

Breaking the cycle of hard-to-heal wounds with electroceutical treatment.

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Leg Ulcers: Right Care, Right Time

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Wounds UK

Content

- The impact of Hard-to-heal wounds for patients.
- Electrical stimulation and electroceutical treatment in wounds.
- Evidence for Accel-Heal[®]
- Pathway for using Accel-Heal[®]
- Case series.
- Using Accel-Heal[®] with compression.
- Summary.

The impact of chronic wounds on quality of life for patients

”It was like living with a rat on my leg gnawing away causing pain and eliminating down my leg causing wetness and malodour”

“Absolute hell.. Something eating at my leg and the pain went from my leg up to my head.. Horrible horrible horrible.. Worried about loosing my foot”



Inflammation and MMP's in acute and chronic wounds

(Nunan et al 2014)

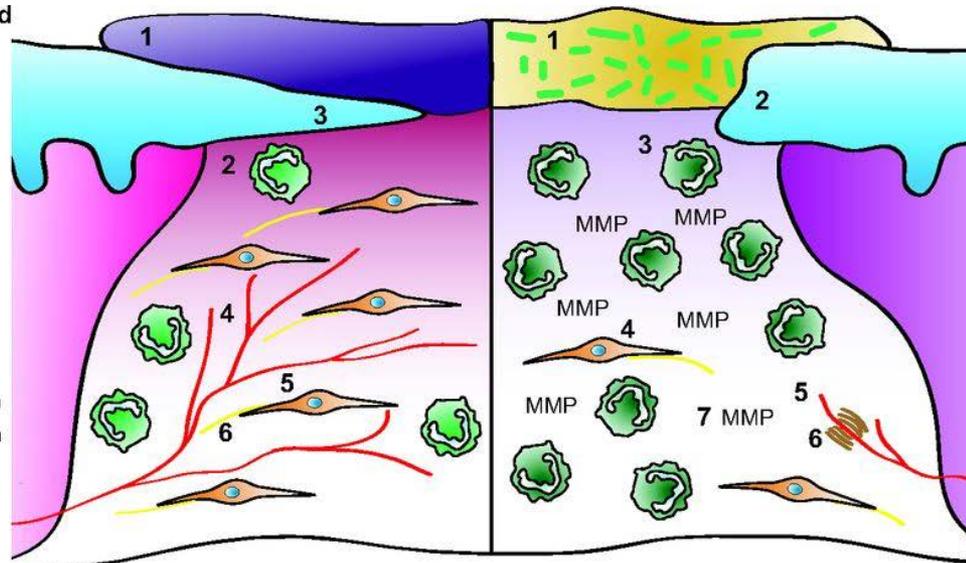
Acute (healing) wound

Initial phase:

1. Scab formation
2. Immune cell infiltration

Healing phase:

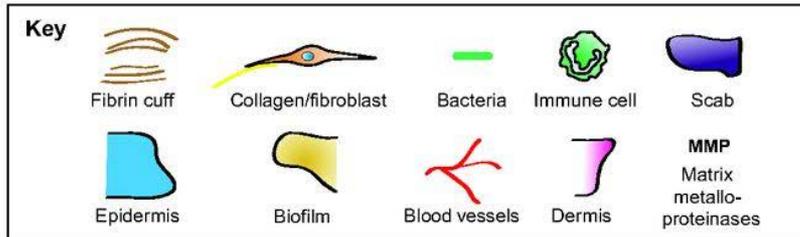
3. Re-epithelialisation
4. Angiogenesis
5. Fibroblast migration
6. Collagen deposition



Chronic (non-healing) wound

Chronic wound abnormalities:

1. Infection/biofilm
2. Hyperproliferative epidermis/ stalled re-epithelialisation
3. Persistent inflammation
4. Fibroblast senescence
5. Impaired angiogenesis
6. Fibrin cuffs (barrier to oxygen)
7. Elevated MMPs



The current of injury

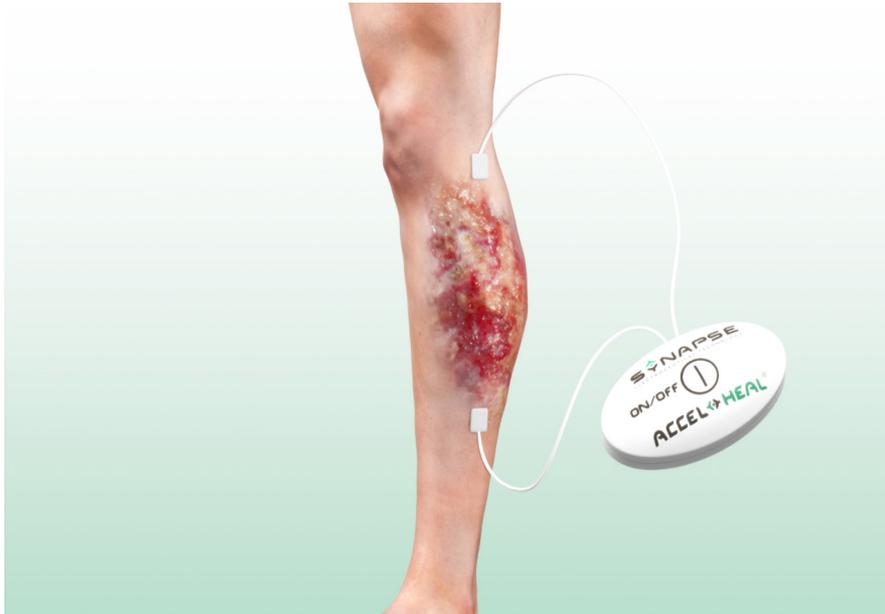
- Human physiology is electrical in nature.
- The difference in voltage between the surface of the epidermis and the deeper layers creates a stream of current known as the 'skin battery.'
- When this current is broken, as in injury, the current flows outwards creating a 'current of injury' (**Kloth 2014**).
- 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.

We have the potential to change.....

with electroceutical treatment



TIME to use innovative technologies for wound management

“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)

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.

Restoring the healing pathway with electroceutical treatment

3 Accel-Heal in Restoring the Healing Pathway



ACCEL+HEAL[®]
a Synapse electroceutical technology

Independent Accel-Heal[®] study

Clinical outcomes and cost 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 VLU's.
- Resource use and associated costs were determined 12 months prior to treatment compared to 12 months following treatment.
- Patients sequentially selected by nurses as they visited either community or hospital clinics and gave informed consent to participate.
- Data collected included age, gender, ulcer duration, ulcer size, pain scores, exudate levels, clinician visits and dressings used.
- Findings consistent with previous independent studies.

(Guest et al 2015)

Patient characteristics

- 30 VLU 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 cm² (range 0.5 – 40.0 cm²)
- 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.

Clinical Outcomes

- 77% of all wounds healed and 23% improved.
- Of 23% un-healed wounds – these reduced in size by 42%
- 100% of wounds with a duration of ≤ 12 months prior to treatment healed.
- 53% of wounds with a duration of > 12 months prior to treatment healed.
- Wounds larger than 12 cm^2 failed to heal.
- Wounds older than 33 months failed to heal.

PRIOR TO TREATMENT

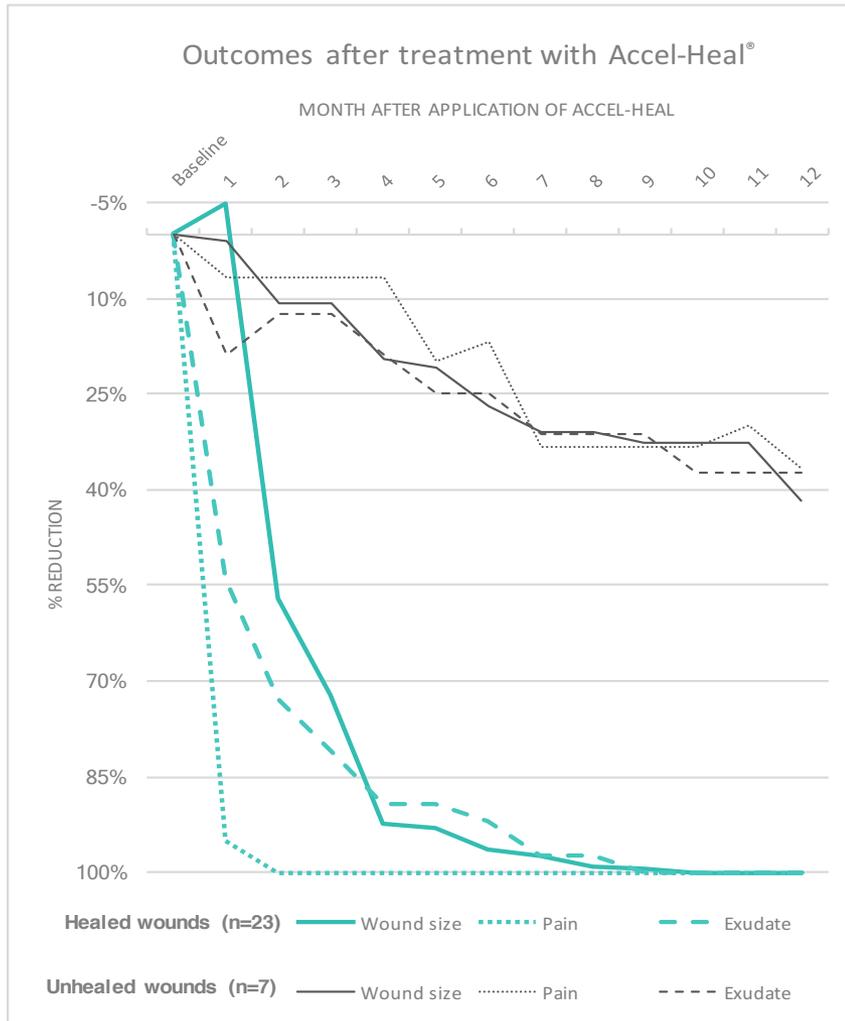
- Mean ulcer size per wound 8.7 cm^2
- Mean pain score 3.6 per patient.
- Exudate levels:-
 - No exudate: 0%
 - Wounds with light exudate: 43%
 - Wounds with medium exudate: 37%
 - Wounds with heavy exudate: 20%

AT 12 MONTHS AFTER TREATMENT

- Mean ulcer size per wound 2.7 cm^2
- Mean pain score 0.63 per patient
- Exudate levels:-
 - No exudate: 77%
 - Wounds with light exudate: 13%
 - Wounds with medium exudate: 10%
 - Wounds with heavy exudate: 0%

(Guest et al 2015)

Analysis



The underlying data for healed wounds and unhealed wounds is analysed opposite. For healed wounds:

- 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.

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 2015)

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

Conclusion of study

Delegates are encouraged to read the publication in full. The study concluded:

- Use of Accel-Heal® affords the NHS a dominant cost effective treatment for managing VLU's compared to leaving patients on their previous care plan.
- 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 cm^2 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
- 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.

Treatment
Unable to tolerate compression therapy due to pain.

Treatment
Compression therapy according to local policy.
Recurrent VLU or increased and/or known risk of failure to heal e.g. co-morbidities

Treatment
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

No

COMMENCE ACCEL-HEAL ELECTROCEUTICAL 12-DAY TREATMENT ALONGSIDE PATIENT'S STANDARD CARE.

Yes

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

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.

Patient discharged with compression garment and monitor.

References

¹ Harding K, Dowsett C, Ejes L et al (2015) Simplifying venous leg ulcer management. Consensus recommendation. Wounds International.

Latest evaluation of Accel-Heal® (awaiting publication)

- Evaluation undertaken in Staffordshire and Stoke-on Trent partnership Trust (SSOTP) using Accel-Heal® treatment.
- Consent obtained. Exclusion criteria included patients with active cancer and pregnancy. Inclusion criteria included patients with non-healing wounds despite best practice.
- Patients were selected by the wound clinic district nurses and tissue viability team.
- Data collection included age, gender, wound duration, ulcer size, pain scores, exudate levels, clinician visits and dressings used, patient and clinician feedback for a 20-week period.
- Resource use and associated costs were determined during the 20-week period.
- Data collected included age, gender, ulcer duration, ulcer size, pain scores, exudate levels, clinician visits and dressings used.
- Findings consistent with previous studies (Guest et al 2015).

Patient characteristics

- 17 patients with 19 failing to heal wounds were included.
- Mean age 66 years (range 16-90 years). 47% male.
- Wound aetiology included:
 - Venous leg ulcers (VLUs) = 16
 - Arterial ulcers = 1
 - Post operative wounds = 2
- Mean wound size per wound of 12.1 cm² (range 0.2 – 78 cm²)
- Mean duration before commencing treatment of 29 weeks (range 10 weeks to 7 years)
- 74% patients had pain. 68% with a pain score ≥ 5 . Mean pain score 6.9
- 11% wounds had heavy exudate and 64% medium exudate.

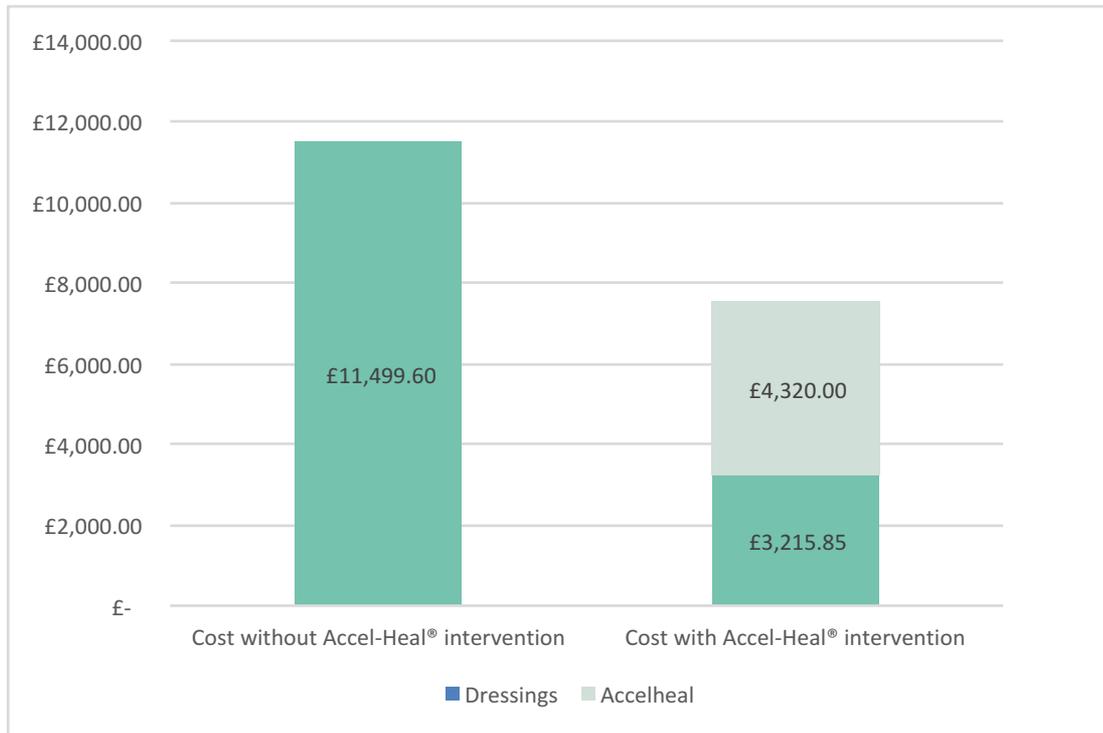
Patient characteristics

- **Wound healing and wound size reduction**
 - 84% all wounds healed within 20 weeks.
 - Mean wound size reduction for all wounds of 73%.
 - 100% of all wounds <12 months healed.
 - Mean healing time was 7.5 weeks and 94% healed \leq 12 weeks.
 - 2 patients with 3 wounds (VLUs) > 12 months did not heal. 1 patient presenting a VLU for > 7 years reduced in size by 98%. 1 patient presenting 2 VLUs and treated with 2 Accel-Heal treatments failed to heal. Mean size reduction of wounds unhealed at 20 weeks was 37%.
- **Pain reduction**
 - Mean pain score reduced to 0.9 within 2 weeks of treatment and 0.3 at 20 weeks.
 - 10 weeks post treatment 95% patients had no pain.
- **Exudate reduction**
 - Within 2 weeks of commencing treatment no patients had heavy exudate and 32% had moderate exudate.
 - At 20 weeks only 16% patients had moderate exudate.

Economic benefits - dressings

- Cost of primary/secondary dressings and bandages being used at start of treatment were calculated. Assumption taken that due to non-progression of wounds, the same or similar treatment wound have continued if the Accel-Heal[®] had not been commenced.

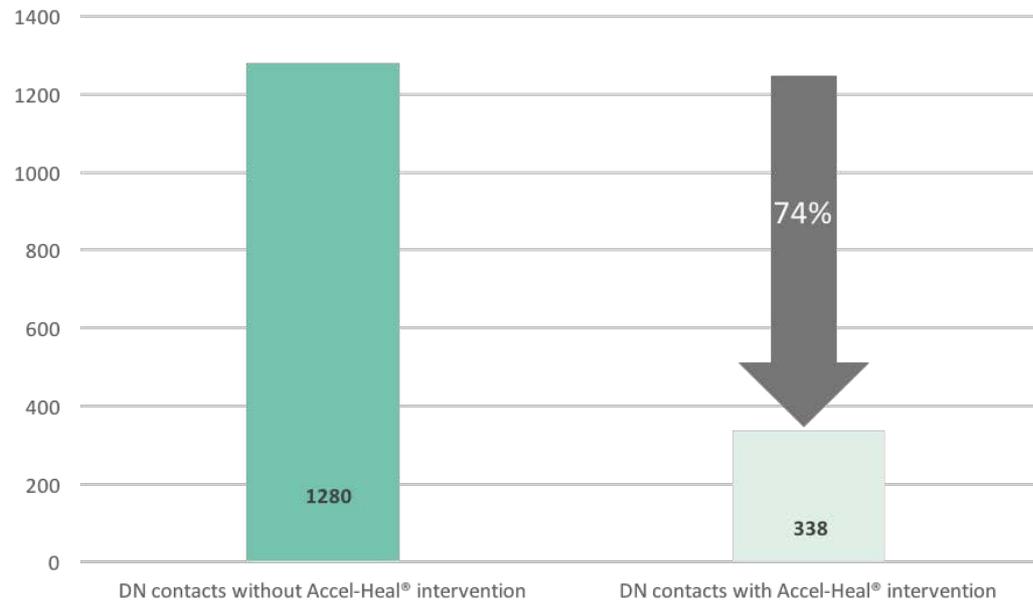
Cost of dressings with/without Accel-Heal[®] intervention for 20-week



- Costs calculated for primary/secondary dressings and bandages including Accel-Heal[®] during the 20-week period.

Economic benefits – nursing time

Number of DN contacts with/without Accel-Heal[®] intervention for 20-week period



Case study 1

- 56 yr. old male.
- PMH Fracture right tibia and fibula with metal plate 1986, Depression. Main carer for mother.
- Wound dimensions:
rt. tibia crest 3 cm². and 0.5 cm²
rt. medial malleolus 4 cm²
- Pain score 6/10.



Case study 1

No Progress – 26th September 2013



Case study 1

Commenced treatment 4th -18th November 2013



Case study 1

Complete healing 31st March 2014



Case study 2

- 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 2

- 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 2

- 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 2 - Healed and discharged 09/02/17



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.

Summary

- Wounds require electrical energy to facilitate the complex healing process.
- Chronic wounds lack electrical energy with the electrical current being disrupted by infection/biofilm and or presence of foreign body.
- Electroceutical treatment restores the abnormal function in the wound restoring the normal wound healing physiological process. Accel-Heal® is a small portable class 11a medical device delivering a sequence of pre-programmed, low-level and sub-sensory electrical energy through the skin surface.
- Accel-Heal® is easy to use and applied alongside patients' treatment plan. It is a single use treatment so no on-going costs.
- Clinical effectiveness from using Accel-Heal® (Guest et al 2015, Ovens 2014, Ovens 2015, Turner and Ovens 2017 (awaiting publication)).

Summary (contd)

- Cost improvements using Accel-Heal[®] estimated to be 11% of NHS budget. (Guest et al 2015).
- Economic benefits with reduction in dressings and nursing time (Turner and Ovens 2017 awaiting publication).
- Reduction in recurrence of VLU's due to deposition of Type 1 collagen (Ovens 2014).
- Earlier treatment intervention increases the probability of healing.

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Thank you

