

Evaluation of a device combining electrostimulation and ultrasound in the treatment of non-healing chronic leg ulcers



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For many years, ultrasound and electrostimulation have been used in the treatment of injuries such as muscle sprains and in wound care. The BRH-A2 is a device combining ultrasound and electrostimulation. This study evaluated the effect of BRH-A2 on healing chronic leg ulcers and the device's impact on pain, wellbeing and mobility.

It has proved difficult to accurately quantify the true cost of wounds in the UK. However, Guest et al placed the figure at between £4.5 billion and £5.1 billion for the 2012/13 financial year (Guest et al, 2015). This study did not include individuals being cared for in nursing homes nor did it consider those wounds that failed to heal within the analysis period. Posnett and Franks reported a figure of £2.3 billion–£3.1 billion for chronic wounds in 2005/6 (Posnett and Franks, 2008). The true costs to individuals and society remains challenging to calculate, but must include lost work days, equipment, social care, social isolation and mental health issues that may arise from increasing isolation.

Posnett and Franks (2008) highlighted the significant incidence of wounds that do not heal within a year, while Guest et al reported the comorbidities suffered by people with non-healing wounds. The chronicity and complexity of these patients and their wounds creates a significant cost pressure. Chronic wounds are costly, both financially and emotionally, leaving both the clinician and patient feeling powerless and lacking solutions to deal with them. Clinicians frequently seek creative and innovative solutions for these wounds that have failed to respond to more conventional techniques.

Ultrasound and electrostimulation

For many years, physical therapy modalities such as ultrasound and electrostimulation have been used in the treatment of injuries such as muscle sprains. There is a significant body of work around the use of physical modalities in wound care, in particular electrostimulation.

Electrical stimulation of muscle fibres for health benefits has been investigated since Galvani first caused a frog's leg to twitch in 1787. Electrostimulation devices deliver different types of current; the recognised effects include increased blood flow, proliferation of fibroblasts and collagen production, neovasculature stimulation, granulation stimulation and bacteriostatic effects – all important in wound healing (Taskan et al, 1997; Hess et al, 2003; Williams et al, 2016).

Ultrasound is a mechanical energy delivered in the form of sound waves that cause molecular vibration. The vibration causes increased heat and blood flow to the treated area (Bailey et al, 2003; Ennis et al, 2006; O'Brien Jr, 2007; Varatharajan et al, 2015; Watson, 2015). As with electrostimulation, there is a significant body of research on its therapeutic value.

BRH-A2

The BRH-A2 device (BRH Medical) combines ultrasound and electrostimulation, and delivers them individually and in combination during treatment. This is designed to create a 'micro-circulation' effect, increasing the blood flow to increase the healing rate. It is a non-invasive, portable device and includes software for keeping patient records, taking photos and measuring wounds [Figure 1].

Aim

The aim was to measure the effect of BRH-A2 on healing of chronic static wounds and assess the device's impact on pain, wellbeing and mobility. The assessment of pain and healing are obvious measures, and the decision was made to include mobility as a measure because it is gaining

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Figure 1. The BRH-A2 in use.



Figure 2. (a) Wound of 11 years' duration at initial assessment (b) The wound at 12 weeks.

increased recognition (Iezzoni et al, 2001; Oliver et al, 2014).

A lack of mobility impacts an individual's mental health because it reduces independence and creates a life of isolation. The physiological impact of immobility is just as important. The efficiency of the muscle pumps in the lower limb in reducing oedema and its role in the venous return of blood and lymph to the body core directly impacts on the ability of the body to heal wounds on the lower leg (Araki et al, 1994; Back et al, 1995; Orsted et al, 2001; Ennis et al, 2006; Varatharajan et al, 2015).

Methods

Patient selection

Patient inclusion criteria are shown in *Box 1*. All patients ($n=10$) had chronic leg wounds, which had been present from 5–31 years. Wound aetiology included peripheral vascular disease, diabetes and renal impairment. The patients were aged between 29 and 88 years.

The patients' existing regimen at the time of commencing treatment with the BRH-A2 device was considered gold standard, including appropriate medications, dressings and optimum compression. All study subjects gave written consent for use of the device in their treatment after its purpose was explained.

For the purposes of the evaluation, the period of treatment with the device was defined as a maximum of 12 weeks, but no fewer than eight treatments. Before commencing the treatment an assessment was carried out. The patient's current health status was updated, including wound measurements and photos.

A quality of life tool was administered using the Cardiff Quality of Life questionnaire (Herman et al, 2011). It is recognised that wounds impact the individual beyond the physical. The questionnaire focuses on the physical, social and psychological impact of the wound, thus the impact upon social life, sleep patterns and mental state can be highlighted. This short questionnaire that provides a numerical score — the lower the score, the better the quality of life.

Pain was recorded using the Wong Baker scale, which is a numerical scale with a pictorial tool that is especially useful for those with English as a second language. Ankle range of motion (plantarflexion and dorsiflexion) was measured using a goniometer and a Timed Up and Go (TUG) mobility test was administered (Podsiadlo and Richardson, 1991; Barry et al, 2014; Rosenblum and Papamichael, 2016).

At each appointment, pain was recorded, and wound measurements and photos were taken;

Box 1. Inclusion criteria.

Inclusion criteria:

- Individuals with chronic static leg ulcer wounds that are difficult to heal.
- Associated underlying venous disease/functional venous disease and mixed aetiology.
- Little or no improvement in the 3 weeks prior to their assessment.
- Have been treated previously for at least 2 months with standard care, including any appropriate systemic and local treatments.
- Able to understand and give consent to using the device.
- Individual able to commit to attending clinic for the treatment for a period of up to 12 weeks.

Exclusion criteria:

- Implanted electronic devices such as pacemakers.
- Malignancy.

these were stored on the BRH-A2. The TUG was repeated monthly. Each of these measures were repeated and recorded at the last treatment.

The BRH-A2 device was applied twice a week during each dressing change for 12 weeks or until the wound healed. Four electrodes were placed around the wound and ultrasound was applied simultaneously with the electrostimulation for 13 minutes. The current applied is interferential, meaning a lower voltage can be used to produce a therapeutic effect.

Findings

These were challenging static wounds, but all responded to the treatment, with three wounds healed, six reducing in size, and one nearly healed. Results across all of the measured outcomes were generally consistent.

The status of the wounds were recorded in the patients' notes and all of the wounds became wetter than before commencing the BRH. However, there was a visible improvement in the peri-wound skin condition and the scar tissue that was laid down appeared to be of good quality [Figure 2].

Ankle range of motion is routinely collected in our clinic. Movement at the ankle is a strong indicator of the ability to heal wounds of the lower limb (Araki et al, 1994; Back et al, 1995; Orsted et al, 2001). Plantarflexion (pointing the foot) reflects the ability of the calf muscle to contract and thus engage the calf pump and achieve normal stride length. At 12 weeks, the majority of the patients had improved their range of motion. This corresponded with an improvement in TUG measurements [Figure 3]. Improvement in mobility corresponded with wound improvement.

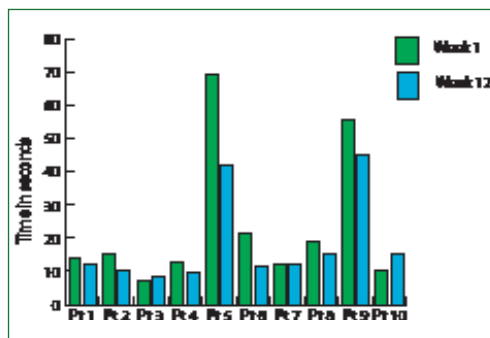


Figure 3. Mobility score at week 1 and 12 using the Timed Up and Go.

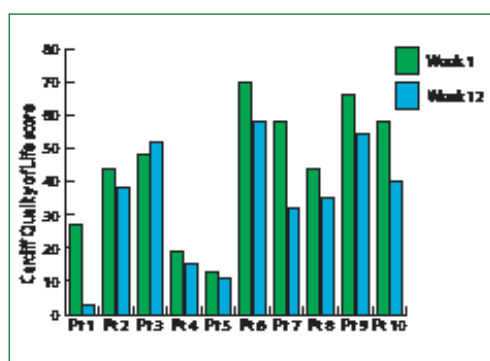


Figure 4. Cardiff Quality of Life questionnaire results at week 0 and 12. The lower the number, the better the quality of life.

One individual with a long history of intermittent claudication reported being able to walk to the shops without his normal rest periods for calf pain.

The Cardiff Quality of Life questionnaire was administered at the beginning and end of treatment. Patients were not shown their initial answers before repeating it. The results are shown in Figure 3. All but patient 4 improved.

The patients' verbal feedback was positive and the process of having the device applied was well tolerated. Discomfort was checked at each treatment, but patients reported nothing more than slight tingling. They were advised to let the clinician know if it became uncomfortable. Patients were consistent in describing that their leg felt "lighter", "less tight" and "relaxed like having a massage". All patients reported a reduction in pain levels and an increased ease in walking and being able to walk further with greater ease and significantly less pain [Figure 5].

Patient 4 was an outlier in his TUG and quality of life measurements. However, discussion revealed that this was not related to his wound, but changes in his personal life.

The only adverse reactions experienced by participants were two episodes of acute pain, which resolved of its own accord within 48 hours.

Working with the BRH-A2

The clinicians noted that when measuring wounds with the device's built-in camera there was no facility to measure more than one wound within a single photo. This has since been resolved. The device has since been upgraded so that this is now possible. Occasionally the device would turn off as it seemed to lose conduction. This seemed to be related to a build-up of waxy keratin on the patient's skin and could frequently be resolved with the use of a Debrisoft pad to exfoliate the surrounding skin.

Measurements presented by the device were confusing, indicating the wounds were static or larger, when visually it was obvious that the wounds were smaller. All issues related to the use of the BRH-A2 were fed back to the company. In the case of the photos and measurement, this led to upgrades in the device.

Discussion

Quantitative data in the evaluation of wounds has been an aspiration for many clinicians for decades. Having a device that is easy to use with retrievable data that includes measurement and outcomes is important. However, measurements presented by the BRH-A2 device were confusing, showing wounds as static or larger when visually it was obvious that the wounds were smaller. We endeavoured to be consistent by having one person doing the measurements, but this had little effect on the results. While this was frustrating the obvious improvements to the wounds and patients negated its impact.

Once practitioners became comfortable with the device, the treatment was straightforward to apply. One leg could be bandaged while the other was being treated. The use of the device did extend appointment time, which presents a challenge in a busy clinic.

The group of patients on which this device was trialled truly represented the terms chronic and complex. Their complex wounds combined with

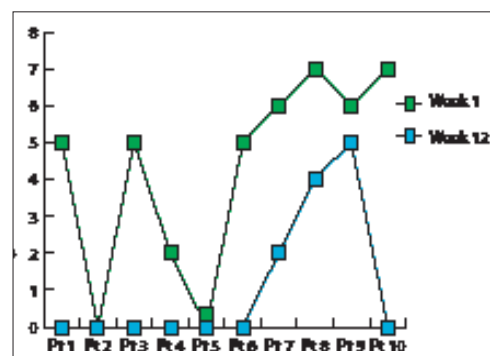


Figure 5. Pain levels at assessment and final treatment using the Wong Baker scale.

their comorbidities makes it unlikely they would ever be included in a randomised controlled trial. Arguably data from randomised controlled trials does not represent real world situations and this could compromise their clinical usefulness.

The wounds being treated in this study appear to be of a longer duration and more chronic than those reported in pilot studies carried out in Israel and the US (Avrahami et al, 2015; Rosenblum and Papamichael, 2016). Time to healing is a desired outcome measure, but it must be related to a number of variables such as fixed ankle, size of wound and mixed wound aetiology.

The chronicity of the wound and the number of factors impacting upon the delayed healing need to be considered alongside wound duration. Realistic expectation of wound healing time has to be considered. Thus a wound that has been present for 30 years with accompanying complexities will need to be considered within a realistic time frame to healing. When care is being carried out in a community environment, this allows patient lifestyle and choices to impact on how wounds heal; these cannot be controlled in the same way as a patient who is in hospital.

Conclusion

This device consistently presented improvement across the group in pain, mobility, QoL and healing. However, the added cost and time cannot be ignored. The benefits of this device must be evaluated against the cost of ongoing treatment for non-healing wounds. The next step would be a sound evaluation of the health economics of using this device.

While there are many clinical guidelines, robust evaluation of the long-term economic value of this device is currently lacking, although a health economics study is under way (Carter, 2014). More work needs to be done around the cost:benefit ratio in the context of value-based care, but clinically the use of biophysical devices such as the BRH-A2 seem to represent a light in a very dark tunnel.

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