

Introduction

Wound pain can make many treatments intolerable. Electrical stimulation is a technology that can stimulate wound healing and has the potential to simultaneously improve compliance to treatment through the early resolution of wound pain. This is supported by a sizable and growing evidence base in many different wound types. This Made Easy describes how Accel-Heal[®], a single-use, portable, easy-to-use electrical stimulation device can be incorporated into clinical practice with the goal of improving pain management and wound healing outcomes.

WHAT IS THE IMPACT OF WOUND PAIN ON PATIENT COMPLIANCE?

Between 50 and 60% of patients with chronic wounds experience persistent wound pain¹². Pain intensity is often significant with up to 35% of patients with chronic wounds suffering a pain intensity ≥ 5 out of 10 (10 being unbearable pain). Pain management should ideally be an integral part of wound care, however, current commonly used pain management approaches are far from optimal³. Pharmaceutical management of persistent wound pain with opioid and non-opioid analgesics is often inadequate as patients often struggle to access the correct analgesic or find it ineffective. Wound pain can lead to lack of compliance with prescribed therapy (Figure 1)^{4,5}.

WHAT IS ELECTRICAL STIMULATION?

Electrical stimulation (E-stim) can be considered a 'catch all' phrase for many different functional therapies and stimuli. E-stim has application through many areas of medicine (Figure 2) including internally applied devices, such as cochlea implants, pace-makers or vagal nerve stimulation⁶, or externally applied

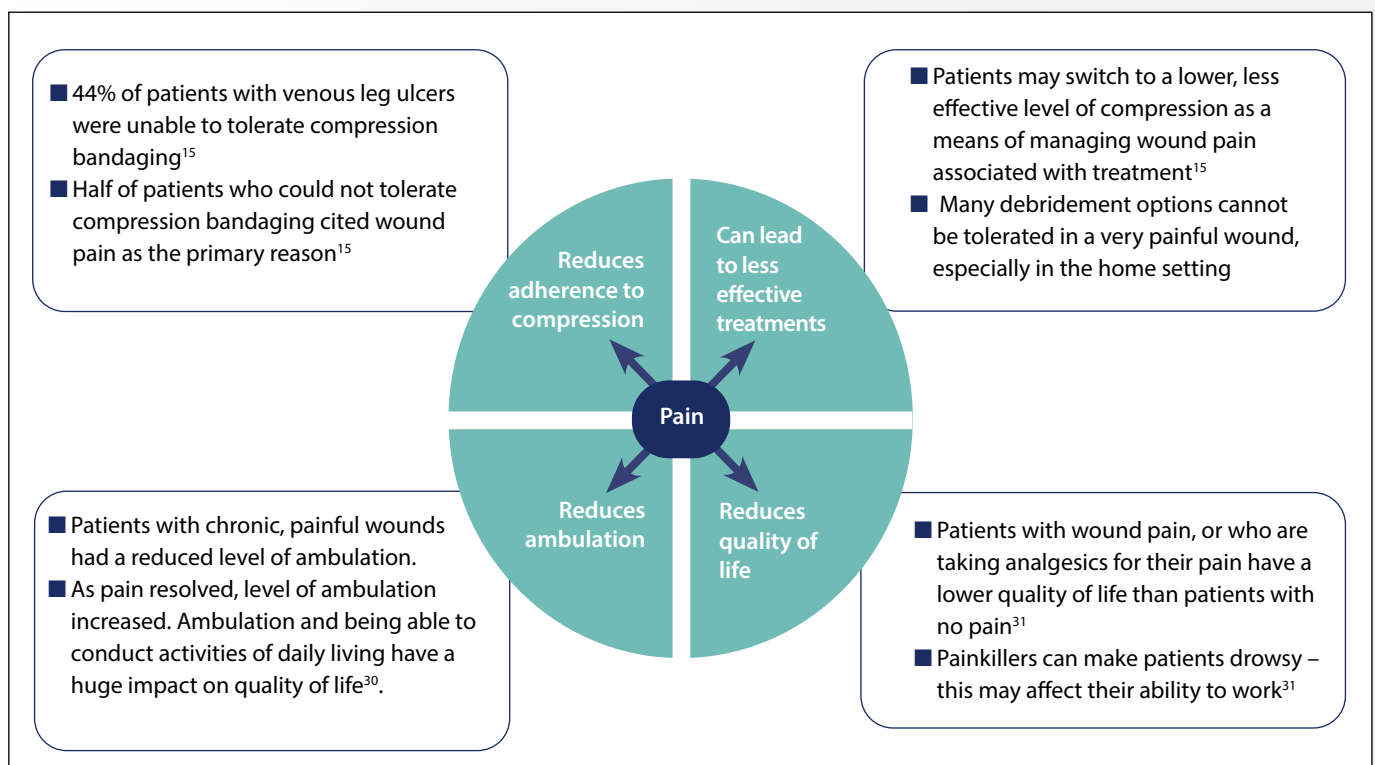


Figure 1. The impact of persistent wound pain.

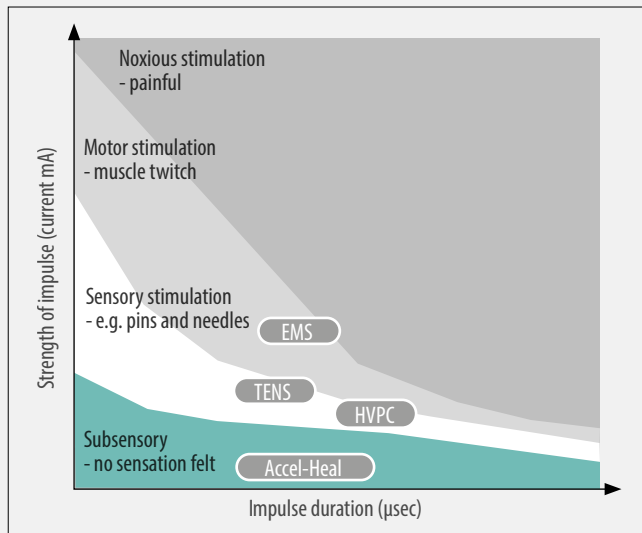


Figure 2. Different electrical stimulation can be applied at different strength and duration of electrical impulse. The stimulus from some types of electrical stimulation typically exceeds the threshold for nerve activation and causes either a sensory effect (that can range from tingling to ‘pins and needles’, i.e. TENS, HVPC) or a motor effect (such as a muscle twitch, i.e. EMS). The electrical impulses of Accel-Heal remain in the subsensory domain. EMS=electrical muscle stimulation; HVPC=high voltage pulsed current; TENS=trans-epithelial nerve stimulation.

devices that can be used for wound management. Many types of E-stim have been used in wound healing including therapies designed for other purposes, such as electrical muscle stimulation (EMS), which primarily stimulate muscle twitch, or trans-epidermal nerve stimulation (TENS), which primarily activate appropriate sensory nerves. These devices need to deliver a relatively high stimulus that exceeds the threshold to fire off nerve impulses, i.e. high voltage pulsed current (HVPC). However, patients can feel these levels of E-stim as “pins and needles”⁷ or experience muscle twitch. These sensations are described as unpleasant by some patients.

E-stim devices used for wound healing do not need to evoke these physical responses and can be effective at a much lower level of stimulus. Accel-Heal[®] is a low voltage pulsed current (LVPC) device (Figure 3) that delivers a very low current at a ‘subsensory’ level, meaning that patients may not feel any stimulation and will not experience muscle twitches.

Many different waveforms and levels of intensity of E-stim have been used to good effect in wound healing studies⁸. It has been suggested that rather than the type of electrical waveform used, it is more important to consider the “dose” provided. Favourable wound healing effects are believed to follow a dose of between 250 and 500 $\mu\text{C}/\text{s}$ ($\mu\text{C}/\text{s}$)⁸. The dose Accel-Heal delivers during its active phase falls within this range.

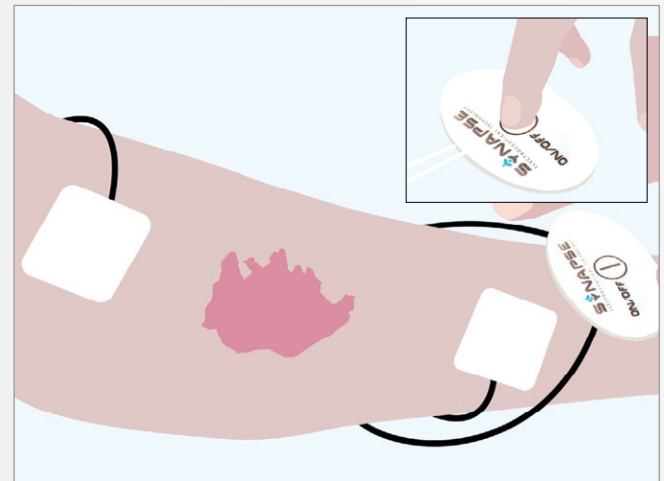


Figure 3. The Accel-Heal device

WHAT DOES ELECTRICAL STIMULATION DO?

Application of E-stim to chronic wounds can markedly reduce wound pain and the need for opioid analgesics as soon as 3 days after treatment commences⁹. This can not be fully explained by progression of the wound towards healing, which typically takes longer to become apparent.

Pain in chronic wounds is often caused by chronic inflammation. The S100A7/8/9 and SERPINB4 proteins, which are involved in acute inflammation, including in several conditions like arthritis, inflammatory bowel disease and psoriasis^{10,11}, are also upregulated in chronic wounds that are stuck in the inflammatory phase of wound healing¹². Treatment with Accel-Heal decreases the expression of these inflammatory proteins within the first 48 hours (randomised placebo-controlled study in volunteers)¹³. This suggests that Accel-Heal may have a rapid “dampening effect” on the chronic inflammation observed in chronic wounds¹⁴.

It is generally understood that reduced inflammation coincides with a reduction in pain. Reduced pain leads to an increased patient tolerance to wound treatment, leading to improved compliance with treatment (Figure 4)¹⁵. Treatment with Accel-Heal was also observed to reduce oedema in the wound and surrounding tissues¹⁶ also consistent with a reduction in inflammation and reduction in pain.

Simultaneously, E-stim is known to promote wound healing processes, including stimulation of fibroblast proliferation and migration, re-epithelialisation, granulation tissue formation, collagen synthesis and growth factor production¹⁷. While it is well known that nerves and muscles rely on electrical stimuli to function, it is also the case that every cell in the human body is finely tuned to tiny electrical stimuli¹⁸. Wounded skin is no

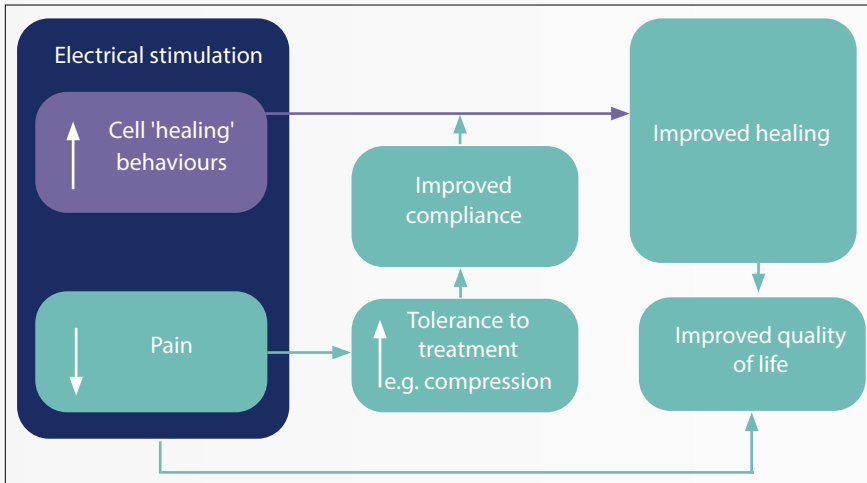


Figure 4. The primary effects of electrical stimulation can influence wound healing and patient quality of life.

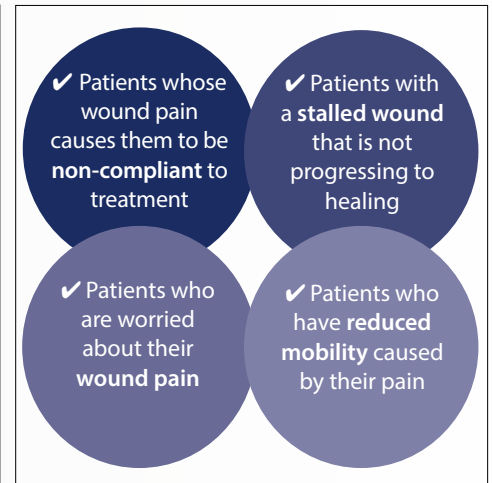


Figure 6. Potential patient groups who may benefit from Accel-Heal.

exception; it communicates via tiny electrical charges which, in an acute wound, activate wound healing pathways. In chronic wounds, this electrical signal gradually dissipates, and the healing pathways are no longer stimulated. It is understood that E-stim re-ignites the normal signalling involved in the healing process (Figure 4).

E-stim is one of the most evidence-based technologies in wound management with 5 meta-analyses, 6 systematic reviews and over 30 randomised controlled trials published to date (Figure 5). It has been shown to have a beneficial effect on wound healing^{17,19-22}, pain reduction^{9,23-26}, and is safe¹⁹. The “pulsed current” type of E-stim, like that used in Accel-Heal, has been shown to perform better than continuous direct current in two meta-analyses^{17,27}.

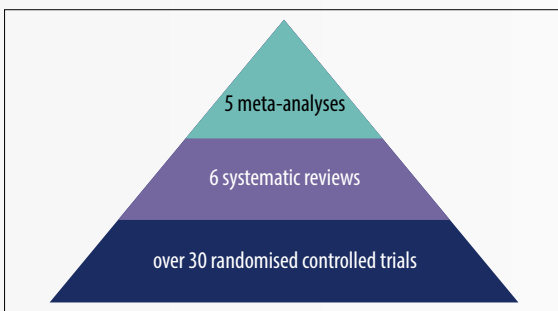


Figure 5. Pyramid of evidence for Accel-Heal.

HOW CAN ACCEL-HEAL IMPROVE ENGAGEMENT WITH TREATMENT?

Adoption of E-stim in the past has been hampered by poor engagement with patients¹⁹, the complexity of choosing appropriate treatment settings^{19,28} and the lack of suitability of devices for continuous use in the patient’s own home²⁹. Some devices (e.g. TENS devices) had led to poor adherence as the stimulus has been

strong enough to stimulate sensory nerves and a “pins and needles” sensation⁷. The low level of stimulus delivered by Accel-Heal reduces the risk of unpleasant sensation, yet is strong enough to trigger the appropriate cellular responses in the wound, re-igniting the healing process (Table 1).

Being able to manage wounds in patients’ own homes, rather than outpatient clinics or hospitals is important in terms of saving resources, ensuring a more continuous and uninterrupted treatment and for patient convenience. Historically, E-stim would be applied on an episodic basis during dressing changes, often requiring out-patients visits²⁹. The Accel-Heal device is portable, discreet and can be used continuously, even under compression, without frequent disruption of the patient’s wound dressing (Figure 6).

Many E-stim devices require that the user choose and set an appropriate level of stimulation from many different variables. This can be complicated and introduce room for error. A pre-programmed device, such as the Accel-Heal device, can often be easier to use, as it is activated by the simple push of a button.

How to use Accel-Heal

After the skin surrounding the wound is cleaned with the alcohol wipes provided, the two electrode pads are applied to intact skin either side of the wound (Figure 3). An on/off switch activates the Accel-Heal device to begin the therapy and the programme of LVPC is delivered. No adjustments are required as the device measures the feedback to ensure the correct dose is delivered. The wound can then be dressed with standard dressings, including compression. Each device delivers 48 hours of therapy before turning off automatically and can be replaced without disturbing the dressings. One 12-day treatment is typically all that is required and corresponds to the consecutive use of the 6 devices provided in a treatment pack.

Table 1. Features and related benefits of Accel-Heal electrical stimulation

Feature	Related benefit
Subsensory stimulation	No unpleasant sensation
Pocket sized	Discreet and easily portable for uninterrupted treatment
Pulsed current waveform	Thought to be the most efficacious type of electrical stimulation ^{17,27}
Automatic stimulation with pre-set parameters	Easy to apply; no need to choose between different settings
Automatic, current-controlled adjustment to ensure accurate dosage	Automatically adjusts the stimulus delivered to the wound to ensure the correct "dose" is always delivered
Simple-to-use device	Easy for patient to manage at home with pre-programmed settings; can be used under compression

SUMMARY

As well as kick-starting the healing process, E-stim can also reduce wound pain. This may improve tolerance of wound management treatments for example compression for the management of venous leg ulcers. Accel-Heal is a pre-programmed, disposable, single-use device that requires minimal intervention from either patients or caregivers that can be used in the home-care setting. The Accel-Heal device delivers LVPC at a subsensory level that stimulates the patient's bioelectric signalling pathways to trigger the healing process, but avoids any unpleasant sensation that may exacerbate an already painful wound.

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