

Electrical stimulation therapy and electroceutical treatment for the management of venous leg ulcers

Leg ulcers cause a significant impact on patient's quality of life (Hareendran et al, 2005; Salome et al, 2013a; Salome et al 2013b; Upton and Andrews, 2013a; Upton and Andrews, 2014) and pose huge financial pressures to the NHS (Guest et al, 2015a; Guest et al, 2016). Clinical outcomes are often poor for these patients (Guest et al, 2012) due to several reasons ranging from inappropriate assessment (Guest et al, 2015a), inappropriate selection of treatment (O'Brien et al, 2002), patient-related factors such as comorbidities and lifestyle choices, extrinsic issues such as polypharmacy, malnutrition and dehydration and wound-associated complications such as biofilms and infection. This article will focus on some wound-related factors and specifically slough, biofilms and chronic inflammation and the benefits of using electrical stimulation therapy and electroceutical treatment to reduce the inflammation, and improve outcomes and quality of life for patients.

Wound and leg ulcer management

Wound management in the UK is mainly nurse-led and accounts for a large proportion of the district nurses (DN) caseload (Simon et al, 2004). Holistic assessment and diagnosis of possible leg ulcer aetiology is key to allow the DN to implement an appropriate care plan working with the patient and multidisciplinary team (MDT). The gold standard treatment for venous leg ulcers (VLUs) is high graduated compression therapy (O'Meara et al, 2012). However, despite appropriate diagnosis and addressing the underlying predisposing, perpetuating and precipitating issues, VLUs often fail to heal and have a high recurrence rate (Guest et al, 2012). Patients cannot always tolerate the required level of compression therapy due to pain and/or lifestyle choices. Pain is often caused by chronic inflammation, biofilm and infection and has a huge impact on quality of life (Herber et al, 2007).

Biofilms and chronic inflammation

A recent systematic review (Malone et al, 2017) found that 78% of non-healing wounds, including VLUs, harbour biofilms. Biofilms are described as a group of bacteria that adhere to each other forming an extracellular polymeric substance, which allows the bacteria to be resistant to topical antiseptics, systemic antibiotics and host defenses (Wolcott et al, 2008). Percival and Suleman (2016) propose that biofilms are found in wound exudate, on the wound bed,

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within slough and necrotic tissue and that slough may act as a reservoir for biofilms. This results in wound chronicity and an increased inflammatory response (Wolcott et al, 2008). Biofilms are difficult to remove and often require either mechanical or sharp debridement of the slough and necrotic tissue, which is the recommended treatment for management of biofilms in VLUs (Bianci et al, 2016).

In clinical practice, mechanical and sharp debridement can be a challenge. In the community there is often no quick access to a medical team with skills to undertake sharp debridement, which frequently falls on a tissue viability nurse (TVN). The very nature of the biofilm, which can re-develop quickly due to presence of planktonic bacteria (free-floating bacteria) promoting development of new biofilms, requires regular sharp debridement to be undertaken, which may not be possible with current time constraints of both the DN and TVN services. Mechanical debridement can be utilised using new technologies (Bahr et al, 2011; Downe 2014), with good effect, but these are not always readily available on local wound management formularies and/or the wound is too painful to undertake the treatment.

Chronic wounds including non-healing VLUs have been demonstrated to have similar biochemical components including elevated inflammatory markers, high levels of proteases, diminished growth factor activity and reduced cell numbers compared to acute and healing wounds (Nunan et al, 2014; Lazaro et al, 2016).

Presence of biofilm, infection and inflammation results in pain, high exudate levels and risks to the peri-wound tissue for the patient and can prevent the application of high compression therapy. Reduction of these factors will improve the wound bed and enhance wound healing while improving the quality of life for patients. Topical wound treatments including dressings and cleansing solutions can enhance the benefit of mechanical and surgical debridement, whilst advanced treatments such as Larvae and topical negative pressure will facilitate the debridement of the biofilm (Gilead et al, 2010; Dowsett, 2012; Upton and Andrews, 2013b) and electrical stimulation therapy/electroceutical treatment

reduces the inflammation and associated symptoms, decreasing bacterial infection, increasing local perfusion and accelerating wound healing (Thackral et al, 2013).

Electrical stimulation therapy and electroceutical treatment for reduction of inflammation

Human physiology is electrochemical in nature and within the skin a stream of electrical current, known as the 'skin battery' is created by the difference in voltage between the surface of the epidermis and the deeper layers, producing a low amperage current known as the 'skin current'. During wounding, the skin current is discontinued at the wound site and the flow of current flows outwards establishing a 'current of injury' (Kloth, 2014). This current of injury is important to orchestrate tissue repair, stimulate cell proliferation and collagen synthesis (Kambouris et al, 2014). However, it can become disrupted when adverse events occur within the wound such as the presence of foreign bodies; slough; necrotic tissue or following the development of biofilms and/or infection (Meng et al, 2011). Chronic wounds have been shown to lack electrical energy (Kloth and McCulloch, 1996).

Electrical stimulation therapy/electroceutical treatment is the application of microcurrents of electrical energy to effectively replace the current of injury, which has become disrupted in chronic wounds. Physicians have used electrical energy for centuries in the management of fractured limbs and analgesia but the development of chemical compounds in the 19th and 20th century diminished its use. More recently it has been re-introduced for analgesia, athletic enhancement (Kambouris et al, 2014), facial therapy (Farris, 2011) and wound management (Kloth and McCulloch, 1996; Kloth, 2005; Junger et al, 2008; Tradej et al, 2010; Herberger et al, 2012; Thackral et al, 2013; Griffin, 2013; Guest et al, 2015b). Delivery of electrical stimulation therapy in clinical practice for wound management has been available in various formats and modes of delivery, which can cause different challenges such as heat and chemical productions resulting in cell and tissue damage (Reid and Zhao, 2014) and many being available in large units requiring frequent application by the clinician.

Electrical stimulation therapy devices

A device used in Germany (Herberger et al, 2012) (not available in the UK), used an electro-stimulation impulse generator (WoundEL®), adapting the intensity according to patient tolerance, applying the current twice daily for 30 minutes for up to 12 weeks via the impulse generator. Patients with various wound types failing to heal with standard therapy were included in the study. The study found that the treatment reduced wound size, encouraged granulation and changed the wound from an inflammatory phase to the repair phase. Four patients ($n=95$) suffered skin reactions to the electrode and one patient developed maceration.

A further treatment modality combines ultrasound and electrical stimulation therapy (BRH-A2) to create a

microcirculation effect using a class II type BF device. The device looks similar to a computer and indeed has a touch screen application to store clinical data and measuring of the results. Avrahami et al (2015) undertook a retrospective study in Israel applying the treatment for 25 minutes twice weekly for patients with VLUs and diabetic foot ulcers (DFUs). Wound size reduction of 50% was achieved in 71.1% ($n=38$) of the VLUs within 4 weeks of treatment. The study found that using a two-combination therapy improved both the healing rates and the quality of the healing tissue. Adverse events and side effects were not discussed. The device is available in the UK including rental/purchase of the system and single use disposable items.

Economic benefits were not included in the studies. The size of the devices and need for such regular applications could cause challenges for its use in the community.

Electroceutical treatment

A treatment recently approved for prescription by the NHS avoids some of these challenges. Instead of large, fixed site machines that provide a physical stimulation through the delivery of a variable amount of electricity over a variable period of time, an electroceutical treatment (Accel-Heal®) delivers a sub-sensory level of electrical energy to cause a physiological change to the impaired biological functions in the wound. The low level of electrical energy, the specific dosage delivered and the specific mode of action differentiates electroceutical treatment from the traditional understanding of electrical stimulation.

The electroceutical treatment (Accel-Heal®) is a one-off treatment that, at a push of a button, provides a precise dose of electroceutical treatment over a fixed period of 12 days. The treatment is delivered by six small (7cm x 4cm x 2cm) portable devices that are simply applied one after another over the 12-day period. The treatment is designed with ease of clinical application and patient comfort in mind and is used alongside standard treatment, including compression bandage.

The treatment does not heal the wound within the 12-day treatment period but kick-starts the wound healing physiological process. Research by Guest et al (2015b) demonstrated that, applied to VLUs with a mean age of 1 year, the electroceutical treatment (Accel-Heal®) caused full wound closure within 2.5 months. Applied to VLUs with a mean age of 6.1 years, the treatment caused a 42% wound size reduction within the study period. All patients experienced improved clinical outcomes including reduction in pain and exudate levels. The research reveals that the use of the electroceutical treatment (Accel-Heal®) affords the NHS a dominant cost-effective treatment for VLUs and indicates that it should be applied early in the patient pathway.

Contraindications of electrical stimulation therapy and electroceutical treatment

Currently contraindications include: active cancer and pregnancy and use should be avoided near the head for



Figure 1. Medial malleolus (30/12/2015)



Figure 2. Medial malleolus (14/01/2016)

patients with epilepsy and near the chest for patients with pacemakers (Kambouris et al, 2014). Caution should be taken to ensure the devices do not get wet and should be removed prior to electrical investigations such as echocardiograms, electroencephalograms and magnetic resonance imaging. As with all devices, individual product literature should always be considered prior to use.

Implications for practice

The use of innovative technologies for transforming and improving clinical outcomes and reducing costs in the NHS was an integral component of the NHS Five Year Forward View (2014). The use of electrical stimulation therapy and electroceutical treatment has been demonstrated to both improve patient outcomes and reduce costs to the NHS (Glegg and Guest, 2007; Taylor et al, 2011) for the management of chronic wounds. An independent study by Guest et al (2015b) found that using an electroceutical treatment (Accel-Heal®) for the management of VLU, at the optimal point in the patient pathway could result in an annual saving to the NHS of at least 35%.

Case study

A case study was undertaken in March 2016 to demonstrate the benefits of using an electroceutical treatment (Accel-Heal®). An 80-year-old male attended the wound clinic on 30 December 2015 with recurrence of a VLU to the

left medial malleolus, which had developed spontaneously. Previous episodes had occurred in 2007 and 2012 despite wearing class II compression hosiery.

Past medical history included atrial fibrillation, hypertension, enlarged prostate and osteoarthritis neck and back.

The wound measured approximately 27cm² with 20% dark granulation, 50% slough and 30% maceration (see *Figure 1*). His pain score was 7/10 on the analogue score despite taking regular analgesia and he was reluctant to increase up the analgesic ladder. Ankle Brachial Pressure Index was 1.3 bilaterally. Limb assessment noted signs of venous disease but high compression therapy was not tolerated and he was commenced antimicrobial cleansing solutions and dressings with reduced compression bandage.

On 7 January 2016, the wound was noted to be infected and broad-spectrum antibiotics were prescribed by the GP and by 14 January 2016 the wound had deteriorated significantly, presenting with cellulitis and high levels of exudate (*Figure 2*). The wound measured 46cm² on 28 January 2016, antibiotics, topical antimicrobials and analgesia continued. On 1 February 2016 a further wound swab was taken but this showed nothing abnormal. Exudate was increasing and causing peri-wound excoriation extending down the leg towards the foot. A different broad-spectrum antibiotic was prescribed following discussion with the General Practitioner (GP) in view of the deterioration and the patient agreed to take stronger analgesia. By 25 February 2016 there was no improvement (see *Figures 4 and 5*) and the excoriation extended around the posterior aspect of the leg (see *Figure 3*) and lateral aspect (see *Figure 6*). Antibiotics continued with no improvement although the pain was reduced to 5/10 with increased analgesia. On 10 March 2016 the patient consented to commencing the electroceutical treatment (Accel-Heal®) with the aims to reduce inflammation, pain and exudate and expedite healing.

The electrode pads were applied opposite each other avoiding any broken or cellulitic skin. Instructions were provided to his wife to change the electroceutical unit every 48 hours and the dressing regime continued twice weekly when the nursing team changed the electrode pads. Treatment



Figure 3. Left posterior aspect (25/02/16)



Figure 4. Left medial aspect (25/02/16)



Figure 5. Left medial aspect (25/02/16)



Figure 6. Left lateral aspect (25/02/16)



Figure 7. Left medial aspect (07/04/16)



Figure 8. Left medial aspect (12/01/17)

was completed 12 days later. Antibiotics were completed on 14 March 2016 and the wounds were considerably drier with only intermittent pain present.

On 7 April 2016 a great improvement was noted (see *Figure 7*), exudate was decreased and the pain score had reduced to 4/10 with no pain by the end of April. The lateral aspect wound measured 4cm² with 100% granulation and the posterior wound had healed. Two further courses of antibiotics were required between April to June but the wound did not deteriorate and in August the patient tolerated high compression therapy. The patient developed varicose excema to the medial malleolus and was referred to Dermatology who prescribed an intensive course of topical steroids and emollients. All wounds were completely healed by the end December 2016 and the patient was measured for class II compression hosiery (see *Figure 8*).

The application of the electroceutical treatment significantly reduced the pain, inflammation and exudate within three weeks of treatment and kick-started the wound healing process, together with standard therapy including compression bandages.

Conclusions

Research and case studies have demonstrated the benefits of using electrical stimulation therapy and electroceutical treatment alongside the patient's standard therapy for the management of patients with VLU. The NHS Five Year Forward View has paved the way for clinicians to consider the use of innovative technologies to enhance patient care. Treatments need to be patient focused, accessible and easy to use allowing patient involvement and improving quality of life. It is recommended that clinicians consider using advanced therapies such as electrical stimulation therapy and electroceutical treatment to reduce chronic inflammation, known to reduce healing in chronic wounds.

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