# Accel-Heal: Evidence Compendium


Accel Heal Solo

ELECTRICAL STIMULATION WOUND THERAPY

## Evidence levels*:

### Purpose of this document:

The purpose of this compendium is to describe the evidence supporting the use of electrical stimulation therapy (EST), in particular the EST device Accel-Heal, in the management of hard-to-heal wounds.

### List of contents:



### Abbreviations:

| | |
|---|---|
| **CI** | Confidence interval |
| **DFU** | Diabetic foot ulcer |
| **EWMA** | European Wound Management Association |
| **EST** | Electrical stimulation therapy |
| **HCP** | Health care professional |
| **HE** | Health economic |
| **IPUAP** | International Pressure Ulcer Advisory Panel |
| **MD** | Mean difference |
| **MoA** | Mode of action |
| **NRS** | Numerical rating scale |
| **PU** | Pressure ulcer |
| **QoL** | Quality of life |
| **RCT** | Randomised controlled trial |
| **SWC** | Standard wound care |
| **T2D** | Type 2 diabetes |
| **VAS** | Visual analogue scale |
| **VLU** | Venous leg ulcer |

### How to navigate:

Click on the home button to return to this page

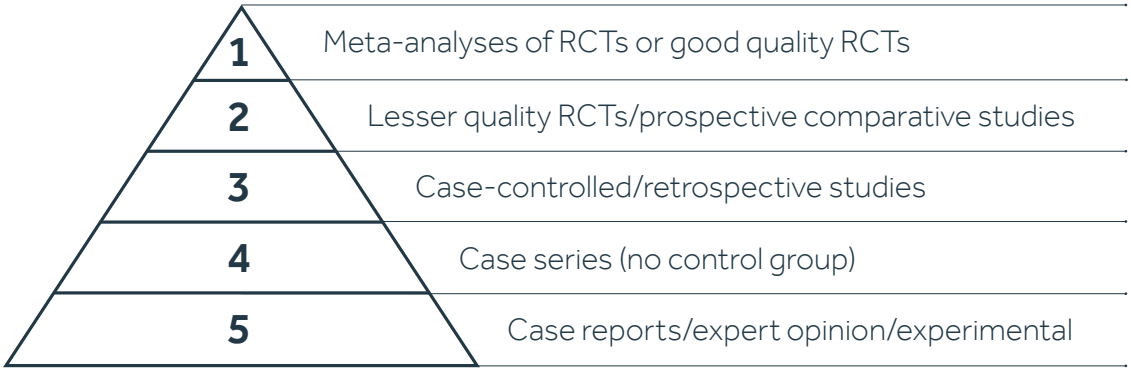
Click on the link for more information

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress

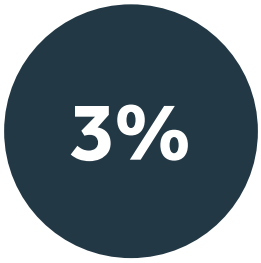
Colour coded by category of evidence

Evidence pyramid, highlight the evidence level of each paper.

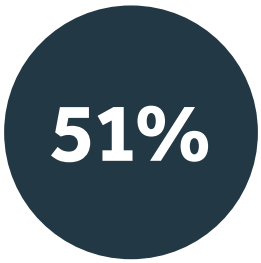



*According to the Oxford Centre for Evidence Based Medicine (OECBM). For more detail click here

## Context: the burden of chronic wounds

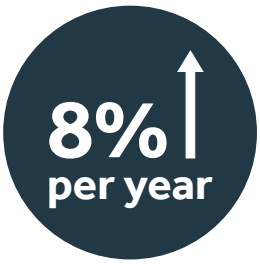


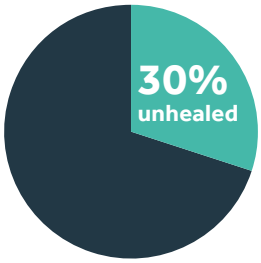

**Chronic wounds are common...**
3% of the total adult population are estimatedto have a chronic wound every year*



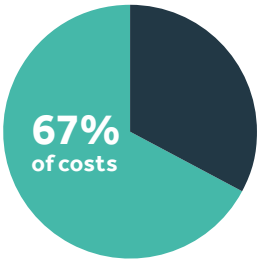

**...and typically of long-duration**
Over half of all chronic wounds fail to healwithin 12 months-*

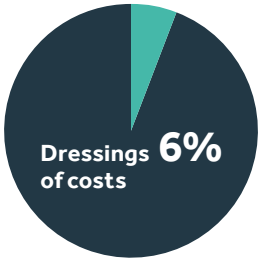
**The financial burden of woundcare is substantial**
Costs vary between countries. In the UK and USA,the annual costs of managing wounds have been estimated as £8.3bn* and $28.1bn^ (conservative estimate), respectively. The cost of wound care is increasing as populations age and more people are living with risk factors for chronic wounds*^




**Failure to heal has a majoreffect on costs**
30% of all wounds do not heal within 12 months
These unhealed wounds accounted for two-thirds of the total costs of wound management* meaning that chronic wounds are costing disproportionately more than acute wounds.




**The greatest costs are relatedto HCP visits**
Whereas wound care products accounted for only 6% the total cost of wound care...*

... HCP visits accounted for over half of all costs*

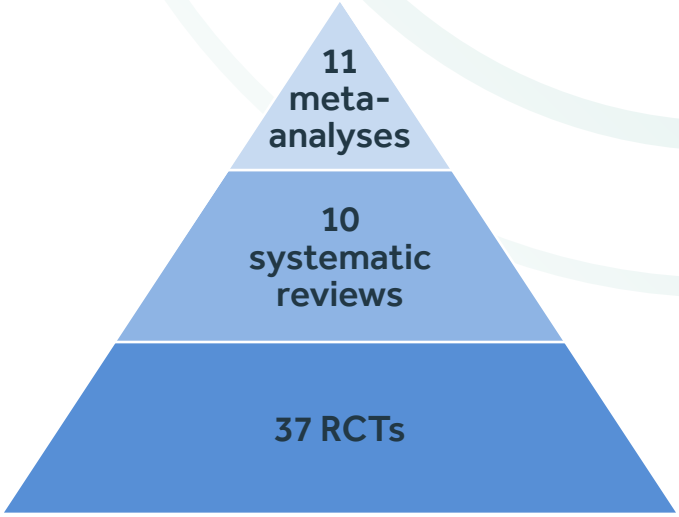

Treatments that can effectively speed up the time to healing, thereby reducing the current burden on healthcare resources, are likely to have a positive health economic impact. One treatment modality with potential to achieve this is electrical stimulation therapy (EST). This compendium describes the evidence supporting the use of EST in the management of hard-to-heal wounds, in particular Accel-Heal an EST device that delivers a micro-current level of electrical stimulation.

*Based on data from UK; Guest JF et al. BMJ Open 2020;10:e045253.
^Data from USA. Sen C. Adv. Wound Care 2019;8(2):39-48.

## Electrical Stimulation Therapy (EST)

Electrical stimulation therapy (EST) is one of the most widely evidence-based therapy areas in wound management. The extensive evidence base includes eleven meta-analyses (listed below), ten systematic reviews and over 35 RCTs, that describe the efficacy of EST in wound management.

Although the EST described in these studies is delivered via a variety of formats and stimulation parameters, this evidence base does provide a high level of validity and confidence in the science, mode of action and clinical effect of this technology platform.




## EST is recognised in wound care guidelines and recommendations*^

Electrical stimulation is effective in treating a wide range of wound types including VLU,DFU, PU and mixed ulcers*

"Consider the use of direct contact (capacitive) electrical stimulation to facilitate wound healing in recalcitrant Category/ Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers."^

### Meta-analyses:

Nine meta-analyses support the ability of EST to enhance wound-related outcomes.

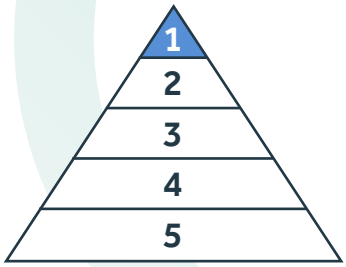
Girgis et al (2023)
Chen et al (2023)
Avendaño-Coy et al (2021)
Arora et al (2020) - Cochrane review
Chen et al (2020)
Girgis et al (2018)
Khouri et al (2017)
Lala et al (2016)
Liu et al (2016)
Barnes et al (2014)
Gardner (1999)

For links to more information **click here**

* Piaggesi et al. J Wound Care, 2018; 27(6), Suppl 6.
^ NPUAP. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. (Haesler E, ed.). Osborne Park, Australia: Cambridge Media; 2014

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




## EST evidence base – list of published meta-analyses

| AUTHOR (YEAR) | TITLE | CITATION | WOUND TYPE | MAIN FINDINGS | LINKS* |
|---|---|---|---|---|---|
| **Girgis et al (2023)** | The effect of high-voltage monophasic pulsed current (HVMPC) on diabetic ulcers and their potential pathophysiologic factors: A systematic review and meta-analysis. | Wound Repair Regen. 2023 Mar;31(2):171-186. | DFU and pressure ulcers | idence for treatment of DFU with EST is growing; confirmed observations that EST is helpful in pressure ulcers | Pubmed click here |
| **Chen et al (2023)** | Effectiveness and safety of electrical stimulation for treating pressure ulcers: A systematic review and meta-analysis. | Int J Nurs Pract. 2023 Apr;29(2):e13041 | Pressure ulcers | EST is a safe and effective treatment for pressure ulcers | Pubmed click here |
| **Avendaño-Coy et al (2021)** | Electrical microcurrent stimulation therapy for wound healing: A meta-analysis of randomized clinical trials | J Tissue Viability. 2021 Dec 4:S0965-206X(21)00132-7. | Any chronic ulcers | Focussed on microcurrent EST. 8 RCTs analysed.EST decreases wound area and decreased pain vs standard care | Pubmed click here<br>Synopsis click here |
| **Arora et al (2020)** | Electrical stimulation for treating pressure ulcers. Cochrane | Database Syst Rev. 2020 Jan 22; 1(1):CD012196. | Pressure ulcers | Cochrane review. | Pubmed click here<br>Synopsis click here |
| **Chen et al (2020)** | Electric Stimulation as an Effective Adjunctive Therapy for Diabetic Foot Ulcer: A Meta-analysis of Randomized Controlled Trials. | Adv Skin Wound Care. 2020 Nov; 33(11):608-612. | DFU | 7 RCTs analysed. Faster healing at 4- and 12-weeks with EST vs control. | Pubmed click here<br>Synopsis click here |
| **Girgis et al (2018)** | High Voltage Monophasic Pulsed Current (HVMPC) for stage II-IV pressure ulcer healing. A systematic review and meta-analysis. | J Tissue Viability. 2018; 27(4):274-284. | Pressure ulcers | EST decreases wound area; EST increases chance of healing | Pubmed click here |
| **Khouri et al (2017)** | Hierarchical evaluation ofelectrical stimulation protocols for chronic wound healing: An effectsize meta-analysis. | Wound Repair Regen. 2017 Sep; 25(5):883-891 | Various chronic wounds | EST enhances healing of chronic wounds | Pubmed click here |
| **Lala et al (2016)** | Electrical stimulation therapy for the treatment of pressure ulcers in individuals with spinal cord injury: a systematic review and meta-analysis. | Int Wound J. 2016; 13(6): 1214-1226. | Pressure ulcer (spinal cord patients) | EST decreases wound area; EST increases chance of healing | Pubmed click here |
| **Liu et al (2016)** | A Quantitative, Pooled Analysis and Systematic Review of Controlled Trials on the Impact of Electrical Stimulation Settings and Placement on Pressure Ulcer Healing Rates in Persons With Spinal Cord Injuries. | Ostomy Wound Manag. 2016; 62(7):16-34. | Pressure ulcer (spinal cord patients) | EST increases rate of healing | Pubmed click here |
| **Barnes et al (2014)** | Electrical stimulation vs. standard care for chronic ulcer healing: A systematic review and meta-analysis of randomised controlled trials. | Eur J Clin Invest. 2014; 44(4):429-440. | Chronic ulcers | EST increases rate of healing | Pubmed click here |
| **Gardner et al (1999)** | Effect of electrical stimulationon chronic wound healing: ameta-analysis. | Wound Repair Regen. 1999; 7(6):495-503. | Chronic ulcers | EST increases rate of healing | Pubmed click here |

*Synopses provided for all meta-analyses published in the previous 5-years (2017 to 2022)

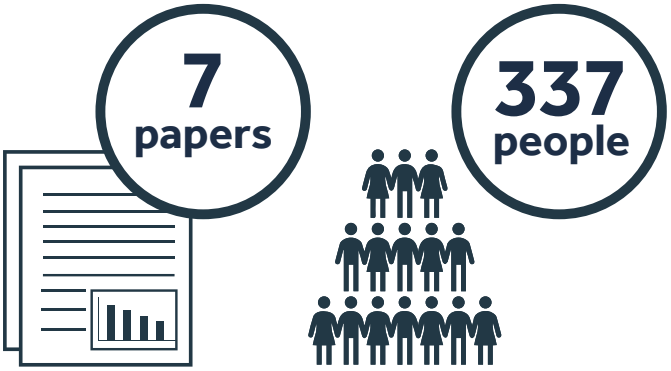
# KEY MESSAGE: MICROCURRENT EST IS AN EFFECTIVE, SAFE TREATMENT FOR IMPROVING WOUND AREA, HEALING TIME, AND PAIN IN A RANGE OF WOUND TYPES

EST delivered at microcurrent levels* consists of the application of low intensity (μA) currents that are similar to endogenous electric fields generated during wound healing.

The aim of this meta-analysis was to examine the effectiveness and safety of EST*, with a focus on microcurrent-based treatments, for improving wound healing and pain in people with acute or chronic wounds.

## What was assessed?

- RCTs
- Published up to August 2020
- Limited to 'microcurrent'-based EST (<1mA)
- Compared EST with SWC




## Compared with standard woundcare (SWC), wounds treated with micro-current EST:^

**8.3cm² smaller**

Reduced significantly more in size (CI 95%: -10.5 to -6.0; p<0.00001)

**7 days faster**

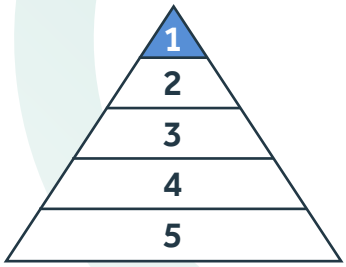
Healed significantly faster (-7.0 days; CI 95%: -11.9 to -2.1; p=0.005)

Were less painful (-1.4 (on the VAS scale from 0-10); CI 95%: -2.7 to –0.2; p=0.0008)

No significant difference in adverse events (p=0.87)

**Conclusion and interpretation:** This meta-analysis supports the hypothesis that incorporating microcurrent EST* to SWC improves healing by reducing the wound area and time to complete healing. of This has been observed in both acute and chronic wounds. Microcurrent EST was also confirmed to reduce the patient's perception of wound pain and has proven to be a safe technique with few minor side effects. The effect on the healing time is thought to be of particular importance in chronic wounds due to the large burden placed on healthcare systems by these wounds.

CITATION: Avendaño-Coy J, López-Muñoz P, Serrano-Muñoz D, Comino-Suárez N, Avendaño-López C, Martin-Espinosa N. Electrical microcurrent stimulation therapy for wound healing: A meta-analysis of randomized clinical trials. J Tissue Viability. 2021 Dec 4:S0965-206X(21)00132-7.
*specifically in this paper, "electrical microcurrent therapy" (EMT) ^ data are expressed as mean difference between EST and SWC.




## KEY MESSAGE: FOCUSSING ON PRESSURE ULCERS ONLY, THIS COCHRANE META-ANALYSIS DEMONSTRATES THAT EST 'PROBABLY' INCREASES THE PROPORTION AND RATE OF HEALING

Some of the earliest clinical studies describing the effects of EST were carried out in pressure ulcers. This review provides an up to date overview of all previous EST-based evidence reported in this indication.

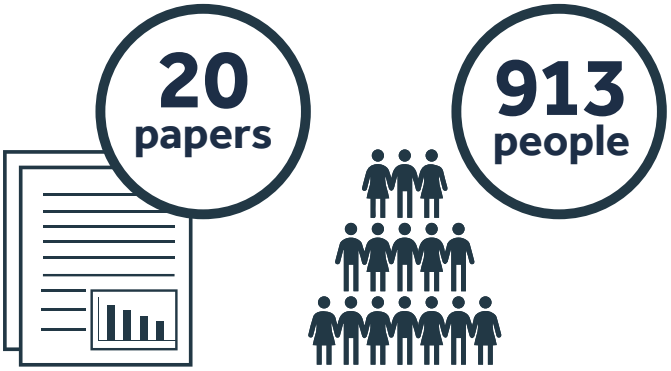
The aim of this meta-analysis was to determine the effects (benefits / harms)of EST for treating pressure ulcers

### What was assessed?

- RCTs
- Published up to July 2019
- Limited to pressure ulcers

Included any type of EST

- Compared EST with no EST




Cochrane Library

### Compared with no EST, pressure ulcers treated with EST:


Are almost twice as likely to heal (RR 1.99, 95% CI,1.39 to 2.85)


Have an increased rate of pressure ulcer healing compared with no EST(MD* 4.59% per week,* 95% CI 3.49 to 5.69)

Heterogeneity between studies did not permit a pooled analysis of:

- Reduction in wound area/size
- Adverse events

**Conclusion and interpretation:** There is evidence to suggest that EST is effective in the treatment of pressure ulcers. The results of this thorough meta-analysis identified that EST 'probably' increases the proportion of pressure ulcers healed and the rate of pressure ulcer healing, these statements being qualified because of the 'moderate' certainty evidence upon which they are based. For some other outcomes (time to healing, reduction in surface area, AE) due to the low quality of the evidence and/or heterogeneity, it was not possible to determine an overall effect of EST when applied to pressure ulcers.

CITATION: Arora M, Harvey LA, Glinsky JV, Nier L, Lavrencic L, Kifley A, Cameron ID. Electrical stimulation for treating pressure ulcers. Cochrane Database Syst Rev. 2020 Jan 22;1(1):CD012196. *represents mean difference.

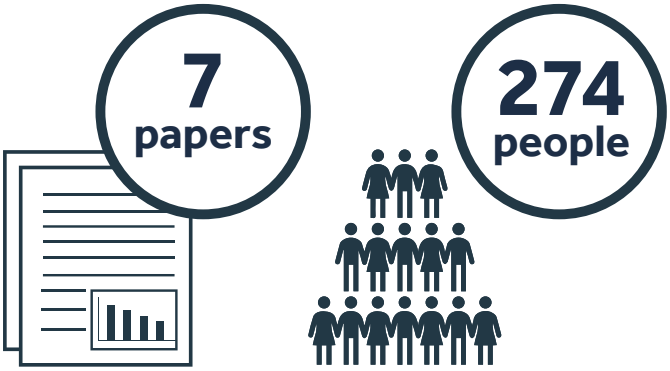
# KEY MESSAGE: IN THIS META-ANALYSIS FOCUSSING ON DFU, TREATMENT WITH EST WAS SHOWN TO IMPROVE OUTCOMES

In people living with diabetes the healing process can be impaired. New technologies to improve the outcomes for people with DFU are needed.

The aim of this meta-analysis was to evaluate the effectiveness of EST for diabetic foot ulcer (DFU) treatment

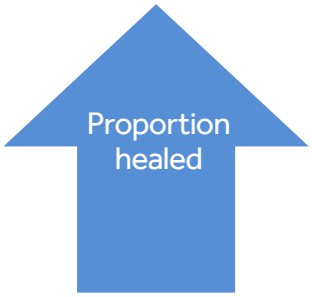
## What was assessed?

- RCTs
- Published up to March 2019
- Studies reporting DFU
- Comparing EST with SWC




## Compared with standard wound care, DFU treated with EST:


Had a significantly greater % decrease in area after 4-weeks (MD* = 1.09; 95% CI, 0.62–1.57; P < .001).




Were statistically more likely to achieve healing after 12-weeks (risk difference, 0.19; 95% confidence interval, 0.06–0.32; P = .005).

**Conclusion and interpretation:** This meta-analysis demonstrates that EST, as an adjunct to best practice wound care, and wider diabetes care, may accelerate the healing of DFU and may be an effective adjunctive therapy for these complex wounds.

CITATION: Chen Z, Chen ZY, Liu WH, Li GS. Electric Stimulation as an Effective Adjunctive Therapy for Diabetic Foot Ulcer: A Meta-analysis of Randomised Controlled Trials. Adv Skin Wound Care. 2020 Nov;33(11):608-612. *represents mean difference.

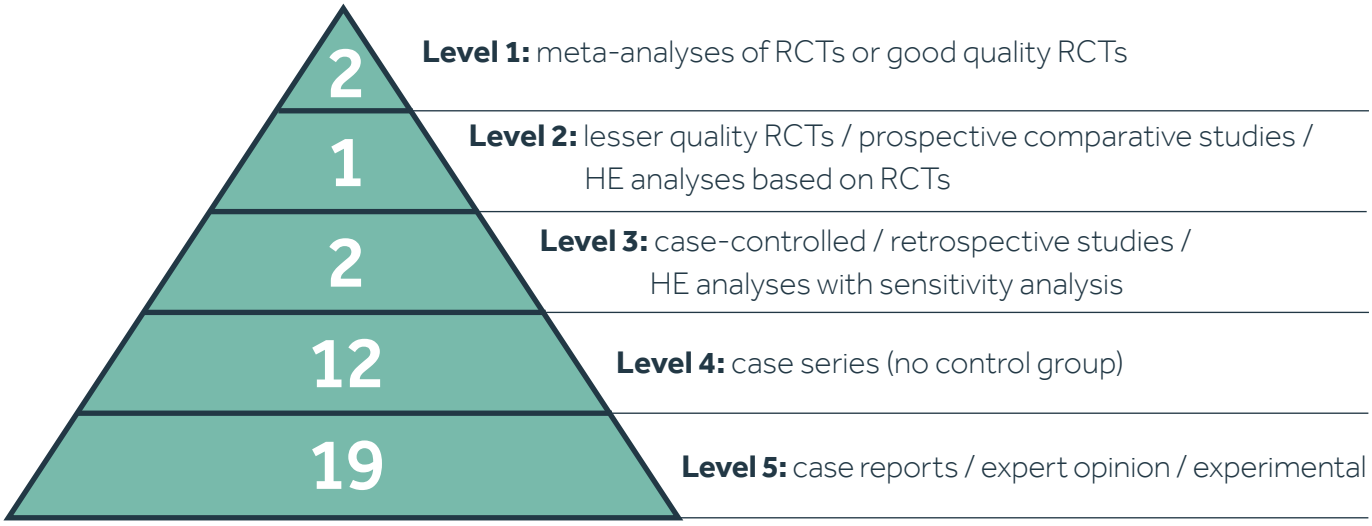
## Accel Heal evidence base


Currently 36 original publications including 19 papers, and 17 posters (with unique data) specifically describe the clinical application of Accel-Heal.*

These publications represent the data of 328 individual patients**

This includes two double blind, placebo controlled RCTs, the first, a clinical study on patients with VLUs and the second, a volunteer mode of action study.

Three Health economic studies are classed as level 2 or 3 evidence.†




For the purposes of this compendium, evidence has been categorised.
Please click on the buttons at the top of the page to explore the different categories.

*Posters containing data subsequently published as a full clinical paper are not included here, to avoid double-counting.
** includes patients in both arms of RCTs
†Evidence graded according to the Oxford Centre for Evidence Based Medicine (OECBM). For more detail click here

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress

## Accel-Heal evidence base – list of key published papers

| AUTHOR | TITLE | CITATION | WOUND TYPE | LINKS* |
|---|---|---|---|---|
| Guest et al | Cost-effectiveness of an electroceutical device in treating non-healing venous leg ulcers: results of an RCT | J Wound Care. 2018;27(4):230-243 | VLU | Synopsis - click here |
| Chapman-Jones D, Young S. | Assessment of wound healing following electrical stimulation with Accel-Heal | Wounds UK 2010. 6:67-71 | VLU | Synopsis - click here |
| Ovens L. | Application of Accel-Heal for patients with chronic venous leg ulcers: an evaluationin a community UK NHS trust. | Wounds 2019; 15(3):78-84 | VLU | Synopsis - click here |
| Turner N, Ovens L. | The results of a clinical evaluation ofAccel-Heal electroceutical treatmentin a large NHS Trust. | Wounds UK 2017; 13(4): 80 . | VLU | Synopsis - click here |
| Griffin J | Improving outcomes through innovation: An evaluation of Accel-Heal in chronic wounds. | Wounds UK 2013: 9 (4):118-121. | VLU | Synopsis - click here |
| Kurz P et al | Activation of healing and reduction of pain by single-use automated microcurrent electrical stimulation therapy in patients with hard-to-heal wounds. | Int Wound J. 2023 doi: 10.1111/iwj.14071 | Chronic wounds | Synopsis - click here |
| Danner G et al. | Clinical Evaluation of the Response Rate to a Continuously Active, Single-use Electrical Stimulation Device in Static Non-Healing Wounds. | Wound Masterclass. 2022; 1:1-4. | Chronic wounds | Synopsis - click here |
| Ovens L. | Electrical stimulation therapy and electroceutical treatment for the management of venous leg ulcers. | Community Wound Care 2017; March: S28-36. | VLU | Synopsis - click here |
| Ovens L. | Using electroceutical treatment toreduce symptoms and improve healing in chronic wounds. | Primary Health Care 27:(6)22-27 | VLU | Synopsis - click here |
| Ovens L. | Getting it right for patients and budgets. | Wounds UK, 2015: 11 (3):96-101 | VLU | Synopsis - click here |
| Greaves T. | Improving patient quality of life with innovative electroceutical technology | Wounds 2014; 10(3): 81-88 | VLU | Synopsis - click here |
| Guest et al | Clinical outcomes and cost effectiveness of an externally applied electroceutical-. device in managing venous leg ulcers in clinical practice in the UK. | J. Wound Care 2015; 24(12) | VLU | Synopsis - click here |
| Taylor et al | Modelling the cost-effectiveness of electric stimulation wwtherapy in non-healing venous leg ulcers. | J. Wound Care 2011; 20 (10):464-472. | VLU | Synopsis - click here |
| Lalyatt et al | Changes in S100 Proteins Identified in Healthy Skin following Electrical Stimulation: Relevance for Wound Healing. | Adv Skin Wound Care. 2018;31 (7):322-327. | Intact skin – volunteer study | Synopsis - click here |
| Young et al | Study to evaluate the effect of low-intensity pulsed electrical currents on levels of oedema in chronic non-healing wounds. | J Wound Care. 2011 Aug;20(8):368, 370-3. | VLU | Synopsis - click here |

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress

## Accel-Heal evidence base – list of key published posters*

| AUTHOR | TITLE | CONFERENCE | WOUND TYPE | LINKS* |
|---|---|---|---|---|
| Tadej et al | Accel-Heal: a new therapy forchronic wounds. | J. Comm. Nurs. 2010; 24(5):16-20. | Non-healing wounds | Synopsis - click here |
| Lim P, et al | Automated electrical stimulation therapy accelerates reepithelialization in a 3D in vitro human skin wound model | Adv Wound Care. 2023 Dec 7. doi: 10.1089/wound.2023.0018 | In vitro MoA study | Synopsis - click here |
| Nair HK | Powering the progression of hard-to-heal with electrical stimulation: an observational analysis of wounds treated with Accel-Heal® | Wounds Asia 5(2): 38-47 | Various chronic wounds | Synopsis - click here |
| Allan and Ovens | Improving Quality of Life Using a Novel Electrical Stimulation Therapy Device to Reduce Pain and Accelerate Healing in Two Patients With Very Different Underlying Aetiologies | Wound Masterclass 2022; 1 | Ulcerated lupus rash | Synopsis - click here |
| Clarke and Ovens | Stepping up treatment with active interventions for hard-to—heal wounds using EST Accel-Heal Solo: a case series demonstrating the benefits of using a simple 12-day EST to stimulate healing when combined with standard care | Poster presented at Wounds UK 2023 | VLU / insect bite | Synopsis - click here |
| Wallace and Leyfleurrie | Wake up that hard-to-heal wound: the transformative effects of using a wearable 12-day EST device on pain reduction and wound healing - an observational study | Poster presented at EWMA, May 2023, Milan, Italy | VLU / mixed ulcers | Synopsis - click here |
| Ovens L | Supporting the Triple Aim Framework1 objectives in Scotland using an innovative electroceutical therapy* to improve clinical and economic benefits for patients with venous leg ulcers (VLUs). | EWMA 2019 | VLU | Synopsis - click here |
| Leyfleurrie K | Hopelessness to healing and hope | TVS, 2023 | VLU | Synopsis - click here |
| Maniya S | Use of continuous electical stimulation in a chronic leg ulcer: a local experience | EWMA, 2023 | VLU | Synopsis - click here |
| Alktebi S, Al Adab A | Use of a novel electrical stimulation device to kick start healing in two patients with lower limb ulcers complicated by diabetes mellitus. | WUWHS, 2022 | DFU | Synopsis - click here |

*Note that posters whose data were subsequently published within a full paper are not shown here.

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress

## Accel-Heal evidence base – list of key published posters cont.*

| | | | | |
|---|---|---|---|---|
| Kiernan C, et al | Effectiveness of a single-use, portable, electrical stimulation device in vascular foot ulcers. | EWMA 2020 | Vascular foot ulcers | Synopsis - click here |
| Terrill P, Ovens L | An innovative approach to manage pain and stimulate healing in arterial ulcers using electrical stimulation therapy. | EWMA 2022 | Arterial ulcer | Synopsis - click here |
| Moon M, Hazell D, Hawes L | Reduction in wound pain associated with electrical stimulation therapy results in a corresponding decrease in analgesic consumption: an evaluation of patients with painful leg ulcers | Wounds UK 2023 | VLU / other | Synopsis - click here |
| Turner N, Ovens L. | Clinical outcome results and quality of life improvements using electroceutical treatment - Patient perspectives | EWMA 2017 | VLU | Synopsis - click here |
| Cancela, C et al | Ease of use of wearable, single-use electrical stimulation device for the management ofhard-to-heal wounds. | EWMA 2022 | Variety of wound types | Synopsis - click here |
| Louison P.. | Management of recurrent venous leg ulcer with electroceutical therapy* to improve pain, expedite healing and reduce risk of recurrence | EWMA 2015 | VLU | Synopsis - click here |
| Layflurrie and Ovens | What can we do differently. | Wounds UK, 2021 | VLU | Synopsis - click here |
| Posnett et al | Cost-effectiveness of a single-use, portable electrical stimulation device in the managementof venous leg ulcers. | EWMA 2020 | VLU | Synopsis - click here |

*Note that posters whose data were subsequently published within a full paper are not shown here.

## Accel Heal evidence - wound outcomes by indication

Accel-Heal is indicated for use in wounds that are not healing as expected including:

- Venous leg ulcers (VLU)
- Diabetic foot ulcers (DFU)
- Pressure ulcers (PU)
- Arterial ulcers
- Mixed ulcers
- Delayed post-surgical wounds
- Wounds where pain is restricting a patientsmobility, or from tolerating some treatments such as compression therapy


The ability of Accel-Heal to improve clinical outcomes has been assessed in many of these wound types. Please click on the items below for more information, categorised by indication.

### VLU:

- Guest et al (2018) → RCT
- Chapman-Jones et al (2010)
- Wallace et al (2023)
- Clarke (2023)
- Ovens (2019)
- Turner and Ovens (2017)
- Ovens (2019)
- Griffin et al (2013)
- Lefleurrie (2023)
- Maniya (2023)

### DFU:

- Alktebi and Al-Adab (2022)

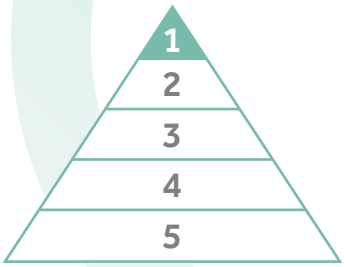
### Other:

- Nair (2022) – variety of wound types
- Allan and Ovens (2022) - ulcerated lupus rash
- Kiernan et al (2020) - vascular ulcers
- Terrill and Ovens (2022) - arterial ulcer

**Click on each item of evidence for more information**

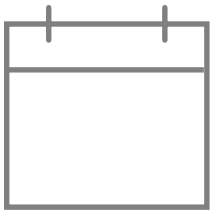
VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

Click here to view the online article | EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: IN A RANDOMISED CONTROLLED TRIAL IN PATIENTS WITH VLU, ACCEL-HEAL WAS SHOWN TO BE EFFECTIVE

The aim of this study was to assess the effect of Accel-Heal on the healing rate of venousleg ulcers (VLUs) and its impact on overall treatment cost



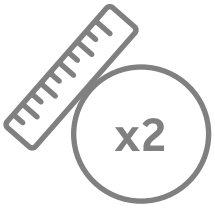
Mean time to healing was shorter by 0.9 months

## Methods:

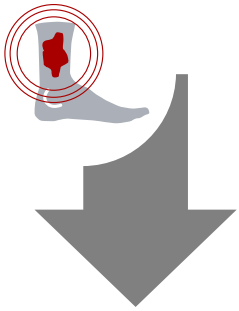
A randomised, double-blind, placebo-controlled trial:

Standard care + sham device (placebo, n=50)

Standard care + Accel-Heal (n=49)



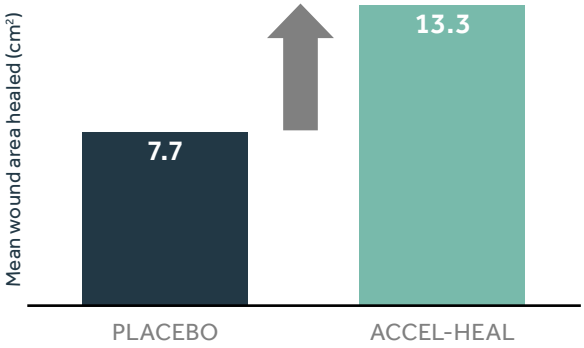

Almost twice the wound area healed with Accel-Heal compared with standard care alone (13.3 vs 7.7cm2)



Wound pain decreased during treatment with Accel-Heal to a greater extent than with standard care

## Results:

1.7-times increase in rate of healing





Patients treated with Accel-Heal reported improved social functioning and wellbeing

Conclusion and Interpretation: The double blinded, placebo controlled clinical RCT of 99 patients, showed differences in healing rates at 8, 12 and 24 weeks, but these did not reach significance. The trial was confounded by significant variances in treatment practices across the centres (current practise was not standardised), and the two groups were vastly heterogeneous; for example the wounds that received Accel-Heal, that healed were on average twice as old as those receiving sham treatment. Nevertheless, the trends were very encouraging with those wounds treated with Accel-Heal that went on to heal doing so a month faster than sham treated wounds, and the mean reduction in wound area being twice that of placebo. More recent learning would suggest that, given the long prior duration of these wounds a 2nd or 3rd treatment with Accel-Heal may have been merited.

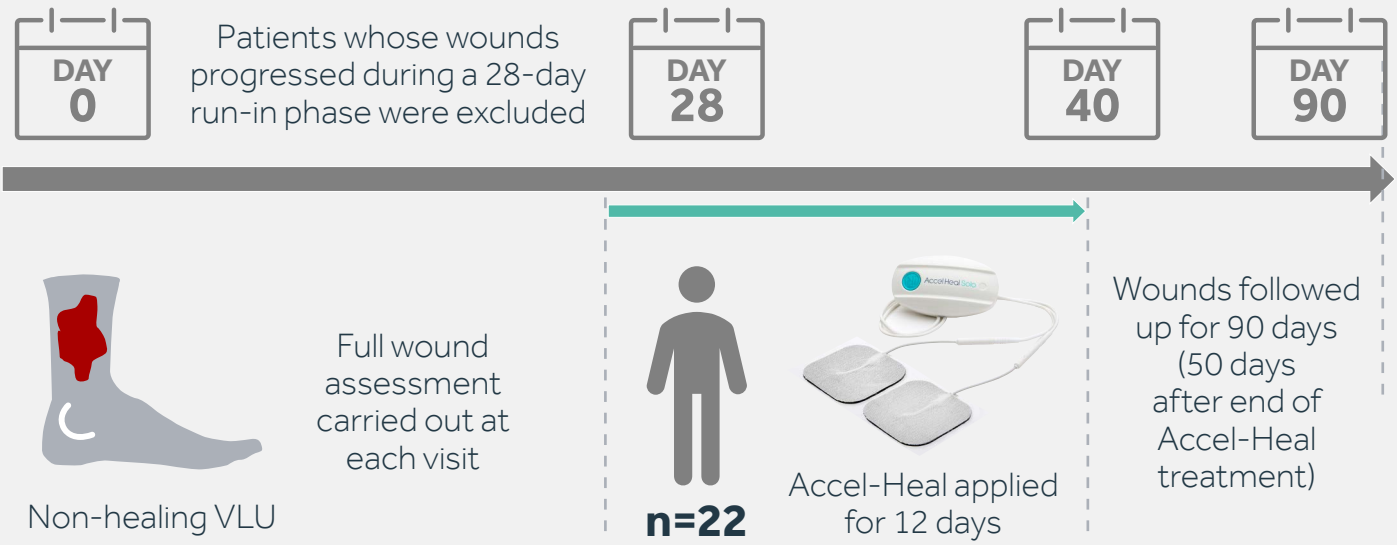
CITATION: Guest J, Singh H, Rana K, Vowden P. Cost-effectiveness of an electroceutical device in treating non-healing venous leg ulcers: results of an RCT. J Wound Care. 2018;27(4):230-243

# KEY MESSAGE: IN A REAL-WORLD STUDY, 95% OF STALLED VLUS RESPONDED POSITIVELY TO TREATMENT WITH ACCEL-HEAL

## Introduction:

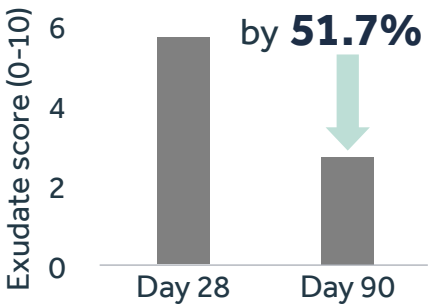
Hard to heal wounds are a resource and financial burden to healthcare systems like the the NHS. In the authors' opinion, mechanical treatment modalities, like electrical stimulation will become increasingly beneficial in chronic wound care.

The objective was to evaluate the clinical and cost-effectiveness of wound healing following the application of **Accel-Heal**.

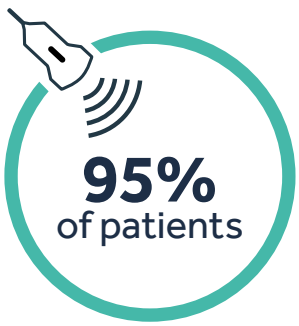



## Pain decreased


## Exudate reduced:




## Healing improved:




Conclusion and interpretation: The wounds in this evaluation had been shown to be unresponsive to gold standard treatments such as compression. The fact that 95% of these wounds subsequently responded to Accel-Heal leading to improved healing was meaningful.

CITATION: Chapman-Jones D, Young S. Assessment of wound healing following electrical stimulation with Accel-Heal Wounds UK 2010; 6 :67-71.

# KEY MESSAGE: AFTER TREATMENT WITH ACCEL-HEAL SOLO, 94% OF THE CLINICAL OBJECTIVES SET BY THE CLINICIANS AND PATIENTS WERE MET

## Introduction:

The current of injury dissipates in hard-to-heal wounds and wounds become "dormant". An observational study was undertaken to demonstrate the effectiveness of **Accel-Heal Solo** on pain reduction and wound healing, for patients with hard-to-heal wounds attending a community leg clinic

The aims of the study were to explore the ability of **Accel-Heal Solo** to reduce case-load, to improve outcomes in wounds of longer than 1-year duration and the ability to improve the Local Quality Requirement of healing at 12 and 24 weeks

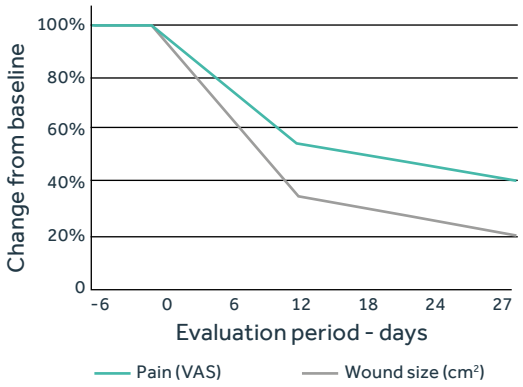
- Mean wound duration; 25 months
- Mean wound size; 64.27 cm2
- VLU (n= 7); mixed ulcer (n= 4)
- Mean pain score was 5.1/10 (VAS) (range 0-10)
- 6 patients were taking regular analgesia

**DAY 0** Accel-Heal Solo applied

**DAY 12** Accel-Heal Solo treatment completed

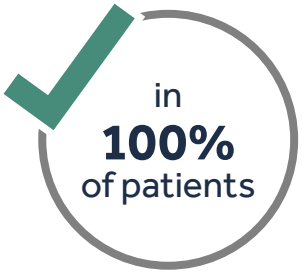
**Follow up -** healing up to day 27

Wound size and pain both reduced within the 12-day treatment time and reduced further by the end of the 27 day study period

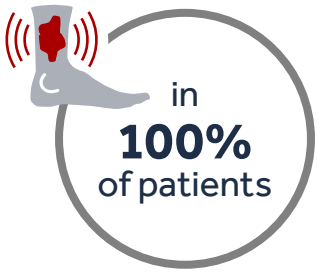



## Results:

### Healing improved:




### Pain reduced:




**"An excellent wound treatment, never fails to improve patient comfort and increase healing rate time."**

**Clinician**

Conclusion and interpretation: Application of Accel-Heal Solo, a unique, compact, easy to use EST, replaces the dissipated current of injury in the patient's wound and can "wake up" the wound healing process as well as reducing pain, when used alongside standard care.

CITATION: Wallace and Leyfleurrie. Wake up that hard-to-heal wound: the transformative effects of using a wearable 12-day electrical stimulation (EST) device on pain reduction and wound healing - an observational study. Poster presented at EWMA, May 2023, Milan, Italy.

Click here to view the online article

VLU - healing outcomes

DFU - healing outcomes

Other - healing outcomes

Mode of action

EST evidence base

Patient benefits

Health Economic benefits

Evidence in-progress

1
2
3
4
5

## KEY MESSAGE: THIS ARTICLE EXAMINED THE USE OF ACCEL-HEAL SOLO IN THREE CASE STUDIES IN SOME VERY CHALLENGING LEG ULCERS

Three hard-to-heal wounds with venous aetiology were unresponsive despite best-practice.

### Patient 1

- 93 year old female
- VLU, 8 months duration
- Pain 3/10
- Wound area, 7.5cm$^2$

### Patient 2

- 68 year old male
- Necrotising fasciitis with venous aetiology
- 8-year duration
- Pain 6.5/10

### Patient 3

- 82 year old male
- VLU, 9 months
- Pain 5.5/10
- Small wound


**Accel-Heal Solo applied for 12-days along-side compression therapy in all cases**

Wound pain reduced to 0 after 12-days

wound healed within **12 days**

Wound pain reduced from 6.5 to 3.5 within days

Exudate reduced, meaning less bulky dressings

Wound pain reduced to 0 after 12-days

wound healed within **42 days**

Conclusion and Interpretation: Accel-Heal Solo, in combination with standard care, was believed to have kick-started the wound healing process in all 3 complex wounds with good outcomes in all three patients. The reduction in pain during and following Accel-Heal Solo, had a significant effect on improving their quality of life, which had not previously been managed with analgesia.

CITATION: Clarke and Ovens. Stepping up treatment with active interventions for hard-to-heal wounds using EST Accel-Heal Solo: a case series demonstrating the benefits of using a simple 12-day EST to stimulate healing when combined with standard care. Poster presented at Wounds UK, Harrogate, 2023.

# KEY MESSAGE: IN A REAL-WORLD STUDY, 88% OF PATIENTS TREATED WITH ACCEL-HEAL WENT ON TO HEAL WITHIN 20-WEEKS

With standard care, the average cost of treating a VLU in the UK is estimated to be **£13455** per year, with only 53% of wounds likely to heal within this timeframe.

This evaluation aimed to determine the clinical outcomes and clinician feedback of using **Accel-Heal** in the treatment of VLUs and to assess the cost implications.

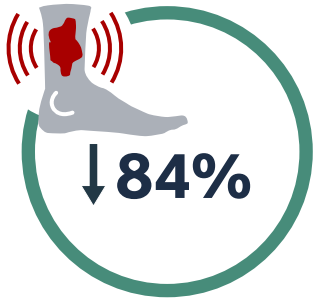
- n=8
- 50% female
- Mean age = 73 years

Non-progressing VLU despite compression


Accel-Heal applied for 12 days

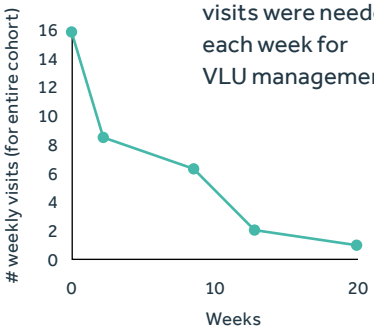
Regular assessments for up for 20 weeks


**of patients healed within 20 weeks**




In wound pain within 2 weeks from 4.3 to 0.7/10


As patients healed they reduced the overall caseload being managed by the team...




...meaning fewer visits were needed each week for VLU management

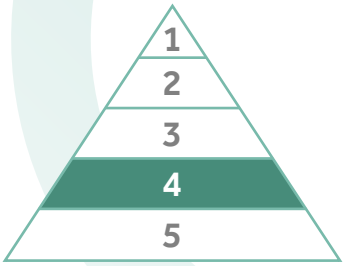
Conclusion and Interpretation: Implementation of Accel-Heal at an optimal time on the patient's care pathway can significantly improve wound healing and reduce the burden of chronic wound care. The protocol used in this evaluation suggests that if a patient is unhealed after 8 weeks of standard care, then addition of Accel-Heal should be considered.

CITATION: Ovens L. Application of Accel-Heal for patients with chronic venous leg ulcers: an evaluation in a community UK NHS trust.Wounds 2019; 15(3):78-84.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress



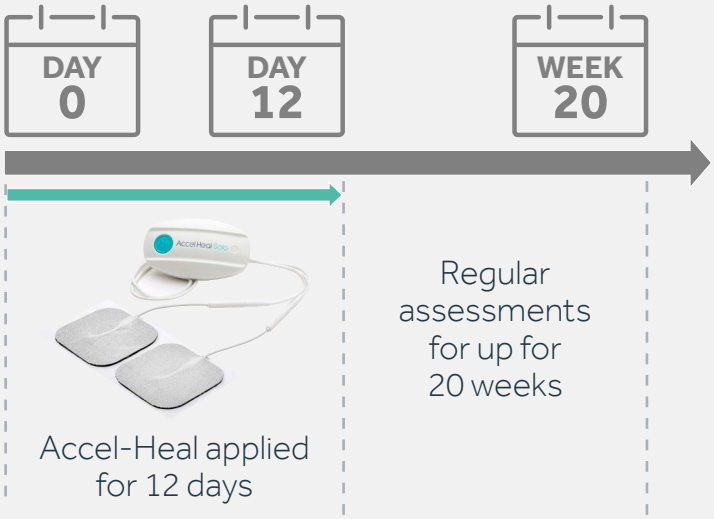

## KEY MESSAGE: IN A REAL-WORLD ANALYSIS, 84% OF PATIENTS TREATED WITH ACCEL-HEAL WENT ON TO HEALING WITHIN 20-WEEKS

The cost of leg ulcers in the UK has been estimated to be **£1.94 billion**. There is a need for more cost-effective treatments. Electrical stimulation may be of benefit.

The objective of this study was to establish the clinical outcomes and experiences for patients and healthcare professionals of using **Accel-Heal**.

- n=17

- 16 VLU, 1 mixed
- 29 weeks duration




**84%**

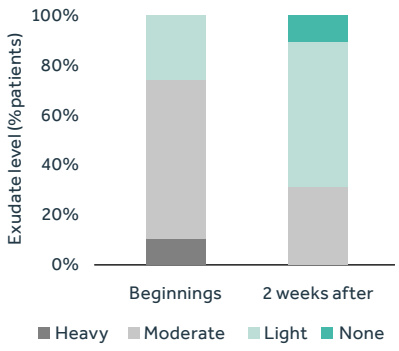
**of patients healed within 20 weeks**

### Pain decreased

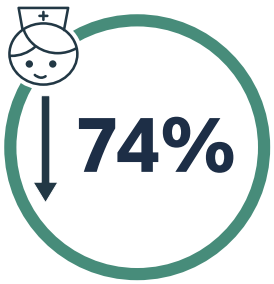

Within 2 weeks

Some patients were able to discontinue their analgesia (gabapentin / morphine)

### Exudate reduced




### Fewer nursing visits




Over 20 weeks

This led to lower overall treatment costs compared with non-healing wounds.

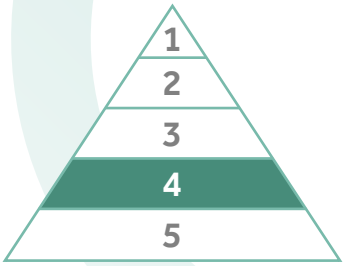
Conclusion and Interpretation: Accel-Heal was an effective treatment; all patients achieved reduced wound size, as well as reduced pain and exudate within 2 weeks of treatment, improving patient quality of life. The majority of wounds healed within the 20 week follow up. Fewer nursing visits were needed leading to reduced cost for the Trust.

CITATION: Turner N, Ovens L. The results of a clinical evaluation of Accel-Heal electroceutical treatment in a large NHS Trust. Wounds UK 2017; 13(4): 80-99.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress



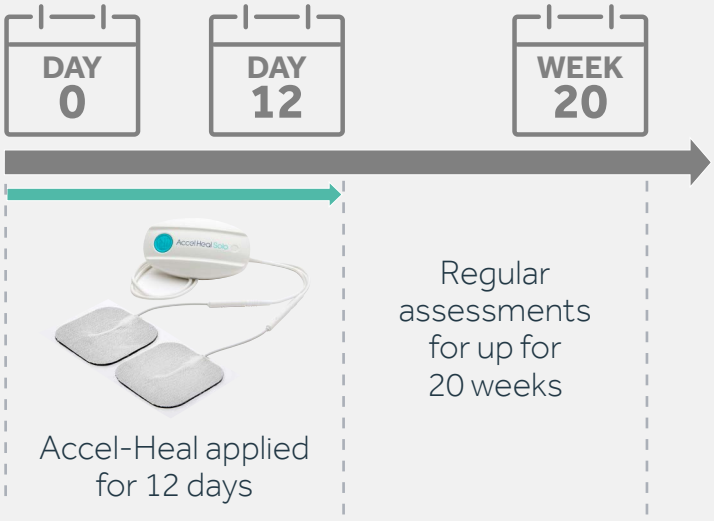

# KEY MESSAGE: IN A REAL-WORLD STUDY IN SCOTLAND, 90% OF PATIENTS TREATED WITH ACCEL-HEAL HEALED WITHIN 20-WEEKS

The Triple Aim Framework aims to optimise health system performance in NHS Scotland by improving three dimensions 1) quality of health-care; 2) health of the population; 3) value and financial sustainability.

The objective of this evaluation was to explore the potential of Accel-Heal to support the Triple Aim Framework by improving wound management.

- n=10
- 80% female
- Mean age = 62 years

Non-progressing VLU despite compression



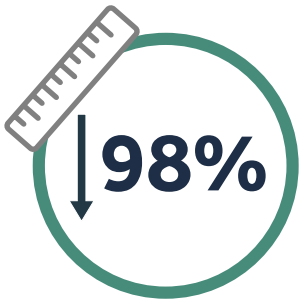


**of patients healed within 20 weeks, including one of 28-years duration**

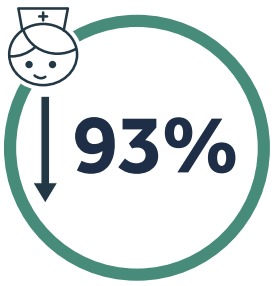
## Within 2 weeks:


Mean pain reduced from 7.2/10 to 3.7

## Within 20 weeks:




reduction of wound area




reduction in nursing visits


of clinicians involved expressed satisfaction with Accel-Heal

Conclusions and interpretation: Accel-Heal improved clinical outcomes and quality of life for patients when used as an adjunct to standard therapy. This resulted in significant cost savings. These benefits support the triple aim framework in NHS Scotland.

CITATION: Ovens L. Supporting the Triple Aim Framework1 objectives in Scotland using an innovative electroceutical therapy* to improve clinical and economic benefits for patients with venous leg ulcers (VLUs). Presented at EWMA 2019.

KEY MESSAGE: THIS ARTICLE EXAMINED THE USE OF ACCEL-HEAL IN THREE CASE STUDIES IN SOME VERY CHALLENGING LEG ULCERS

## Patient 1

- Mixed ulcer
- 8 years duration
- Corticosteroids (for arthritis)

## Patient 2

- Venous ulcer
- >1 year duration
- Diabetes

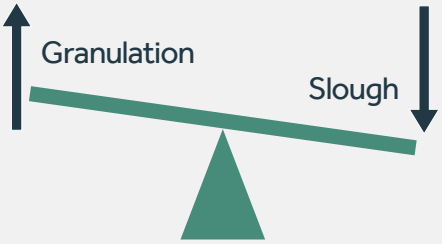
## Patient 3

- Venous ulcer
- 13 year history of skin breakdown
- Heart failure


**Accel-Heal Solo applied for 12-days**

## Wound area


## Improved wound bed




## Wound area


Conclusion and Interpretation: All patients had long histories of chronic ulceration and healing was hampered by a range of comorbidities. Gold standard treatments had failed to progress healing. Following the application of Accel-Heal, all patients had positive outcomes including reduced wound area, and improved wound bed.

CITATION: Griffin J. Improving outcomes through innovation: An evaluation of Accel-Heal in chronic wounds. Wounds UK 2013:9 (4):118-121.

Click here to view the online article

VLU - healing outcomes

DFU - healing outcomes

Other - healing outcomes

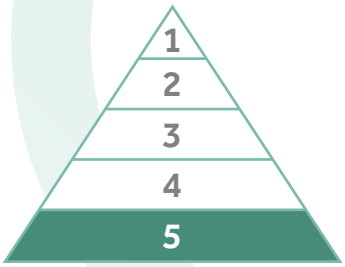
Mode of action

EST evidence base

Patient benefits

Health Economic benefits

Evidence in-progress

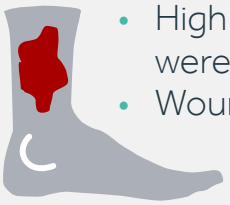



# KEY MESSAGE: ACCEL-HEAL SOLO PROVIDED HOPE AND INDEPENDENCE FOR A PATIENT WITH A HARD-TO-HEAL VLU PRESENT FOR 25 YEARS DESPITE FOLLOWING GOLD STANDARD PRACTICE

Hard-to-heal wounds cause distress for patients, many of whom give up any hope of improvement. The loss of independence and financial implications of living with a hard-to-heal wound are significant, which has been described by patients as "a forever healing" and "powerlessness".

## Patient:

- 77- year old male, shop-worker
- Lives independently, walks with a stick
- Polymyalgia Rheumatica
- Right saphenous vein surgery
- Fracture of left radius and ulna
- No smoking or alcohol



- VLU of 25 year duration
- High levels of exudate and odour were difficult to manage
- Wound size; 15cm$^2$; 40% slough,
- Lack of progress despite 4-layer compression

## The VLU was treated with Accel-Heal Solo


## Wound area:

**↓27% after 12 days**

Marked reduction in exudate by 4-weeks

**↓97% after 35 weeks**

At 0.3cm$^2$ this is the smallest the wound has been for 25 years

**"[The patient] had lost all hope of ever achieving any healing, facing the rest of his life in bandages, with odour and "wet" legs"**

**Clinician, UK**

**"I [now] have every hope the ulcer will heal"**

**Patient, UK**

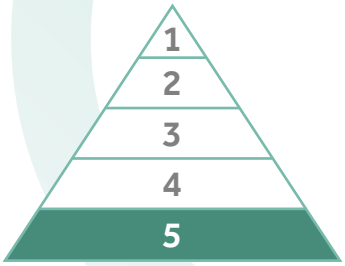
Conclusion and Interpretation: Different approaches need to be considered for patients with hard-to-heal wounds, rather than just continuing with standard care alone, to kick-start the wound healing process and reduce inflammation. Treatment with Accel-Heal Solo transformed this complex and long duration wound, and provided the patient with a new prospective on life, with hope for the future

CITATION: Leyfleurrie K. Hopelssness to healing and hope. Poster presented at TVS 2023, Peterborough UK.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: ACCEL-HEAL KICK-STARTED HEALING IN A RECALCITRANT, RECURRING VLU OF 19-MONTHS DURATION

A patient with a 19-month duration VLU, with history of recurrence was treated with Accel-Heal

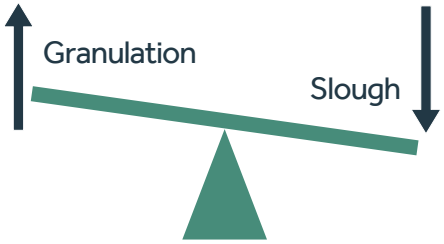
The aim of this case report was to evaluate the response of a hard-to-heal ulcer to Accel-Heal

## Patient:

- 69-year old male, security worker with long periods spent standing
- Hypertension, hyperlipdaemia, eczema
- Past, multiple surgeries for incompetent veins

- VLU which had previously recurred despite compliance with 4-layer compression
- 19 month duration

## Wound bed improved within 5-days:




## Reduced wound size:

Complete healing was achieved

**50%** reduction within 3 weeks

within **24 weeks**

## Treated with Accel-Heal underneath the compression bandaging


## Skin condition improved:

Excema reduced with fewer flares

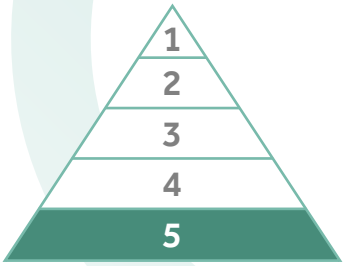
Conclusion and Interpretation: The quick turnaround in clinical signs towards healing suggested that Accel-Heal was responsible for changing the physiology of the wound towards healing. Accel-Heal was used easily along-side gold standard care, compression bandaging.

CITATION: Maniya S. Use of continuous electical stimulation in a chronic leg ulcer: a local experience.
Poster presented at EWMA May 2023, Milan, Italy.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: EARLY EVIDENCE SUGGESTS THAT ACCEL-HEAL MAY ALSO SUPPORT GOOD OUTCOMES IN DFU

Electrical stimulation therapy has been shown to kickstart lower limb ulcer healing with a strong evidence base in the treatment of VLU and pressure ulcers, but less information is available in DFU

This study aimed to investigate the use of Accel-Heal as an adjunctive therapy in the management of DFUs.

**DAY 0**
Accel-Heal applied

**DAY 12**
Accel-Heal treatment completed

**Follow up -** healing continues

## Patient 1:

- 65-year old male
- Well-controlled type 2 diabetes
- DFU; 3x2x2 cm, following below knee amputation
- Stalled for 3 months.

Accel-Heal was applied. Wound progress was apparent by the end of the 12-day treatment period.

The wound continued to improve and healing was achieved within 8-weeks

Healing was achieved:

within 8 weeks

## Patient 2:

- 67-year old male
- Poorly-controlled type 2 diabetes, hypertension, dialysis.
- DFU
- 15-years duration
- Reluctant regarding off-loading devices

Accel-Heal was applied. Wound progress was apparent by the end of the 12-day treatment period.

The wound continued to improve and healing was achieved within 11-weeks.

Healing was achieved:

within 11 weeks

Conclusion and Interpretation: Accel-Heal was used with the aim of kick-starting healing in two previously non-healing diabetic foot ulcers. During the 12-day treatment period, the condition of both wounds improved. This improvement continued after the Accel-Heal treatment came to an end; excellent results were observed in both patients, achieving full wound closure within 2 months of starting treatment with Accel-Heal.

CITATION: Alktebi S and AlAdab A. Use of a novel electrical stimulation device to kick start healing in two patients with lower limb ulcers complicated by diabetes mellitus. Presented at WUWHS, 2022.

# KEY MESSAGE: ACCEL-HEAL WAS ASSOCIATED WITH GOOD OUTCOMES IN AN IN-SERVICE EVALUATION IN MALAYSIA

A observational study was carried out to explore the effect of Accel-Heal in patientswith recalcitrant wounds attending Kuala Lumpur General Hospital, Malaysia.

## Patients:

- N=10 (6 DFU, 2 VLU, 2 other)
- Mean duration 12-months
- Mean wound area 66.4cm²

## Study design:

- A non-comparative, observational study
- All patients received treatment with Accel-Heal
- Outcomes were measured at baseline, week-1 and week-2 after Accel-Heal was applied, and at a final observation visit

Group 1 (n=6)

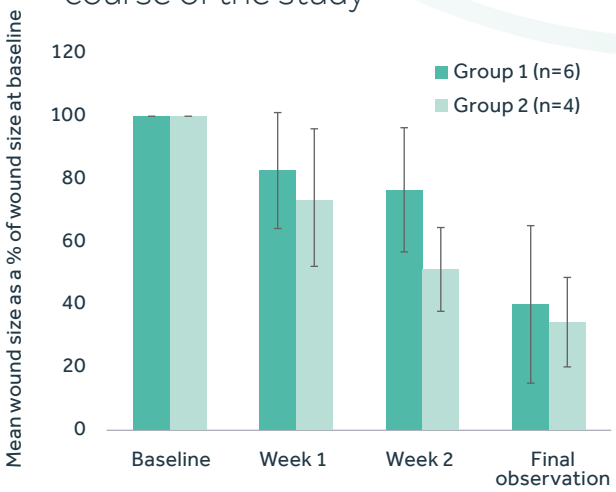
Larger, contaminated, very complex "high challenge" wounds

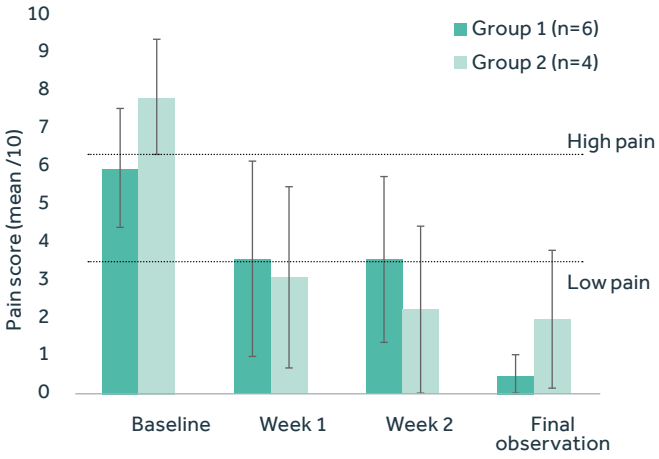
Group 2 (n=4)

Clean, well-prepared wounds

## Results:

Wounds reduced in area over the course of the study



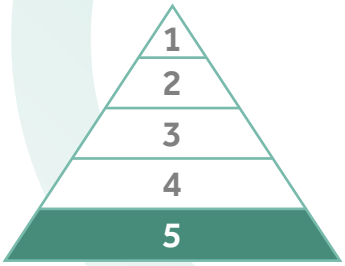

Conclusion and interpretation: A reduction in wound area and a large mean decrease in wound pain was observed over a relatively short time frame. This small, observational study demonstrates a treatment effect in both high-challenge as well as well-prepared wounds. We believe these data represent the first published use of Accel-Heal in Malaysia.

CITATION: Nair H. Powering the progression of hard-to-heal with electrical stimulation: an observational analysis of wounds treated with Accel-Heal.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: ACCEL-HEAL SOLO WAS USED EFFECTIVELY IN TWO PATIENTS WITH COMPLEX WOUNDS AND MEDICAL HISTORY

Patients with complex co-morbidities, such as lupus erythematosus, and underlying pathologies related to arterial stenosis, invariably cause challenges in wound healing

The aim of this case report was demonstrate the benefits of using **Accel-Heal Solo**, in pain reduction and healing on extremely challenging hard-to-heal wounds in complex patients

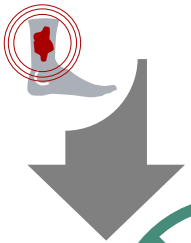
## Patient 1

- A female patient with a lupus erythematosus rash on the abdomen, measuring 15 cm x 15 cm, with 16 open wounds within that area which varied in size
- Pain 7-10/10; required morphine pregabalin and paracetamol
- Complex medical history

## Patient 2

- Female. 89 years
- Arterial ulcer to bunion; duration 12-months
- Pain score 7/10 despite analgesia; causing sleep deprivation and impacting on mood and ability to cope
- 2cm x 1.5 cm; rolled edges, pus-like exudate

## Accel-Heal Solo applied for 12-days



Pain reduced to 0 within 19 days after the start of treatment

Analgesia was stopped and complete healing was achieved:



Pain reduction was reported within 48 hours, allowing patient to sleep. Pain reduced to 0 during 12-day treatment

Wound size reduced by 33% during the 12-days


**"The pain and wound have been so much better since using the treatment, I haven't looked back and I am walking much better"**

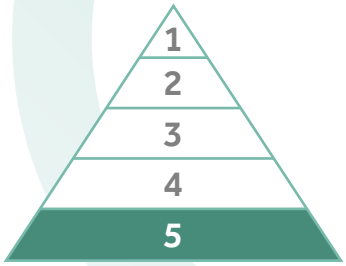
Conclusion and Interpretation: These case reports, using Accel-Heal Solo, a cost-effective, novel, compact device, demonstrated the benefits to patients and clinicians of having an easy to use device available in all clinical settings, for patients with hard-to heal wound

CITATION: Allan C and Ovens L. Improving Quality of Life Using a Novel Electrical Stimulation Therapy Device to Reduce Pain and Accelerate Healing in Two Patients With Very Different Underlying Aetiologies. Wound Masterclass 2022; 1 (Dec).

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: IN A CASE SERIES, ACCEL-HEAL WAS USED SUCCESSFULLY ON RECALCITRANT VASCULAR ULCERS COMPLICATED BY DIABETES

Accel-Heal is a single-use, portable, electrical stimulation device that can be used in the management of hard-to-heal leg ulcers.

The aim of this evaluation was to assess the efficacy of Accel-Heal in the management of vascular foot ulcers.

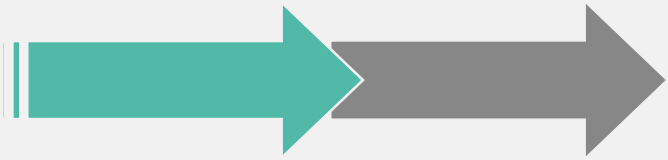
## Method:

- n= 8 patients with a foot ulcer
- Attending vascular outpatient clinic

**DAY 0** Accel-Heal applied

**DAY 12** Accel-Heal treatment completed

**Follow up -** healing continues



All patients successfully managed their treatment at home

## Results:

**7/8** Patients achieved a reduction in wound volume during treatment with Accel-Heal

**42%** On average, wound volume decreased by 42% during treatment

Half of patients healed within follow up period


**50%**

Conclusion and Interpretation: Accel-Heal was well managed by patients in their own homes. Progress towards healing was seen in most patients over the 12-day treatment period which continued after treatment, suggesting that Accel-Heal may kick-start the healing process in hard-to-heal wounds.

CITATION: Kiernan C, Strapp H, Cafrey B, Aherne T, Lynch OE Boyle E, Egan B, Tierney S. Effectiveness of a single-use, portable, electrical stimulation device in vascular foot ulcers. Presented at EWMA 2020.

Click here to view the online article

VLU - healing outcomes

DFU - healing outcomes

Other - healing outcomes

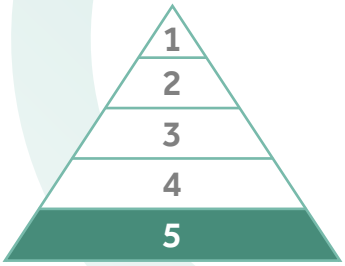
Mode of action

EST evidence base

Patient benefits

Health Economic benefits

Evidence in-progress



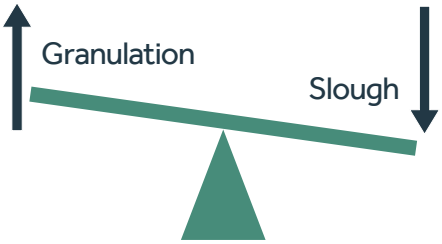

# KEY MESSAGE: GOOD RESULTS WERE OBTAINED WHEN TREATING AN ARTERIAL ULCER WITH ACCEL-HEAL

Arterial ulcers are notoriously difficult to heal, despite vascular interventions, with pain being a major factor affecting quality of life. Many patients with arterial ulcers experience non-healing and risk of amputation.

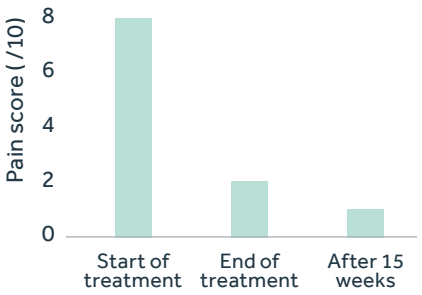
This case study was undertaken to demonstrate the effectiveness of applying Accel-Heal on pain and wound healing for a patient with a complex, long-standing, painful arterial leg ulcer.

- 84-year old female
- Arterial ulcer of 3-years duration
- 2 x 1.7 cm
- Wound infection
- Severe pain (8/10 VAS) requiring regular analgesia
- Failed topical antimicrobials dressings
- Previous procedures:
- Graft procedures with only partial success
- Several previous debridements
- 10 revascularisation procedures (including angioplasties and arterial stents in her common femoral and peroneal arteries.
- Recurrent restenosis despite Warfarin therapy

## Quality of wound bed improved




## Pain was reduced:




## Complete healing was achieved:

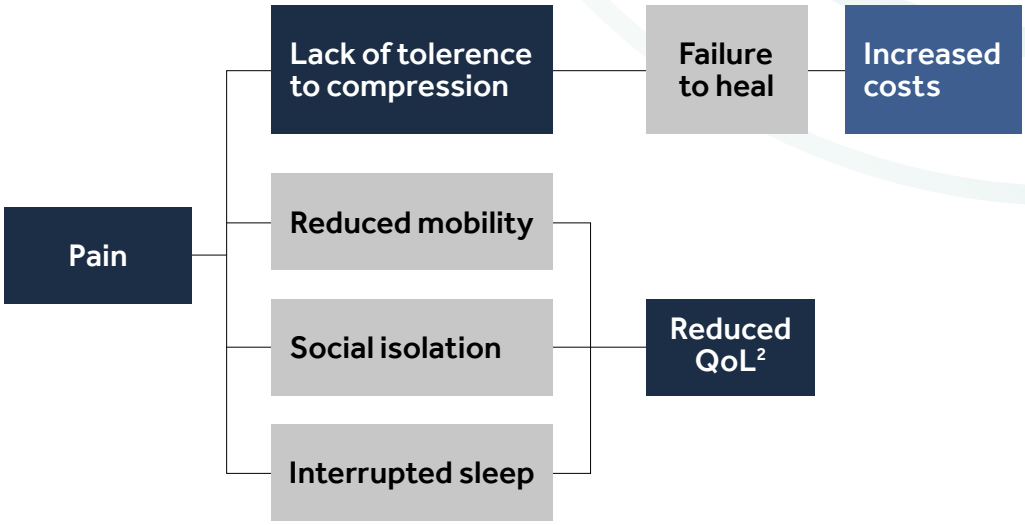

Conclusion and interpretation: Prior to treatment with Accel-Heal, the patient had been very distressed by the wound pain and the need for long-term, long-acting narcotic analgesia. She was struggling to cope at home with managing the wound, pain medication and dressing regime. She expressed profound relief at achieving a healed wound after living with the ulcer for so many years.
The clinical team were delighted to see this long-term wound remaining healed, Application of an easily operated, wearable and pre-programmed EST* can reduce pain and stimulate wound healing for this patient group, particularly if conservative approaches are the mainstay of treatment.

CITATION: Terrill P, Ovens L. An innovative approach to manage pain and stimulate healing in arterial ulcers using electrical stimulation therapy. Poster accepted to EWMA 2022.

## Benefits of Accel Heal

The Health Economic benefit of Accel-Heal has been reported in both formal and informal analyses.

Pain can lead to reduced mobility, social isolation and interrupted sleep, all of which can contribute to reduced QoL. Pain can also make some gold standard treatments, like compression therapy, intolerable to patients and this can contribute to a failure to heal.




Accel-Heal's ability to reduce wound pain is key in helping to improve patient QoL, sleep, social interaction and has been reported to directly improve tolerance of compression therapy, enabling patients to benefit from this gold standard treatment.

The Health Economic benefit of Accel-Heal has been reported in both formal and informal analyses.

### Patient-related benefits:

- Kurz (2023)
- Moon (2023)
- Danner (2022)
- Turner and Ovens (2017)
- Cancela (2022)
- Ovens (2017a)
- Ovens (2017b)
- Ovens (2015)
- Louison et al (2015)
- Greaves et al (2014)
- Layflurrie (2021)

### Health Economic benefits:

- Guest et al (2015)
- Posnett et al (2020)
- Taylor et al (2011)

**Click on each item of evidence for more information**

# KEY MESSAGE: ALMOST ALL PATIENTS EXPERIENCED SOME WOUND PAIN REDUCTION WITHIN THE FIRST 2-DAYS OF TREATMENT

A series of in-service evaluations in France, Austria and Malaysia, were amalgamated into one analysis.

## Method:

- 40 wounds in 39 patients
- Mean age 68.9 years
- Various types of non-healing wound
- Mean wound duration 30.1 months
- Mean wound area 26.2cm$^2$
- Mean pain VAS 5.5/10; 68% of patients had pain score >5

Improvement in wound, measured using a clinical response score (from 0-5) to assess changes in pain, oedema, inflammation, size and tissue type

**5** Excellent - marked changes in all criteria

**4** Good - marked changes in most criteria

**3** Modest - some changes in most criteria

**2** Limited - detectable changes in 1 or 2 criteria

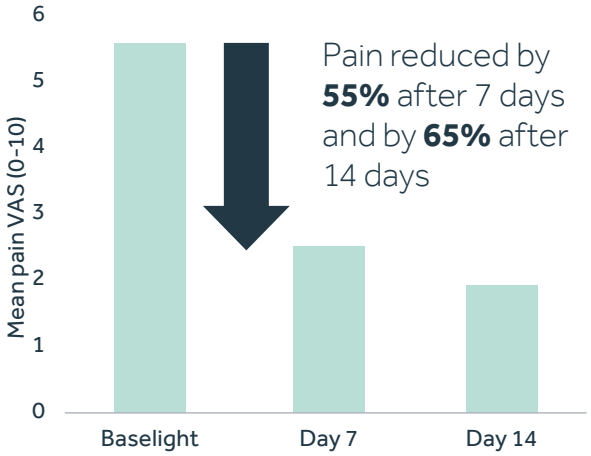
**1** Minor - barely detectable changes

**0** No response

## Results:

**96%**

Of patients reported some pain reduction within 48-hours of starting treatment




Pain reduced by **55%** after 7 days and by **65%** after 14 days

**78%**

78% of wounds had an excellent or good clinical response (score of 4 or 5) to Accel-Heal

Conclusions and interpretation: simple single use EST devices have the potential to allow patients with a wide range of hard-to-heal wounds to benefit from activation of healing and rapid reduction of pain

CITATION: Kurz P, Danner G, Lembelembe JP, Nair HKR, Martin R. Activation of healing and reduction of pain by single-use automated microcurrent electrical stimulation therapy in patients with hard-to-heal wounds. Int Wound J. 2023 Jan 5. doi: 10.1111/iwj.14071.

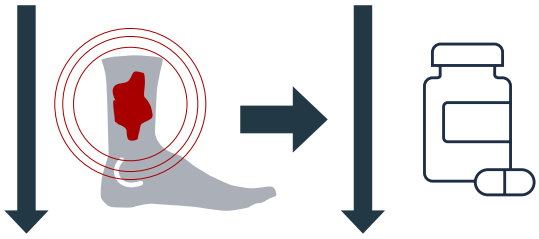
# KEY MESSAGE: AS WELL AS KICK-STARTING THE HEALING PROCESS, EST MAY PROVIDE A VALID ADJUNCT TO ORAL MEDICATION IN THE ATTEMPT TO ADDRESS PERSISTENT WOUND PAIN IN PEOPLE WITH LONG-STANDING HARD TO HEAL WOUNDS

Preliminary case results from a 20-patient study investigating the effect of Accel-Heal Solo on wound pain and analgesic consumption.

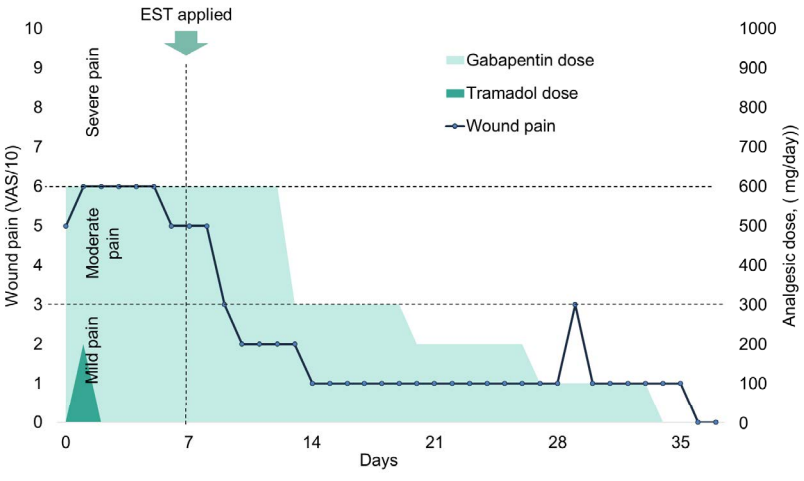
## Methods:

- 20 patients
- Mostly VLU
- Wound pain VAS was greater than 4/10 in all enrolled patients
- Daily wound pain and analgesic use was recorded in a diary for a 7-day run-in period and during treatment with Accel-Heal (applied as two back-to-back applications (24 days of therapy)

## Results:



- As wound pain reduced, the dose of analgesics needed to manage wound pain was reduced
- Reductions in wound size were also observed




## In the example shown:

- Wound pain reduced from 5-6/10 in the 7-days prior to Accel-Heal Solo, to 1/10 within 7-days of treatment
- Occasional tramadol use (dark green) was no longer required
- Gabapentin dose reduced gradually (pale green) and eventually was ceased 4-weeks after starting treatment

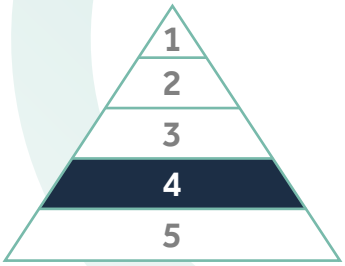
Conclusions and interpretation: Treatment of painful, hard to heal wounds with EST resulted in a meaningful reduction in wound pain that enabled a corresponding reduction in pain medication, including the complete cessation of controlled analgesics in some cases. Cessation of controlled analgesics in people with hard to heal wounds, typically elderly and medically compromised individuals, is important because side-effects from these medications can lead to an increased risk of falling and other treatment-related adverse events.

CITATION: Moon M, Hazell D, Hawes L. Poster presented at Wounds UK, Harrogate, Nov 2023.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: IN 90% OF PATIENTS, HIGH WOUND PAIN* REDUCED SIGNIFICANTLY' IN THE FIRST 48 HOURS OF TREATMENT WITH ACCEL-HEAL

The aim of this evaluation was to assess the response of static non-healing wounds to Accel-Heal, an automatic, continuously active, single-use low-voltage pulsed microcurrent ES device

## Methods:

- N=20
- Median age; 70 years
- 40% female
- Median wound duration; 36 months

All wounds: Accel-Heal for 12-days

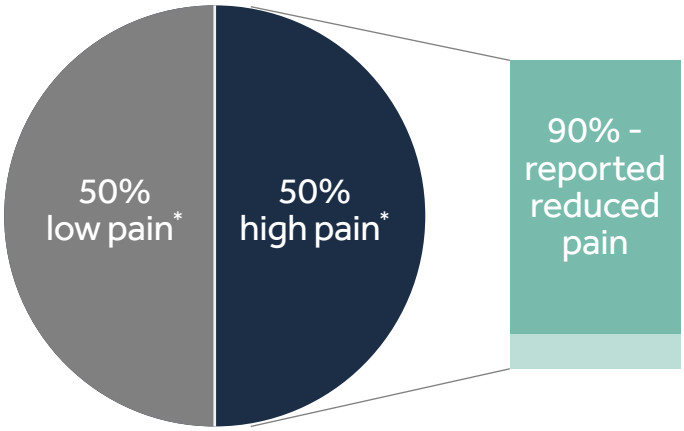
Patients were followed

8 wounds received a second treatment

Clinical response was scored on a 0-5 scale


## Results:

Half of the patients had highly painful* wounds at baseline. Of these, 90% reported a meaningful reduction in pain in the first 48 hours of treatment with **Accel-Heal**




* low pain <4/10 and high pain >4/10 on VAS pain scale

Overall, 70% of wounds (14/20) showed an excellent or good clinical response...


...typified by


Changes were often observed within 14 days.

Conclusion and Interpretation:. Accel-Heal delivered multiple benefits in patients with stalled, non-healing wounds. Firstly in patients with painful wounds, 90% felt pain relief withing the first 48 hours of treatment, Secondly, 70% of wounds treated showed a significantly positive clinical response within 14 days of treatment. Use of multiple consecutive Accel-Heal devices was reported to good effect.

CITATION: Danner G, Kurz P, Martin R. Clinical Evaluation of the Response Rate to a Continuously Active, Single-use Electrical Stimulation Device in Static Non-Healing Wounds. Wound Masterclass. 2022; 1:1-4.

# KEY MESSAGE: THE 83% REDUCTION IN WOUND PAIN REPORTEDIN THIS STUDY HAD A MASSIVE IMPACT ON PATIENT'S QOL

A previous study (click here) explored the effect of Accel-Heal on wound outcomes and cost efficiencies when used to treat hard-to-heal wounds in the community.

This study reports the perspective of the patients who were involved in the research.

## Methods:

17 patients with 19 non progressing wounds (mostly VLU)

Day 0 — Accel-Heal applied for 12 days

Day 12 — Wound assessment every 2-4 weeks

Week 20 — 3 patients interviewed about their experience of having a wound and the impact of Accel-Heal

**Over 20 weeks:**

**83%** **Reduction in pain**

## Patient perspective (n=3):

| Before Accel-Heal | After Accel-Heal |
|---|---|
| "I was on morphine ... begging to have stronger painkillers" | "painkillers were reduced..." |
| "couldn't get comfortable in bed.. continual broken sleep ..wears you down" | "no longer painful" "I stay asleep" |
| "my whole social life was took away" | "back to swimming... and playing snooker with my friend" |
| "I couldn't walk anywhere" | "my leg started to heal and I started to get my life back" |

Conclusion and interpretation: Using Accel-Heal as an adjunct to standard therapy can improve the patients journey towards healing. As well as improving clinical outcomes, in this study, Accel-Heal improved patient's quality of life and the patient experience.

CITATION: : Turner N, Ovens L. Clinical outcome results and quality of life improvements using electroceutical treatment - Patient perspectives. Presented at EWMA 2017.

# KEY MESSAGE: CLINICIANS REPORTED A HIGH LEVELOF SATISFACTION WITH ACCEL-HEAL'S EASE OF USE

Traditional EST devices have proved difficult to use in everyday practice; this has limited adoption of the technology.

Accel-Heal has been designed to overcome these issues, through being easy to use and easy for patients to manage at home.

This evaluation aimed to demonstrate the ease of use of Accel-Heal in 3 different countries; Austria, Finland and Portugal.

## Methods:

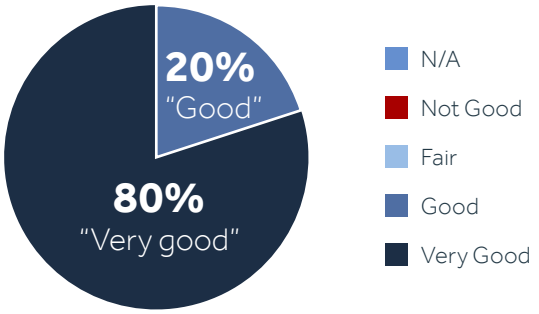
- 15 patients with ahard-to-heal wound
- Attending outpatient wound clinic


Accel-Heal was applied for 12-days

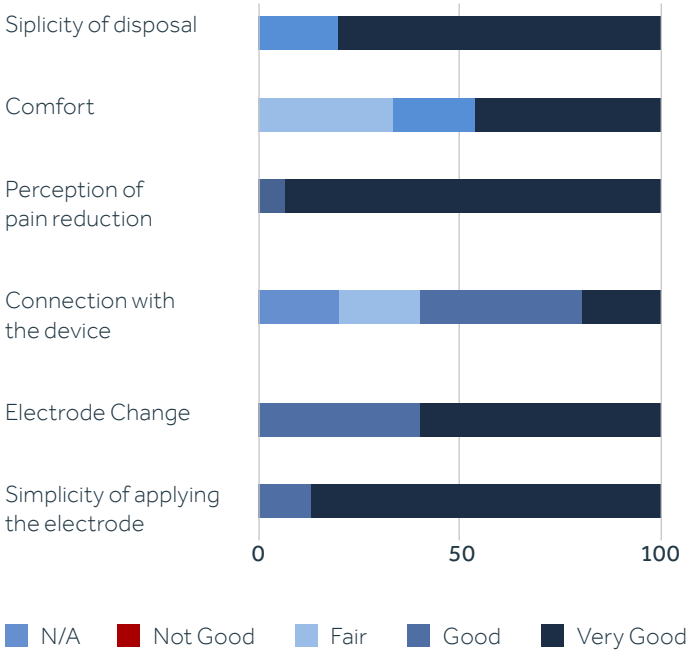
The HCP's experience with each patient's treatment was evaluated, via a questionnaire.

## Results:

Overall, clinicians were highly satisfied with Accel-Heal




Individual aspects of using the device were considered good or very good, in the majority of responses.




Conclusions and interpretation. Accel-Heal was easy to apply and manage in outpatient settings. HCPs were highly satisfied with its use. Accel-Heal may enable HCPs to adopt an evidence-based technology (EST) that has previously been difficult to implement because of issues relating to ease of use.

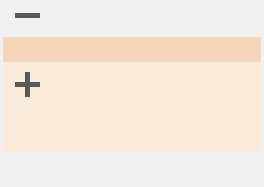
CITATION:. C. Cancela,1 M. Cruz,2 E. Kaha,3 P. Kurz,4 H Leemet. Ease of use of wearable, single-use electrical stimulation device for the management of hard-to-heal wounds. Accepted to EWMA 2022.

# KEY MESSAGE: BENEFITS OF ACCEL-HEAL, INCLUDING REDUCED PAIN, EXUDATE AND INFLAMMATION AND IMPROVED TOLERANCE TO COMPRESSION, ARE EXEMPLIFIED IN THIS CASE STUDY

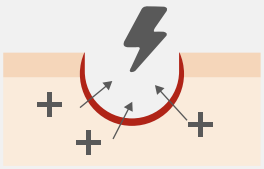
This review describes the role of electrical signalling in wound healing and how electrical stimulation (ES) can stimulate a stalled wound.

## Electrical signalling in wounds:

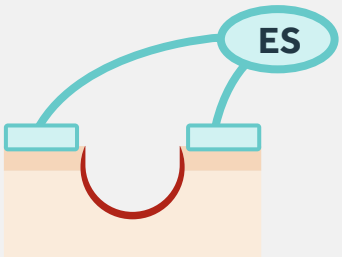
"Human physiology is electrochemical in nature." Voltage flows along with charged ions from positive (+) to negative (-).




Intact skin acts as a battery



Wounded skin has a small electrical current This dissipates as a wound becomes chronic

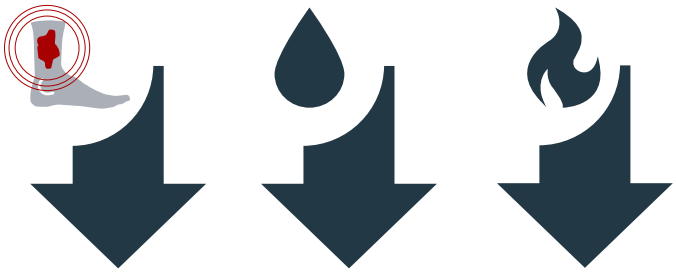



Application of ES can replace this "current of injury" to stimulate healing

## Case study:

- 80 year old male
- Recurring venous legulcer (VLU)
- Pain managed withstrong analgesics
- Compression not tolerated

## Accel-Heal was applied for 12-days




The patient became able to tolerate compression bandaging and the wound went on to heal

Conclusion and Interpretation: The benefits of using electrical stimulation therapy alongside the patient's standard therapy are well researched. Clinicians are recommended to consider the use of innovative technologies such as electrical stimulation to enhance care of patients with chronic wounds. Treatments need to be patient focused, accessible and easy to use allowing patient involvement and improving quality of life.

CITATION: Ovens L. Electrical stimulation therapy and electroceutical treatment for the management of venous leg ulcers.Community Wound Care 2017; March: S28-36.

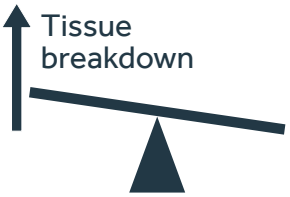
# KEY MESSAGE: A SEVERELY PAINFUL VLU BENEFITEDFROM TREATMENT WITH ACCEL-HEAL

Chronic wounds are a persistent challenge to healthcare professionals. They pose both a financial burden as well as a humanistic burden; the symptoms related to chronicity are both relatively expensive to manage and also affect the quality of life of patients living with a chronic wound.

## Chronic wounds:

Reduced inflammation


Reduced inflammation




Reduced inflammation

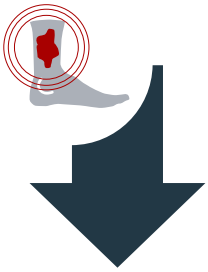
Reduced inflammation


## Electrical stimulation:

- Reduces chronic inflammation
- Stimulates normal healing
- Reduces associated symptoms, e.g. pain and exudate

## Case study:

- 50 year old female
- Recurring venous leg ulcer
- High levels of pain (10/10) managed with co-codamol and pregabalin



Pain reduced to 3/10

Exudate reduced


Sleep improved


Granulation tissue increased

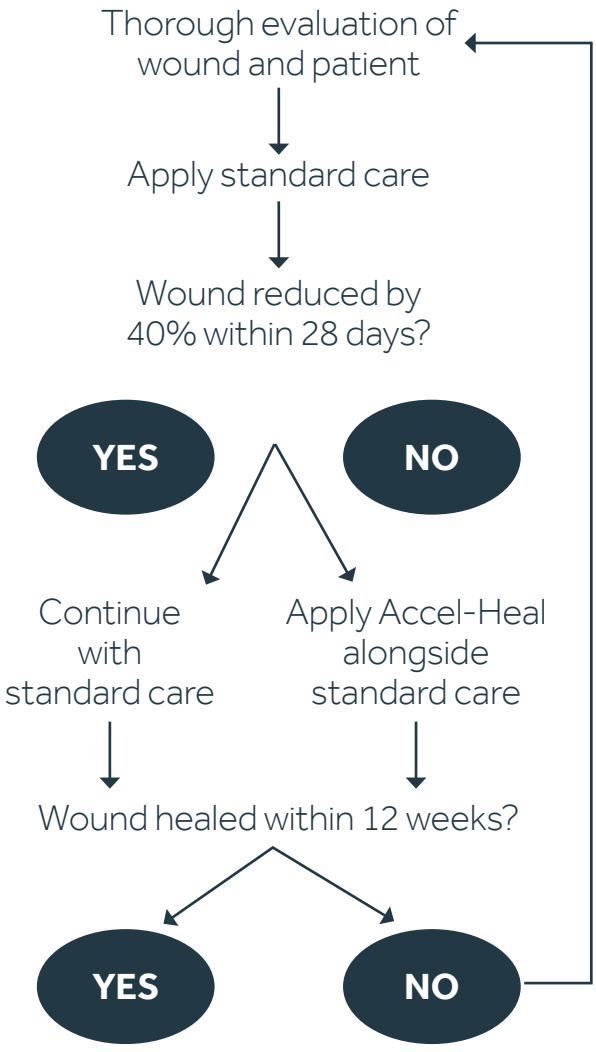
Conclusion and Interpretation: Advanced treatment modalities e.g. electrical stimulation can aid wound bed preparation by helping to reduce chronic inflammation, pain and exudate, and stimulating cell proliferation and collagen synthesis.

CITATION: Ovens L. Using electroceutical treatment to reduce symptoms and improve healing in chronic wounds. Primary Health Care 27:(6)22-27.

# KEY MESSAGE: ONE OF THE FINDINGS FROM THIS CASE SERIES WAS THAT FOLLOWING TREATMENT WITH ACCEL-HEAL, SOME PATIENTS COULD NOW TOLERATE COMPRESSION BANDAGING

This article is based on a symposium held at the Wound Essentials annual summer conference in Birmingham, UK, on 2nd July 2015.

## Proposed treatment algorithm:




The objective was to explore the impact of Accel-Heal on patient outcomes and to consider how this device can be incorporated into existing clinical protocols and budgets.

## Observations from case series:

A series of 5 cases highlighted the following themes:

- Wound pain decreased during treatment with Accel-Heal
- This meant that some patients could now tolerate compression therapy
- One of the biggest effects was the improvement in quality of life (QoL)
- Improvements in healing meant reduced nursing time
- The combined effect was a reduction in budgets

Conclusion and Interpretation: Using Accel-Heal in clinical practice improved wounds and QoL outcomes for patients and led to closure in most of these cases. It was easy and simple to use as an adjunct to patients' usual therapy, including compression bandaging.

CITATION: Ovens L. Getting it right for patients and budgets. Wounds UK, 2015: 11 (3):96-101

# KEY MESSAGE: TREATMENT BENEFITS ASCRIBED TO ACCEL-HEAL INCLUDED, REDUCED PAIN, REDUCED ANALGESIA AND IMPROVED HEALING

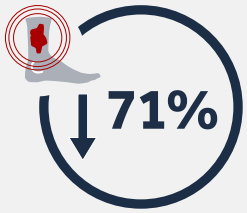
Venous leg ulcers (VLU) are often difficult to heal; healed wounds often recur, leading to additional cost and lowered quality of life (QoL) for patients.

Two case studies are presented to determine the effect of Accel-Heal to reduce pain, expedite healing and reduce risk of recurrence.

## Patient 1:

- 57 year old male
- 4th recurrence of VLU despite wearing compression hosiery
- 6 weeks duration
- Pain 7/10; co-codamol
- Wound area 3cm$^2$

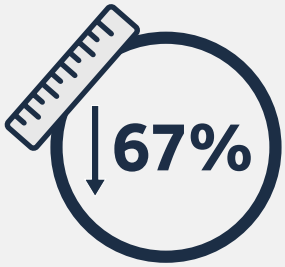
**During the 12-day treatment with Accel-Heal:**




Pain reduced to 2/10

Less analgesia

Reduced drowsiness




Wound area reduced to 1cm$^2$

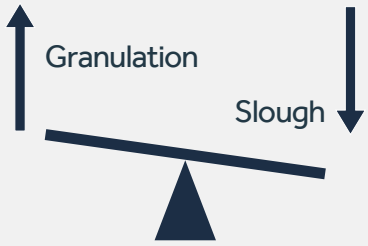
- Wound healed within 8 weeks
- Remained healed for at least 5 months

## Patient 2:

- 65 year old male
- 3rd recurrence of VLU
- 4 months duration
- Pain 6/10; reluctant totake analgesia
- Wound area 2.5cm$^2$

**During the 12-day treatment with Accel-Heal:**


Pain reduced 10 1/10




Quality of wound bed improved

- Wound healed within 4 months
- Remained healed for at least 2 months

**"The healed tissue feels much stronger and less delicate than anytime previously"**

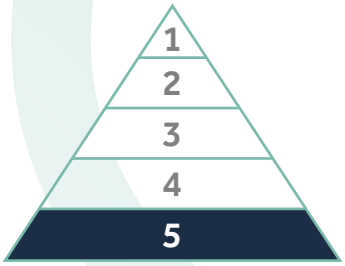
Conclusion and Interpretation: After treatment with Accel-Heal, previously recurring VLUs remained healed. Both patients had improved QoL and improved quality of healing and resume daily living.

CITATION: Louison P. Management of recurrent venous leg ulcer with electroceutical therapy* to improve pain, expedite healing and reduce risk of recurrence. Presented at EWMA, London, May 2015

Click here to view the online article or here

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: THREE CASES SHOWED BENEFITS OF ACCEL-HEAL, INCLUDING REDUCTION IN WOUND PAIN LEADING TO IMPROVED TOLERANCE OF COMPRESSION THERAPY

## Patient 1:

- Venous leg ulcer
- Pain score of 10/10 despite tramadol and co-codamol
- Sickle cell trait; history of laser ablation for varicose veins

## Patient 2:

- Venous leg ulcer
- 1 year duration
- Pain score of 10/10

Not able to tolerate compression due to pain

## Patient 3:

- Venous leg ulcer
- 2 year duration
- Dementia; type 2 diabetes
- History of failed compression

## Accel-Heal Solo applied for 12-days

### Wound pain

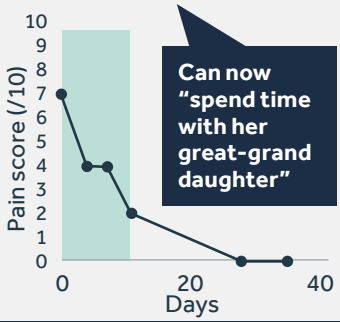
Reduced dramatically during treatment and continued after Accel-Heal treatment.


### Pain and healing

Wound pain reduced meaning that the patient could now tolerate compression


### Wound healing

Wound pain reduced after starting treatment with Accel-Heal and continued to reduce after treatment had finished.




Conclusion and Interpretation: The improvement to quality of life and wellbeing of patients as a result of using Accel-Heal was evident to these patients and their carers, meaning that these patients were able to carry out daily activities that had become difficult before treatment with Accel-Heal. Of note is the observation that in patients where wound pain reduces their ability to tolerate compression therapy, reduction in pain during and after treatment with Accel-Heal, enabled this patient to tolerate compression, undoubtedly contributing to her good outcome.

CITATION: Greaves T. Improving patient quality of life with innovative electroceutical technology: a case series. Wounds 2014; 10(3):81-88.

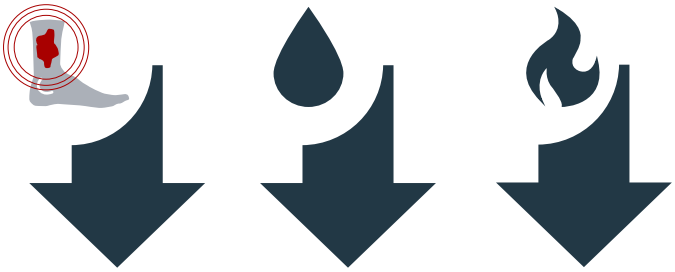
# KEY MESSAGE: ACCEL-HEAL SOLO WAS USED ON AN EXTENSIVE VLU OF 5-YEAR DURATION, WITH GOOD OUTCOMES

## Case study:

- 90 year old female
- Bilateral VLU of >5-years duration, despite compression
- Left leg, extensive ulceration on lateral and posterior aspect; not progressing with gold-standard care
- Congestive cardiac failure
- Atrial fibrillation-cardioversion
- Hypertension
- DVT right leg 2017
- Pneumonia and sepsis 2017 resulting in left sided foot drop, tendon injury and left fixed ankle inversion deformity

## Accel-Heal Solo applied for 12-days

### Within 10-days:



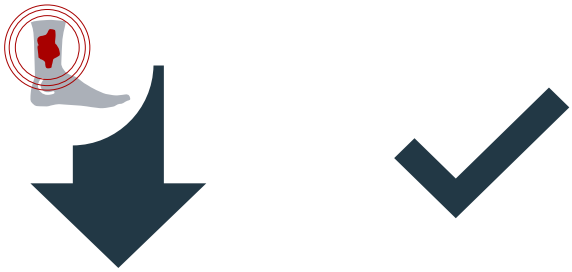
Pain reduced from 5/10 to 2.5

Reduced slough, exudate and malodour

Reduced oedema

The patient achieved her personal goal which was to attend her great-granddaughter's wedding – the wound was so much improved that she had no concerns about leakage or odour from the wound, and was able to enjoy the day without any pain.

### After 21 weeks:



Pain reduced from 0

Posterior aspect healed; Lateral aspect improved

**"for a long time we were getting nowhere, I feel like because of that I lost a few years as it was a real struggle so now I'm delighted to start improving...I have a great family around me who are all so pleased with the progress, just ask my daughter-in-law; she's thrilled'**

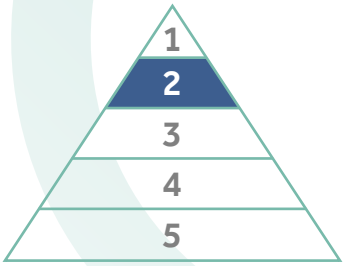
Conclusion and Interpretation: Use of Accel-Heal facilitated healing of a patient's VLU, of 5-year's duration, in the community, reducing her pain and providing her with an improved quality of life.

CITATION: Layflurrie and Ovens. What can we do differently. Presented at Wounds UK, 2021.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: FASTER HEALING ACHIEVED WITH ACCEL-HEAL CAN REDUCE RESOURCES, LEADING TO REDUCED OVERALL COSTS

A meta-analysis of published literature has demonstrated that electrical stimulation enhances chronic wound healing, reducing the resource-burden and costs.

This analysis aimed to explore the cost-effectiveness of using Accel-Heal in patients with venous leg ulcers (VLU).

## Methods:

Post-hoc analysis of previously published studies reported...

**34% healed**

...34% of wounds treated with Accel-Heal healed; on average 3.6 weeks faster vs standard care

**3.6 weeks faster**

**£260 per week**

... at a weekly cost of £260 on average

## Results:

For the 34% of patients who healed in the published study, the faster healing time achieved with Accel-Heal saved, on average £936 per patient.

### For a caseload of patients treated with Accel-Heal:

This takes into account those who heal within 24 weeks and those who do not

**£78 saving per patient**

### For every 100 patients treated with Accel-Heal:

**122 weeks**

of GP or nurse time can be saved

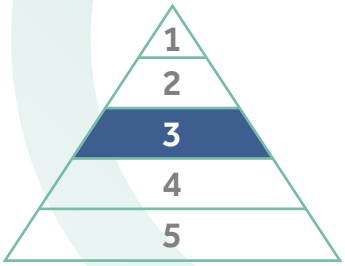
Conclusion and Interpretation: When used along with compression, Accel-Heal may reduce the overall cost of healing in VLU and reduce the resource burden associated with non-healing wounds.

CITATION: Posnett J, Smith J, McKenna P. Cost-effectiveness of a single-use, portable electrical stimulation device in the management of venous leg ulcers. Presented at EWMA 2020.

Click here to view the online article

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




# KEY MESSAGE: IN A FORMAL HEALTH ECONOMIC ANALYSIS, ACCEL-HEAL WAS FOUND TO BE A DOMINANT TREATMENT

Electrical stimulation has been shown to improve wound outcomes, however these devices represent additional upfront cost. Research is needed to understand the cost-benefit of the technology.

This study aimed to estimate the cost-effectiveness of treating patients with a venous leg ulcer (VLU) with Accel-Heal, versus their previous treatment.

## Method:

- Non-healing VLU
- n=30 wounds
- Mean duration 2.2 years

**Step 1**

£ Costs of **previous** 12 months of treatment calculated

Accel-Heal applied for 12 days along with usual dressings inc compression

Wounds followed up for **12 months**

£ Costs of treatment calculated

**Step 2**

**Step 3**

## Within 12 months of starting Accel-Heal:

**77%** of wounds healed; 100% improved

**QoL ↑12%** improvement in health gain

**↓34%** reduction in nursing visits

**↓26%** reduction in dressings

**↓11%** reduction in overall costs

Conclusion and Interpretation: The use of Accel-Heal was found to be a dominant treatment, meaning that it improved outcomes for lower overall cost. Adoption of Accel-Heal may provide the NHS with a cost effective treatment for managing VLUs when compared with patients remaining on their previous care plan.

CITATION: Guest J, Ayoub N, Greaves T. Clinical outcomes and cost effectiveness of an externally applied electroceutical device in managing venous leg ulcers in clinical practice in the UK. J. Wound Care 2015; 24(12)

# KEY MESSAGE: MARKHOV MODELLING HAS SHOWN THAT ACCEL-HEAL IS A POTENTIALLY COST-EFFECTIVE TREATMENT IN THE NHS

Care of non-healing venous leg ulcer (VLUs) can be expensive. Some interventions may add cost but, if they are efficacious, may result in **lower overall treatment costs**.

The objective was to estimate the cost-effectiveness of Accel-Heal intreating chronic, non-healing VLUs of > 6 months' duration.

N=21 all with VLUs of greater than 6 months duration.

Mathematical model (Markhov model) compared two treatment regimes:

**1**

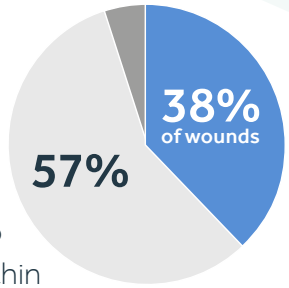

VS

**2**


Outcomes at 5 months and associated treatment costs were **predicted** by the model.

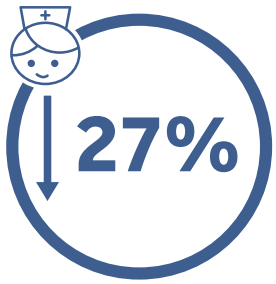
## Results:

After treatment with Accel Heel:

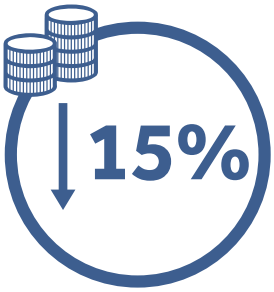



Expected to **heal** within 5 months

Expected to **improve** within 5 months




Nursing visits reduced from 49 to 36 per patient over 5 months




Costs reduced from £880 to £749 per wound

Conclusion and Interpretation: Use of Accel-Heal is potentially a cost-effective treatment for the NHS, when managing chronic, non-healing VLUs of > 6 months' duration. Treatments regimens supplemented with Accel-Heal were more cost-effective compared with patients remaining on a gold standard care plan.

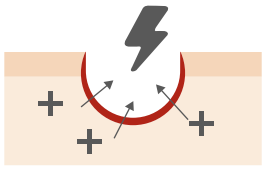
CITATION: Taylor R, Sladkevicius E, Guest J. Modelling the cost-effectiveness of electric stimulation therapy in non-healing venous leg ulcers. J. Wound Care 2011; 20 (10):464-472.

# MODE OF ACTION ACCEL-HEAL

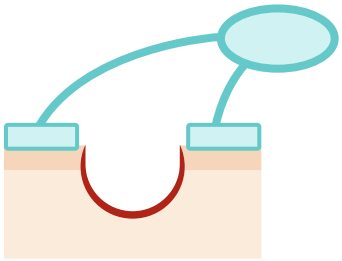
Accel-Heal delivers a microcurrent level of electrical stimulation, to kickstart the healing process that has become stalled in chronic wounds. This harnesses basic principles of human physiology, which is electrochemical in nature. Voltage flows along with charged ions from positive (+) to negative (-) and cells in human tissue respond to these tiny changes in voltage, a process known as bioelectrical signalling.

Electrical stimulation therapy is known to influence the inflammatory phase, proliferative phase and remodelling phases of healing, through these bioelectrical signalling pathways. Electrical stimulation can activate macrophages and stimulate the production and release of growth factors. Proliferation and migration of many cell types can be stimulated including fibroblasts, endothelial cells and keratinocytes, all important in the proliferative phase of healing, for the production of granulation tissue and for re-epithelialisation. Additionally electrical stimulation promotes angiogenesis, essentially a combination of endothelial cell proliferation, migration and morphogenesis, collagen matrix formation as well as wound contraction and cellular differentiation, and organisation of the extracellular matrix, all important in the remodelling phase of healing.


Intact skin acts as a battery



Wounded skin has a small electrical current This dissipates as a wound becomes chronic



Application of Accel Heal can replace this "current of injury" to stimulate healing

**Published Accel-Heal MoA evidence:**

- Lalyatt et al (2017) → RCT
- Young et al (2011)
- Tadej et al (2010)
- Lim et al (2023)

**Click on each item of evidence for more information**

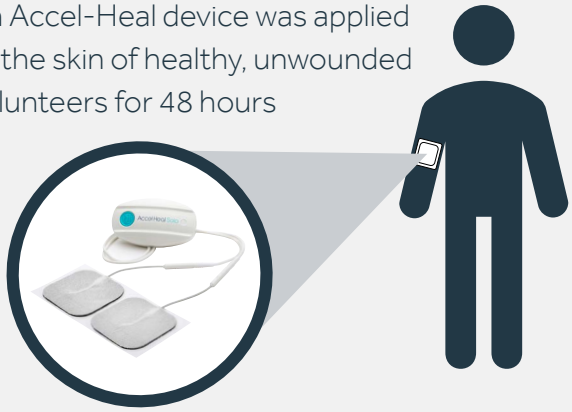
*CITATION: Ovens L. Electrical stimulation therapy and electroceutical treatment for the management of venous leg ulcers. Community Wound Care 2017; March: S28-36.

# KEY MESSAGE: IN A VOLUNTEER STUDY, ACCEL-HEAL HAS BEEN SHOWN TO DOWN-REGULATE 25 GENES IMPLICATED IN CHRONIC WOUNDS AND INFLAMMATION

Although **electrical stimulation** has been shown to improve the rate of wound-healing, the way in which it works is not fully understood. To support a deeper understanding of the mode of action, the volunteer trial conducted at University of Manchester in 2017.

In a volunteer study, conducted on intact skin,this study aimed to identify which genes respond to electrical stimulation.

**1.** An Accel-Heal device was applied to the skin of healthy, unwounded volunteers for 48 hours



**2.** Biopsies were taken from the test site and the opposite (untreated) side.

**3.** Gene expression in these paired biopsies was tested by microarray, and compared

## Results:

**105** 105 individual genes were affected by Accel-Heal

25 of those genes were known to be increased in a chronic wound...

**25**

**25** ...but were **decreased** in Accel-Heal treated skin. This included 3 genes involved in **inflammation**

Conclusion and interpretation: After 48 hours of stimulation, Accel-Heal was found to affect gene expression in human skin. In particular Accel-Heal down-regulated 25 pro-inflammatory genes that are implicated in painful, chronic ulcers and in inflammation. This change in gene expression may represent a dampening effect and may be of benefit to wounds. This supports the hypothesis that Accel-Heal can help move a wound from the inflammatory phase into a healing phase. As inflammation is linked to pain, this study may also suggest a mechanism behind the pain reduction that is seen in clinical practice.

CITATION: Lallyett C, Yeung C-YC, Nielson RH, et al. Changes in S100 Proteins Identified in Healthy Skin following Electrical Stimulation: Relevance for Wound Healing. Adv Skin Wound Care. 2018;31(7):322-327.

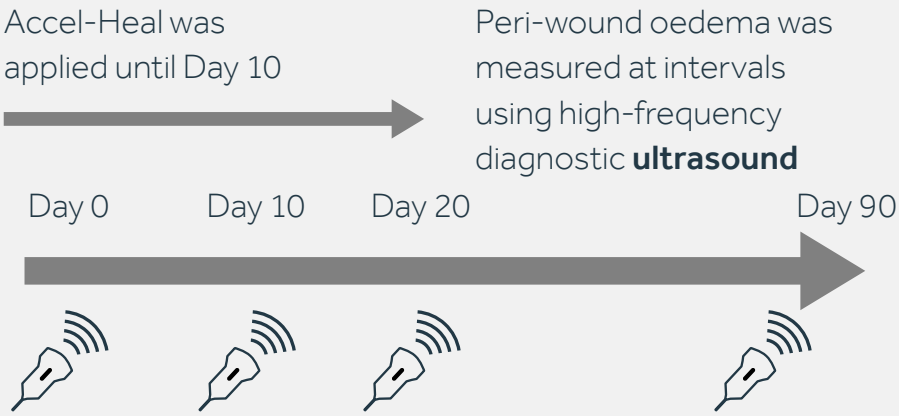
# KEY MESSAGE: IN PATIENTS WITH VLU, AFTER RECEIVING TREATMENT WITH ACCEL-HEAL PERI-WOUND OEDEMA REDUCED BY 60%

**Oedema** causes problems with peripheral circulation and tissue oxygenation in patients with venous leg ulcers (**VLUs**) and can be a barrier to healing.

The objective was to evaluate the effect of electrical stimulation on the management of oedema in previously non-healing VLUs.

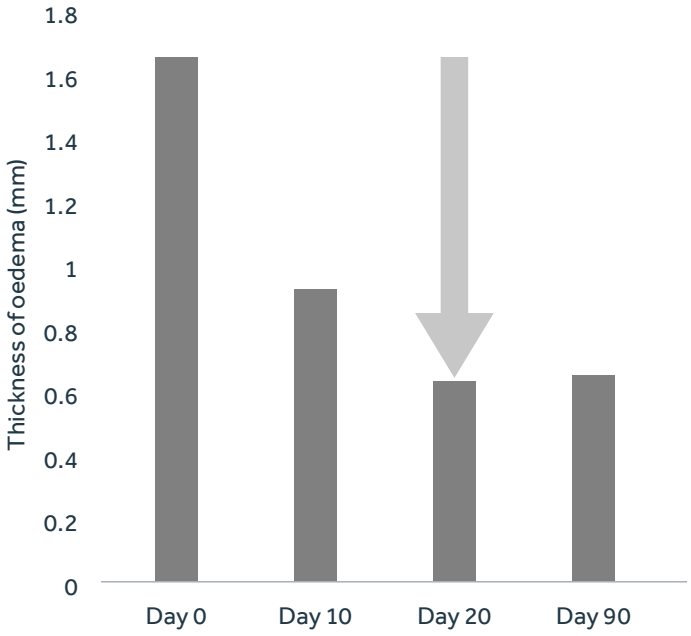
## Methods:

- N=30
- Median age; 74 years
- 57% female
- Median duration of VLU; 17 months




## Results:

- Significantly reduced oedema in the wound bed and the peri-woundwere observed during treatmentwith Accel-Heal.
- A 60% reduction in oedema was measured by day 20.
- This was maintained for up to 3 months after the end of treatment.




Conclusion and Interpretation: Accel-Heal appeared to be effective in reducing oedema in a range of previously non-healing venous leg ulcers and their surrounding tissues

CITATION: Young S, Hampton S, Tadej M. Study to evaluate the effect of low-intensity pulsed electrical currents on levels of oedema in chronic non-healing wounds. J Wound Care. 2011 Aug;20(8):368, 370-3.

# KEY MESSAGE: PERI-WOUND OEDEMA REDUCED FOLLOWING TREATMENT OF HARD-TO-HEAL WOUNDS WITH ACCEL-HEAL

High frequency ultrasound is a usefulmethod to visualise and quantify the amount of exudate in a chronic wound.

This paper describes the results of astudy using Accel-Heal to kick-starta series of non-healing wounds.

## Methods:

1. Only patients with non-healing wounds were enrolled

n=30

2. Accel-Heel applied for 12 days

3. Wound oedema was visualised using ultrasound before and after treatment

## Results:

### Oedema decreased

Wound oedema decreased during treatment with Accel-Heal

### An interesting case study:

- 64-year old male
- Large wound on medial malleolus
- 4 years duration; painful


Accel-Heal applied. Wound progressed well but after treatment ended the wound deteriorated.

Accel-Heal treatment was repeated.


Wound now made excellent progress and went on to heal.

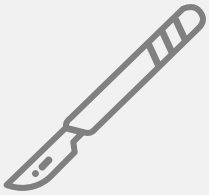
Conclusion and Interpretation: Accel-Heal can reduce wound oedema visualised by ultrasound. Large wounds may benefit from a second application of Accel-Heal

CITATION: Tadej M, Young S, Hampton S. Accel-Heal : a new therapy for chronic wounds. J. Comm. Nurs. 2010; 24(5):16-20.

# KEY MESSAGE: AN IN VITRO STUDY HAS SHOWN THAT ACCEL-HEAL INCREASES THE RATE OF RE-EPITHELIALISATION

Although electrical stimulation has been shown to improve the rate of wound-healing, the way in which it works is not fully understood. To support a deeper understanding of the mode of action, this benchtop study was conducted.

1. Human skin wound model: de-epidermised human donor skin was seeded with cultured human-derived keratinocytes to make multi-layer de-epidermised dermis human skin equivalents (DED-HSEs).
2. The DED-HSEs were wounded with a 4mm punch biopsy



3. Half were treated with Accel-Heal and half were treated with an inactivated device

**Group 1.**
Active device

**Group 2.**
Device off

4. Cellular responses were assessed after 4- and 7-days of treatment by a variety of histological assessments

## Objective:

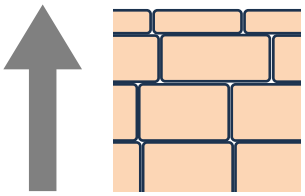
To evaluate the effect of a new EST clinical device on epidermal repair using an in vitro human skin wound model.

## Results:


1.3-times greater wound size reduction was seen in Accel-Heal treated wounds after 4-days, compared with the inactive device. This was statistically significant (<0.05)

### Microcurrent EST improves the quantity and quality of re-epithelialization


In wounds treated with Accel-Heal, 50.3% were covered in keratinocytes after 4 days vs 26.2% of control wounds (p<0.001)



Faster keratinocyte differentiation in Accel-Heal treated wounds resulted in more mature epithelium compared with control

Conclusion and interpretation: This in vitro model, provided experimental evidence that the microcurrent therapy delivered by Accel-Heal accelerates wound closure and improves the quantity and quality of re-epithelialization. These findings support clinical observations published elsewhere.

Lim LKP, Balakrishnan Y, Goh G, Tham KC, Ng YZ, Lunny DP, Leavesley D, Bonnard C. Automated electrical stimulation therapy accelerates re-epithelialization in a 3D in vitro human skin wound model. Adv Wound Care (New Rochelle). 2023 Dec 7. doi: 10.1089/wound.2023.0018. Epub ahead of print. PMID: 38062745.

## EVIDENCE IN PROGRESS

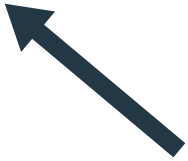
To support the continued adoption of the device, and following the set-up of the new company in 2020, the existing published evidence is now being complemented by further studies conducted in several geographies and with experienced wound care specialists.

Most of these studies have been on a variety of non-healing wounds in particular diabetic foot ulcers, pressure ulcers and arterial ulcers. A number of publications (papers and posters) are in the pipeline.

Please click on the links below to explore further

**On-going studies include:**

- Company sponsored clinical RCT
- In-service patient evaluations at multiple sites globally



**Click on each item of evidence for more information**

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress

1 2 3 4 5

KEY MESSAGE: A COMPANY SPONSORED PILOT RCT, TO EXPLORE THE IMPACT OF ACCEL-HEAL ON WOUND PAIN, IS CURRENTLY IN THE ADVANCED PLANNING STAGE*

Planning phase → Live phase → Analysis/ interpretation → Manuscript preparation → Paper in print

## Primary objective

To pilot the study design for a future powered RCT assessing the ability of Accel-Heal to reduce pain in VLU patients so that they remain in concordance with their prescribed compression therapy.

## Study design:

- Pilot RCT
- Accel-Heal
- Outcomes were measured at baseline, after the 12-day Accel-Heal treatment period, and after 6-weeks.

Group 1 (n=20) → Treated with working Accel-Heal with compression

Group 2 (n=20) → Treated with sham device with compression

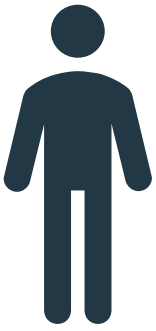
## Collaborating centres:

- University of Huddersfield, UK
- University of Birmingham, UK

## Status and timescales:

- Currently in advanced planning
- Live phase estimated at 12-months

## Patients:

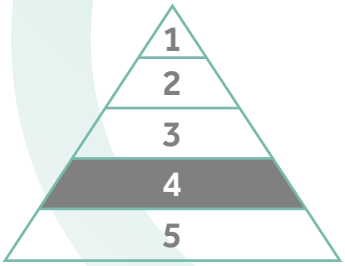


- N=40
- Painful VLU (>4/10 NRS scale) despite analgesics
- VLU <12-month duration
- VLU area >1cm$^2$

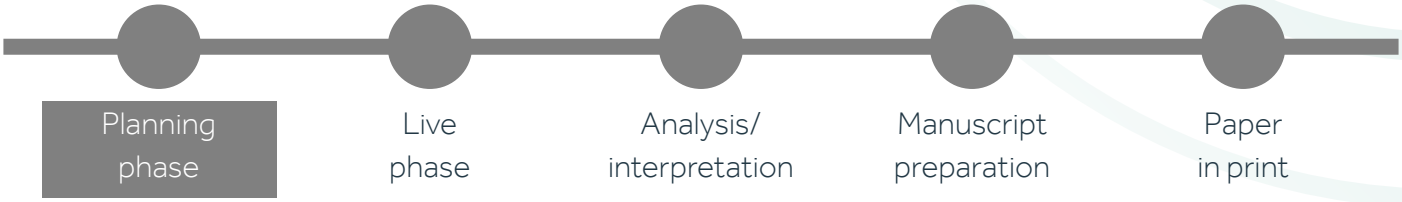
*Status April 2022

VLU - healing outcomes | DFU - healing outcomes | Other - healing outcomes | Mode of action

EST evidence base | Patient benefits | Health Economic benefits | Evidence in-progress




## KEY MESSAGE: A SERIES OF OTHER IN-SERVICE CLINICAL EVALUATIONS ARE ON-GOING, IN SEVERAL COUNTRIES GLOBALLY*




A series of in-service evaluations are underway in France, Austria, Australia and the Middle-East

Conclusions and interpretation: Multiple, parallel in service evaluations are on-going in several countries globally. All have potential for development into local, national or international publications.

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Accel-Heal Technologies Limited
The Old Station, Hever, Kent, TN8 7ER, UK
accelheal.com
customerservices@accelheal.com
+44 (0)1959 569 433