

The results of a clinical evaluation of Accel-Heal[®] electroceutical treatment in a large NHS Trust

KEY WORDS

- ▶ Wounds
- ▶ Electroceutical treatment
- ▶ Accel-Heal[®]
- ▶ Clinical outcomes
- ▶ Economic benefit

The cost of leg ulcers in the UK was estimated to be £1.94 billion (Guest et al, 2016). Leg ulcers are a common ailment that have a negative impact on patients' quality of life, often resulting in lengthy healthcare professional consultations, out-patient appointments and hospital admissions. An evaluation was undertaken to establish the clinical outcomes and experiences for patients and healthcare professionals of using an electroceutical treatment in the community setting. The treatment had a significant effect on the patient group with all patients experiencing either complete healing and/or reduction in wound size, pain and exudate as well as decreased nursing visits. This in turn had a positive effect on patients' quality of life and demonstrated a cost improvement for the Trust.

The cost of chronic wounds in the UK has recently been estimated to be between £4.5–5.2 billion annually, including comorbidities (Guest et al, 2015a), with leg ulcers alone costing £1.94 billion (Guest et al, 2017a). Reported healing rates for wounds and venous leg ulcers (VLUs) has been poor (Guest et al 2015a; Guest et al, 2017a) despite national guidance. Management of VLUs includes compression therapy and/or varicose vein surgery to treat the underlying pathophysiology. The mean year-on-year cost of managing a patient with an unhealed leg ulcer is £5,890 compared to a one-off mean cost of £1,684 for managing a patient with a leg ulcer that heals (Guest et al, 2017a). With an ageing population and poor healing rates, the numbers of chronic and unspecified wounds will continue to increase at an estimated 13% per year (Guest et al, 2017b) and will have a significant impact on clinical commissioning groups/health boards in the UK.

The impact for patients living with chronic wounds is huge with many suffering social isolation; sleep deprivation, anxiety and depression (Herber et al, 2007). To demonstrate efficiencies and improve clinical outcomes for patients, the number of non healing wounds needs to be reduced (Guest et al, 2017b). A new framework aligned with the NHS Five Year Forward Plan (NHS, 2015; 2016) builds on the Compassion in practice strategy (Department of Health [DH], 2012), focusing on 'better outcomes,

better experience and better use of resources'. The NHS RightCare programme reference includes long-term condition scenarios to compare a sub-optimal, but typical scenario against an ideal pathway. One such scenario involves the story of 'Betty' who develops a chronic VLU and demonstrates the difference both to improved quality of life and economic improvements for the NHS by ensuring the optimal pathway is followed. The NHS 5-year forward plan (NHS, 2015) supports using innovative technologies across the healthcare system. Using electroceutical treatment (Accel-Heal[®]) for the management of hard-to-heal wounds can improve outcomes for patients and reduce costs (Griffin, 2013; Greaves, 2014; Guest et al, 2015b), and is a simple innovative treatment in line with the NHS' forward view.

ELECTROCEUTICAL TREATMENT.

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) which is important for tissue

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Table 1. Wound aetiology (n=9)

Wound type	Number (percent)
VLU	16 (84%)
Mixed aetiology leg ulcer	1 (5%)
Post-operative	2 (11%)

Table 2. Wound size and pain score prior to treatment

Mean size in cm ² with (range)	Mean pain score (VAS) with (range)
12.1 cm ² (0.2–78 cm ²)	6.9 (1–10)

Table 3. Duration of wound prior to treatment (n=19)

	<3 months	<4–6 months	7–9 months	10–12 months	Over 12 months
VLU	2	6	2	2	4
Mixed aetiology leg ulcer	–	1	–	–	–
Post-operative	–	1	–	–	1

Table 4. Exudate levels prior to treatment (n=19)

	Light	Moderate	Heavy
VLU	3	11	2
Mixed aetiology leg ulcer	–	1	–
Post-operative	2	–	–

Table 5. Wound Healing at 20 weeks (n=19)

Wound type	Healed	Increased	Remained same	Reduced in size
VLU (n=16)	13	–	–	3
Mixed aetiology leg ulcer (n=1)	1	–	–	–
Post-operative (pilonidal sinus) (n=1)	1	–	–	–
Post-operative (Achilles repair site) (n=1)	1	–	–	–

repair to stimulate cell proliferation and collagen synthesis (Kambouris et al, 2014). However, 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, the current of injury becomes disrupted (Meng et al, 2011). Chronic wounds have been shown to lack electrical energy (Kloth and McCulloch, 1996).

Electroceutical treatment is the use of specifically targeted, sub-sensory level of electrical energy, which cause a physiological change to amend the impaired current of injury in the wound. Accel-Heal® is a small disposable class IIa portable medical device that delivers a precise dosage of electroceutical treatment through the skin surface by applying two electrodes to healthy skin either side of the wound edge, which can be left *in-situ* between dressing change. The small unit is attached to the electrode pads and the treatment is worn continuously for a 12-day period during which time standard wound therapy including compression bandages are continued and applied as appropriate. It is a one-off 12-day treatment and is available on prescription in the UK. The treatment does not heal the wound within the 12-day treatment period but kickstarts the wound healing physiological process.

AIM

An evaluation using Accel-Heal® was undertaken in a large community NHS Trust, the largest provider of community health and adult social care service within the NHS, which services a population of 1.1 million, of which 19% are aged 65+.

The evaluation was undertaken to establish the clinical outcomes for patients and clinicians' experience of using Accel-Heal® in the community setting. The aims were to determine wound size, pain and exudate reduction in hard-to-heal wounds and demonstrate cost efficiencies within the locality following the treatment. The large community NHS Trust was in the process of developing new pathways for VLU and were, therefore, keen to implement a treatment option to work alongside standard therapy. With the introduction of the Commission for Quality and Innovation (CQUINs) payment for wound wound assessment" (NHS England 2016). The aim was to identify treatment options to improve quicker healing rates to meet their targets and improve quality

of life for patients. Ease of use for clinicians was also a key factor to reduce time for application and enable fast adoption of the pathway with minimal training.

METHOD

Study sample

Seventeen patients were selected with history of non-progressing wounds despite best practice including compression therapy as appropriate. Fourteen patients were attending the specialist wound care clinics and three patients had been seen by the tissue viability nurses in the community and provided consent to participate. Exclusion criteria included patients with active cancer and pregnancy. Seventeen patients with 19 wounds were included in the study (*Table 1*). 84% ($n=16$) wounds were VLU, 1 wound was a mixed aetiology leg ulcer and 2 wounds were post-operative wounds including an Achilles tendon repair and a pilonidal sinus. 47% patients were male. Mean age was 66 years (range 16 – 90 years).

Prior to treatment with Accel-Heal® (*Tables 2, 3 and 4*):

- » Mean duration of the wounds was 29 weeks (range 10 weeks – 7years)
- » In total, 74% of patients had pain, with 13 (68%) having a pain score ≥ 5 and 3 (16%) having a pain score of 10 with a mean pain score of 6.9 on the visual analogue score (VAS). Pain causes distress, anxiety, sleeplessness and depression for the patient and has a significant cost burden.
- » Mean wound size was 12.1 cm² (range 0.2 cm – 78 cm²).
- » 11% patients experienced heavy wound exudate and 64% patients medium wound exudate, which was measured by the attending clinicians according to the amount of dressing changes and strike through present. Medium/heavy exudate requires increased nursing vigilance and dressings to prevent maceration, peri-wound excoriation, infection and further wound breakdown. Extra resources are required to increase nurse visits and dressing changes.

TREATMENT AND DATA COLLECTION

The treatment with Accel-Heal® continued for 12 days and standard therapy continued throughout and following the treatment. Data was collected as they attended the clinic or were seen in their

homes for wound treatment up to 20 weeks post treatment or until complete healing. Healing was defined as complete closure with no exudate. This included factors such as duration, wound size, pain scores, exudate levels and patient experience. Data was collected every 2 to 4 weeks. Ease of use by the clinician was also recorded. Data was analysed by the authors.

RESULTS/CLINICAL OUTCOMES

Wound size reduction and healing

Within the 20 week period following treatment, 84% of all wounds healed and 100% of all wounds <1 year old prior to treatment healed. 3 wounds (VLUs) present for over 12 months did not heal but these reduced in size by a mean of 37.3%. One VLU present for 7 years prior to treatment reduced in size by 98%. For all wounds there was a mean wound size reduction of 73% with a mean wound size of 3.27 cm square at the end of the study period. The mean healing time was 7.5 weeks and 15 wounds (94%) healed ≤ 12 weeks (*Table 5, Figure 1 and 2*).

Pain reduction

Within 2 weeks of commencing the treatment, the mean pain score was reduced to 0.9.

At 10 weeks post treatment, 18 (95%) patients' wounds had no pain and one patient had their pain score reduced from 5 to 3 on the VAS scale. At 20 weeks the mean pain score was 0.3. One patient discontinued their Gabapentin and one patient discontinued their morphine medication due to pain reduction. Reduction in pain improves quality of life for patients and can improve their general mobility and well-being. *Figures 2 and 3* demonstrating reduction in pain level over the 20-week period for the healed and un-healed wounds.

Reduction in exudate

Within 2 weeks of commencing treatment no patients had heavy exudate and only 32% patients had moderate exudate. At the end of the study period 16% patients had moderate exudate (*Figures 2 and 4*). A reduction in exudate reduces dressings and/or nurse visits and therefore reduces costs to the NHS and improves patients' quality of life.

Economic benefits

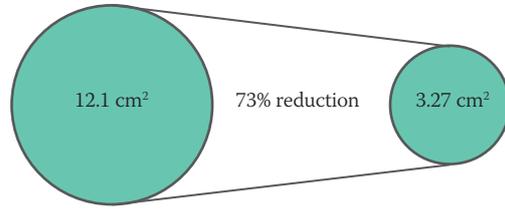


Figure 1. Mean wound size reduction for all wounds (n=19)

With financial constraints within the NHS it is vital to consider not only the clinical outcomes but also the financial impact of treatments/ interventions. Accel-Heal® is currently available on the drug tariff at a cost of £240.00 and is a one-off treatment. A business case for the use of Accel-Heal® in the Partnership Trust is being developed. This will demonstrate the potential savings of using the treatment alongside standard care as opposed to leaving patients on standard care alone.

Leg ulcers are typically treated in the community with 66% of the total annual NHS cost of managing chronic wounds incurred in the community with the remainder being incurred in secondary care (Guest et al, 2015a) Of the costs incurred in the community, some 36% relates to nurse visits and GP visits; an equivalent cost relates to drug prescriptions and some 27% relates to wound care products including dressings and negative pressure devices (Guest et al, 2017b). Secondary care admissions for acute episodes such as infection,

cellulitis, and amputations also contribute to a significant cost for this patient group.

During this evaluation, data was also collected on dressing usage and nurse visits.

The dressings spend on wound care products was analysed on the 17 patients (19 wounds). Calculating the primary/secondary dressing and compression therapy, the patient was being treated with when commencing Accel-Heal®, a cost per dressing change was established. As they were all non-healing wounds the assumption was taken that they would have continued with the same or similar treatment over the 20-week period. The costs were also calculated on the assumption that because all the wounds had been previously non healing, despite following best practice, and the average wound duration was 12 months, they would likely to have continued without healing/improving during the 20-week period. The cost of dressings for 19 wounds over the 20-week period would have been £11,499 if the patients had continued on standard care alone. During the 20-week evaluation period, the cost for dressings, compression and Accel-Heal® was £7,535. Accel-Heal® treatment affording a saving of £3,964 (average £233 per patient) over the 20-week period on wound care dressings and bandages (Figure 5) compared to leaving the patients on standard care alone.

The same methodology was used to determine the impact on nursing time based on the number of visits at commencement of treatment and the

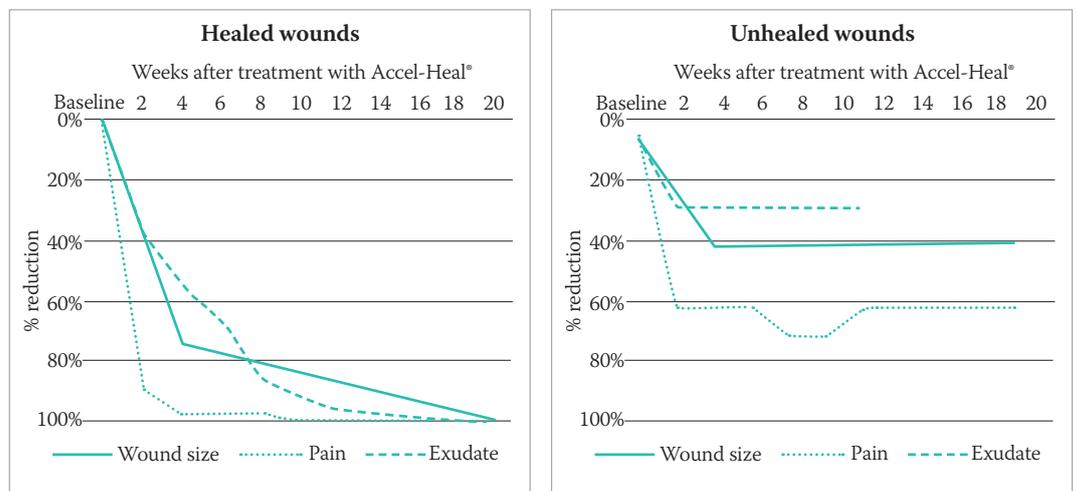


Figure 2. Healing time, pain and exudate reduction for healed (n=16) and un-healed wounds (n=3)

Figure 3. Mean pain score (VAS) reduction, at start of Accel-Heal® and at week 2

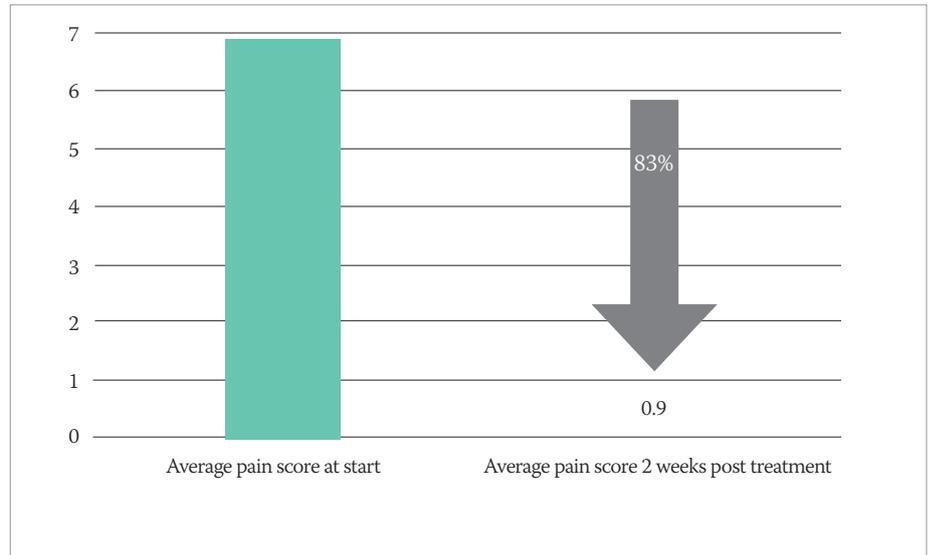
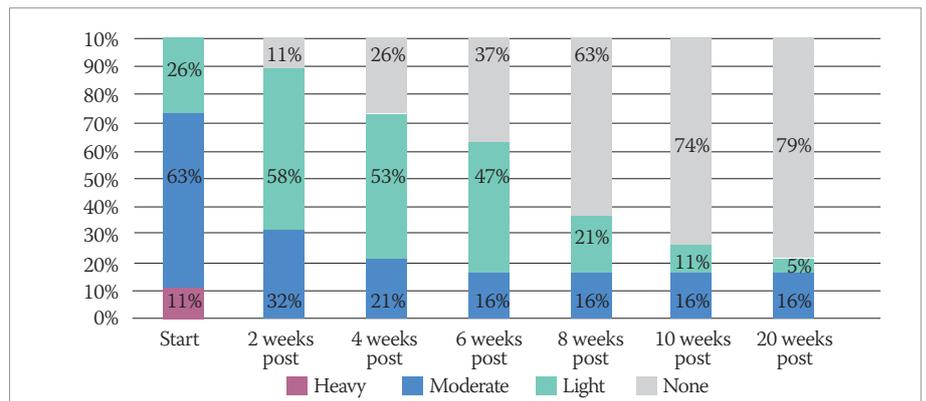


Figure 4. Exudate reduction over a 20-week period with Accel-Heal®



reduction throughout the 20-week period with Accel-Heal®. The total number of visits required without having the Accel-Heal® treatment over the 20 weeks would have been 1,280. With Accel-Heal® the number of District Nurse (DN) contacts reduced to 338, representing a reduction in DN contacts of 942 (74%) (Figure 6). The visits per patient over the 20-week period reduced from an average of 71 to 17 per patient with the Accel-Heal® intervention. Using data from the NHS reference costs (DH, 2016) the average cost for a face-to-face contact in district nursing services for 2014/2015 was estimated to be £38. Using this figure the estimated cost of the prevented 942 visits would be £35,796.

Combining the expenditure of dressings, bandages and nursing time, it is estimated that the 19 wounds would have cost the Partnership Trust

£60,140 (£3,165 per wound) to manage for a 20-week period without the Accel-Heal® intervention. The introduction of Accel-Heal® reduced this cost to £20,380 (£1,073 per wound), representing a saving of £39,760 (66%) over the 20-week period (Figure 7). Cost reductions would continue after the 20-week period for this cohort of patients due to the 84% healed wounds (no further cost) and the 16% un-healed wounds which had reduced in size. In addition, a significant reduction in secondary care costs and drug prescriptions is expected.

With a population of 1.1 million within the Partnership Trust and aligning this to the national leg ulcer prevalence and healing rates (Guest et al, 2015a; Guest, 2017a), there is a potential cohort suitable for this treatment plan of 3,260 patients for the trust. If results from the evaluation were to be replicated for these patients, a potential saving

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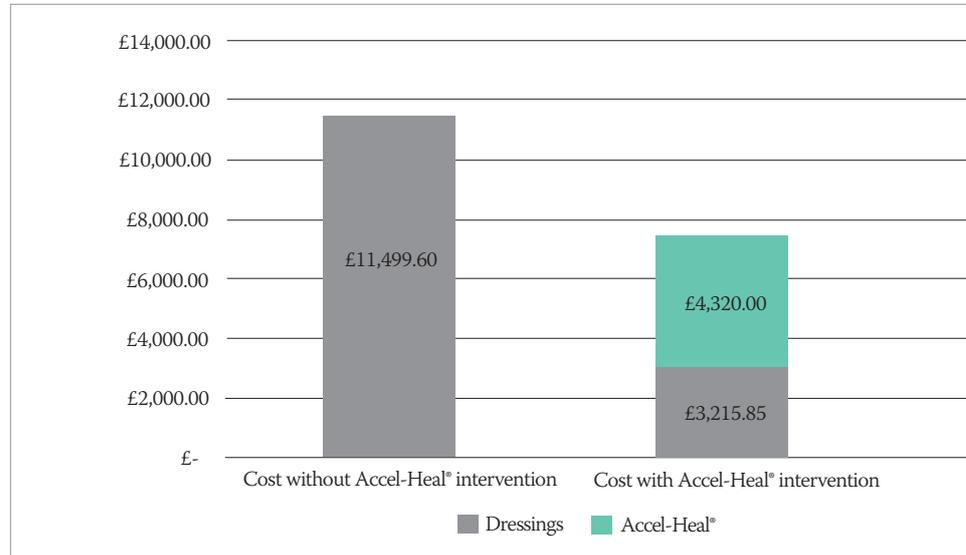


Figure 5. Cost of dressings with/without Accel-Heal® Intervention for 20-week period

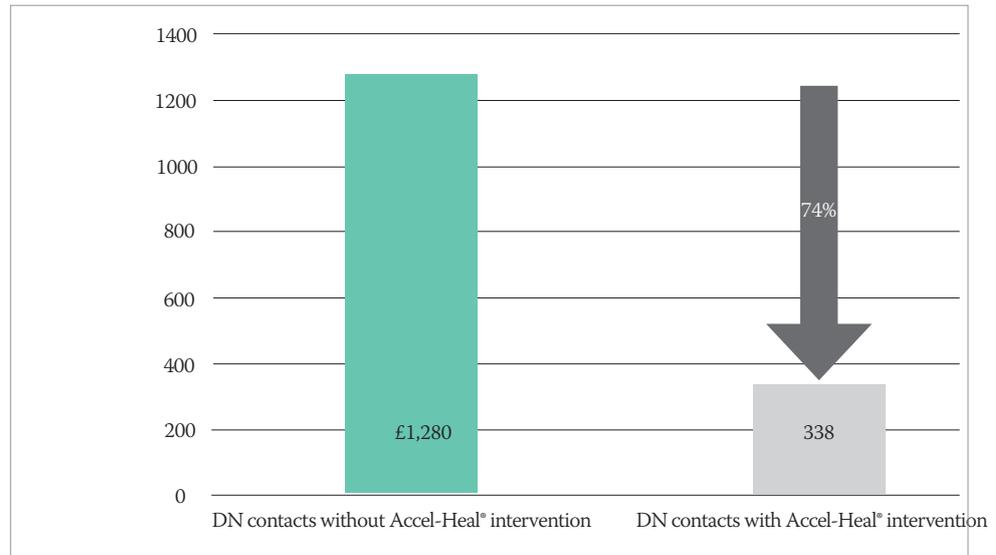


Figure 6. Number of DN contacts with/without Accel-Heal® Intervention for 20-week period

of £ £759,580 on dressings alone, and £6,689,520 on district nursing clinic visits could be afforded, totaling a potential saving of £7,449,100 before secondary care costs and drug prescriptions are factored in.

EASE OF APPLICATION BY CLINICIAN AND PATIENT COMMENTS

Patient satisfaction

Only 1 patient with the pilonidal sinus expressed

some interference whilst having the treatment and this was likely to be due to his age and lifestyle choices. All other patients experienced positive experience whilst using the treatment. No untoward events were reported.

Clinician experience

All clinicians using the treatment expressed 100% satisfaction with using the treatment regarding the ease of application and results.

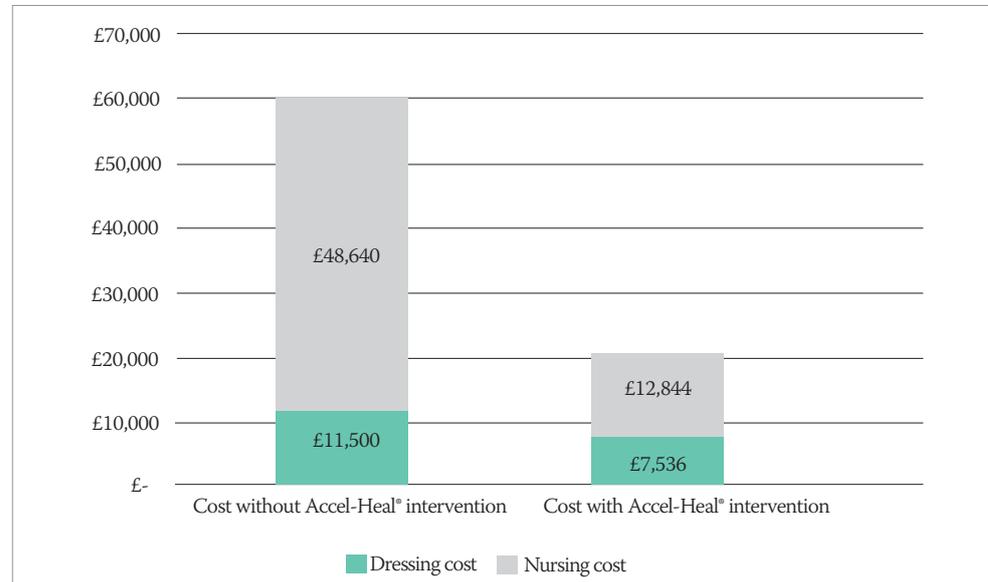


Figure 7. Cost including dressings and nursing time of 20-week period with/without Accel-Heal[®] intervention

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Application to clinical practice

The treatment had a significant effect on the patient group with all patients experiencing either complete healing or reduction in wound size, pain and exudate and decreased nursing visits. This had a positive effect on patients' quality of life and demonstrated a cost improvement for the Partnership Trust. The business case is being put forward with a view to incorporating Accel-Heal[®] as part of the Leg Ulcer specialist pathway. The Tissue Viability Team propose that at the 8 week assessment all wounds which have not progressed as expected within the pathway guidance will be commenced on Accel-Heal[®] and continue to be reassessed 4 weekly.

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CONCLUSION

Using Accel-Heal[®] can improve clinical outcomes for patients when used as an adjunct to standard therapy and can significantly reduce the cost of managing patients with wounds. The results are similar to previous studies using Accel-Heal[®] (Guest et al, 2015b). Improved outcomes allow clinicians more time and resources to care for other patients with long-term conditions. Development of a pathway to be incorporated into Trusts' formularies and guidelines provides clinicians with the appropriate tool to ensure the right care is given at the right time (NHS, 2016), with treatments being patient focused, accessible and easy to use.



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