

Innovative Medical Technology Overview

Accel-Heal[®] for the management of non-healing venous leg ulcers



The technology

Accel-Heal[®] is a non-sterile, single-use micro-current stimulation device intended to reduce inflammation, pain and exudate, and stimulate healing in wounds that are not progressing satisfactorily. Accel-Heal[®] is a small (7cm x 4cm x 2cm), disposable class IIA portable device that consists of electrode pads and six 48-hour, single-use, electrical energy units - applied consecutively to the pads to provide 12 days of treatment^{1, 2}. The device delivers a targeted, sub-sensory and precise dose of pulsed electrical energy through the electrode pads, which are applied to healthy skin on either side of the wound edge. The electrical energy aims to modify specific functions in the dermal tissue to improve and accelerate healing. The one-off treatment does not heal the leg ulcer during the 12-day treatment period but may initiate the wound healing physiological process.

The device is manufactured by Synapse Electroceutical Limited. The manufacturer notes that the mode of action, dosage delivered and low level of electrical energy differentiate it from other traditional electrical stimulation therapy (EST)^{1, 3}. Contraindications include use of the device in pregnancy and active cancer, near the chest for patients with pacemakers and near the head for patients with epilepsy. Adequate care is needed to ensure the device does not become wet. The device also needs to be removed prior to electrical investigations like magnetic resonance imaging, electroencephalograms and echocardiograms¹.

Patient group

Accel-Heal® is an adjunct treatment for managing patients with non-healing venous leg ulcers (VLUs) and those who are unable to use standard treatment. A VLU is an open skin lesion that usually occurs on the medial side of the lower leg between the ankle and the knee as a result of chronic venous insufficiency and ambulatory venous hypertension and that shows little progress towards healing within 4–6 weeks of initial occurrence⁴. VLUs account for up to 80% of leg ulcers⁵. Symptoms include swelling, itching and pain in the affected leg⁶.

The precise prevalence of VLU in the United Kingdom (UK) is currently unclear. The estimated UK prevalence of VLUs varies between 0.1% and 1.1%^{5,7}. Age is a major risk factor. Other risk factors include: history of deep vein thrombosis, paralysis, obesity, leg injury and osteoarthritis⁶. VLUs are usually associated with long and frequent clinical appointments, consultations and hospital admissions^{2,3} due to considerable morbidity and impaired quality of life⁵. VLUs have a high reoccurrence rate (between 26% and 69%), unless the underlying cause is addressed^{5,6}.

Current practice: comparators and use in pathway of care

The gold standard treatment for VLUs involves the use of high graduated compression (stockings, bandages or garments) to improve blood flow in the legs. However, standard wound management is not always effective. Some wounds may heal after longer periods, while a few may never heal. Furthermore, due to pain, persistent infections and lifestyle choices, some patients are not able to use compression therapy¹.

Accel-Heal® is designed to be used as an adjunct to standard treatment. The device is worn continuously over the fixed 12-day treatment period while continuing standard wound therapy, as appropriate. The device does not heal the wound during the 12-day period but initiates the wound healing physiological process. The following scenarios have been proposed for the use of Accel-Heal® in VLU management:

1. Failure of the wound to reduce in size by 20–30% in 4-6 weeks despite following best practice including compression therapy.
2. Intolerance of any, or high, compression therapy due to the presence of pain.
3. Compression therapy is tolerated but the patient has a recurrent ulcer, co-morbidities such as diabetes or a previous history of hard-to-heal ulcers.
4. Pain is unmanaged despite compression therapy

Product performance: published data

Seven studies^{1-3, 8-11} investigating the clinical effectiveness and safety of Accel-Heal® were identified. Of these, one was a randomised controlled trial (RCT)¹⁰, three were observational studies^{3, 8, 11} and three were case studies^{1, 2, 9}. Aside the RCT, which was adequately powered to detect significant differences in healing rates between the treatment and control groups, none of the other studies included a control or comparator. Participants acted as their own control and the effect of the device was assessed by comparing the outcomes before and after treatment. All the studies were UK-based and the majority were sponsored by the manufacturer of the device. Where reported, patients recruited in the studies were managed by tissue viability specialists.

In the placebo-controlled, double-blind, multi-centre RCT¹⁰, patients aged ≥18 years were randomised (1:1) to receive either Accel-Heal[®] or an identical-looking placebo device over 12 consecutive days and followed up for 24 weeks. The treatment was carried out alongside standard care, which varied across different sites. After 24 weeks, results showed that 34% and 30% of VLU had healed, with a mean healing time (MHT) of 2.6 and 3.5 months in the treatment and control groups, respectively. The area of healing in the treatment group was almost double that observed in the control group (mean: 13.3 cm² vs 7.7 cm² per VLU). The duration of the wounds that healed in the treatment group was double the duration of wounds in the control group (mean: 2.6 vs 1.2 years per VLU). The treatment group also reported greater overall wellbeing or satisfaction, more social functioning and less pain compared with the control group. None of the findings demonstrated statistically significant differences between treatment groups.

Product performance: local data

Two evaluations, involving small numbers of patients, have been carried out in two NHS boards in NHSScotland (NHS Greater Glasgow & Clyde (GG&C) and NHS Borders).

The evaluation in NHS GG&C included 10 patients, each with a non-healing VLU. Nine patients experienced pain at baseline, with 80% having a pain score >5 on the visual analogue score (VAS) scale. The mean wound size (MWS) was 7.3 cm², the mean number of dressing changes was 2.8 per week and 30% of the wounds had moderate exudate. The results of the evaluation showed that six wounds healed within 12 weeks, increasing to nine healed wounds at 20 weeks. The wound with the largest (24.5 cm²) and longest duration (28 years) healed within 20 weeks. The pain score reduced by a mean of 49% (mean VAS score 3.7) after two weeks and a mean of 92% (mean VAS score 0.6) after 12 weeks. Of the 10 wounds, only one had moderate exudate at two weeks and no wounds had exudate at 20 weeks. There was a 50% and 93% reduction in dressing changes and nursing visits at eight and 20 weeks respectively. The study also reported positive feedback from patients and clinicians.

The evaluation in NHS Borders included 12 patients with 14 non-healing VLUs. At baseline, the duration of wounds ranged from three to 12 months, and five were older than six months. The mean VAS pain score was 3.14 (37% of the wounds had a pain score of 10), the MWS was 7 cm², and 43% had moderate exudate and 57% light exudate. The mean number of dressing changes was 1.4 weekly (range: 1–2 times weekly) before treatment: two wounds needed to be dressed twice weekly and 12 wounds required weekly dressings. The study is still ongoing. Early results report that 29% and 71% of the wounds healed at 12 and 20 weeks, respectively. At 20 weeks, the MWS reduced by 87%, while the mean pain VAS score reduced by 64% (1.14), 92% (0.6) and 95% (0.14) within four weeks, 12 weeks and 20 weeks respectively. Three wounds (21%) had moderate exudate at four weeks and no wound had moderate exudate at 20 weeks. The dressing changes and nursing visits reduced by 39% and 78% at 8 weeks and 20 weeks respectively.

Patient and clinician views

Evidence relating to the experience of using Accel-Heal® is also limited. None of the studies that reported on the experience of patients and clinicians after using the device noted if validated assessment tools were used. The treatment was generally easy to use and well tolerated by the patients. One patient had a negative experience during treatment and the study reported that it could have been due to lifestyle choices and age. One study³ examining clinician experience reported a 100% clinician satisfaction with regards to the ease of application and results derived after using the treatment.

Economic and cost considerations

The management of VLU poses a considerable cost to the National Health Service (NHS). In 2001, the Scottish Intercollegiate Guidelines Network (SIGN) estimated the cost of treating one ulcer to be between £1,298 and £1,526 per year⁵. A more recent study estimated the average cost associated with treating a non-healing VLU as £1,727 per patient per year¹².

Three cost-effectiveness analyses (CEA)^{10, 11, 13} comparing EST with Accel-Heal® for the treatment of non-healing VLUs and two service evaluations investigating the costs of EST in two NHS England catchment areas were identified. The health economic evidence was based on low quality clinical evidence (for example, pre and post study design, and small sample sizes), but suggests that Accel-Heal® could be a cost-effective treatment; improving the quality of life of patients, and having the potential to realise savings through a reduction in dressings and nurse visits and improve patient quality of life.

One of the economic analysis was conducted on the back of a placebo-controlled RCT¹⁰ and indicated Accel-Heal® to be associated with faster wound healing and a lower cost per patient at 24 weeks (-£191pp). The additional cost of the device (+£240pp) was offset by fewer nurse visits (-£309), compression (-£121), hospitalisation (-£39) and dressings (-£20) although cost of clinician visits was higher in the Accel-Heal® group (+£66). The study concluded that at 24 weeks, Accel-Heal® is cost-effective at a threshold of £20,000 per quality-adjusted life year (QALY) gained. These results are based on a non-significant difference in healing rates, EQ-5D scores, and resource use and hence are subject to uncertainty. A probabilistic sensitivity analysis showed Accel-Heal® to have a high probability of being cost-effective at commonly accepted cost-effectiveness thresholds. The study was confounded by unwarranted variation in patient management.

Safety issues

Accel-Heal® is CE marked and included on the Scottish Drug Tariff. Evidence relating to the safety of Accel-Heal® is very limited. The RCT¹⁰ highlighted a number of adverse events associated with the treatment, including infection, wound deterioration, skin rash and pain. The manufacturer report that, including the adverse events highlighted by the RCT, there have been seven minor adverse events and no serious adverse events associated with the device since 2008. The minor adverse events include skin damage due to electrode pad or wires, and pain and rash under pads.

Conclusions

Overall, the evidence identified suggest that Accel-Heal® may be an effective adjunct treatment for managing patients with non-healing VLUs and those who are unable to use standard treatment. There were improvements in the number of healed VLUs, mean healing times, exudate, pain scores and area of healing observed due to the treatment group.

Although the improvement in healing outcomes is encouraging, it should be noted that the evidence was mainly from studies of low quality with relatively small sample sizes that were not adequately powered to detect statistical significance. The only RCT identified did not find any statistically significant difference in clinical and patients' outcomes between the treatment and control groups. The results of two small, local evaluations in NHS GG&C and NHS Borders suggest that Accel-Heal® is associated with improved wound healing and a reduction in pain for individuals with non-healing VLUs.

The health economic evidence, although based on limited and generally low quality clinical evidence, suggests that Accel-Heal® could be a cost-effective treatment with the potential to realise savings through a reduction in dressings and nurse visits and improve patient quality of life.

Large, well-designed randomised controlled trials assessing relevant clinical, safety, cost and patient outcomes for longer periods are needed.

References

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What is an Innovative Medical Technology Overview (IMTO)?

An IMTO is a high-level, light-touch summary of the evidence surrounding an innovative technology. An IMTO seeks to offer an early indication of the strengths and weaknesses of the technology, with a view to contributing to local decision-making by NHS health professionals, managers and procurement colleagues.

IMTOs are not peer reviewed and do not contain recommendations. IMTOs should be considered alongside existing guidance applicable to NHSScotland.

All new and innovative technologies need to have been registered on the NHSScotland Health Innovation Assessment Portal (HIAP).