IMPACT OF A SINGLE-USE 12-DAY ELECTRICAL STIMULATION THERAPY DEVICE* ON WOUND PAIN, HEALING, AND COMPRESSION TOLERANCE IN LOWER LIMB VENOUS ULCERS

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Introduction

In the UK, over 500,000 people develop chronic venous leg ulcers annually [1]. The best practice medical management of these ulcers is compression therapy along with venous intervention, if clinically appropriate, however many patients are unable to tolerate compression therapy due to wound-related pain. Managing wound-related pain to enable compression therapy remains a major challenge in complex wound care clinics. Beyond trialling different types of compression therapy and analgesics there are limited tools available to address this issue. One potential solution is the use of electrical stimulation therapy (EST), which has been shown to significantly reduce wound-related pain [2,3]. The aim of this study was two-fold; primary outcome was to determine the benefits of pain reduction to enable tolerance of therapeutic compression using EST*, for patients with non-healing venous leg ulcers; secondary outcome was to determine the healing benefits for patients with non-healing lower limb ulcers.

Method

An evaluation of ten patients was undertaken in a vascular clinic. A single-use 12-day EST device* was applied alongside standard care, including compression therapy where clinically appropriate and tolerated. Wound dimensions and pain scores (visual analogue score [VAS, 0= no pain- 10= worst pain] were measured prior to (baseline) and following application of EST*. Patients were followed up for 4 weeks after completion of the 12-day treatment.

Results:

Eight patients had primary venous pathology, one had lymphoedema, and one had mixed aetiology. Five patients were unable to tolerate therapeutic compression therapy. Compression therapy was contraindicated for one patient with a mixed aetiology leg ulcer. Mean wound duration was 37 months (range 6–60). Of five patients unable to tolerate compression at baseline, all commenced therapy after the initiation of Accel-Heal Solo - three maintained compression beyond four weeks. By day 12 after the start of treatment with Accel-Heal Solo, median pain score reduced from 4/10 (mean 4.35, range 0–10) to 0/10 (mean 2.2, range 0–8) (**Figure 1**). The number of patients reporting no pain increased from 2/10 to 6/10 after treatment. Mean wound area reduced by 44.7% (SD, 45.3%) over four weeks, from 125.7 cm² to 51.9 cm² (**Figure 2**).

Figure 1. A

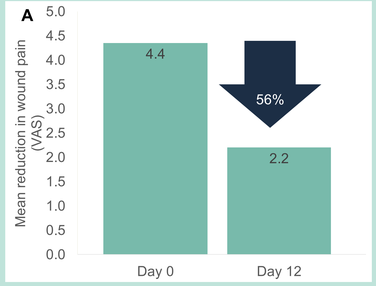


Figure 1. B

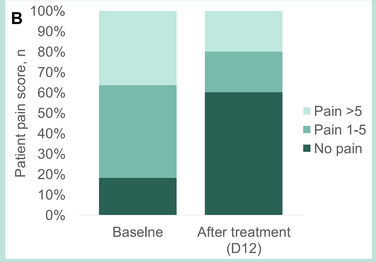
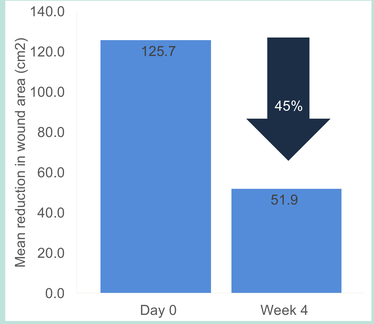


Figure 1. A. Pain score reduction over 12 days treatment period with Accel-Heal Solo (n=8); **B.** proportion of patients with no pain.

Figure 2. Wound size reduction within 4 weeks of start of treatment with Accel-Heal Solo (n=8)

Figure 2



Case study:

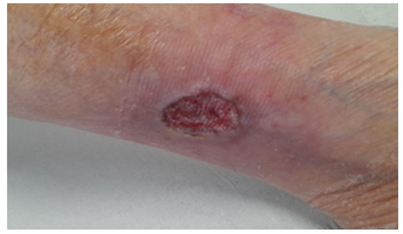
Doris is a 91-year-old female with a recurrent mixed ulcer to her left gaiter, present for 8 months. Comorbidities included ischemic heart disease, COPD and CKD. Venous duplex demonstrated deep and superficial incompetence, unsuitable for venous intervention. MR Angiogram (MRA) showed iliac stenosis which would require complex intervention. However, the multi-disciplinary team decided that conservative management was more suitable due to the high risks. Although the ulcer was stable, Doris' main concern was pain. She described the pain as a sharp pain to the whole leg which occurred at any time and also caused twitching/involuntary leg movements. This pain significantly reduced her quality of life, affecting her sleeping and activities of daily living. Analgesic use was complicated due to significant side effects and her reluctance to take them due to frailty and lone living. Pain score was 10 (VAS) and the wound measured 5.4 cm² at baseline (**Fig 3A**) with minimal exudate, 50% slough and 50% granulation tissue. Peri-wound skin was very fragile.

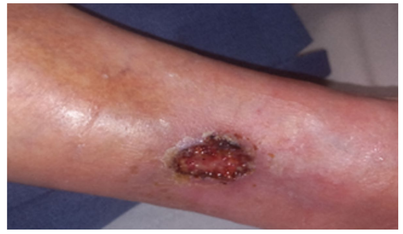
Following the 12-day EST*, Doris had an improvement of pain symptoms with a pain score of 8 (VAS), enabling her to sleep and rest. The wound measured 3.2 cm² (41% reduction), with minimal exudate and now with signs of epithelisation to the wound edges (**Fig 3B**). Following family request, a second EST* was applied with the aim of achieving further pain reduction. 32 days after commencing the first Accel-Heal Solo therapy Doris' pain score was 0 (VAS) (100% reduction, **Fig 3C**). The wound now had a dry scab with no exudate. Doris was now pain free and she was able to resume her normal activities. She is very grateful for the opportunity given to her with the EST*, in gaining back her quality of life. The wound went onto heal (**Fig 3D**, date unknown), with no recurrence, despite her high risks.

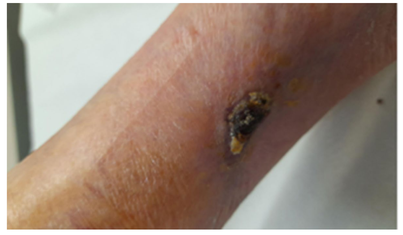
Discussion/Conclusion:

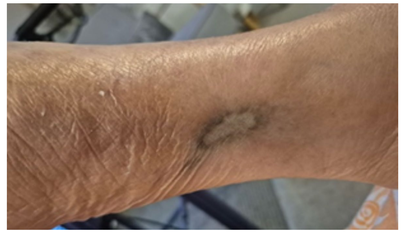
EST* reduced wound-related pain, enabling previously compression-intolerant patients to tolerate and comply with therapy. The combination of pain reduction, compression compliance, and direct EST* effects likely contributed to healing. Although limited by small sample size, three patient groups appeared to particularly benefit: those unable to tolerate compression due to pain; those unresponsive to compression alone; one patient with recurrent non-healing painful mixed aetiology leg ulcer, whose pain was eliminated and the wound healed.

Figure 3. Case study following initiation of Accel-Heal Solo


A. Day 0


B. Day 13


C. Day 32


D. Wound healed within 6 months

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Abbreviations: CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease;

References: 1. Guest JF, Fuller GW, Vowden P. BMJ Open. 2020 Dec 22;10(12):e045253; **2.** Avendaño-Coy J, López-Muñoz P, Serrano-Muñoz D, et al. J Tissue Viability. 2022 May;31(2):268-277; **3.** Moon M.,Hawes L., Hazell D. Poster presented at Wounds UK 2023.

Disclosures: Accel-Heal Solo devices used in this study were provided by Accel-Heal Technologies Limited. Writing services were paid for by Accel-Heal Technologies Limited but were carried out independently.

*Accel-Heal Solo, Accel-Heal Technologies Limited, Hever, Kent, UK. Presented at Wounds UK, Harrogate, 2025