Reducing the cost burden of Venous Leg Ulcers (VLUs) in the community – A new approach

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- Summary.
A venous leg ulcer (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 (CVI) and ambulatory venous hypertension, and that shows little progress towards healing within 4–6 weeks of initial occurrence.

(Wounds UK 2015)
Simple and complex VLU

A 'Simple' VLU is defined as:-
- ABPI 0.8–1.3
- Area <100cm²
- Present for <6 months

Manage in a primary care/community-based setting - If clinicians not competent in compression therapy and are not available then refer to a specialist service that manages VLUs

A complex VLU is defined as having any one of the following characteristics:-
- ABPI outside of 0.8 – 1.3.
- Wound size ≥100 cm².
- Present for > 6 months.
- Controlled/uncontrolled cardiac failure.
- Current infection and/or history of recurrent infections.
- History of non-concordance with treatment.
- Wound has failed to reduce in size by 20-30% at 4-6 weeks despite best practice.
- Fixed ankle or reduced range of motion.
- Foot deformity.
- Unmanaged pain.
- Refer to specialist service that manages VLUs Depending on local service provision, this may be specialist wound management clinic/service, a community-based service (e.g. Leg Club) or a dermatology, phlebology or vascular service.

(Wounds UK 2015)
Mixed aetiology and other aetiologies leg ulcers

Mixed aetiology ulcer:

- Classified as ‘mixed aetiology’, which is defined as having venous and arterial components. These may include the following characteristics:
  
  - ABPI <0.8 or >1.3 (NB: if ABPI <0.5, no compression should be applied and urgent referral for consideration for revascularisation should be made)
  
  - Symptoms of arterial disease – such as intermittent claudication (muscle pain that is experienced upon exercise and relieved when rested) – even if ABPI is within the normal range.

Other aetiologies include: diabetes/ peripheral neuropathy; rheumatoid arthritis (vasculitic ulcer); autoimmune disease; vasculitis; sickle cell disease; uncontrolled cardiac failure.

- Mixed and other aetiology ulcers may still require management with compression, however, they should be referred to the appropriate specialist for further investigation and care. Further investigations may be required, such as duplex scanning or biopsy.

(Wounds UK 2015)
What is a hard-to-heal wound?

A *hard-to-heal* wound has been described as:

“one that fails to heal with “standard therapy” in an orderly and timely manner”

(Troxler et al 2006)
Contributory factors

- Intrinsic factors of the patient e.g. comorbidities, age, psychological, adverse condition in the wound.

- Extrinsic factors such as medication, malnutrition and dehydration, socio-economic factors, care and support network.

- Poor diagnosis.

- Incorrect application of treatment/poor wound management.

- Lack of funding to enable application of some treatments.

- Non-concordance and lifestyle choices.
Management of wounds following best practice national guidelines and local policy.

- Treat underlying aetiology of the wound e.g. vascular, dermatological, malignancy.
- Manage associated disease, risk factors and symptoms, comorbidities, neuropathy, nutrition and hydration, mobility, psychological, pain, social factors.
- Moist wound healing.
- Advanced therapies e.g. TNP, Larvae, Hyperbaric oxygen, growth hormones.
- Refer to appropriate specialists as indicated.
The prevalence of wounds in UK

- Estimated to be 2.2 million patients with a wound in the UK:
- Study determined 31% wounds had no differential diagnosis.
- Only 16% patients with a leg ulcer had a doppler assessment.
- 39% remained unhealed at end of study year.
- 13% (278,000) of wounds were VLUs but there were 19% (420,000) unspecified ulcers some of which would also be venous in origin.
- 53% of VLUs and 53% of unspecified ulcers remained unhealed at the end of the study year.

(Guest et al 2015a and 2016)
Cost of wounds in the UK

- Cost of managing wounds and associated co-morbidities is £5.3 billion a year.
- Adjustments were made for co-morbidities determining an estimate of between £4.5 to £5.1 billion a year.
- Comparable to managing obesity. Represents 4% of total NHS budget.
- 66% of costs incurred in community. Majority of spend is on healthcare professional time. Wound dressings only account for 14% of total spend.
- Costs of managing leg ulcers is £2.3 billion a year.
- Cost of treating a healed leg ulcer was a mean cost of £1,875.20 per patient.
- Cost of treating an unhealed leg ulcer was a mean cost of £5,601.60 per patient.
- Mean difference of £3,726.40 per patient between treating a healed and a non-healed leg ulcer.
- £580 million spent on wounds that healed and £1.74 billion on wounds not healed.

(Guest et al 2015a and 2016)
Commissioning for Quality and Innovation (CQUIN) targets

- Aim/focus of CQUIN between 2017-2019:-
  - Thorough assessment in order to target treatment effectively.
  - Save time and improve practice in the long term.
  - Improved healing rates will cut the number of patients requiring treatment.

- CQUIN targets are agreed locally between commissioners and providers.

- Financial penalty/reduced income If CQUIN target not met.

- Nurses will need to prove they deliver safe, effective and patient-centred care in line with the CQUIN framework.

- Assessment :- General health including PMH, co-morbidities, nutritional status, age, lifestyle factors, cause of the wound, lower limb assessment, wound assessment.

- Ultimately following 2019 focus will be outcome based to include e.g. wound size reduction and healing, reduction in pain, malodour, exudate levels and improved health improvements such as improved mobility, sleep, psychological factors.
We have the potential to change – with electroceutical treatment

“Supporting innovation across the healthcare system is more important than ever, and will be central to securing transformation and improved patient outcomes. Creating the conditions for more collaborative approaches to innovation, and enabling the fast adoption of cost-effective new technologies will be key”

(NHS England Innovation into Action 2015)
WHY do some wounds not heal despite following national guidelines?

Inflammation and MMP’s in acute and chronic wounds
(Nunan et al 2014)
The current of injury

• Human physiology is electrical in nature.

• The difference in voltage between the surface of the epidermis and the deeper layers creates a stream of current known as the ‘skin battery.’

• When this current is broken, as in injury, the current flows outwards creating a ‘current of injury’ (Kloth 2014).

• The current of injury activates regenerative and immune cells, induces extracellular matrix production and activates specific gene expression important in tissue repair (Kambouris et al 2014).

• Current of injury ceases at epithelialisation (Kambouris et al 2014).

• If healing halts for any other reason, e.g. infection, foreign body in wound etc. then this impacts healing trajectory and disrupts the current of injury (Meng et al 2011).

• Chronic and non-healing wounds have been shown to lack electrical energy (Kloth and McCulloch 1996).
Electrical stimulation and electroceutical treatment

- Electrical stimulation (ES) stimulates cellular physiology and growth by applying low energy electric stimuli, similar to endogenous ones.

- Electrical energy has been used by physicians for years.

- In wound management ES leads to a reduction in inflammation, extra-cellular matrix production, cell proliferation and collagen deposition. *(Thackral 2013, Kloth 2014, Kambouris et al 2014)*. The up-regulation of different cell types and other metabolites results in increased oxygenation levels and membrane permeability and thus facilitating restoration in the tissues.

- Reduced inflammation reduces pain and exudate levels and allows the wound to move into the normal wound healing physiological process.

- ES has been available for wound management for many years but its application has been variable and challenging.

- Electroceutical treatment implies a more accurately targeted clinical application using low level electrical energy with a specific dosage and mode of action.
Accel-Heal® - an innovative treatment for leg ulcers

- Accel-Heal® is an active 12-day electroceutical treatment delivered by a small, disposable medical device.
- A Class IIa medical device delivering a sequence of pre-programmed, low-level and sub-sensory electrical energy through the skin surface.
- The treatment consists of 6 X 48 hour small single use devices.
- Treatment is one-off and designed for ease of application and patient comfort, used alongside standard treatment.
- Does not heal the wound within the 12-day treatment period but kick-starts the physiological wound healing process.
Latest independent Accel-Heal® study

A study was performed to determine the clinical effectiveness of using Accel-Heal® in clinical practice in the UK.

• Prospective, single arm, non blinded study to determine clinical outcomes and economic evaluation of using Accel-Heal® on VLUs.

• Patients sequentially selected by nurses as they visited either community or hospital clinics and gave informed consent to participate. Nurses collected the data as patients attended the clinic.

• Data collected included age, gender, ulcer duration, ulcer size, pain scores, exudate levels, clinician visits and dressings used.

• Data was analysed by health economist to determine the results following treatment and resource use and associated costs were determined 12 months prior to treatment compared to 12 months following treatment.

(Guest et al 2015b)
Patient characteristics

- 30 VLUs in the study - 28 patients with 1 VLU and 1 patient with 2 VLUs were included.
- Mean age of patients was 66 years. 62% male.
- Mean ulcer size per wound of 8.7 cm$^2$ (range 0.5 – 40.0 cm$^2$)
- Mean duration before commencing treatment of 2.2 years with 23% having their wound for ≤ 3 months and 50% present for > 1 year (range 14 days – 21.5 years).
- 3% patients were diabetic.

(Guest et al 2015b)
## Results

Primary outcome was wound closure**

<table>
<thead>
<tr>
<th></th>
<th>Healed</th>
<th>Unhealed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of venous leg ulcers</td>
<td>23 (77%)</td>
<td>7 (23%)</td>
</tr>
<tr>
<td>Average age of ulcer*</td>
<td>1 Year 1 month</td>
<td>5 Years 11 months</td>
</tr>
<tr>
<td>Average size of ulcer*</td>
<td>5.2cm²</td>
<td>20.1cm²</td>
</tr>
<tr>
<td>Wound closure in study period</td>
<td>100%</td>
<td>42%</td>
</tr>
<tr>
<td>Average healing rate</td>
<td>80 days</td>
<td>0</td>
</tr>
<tr>
<td>(after one 12 day treatment of Accel-Heal®)</td>
<td></td>
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It is recommended that Accel-Heal® is used on leg ulcers that have not progressed satisfactorily after 6 weeks of treatment.

* at start of treatment **Data on file
The population of healed ulcers

- Patients typically experience a marked reduction in pain and exudate during the course of the 12 day treatment and total wound healing within 3 months.**

From a baseline - measured at the time Accel-Heal® was applied, on average:

- Pain reduced by 95% after 1 month
- Exudate reduced by 73% after 2 months; and
- Wound size reduced by 72% after 3 months and all wounds healed within 9 months.

**Data on file
The population of un-healed ulcers

- Where ulcers are significantly older and larger, wound healing will typically take longer after one 12-day treatment of Accel-Heal® **

From a baseline - measured at the time Accel-Heal® was applied:
- Pain reduced by 37% after 12 months
- Exudate reduced by 38% after 12 months
- Wound size reduced by 42% after 12 months

**Data on file**
Cost effectiveness of using Accel-Heal®

• Mean annual NHS cost per patient with a VLU (after adjustments for comorbidities)
  • Unhealed = £4472
  • Healed = £788 (Guest et al 2016)

• Cost effectiveness of using the treatment is due to clinical effectiveness i.e. the reduction in the population of VLUs.

• In the study, for the population of ulcers that healed, total costs post application of Accel-Heal® were 35% lower than costs prior to the application of Accel-Heal®.

• Reduction in nurse visits. Using Accel-Heal® is expected to lead to a 34% decrease in number of nurse visits over the first 12 months after start of treatment. (Guest et al 2015b)

• Accel-Heal® is a 12-day, fixed cost treatment that is available for clinical prescribing with a reimbursable cost of £240.
Cost effectiveness cont..

The study concluded:

- Use of Accel-Heal® affords the NHS a cost effective treatment for managing VLU’s compared to leaving patients on their previous care plan i.e. 11% cost reduction in wound management cost.

- All patients demonstrated either complete healing or a reduction in wound size:
  - 100% of VLUs with a duration of ≤ 12 months and 53% with a duration > 12 months healed within the study period.
  - VLU’s with a duration of > 33 months did not heal within the study period.
  - VLU’s with an area of 12 cm² did not heal within the study period.

- Improved symptoms such as reduction in pain and exudate following treatment.

- Expected reduction of 34% in nurse visits over the first 12 months following treatment. *(Guest et al 2015b)*

- Findings comparable to a previous study using an electrical stimulation treatment *(Glegg and Guest 2007).*
Clinical pathway for using Accel-Heal® Electroceutical treatment for the management of venous leg ulcers.

**Holistic assessment including for example:**
- Patient related factors such as past medical history, age, mobility, pain.
- Wound related factors such as biofilm, infection, peri-wound maceration.
- Extrinsic factors such as medication, radiotherapy, malnutrition and dehydration.
- Limb assessment including clinical presentation and Doppler ultrasound to determine an Ankle Brachial Pressure Index (ABPI).
- Wound measurement and digital images.
- Pain assessment.

**Diagnosis**
Determine a possible venous aetiology or mixed aetiology ulcer suitable for compression. Consider the wider factors that may reduce healing. May require management in specialist clinic.¹

**Treatment**
Work in partnership with patient to decide treatment plan following national and local guidelines.

**Treatment**
- Compression therapy according to local policy.
- Unable to tolerate compression therapy due to pain.
- Recurrent VLU or increased and/or known risk of failure to heal e.g. co-morbidities
- Compression therapy according to local policy Un-managed pain despite compression therapy.

**Good wound progress.**
Wound progressed and reduced in size by 20-30% at 4-6 weeks with standard practice.¹

**Wound Healing**
Wound follows normal wound healing trajectory and achieves healing within 12 weeks.

**Patient discharged**
with compression garment and monitor.

**Pain improvement**
Commence compression therapy and monitor wound

**No pain improvement**

**Failure in wound progress 12 weeks after end of Accel Heal® treatment and/or un-managed pain**
- Re-consider wound aetiology
- Consider referral to specialist such as tissue viability, dermatology, pain clinic, vascular team.

References
Contraindications to using electroceutical treatment

Contraindication
• Do not use near head for patients with epilepsy or in close proximity to pacemakers.
• Do not use on patients with active cancers.
• Do not use in pregnancy.

Other considerations
• Exclude other aetiologies for wound e.g. cancer.
• Do not apply electrode pad over broken capillaries or varicose veins or directly over main arteries such as carotid.
• Do not allow any of unit to become wet as with all electrical devices.
• Remove if other electrical devices in use e.g. ECG, EEG, MRI, alarms as may interfere.
Case study 1

- 50 yr. old female with recurrent VLU rt. medial malleolus present for 3 weeks.
- Had several course antibiotics.
- PMH Ca right breast cleared, fracture rt. ankle. Reduced ankle flexion.
- High pain score 10/10.
- Unable to tolerate Doppler. Tri and Bi-phasic sounds.
- Wound measured 7.5 cm² and 0.75 cm deep in one area with 10% slough.
- Dressing regime with anti-microbial cleansers and dressing with support bandage.
Case study 1

- Commenced Accel-Heal® on 15/12/16.

- Aims to reduce inflammation and pain to undertake Doppler and commence high compression therapy.

- Patient taught to change the units and continued with previous dressing regime twice weekly.

- On 20/12/16 (5 days following Accel-Heal®) pain reduced to 3/10 with improved sleeping and tolerated dressing change. Wound 100% granulation.
Case study 1

• On 23/12/16 pain continued to improve and the wound significantly reduced in size.

• 12-day treatment completed on 29/12/16.

• On 09/01/17 Doppler assessment undertaken. Normal ABPI and high compression commenced. Small scabs remaining.
Case study 1 - Healed and discharged 09/02/17
Case study 2

- 65 yr. old male.
- 3rd recurrence VLU left medial malleolus in Oct 2014.
- PMH asthma, hypothyroidism, arthritis left ankle, CKD stage 3, hypertension.
- Present for 7 months despite high compression.
- Pain score 9/10.
- Wound dimensions: 2 cm²
Case study 2

Completion of treatment
5th November 2014

4th December 2014
Case study 2

Healed 12th February 2015 with no recurrence to date.
Summary

• Prevalence and cost of leg ulcers in the UK is huge with health care professional time accounting for majority of the cost.

• Cost of an unhealed wound estimated to be a mean of 135% more than a healed wound.

• Imperative to ensure accurate diagnosis, wound prevention and improved healing in order to improve clinical outcomes and economic benefits.

• Clinical effectiveness from using Accel-Heal® (Guest et al 2015, Ovens 2014, Ovens 2015).

• Cost improvements using Accel-Heal® estimated to be 11% of NHS budget.
  • (Guest et al 2015).

• Reduction in recurrence of VLU’s due to deposition of Type 1 collagen (Ovens 2014).

• Accel-Heal® is easy to use and applied alongside patients’ treatment plan. It is a single use treatment so no on-going costs.

• Earlier treatment intervention increases the probability of healing.
References

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- NHS (2015) Innovation into action. Supporting delivery of the NHS five year forward plan
- Nunan R., Harding KG., Martin P. (2014) Disease models and mechanisms 7, 1205 -1213
Thank you