# The role of the geko™, portable electrical stimulation device, in assisted healing of an intractable mixed arterio-venous leg ulcer.

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## Background

Leg ulcers occur as a result of various aetiologies. It is thought that more than half are of venous origin, while the remainder are due to arterial, mixed arterial/venous or other pathologies (Briggs et al 2003). Venous ulcers develop as a result of ineffective venous return from the lower legs that causes chronic venous hypertension resulting in progressive changes in the skin and subcutaneous tissue of the lower legs such as oedema, pigmentation, varicose eczema and cellulitis leading to the development of lipodermatosclerosis and ultimately ulceration. (Morison and Moffatt, 2004).

Arterial ulcers occur when flow of blood through the arteries is impaired, commonly due to atherosclerotic plaque in the arterial wall causing stenosis or occlusion. This restricts the supply of oxygen and nutrients to the lower leg, as a result of which the tissues become hypoxic and are at risk of necrosis, and ulceration following further compromise such as minor trauma. The lack of an adequate blood supply means that the wound can be very slow to heal, or may not heal at all (Herbert, 1997).

Mixed aetiology ulcers result from a combination of venous disease and arterial disease. Approximately 20% of leg ulcers develop as a result of mixed arterial and venous disease. The prevalence of mixed aetiology leg ulceration is likely to increase as the population becomes older as elderly people are more likely to have arterial disease (Moffatt, 2001).

Accurate assessment of venous and arterial function of the leg is paramount in determining the treatment of leg ulcers (Vowden and Vowden, 1996). In addition to clinical examination further investigations that are usually required include ankle-brachial pressure index, Duplex ultrasound scanning of the veins and arteries of the legs. Toe-brachial pressure index may be required in patients with diabetes mellitus.

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Improving venous return is the mainstay of treatment of venous ulcers. Compression of the lower leg with stockings and multi-layered bandages are well-established and effective treatment of venous leg ulcers. High levels of compression are more effective than lower levels of compression, but also increase the risk of microcirculatory occlusion due to pressure. Therefore, high compression should be used only in the absence of significant arterial disease. Applying full compression to a limb with an ulcer of mixed aetiology may be catastrophic (Moffat, 2004). Intermittent pneumatic compression of the legs with single cuff or sequential compression therapy by multi-compartment sleeves are also known to increase venous return and help in healing of difficult ulcers. Recently geko ™ device has been shown to substantively increase venous return and microcirculation of the legs (Tucker 2010).

## Device

The geko™ device (CE 558928; British Standards Institute notified body 0120), is a small, battery operated electrical stimulation device. It is applied to activate the common peroneal nerve within the popliteal fossa, in turn activating the venous muscle pumps of the lower leg

A study by Tucker et al (2010), at St Bartholomew's examined the role of the geko™ device in 30 healthy volunteers and demonstrated that it resulted in an up to a fourfold increase in blood flow velocity and a significant increase in venous volume flow ($P<0.01$) at all stimulation levels, measured with ultrasound Doppler. This also corresponded to up to a 25 fold increase in microcirculatory flow when measured with the laser Doppler. Another study by Jawad et al (2011) demonstrated that not only did the geko™ device increase venous blood volume flow by 33% from baseline on high stimulation and 14% on low stimulation, but on high stimulation settings also increased arterial blood volume flow by 30%. Further, the technique has been recently demonstrated to substantively increase arterial, venous and microcirculatory blood flow; together with a significant decrease in Tissue Plasminogen Activator (tPA) antigen with indicates increased fibrinolytic activity (Jawad 2012).

Here, we describe a case of a patient with a long history of venous leg ulcers that had recently developed peripheral arterial disease of the lower leg resulting in an intractable ulcer. The patient also had a rare history of serious allergy to lidocaine with anaphylaxis, which has made the treatment of his leg ulcers extremely challenging.

## Case presentation

A 75 year old gentleman presented with a painful non-healing venous ulcer in his left leg. He had a past history of multiple bilateral venous leg ulcers. He also gave a history of deep vein thrombosis in the left leg (1992), and subsequent pulmonary embolism. He has had bilateral varicose veins and chronic venous insufficiency with lipodermatosclerosis. Over the last few years he had multiple venous ulcers in both legs and had them successfully treated by four-layer bandaging.

Following minor trauma to his left leg in 2010 he developed an ulcer in the gaiter area, which has been affected by longstanding lipodermatosclerosis and was treated at the nurse-led ulcer clinic with compression bandaging for 36 months without healing. Hence, he was referred to the vascular surgery clinic. In addition to the above history of venous disease, on direct questioning the patient admitted to

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having symptoms of bilateral calf claudication. He has been a heavy smoker most of his adult life. His pedal pulses were absent bilaterally and the ABPI was reduced bilaterally. He had an ulcer in the left gaiter area measuring 4cm x 3cm with slough and exudation.

Lower limb duplex scan showed bilateral superficial femoral artery (SFA) disease with occlusion on the right and severe stenosis on the left. The Duplex Scan also showed extensive post-thrombotic scarring of the deep venous system in the left leg with reflux of the popliteal vein.

The apparent mixed arterio-venous disease of the leg explained why the ulcer did not heal with prolonged compression and why the ulcer was very painful. The patient required an angioplasty of the left SFA. However, he had a history of severe allergy to lidocaine and therefore he could not have this procedure under local anaesthesia. Angioplasty under general anaesthesia is possible, but subjects the patient to a higher level of risk. Hence, any alternative ways of increasing arterial blood flow and or increasing venous return was considered a potential treatment with unknown success rate.

Any form of compression to the leg caused severe pain. Hence, we tried a novel form of treatment to increase venous return without causing compression or pain. The patient was trained in applying and changing the geko™ device as required. He was able to demonstrate visible muscle twitching of the peroneal compartment and the foot. The geko™ device was positioned (as per the instructions for use) to the skin overlying the common peroneal nerve at the head of fibula on the affected leg a moderate regular twitch of the foot indicated that the muscles of the leg were being stimulated. This optimum positioning of the device was marked so that the patient could change the device at home on a daily basis.

In order to demonstrate the efficacy of the geko™ device femoral vein blood flow measurements using a duplex scanner were taken at the following situations.

1. No intervention to establish base line venous flow.
2. Following the application of the geko ™ device alone
3. Following the application of compression bandage plus the geko™ device.

The blood flow results were as follows:

| Intervention | Venous flow |
|---|---|
| Base line | 33cc/min |
| Stand-alone geko™device | 85cc/min |
| Compression plus geko ™ device | 153cc/min |

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The above results demonstrated that the geko™ device does improve venous return when applied to the leg with or without compression bandage. As our patient could not tolerate compression due to his co-existing arterial disease, he used the geko™ device alone (with light dressing on the wound) to increase venous return. The device was activated for a period of 24hrs followed by a rest period of 24hrs and this cycle was repeated for 5 weeks with a new device applied by the patient for each active cycle. The wound dressing was changed as per standard protocol.

## Outcome

After 2 weeks of using the geko™ device alone the ulcer had reduced in size to 2.5cm by 1cm a significant reduction from the original size of 4cm by 3cm. There was also a significant reduction in the self-reported pain, and the patient reduced his intake of painkillers. Likewise, there was a significant reduction in left leg cramp and the patient reduced his intake of quinine. Oedema was also noted to have been reduced. To the pleasant surprise of the patient there was significant improvement in his exercise tolerance. The patient was able to increase his daily use of a sewing machine treadle from 2 mins to 1 hour and it helped improve his efficiency at work. Subsequently, geko™ was discontinued, because the patient, who has a known allergy to sticking plasters, developed a rash and treatment will continue as soon as possible under medical supervision.

## Discussion

Clarke Moloney et al (2006) demonstrated an increase in venous velocity using electrical stimulation as a treatment adjunct for venous ulceration. A meta-analysis by Gardner et al (1999) reported a 13% net healing rate per week with electrical stimulation, equating to a 144% increase over the control population. Studies to investigate the cost effectiveness of stimulation therapies in the healing of chronic venous ulcers have revealed it to be a ‘dominant treatment’ i.e. improved outcome for less cost (Taylor 2011).

The use of electro-stimulation to heal ulcers where the aetiology has an arterial component is of particular interest, since compression is less applicable as a treatment.

The geko™ is the first fully portable stimulation device, which does not require separate electrodes and console. This affords it the advantage of being discrete and enabling the patient to be fully mobile while wearing the device.

The geko™ device has been shown (Tucker 2010) to augment arterial flow, as well as microcirculation, whereas compression therapy generally has a beneficial effect on venous flow only, and may reduce arterial and microcirculatory flows. W here an ulcer has an arterial component to its aetiology, the geko™ device would be expected to be more efficacious than compression, by virtue of the augmentation of arterial inflow. Additionally, since healing any ulcer requires perfusion at the wound bed, the augmentation of microcirculatory flow brought about by the geko™ device is expected to be beneficial.

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The use of the geko™ device in this case has accelerated the improvement and healing of this hard to heal ulcer. The enhancement of both venous flow and the additional enhancement of microcirculatory flow delivered by the device would have created a positive benefit. This case suggests that the use of geko™ offers an exciting treatment option for hard to heal ulcers of venous, arterial or mixed aetiology.

The stimulation delivered by the device is tolerable to patients and as such it would appear that the geko™ device is a useful treatment option for patients with chronic leg ulcers.

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MPDCA0042V2