

Bio-electrical stimulation therapy using POSiFECT®RD

Electric stimulation for the treatment of chronic wounds has been demonstrated to be of value in many published experimental clinical studies. A new bio-electric dressing, POSiFECT®RD, has recently been introduced that applies bioelectric currents to the chronic wound in a way that mimics those generated by normally healing wounds. The dressing is a self-contained single-use device designed for ease of use. This article briefly reviews the history and use of electric stimulation, describes the POSiFECT®RD dressing and its use in detail and concludes with a consideration of the recent clinical data describing treatment outcome.

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KEY WORDS

Bio-electric stimulation therapy
 POSiFECT®
 Pressure ulcer
 Venous ulcer
 Treatment

In recent years, the variety of products available for treating and managing wounds has expanded considerably. In spite of the numerous options available, however, many wounds remain non-healing. As interest in treating chronic wounds has grown, so has interest and research into novel treatment modalities such as bio-electric stimulation therapy. Electric stimulation has been around in healthcare applications for many years, but attempts to establish its use in wound healing have not yet met with great success (Malone, 2003). An exhaustive review of the experimental and clinical evidence in the literature relating to electrical stimulation in tissue repair can be found in a paper published by Kloth (2005).

The physiology of wound healing is a fragile and complex process that is

dependant on many inter-related factors (Flanagan, 1999). Wound assessment and treatment should be based on an understanding of normal tissue repair and factors affecting the process. In particular this knowledge should be

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considered when assessing the potential for treatment with new devices or new therapeutic modalities. It also has to be considered that the chronic wound healing process differs in many important respects from that seen in acute wounds. For example, one way in which they differ is the inflammatory process. Acute inflammation found in the acute wound stimulates wound healing, whereas chronic inflammation found in chronic wounds can delay healing (Diegelmann and Evans, 2004) and treatment strategies have to be used that will convert the chronic inflammation to a resolving, healing inflammatory response.

Electrical stimulation

The use of electric stimulation has a long history. Its first use dates back to the late 1600s when gold foil was applied topically over ulcers to enhance healing and prevent scarring. Benjamin Franklin wrote about applying electrical shocks to a frozen shoulder in 1757. More recent work has investigated the existence of a direct current system controlling tissue healing. This has developed into the concept that an injury to a living system causes a localised shift in current flow that triggers repair mechanisms known as the 'current of injury'.

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It can be demonstrated that living tissues possess direct current surface electropotentials that, at least in part, regulate the healing process (Weiss et al, 1990). This has led to the conclusion that electric stimulation mimics the natural current of injury, helping correct the damage to the human skin (Kloth and McCulloch, 1996).

Following their review of the literature, Hampton and Collins (2006) identified that nearly every clinical trial using applied external electric fields

to stimulate healing in mammalian wounds reported a significant increase in the rate of healing from 13% to 50%. They outlined the potential benefits of bio-electric stimulation to wound healing as:

- ▶ Accelerated healing with resultant improved tensile strength particularly in intractable ulcers
- ▶ Improvement of peri-wound microcirculation
- ▶ Decreased oedema
- ▶ Debridement of necrotic tissue
- ▶ Attraction of neutrophils and macrophages
- ▶ Stimulation of receptor sites for growth factors
- ▶ Stimulation of growth of fibroblasts and granulation tissue
- ▶ Increased blood flow
- ▶ Induction of keratinocyte migration
- ▶ Prevention of post-ischæmic oxygen free-radical-mediated damage
- ▶ Anti-bacterial effects
- ▶ Reduction in number of mast cells.

Given the clinical evidence and the wide range of potential benefits to the open wound, bio-electric stimulation therapy is, therefore, considered beneficial for wound healing. Cutting (2006) outlines the current thoughts on electrical stimulation with a comprehensive review of the evidence supporting the above mentioned potential benefits. He also states that it can be difficult to compare outcomes

reported by different studies in the literature as there are differences in methodology and therapeutic modality, and the nature of such trials is that the number of participants tends to be small. He concludes that the use of electric stimulation for wounds that have resisted attempts to stimulate healing using conventional approaches is supported by a reputable body of evidence and that clinicians may therefore be encouraged to consider it as a useful therapy.

POSiFECT® RD bio-electric wound care dressing

POSiFECT®RD bio-electric wound dressing (*Figure 1*) is a unique therapy that harnesses the natural current of healing (Cutting, 2006). It uses the principle of bio-electric stimulation therapy for the treatment of chronic wounds. The dressing contains a miniature electric circuit that will deliver a microcurrent to the wound bed for a minimum of 48 hours. The current is derived from two lithium non-rechargeable coin cell batteries. The two electrode system delivers bio-electrical stimulation. The first electrode, the anode, is a soft metal ring set into a hydrogel in the dressing (*Figure 2*). The second electrode is a small cathode paddle, which sits on the wound bed (Hampton and Collins, 2006). The POSiFECT®RD dressing is indicated for the management of chronic wounds

where conventional therapies have failed. POSiFECT®RD dressings must not be used:

- ▶ In the neck or head region
- ▶ In patients with a demand-type cardiac pacemaker. Electronic monitoring equipment (such as electrocardiogram [ECG] monitoring and ECG alarms) may not operate properly when the POSiFECT®RD bio-electric wound dressing is in use
- ▶ With other active or advanced wound care products such as hydrogels or silver dressings
- ▶ When there are visible signs of infection
- ▶ In the presence of medical imaging equipment, such as magnetic resonance imaging or X-ray.

Biofisica UK Ltd, the company that manufacture POSiFECT®RD dressings, say that isolated cases of skin irritation may occur at the site of the electrode placement in long-term use. Potential complications may include:

- ▶ Sensitivity or irritation
- ▶ Infection
- ▶ Chronic inflammation.

Method of use

The wound should first be cleansed (according to good practice and local policy) and then the surrounding skin gently dried. The dressing is then unpacked (*Figure 1*) and the black pull-tab removed to confirm that the red light is flashing. If the red light is not flashing, the dressing should not be used. Using the tabs of the protective liner to facilitate aseptic application, the protective liner should be removed. The adhesive side of the dressing, which looks like a ring, should then be placed onto the non-wounded skin around the wound and pressed firmly. The lid should then be opened and the protective liner removed from the centre electrode (cathode paddle). The centre electrode is then placed directly onto the wound itself, ensuring contact with the wounded tissue at or near the centre of the wound or wound bed. As an optional step, if desired, the wound can be lightly packed with a suitable packing material to absorb excess exudate. Ensure the wound packing is placed over the central electrode taking



Figure 1. The POSiFECT® RD supplied as a single use bio-electric wound dressing.

care not to disturb the contact the electrode is making with the wound.

Finally, remove the protective liner from the lid and close the lid, sealing it to the dressing and covering any packing material and the central electrode. Confirm that the red light is no longer flashing. If the red light continues flashing after applying the dressing, ensure that the entire dressing is lying flat against the non-wounded skin and that the central electrode is in contact with the wound. If the red light continues to flash do not use the dressing. If at any time during application the red light begins flashing, check to be sure the entire dressing is lying flat against the skin and make any adjustments necessary. If the red light continues to flash, remove the dressing and apply a new one. Change the dressing as needed to maintain a moist, clean wound area.

POSiFECT®RD wound dressing clinical data

Feldman et al (2005) reported on a randomised, double-blind, crossover study in which they included 15 patients with grade 3 and 4 pressure ulcers. Of the 15 patients included, four patients completed the trial. Two patients received active treatment with an earlier version of POSiFECT® dressing and two received sham treatment. Patients received their treatment in blocks of 8 weeks. Those patients who received the sham treatment then received 8 weeks of POSiFECT® treatment. All the patients were followed up for 16 weeks. Feldman et al (2005) found that there was improvement in the healing rates of the pressure ulcers in weeks one to three in the POSiFECT® treatment patients. As a consequence of this study the treatment protocol was changed so that patients received three weeks on and one week off treatment in subsequent studies.

Hampton and King (2005) detailed the use of POSiFECT®RD dressing on a 70-year-old woman with an intractable wound following elective surgery for a knee replacement 18 months previously. The prosthesis appeared to carry bacteria and her leg had become oedematous with a shallow ulcer appearing that exhibited the



Figure 2. POSiFECT® RD with centre flap raised (it has a centre flap to allow inspection of the wound and to facilitate placement of the central cathode paddle. The circular anode is embedded in hydrogel on the underside of the dressing).

characteristic signs of a *Pseudomonas aeruginosa* infection. This patient had three weeks on treatment and one week off. By week four, *P. aeruginosa* was no longer present and there was a reduction in exudate levels. By week 8, the wound was granulating well and had islands of epithelial tissue. At this point, as POSiFECT®RD had appeared to 'kick start' the wound into a healing phase, it was discontinued and conventional dressings were used. The wound had completely healed in just over 4 months.

Hampton and Collins (2006) described the use of POSiFECT®RD dressing on a male who had a necrotic pressure ulcer on his heel. The pressure ulcer had not changed over an 18-month period and still contained a large quantity of stubborn fibrous slough. The authors reported an early therapeutic response with debridement and decrease in wound area of approximately 50% occurring within 7 days of treatment initiation. Complete healing was achieved 13 weeks after initial treatment.

A prospective, descriptive, evaluative, non-blinded clinical trial with a sample size of 18 patients with 21 recalcitrant wounds has recently been completed (Hampton et al, 2005).

All the wounds were previously non-healing for more than 6 months. The wounds were treated for three weeks with POSiFECT®RD bioelectric therapy followed by one week of standard care. The cycle was repeated just once. They were assessed at 8 weeks and again at 16 weeks. The total mean surface area of all of the wounds was 18cm² at commencement of the study and 10.3 cm² at the end of 8 weeks. Thus for previously non-healing wounds treated for 8 weeks, an average overall decrease in wound area of 7.65cm² was achieved. At 16 weeks, six wounds had healed completely and six were almost healed. All the other wounds showed some improvement — even in the patients who discontinued/dropped out part way through the programme. Hampton et al (2005) concluded that the results of this small trial were significant and demonstrated the clinical effectiveness of POSiFECT®RD, illustrating the potential for the activation of wound healing. Also noted was that POSiFECT®RD did not cause any pain or discomfort in any wounds and the investigators considered that there is a possibility that it may actually decrease pain in painful wounds although this would require further investigation. At one-year follow up, ten wounds had healed, and none of the previously healed wounds had recurred.

Recent data has emerged to indicate that biofilm disruption may be one of the many modes of action of POSiFECT®RD. Biofilms are bacterial communities living within an extracellular polysaccharide matrix produced by bacteria following adhesion to a suitable surface. Bacteria growing as biofilms are resistant to antibiotics and contribute to wound chronicity. Electric stimulation has been shown to disrupt biofilms (Costerton et al, 1994). White et al (2006) presented a case study of an 83-year-old female with a chronic non-healing venous leg ulcer of two years' duration in which a bacterial biofilm was judged to be delaying healing. The patient was unable to tolerate compression therapy. Within 6 days of treatment with POSiFECT®RD the wound had reduced in size and the slough had reduced by 50%. After a further 17 days the wound had 100% granulation tissue. They concluded that electric fields are known to prevent biofilm formation and that POSiFECT®RD is an interesting new option in the treatment of chronic wounds that may be harbouring biofilms.

Conclusion

The medical application of electrical stimulation has an extensive history, with records of its use existing from the 17th century. It has acquired a substantial body of evidence to support its use in wound management (Kloth, 2005) and has been demonstrated to have potentially multiple positive effects on all phases of wound healing (Cutting, 2006).

The recently introduced POSiFECT®RD utilises this body of knowledge to bring bio-electric stimulation therapy into the UK wound care arena. It applies the novel concept of mimicking the natural healing currents that are found in normally healing wounds (Cutting, 2006) to chronic wounds. It delivers an electrical stimulation system to the practitioner as a single use self-powered bioactive dressing for direct application to the wound. It can either be used alone, e.g. for the treatment of pressure ulcers, or in combination with compression bandaging for the treatment of venous leg ulcers. Clinical studies performed using POSiFECT®RD

have demonstrated a clear clinical benefit when treating ulcers that have been previously non-responsive to treatment. **WUK**

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Key Points

- ▶▶ Electric stimulation for the treatment of chronic wounds has been demonstrated to be of value in many published clinical studies.
- ▶▶ Bio-electric stimulation therapy is considered beneficial for wound healing based on the clinical evidence and the wide range of potential benefits to wound healing.
- ▶▶ POSiFECT®RD bio-electric wound care dressing provides a bio-electric stimulation therapy in a single-use dressing that is applied directly to the wound and may be used alone for chronic wounds or in conjunction with compression bandaging for treatment of venous leg ulcers.
- ▶▶ POSiFECT®RD bio-electric wound dressing is a unique therapy that harnesses the natural current of healing to activate healing in non-healing wounds.
- ▶▶ In a study of 18 patients with 21 recalcitrant wounds treated with POSiFECT®RD, six wounds healed completely by 4 months and six were almost healed — all the remaining wounds showed some benefit. At one-year follow up, four additional wounds had healed, and none of the previously healed wounds had recurred.