What Is the Role of Electrical Stimulation Therapy?

Abstract

The burden of hard-to-heal wounds continues to grow and has a disproportionate impact on resources[1]. Chronic wounds account for two-thirds of the total cost of wound care within the U.K. (£6.5 bn) and costs continue to increase[1]. Despite following best practice, many wounds do not heal. New innovative technologies should be considered in everyday clinical practice, to expedite healing and improve the quality of life for the patient. Often it is wound pain which the affects patients' quality of life most significantly and its management should avoid the use of analgesics where possible.

This article will explore how electrical stimulation therapy (EST) has a unique combined effect of reducing wound pain and stimulating wound healing and is in fact one of the most evidence based modalities in wound management today. A new device, Accel-Heal Solo, is now available that supports much easier adoption into frontline clinical practice. Accel-Heal Solo provides the benefits of EST, delivered by a single-use, pre-programmed, wearable, easy to use device. Observational studies on the predecessor device, Accel-Heal, report significant reductions in wound pain within 2 weeks of treatment and accelerated healing rates, which translate into significant cost savings and improved patient quality of life. Improved outcomes are also shown in real life settings and individual case studies will be shared.

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Introduction

Despite the huge number of dressings currently available, there has been surprisingly little real innovation in wound management over the last 20 years[2] and the financial burden of hard-to-heal wounds on the UK's National Health Service (NHS) continues to grow[1]. Recent prevalence of wounds was estimated to be 3.8 million among the adult population of the UK, increasing year on year[2]. Guest et al (2020) determined that 51% of chronic wounds remained unhealed in the study year, accounting for two-thirds of the total cost of wound management, which is estimated to be £8.3bn per annum. The majority of patients are managed in the community setting, with health care professionals (HCPs) accounting for 53% of the costs. With prevalence and costs increasing, this will continue to have a significant effect on an already depleted NHS workforce and resources. Some expert panels[3] have even suggested that globally 'wound care is in crisis'.

The impact for patients and their family of living with a chronic non-healing wound is also well documented[4-9], many of whom live without any hope of improvement, whilst suffering pain, non-healing, infection, sepsis, risk of amputation and death[10-11].

Challenges in management centre upon achieving healing and the avoidance of adverse events such as infection, sepsis and amputation, together with symptom management, including pain, exudate and irritation, to improve quality of life. Best practice should be instigated to include: holistic management of the wider factors that delay healing; prevention of wounds; revascularisation; lifestyle changes such as smoking cessation and nutrition; reducing and

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managing infection; wound bed preparation/ management; pressure off-loading/ reduction and pain management[10,12-19].

However, despite following best practice, many wounds still fail to heal. Alternative approaches need to be considered, rather than by simply applying yet another topical dressing, many of which have been around for 50 or 60 years[2], and in the main, focus on exudate and anti-microbial management, to facilitate the body to self-heal, rather than being an interactive treatment to stimulate cell processes and promote wound healing. Most wounds fail to heal due to underlying conditions of the patient and within the wound itself, and the primary dressing alone is
unlikely to address this.

The National Wound Care Strategy Programme (NWCSP) has been commissioned by NHS England and NHS Improvement for pressure ulcers, lower limb and surgical wounds, and seeks to improve care for people with wounds, to reduce patient suffering, improve healing rates and prevent wound occurrence and recurrence.

Leg ulcer assessment, diagnosis and treatment are included in the 2022/ 2023 Commissioning for Quality and Innovation (CQUIN)[20], in the community setting, in order to increase the number of patients receiving high compression therapy if indicated. However, despite compression therapy being one of the most evidence based therapies for venous leg ulcers, it is often not tolerated by patients due to the pain[21], with evidence suggesting that 40% of HCPs would remove or reduce compression if the patient had significant pain[22].

How can we do things differently to reduce patient suffering, promote healing, improve clinical outcomes and meet the new CQUIN targets?

Innovation is being supported for use across the healthcare system in the NHS Long Term Plan[23], and will be central to securing transformation and improved patient outcomes. Fast adoption of cost-effective new technologies will be accelerated[23], so that proven innovations get to patients faster.

So, the green light has been given to HCPs, to use alternative approaches in managing hard-to-heal wounds, rather than just using another dressing.

This article will explore EST and the compelling evidence base behind it. EST has been used for many years for wound management, but widespread adoption has previously been challenging due to the format it was available in.

Whilst very efficacious, devices were complicated clinic based units, requiring specialist training and could not be used in conjunction with preferred dressing regimes and compression therapy if indicated.

The innovative treatment (Accel-Heal Solo) has now made frontline adoption of EST possible. Accel-Heal Solo is a single-use wearable device that delivers a fixed 12-day programme of subsensory electrical stimulation therapy to hard-to-heal wounds to relieve pain and accelerate healing. The article will further discuss the mode of action, benefits, application, indications and contra-indications for using Accel-Heal Solo together with the growing evidence that is available.

Electrical Stimulation Therapy (EST)

Human physiology is electrochemical in nature. Within the skin, a stream of Na+, K+ and Cl- ions moving in opposite directions create a difference in voltage between the surface of the epidermis and the deeper layers, establishing a stored electrical potential or 'skin battery".

After wounding, microcurrents flow into the wound site, establishing a 'current of injury'[24], which stimulates cellular activity such as migration and activation of gene expression in macrophages, endothelial cells, fibroblasts and keratinocytes[25], as part of normal wound healing (see Figure 1). The current of injury extends up to a radius of 2-3mm around the wound[26]. As the wound closes, the current of injury progressively reduces.

Due to adverse events occurring within the wound such as the presence of foreign bodies; accumulation of slough and necrotic tissue or following the development of biofilms and/ or infection, many wounds become stuck in the inflammatory phase. In chronic non-healing wounds, microcurrents are thought to dissipate and become dysfunctional or completely absent[27].

Application of electrical stimulation therapy is effectively restoring a normal process in wound healing to mimic the current of injury, which has become "exhausted" due to the chronicity of the wound (see Figure 2). So, far from being a sideshow or a curiosity, electric fields are established as part of the fundamental mechanisms of cell and tissue growth and control[28].

This video link describes the mode of action of EST, in further detail:

tinyurl.com/3hzt4dzy

EST has been used in medicine for many years, for example; in cochlear implants, cardiac pace-makers, spinal cord nerve stimulation and facial therapies for aging skin. The level of electricity delivered varies, depending on the type of stimulation required.

Where strength-duration of the stimulus exceeds the threshold for nerve activation, electrical stimulation causes either a sensory effect (that can range from tingling to 'pins and needles'), or a motor effect such as a muscle twitch, some of which can be painful for the patient[25]. Electrical stimulation devices for wound healing can be effective at a much lower level of stimulus (see Figure 3).

Figure 2: Wound Healing relies on 'a current of injury'.

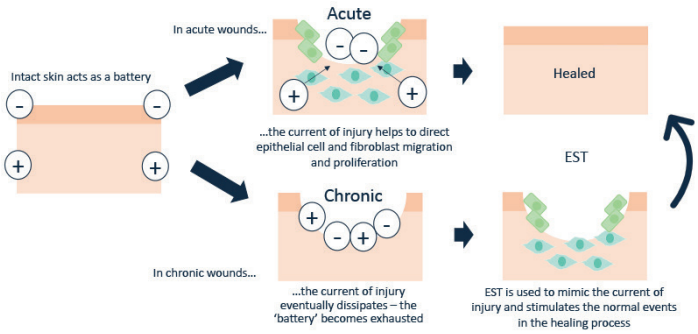


Figure 1: EST stimulates many aspects of the healing pathway.

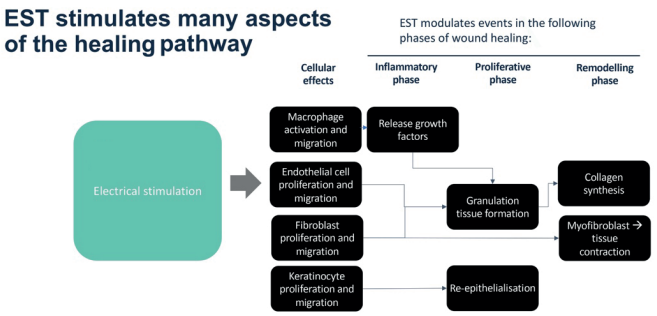
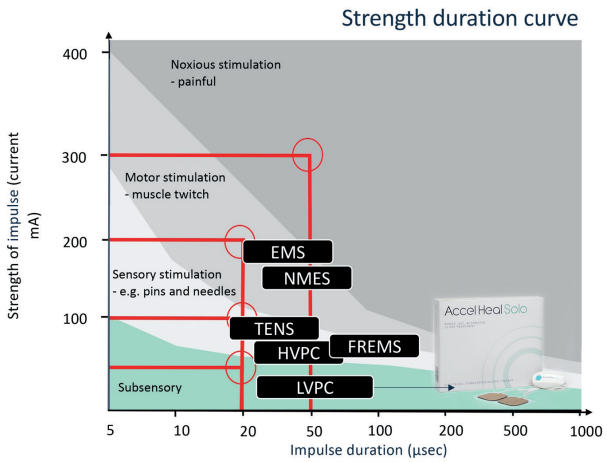


Figure 3; EST: Where strength-duration of the stimulus exceeds the threshold for nerve activation electrical stimulation causes either a sensory effect (that can range from tingling to 'pins and needles') or a motor effect such as muscle twitch.

The electrical impulses of Accel-Heal Solo remain in the subsensory domain.



"Electrical stimulation therapy (EST) is one of the most widely evidence-based therapy areas in wound management."

Electrical stimulation therapy (EST) is one of the most widely evidence-based therapy areas in wound management. The extensive evidence base includes nine meta-analyses[30-38], eight 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, to reduce pain and stimulate wound healing.

Electrical stimulation has been recognised for use internationally in guidelines and recommendations from the European Wound Management Association and the National Pressure Ulcer Advisory Panel[16,39] for a range of chronic wounds, such as pressure ulcers, leg ulcers and diabetic foot ulcers.

Accel-Heal Solo

Accel-Heal Solo is a class IIa medical device which delivers low voltage biphasic monophasic pulsed current (LVBMPC) electrical stimulation therapy to the wound, mimicking levels seen in the body's natural systems. The device delivers repeated treatment sessions, each lasting 28 minutes and 40 seconds, with a resting period repeated several times daily throughout the 12-day treatment period. Meta-analyses[34,43] have shown that EST devices, like Accel-Heal Solo, that deliver a "pulsed current" stimulation are more efficacious than other types of devices.

Accel-Heal Solo is small and discreet, about the size of a car key fob, and can be worn unobtrusively by the patient in all settings, without the need to attend specialist clinics. Accel-Heal Solo is worn continuously over the therapy period and is used alongside standard therapy to ensure wound bed preparation strategies are continued according to best practice[40-42], and compression therapy if indicated for leg ulcers.

Accel-Heal Solo (see figure 4), is the next generation of Accel-Heal and offers all the benefits of the original device (which needed changing every 48 hours) while providing the therapy using one device which runs for the duration of the 12-day treatment. While the 12-day programme of electrical stimulation is identical, the use of a single device ensures a more regulated and controlled delivery of the therapy and simpler management by clinicians, carers and patients alike. Accel-Heal Solo also provides a new LED light feature, to provide the patient/ carer/ clinician information regarding the operational status, and a clip and strap to secure the device.

Accel-Heal Solo is recommended for:

- Any wounds not healing as expected including leg ulcers, DFUs, post-operative wounds, pressure ulcers and burns.
- Patients with unmanaged pain.
- Patients who are unable to tolerate any or high compression therapy due to pain.
- Patients who are unable to tolerate treatment regimes such as debridement
- Patients with high risk of delayed healing such as immunocompromised, diabetes, ischaemia; recurrent wounds.

Figure 4: Accel-Heal Solo

Indications and contra-indications for use are provided in the IFU:

tinyurl.com/3748m4h9

"In chronic wounds, there is strong and growing evidence demonstrating that Accel-Heal Solo can reduce pain, kick start the healing process, improve quality of life for patients, and provide economic benefits."

Please see link below for application guide and LED light indicator status, and video illustrating the use of Accel-Heal with compression bandaging:

tinyurl.com/dte6x7yh

tinyurl.com/yc2yb6s9

Application of Accel-Heal Solo

Accel-Heal Solo is a current controlled device, which monitors current flow through the electrodes and automatically adjusts the voltage to ensure the required current program is delivered, regardless of variables, such as skin texture and distance of electrode pads. This enables the electrode pads to be placed at some distance from the wound edges, and the device will still deliver the prescribed dose of EST[44], thus enabling the pads to be placed away from pressure points, for example sacral wounds and diabetic foot ulcers to the foot plantar (see figure 5).

Application Of a Second Accel-Heal Solo Treatment

Hard-to-heal wounds may have an initial response to Accel-Heal Solo therapy, but as with any wounds, can then deteriorate or become stalled again. This can be due to untoward events in the wound such as infection, or a general deterioration in the general health of the individual. In the author's experience, and that of key opinion leaders[45], although the majority of cases only require one Accel-Heal Solo therapy to expedite complete healing of the wound, those patients who had a positive response to the initial treatment, which then become stalled or exacerbated, might benefit from a second application of the Accel-Heal Solo therapy. It is recommended to wait approximately 4 weeks after initiating the first therapy, to enable the wound to kick start and to demonstrate the early clinical signs of improvement that is so frequently observed.

How Does Accel-Heal Solo Improve Clinical Outcomes?

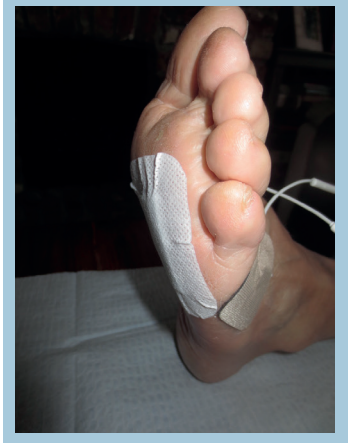
In chronic wounds, there is strong and growing evidence demonstrating that Accel-Heal Solo can reduce pain, kick start the healing process, improve quality of life for patients, and provide economic benefits[28,46-69].

Pain Reduction

NICE[70], advocates to consider using alternative non-pharmacological approaches to manage chronic pain. Analgesia is known to have many adverse effects, and often patients are reluctant to take them, or they are ineffective.

One widely used device for pain management across a range of co-morbidities, is transcutaneous electrical nerve stimulation (TENS), involving the use of milliamp current to reduce pain and muscle spasms. The stimulus exceeds the threshold to cause a deliberate sensory effect (see Figure 3), so is an intentionally high stimulus, adjusted by the individual, to interfere with/ block the gate control for pain signals in nerve fibres. It can take some time for tolerance to be established, and causes tingling through to throbbing and even discomfort[71].

Figure 5:



"The evidence demonstrating the positive clinical outcomes regarding pain reduction using Accel-Heal therapy is significant."

However, TENS is not a cure for the pain, and often only provides short-term relief while the TENS machine is being used. Alternatively, a microcurrent device, such as Accel-Heal Solo, acting at a much lower level of stimulation, (1000 times weaker than TENS[71]), restores the natural endogenous current to tissue, in order to provide a healing effect, and in doing so also has an analgesic impact at the localised level by dampening down the inflammatory response[71]. Evidence has highlighted that Accel-Heal reduces pain within a few days and sometimes even within a few hours of application, and this pain reduction is sustained following the 12-day therapy.

The exact mechanism of pain reduction using EST is unknown, but it appears that the pain reduction is often noted well before wound healing is achieved, indicating a more active and specific effect[25].

A randomised gene expression analysis[72], demonstrated that 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.

The evidence demonstrating the positive clinical outcomes regarding pain reduction using Accel-Heal therapy is significant. Information has been extrapolated from previous studies, to include any patients/ wounds who had their pain score recorded (visual analogue score (VAS) range 0-10), prior to Accel-Heal therapy, at the end of the 12 day treatment and at the end of the study period[28,51,53,55,58,62,66-69].

71 patients from 11 studies were included in the analysis, and had been evaluated for usage of Accel-Heal EST for a period of between 4.3 to 21 weeks. Many patients had pain scores >5, and were taking several types of analgesia, and suffering sleeplessness and social isolation.

The data demonstrated a mean pain score of 6.81 (VAS) prior to therapy, reducing to a mean of 2.62 (61.5% reduction) after the 12 day therapy and reducing to a mean of 0.4 (94.2% reduction) by the end of the evaluation (see Figure 6).

This pain reduction had a significant impact on many patient's lives, with many reducing their analgesia, reporting improvements in their mobility and social lives and sleeping.

Please see link below demonstrating the real-life effect Accel-Heal had on healing patients' wounds and improving quality of life:

tinyurl.com/yafers74

Healing and Wound Size Reduction

A range of evidence has demonstrated the positive impact Accel-Heal has on wound size in hard-to-heal wounds. In three observational studies[28,51,58], involving 37 non-healing wounds, healing was achieved in 84-90% within 20 weeks. 27% (n=10) of wounds had been present for over one year prior to Accel-Heal therapy.

To validate the healing potential even further, information has been extracted from several previous studies to include any patients' wounds who had their wound dimensions recorded prior to Accel-Heal therapy, following the treatment and at the end of the study

period[28,46,51,53,55,58,60,62,65-69]. 120 patients/ wounds from 14 studies were analysed. The studies included a range of complex non-healing wounds, including venous leg ulcers (failed to heal despite compression therapy), DFUs, post-operative wounds and arterial ulcers. Some wounds were extensive and had been present for many years. Patients had been seen for the evaluation process for a period of between 12 days to 182 days. The analysis demonstrated a mean wound size of 17.25 cms square (range 0.04 - 133), prior to Accel-Heal therapy. Following the therapy (assessed between 12 days to 8 weeks), the mean wound size was reduced to 12.8 (reduction of 25.8%). At the end of the evaluations, the mean size was 4.97 (reduction of 71.2% (see Figure 7).

Pain Reduction and Wound Healing

The combined effect of the pain relief and wound size reduction results are illustrated (see Figure 8) to demonstrate how applying Accel-Heal to static wounds results in immediate and significant pain reduction followed by wound healing over a 12 week period. Accel-Heal restores the normal wound healing process, which relieves the pain and stimulates healing.

Cost Effectiveness

Several economic studies have demonstrated the cost effectiveness of using Accel-Heal[46-49]. One study[51] demonstrated a decrease of 74% in district nursing time over the 20 week study period (see Figure 9), resulting in cost-efficiencies in nursing time and cost savings in dressings and bandages. Analysis of a previously reported RCT[47] determined that wounds being treated with Accel-Heal, healed on average 3.6 weeks faster vs standard care, resulting in cost savings of £936 per patient on average.

Figure 6: Reduction in pain at 12 days following therapy, and at the end of the study periods (range 4.3 - 21 weeks) (n=71)

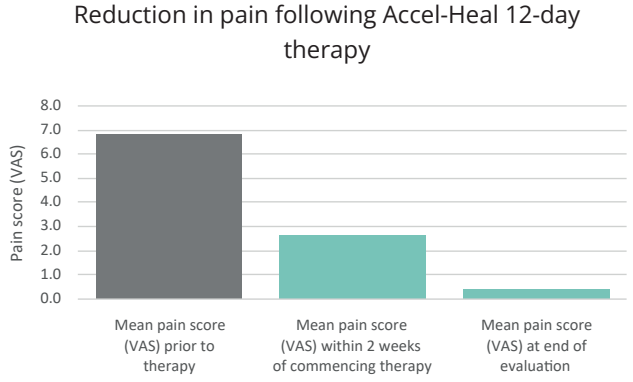


Figure 7: Reduction in wound size following therapy and at the end of the study periods (n=120)

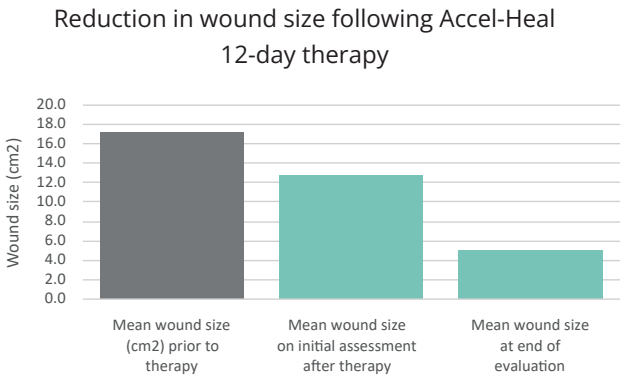
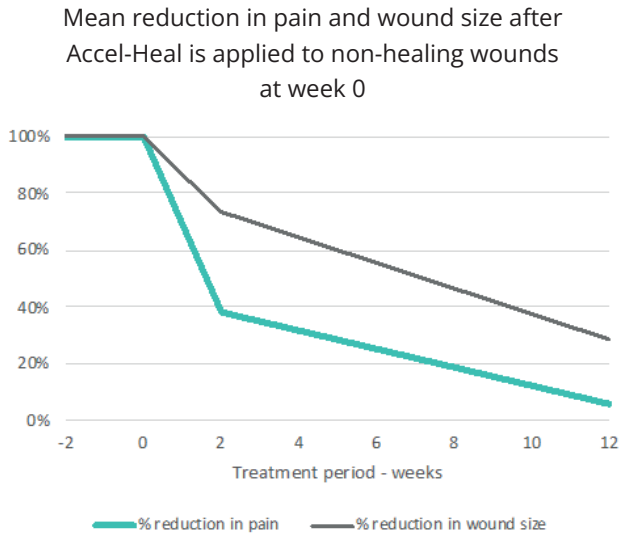


Figure 8: Mean reduction in pain and wound size after Accel-Heal is applied to non-healing wounds at week 0



Examples in Practice Using Accel-Heal to Reduce Pain and Stimulate Healing in Hard-To-Heal Wounds

An observational study (n=14) was undertaken in a community trust in Scotland, to demonstrate the effectiveness in pain reduction and wound size reduction for patients with hard-to-heal wounds using the 12-day Accel-Heal therapy. Data was collected prior to the application of

"Wounds being treated with Accel-Heal, healed on average 3.6 weeks faster vs standard care, resulting in cost savings of £936 per patient on average."

Accel-Heal, following the 12-day therapy, and every 4 weeks, for up to 20 weeks. Wound aetiology included venous leg ulcers (VLUs) (n=13) and unknown aetiology leg ulcers (n=1).

57% (n=8) patient's wounds had pain, with a mean pain score of 3.14 (range 0-10), and 29% (n=4) had a pain score >5. On completion of the Accel-Heal therapy, the mean pain score was reduced to 2.79 (range 0-10) demonstrating an 11.4% reduction. At the end of the study period, the mean pain score was reduced to 0.14 (range 0-2), demonstrating an overall pain reduction of 95.5% during the study period (see Figure 10). The study also demonstrated a mean wound size reduction of 29% and 87% within 2 weeks and 20 weeks of commencing the therapy respectively. 71.4% (n=10) of all wounds healed within the study period.

Case Studies, 1

A 66 year old gentleman was in hospital in Kuala Lumpar with a DFU to the lateral aspect of the right foot, which had been present for 2 years. Past medical history included Diabetes Mellitus and renal transplantation.

Despite multiple sessions of wound debridement, the wound showed no improvement. Treatment with Accel-Heal therapy commenced (day 0) on 21/04/21, and the wound measured 105 cm square with approximately 90% slough and exposed tendon (see Figure 11) and moderate purulent exudate. Dressings continued with protective absorbent dressings. His pain score was 4/10 (VAS), which was affecting his sleeping.

On day 9, the wound had reduced in size, measuring 97.5 cm square (see Figure 12). The pain score reduced to 2/10 (VAS), with a significant improvement with his sleeping.

Fourteen weeks after commencing Accel-Heal therapy, the wound had improved considerably

Figure 9: Reduction in district nursing visits with/ without Accel-Heal intervention for the 20 week period[52].

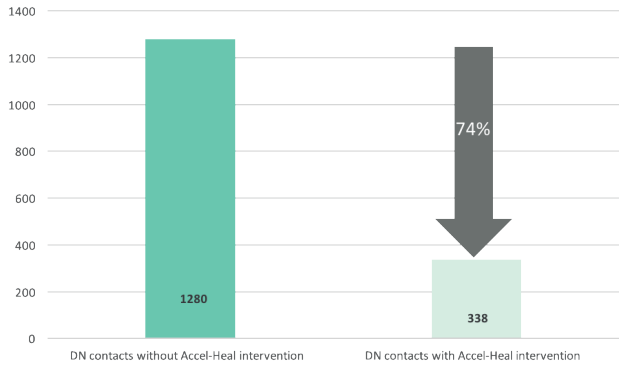
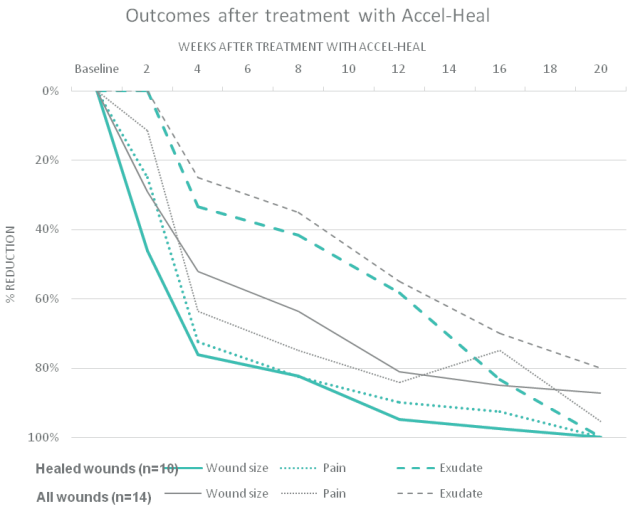


Figure 10: Wound size reduction and pain reduction of observational study undertaken in Scotland using Accel-Heal therapy (n=14).



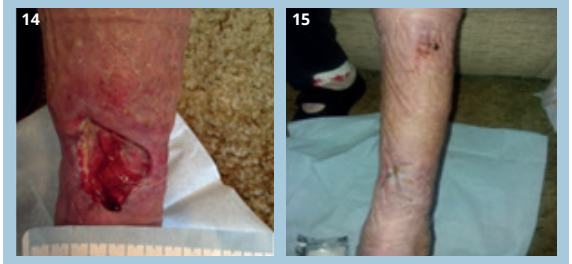
and measured 40 cm square with 50% slough, demonstrating a 62% reduction in size (see Figure 13), and a pain score of 1/10 (VAS).

Case Studies, 2

A 90 year old female was being seen at home by community nurses in the UK, for a non-healing VLU to her tibial crest following a traumatic injury 4-6 months previously. Past medical history included dementia. Her ankle brachial pressure index (ABPI) was within normal limits, but she had a history of intolerance to compression therapy due to the presence of

Figure 11: Day 0 - Extensive DFU to lateral aspect right foot prior to Accel-Heal therapy.
Figure 12: Day 9 - DFU to lateral aspect right foot following Accel-Heal therapy.
Figure 13: Week 14 - DFU to lateral aspect right foot following Accel-Heal therapy.

Figure 14: Day 0 prior to Accel-Heal treatment
Figure 15: Wound healed within 12 weeks of commencing Accel-Heal



high pain levels. Prior to Accel-Heal therapy (day 0), the wound measured 24.75 cm square, with 30% slough and evidence of friable tissue (see Figure 14), requiring twice weekly visits for application of honey dressings and high compression therapy. Her pain score was 5/10 (VAS).

Following the 12-day Accel-Heal therapy (day 14), the wound measured 10.25 cm square (reduction of 58.5%), and dressings were reduced to weekly. The pain score reduced to 1/10 (VAS).

Within 12 weeks of commencing Accel-Heal, the wound healed with no pain (see Figure 15).

Patient Feedback

Patient feedback has been significantly positive[55,61-63,66-67]. Patients who were previously taking opiates have been able to remove their analgesia and reported improved sleeping and mobility. Some testimonials from patients include:

"If I hadn't had the device put on I think I would have been struggling."

Patient in UK

"I would recommend it to anybody... If I had to have the treatment again I would have it willingly because I couldn't stand to have that pain again."

Patient in UK

"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."[66]

Patient in UK

For more case studies, see the following link:

tinyurl.com/2p93uj5z

Conclusion

EST needs to be considered for use by clinicians, in order to replenish the diminished/absent microcurrent signalling in chronic wounds, which is so vital in the complex healing cascade.

There is a wealth of evidence to demonstrate the significant improved clinical outcomes and economic benefits of using Accel-Heal Solo for hard-to-heal wounds. Benefits include early relief of pain, reduced inflammation, oedema and exudate and stimulation of the healing cascade. These benefits result in improved mood, reduced anxiety and sleeplessness and improved mobility for patients, many of whom have given up any hope of their wound/s healing and suffer endless unmanaged pain.

Accel-Heal Solo also enables tolerance to other gold standard treatments such as debridement, wound cleansing and compression therapy, which are frequently poorly accepted by patients due to the pain and inflammation.

Accel-Heal Solo is a cost effective, easy to use EST, which is readily available for use in the UK, for use in hard-to-heal wounds to relieve pain and accelerate healing. The unique, compact device is ideal for use in a variety of settings, and the ease of use enables it to be accessible for patients, carers and clinicians.

"The unique, compact device is ideal for use in a variety of settings, and the ease of use enables it to be accessible for patients, carers and clinicians."

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