis as healing was stalled. The patient applied the device to each leg 5 days per week, 6 hours per day with only minor skin irritation that settled during weekend time off the device.

Findings:
After almost three months of minimal healing, the patient's nail beds healed in 6 weeks. Bilateral leg edema was significantly reduced, without the patient wearing therapeutic compression. (Patient was unable to wear graduated compression stockings because they caused increased pain in her toes). The patient wore the device one month after healing. Subjectively, the patient stated her legs were much less swollen and her pain was less when she used the device.

DECEMBER 15 2015
1409HR MST
NP#348 MS

DECEMBER 29 2015
1205HR MST
NP#348 MS

JANUARY 27 2016
1541HR MDT
RN#1088 CC



Case 3

67 year old man with Type 2 diabetes and recurrent foot complications. History includes atrial fibrillation and advanced chronic venous insufficiency. The patient wore appropriate compression stocking and therapeutic footwear with total contact orthoses. Despite best care, intermittently he developed chronic foot ulcerations that would take months to years to heal.

Patient developed a blister over his right 1st metatarsal head May 24th, 2015. This resulted in a chronic ulceration that persisted despite best practice wound care, maintenance debridement, appropriate footwear with restricted weight bearing and therapeutic compression. PPGs (R) 80 (L) 75 Monofilaments 0/10 bilaterally.

Call Procedure:
geko™ muscle pump activator device was initiated February 29th, 2016. The device was applied by the patient 5 days per week, 6 hours per day in addition to previous care.

Findings:
Full wound closure was achieved in 2 weeks with the geko™ device continued one month following healing. Secondary findings included fading of hemosiderin staining and softening of tissue fibrosis. Edema was markedly improved from baseline. Subjectively, the patient noted a difference in the skin texture and sensation, that he wanted to continue using the device indefinitely.

FEBRUARY 29 2016
1133HR MST
RN#1074 LM

MARCH 14 2015
1430HR MDT
RN#425 CL

MARCH 29 2016
1431HR MDT
RN#1088 CC

The geko™ device is a muscle pump activator that stimulates the common peroneal nerve to activate the lower leg muscle pumps generating about 60% of the blood flow achieved by continuous walking. This translates into a venous return increase of up to 100%, arterial flow improvement by up to 75% and microcirculatory flow by up to 400%.

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