Improving outcomes through innovation: An evaluation of Accel-Heal® in chronic wounds

KEY WORDS
- Accel-Heal®
- Electrical stimulation
- Clinical evaluation
- Innovation

Management of chronic wounds is a growing problem. Many wounds heal slowly, do not heal, or deteriorate, despite efforts to promote tissue repair. In light of changes to health policy and a drive for innovation, clinicians should be taking advantage of emerging technologies to improve patient outcomes and reduce costs. Accel-Heal® (Synapse Micro-Current Ltd) is an innovative medical device that uses a specific proprietary sequence of micro-current electrical pulses that interact with biological processes that are dormant within a wound. This article examines the use of Accel-Heal in three case studies.

Traditional wound care can be described as the use of sterile wound care products to achieve the optimum environment for healing to be maintained. Chronic wounds can have a severely debilitating effect on patients, causing depression and anxiety (Walshe, 1995). More recently, Franks and Morgan (2003) have looked at the concept of wellbeing, concluding that a patient's view of their life can have either a positive or negative effect on wound healing.

ACCEL-HEAL®

Bio-currents established through chemical interactions and reactions are integral to cell function. Molecules and electrical impulses between cells control a range of cellular functions. Disruption of this process can impede normal cellular function and interaction, and contribute to poor wound healing (Illingsworth and Barker, 1980; Jaffe and Vanable, 1984; Vanable, 1989).

The Accel-Heal (Synapse Micro-Current Ltd) system uses micro-currents to support tissue repair by interacting with biological processes that have become static within the wound. Bio-currents controlling cell behaviour, communication and transfer of molecules are restored, inducing the healing process (Chapman-Jones et al, 2010). The bio-electric process is believed to support wound healing by attracting cells and molecules responsible for repair, altering cell membrane permeability and enhancing cellular secretion through cell membranes. Current is generated between the skin and inner tissues when there is a break in the skin. The current is maintained until the wound is healed.

Accel-Heal is based on a 12-day treatment course. The treatment comprises six battery-powered, 48-hour, single-use units, applied consecutively. It improves granulation, reduces pain, oedema and exudate while the wound heals. It is not expected or designed to heal the wound within the 12-day treatment course, but induces the healing process while standard care is continued (Tadej et al, 2010).

To evaluate Accel-Heal, a district nursing team was identified and given an explanation of the therapy. Under the guidance of the tissue viability clinical nurse specialist, three patients were identified as potential candidates for the treatment. All patients had chronic leg ulceration that had failed to achieve wound closure using standard wound therapies for varying lengths of time ranging from 9–50 years. It is worth noting that not all patients are able to follow what is considered best practice, and that adaptation, such as reducing compression, may be needed.

Following a detailed explanation of Accel-Heal and having been provided with patient information supplied by the device manufacturer, all three patients agreed to be included in the evaluation programme.

It was explained to the patients that the Accel-Heal units would need to be changed every 48 hours, even if the primary dressing itself did not require changing. Unit replacement is straightforward. The electrode pads are placed on healthy skin either side of the wound during a primary dressing change. The electrode wires are threaded through the standard dressing and are connected to the device, which is then activated via an on/off switch and tucked into the external dressing. Once the 48-hour dose of treatment

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has finished, the unit will automatically turn itself off. The used unit is then removed by disconnecting it from the electrode pad wires, a new unit attached to the electrodes, and the used unit disposed of safely. As all patients were deemed capable of completing the unit change themselves, all three were given time with dummy versions to practice the technique.

All patients followed the same 2-week assessment process (*Table 1*). As Accel-Heal is not currently listed within the Powys Health Board formulary, written consent from the patients was obtained. All patients were given information about the product, the length of the study, and what would be done following review and write up of their information. Consent was obtained for photographs being taken and published. Photographs were taken at set times over the study period, beginning with a full wound assessment prior to application of Accel-Heal. The link nurse for tissue viability from the district nursing team and one other nurse undertook all the assessments.

CASE STUDIES

Patient 1. Mrs EAD

Mrs EAD has a 50-year history of venous problems, starting back in 1964 when she was treated for varicose veins in both legs. Almost 20 years later she had stripping of bilateral long saphenous veins. In 1993 she was diagnosed with rheumatoid arthritis and has been receiving corticosteroids since then – a class of drugs associated with delays in wound healing. In 2005, Mrs EAD had a myocardial infarction and underwent a saphenous vein graft replacement of a coronary artery in 2006.

The ulcer was of 8 years' duration and had been treated as a mixed aetiology ulcer, mid-calf on the outer aspect of her left leg. The patient had refused ankle brachial pressure indices (ABPI) tests on multiple occasions. Although reduced compression therapy had been tried, Mrs EAD was unable to comply with this because of pain. Mrs EAD indicated that she hoped this therapy would achieve wound closure as she thought that once this had happened she might be able to manage compression hosiery to prevent recurrence.

Wound state and size are recorded during the evaluation period in *Table 2*. *Figures 1a* and *1b* show the wound on days 1 and 13. The periwound skin has improved in appearance. The wound edges were clean and the periwound was healthy apart from a slight build up of skin scales. A reduction in size of the ulcer of 2.7 cm^2, equivalent to a 28.9% reduction, was achieved. *Figure 1c*, taken on 13 August 2013, shows the ulcer continuing to heal. Following completion of the Accel-Heal treatment, a simple non-adherent foam held in place with a tubular bandage was used. The wound achieved closure on 5 September 2013.

Patient 2. Mr WD

Mr WD has type 2 diabetes treated with oral medication. His BMI is >30 kg/m^2. He has a long history of both venous and arterial problems, with phlebitis and thrombophlebitis recorded in 1988. His first ulcer was in 1996, with ligation of varicose veins to his right leg in 1998. In 2012, he had a left saphenous femoral artery occlusion leading to angioplasty. The treated ulcer was on the right leg and had been open

Table 2. Mrs EAD's wound bed description at each dressing change.

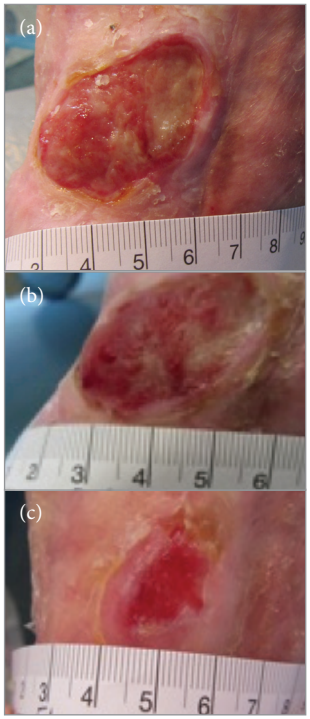
Description	19.03.13	23.03.13	27.03.13	31.03.13	16.04.13
Sloughy (%)	50	50	30	30	10
Granulating (%)	50	50	70	70	90
Length (cm)	4.1	4.0	3.9	3.8	3.5
Width (cm)	2.4	2.2	2.1	2.1	2.0

Regular dressing changes took place between 31.03.13 and 16.04.13 but wound measurements were not recorded until 16.04.13.

Table 1. Treatment schedule during the evaluation.

Week 1	Action	Week 2	Action
Day 1	Full wound assessment; photograph taken; application of dressing and electrodes; application of first device.	Day 9	Removal of fourth device; dressing changed; full wound assessment done; photograph taken; electrodes checked and left in place/changed if loose; application of fifth device.
Day 3	Removal of first device; electrodes checked and left in place; dressing left in place unless there was clinical need to change; application of second device.	Day 11	Removal of fifth device; electrodes checked and left in place/changed if loose; dressing left in place unless there was clinical need to change; application of sixth device.
Day 5	Removal of second device; dressing changed; full wound assessment done; photograph taken; electrodes checked and left in place/changed if loose; application of third device.	Day 13	Treatment completed; removal of device and electrode pads; full wound assessment done; photograph taken; application of standard appropriate dressing.
Day 7	Removal of third device; electrodes checked and left in place/changed if loose; dressing left in place unless there was clinical need to change; application of fourth device.	2 weeks post-treatment	Full wound assessment done; photograph taken.

Figure 1. Mrs EAD's wound on days (a) 1, and (b) 13, and (c) on 13 August 2013.



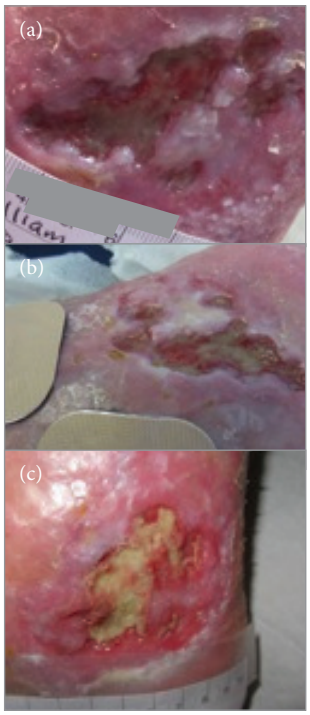


Figure 2. Mr WD's wound on days (a) 1, (b) 13 (with electrodes in place), and (c) 16 weeks after the end of treatment.

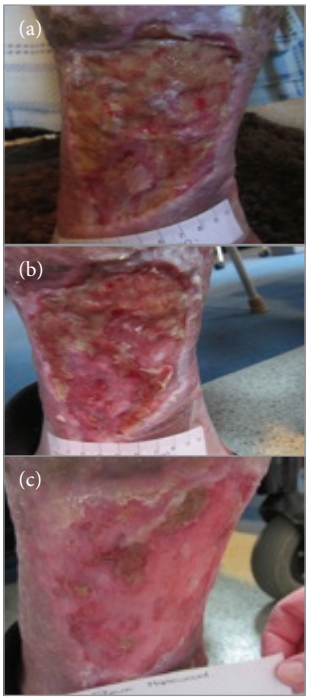


Figure 3. Mr SH's wound on days (a) 1, (b) 13, and (c) 16 weeks after the end of treatment.

for over a year. His ABPI prior to treatment was 1.11 (right) and 0.61 (left). *Figures 2a* and *2b* show the wound on day 1 and day 13.

On the final day of the initial evaluation period, Mr WD presented with a painless area of redness below his knee, level with the top of bandages, and also in several patches down the shin. He was referred immediately to the GP and, therefore, the last full wound assessment was not undertaken. The device manufacturer was contacted and informed of the problem. It was the first time a problem of this kind had been reported and it is not known if it was related to the therapy or not. The redness resolved without complications.

The ulcer had increased in size by the end of the evaluation *(Table 3)*. Mr WD had cut his compression bandages and now had leaking oedema. However, the ulcer wound bed had new granulation tissue and the wound edges were more clearly defined and showing signs of epithelisation *(Table 3)*. Mr WD was seen again by the team 16 weeks after the end of the evaluation. Further healing was observed, with the wound bed improving, less deep, and showing improved granulation *(Figure 2c)*.

Patient 3. Mr SH

Mr SH has a 12-year cardiac history. In 2000, Mr SH had atrial fibrillation and was diagnosed with cardiomegaly, congestive cardiac failure and a venous leg ulcer to his right leg. In 2003 he developed ulceration to his left leg. Both ulcers have a history of almost closing then breaking down again. MR SH has a BMI of 43 kg/m^2, has reduced mobility and uses an electric chair. He is a smoker and drinks regularly. Prior to evaluation he attended the Lindsay Leg Club weekly, where his legs were washed and compression bandages applied. Depending on the levels of exudate he was also visited at home for additional dressing changes. His ABPI was 0.64 (right) and 1.03 (left). These results must be reviewed as part of Mr SH overall assessment and may be limited in accuracy because of his obesity.

Table 3. Mr WD's w ound bed description over time.

Description	19.03.13	23.03.13	27.03.13	31.03.13	16.04.13
Sloughy (%)	90	85	50	50	ND
Granulating (%)	10	15	50	50	ND
Length (cm)	5.2	5.2	5.2	5.1	5.4
Width (cm)	1.2	1.2	1.2	1.2	1.9

ND, not done. Regular dressing changes took place between 31.03.13 and 16.04.13 but wound measurements were not recorded until 16.04.13.

Over the past 10 years, Mr SH has tried many different compression kits and both multilayer bandages and two-layer kits. Mr SH's poor mobility, related to a crumbling hip, has led to limited weight-bearing ability in his left leg and also a drop foot. This, in turn, reduces the effectiveness of inelastic compression, so long stretch bandages are used. He has repeated colonisation and infections requiring both topical antimicrobial dressings and antibiotic therapy. At the time of the evaluation both ulcers were open.

Mr SH requested that the treatment was applied to the left lateral aspect ulcer. *Figures 3a and b* and *Table 4* show the change in Mr SH's ulcer during treatment, and *Figure 3c* illustrates the final review, 16 weeks after the end of treatment. Between treatment and final review, a simple nonadhesive dressing under a two-layer compression bandage system was used. A significant improvement in appearance of the treated ulcer was observed. The ulcer had a uniform depth and large areas of epithelisation. The wound reduced from 122.2 cm^2 to 84 cm^2 – a reduction of 38 cm^2 (31.3%).

DISCUSSION

Within Powys Health Board, the majority of leg ulcer management is via Lindsay Leg Clubs, which comprise >1600 members across six clubs. These have been running for around 8 years, and since inception have demonstrated decreased healing times, reduction in reoccurrence and improved wellbeing in both patients and staff (Thompson, 2012). Despite this, not all patients achieve wound closure. By taking part in this evaluation, the patients were taking an active role within their care, reflecting the model of empowerment and self-responsibility supported by the Lindsay Leg Club model.

Alongside clinical outcomes, the financial implications of new therapies must be addressed, particularly in this current climate of austerity. Wound care specialists have to be aware of the multiple

Table 4. Mr SH. Wound bed description at each dressing change.

Description	05.4.13	09.04.13	14.04.13	17.04.13	30.04.13
Sloughy (%)	50	50	25	25	15
Granulating (%)	50	50	75	75	50
Epithelising (%)	0	0	0	0	35
Length (cm)	13.0	13.0	13.0	12.0	12.0
Width (cm)	9.4	9.0	8.0	7.0	7.0

Regular dressing changes took place between 17.04.13 and 30.04.13 but wound measurements were not recorded until 30.04.13.

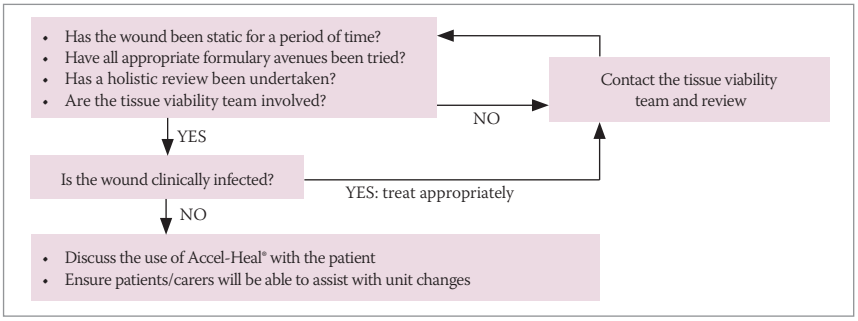
agendas faced by their local healthcare communities and the wider NHS. In the UK, approximately 200 000 patients have a chronic wound, at an estimated annual cost to the NHS of £2.3bn–£3.1bn (2005–2006 costs), approximately 3% of the total estimated expenditure on health for that period. An estimated 70 000–190 000 people in the UK are affected by leg ulceration, most commonly caused by venous hypertension. The cost of treatment to the NHS, usually in primary care and through community nursing services, is at least £168m–£198m per year (Posnett and Franks, 2008).

There is a clinical argument for Accel-Heal to be used when an ulcer shows the initial signs of senescence, which can be described as a halt in a cell's power to divide and grow demonstrated by a stable wound size. Stephen-Haynes et al (2011) suggest that with correct assessment and choice of readily available wound-care products, there is potential for more cost-effective wound care. This assumes that products are used to the optimum as determined by their manufacturers. It should also be borne in mind that in the community setting, the majority of the cost of any dressing change is that of the nurse's visit.

In this evaluation, both venous and mixed aetiology leg ulcers were treated. In their cost-effectiveness model, Guest et al (2012) suggest that, when used in conjunction with compression bandaging, Accel-Heal – specifically in the case of venous ulceration – has the potential to save the NHS up to 15% of costs, and up to a 27% reduction in the number of nurse visits, over a 5 month treatment period. However, I would suggest that this saving in nurse time would occur following the initial period of treatment, which was reflected in our experience. Prior to treatment all patients were having their wounds dressed twice a week, which was reduced to once a week following treatment.

Accel-Heal is available through the usual supply routes, except at present on prescription, which is expected to be available early in 2014. In Powys, previous work in wound healing and protocol development (Griffin, 2007) has enabled us to purchase the Accel-Heal treatments. *Figure 4* illustrates how Accel-Heal could be brought into a treatment protocol. Powys Health Board is unique in that all services offered are within primary care. The estimated proportion of the population aged 65–84 years is 20.7%, and a further 3.2 % aged >85 years (NHS Wales, 2012). When presenting to nursing services, this population often has multiple comorbidities, further complicating wound management. Because of financial pressures, and the need for the provision of the most cost-effective care near to the patient's home, community nursing teams are put under increasing pressure to facilitate earlier discharge from commissioned care in the acute sector. Leading on from this is the need for the district nursing teams to review their current caseloads and management strategies using the specialist nurses as appropriate.

Figure 4. Algorithm for the use of Accel-Heal® (Synapse Micro-Current Ltd).



CONCLUSION

The patients in this case series had long histories of leg ulceration and a range of comorbidities. Current optimal treatments had failed to make a significant impression on ulcer healing, with associated distress to the patient and cost to the healthcare providers. However, following the application of Accel-Heal, all patients had positive outcomes, demonstrated by the reduction in slough to their wounds and an increase in granulation tissue.

Given the range of clinical evidence, Accel-Heal should be considered as beneficial for all wound healing, and Cutting (2006) has suggested that clinicians should be encouraged to consider it as a therapeutic approach. With the potential to save costs in nurse visits, and the improvement in patient outcomes resulting from earlier wound closure, referral to the tissue viability service to review the potential for Accel-Heal use must be considered. WUK

ACKNOWLEDGEMENT

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