PRODUCT MONOGRAPH

Relieve the pain, stimulate healing

Innovative electrical stimulation
for hard-to-heal wounds

accelheal.com

AccelHeal
ELECTRICAL STIMULATION WOUND THERAPY

ACCEL-HEAL: ELECTRICAL STIMULATION WOUND THERAPY

Despite treatment advances in wound management over the past 30 years, chronic wounds are becoming increasingly burdensome.

One unresolved issue is poor patient compliance to the accepted gold standard treatments, for example because wound pain can make many treatments intolerable. Approaches are needed that not only stimulate wound healing but also have the potential to improve compliance through the early resolution of pain.

Electrical stimulation is one such treatment technology that has the potential to achieve this. Electrical stimulation is one of the most evidence-based technologies in wound management with five meta analyses[1–5] and over 30 RCTs[2,6] published to date. It has proven to be effective in accelerating healing in multiple wound types[2,7] and is also shown to be beneficial in reducing wound pain. [6,14-23] It is safe to use with minimal side effects.[1,7]

THE ACCEL-HEAL DEVICE

Accel-Heal® is a single-use, portable, easy to use electrical stimulation device. Accel-Heal delivers an automated program of sub-sensory electrical pulses over a treatment period of 12 days.

The small, pocket-sized dimensions of Accel-Heal mean that it is discreet and makes it an ideal device for use in the patient's own home. It can be clipped to compression hosiery where it does not hinder the patient's ability to move around.

Incorporation of Accel-Heal into a patients' wound management plan is easy. It can be used along-side many gold standard treatments like compression therapy and advanced wound dressings. Every 48-hours, over the 12-day treatment period, the Accel-Heal device is changed for a new device. This is easily carried out by the patient or carer and there is no need to disrupt the wound dressing or replace the electrodes underneath the dressing. Once each device is switched on, it automatically delivers advanced electrical stimulation therapy with no need for the patient to intervene and no need to disrupt the dressing in between routine dressing changes.

23 published articles, including 10 papers and 13 posters, describe the effects of Accel-Heal.

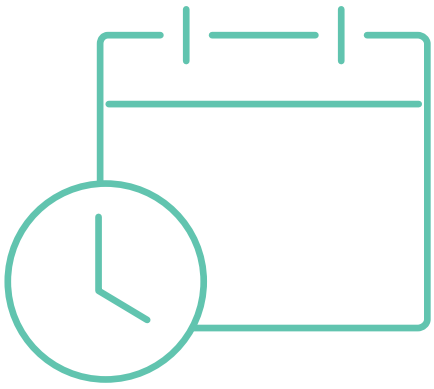
The results of 160 patients treated with Accel-Heal have been published in the clinical literature.

TARGETED THERAPY FOR HARD-TO-HEAL AND PAINFUL WOUNDS

Accel-Heal is indicated for patients with hard-to-heal wounds including leg ulcers, diabetic foot ulcers and pressure ulcers and may be used to kick-start the healing process in a wound which has stalled.

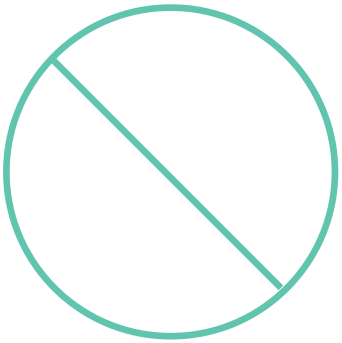
In particular, Accel-Heal can help patients with painful wounds, including patients whose wound pain means they may not be able to tolerate gold standard treatments such as compression therapy and whose pain prevents them from carrying out their daily activities.

CANDIDATES FOR ACCEL-HEAL



Patients with a hard-to-heal wound that is not progressing to healing

Patients who are frustrated by the reduced mobility caused by their pain



Patients whose wound pain causes them to be non-compliant to treatment

ACCEL-HEAL DELIVERS THE OPTIMUM DOSE AND WAVEFORM OF ELECTRICAL STIMULATION

Accel-Heal delivers sub-sensory stimulation.

Accel-Heal delivers an automatic, pulsed electrical stimulation with a current varying from 40 to 500micro Amps (μA) during the treatment programme. Even the strongest pulses are below the threshold for sensory stimulation, meaning that patients should not typically feel any stimulation and will certainly not experience twitchy muscles. The stimulus being delivered is enough to trigger the appropriate cellular responses, re-igniting the healing process without an unpleasant sensation.

Other types of electrical stimulation, for example high voltage pulsed current (HVPC) and many forms of TENS are delivered above the threshold for sensory stimulation. Patients can feel these levels of electrical stimulation either as a feeling of "pins and needles" (HVPC)[8] or can cause muscles to twitch (EMS and occasionally TENS). When applied to an already painful wound, these sensations, have been described as unpleasant. Electrical stimulation devices do not need to evoke such strong physical responses to stimulate the appropriate cellular effect in the wound bed. Accel-Heal's sub-sensory stimulation avoids these unpleasant sensations.

THE DOSE DELIVERED BY ACCEL-HEAL FALLS WITHIN THE RECOMMENDED RANGE **(250-500μC/s)**

Accel-Heal delivers the optimal dose of electrical stimulation.

In the numerous studies investigating electrical stimulation, many different waveforms have been used.

The optimal 'dose' of electrical stimulation has been estimated to be between 250 and 500 micro Coulombs per second (μC/s).[9] Accel-Heal delivers a dose of electrical stimulation within this range.[3,4]

PULSED WAVEFORMS, LIKE THOSE DELIVERED BY ACCEL-HEAL, ARE THE **MOST EFFECTIVE** TYPE

Accel-Heal employs the most effective waveform – pulsed current.

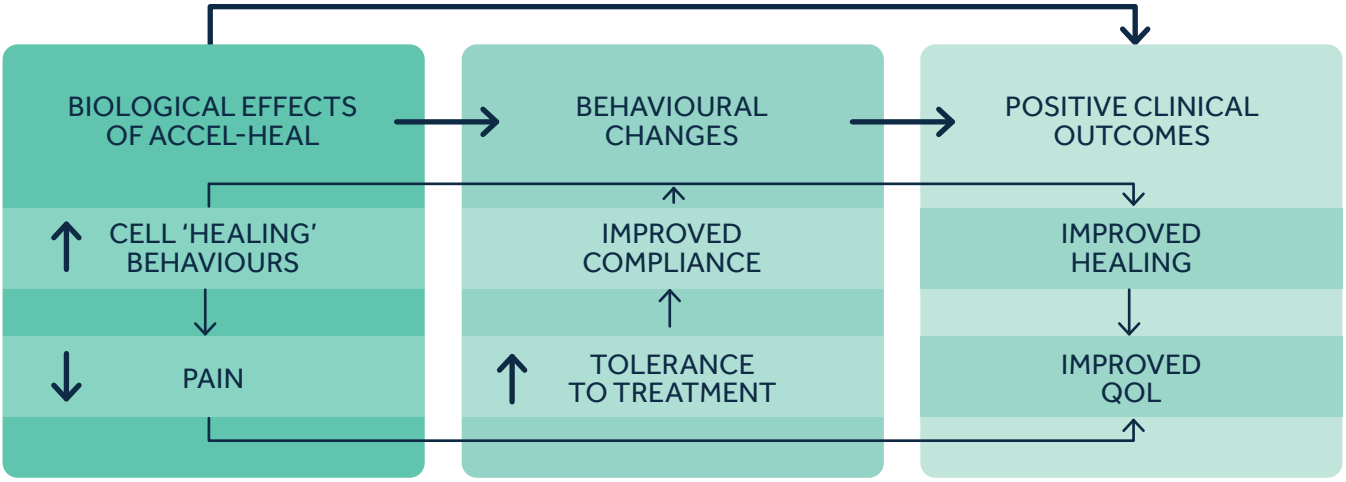
Meta-analyses have also shown that devices, like Accel-Heal, that provide a "pulsed current" stimulation are more efficacious than other types of stimulation.[2,10]

BENEFITS OF WOUND TREATMENT WITH ACCEL-HEAL

Accel-Heal relieves pain and stimulates healing by directly affecting cell behaviour in and around the wound bed.

Relief of pain enables patients to receive wound treatments that they would otherwise not have been able to tolerate. This can lead to behavioural changes in the patient and an increased compliance to their prescribed therapy.

The cumulative effect of improved compliance to treatment and an improvement in the cell 'healing' behaviours, lead to positive clinical outcomes, including improved rates of healing and improved patient quality of life. Simultaneously, electrical stimulation devices, such as Accel-Heal, also stimulate wound bed cells into 'healing' behaviours, kick-starting the wound-healing process.



BIOLOGICAL EFFECTS OF ACCEL-HEAL

Triggers cell 'healing' behaviours.

In a hard-to-heal wound, electrical stimulation can trigger the cellular processes needed to kick-start wound healing. These processes include proliferation and migration of fibroblasts, keratinocytes and endothelial cells, and the release of growth factors.[11] All of these events are necessary for the formation of granulation tissue and for re-epithelialisation to take place.

Within the first 48 hours of application, Accel-Heal can alter the expression of over 100 genes, many of which are involved in wound healing and inflammation.[12 13] Some of the genes downregulated by Accel-Heal are related to macrophage function and production of pro-inflammatory factors.

Some of these genes are known to be overexpressed in non-healing venous leg ulcers, including the genes that control production of three proteins in the "S100" family involved in inflammation and SERPINB4 proteins which are involved in protease inhibition.[12] The ability to suppress these genes in an inflamed, hard-to-heal wound using Accel-Heal, may be a positive step towards healing.[13]

These cellular changes suggest that Accel-Heal may dampen down the inflammatory environment that is present in hard-to-heal wounds. Case studies have reported a visually apparent reduction in wound inflammation in as little as 7-days after applying the Accel-Heal device.[14]

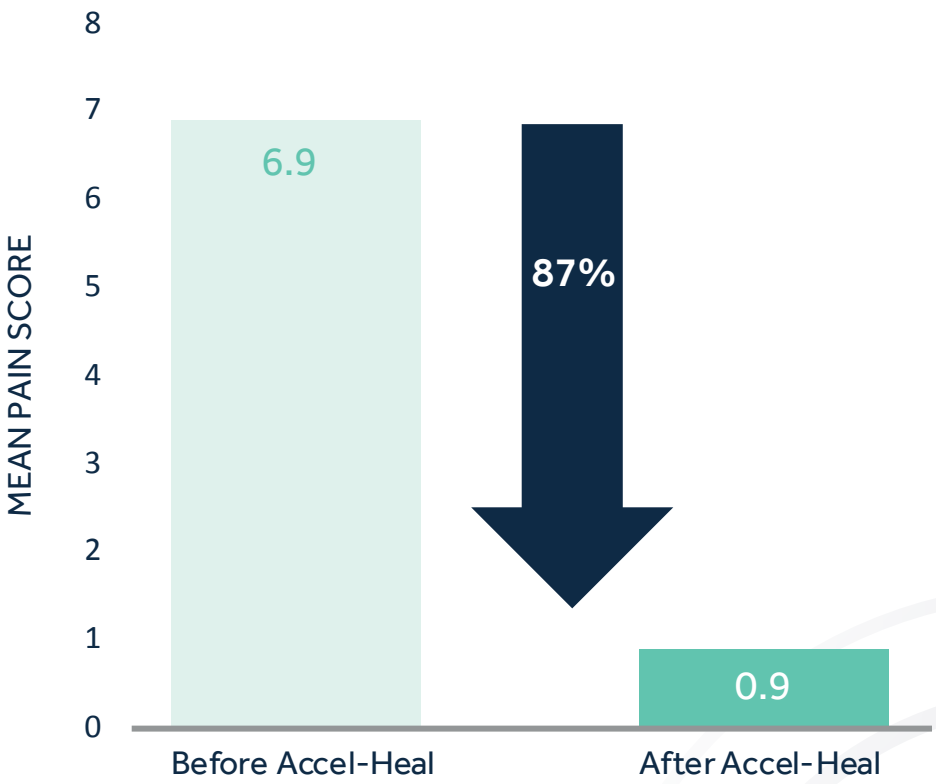
BIOLOGICAL EFFECTS OF ACCEL-HEAL

Accel-Heal relieves wound pain.

Patients have reported marked pain relief following treatment with Accel-Heal in a number of studies [6,15–20] and case studies. [14,21–23] In some cases, rapid relief from pain has been observed within hours of application of Accel-Heal.[18] Large reductions in pain from a score of 8 (out of 10 where 10 represented the worst possible pain) to minimal or no pain within 7-days of Accel-Heal therapy have also been reported.[14,23] In one study of 19 lower limb ulcers, a marked pain score reduction from a mean score of 6.9 before treatment with Accel-Heal to 0.9 within 2-weeks was observed, a reduction of 87%.[17]

In a randomised controlled trial of 99 patients, Accel-Heal reduced mean pain scores to a greater extent than in patients who received a placebo device.[6]

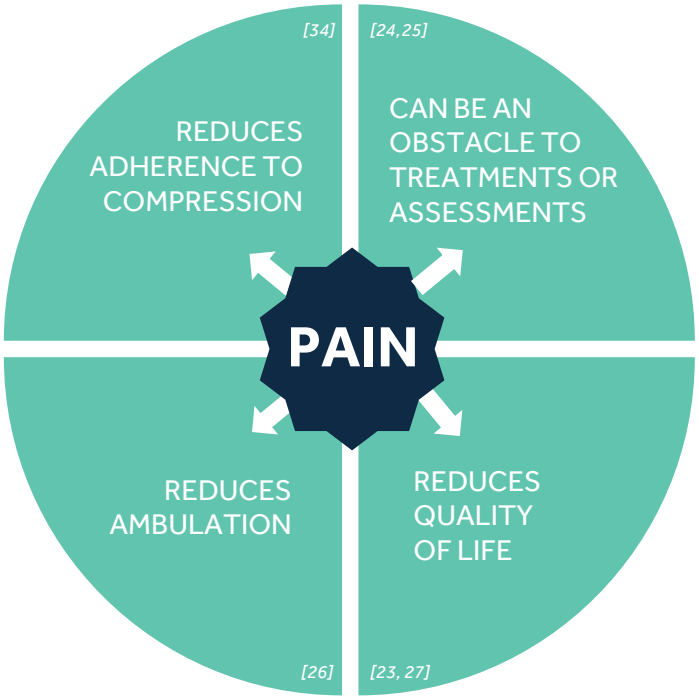
Relief of pain has enabled many patients to reduce their pain medication; some patients treated with Accel-Heal have been able to come off their tramadol, gabapentin or morphine medication altogether as a direct result of the rapid and marked pain relief after starting treatment with Accel-Heal.[22,23] Pain medication can often make patients drowsy and unable to work; for some patients the pain relief afforded by Accel-Heal and their reduced need for pain medication meant that they could go back to work.[23]



HOW ACCEL-HEAL CAN INFLUENCE PATIENT BEHAVIOURS

Wound pain can strongly influence many patient behaviours. Pain often prevents patients from conforming to advice or prescriptions given to them by the healthcare providers (HCP). In this way, wound pain can have a major negative impact on wound healing.[24] Some examples of how this has been shown in clinical practice are described below:

The ability of Accel-Heal to relieve pain can reduce the negative influence of pain and allow patients' behaviour to conform to their prescribed therapy or the level of activity advised by their HCP.



Accel-Heal improves compliance to gold standard compression.

4-layer compression bandaging is a gold standard treatment for venous leg ulcers. Painful wounds can reduce a patient's tolerance to and compliance with compression therapy.[24,25]

These patients are sometimes managed by putting them in a lower level of compression which has been shown to be less effective.[24] Patients treated with Accel-Heal were able to tolerate full compression as a direct result of the pain relief afforded by Accel-Heal therapy.[14,23] This is expected to have contributed to positive healing outcomes observed in these patients.

Accel-Heal improves compliance to efficacious wound treatments and essential investigations.

Some centres have set up a protocol where the use of Accel-Heal therapy can be used to manage patient pain to allow HCPs to carry out routine investigations such as Doppler investigation of blood flow in the lower limb.[18] In a very painful wound, these and other investigations would otherwise not be tolerated by the patient.[18,25]

These investigations are essential in providing an accurate diagnosis of a lower limb ulcer and in developing a wound management plan. Debridement is also an effective treatment which is difficult to carry out, especially in a home setting, on a patient with a very painful wound. Accel-Heal may be a useful therapy to improve compliance to these and other treatments and investigations otherwise not tolerated.

HOW ACCEL-HEAL CAN INFLUENCE PATIENT BEHAVIOURS

Accel-Heal reduces the barrier to ambulation and exercise.

Exercise and ambulation are advised for the general health of the patient but also to aid blood flow to the lower limb and can improve the chances of wound healing. Wound pain can worsen during movement and can make moving about very difficult for the patient, making patients less likely to comply with this medical advice.[26]

Patients treated with Accel-Heal noted huge differences in their ability to move about freely compared with the restrictions they had experienced before treatment. This was often related to the reduction in pain.[17,22] Rediscovered activities included being able to play snooker with friends, visit family, play with their grandchildren and even get into their usual bedroom, all of which has been difficult before they received treatment with Accel-Heal, as an adjunct to their wound management plan.[17,22]

Accel-Heal improves patient quality of life.

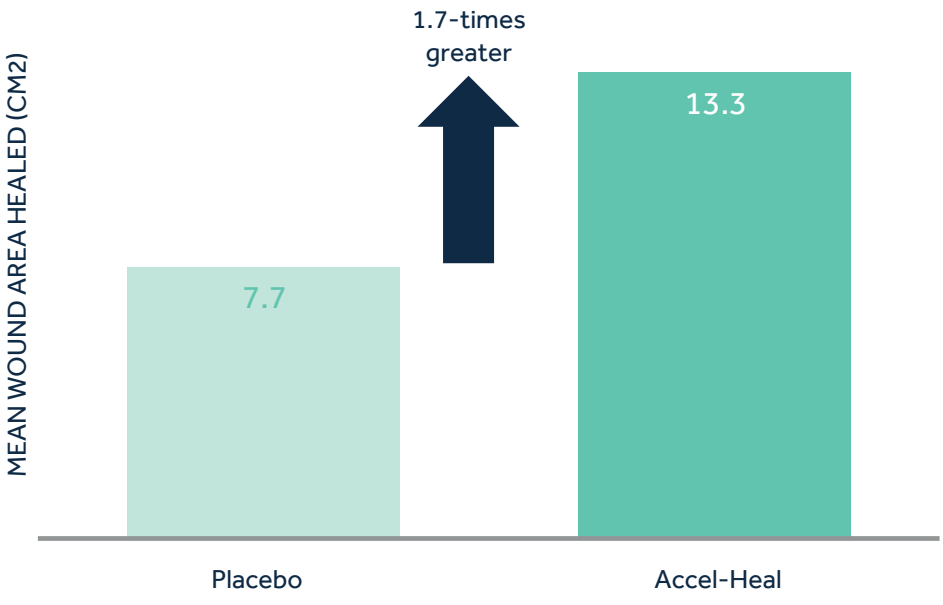
Wound pain has a direct impact on quality of life.[27] The feeling of being free of the burden of pain was a huge relief and helped patients return to a better quality of life. [17,19,28,29]

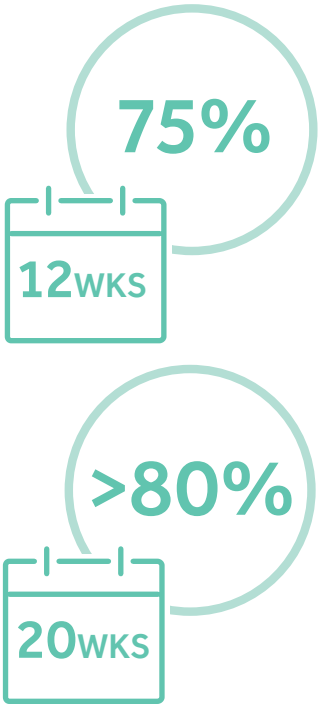
This included being able to go back to work.[23] Many patients noted that the improvement in mobility that came with having less pain, meant a return to their normal social activities and that this had a major impact on their quality of life.

HOW ACCEL-HEAL CAN IMPROVE WOUND HEALING OUTCOMES

Accel-Heal has been reported to improve wound healing outcomes in many studies.[6,14,15,17,19,30]

In a randomised controlled trial comparing Accel-Heal with a placebo device, the mean area of wounds that achieved healing after treatment with Accel-Heal was nearly twice as large (1.7-times) as in the placebo group.[6]

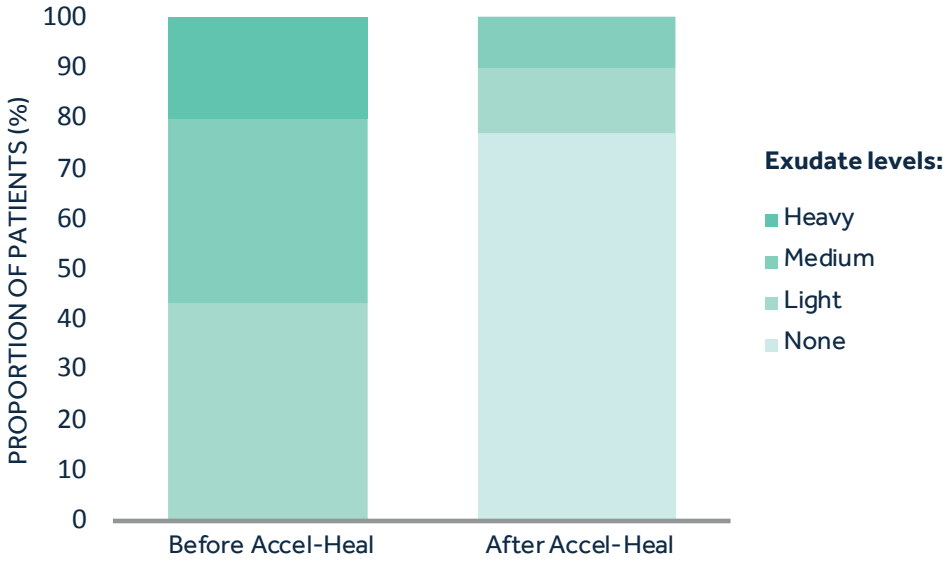




Clinical studies have reported complete wound healing **up to 75%** (range 38-75%) **after 12 weeks** of follow up,[6,18] and **over 80%** after **20 weeks** (range 80-90%).[18,19,31]

Accel-Heal therapy also had a positive effect on wound oedema. Oedema was found to decrease markedly following application of Accel-Heal for the 12-day treatment phase.[16,32]

The depth of oedematous tissue was reduced by a third within the first 10 days of Accel-Heal therapy and continued to decrease to only 40% of the original depth after the course of treatment had finished.[32] Exudate levels also consistently fell following treatment with Accel-Heal [6,15,16,19,20,30] as shown in the diagram below.[6]



HOW ACCEL-HEAL CAN REDUCE COSTS

In a randomised controlled trial, more patients who achieved healing when treated with Accel-Heal did so, on average, 3.6 weeks faster than patients being treated with conventional treatment.[6] Based on published estimates of the weekly cost of treating patients with venous leg ulcers[33] this increased speed of healing could save up to £936 per patient.[35]

Factoring the cost of the Accel-Heal 12-day therapy, and the proportion of patients who were successfully healed in a 24-week period,[6] there was a clear cost saving of £7800, and 122 weeks of GP and nurse time per 100 patients treated, when treating patients with Accel-Heal.[35]

TIMETABLE OF ACCEL-HEAL THERAPY

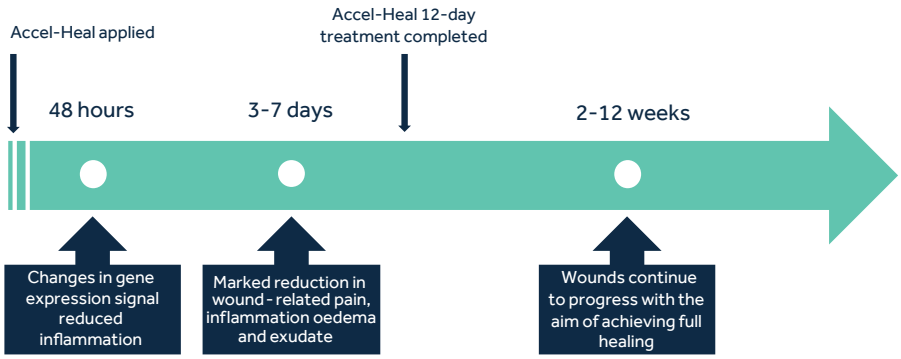
It is not expected that previously hard-to-heal wounds will heal completely within Accel-Heal's 12-day treatment period. Rather, treatment with Accel-Heal should be seen as a way of kick-starting the healing process and for that process to continue after the therapy has been completed.

Following the application of Accel-Heal, patients often experience pain relief within days[6,14–23] and sometimes within hours.[18] Within the first 3-7 days, a reduction in oedema, [16,32] exudate[8–10,13,14,2] and inflammation[14] have been observed.

Evidence of healing has been reported, in a previously static wound, as soon as 5 days after the application of Accel-Heal.[23] These changes continue to progress gradually throughout the 12-day treatment period.

Once the Accel-Heal therapy has been completed, the wound continues to progress towards healing. For some wounds of long duration (over 12 months) or for very large wounds, a second treatment with Accel-Heal may be necessary to get the wound onto a healing trajectory.[16]

Timeline of the response to Accel-Heal



CONCLUSION

As well as kick-starting the healing process, Accel-Heal can also reduce wound pain in a few days and, in some patients, even in a few hours. This has been shown to improve patients' tolerance of wound management treatments, for example compression for the management of VLU[14,23] and investigations such as wound Doppler assessments.[18] The Accel-Heal device delivers low intensity, pulsed current at a sub-sensory level. This stimulates the patient's bioelectric signalling pathways to trigger healing events but avoids any unpleasant sensation that may exacerbate an already painful wound.

The portability and intuitive design of the Accel-Heal device is suitable for delivery of uninterrupted use in a home-care setting. Accel-Heal is an easy to use, pre-programmed device that requires minimal intervention from either patients or caregivers. Given the wealth of evidence, it is clear that electrical stimulation should be part of the armamentarium used to address the many challenges of treating chronic and complex wounds. The Accel-Heal device now provides an ideal opportunity for clinicians to easily and conveniently incorporate this treatment method into their everyday practice with the aim of relieving pain and stimulating healing.

REFERENCES

1. B BG, Duarte J. 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.
2. Khouri C, Kotzki S, Roustit M, Blaise S, Gueyffier F, Cracowski J. Hierarchical evaluation of electrical stimulation protocols for chronic wound healing : An effect size meta-analysis. Wound Repair Regen. 2017:883-891.
3. Lala D, Spaulding S, Burke S, Houghton P. 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.
4. Gardner S, Frantz R, Schmidt F. Effect of electrical stimulation on chronic wound healing: a meta-analysis. Wound Repair Regen. 1999;7(6):495-503.
5. Liu L, Moody J, Gall A. 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.
6. 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.
7. Piaggesi A, S L, F B, Al. E. EWMA document: advanced therapies in wound management: cell and tissue based therapies, physical and bio-physical therapies smart and IT based technologies. J Wound Care. 2018;27(Suppl 6):1-137.
8. Draper DO, Knight KL, Rigby JH. High-volt pulsed current: Treatment of skin wounds and musculoskeletal injuries. Int J Athl Ther Train. 2012;17(4):32-34.
9. Kloth LC. Electrical Stimulation Technologies for Wound Healing. Adv Wound Care. 2014;3(2):81-90.
10. Ashrafi M, Mohamed TA, Ardeshir B. The efficacy of electrical stimulation in lower extremity cutaneous wound healing : A systematic review. 2017;(August 2016): 171-178.
11. Hunckler J, Mel A De. A current affair : electrotherapy in wound healing. 2017:179-194.
12. Lallyett C, Yeung CYC, Nielson RH, et al. Changes in S100 Proteins Identified in Healthy Skin following Electrical Stimulation: Relevance for Wound Healing. Adv Ski Wound Care. 2018;31(7):322-327.
13. Lallyet C, Nielson RH, Zeef L, et al. Gene expression changes in skin following microcurrent treatment. Present Collagen Gordon Res Conf.
14. Ovens L. Electroceutical therapy to manage complex leg ulcers: A case series of three patients. In: Wounds UK. ; 2014.
15. Chapman-Jones D, Young S, Tadej M. Assessment of wound healing following electrical stimulation with Accel-Heal®. Wounds UK. 2010;6(3):67-71.
16. Tadej M, Young S, Hampton S. Accel-Heal® : A new therapy for chronic wounds. J Community Nurs. 2010;24(5):16-21.
17. Turner N, L. Ovens. Clinical outcome results and quality of life improvements using electroceutical treatment - Patient perspectives. In: EWMA 2018. ; 2018.
18. Ovens L. Improving clinical outcomes and reducing the cost of venous leg ulcers (VLUs) using externally applied electroceutical therapy in a Community NHS Trust In: Wounds UK. ; 2018. doi:10.1111/12
19. L. Ovens. Supporting the Triple Aim Framework objectives in Scotland using an innovative electroceutical therapy to improve clinical and economic benefi ts for patients with venous leg ulcers (VLUs) Using an innovative electroceutical therapy to improve clini. In: Presented at EWMA. ; 2019.
20. Chapman-Jones D, Young S, Tadej M. An observational study evaluating the efficacy of Accel-Heal on the management of non-healing venous leg ulcers. In: Presented at EWMA. ; 2011.
21. Ovens L. Electrical stimulation therapy and electroceutical treatment for the management of venous leg ulcers. Br J Community Nurs. 2017;22(March):S28-S36.
22. Louison P, Sister S, Viability T, Study C. Management of recurrent venous leg ulcer with electroceutical therapy to improve pain , expedite healing and reduce risk of recurrence. Present EWMA. 2015.
23. Greaves T. Improving patient quality of life with innovative electroceutical technology: A case series. In: Presented at Wounds UK. ; 2014.
24. Briggs M, Closs SJ. Patients' perceptions of the impact of treatments and products on their experience of leg ulcer pain. J Wound Care. 2006;15(8):333-337.
25. Griffin J. Improving outcomes through innovation: An evaluation of Accel-Heal® in chronic wounds. Wounds UK. 2013;9(4): 118-121. http://www.embase.com/search/
26. Ducic I1, Mafi AA, Attinger CE, Couch K A-AA. The role of peripheral nerve surgery in the management of painful chronic wounds: indications and outcomes. Plast Reconstr Surg - Glob Open. 2008;122(1):193-197.
27. Lentsck MH, Baratieri T, Trincaus MR, Mattei AP, Miyahara CTS. Quality of life related to clinical aspects in people with chronic wound. Rev da Esc Enferm da USP. 2018;52(0):1-9.
28. N. Turner. Right Care , Right Time : - An evaluation using an electroceutical treatment to determine the clinical outcomes in a large NHS Trust In: Wounds UK. ; 2017.
29. Lynch O, Kiernan C, Strapp H, et al. A study to evaluate the effectiveness of the Accel Heal electroceutical device as an adjunctive treatment to vascular foot ulcers. In: EWMA 2019. ; 2019.
30. Guest JF, Ayoub N, Greaves T. Clinical outcomes and cost- in managing venous leg ulcers applied electroceutical device effectiveness of an externally in clinical practice in the UK. J Wound Care. 2015;24(12):574-580.
31. 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):92-99.
32. Young S, Hampton S, Tadej M. Study to evaluate the effect of low-intensity pulsed electical currents on levels of oedema in chronic non-healing wounds. J Wound Care. 2011;20(8):1-6.
33. Guest J, Fuller G, Vowden P. Venous leg ulcer management in clinical practice in the UK: costs and outcomes. Int Wound J. 2018;15(1):29-37.
34. Data on file 190901CESPS
35. Data on file 20191005JP

Accel Heal

ELECTRICAL STIMULATION WOUND THERAPY

ORDERING DETAILS

Item	Size	Product code	PIP code	NHS code
1 x Accel-Heal® treatment (6 x 48 hour units)	7cm x 4cm x 2cm	K560-6	373-0942	ELZ752

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