EP064 - Clinical Evaluation of the Response Rate to a Continuously Active, Single-use Electrical Stimulation Device in Static Non-Healing Wounds

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Background

Endogenous bioelectricity is a fundamental mechanism of normal wound healing. Measurements show that microamp (µA) bioelectric currents are naturally released upon injury to the skin. Bioelectric fields operate through known pathways of cell signaling to switch on functions such as cell migration, growth factor and growth factor receptor expression and generally co-ordinate wound healing (Zhao 2009, Martin-Granados & McCaig 2014).

In chronic wounds, diminished endogenous bioelectric signals can be supplemented by electrical stimulation (ES) devices. The *in vitro* and clinical evidence for the beneficial effects of ES on wound healing are now quite substantial, (Houghton 2017) but ES has yet to become a mainstream wound therapy. One reason is the predominant use of large, expensive, periodic, clinic-based ES treatments which are inconvenient for patients and poor business models for providers. Chronic wounds are often painful and ES therapy has frequently been shown to be able reduce pain in patients with non-healing painful wounds (Milne et al. 2021).

The aim of this evaluation was to assess the frequency of a positive response for pain and healing, in stalled non-healing chronic wounds to a portable automatic, continuously active, disposable low-voltage pulsed microcurrent ES device.*

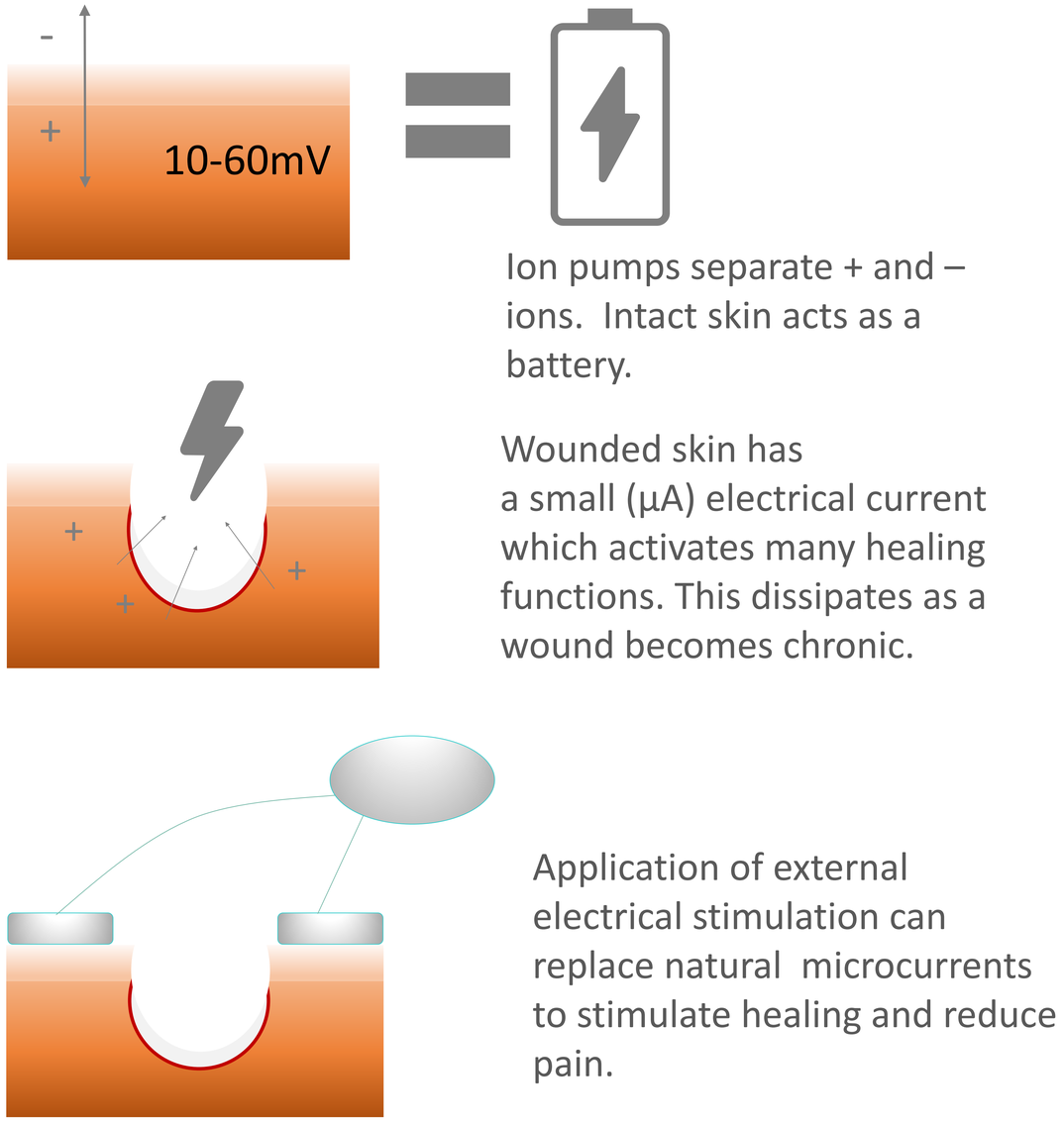

Figure 1 Rationale for use of electrical stimulation on wounded tissues.

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Methods

This was an observational evaluation of a CE marked Single-use Electrical Stimulation Device* **(see Figure 2)** in a population of patients with static chronic non-healing wounds.

Following a period of 3 weeks to establish the wound was static, ES therapy was applied to all wounds for 12 days. Eight wounds subsequently received a further 12-days of ES therapy and some wounds received up to 4 x 12 days ES therapy in total.

Changes in clinical parameters such as area, depth, nature of granulation tissue, condition of peri-wound skin and pain were recorded. An overall informal clinical response, reflecting changes in these parameters, was scored on a 0-5 scale (where 5 is excellent and 0 indicates no clinical response) see **Table 1**

No response	0
Minor	1
Limited	2
Modest	3
Good	4
Excellent	5

Table 1. Clinical response scores

Figure 2. * Single-use Electrical Stimulation Device

The ES device is single-use, and delivers a pre-set 12-day therapy which is:

- Continuously active
- Subsensory
- Pulsed μcurrent
- Low voltage

The device monitors current flow through the electrodes and automatically adjusts the voltage to ensure the same current is delivered across all patients, even if the electrodes are different distances from the wound edge. ES therapy is applied for 12 days during which time a 30-min ES stimulation protocol is automatically delivered every 2hours (odd days) and 4 hours (even days). The device can be used at the same time as any dressing or bandaging.

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Results

A total of 20 wounds were recruited in early 2021: 19 patients, 8 female 11 male, mean age 69.6 years. Wounds had been present a mean 35.7 months and static during this evaluation for a mean of 3 weeks, despite a range of interventions including Wound Bed Preparation. The wound indications are shown in **Table 2**.

Patients reported their assessment of pain on a 0-10 visual analogue scale (VAS) where 0 is no pain and 10 is worst imaginable pain. Many of the wounds (10/20) were causing significant pain (>4).

Reductions in pain, peri-wound oedema, exudate, inflammation, wound depth and area and increases in granulation tissue growth and re-epithelialisation fed into the overall rating of each patient on a 0-5 clinical response score.

Indications	Number of wounds
Post-surgical	5
Diabetic ulcer	5
Pressure ulcer	3
Venous ulcer	3
Arterial ulcer	1
Post Trauma	3
	20

Table 2. breakdown of wound indications.

Figure 3 shows that 14/20 (70%) of wounds showed a significantly positive clinical response (scoring either 5 or 4) with reductions in pain, peri-wound oedema, exudate, inflammation, and increases in granulation and re-epithelialisation. Changes were typically observed within the first 14 days.

Table 3 shows that 9/10 (90%) of those patients with significant pain, there was reduction in pain scores within the first 48 hours.

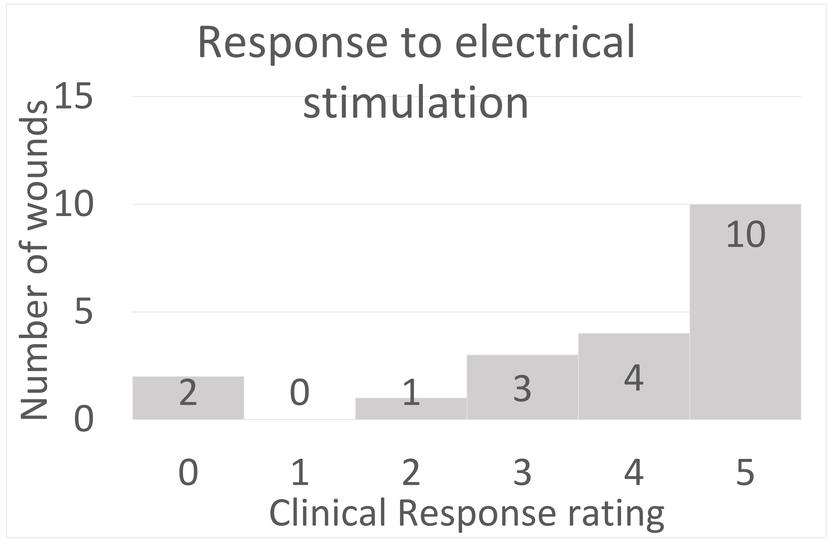

Figure 3. Clinical responses to* Single-use Electrical Stimulation Device

Wounds with pain	Significant pain reduced within 48hours
10/20 have significant pain	9/10 (90%)
Mean significant pain score = 5.0	Mean sig wounds pain score at 1 week = 2.0

Table 3. Effects of electrical stimulation on significantly painful wounds

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Example of one patient case

Figure 4 Case study trauma

(a) Day 1 - 32-year-old male. Farming accident 5 months ago. No healing for 1 week under standard care. Pain score 5. Wound area 7.4 cm^2

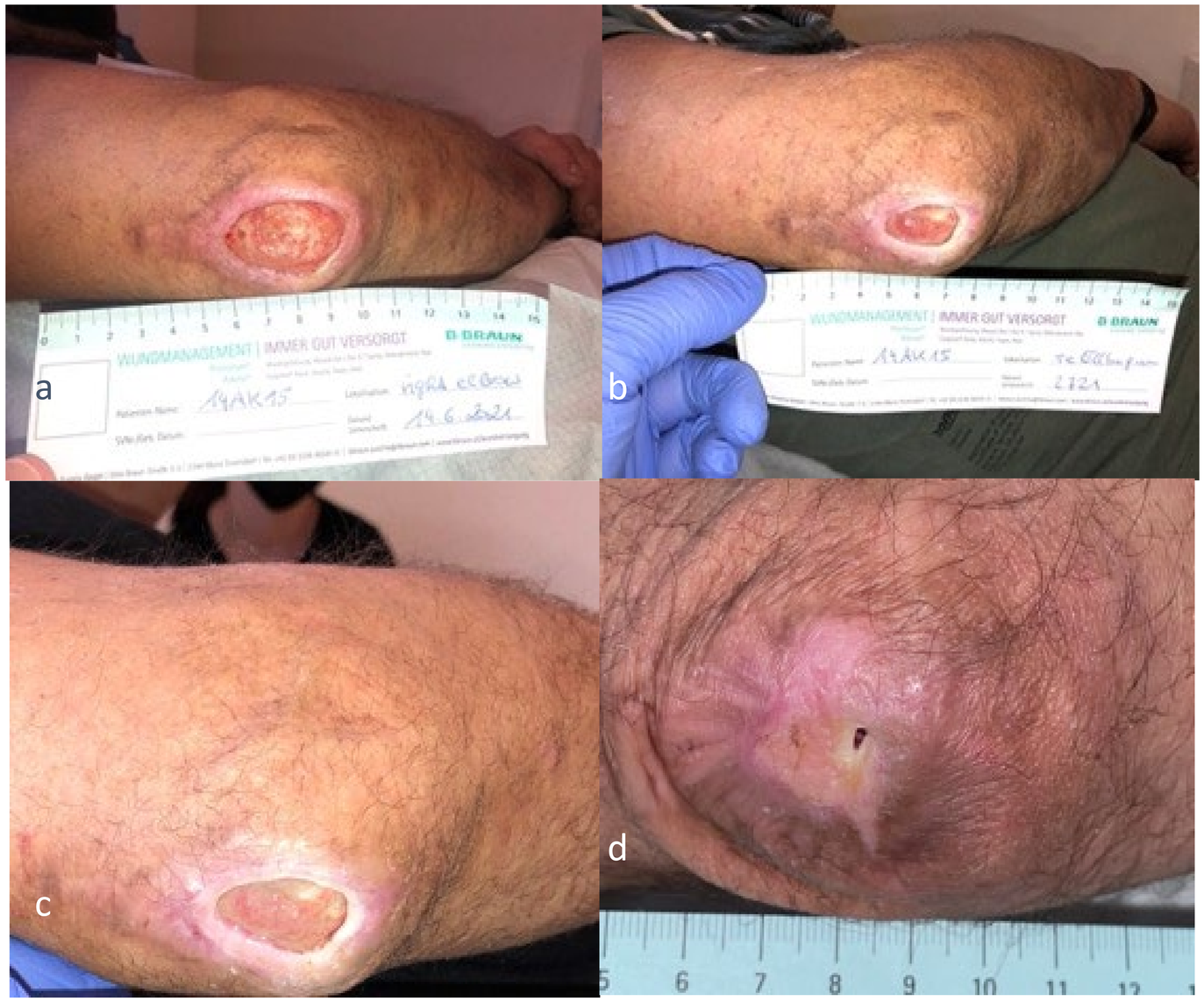
Recurrent massive local infections with surgical interventions, NPWT, etc. Problem with alcohol consumption

No healing for 1 week under standard care.
Pain score 5. Wound area 7.4 cm^2

(b) Day 24 – After 1st & 2nd 12-day ES* therapy
Pain score 4. Wound area 2.3 cm^2

(c) Day 62: after 3rd 12-day ES therapy.

(d) Day 148: After 4th 12 ES therapy



Patient reported pain reduction in 48 hrs

Clinical response score 5 (Excellent)

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Discussion

The purpose of this investigation was to explore in greater breadth, the clinical capabilities of a small continuously active pulsed microcurrent *ES device (Ovens 2017). In a population of 20 static non-healing wounds, including post-surgical and DFUs, 70% of wounds displayed significant positive responses such as reductions in peri-wound oedema, reductions in inflammation, wound depth and area, or increases in granulation, that had not been seen during the preceding weeks of care.

In these wounds the clinical signs suggest ES was responsible for changing the physiology of the wound and that reparative processes were in motion. In addition, 90% of patients with significant pain recorded a reduction in pain by the end of the first 48hrs.

With the ability to allow patients to receive electrical stimulation therapy at home, in combination with any type of dressing, this device will be able to greatly expand the access of patients to this ES therapy. Further studies with greater numbers of wounds should be performed to further reveal its full potential.

Acknowledgements and conflicts of interest
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References

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