WoundsUK

VOLUME 8| ISSUE 4| NOVEMBER 2012

Accel-Heal® made easy

PRODUCTS FOR PRACTICE

Introduction

Electrical stimulation (ES) can be used to stimulate healing in hard-to-heal wounds in conjunction with standard wound management, such as compression therapy. ES therapy has been used for more than 30 years to facilitate wound healing but, historically, its use in clinical practice has been perceived as problematic and complex and key ES research findings have not been clearly interpreted. This made easy looks at Accel-Heal® (Medicareplus International Ltd), a modern device that delivers a condition-specific microcurrent treatment programme for non-healing and poorly healing wounds in order to stimulate healing.

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WHY SOME WOUNDS DON'T HEAL

A hard-to-heal wound is defined as one that fails to heal with standard therapy in a timely fashion (Troxler et al, 2006). Normal wound healing starts with haemostasis, progresses through a destructive inflammatory phase and then a restorative phase. It finishes with remodelling of the wound. This process can be interrupted at any stage due to a number of intrinsic and extrinsic factors (Vowden, 2011). For patients in which healing is prolonged, clinicians face the dual challenge of managing the wound environment and the patient, whose wellbeing may be significantly compromised (EWMA, 2008).

Treating hard-to-heal and long duration wounds is costly, and impacts on staff time and product use. To ensure good symptom management (eg pain or exudate) and minimise healthcare costs, it is important that hard-to-heal wounds are identified early. A careful wound and patient assessment can identify intrinsic and extrinsic factors that can delay healing, such as ischaemia, infection and underlying comorbidities. Recognising non-healing requires careful reassessment over several weeks while delivering a treatment plan to move the wound towards healing (Troxler et al, 2006). If the wound fails to reduce in size or there is no improvement within the expected timeframe, it is essential to reassess the patient and alter the treatment plan.

The role of advanced wound therapies

Wound bed preparation is recognised as having an important role in promoting healing and preventing the breakdown of the extracellular matrix (ECM) in wounds that are failing to heal (Schulz, 2009). The ECM is the major structural component of the dermis and primarily contains collagen, which provides support for cells, growth factors and receptors essential for wound healing. Introducing advanced wound therapies can be considered in patients who are not responding to standard therapy. This can result in improved symptom control, healing rates and reductions in long-term healthcare costs, despite the initial outlay for treatment, which might seem significant (Vowden, 2011).

Advantages of advanced therapies include:

- *Earlier control of symptoms*
- *Promotion of wound closure*
- *Improved quality of life*
- *Reduced healthcare costs.*

WHAT IS ELECTRICAL STIMULATION?

The interactions and effects electricity has on biological and physiological processes are many, varied and complex. The cell membrane has been identified as a key point of interaction with an externally applied current (Lee et al, 1993). As far back as 1850 it was recognised that the body generates natural electrical fields (Kloth, 2005). These create positive and negative charged ions that transfer across wound tissues and generate an electrical current (Vanable 1989). This endogenous 'skin battery' is believed to produce an electrical current in response to the resistance of the skin (Foulds and Barker 1983). When injury occurs (eg a break in the skin) there is a break in the continuity of the current resulting in the electrical potential being discharged as an electric field (Barker et al, 1982; Vanable, 1989; Jaffe and Vanable 1984).

It is believed that the discharge of current (known as the 'current of injury') helps to orchestrate tissue repair by attracting different cell types into and across the wound, stimulating cell proliferation and collagen synthesis (Tadej et al, 2010) and activating specific gene expression important in tissue repair (Zhao et al, 2004). This current of injury extends up to a radius of 2–3mm around the wound (Tadej et al, 2010). As the wound closes, the current of injury progressively reduces. In wounds in which healing is delayed, the current of injury is disrupted. Dry wounds, for example, have increased electrical resistance, resulting in the current being 'switched-off' (Cheng et al, 1995). Non-healing wounds also show a lack of electrical activity (Kloth and McCulloch, 1996).

ES therapy involves the transfer of an electrical current to the skin surface adjacent to the wound, creating a flow of ions through the wound tissue (Chapman-Jones et al, 2010).

EVIDENCE FOR ES AND WOUND HEALING

Stimulation of wounds with an external electric current has been investigated as a potential method for promoting or stimulating the wound healing process. It has been shown that externally-applied electrical currents can induce changes capable of increasing healing potential and the rate of wound repair. The exact mechanisms of some of these effects are still being investigated, but the most notable outcomes include:

- Faster wound closure (van Rijswijk, 1993; Arnold et al, 1994; van Rijswijk and Polansky, 1994; Robson et al, 2000)
- Increased migration of neutrophils, macrophages and fibroblasts (Assimacopoulos, 1968a, 1968b; Ottani et al, 1988)
- Increased angiogenesis and capillary density (Zhao et al, 2004)
- Increased blood flow and oxygenation (Gagnier et al, 1988; Peters et al, 1998)
- Increased fibroblast proliferation and activity (Gagnier et al, 1988; Peters et al, 1998; Sugimoto et al, 2012)
- Decreased oedema (Mohr et al, 1987; Reed, 1988; Chapman-Jones et al, 2010)
- Increased collagen synthesis and tensile strength (Assimacopoulos, 1968; Kloth, 2005)
- Disruption of biofilms and reduced bacterial proliferation (Kincaid and Lavoie, 1989; Moore, 2007)

USE OF ES IN CLINICAL PRACTICE

Historically, the use of ES in clinical wound care practice has been problematic. Many units were large and needed to be attached to the patient several times a day, often requiring a mains electrical supply. This would pose difficulties for patients who were cared for in the community, who were seen for 10–15 minutes twice a week. In addition, the need for health professionals to set therapeutic delivery parameters adversely affected the adaptability and cost of ES therapy. The introduction of the Accel-Heal® system has been designed to overcome these difficulties and can be fully integrated into existing care packages.

WHAT IS ACCEL-HEAL®?

Accel-Heal® is a registered class IIa medical device which delivers low-level ES therapy for use in the management of chronic, non-healing wounds. Each unit comprises a single-use, disposable current generator that is applied using a pair of disposable electrodes. The system delivers a pre-set series of low-intensity electrical pulses which deliver a microcurrent to the wound.

WHEN TO USE ACCEL-HEAL®

Accel-Heal® is indicated for patients with a hard-to-heal venous leg ulcer of over six months' duration. It can be applied at any stage of healing and is an adjunct therapy to be used alongside existing management strategies. It can be used under compression bandaging.

Contraindications

Accel-Heal® should not be used for patients with active cancers. Some patients might have an allergic reaction to the pads, although this is rare. The electrode pads should not be placed directly over broken capillaries or varicose veins.

CLINICAL APPLICATION OF ACCEL-HEAL®

How to apply Accel-Heal®

The electrode pads are placed close to the wound border on either side of the wound (Fig 1). The thin electrical cables can be placed under dressings or bandages and are connected to the current generator, which is placed into the bandage or patient's clothing (Tadej et al, 2010). The device is activated by pressing a button and generates a pulsed microcurrent in a preset sequence. This current is below the threshold needed to stimulate muscle or nerve activity and so goes undetected by the wearer. The electrode pads conduct the naturally changing resistance of the skin to the unit and it automatically adjusts its electrical output to ensure continuous delivery of the required therapeutic current.

How long to use Accel-Heal®

A standard Accel-Heal treatment programme runs for 12 days and uses six device units (varying numbers of units have been used in trials and evaluations but a 12-day treatment programme is recommended). Once activated, each unit delivers therapy continuously for 48 hours of treatment. When a unit reaches the end of its preset therapy sequence it can be changed either by the patient, his/her carer or by a health professional at the next dressing change.

On average, wounds smaller than 15cm^2 require six Accel-Heal® units to achieve effective treatment outcomes. For wounds larger than 15cm^2 it has been suggested that Accel-Heal® be used until the wound has reduced in size by 50% (Chapman et al, 2010).

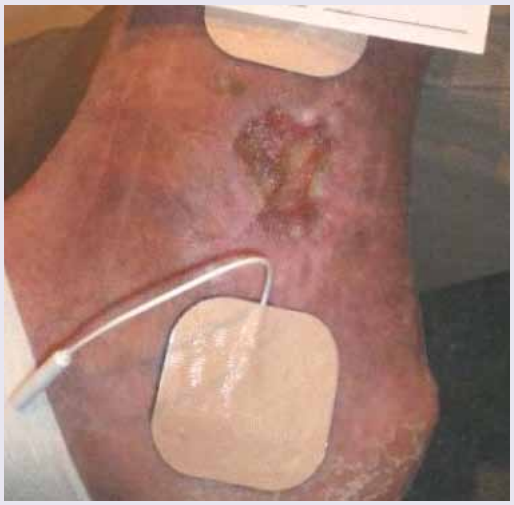

Figure 1: The electrodes are attached to the intact skin either side of the wound itself

When should I see an improvement in the wound?

Although progress may be seen immediately, Accel-Heal® is not expected to heal the wound within the 12-day treatment programme. However, the therapy 'kick starts' the healing process, while the management regimen is continued or modified. A predictive model has shown that wounds less than 15cm^2 might be expected to heal within an 8-week period (Chapman et al, 2010).

EVIDENCE FOR ACCEL-HEAL®

Young et al (2011) undertook a non-blinded, clinical evaluation using Accel-Heal® of 30 patients with full thickness, venous leg ulcers that had been non-healing for more than 6 months. The wounds were formally assessed and confirmed as non-healing for two months prior to the evaluation of Accel-Heal®.

All patients were treated for 10 days and patients' wounds were monitored over a 3-month period. During this time periwound oedema had decreased by approximately 60% of the original level. This was maintained at 90 days (Young et al, 2011). In addition mean pain levels had reduced to 1.6 from 5.3 (using an 11-point score of 0=no pain and 10=worst pain) over the treatment period (Tadej et al, 2010). Exudate levels also reduced (with 51.7% lower fluid loss) at the end of the treatment period.

Chapman-Jones et al (2010) reported that 95% of chronic, non-healing venous leg ulcers studied had improved at 90 days, with 38% of going on to achieve full closure within 19 weeks. Further studies are needed to confirm the benefits of using Accel-Heal®.

CLINICAL BENEFITS OF ACCEL-HEAL®

Improving rates of healing can have significant benefits for the patient: with a reduction in pain and exudate levels and improved quality of life (EWMA, 2008). Preliminary results may suggest that the device can have a positive impact on quality of life and can help to manage symptoms effectively, such as pain, exudate and oedema.

Patients can wash with the device in place. They may shower but the unit must be detached from the electrical cables. Patients' reliance on carers and nurse visits is reduced, allowing them to feel more in control and visualise a future without a wound (International Consensus, 2012).

COST BENEFITS OF ACCEL-HEAL®

Taylor et al (2011) undertook a formal cost-analysis of the use of Accel-Heal® on non-healing venous leg ulcers. They assumed that three devices were used per patient at a cost of £40 each. Using a Markov model, they demonstrated that Accel-

Case report 1

Background

A 67-year-old man presented to the tissue viability clinic at Eastborne with a wound of three years' duration on the lateral aspect of his left ankle. He had a history of rheumatoid disease and was taking allopurinol and half an aspirin a day for gout. The patient was active outside the home and concordant with treatment.

The wound had been treated with AQUACEL® (ConvaTec) and compression bandages for six weeks. When the man was admitted to the wound healing centre, the skin was macerated and very painful (Fig 1). It was decided to apply ES therapy (Accel-Heal®) under Class 2 compression hosiery.

Treatment

Prior to application the skin was thoroughly washed and Cavilon™ (3M) applied. The electrodes were threaded through the bandages as they were applied and connected with the therapy unit, which was then attached to the top of the compression bandage.

The dressings were changed every 2 days, or 3 days at weekends. The leg was soaked in warm tap water and the dressing, Accel-Heal® unit and compression bandage were reapplied.

Outcomes

After four weeks, there was good granulation tissue coverage and the wound had achieved almost full closure (Fig 2). The patient reported that the pain had almost gone: before treatment with Accel-Heal® began he had reported a pain score of 8 on a visual analogue scale and post-treatment he scored his pain as 2.

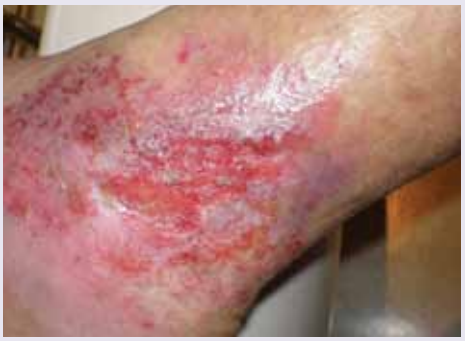

Fig 1: Three-year-old non-healing ankle wound after treatment with compression therapy. The periwound skin is macerated.

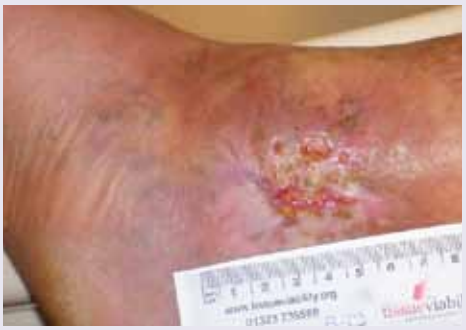

Fig 2: Good granulation tissue formation and healing after four weeks of using Accel-Heal® ES therapy, in conjunction with compression.

Heal® was a cost-effective treatment that could produce savings. Despite the £240 upfront investment for six Accel-Heal® devices, the five-month healthcare costs of using Accel-Heal® plus dressings and compression bandaging was given as £748.94, versus £879.90 for dressings plus compression bandaging alone (Taylor et al, 2011). Use of the product as an adjunct to appropriate topical management was estimated to achieve a 27% reduction in nurse visits, a 56% reduction in bandage usage and a 27% reduction in dressings leading to a 15% reduction (£6.2 million) in total costs to the NHS.

SUMMARY

When the body's endogenous bioelectric system fails and cannot contribute naturally to the repair processes, introducing therapeutic levels of electrical current into the wound tissue from an external source may help to stimulate healing. This treatment has been found to be useful in hard-to-heal wounds and chronic venous leg ulcers in particular. Accel-Heal® provides a simple, safe and potentially cost effective method of ES treatment, offering benefits to patients and healthcare services alike.

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Supported by Medicare Plus
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