

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

Editorial Summary

Despite following best practice, many wounds fail to heal, due to the underlying pathology, with prevalence of wounds increasing year on year,¹ and recalcitrant wounds creating the greatest resource challenges in nursing time and dressing costs. Interventional therapies such as electrical stimulation therapy (EST), can lessen this burden of wounds and improve the patient's quality of life by reducing the pain and kick-starting the wound healing cascade, thus preventing exacerbation and the risk of complications in this patient group. A case series using a cost-effective, novel, compact EST (Accel-Heal Solo), 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 wounds.



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Introduction

A hard-to-heal wound has been defined as one that fails to heal with standard therapy in an orderly and timely manner,² which is applicable to both acute and chronic wounds and is independent of the wound type and aetiology.

Hard-to-heal wounds have an enormous effect on the quality of life for patients,^{3,4,5,6} and their family, who often have to endure living without any hope of improvement. Social isolation, psychosocial factors, malodour, pain, infection and sepsis, all contribute to reduced well-being for this patient group.

The prevalence of wounds in the UK is estimated to be 3.8 million among the adult population, which is increasing annually,¹ at a cost of £8.3bn per annum, with 51% of chronic wounds remaining un-healed in the study year. The financial impact of this is significant, in an already depleted NHS workforce and resources.

Patients with complex co-morbidities, such as lupus erythematosus, and underlying pathologies related to arterial stenosis, invariably cause challenges in wound healing for clinicians, but also have a huge impact on quality of life, with pain being a huge factor. Most people with lupus experience skin involvement during the course of their disease, with a range of presentations and complications, including inflammation, photosensitivity, alopecia (hair loss), Reynaud's phenomenon and cutaneous vasculitis.⁷ Invariably, these wounds can be very painful and result in slow healing,^{8,9,10} affecting patient's well-being and life-style

factors.

Pain Management

Evidence has demonstrated that pain is particularly distressing for patients with hard-to heal wounds,^{11,12} with wound pain reported to be the worse thing about having a leg ulcer.¹³ Presence of pain also prevents patients' tolerance to effective treatment, such as compression therapy, wound debridement and exercise, which ultimately have an effect on healing.¹⁴ Pain management options are often limited, due to the type of pain, ageing, side effects and reluctance by patients to adhere to them, and they can often be ineffective.¹⁴ Patients often request priority for their pain to be removed over wound healing, but this can prove challenging for health care professionals.

A widely alternative non-pharmacological therapy for pain management is transcutaneous electrical nerve stimulation (TENS), involving the use of milliamp current to reduce pain and muscle spasms, which is used across a range of co-morbidities and pain types, to interfere with/block the gate control for pain signals in nerve fibres. It has been demonstrated to cause tingling, throbbing and even discomfort.¹⁵ Historically, it was not designed for wound care, and is not a cure for the pain, often only providing short-term relief while the TENS machine is being used.

Recent innovations in wound care have seen the development of sub-sensory EST designed to act at a cellular level to reduce pain and accelerate wound healing.

“Human physiology is electrochemical in nature, and normal wound healing relies on electrical energy,¹⁶ to stimulate cellular activity such as macrophages, endothelial cells, fibroblasts and keratinocytes.”¹⁷

Wound Healing

Wound healing is a complex and carefully co-ordinated process, the barriers to which include co-morbidities, wound aetiology, patient age, pharmacological effects and wound related factors such as chronic inflammation, biofilm and infection.

Human physiology is electrochemical in nature, and normal wound healing relies on electrical energy,¹⁶ to stimulate cellular activity such as macrophages, endothelial cells, fibroblasts and keratinocytes.¹⁷ Chronic wounds have been demonstrated to lack electrical energy (known as the current of injury),¹⁸ which will inhibit the normal wound healing cascade.¹⁶ The magnitude of the electrical field near the wound, has also been demonstrated to dissipate by 48% in the over 65 year olds,¹⁹ potentially increasing the risk of non-healing in these patients, many of whom may require surgical interventions, develop pressure ulcers and vascular problems, due to the mere ageing process ([Click for previous article, 'What is the Role of Electrical Stimulation Therapy'](#)).

Wound Healing Using Electrical Stimulation Therapy

In order to restore the reduced or absent electrical energy, which has become “exhausted” due to the chronicity of the wound, external EST can be applied to mimic the current of injury, to “switch on” the wound healing process. Electric fields are established as part of the normal fundamental mechanisms of cell and tissue growth and control.²⁰ Some clinicians have described this as “waking up the wound”. EST is one of the most evidence based modalities in wound management with nine meta-analysis,^{21,22,23,24,25,26,27,28,29} eight systematic reviews and over 35 randomised controlled trials, and has been recognised for use internationally,^{30,31} for a range of chronic wounds ([Click for previous article, 'What is the Role of Electrical Stimulation Therapy'](#)).

Reduction in Pain Using EST

EST has been demonstrated to reduce pain in chronic wounds.^{17,32,33,34,35,36,37} The exact mechanism of pain reduction using EST is yet to be established, but pain reduction is often noted well before wound healing is achieved,^{36,38,39} signifying a possible active and specific effect,¹⁴ related to a reduction in inflammation⁴⁰ ([Click for previous article, 'What is the Role of Electrical Stimulation Therapy'](#)).

Accel-Heal Solo Electrical Stimulation Therapy

Accel-Heal Solo is a class IIa medical device, which delivers a one-off sub-sensory 12-day pre-programmed, low voltage pulsed current (LVPC) to the wound. It is a small discreet device, which 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 12-days and is be used alongside standard therapy, to ensure wound management is delivered according to best practice,^{31,41,42,43,44,45} such as moist wound healing, anti-biofilm management and compression therapy, as clinically indicated ([Click for previous article, 'What is the Role of Electrical Stimulation Therapy'](#)).

Evidence has demonstrated the benefits of using Accel-Heal (original device) for pain reduction and wound healing,⁴⁶ with a mean pain score reduction of 61.5% (n=71), and wound size reduction of 25.8% (n=120) noted within 12 days. Quality of life is improved,³⁶ with many patients reducing or discontinuing their analgesia.³⁸

A case series of two patients was undertaken to demonstrate the benefits of using Accel-Heal Solo, in pain reduction and healing on extremely challenging hard-to-heal wounds.

“The surrounding skin (was) significantly improved with no maceration, reduced inflammation and (showed) a reduction in the wound sizes.”

Case Study 1

A case study was undertaken to determine the effectiveness of using Accel-Heal Solo on a complex patient with a Lupus erythematosus rash.

Assessment

A 47 year old female presented to the district nursing team (DN) in June 2021 with multiple wounds to her abdomen due to a Lupus rash, which she reported had been present for several years, and was extremely painful. She had been using hot water bottles applied to her abdomen to reduce her pain. The patient (known as Dorothy) had recently moved into the area and the previous clinical records were unavailable to the team. Several topical treatments were applied including wound bed preparation strategies and anti-biofilm cleansers, but there was no improvement to the wounds, and dressing changes became challenging due to intolerability of adhesive dressings and pain during dressing removal (see Figure 1).

Relevant past medical history included: chronic disease related malnutrition; femoral artery occlusion; Amaurosis fugax; Lupus erythematosus; Depressive disorder; Anorexia Nervosa; irritable bowel syndrome; Chronic liver disease; Hyperthyroidism; Graves disease.

Dorothy lived with her husband and older son, who were the main carers, having no outside care support. She was self-caring for transfers and used a wheelchair during the day. Dorothy was under the dietician for prescribing of naso-gastric feeding and her anorexia. She was seen regularly by the occupational therapist for support regarding equipment and mobility.

The tissue viability team requested the Clinical Lead for the DN team, to refer Dorothy to the dermatologist and rheumatologist regarding the abdominal wounds but has not yet been seen by them. On-going wound management was undertaken by Dorothy’s husband, under a shared care agreement with the DN team as the family requested limited visits due to the COVID-19 pandemic.

On 26/5/22, prior to commencing Accel-Heal Solo, measurement of the whole area was approximately 15 cm x 15 cm, with 16 open abdominal wounds, which varied in size. No photos were undertaken, but the district nurses reported there had been no change in the wounds since March 2022, apart from very slight less inflammation (see Figure 1). Exudate levels were low to moderate. However, due to Dorothy being aware of wound odour, her husband changed her dressings every 2-3 days. Peri-wound skin was very tender to touch and occasionally developed maceration, which was managed with a skin protectant. Pain score was between 7-10/10 (Visual Analogue Score (VAS)) all day, despite taking Morphine 10 mgs twice daily, Paracetamol 1000 mgs four times daily, and Pregabalin, 300 mgs twice daily. She was also applying heat pads topically.

Figure 1: Abdominal wounds. 01/03/22.



Treatment with Accel-Heal Solo commenced on 26/05/2022, together with an antimicrobial cleansing solution, skin protectant, emollient, and silicone foam border dressings. Dorothy's husband undertook all dressing changes, every 2 days, during the treatment with Accel heal Solo, and took photos (see Figure 2), which the family provided consent to share for this article.

On 01/06/22 (day 6) her pain score reduced to 5/10 (VAS), and her husband reported that one of the wounds had already started to dry up and her skin did not appear to be as red (see Figure 2b). The DN team reviewed on 14/6/22 (day 19), and noted the surrounding skin to be significantly improved with no maceration, reduced inflammation and a reduction in the wound sizes (see Figure 2c). Her pain score was 0/10 (VAS).

On 24/06/22 (day 29) there were only two open wounds remaining, which each measured 1.5 cm x 1 cm. The pain score reduced to 3/10, which was only occasional and mainly attributable to issues with constipation. Her wound pain was 0/10. Wound management continued by her husband.

The DN clinical Lead reviewed Dorothy on 08/08/22, when all wounds were noted to be

healed (see Figure 2d), with no exudate. Her pain score remained 0/10 and she no longer required the use of any hot water bottles and she managed to discontinue all her analgesia.

Patient Feedback

Dorothy reported to the team that the device was amazing, and that it had improved her quality of life dramatically.

Clinician Feedback

"Having used Accel heal previously the new Accel-Heal Solo is just as easy to use and to also teach her husband how to use. The instructions provided are easy to follow. Dorothy was made aware that Accel-Heal Solo may not improve her lupus rash/ open wounds but hopefully would improve her pain and in turn improve her quality of life. However, Accel-Heal Solo not only improved her pain from 7/10 to 0 it also improved her lupus rash and dried all the wounds within 2 months of commencing on the treatment, it has given Dorothy independence again and improved her quality of life. As clinical lead for the district nurse team this product has shown that it is versatile and has given confidence to the district nurse team to consider using this again for patients who may have similar pain scores with their wounds."

Figure 2:
2a: Day 2. Abdominal wounds on 28/05/22.
2b: Day 6 Abdominal wounds on 01/06/22.
2c: Day 19 Abdominal wounds on 14/06/22.
2d: Abdominal wounds healed on 08/08/22 (74 days after commencing Accel-Heal Solo therapy).



Case Study 2

A case study was undertaken to demonstrate the effectiveness of using Accel-Heal Solo on a painful, recalcitrant arterial foot ulcer to the bunion. The primary objective of the treatment was to reduce the pain, and the secondary aim was to facilitate wound size reduction.

Assessment

An 89 year old female (known as Beryl) presented for assessment by the tissue viability team in May 2021, with a recalcitrant wound to her left bunion, which had developed spontaneously approximately 12 months previously. Past medical history included chronic obstructive airways disease, myocardial infarction, ischaemic heart disease, intermittent claudication, and malignant neoplasm of the bladder. She lived alone in a warden controlled flat and had regular carers. She also had some short term memory loss. She had a low body mass index, although her appetite and nutrition were well balanced. She declined referral to the dietician and was encouraged to have a high protein diet and milky drinks.

Vascular assessment determined a reduced ankle brachial pressure index of 0.5, with monophasic sounds. Her pain score was 7/10 (VAS), despite taking regular prescribed analgesia, which was predominant at night, likely due to likely presence of arterial disease. Due to the longevity of the wound and pain level, osteomyelitis was suspected.

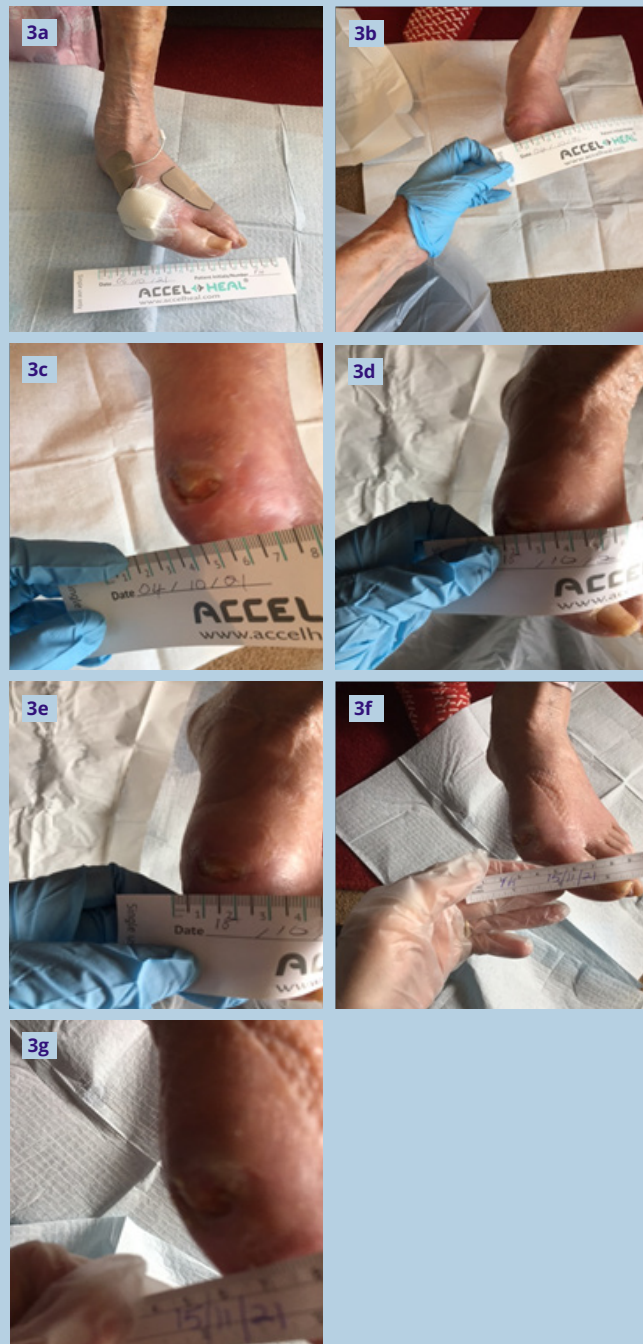
The wound measured 2cm x 1.5 cm, with rolled, un-healthy edges and leaking thick pus-like fluid, which had been treated with several courses of antibiotics. Following discussion with the GP, she was referred to the vascular team and a foot X-ray was arranged to eliminate osteomyelitis.

Further assessment in early September 2021 determined no improvement. The vascular appointment had been delayed due to the COVID-19 pandemic, and she was due to see them in November 2021. The foot X-ray showed no signs of osteomyelitis. Beryl was feeling very depressed due to sleep deprivation, and she reported that she wanted to go into a care home, as she felt she could no longer manage at home. Discussions were undertaken with Beryl regarding Accel-Heal Solo, and the possible

benefits this intervention could offer, in terms of pain reduction and sleep improvement. Beryl agreed to having the treatment and was excited at the prospect of trying a new therapy, which she hoped might improve her quality of life.

Treatment with Accel-Heal Solo commenced on 04/10/21 (see Figure 3a). The wound measured 2 x 1.5 cm with rolled un-healthy edges and under-mining, and was leaking thick pus-like fluid (see Figures 3b and 3c). Her pain score remained at 7/10 (VAS), and she reported continued sleeping difficulties.

Figure 3:
3a: Accel-Heal Solo in-situ
3b, 3c: Accel-Heal Solo commenced on 04/10/21
3d, 3e: Wound following completion of Accel-Heal Solo on 18/10/21
3f, 3g: Wound on 15/11/21 (42 days after commencing Accel-Heal Solo therapy).



Results

Within 48 hours of commencing the Accel-Heal Solo therapy, Beryl reported no pain, and she had managed to sleep without being awoken in extreme discomfort. Less exudate was noted on 06/10/21. At the end of the 12-day treatment, the wound had reduced by 33%, to 2 x 1 cm with healthier wound edges and had lost some depth (see figures 3d and 3e). The exudate reduction continued and it had lost its thick consistency, and some reduction in peri wound oedema was noted. A 100% reduction in pain was noted during the 12-day therapy.

Beryl was smiling again, and reported that she no longer wanted to go into a care home. Her mobility improved, and she became hopeful that the wound may continue to heal. Her appetite increased, and there was a general change in her whole persona over the 12-day period.

Following completion of the Accel-Heal Solo therapy, she had developed occasional pain, but reported this to be 3/10 and was well controlled with over-the-counter analgesia.

Beryl was seen by the vascular team on 11/11/21, who planned to regularly review her to determine any plans for intervention. By 15/11/21, the wound showed minimal size reduction, measuring 2 cm x 0.75 cm, with light slough (see Figures 3f and 3g). Unfortunately following light slough debridement, some bone was noted in the middle of the wound base. The wound had moderate thick exudate. Further liaison was undertaken to the GP, to request a referral to the orthopaedic team to eliminate osteomyelitis. The pain was described as an occasional “niggle” at approximately 2.5/10 with no complaints of pain during the night.

The plan was to consider the use of a second Accel-Heal Solo therapy once she was reviewed by the orthopaedic team and osteomyelitis was either eliminated or treated. However, sadly Beryl died of other co-morbidities in March 2022. Her carer reported how grateful she and Beryl were that her last few months of life were relatively pain free.

Patient Perspective

Beryl stated: *“The pain and wound have been so much better since using the treatment, I haven’t looked back and I am walking much better”.*

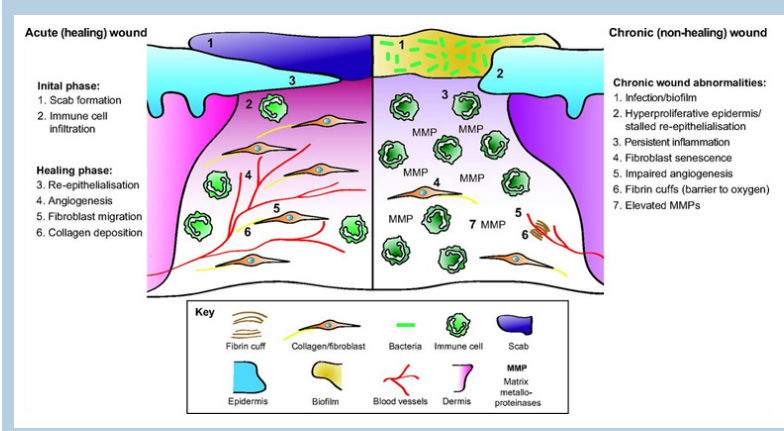
Clinician Perspective

“The new Accel-Heal Solo device, offers the advantages of Accel-Heal electrical stimulation therapy, in that it facilitates healing and reduces pain for patients with recalcitrant wounds, with the added benefits of being a continuous 12-day therapy. My patient lives alone and has some short-term memory loss, and although she has carers, it was likely to be challenging to change the device every 48 hours, due to staff capacity and irregular visit times. So, knowing that I could apply the treatment and only disturb it during dressing changes, twice a week was a real bonus. I was able to demonstrate the new LED light to her carer who kept an eye that it was working when she visited. The clip and strap made application much easier rather than using tape to secure it.”

Discussion

Evidence suggests that chronic wounds are “stuck” in a chronic inflammatory state,⁴⁷ and are therefore unable to move forward in a normal wound healing trajectory. This chronic inflammation causes elevated inflammatory markers, high levels of proteases, including MMPs, diminished growth factor activity, reduced fibroblast production and impaired angiogenesis, compared to an acute wound (see Figure 4).⁴⁷

Figure 4: Chronic inflammation. Acute vs chronic wound healing.⁴⁷



Current approaches to reduce the MMPs and biofilm, include wound bed preparation strategies such as debridement, moisture management, topical anti-microbials and protease modulators.⁴² However, despite following best practice, many wounds still fail to heal and invariably cause pain, which is likely due to the chronic inflammation, together with the absent or diminished electrical energy.

A randomised gene expression analysis,⁴⁰ demonstrated that Genes linked to inflammation, which are usually increased during wound healing, were down regulated in the skin of the healthy volunteers using Accel-Heal, but not where the volunteers were wearing the placebo devices. This provides evidence that Accel-Heal causes some specific responses in the skin to reduce inflammation, which is likely to have an effect on pain reduction. Delivery of EST to the wound can “kick-start” or “wake-up” the wound back into an “acute” phase by reducing the chronic inflammation.

Due to Accel-Heal Solo being such a compact and pre-programmed device, it is very easy to use in all settings by patients, carers and clinicians, and does not interfere with the patient’s standard wound therapy.

With increasing financial pressures on the NHS, it is imperative that clinicians consider new approaches to facilitate healing of chronic wounds. Guest et al., determined the costs of wound management are increasing year on year,¹ and are in excess of managing other complex conditions, such as obesity. Cost effectiveness has been demonstrated for using Accel-Heal,^{48,49,50,51} which may reduce the cost of treating venous leg ulcers in the NHS by 11%.⁵⁰ Healing wounds results in fewer nursing interventions, dressings⁴⁹ and hospital admission.

Conclusion

Using Accel-Heal Solo for these two patients completely transformed their mental health. The fast and significant pain reduction noted for both patients improved their well-being together with wound improvements.

EST needs to be considered for use by clinicians, in order to replenish the diminished/ absent electrical energy in chronic wounds, which is so vital in the complex healing cascade. Accel-Heal Solo has demonstrated improved quality of life for patients, many of whom have given up any hope of their wound/s healing and suffer endless un-managed pain.

Accel-Heal Solo is a cost effective easy to use EST, which is readily available for use in the UK. 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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