Application of Accel-Heal® for patients with chronic venous leg ulcers: an evaluation in a community UK NHS trust

KEY WORDS
- Clinical outcomes
- Clinical pathway
- Exudate
- Electroceutical therapy
- Pain
- Venous leg ulcers

Venous leg ulcers (VLUs) place a significant economic burden on the NHS and have a significant effect on patients' quality of life. The cost of managing a VLU was recently estimated to be a mean of £13,455 per annum (Guest et al, 2018). An evaluation was undertaken in a community NHS trust to determine the clinical outcomes, including healing time and symptom reduction, in eight patients with non-healing VLUs despite following best practice including compression therapy, using a single-use electroceutical therapy device. Clinician feedback was also considered. The patients experienced a significant improvement in all aspects, resulting in fewer dressings and less nursing time. Development of a pathway for using electroceutical therapy for the management of VLUs ensures the right treatment is given at the right time to reduce pain and improve healing for patients and reduce costs to the NHS.

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Venous leg ulcers (VLUs) have a significant impact on patient's quality of life (Hareendran et al, 2005; Green and Jester, 2010) and are a major cause of morbidity, posing significant economic pressures to the NHS (Guest et al, 2018; 2017b).

It has been estimated that the UK NHS manages a total of 2.2 million wounds in a single year, a number equivalent to 4.5% of the adult population (Guest et al 2015a). A third (33%) of all wounds are leg ulcers of one kind or another, comprising either venous insufficiency (13%), arterial insufficiency (<1%), mixed (1%) and an additional 19% of unspecified leg ulcers, many of which may be undiagnosed VLUs (Guest et al, 2015a). The estimated mean cost of managing an unhealed VLU in the UK is estimated to be £13,455 per annum compared to the cost of managing a healed VLU costing £2,981 per annum (Guest et al, 2018). The costs are likely to increase year on year with an ageing population (Guest, 2017b).

The treatment of VLUs includes compression therapy, lifestyle changes and surgery, if appropriate, and requires long-term management. Patients often experience ulcer recurrence, pain, social isolation, anxiety and reduced mobility (Herber et al, 2007); and clinical outcomes for these patients are often poor (Guest et al, 2012) even in cases where best practice is followed.

In order to reduce the prevalence of VLUs and suffering caused for patients, the number of non-healing wounds must be reduced (Guest et al, 2017b). Several national frameworks have been initiated to improve efficiencies and outcomes for patients including:

- Improving the assessment of wounds CQUIN (NHS, 2016a)
- The NHS Five Year forward plan (NHS, 2015)
- Leading change, adding value (NHS, 2016b)
- Getting It Right First Time (GIRFT) (NHS, 2017)
- The development of a National Wound Care Strategy/Programme, which views lower leg management as a priority area (Adderley, 2018).

These initiatives can be instrumental in ensuring that nurses can achieve the appropriate care for patients using innovative technologies and developing care pathways to improve quality of life for patients.

ELECTROCEUTICAL THERAPY

An innovative treatment using electroceutical therapy (Accel-Heal) is available in the UK for the management of hard-to-heal wounds including VLUs. Electrical stimulation and electroceuticals have been available in wound management for many years in various formats and applications and have demonstrated positive outcomes in reducing inflammation, pain and exudate and healing of wounds (Tradej et al, 2010; Herberger et al, 2012; Thakral et al, 2013; Griffin, 2013; Guest et al, 2015b; Turner and Ovens, 2017; Turner and Ovens, 2018).

Far from being a sideshow or a curiosity, electric fields are established as part of the fundamental mechanisms of cell and tissue growth and control. Epithelial tissues, such as skin or cornea, generate a voltage between upper and lower layers through the action of ion pumps asymmetrically distributed within the cells. Tight junctions and gap junctions respectively insulate or transmit current flow. Wounding an epithelial layer produces the so-called "current of injury", a direct current with -ve polarity in the wound and +ve in the uninjured skin (Reid and Zhao, 2014). In in vitro scratch assays, corneal epithelial cells can be made to migrate towards the negative electrode to either close or open the wound. Evidence generated over the last decade shows that electrical stimulation operates through the same signal transduction systems as cytokines or growth factors (Zhao et al, 2006; Martin-Granados and McCaig, 2014). Electric fields are detected during development of embryos where they appear to regulate pattern of cell movement in development (McCaig et al, 2005).

A randomised gene expression analysis was recently carried out at the University of Manchester on healthy skin in 12 volunteers using active and placebo Accel-Heal devices. Genes that are usually increased during wound healing: S100A7, S100A8 and S100A9, were downregulated in the skin of the healthy volunteers by Accel-Heal but not where the volunteers were wearing the placebo devices providing evidence that the Accel-Heal device causes some specific responses in skin (Lallyett et al, 2018).

THE TREATMENT

Accel-Heal is a one-off 12-day therapy, which delivers a precise, specifically targeted, sub-sensory level of electroceutical energy to the wound. It is a small portable class IIa medical device, which delivers the electroceutical therapy through two electrode pads placed either side of the wound edges. The electrode pads can be left in situ in-between dressing changes for up to a week. The pads are attached to a small unit, which is worn continuously over the 12-day period whilst standard care continues. Reduced pain and exudate is typically noted in the wound (Ovens, 2014; Griffin, 2013; Turner and Ovens, 2017) during and immediately following the treatment and wound healing is kick-started into a normal physiological process whilst standard care continues. The reduction in pain was also shown to improve compliance to compression therapy in patients initially unable to tolerate it. Accel-Heal is available for clinical prescribing in UK at a cost of £240.

AIM

An evaluation was undertaken in a UK NHS community health provider, which serves a population of 730,000.

The aims were to determine the clinical outcomes and clinician feedback of using Accel-Heal electroceutical therapy for the management of complex wounds. The aim was to measure healing rates, wound size reduction, pain reduction, exudate reduction and reduced nursing time and dressings for patients with non-healing wounds, despite following best practice including compression therapy as appropriate.

METHOD

Study population

Eight patients were selected with a history of non-progressing wounds despite following best practice. All patients were having compression therapy. Patients were seen by the district nurse, practice nurse or tissue viability nurse in wound clinics, GP surgeries and/or their own home in the community and provided consent to participate. Exclusion criteria included patients with active cancer and pregnancy. Eight patients, each of whom had eight VLUs were included in the study. 50% patients were male. Mean age was 73 years (range 57–90 years).

Prior to Accel-Heal electroceutical therapy:

- Mean wound size was 13.3 cm^2 (range 0.8 cm^2 – 24.8 cm^2)
- 38% patients had pain with a mean pain score of 4.3 (range 3–5) on the visual analogue score (VAS). Pain reduces quality of life for patients and

Table 1. Wound size and pain score prior to treatment (n=8)	
Mean size in cm² with (range)	**Mean pain score (VAS) with (range)**
13.3 cm square (0.8 – 24.8 cm²)	4.3 (3–5)

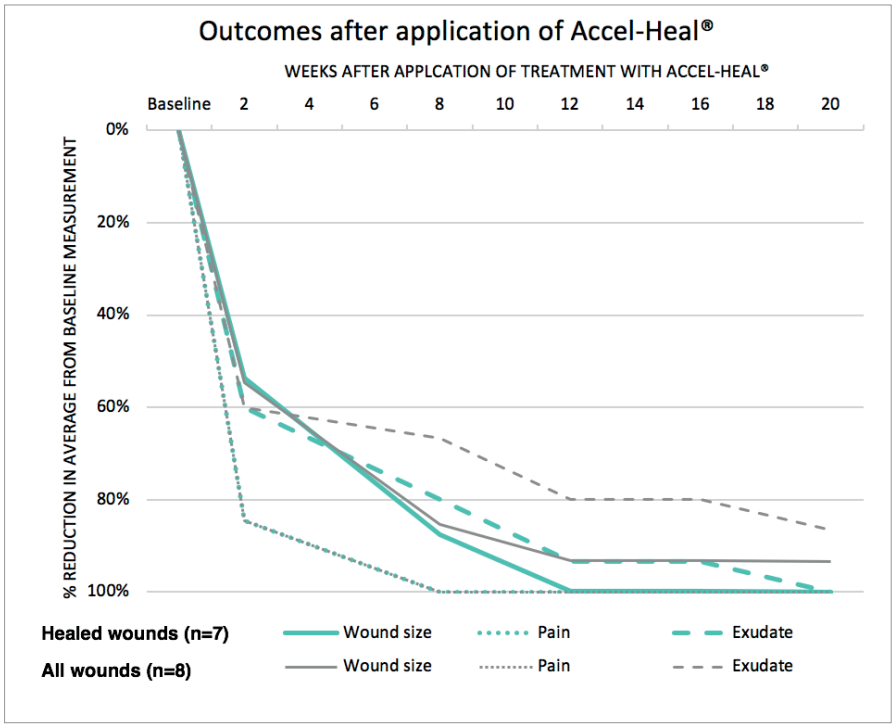
Table 2. Exudate levels prior to treatment (n=8)				
	None	**Light**	**Moderate**	**Heavy**
VLU	1	1	4	2

Table 3. Duration of wound prior to treatment (n=8)			
	<3 months	**4–6 months**	**Over 12 months**
VLU	1	3	4

accounts for increased spend for the NHS (Guest et al, 2018) *(Table 1)*

- 50% patients had moderate exudate and 25% had heavy exudate. This was measured by clinicians according to the amount of strike through of exudate and the amount of dressings required *(Table 2)*
- Duration of wounds: One patient 0–3 months, three patients 4–6 months and four patients >12 months (range 0–36 months) *(Table 3)*
- The mean number of dressing changes was 1.9 weekly (range 1–4 times weekly). 50% patients were having twice weekly dressing changes, 38% were having weekly dressing changes and one patient (13%) was having four times weekly dressings.

Figure 1. Outcomes after application of Accel-Heal



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 epithelial tissue with no exudate. This included factors such as, wound size, duration, pain scores, exudate levels and number of dressing changes per week. Data was collected every 2 to 4 weeks. Ease of use by the clinician was also recorded. Data was analysed by the author.

RESULTS/CLINICAL OUTCOMES

Pain reduction

The first and highly significant outcome of the therapy is typically a marked reduction in pain; often experienced within hours of application of the treatment and possibly as a result of the impact the treatment has on inflammation. A prolonged inflammatory response results in spontaneous pain and an increase in wound sensitivity. Pain often dominates the patients' lives and limits their functioning. In this evaluation, the three patients experiencing pain at the start quickly reported pain reduction. Within 2 weeks of commencing Accel-Heal therapy, the pain score was reduced by 84% with a mean pain score 0.7 on the VAS scale *(Figure 1)*. Eight weeks following application of the treatment no patients had pain.

Figure 2. Patient B wound at start of treatment on 26/10/17

Figure 3. Patient B wound at the end of treatment on 07/11/17

Exudate reduction

Within 2 weeks of commencing Accel-Heal therapy, no patients had heavy exudate, one patient (13%) had moderate exudate and 50% (n=4) had light exudate. The patient who failed to heal had moderate exudate at the end of the 20-week period *(Figure 1)*.

Wound size reduction and healing

At the end of the 20-week period, 88% (n=7) wounds healed and 100% of all wounds < 12 months old prior to treatment healed. 12 weeks following the therapy, 75% of all wounds had healed. The mean healing time was 10 weeks (range 2 weeks–20 weeks). There was a 93% reduction in size for all wounds at 12 weeks and 20 weeks, resulting in a mean wound size of 0.9 square centimeters *(Figure 1)*.

A 75-year-old male (Patient B) had his VLU for 15 months and was under the care of the vascular team who had tried several different modalities of treatment without any improvement. The patient had Parkinson's disease, which significantly reduced his mobility. Prior to Accel-Heal therapy, the wound was malodourous with 95% slough requiring dressing changes 3–4 times weekly *(Figure 2)*. Following the 12-day therapy, the wound had 100% granulation with no odour and dressings were reduced to twice weekly *(Figure 3)*. The wound completely healed within 12 weeks.

The one wound that failed to heal had been present for 16 months. The patient was under the care of the vascular team and surgery was not indicated. The wound had been static for several months and improved initially following treatment but a second wound developed close by, resulting in an overall increase in size of the wound.

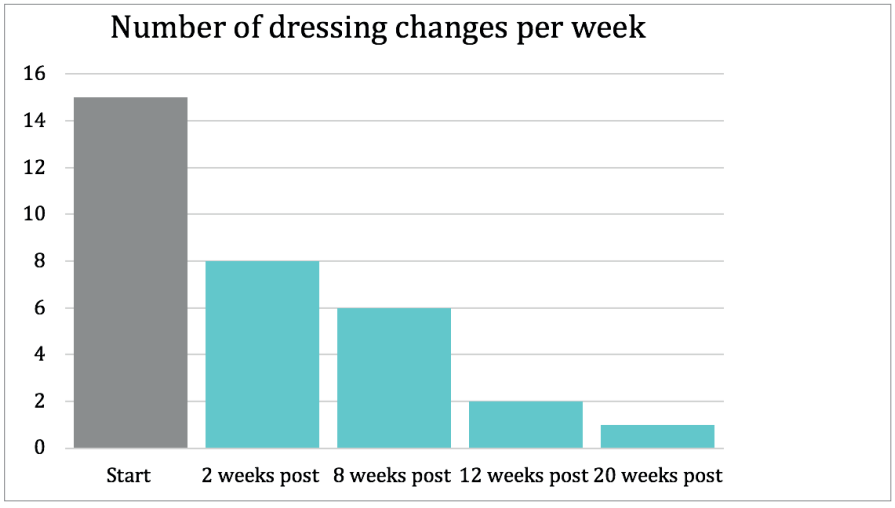


Figure 4. Reduction in dressing changes over the 20 week period following application of Accel-Heal

Reduction in dressings changes

- After 2 weeks, one (13%) wound had healed and the number of dressing changes had dropped by 47% to an average of 1 per week.
- After 12 weeks 6 (75%) wounds had healed and the number of dressing changes had dropped by 87% to an average of 0.3 per week.
- At 20 weeks 7 (88%) wounds healed and the number of dressing changes had dropped by 93% to an average of 0.1 per week *(Figure 4)*

Patient B who had been having four times weekly dressing changes, had their visits reduced to twice weekly within 2 weeks of commencing treatment and reduced to weekly within 8 weeks of treatment. The patient healed within 12 weeks.

Cost improvements using ACCEL-HEAL

A reduction in dressing changes and healing of wounds results in cost savings for dressings, bandages, nursing time, analgesia, antibiotics, possible hospital admissions and appointments. Applying the annual cost of an unhealed VLU of £13,455 (Guest et al, 2018) and extrapolating it over the longevity of wounds in this evaluation, the estimated cost of managing the 8 VLUs prior to treatment with Accel-Heal was approximately £111,002.

Following the therapy, 75% wounds had healed within 12 weeks and 88% of wounds healed within 20 weeks. Only one patient remained unhealed with an estimated on-going mean cost of £13,455 per annum. The seven healed wounds had previously been non-progressing and, therefore, would have resulted in an on-going cost to the NHS Trust of up to £94,185 per annum.

The savings are a combination of real cash savings and efficiency gains. Real cash savings result from significantly lower dressing costs, significantly lower agency and bank nursing costs and significantly lower cost of analgesia. As a result of the reduction in a nurses' caseload *(Figure 5)*, significant efficiency gains are generated, which enables nurses to provide

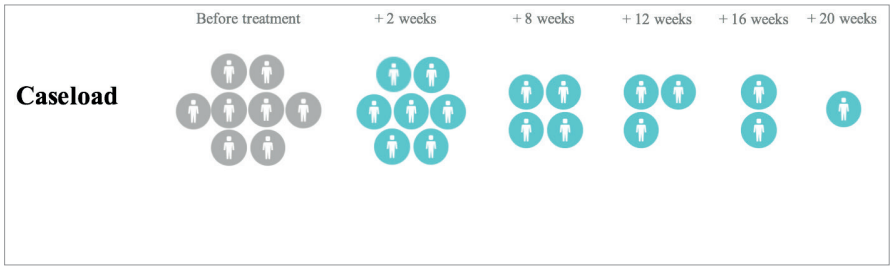


Figure 5. Reduction in caseload

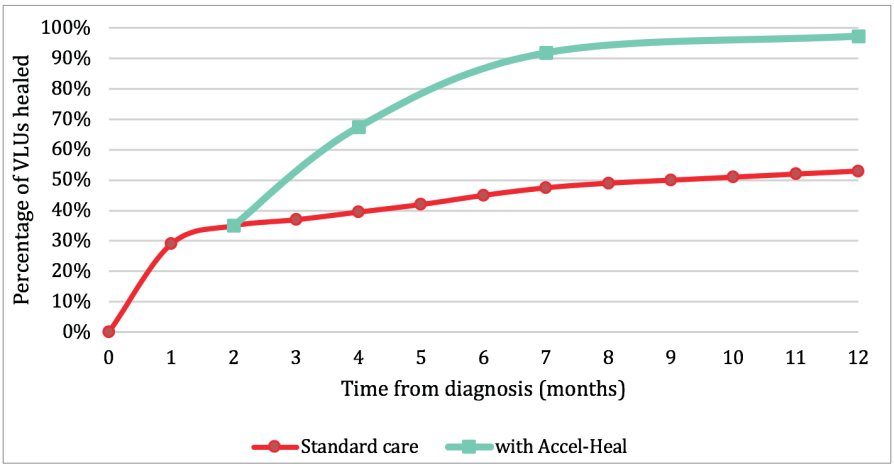


Figure 6. Improvement in healing by adding Accel-Heal therapy to VLUs not progressing satisfactorily at 8 weeks

more focused care to all patients. A positive feedback loop is created with patients, which empowers nurses, reduces stress and reduces sick time.

It is estimated that incorporating Accel-Heal therapy into a care pathway for VLUs that were not progressing satisfactorily at 8 weeks would increase the percentage of wounds healing within 12 months from 53% (Guest et al, 2018) to 97% *(Figure 6)*.

CLINICIAN FEEDBACK

Clinicians provided feedback regarding the ease of application and comments from patients. The treatment was noted to be easy to apply *(Box 1)*.

Adverse events

Only one very mild adverse event was reported when a patient developed slight maceration under the pads. However, this patient healed within 20 weeks. Occasionally the exudate can increase during the first few days of applying the treatment and therefore increased dressing changes and/or absorbent pads may be required to prevent any maceration occurring.

Box 1. Comments provided by the healthcare professionals using Accel-Heal

- *"No complaints"*
- *"Patient reported it was comfortable and easy to change battery"*
- *"At start wound had strong odour — this cleared up after 2 weeks and was able to see grandchild with no odour. Dressings down from 3-4 dressings per week to 2 per week by day 12. This product is amazing. This product has worked so well on a patient with comorbidities"*
- *"Very comfortable + pt. (patient) very happy. Improvement noted on every change until healed. Pt remains healed post 6 weeks now. Pt has never fully healed before this device he is now healed. Ongoing 3 years. Improvement noted on 1st change".*
- *"This product was applied with ease. Simple for patients to change at home. Only problem for this patient is that the pa mascerated (sic) the skin beneath it, wounds are all healed now"*
- *Easy for patients to use"*

Application to clinical proactice for management of VLUs

The results of this evaluation are consistent with previous studies (Guest et al, 2015b; Turner and Ovens, 2017). With more focus being targeted on reducing chronic wounds within the NHS to facilitate better outcomes and reduce costs, clinicians can consider alternative approaches to managing VLUs, particularly when healing is halted despite following best practice.

In order to achieve this, pathways can be developed to enable appropriate treatment to be provided at the right time (NHS, 2017). Pathways designed for the management of legs ulcers have demonstrated benefits to patients and clinicians (Atkin and Critchley, 2017; Mullings and Merlin-Manton, 2018).

A suggested pathway for using Accel-Heal has been developed following the development of the new guidelines for management of VLUs (Wounds UK, 2018). The pathway *(Figure 7)* explains the importance of holistic assessment to determine an aetiology, and working in partnership with

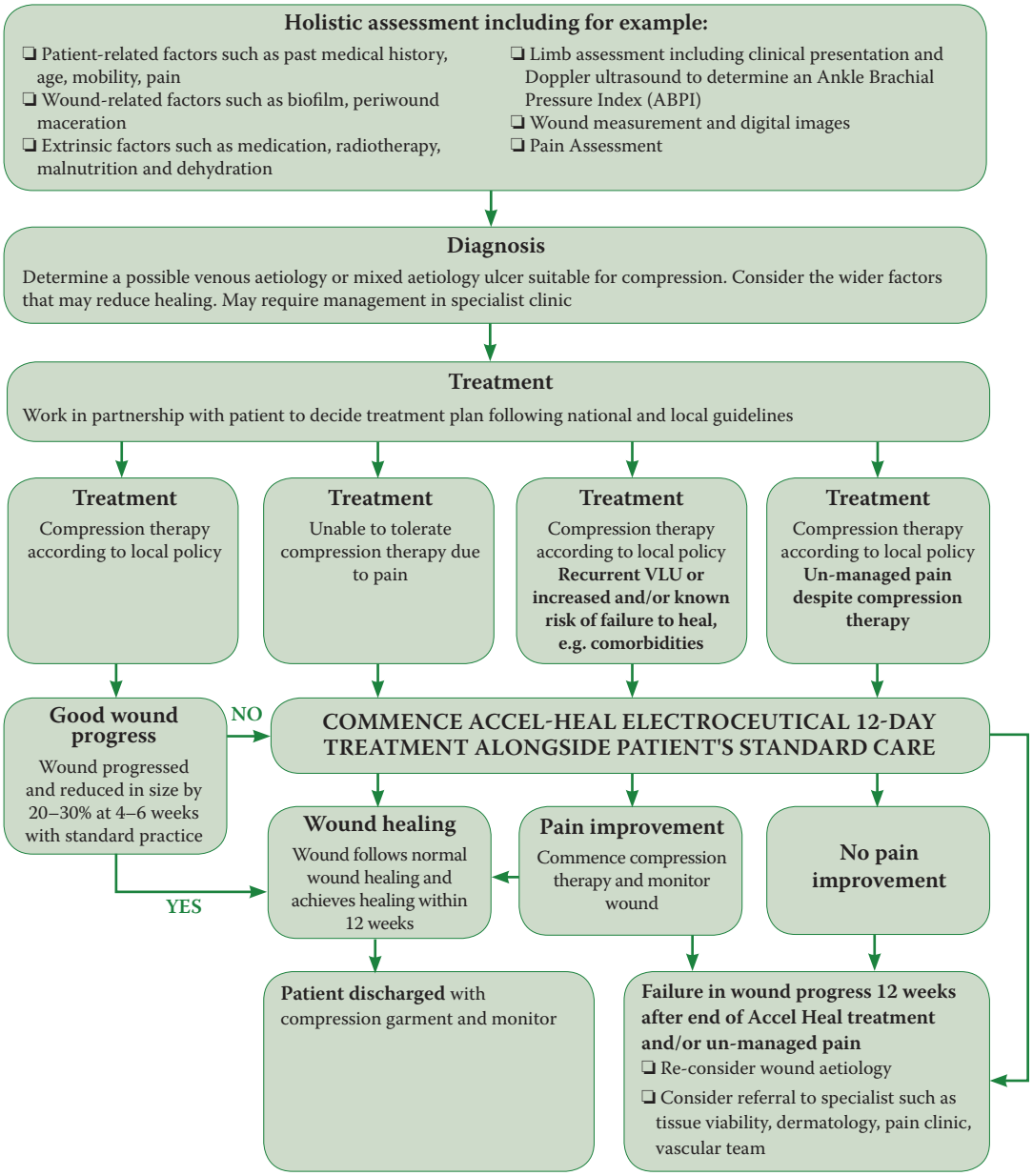


Figure 7. Suggested pathway for using Accel-Heal for the management of VLUs

the patient to decide treatment options following national and local guidelines. The pathway recommends four scenarios to use Accel-Heal in the management of patients with VLUs:

- Failure of the wound to reduce in size by 20-30% in 4-6 weeks (Harding et al, 2015) despite following best practice including compression therapy
- Intolerance of compression therapy due to the presence of pain
- Compression therapy tolerated but the patient has a recurrent ulcer, co-morbidities such as diabetes and/or a previous history of hard-to-heal ulcer/s
- The pain is un-managed despite compression therapy.

CONCLUSION

The treatment with Accel-Heal improved clinical outcomes within 20 weeks for 88% of patients with previous non-progressing wounds. Pain, exudate and dressing changes were notably reduced within 2–4 weeks following the application of treatment.

The results of the evaluation were consistent with previous studies (Guest, 2015b; Turner and Ovens, 2017; Turner and Ovens, 2018). Achieving healing of VLUs can significantly reduce the cost of chronic wounds in the UK. Improved outcomes can be achieved through the development of leg ulcer pathways and considering new innovative approaches to wound management. WUK

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