PRODUCT MONOGRAPH

Relieve the pain, stimulate healing

Innovative electrical stimulation for hard-to-heal wounds
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. 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 alongside 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.

**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

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.
Accel-Heal delivers sub-sensory stimulation. Accel-Heal delivers an automatic, pulsed electrical stimulation with a current varying from 40 to 500 microamps (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.

The optimal ‘dose’ of electrical stimulation has been estimated to be between 250 and 500 micro Coulombs (μC/s). Accel-Heal delivers a dose of electrical stimulation within this range.\(^\text{[34]}\)

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.

**Benefits of Wound Treatment with Accel-Heal**

- **Pain**: Patients can feel these levels of sub-sensory stimulation avoids these unpleasant sensations.
- **Tolerance to Treatment**: The stimulus being delivered is enough to trigger the appropriate cellular responses, re-igniting the healing process without an unpleasant sensation.
- **Compliance**: Some of these genes are known to be overexpressed in non-healing venous leg ulcers, including the genes that control production of three proteins which are involved in protease inhibition.\(^\text{[12]}\) The ability to suppress these genes in an inflamed, hard-to-heal wound using Accel-Heal, may be a positive step towards healing.\(^\text{[13]}\)

**Biological Effects of Accel-Heal**

- **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.\(^\text{[12]}\) 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.\(^\text{[12]}\) Some of the genes downregulated by Accel-Heal are related to macrophage function and production of pro-inflammatory factors.

**Behavioural Changes**

- **Improved Compliance**: Meta-analyses have also shown that devices, like Accel-Heal, that provide a “pulsed current” stimulation are more efficacious than other types of stimulation.\(^\text{[2,10]}\)

**Positive Clinical Outcomes**

- **Improved Healing**: Some of these genes are known to be overexpressed in non-healing venous leg ulcers, including the genes that control production of three proteins which are involved in protease inhibition.\(^\text{[12]}\) The ability to suppress these genes in an inflamed, hard-to-heal wound using Accel-Heal, may be a positive step towards healing.\(^\text{[13]}\)

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.\(^\text{[14]}\)
Accel-Heal relieves wound pain.
Patients have reported marked pain relief following treatment with Accel-Heal in a number of studies and case studies. In some cases, rapid relief from pain has been observed within hours of application of Accel-Heal. 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. 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%.

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. 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. 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.

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. 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.

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

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.

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, in a very painful wound. 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.

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.

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PAIN

REDUCES ADHERENCE TO COMPRESSION

REDUCES AMBULATION

REDUCES QUALITY OF LIFE

CAN BE AN OBSTACLE TO TREATMENTS OR ASSESSMENTS

Accel-Heal relieves wound pain. Patients have reported marked pain relief following treatment with Accel-Heal in a number of studies and case studies. In some cases, rapid relief from pain has been observed within hours of application of Accel-Heal. 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. 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%.

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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.¹³,²⁴ 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.¹³,²⁴

Accel-Heal improves patient quality of life.
Wound pain has a direct impact on quality of life.¹⁰ 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.²¹ 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.

Accel-Heal has been reported to improve wound healing outcomes in many studies.²,⁶,¹⁵,¹⁷,¹⁹,²⁰,³¹

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.²⁰

Clinical studies have reported complete wound healing up to 75% (range 38-75%) after 12 weeks of follow up,²⁶-²⁸ and over 80% after 20 weeks (range 80-90%).²⁶,²⁸,³⁰

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.²⁶,³¹

HOW ACCEL-HEAL CAN IMPROVE WOUND HEALING OUTCOMES

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.²⁶ Based on published estimates of the weekly cost of treating patients with venous leg ulcers²⁹ this increased speed of healing could save up to £3936 per patient.²⁶

Factoring the cost of the Accel-Heal 12-day therapy, and the proportion of patients who were successfully healed in a 24-week period,²⁶ 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.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.²,⁶,¹⁵,¹⁶,¹⁹,²⁰,³¹,³³ as shown in the diagram below.³⁴
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[10,11] and sometimes within hours.[14] Within the first 3-7 days, a reduction in oedema,[13,14] exudate,[8–10,13,14,2] and inflammation[7] has been shown to improve patients’, even in a few hours. This improves wound pain in a few days and, in some cases, pain may exacerbate an already painful wound.[8]

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.[14]

Table: Timeline of the response to Accel-Heal

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Description</th>
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<tbody>
<tr>
<td>48 hours</td>
<td>Reduction in swelling, expression of reduced inflammation</td>
</tr>
<tr>
<td>3-7 days</td>
<td>Reduced wound pain, reduced inflammation, oedema and exudate</td>
</tr>
<tr>
<td>2-12 weeks</td>
<td>Wounds continue to progress with the aim of achieving full healing</td>
</tr>
</tbody>
</table>

The porosity 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 electrotherapy 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 incorporate this treatment method into their everyday practice with the aim of relieving pain and stimulating healing.

Timeline of the response to Accel-Heal

48 hours 3-7 days 2-12 weeks

Evidence of healing has been reported, in a previously static wound, as soon as 5 days after the application of Accel-Heal.[2] These changes continue to progress gradually throughout the 12-day treatment period.

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 VLUs[23] and investigations such as wound Doppler assessments.[14] 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.

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 VLUs[23] and investigations such as wound Doppler assessments.[14] 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.

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## ORDERING DETAILS

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<thead>
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<th>NHS code</th>
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<tbody>
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<td>K560-6</td>
<td>373-0942</td>
<td>ELZ752</td>
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