

Use of electrical stimulation therapy to reduce pain associated with hard-to-heal wounds and reduce reliance on pharmacological analgesics, including controlled analgesics

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Background

- Despite widespread use of analgesics, wound pain is common and often remains unresolved¹
- EST is one non-pharmaceutical option that has been shown to help relieve pain in hard to heal wounds as well as kick-starting healing²⁻⁴

Aim

- To assess the effect of an easily operated, wearable EST device* on pain from hard-to-heal wounds; assess the effect of EST on quantity/type of analgesic needed to manage wound pain

Methods

- Twenty patients with painful, stalled leg ulcers were treated with an EST device* The EST device* delivers a pre-set programme of sub-sensory microcurrent over a continuous 12-day treatment period
- Pain scores and analgesic consumption were recorded daily for a 7-day run-in period and during treatment with EST for 24 days
- Changes in pain and wound dimensions were also summarised weekly
- Wound pain and healing was monitored during a 6-month follow up

Patient characteristics

- N=20; mean age 74 (range 50-91)
- 75% female
- Wound type: VLU 14; 5 arterial ulcer; 1 mixed ulcer
- Median wound duration 12-months (range 1.5 to 72)
- Common comorbidities:
 - Anxiety/depression 35%
 - Hypertension 30%
 - High cholesterol 30%
 - Arthritis 30%
- Despite widespread use of analgesics, wound pain was unresolved in all patients



*Accel-Heal Solo, Accel-Heal Technologies Limited, Hever, Kent, UK.

1. Milne J, et al. J Wound Care. 2021 Jul 2;30(7):568-580; 2. Arora M, et al. Cochrane Database Syst Rev 1, Cd012196 (2020); 3. Chen Z, et al. Adv Skin Wound Care 33, 608-612 (2020); 4. Avendaño-Coy, J, et al. J Tissue Viability 31, 268-277 (2022).

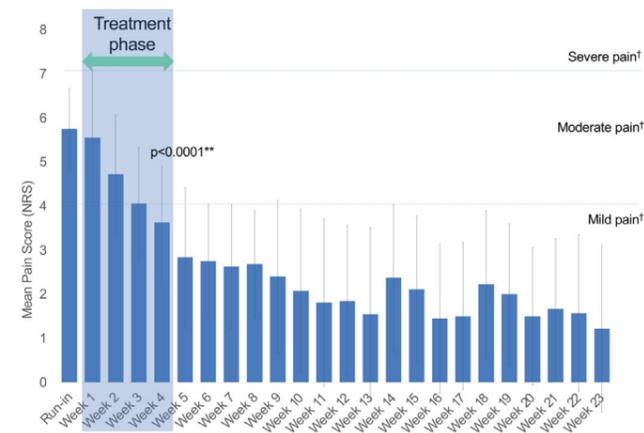
Wound pain significantly reduced within the treatment period and continued to fall through follow up period



- Mean wound pain significantly reduced from 5.75 (range 4.0-7.3) to 3.63 (range 0-6.0); $p < 0.0001^{**}$

- 10/20 (50%) of patients reported a shift to a lower pain category within treatment period
- All 3 patients with severe pain† at baseline dropped into a lower category by the end of the treatment period (1 to moderate and 2 to mild pain)†

- Median reduction in pain NRS was 1.99 points (mean 2.12; range -0.286 - 6.43 points)
- This was very similar to the **minimal clinically important difference** for wound pain as measured on the NRS scale of a difference of 2-points⁵



5 weeks

- Median time to 50% reduction of baseline wound pain was 5-weeks (range 2-16) after starting treatment
- Median time to mild wound pain was also 5-weeks (range 1-10)

*Treatment period was 24 days, which included two back-to-back applications of EST (Accel-Heal Solo), both of which were 12-days in duration. ** $p < 0.0001$: Student's t-test (parametric, paired test) comparing baseline wound pain and wound pain at end of 4-week treatment period. Significance of p-value was set at alpha 0.05. †Pain scores between $>0 < 4$ were classed as low pain, $>4 < 7$ as moderate pain and ≥ 7 as high pain. Scores of 0 represented no pain. EST, electrical stimulation therapy; IM, intramedullary; NPWT, negative pressure wound therapy; VAS, visual analogue scale. 5. Farrar, J. T., Young, J. P., Jr., LaMoreaux, L., Werth, J. L. & Poole, M. R. Pain 94, 149-158 (2001).

Results: Need for analgesics was reduced



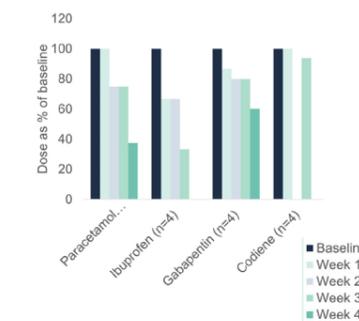
- The median number of analgesics being taken reduced from 2 per patient (range 0-4) at baseline to 1 per patient (range 0-4) by the end of the 4-week EST* treatment period (n=20)



- The number of patients requiring analgesics to relieve wound pain (any type or dose) reduced from 19/20 (95%) at baseline to 16/20 (80%) by the end of the 4-week EST* treatment



- 3/20 patients stopped using analgesics for wound pain within treatment period:
 - 2 stopped using non-controlled analgesics and 1 stopped using controlled analgesics (tramadol and gabapentin)



- Median daily dose reduced for some analgesics**:
 - Paracetamol (n=14); 4000mg to 1500mg
 - Ibuprofen (n=4); 600mg to 0
 - Gabapentin (n=4); 750mg to 350mg
 - Morphine: no changes recorded in the 2 patients taking this analgesic (not shown)

EST, electrical stimulation therapy.

*Accel-Heal Solo, Accel-Heal Technologies Limited, Hever, Kent, UK. **Median daily analgesic dose during 7-day run-in period compared with median daily dose during the final week of the 4-week treatment period. †One patient was lost to follow up after week 12 of the follow up period; as this patient had not healed by week 12, it was assumed that they had not healed by the end of the follow up period.

Discussion

- Treatment of painful, hard to heal wounds with EST* resulted in a meaningful reduction in wound pain that, in some patients, enabled reduction in pain medication
- This included the complete cessation of controlled analgesics in some cases
- Cessation of controlled analgesics in people with hard to heal wounds, typically elderly and medically compromised individuals, is important
- side-effects from these medications can lead to an increased risk of falling and other treatment-related adverse events
- As well as the positive pain-related outcomes, the measured changes in wound dimensions during treatment demonstrated clear progress towards healing
- Improved pain in some patients may have been masked by their increased ability to mobilise – this association has been reported elsewhere⁶

*Accel-Heal Solo, Accel-Heal Technologies Limited, Hever, Kent, UK.

References: 1. Milne J, Swift A, Smith J, Martin R. Electrical stimulation for pain reduction in hard-to-heal wound healing. J Wound Care. 2021 Jul 2;30(7):568-580; 2. Arora, M, et al. Electrical stimulation for treating pressure ulcers. Cochrane Database Syst Rev 1, Cd012196 (2020); 3. Chen, Z., Chen, Z. Y., Liu, W. H. & Li, G. S. Electric Stimulation as an Effective Adjunctive Therapy for Diabetic Foot Ulcer: A Meta-analysis of Randomized Controlled Trials. Adv Skin Wound Care 33, 608-612 (2020); 4. Avendaño-Coy, J, et al. Electrical microcurrent stimulation therapy for wound healing: A meta-analysis of randomized clinical trials. J Tissue Viability 31, 268-277 (2022); 5. Farrar, J. T., Young, J. P., Jr., LaMoreaux, L., Werth, J. L. & Poole, M. R. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 94, 149-158 (2001); 6. Probst S, et al. Patients' acceptance of chronic wound-associated pain - A qualitative descriptive study. J Tissue Viability. 2023 Nov;32(4):455-459.

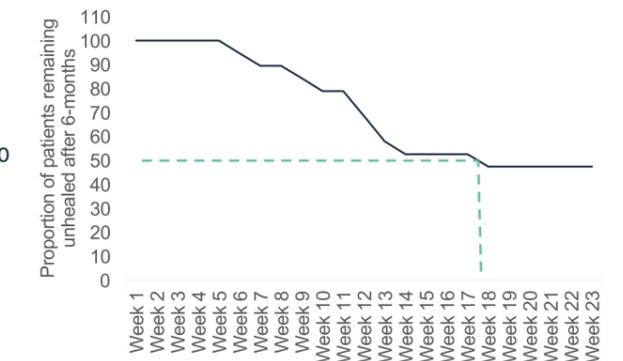
Results: Wound healing progressed overall



50% healed within 6 months

- On average, wound area reduced by 41% of baseline area during the treatment period
- Mean weekly reduction in wound area, from baseline to week 4 was 10.2% (range 0-24.6%; SD, 6.2) per week

- 10/20 (50%) of patients healed within the 6-month follow up (median 18 weeks) following initiation of EST†
- Of patients who achieved healing, most patients achieved full healing of the wound between week 8 and 14 post initiation of Accel-Heal



Conclusions

- Patients treated with EST* reported reduction in pain and corresponding reduced analgesic consumption
- As well as kick-starting the healing process, EST may provide a valid adjunct to oral medication in the attempt to address persistent wound pain in people with longstanding hard to heal wounds.