Getting it right for patients and budgets

This article is based on a symposium held at the Wound Essentials annual summer conference in Birmingham, UK, on 2nd July 2015. The symposium highlighted the role and impact of Accel-Heal, an electroceutical medical treatment device (*Box 1*) from Synapse, on patient outcomes, how this can be incorporated into clinical wound care pathways and its impact on clinical budgets. Accel-Heal will be included on the Drug Tariff listing from 1 October 2015 in England and Wales, and on the Scottish Drug Tariff listing from 15 October 2015.

Figure 1: Accel-Heal unit

WHAT IS ACCEL-HEAL?

Accel-Heal is a 12-day electroceutical Class IIA medical treatment (*Box 2*) that has been demonstrated to be effective in wound healing (Tadej et al, 2010). The treatment consists of six 48-hour single-use electroceutical device units, to be applied consecutively, with electrode pads to be attached to the skin surface approximately 2 cms from the wound edges (*Figure 1*). The single-use, pre-programmed units manipulate gene expression in order to modify specific functions in dermal tissue, facilitating wound healing (www.accelheal.com). As an adjunct treatment, Accel-Heal is applied alongside the patient's standard wound therapy regime and can be used under compression bandaging. A video resource on application of Accel-Heal is available at www.accelheal.com/resources.

Liz Ovens explained that she started using Accel-Heal with her patients around 3 years ago. She estimated that of the approximately 40 patients with whom she has used Accel-Heal, 90% have seen benefits; these have included complete healing and reductions in wound pain, exudate and size. She has also noticed a reduction in recurrence, particularly in venous leg ulcers. In her experience, Accel-Heal has also been found to dissolve biofilm

Box 1. What are electroceuticals?

- 'Electroceuticals' is a recently coined term that broadly encompasses all bioelectric medicine that uses electrical energy to affect and modify functions of the body.
- Electroceutical research is developing medicines and devices that use electrical impulses to modulate the body's neural circuits and other physiological functions where electrical energy is used to initiate a biological change.
- Virtually all of the body's organs and functions are regulated through circuits of neurons communicating via electrical impulses and molecules acting to establish electrical potentials to facilitate bodily functions. By accurately mapping out the neural signatures of certain diseases, it is then possible to stimulate or inhibit malfunctioning pathways with tiny electrodes in order to restore health, without having to use systemic medicines that can have secondary and sometimes deleterious effects.
- The last decade has seen remarkable progress in molecular bio-electricity, with the development of genetic tools for tracking and functional modulation of bioelectric gradients in vivo. This is far beyond classical approaches of electric field and electrical stimulation-type applications where the approach has been non-specific.
- Functional data conclusively show that bioelectric pre-patterns in non-neural tissues are a traceable and powerful regulator of pattern formation that can reprogram not only individual cells but whole organs. This type of data helps to explain the increasing implications of ion channels with bioelectric properties of cell groups being master regulators that can now be manipulated for rational control of growth, form and repair.

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and to increase the production of collagen, which has resulted in long-term benefits for patients. Anecdotally, patients have commented to Liz that the healed tissue feels stronger and less tender.

PRACTICAL TIPS FOR USE

Liz gave a brief practical overview of how to apply Accel-Heal. The treatment is delivered via electrode pads placed on healthy skin on either side of the wound during a dressing change. As Accel-Heal is designed to allow simplicity of application and unit change, patients are generally able to change the single-use units themselves, which Liz has found works very well and helps to involve patients in their own care. She emphasised that it is important to explain to patients that the treatment is not designed to heal the wound completely within the 12-day treatment period, but that it works to affect physiological processes in the human body responsible for wound healing and that these processes, and healing, will continue after the 12-day treatment with Accel-Heal has ended.

Accel-Heal is contraindicated for use in some patients (*Box 3*), particularly in patients with active cancer — Liz stressed that this must be excluded before commencing treatment.

She went on to describe several case studies of patients who have benefited from use of Accel-Heal.

Case Study 1

This patient was a 92-year-old female with a recurrent left medial venous leg ulcer complicated by small vessel disease, which had been present for over 2 years and prone to persistent infection. The patient had a pain score of 8/10 and took painkillers, but she was intolerant of tramadol and also unable to tolerate any compression therapy; she was prescribed antibiotics and the wound was regularly debrided. The wound measured 13cm^2 with periwound inflammation, moderate exudate, malodour and slough (*Figure 2*).

After 1 week of treatment, the patient's pain score was 5/10 and periwound inflammation had reduced. The primary dressing was changed to a honey-impregnated dressing to manage persistent slough. By the end of treatment, the patient's pain score was 4/10, which meant that compression therapy could be commenced (*Figure 3*). This healed the wound and it has remained healed, with no further recurrence.

Box 2. What is Accel-Heal?

Accel-Heal is a certified and patented 12-day electroceutical treatment (Class IIA) designed to improve and accelerate healing rates in patients with complex wounds. The Accel-Heal treatment course consists of six compact (7cm x 4cm x 2cm), pre-programmed and battery-operated 48-hour single-use units to be applied consecutively, and electrode pads. The pads are applied to healthy skin on either side of the wound and then connected to the Accel-Heal unit during a standard care procedure (dressing change). The unit is then activated using an on/off switch, tucked into the external dressing, and left to work for 48 hours. Once the 48-hour dose of treatment has finished, the unit will automatically turn itself off. A new unit is then attached, and the old unit disposed of safely.

Box 3. Contraindications for use of Accel-Heal

Contraindications

- 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 the unit to become wet (as with all electrical devices)
- Remove if other electrical devices are in use (e.g. ECG, EEG, MRI, alarms)

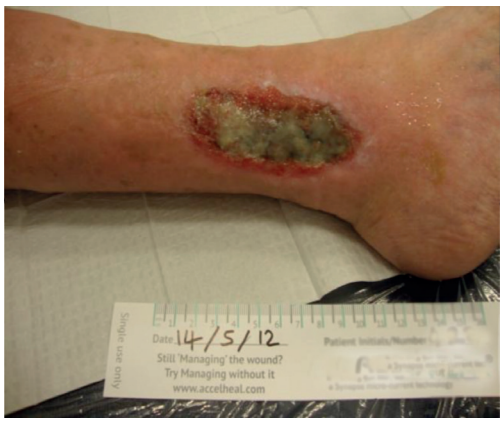


Figure 2: Case Study 1 wound prior to Accel-Heal treatment

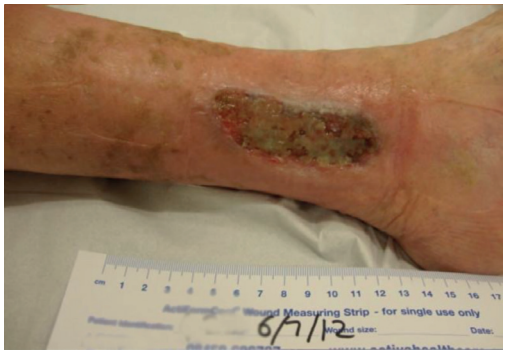


Figure 3: Case Study 1 wound after Accel-Heal treatment, before commencing compression therapy

Figure 4: Case Study 2 wound prior to Accel-Heal treatment

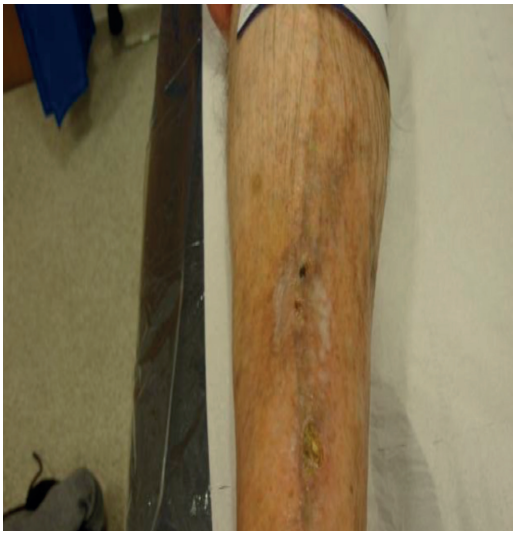


Figure 5: Case Study 2 after Accel-Heal treatment

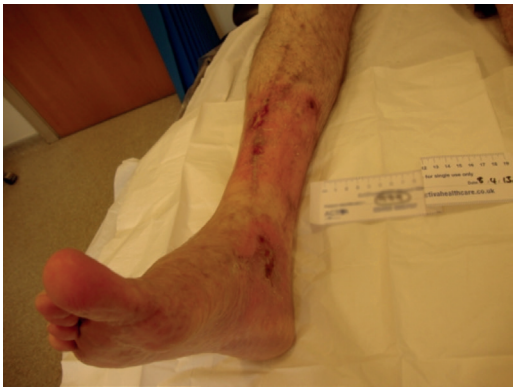


Figure 6: Case Study 3 wound prior to Accel-Heal treatment

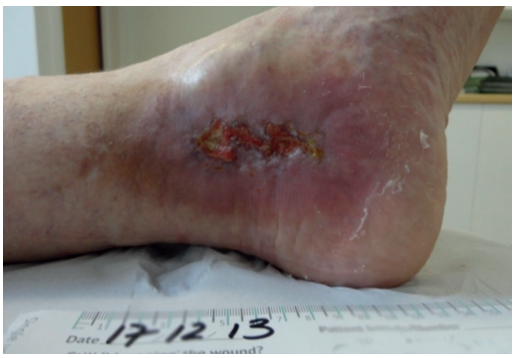
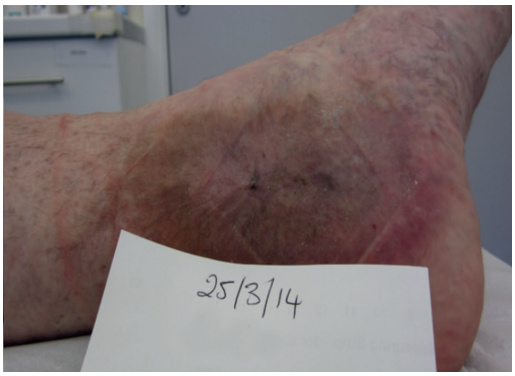


Figure 7: Case Study 3 wound after Accel-Heal treatment



Case Study 2

This patient was a 56-year-old male with wounds to the tibial crest and medial maleolus right leg, which were caused by scars from a debilitating case of adult chicken pox in July 2012 (*Figure 4*). The patient had a previous history of right fracture tibia and fibula with metal plate following a road traffic accident (RTA) in 1986. The patient was unable to tolerate compression therapy and had a pain score of 8/10. The patient suffered from severe depression and was very resistant to the recommended therapy. Liz recalled the patient saying 'he wanted us to chop his leg off', while declining any other options or referrals to other specialists.

The patient eventually consented to Accel-Heal treatment and he was able to change the units himself, which Liz said helped his overall treatment as he found it empowering. His pain score reduced to 2/10 and his mental health 'greatly improved'. His wounds went on to complete healing and have not recurred, even though the patient still could not tolerate compression therapy (*Figure 5*).

Case Study 3

This patient was a 46-year-old male with the fourth recurrence of a venous leg ulcer following a fracture to his left tibia and deep vein thrombosis following a RTA in 1989 (*Figure 6*). The wound was recurrent despite use of Class 3 compression hosiery, and the patient being very concordant with treatment. The patient was depressed and unable to return to work; Liz said 'he saw no future for himself with these recurring wounds'.

After 1 week of treatment, slough was reduced. The wound went on to heal and has remained healed since treatment (*Figure 7*).

Case Study 4

This patient was a 57-year-old male with a fifth recurrence of a venous leg ulcer to the left medial malleolus (*Figure 8*). He had a history of deep vein thrombosis and had previously had varicose vein surgery. Despite wearing Class 3 compression hosiery, the wound had not remained healed for longer than 3 months. The patient said 'he never felt the wound healed completely after each recurrence'. His pain score was 7/10.

Within 1 week of treatment, the size of the

wound had reduced and the patient's pain score lowered considerably. Vascular assessment determined scarring from previous DVT to be managed conservatively. The wound went on to heal completely within 2 months (*Figure 9*), with no recurrence 8 months later, and is still being monitored; Liz said 'we're hopeful it will remain healed for him.'

Case Study 5

This patient was a 65-year-old male with advanced venous disease and the third recurrence of a venous ulcer to his left medial leg (*Figure 10*). The wound had been present for 7 months and persisted despite 3 months of compression treatment. The patient's pain score was 9/10.

Soon after commencing treatment, there was less slough, and areas of granulation were visible (*Figure 11*). The patient's pain score reduced significantly to 1/10. The wound size did not reduce at first, but the wound went on to heal completely by February 2015. Liz noted that 'there was a huge improvement to the patient's walking and general quality of life' and has remained healed.

ACCEL-HEAL IN PRACTICE

Liz went on to introduce the proposed clinical pathway for using Accel-Heal in practice (*Figure 12*).

Liz stressed that holistic assessment is 'very important' – it is vital to consider patient-related factors as well as the wound itself (e.g. allergies, comorbidities, concordance and psychosocial factors), as they are all contributing factors to wound complexity. Accel-Heal's clinical pathway recommends the use of standard therapy for the first 28 days, according to local/national guidelines, and then to consider Accel-Heal if the wound has not reduced by 40% (Howard et al, 2013).

Synapse would very much welcome feedback from clinicians regarding the proposed clinical pathway for Accel-Heal. If you would like to receive a full version of the proposed clinical pathway in order to provide feedback please contact Synapse at info@accel.com

IMPACT ON CLINICAL BUDGETS

Speaking about the potential effect of Accel-Heal on clinical budgets, Liz highlighted that the use of Accel-Heal has resulted in long-term cost savings, with data compiled across clinical settings (*Figure*

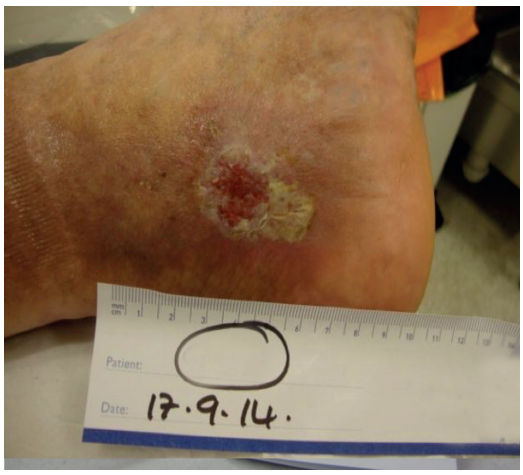


Figure 8: Case Study 4 wound prior to Accel-Heal treatment

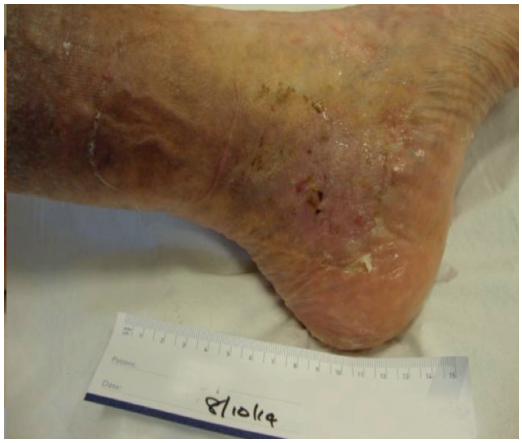


Figure 9: Case Study 4 wound after Accel-Heal treatment

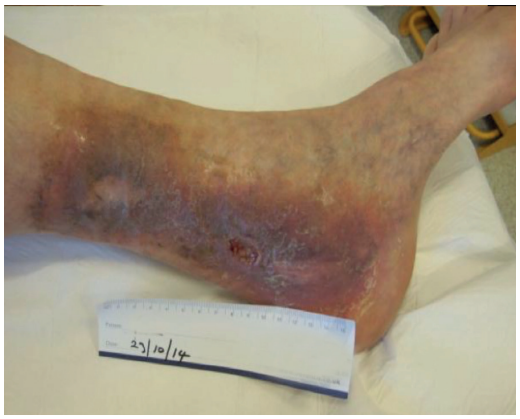


Figure 10: Case Study 5 wound prior to Accel-Heal treatment

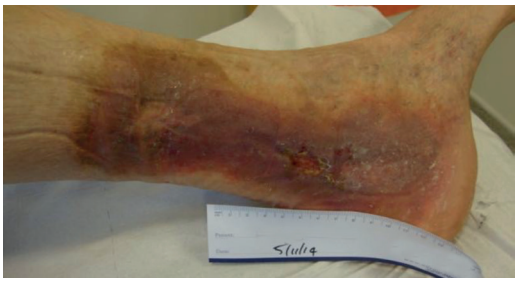
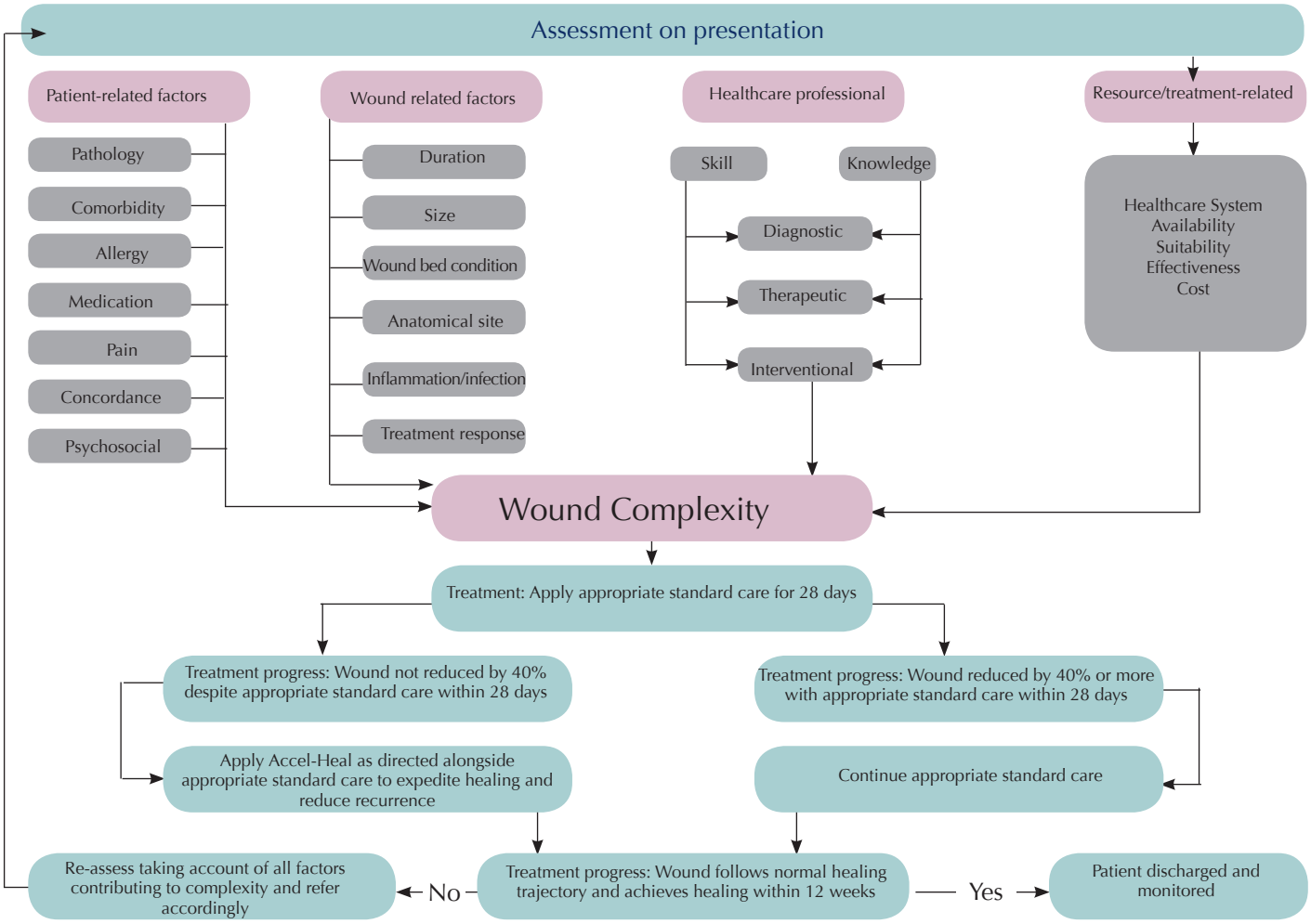


Figure 11: Case Study 5 wound following Accel-Heal treatment



It is recommended that only one full treatment course of Accel-Heal is used as part of a patient's care pathway

Figure 12: Proposed clinical pathway

13). Nursing time costs were significantly reduced with the use of Accel-Heal. In all of the cases highlighted, the costs of care post-treatment with Accel-Heal were significantly reduced (*Figure 13*), taking into account both the cost of the Accel-Heal device and the necessary nurse visits. As patients' pain scores were generally reduced, this also contributed to lowered costs and improvement to patients' quality of life. In general, following treatment with Accel-Heal, Liz noted that for patients with healed venous leg ulcers, the only cost is provision of hosiery to maintain venous return and prevent recurrence. In all cases highlighted in *Figure 13* there is 'significant cost reduction in the long term' and improved outcomes for patients. Accel-Heal will be included on the Drug Tariff listing from 1 October 2015 in England and Wales, and on the Scottish Drug Tariff listing from 15 October 2015. Incorporating Accel-Heal into clinical care pathways will ease the resource burden on the NHS and its availability on Drug Tariff will make it more widely available to all patients who need it.

SUMMARY AND QUESTIONS

Summarising the benefits of Accel-Heal, Liz said that in addition to the cases she highlighted and the impact on cost, the most significant effect has been to her patients' quality of life.

Opening the discussion up to questions from the audience, Liz was asked whether any side effects have been observed during treatment with Accel-Heal. Liz explained that, in wounds where healing processes have been impaired, the electric micro-current induces the body's natural physiological processes, through affecting gene behaviour, and that no side effects have been found.

Liz was also asked about her experience of using Accel-Heal on different types of wounds, other than venous leg ulcers. She advised that she has used Accel-Heal for a very deep sacral pressure ulcer —although healing was not achieved, the patient's pain was reduced. She explained that she also achieved complete healing of an arterial foot ulcer. Similarly, she has used Accel-Heal

Duration of ulcer (weeks)	Wound size (cm^2)	Date Accel-Heal applied	Type of ulcer	Pain score at start of treatment	Healed status (H=healed, P=partially healed, N=not progressed	Percentage of healing progression	Time to healing (weeks)	Treatment cost pre Accel-Heal (Nurse visits costed at 2 x a week @£90 per visit)	Treatment costs post Accel-Heal (Accel-Heal @£240 plus nurse visits 2 x a week at £90 per visit)	Impact of Accel-Heal on costs
-117	3 cm^2	4/10/13	Venous	0	H	100%	9	£21,160	£1,860.00	Long-term cost reduction as no ongoing treatment costs.
104	7.5 cm^2	4/10/13	Venous	7	H	100%	5	£18,720	£1,050.00	Long-term cost reduction as no ongoing treatment costs.
52	3 cm^2	3/10/13	Venous	0	H	100%	6	£9,360	£1,320.00	Long-term cost reduction as no ongoing treatment costs.
52	3 cm^2	8/10/13	Venous	10	H	100%	5 1/2	£9,360	£1230.00	Long-term cost reduction as no ongoing treatment costs.
8	1 cm^2	1/11/13	Venous	0	H	100%	4 1/2	£1,440	£1,050.00	Long-term cost reduction as no ongoing treatment costs.
52	0.5 cm^2	14/11/13	Venous	0	H	100%	3	£6,240	£780.00	Long-term cost reduction as no ongoing treatment costs.
35	3 cm^2	21/11/13	Venous	1	H	100%	4	£6,240	£960.00	Long-term cost reduction as no ongoing treatment costs.
35	3 cm^2	18/12/13	Venous	1	H	100%	4	£6,240	£1,680.00	Long-term cost reduction as no ongoing treatment costs.
-117	3 cm^2	3/1/14	Venous	0	P	90%	N/A	£21,160	£9,720.00	Ongoing costs as not healed. Accel-Heal contribution of £240 to overall cost.
17	3 cm^2	6/3/14	Venous	1	H	100%	15	£3,060	£2,940.00	Long-term cost reduction as no ongoing treatment costs.

Figure 13: Impact of Accel-Heal on clinical budgets

for rheumatoid ulcers for the purpose of pain reduction rather than complete wound healing, which was significantly achieved. Another delegate asked whether the condition of the surrounding skin was a factor for using Accel-Heal, such as in wounds with heavy exudate and maceration. Liz described using Accel-Heal on one patient with severe exudate and excoriation, saying that the pads used can be positioned further away from the wound site, treating the periwound area as part of the wound for treatment purposes; she said that as long as the pads are positioned properly, they can still be very effective from quite far away from the wound. Again, she suggested using clinical judgement and monitoring the patient's response to treatment. She also noted that exudate may increase initially on commencing treatment, so it is important to monitor dressing change frequency, but that this is a temporary effect and will then reduce.

Summing up the session, Liz highlighted that chronic wounds bring huge challenges to healthcare professionals and cause misery, pain and reduce wellbeing for patients (Persoon et al, 2004). She found that using Accel-Heal in her clinical practice improved wounds and quality of life outcomes for her patients. This is also documented in previous Accel-Heal clinical case studies (Greaves, 2014).

Use of Accel-Heal resulted in a reduction in pain, inflammation and exudate in all patients and facilitated the re-activation of normal wound healing physiology, leading to wound closure in the vast majority of her patients. It is easy and simple to use as an adjunct to patients' usual therapy, including compression, and patients did not experience any pain or sensitivity during the treatment period. Liz also highlighted that Accel-Heal is an inexpensive treatment regimen when compared with other advanced modalities such as laser, negative pressure wound therapy, hyperbaric oxygen or bio-healing. WUK

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