

Improving patient quality of life with innovative electroceutical technology: a case series

This article presents three case studies of patients with complex leg ulcers. As well as looking at the clinical efficacy of advanced modalities such as the electroceutical Accel-Heal® (Synapse Electroceutical) in improving healing outcomes, the article will examine the impact that living with a chronic wound has on patients' wellbeing and quality of life. It also considers the emotional effects that such wounds have on patients and their families. Permission was obtained from all patients and relatives, where appropriate, regarding their contribution to these clinical case studies via photographs and interviews.

KEY WORDS

- » Accel-Heal®
- » Complex leg ulcers
- » Chronic wound
- » Electroceutical technology
- » Pain
- » Quality of life

Leg ulcers are a type of complex wound that becomes more common with age. It is estimated that around 2% of all people over 80 years of age have a venous leg ulcer (VLU) (NHS Choices, 2014), although it is noted that this problem is not isolated to this age range and does effect the younger population. A recent study conducted by Guest et al (2013) suggested that up to 90% of all VLUs remain unhealed after 6 months and that the accepted best practice of compression therapy is not always successful at healing the ulceration.

Leg ulcers are associated with continuous pain, restricted mobility and decreased quality of life (Persoon et al, 2004; Jones et al, 2006). While many patients with leg ulceration experience high pain levels, patient wellbeing reaches beyond just being free of pain. In their 2012 study, Upton et al demonstrated that people living with chronic or acute wounds often experience poor psychological wellbeing. It is, therefore, necessary to look at quality of life as a component of wellbeing (Wounds International, 2011). The Government Office for Science (2008) defines wellbeing as "a dynamic state in which an individual is able to develop their potential, work productively and creatively, build strong relationships with others and contribute to their community". The World Health Organization (1948) in its constitution states that: "Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity." Physical wellbeing is the ability to function

normally in activities such as bathing, dressing, eating and mobility. Mental wellbeing stipulates cognitive faculties to be intact and patients to be free from fear, anxiety, stress, depression or other negative emotions. Social wellbeing includes the ability to participate in and engage with family, society, friends and colleagues.

BROMLEY HEALTHCARE

Bromley Healthcare has a long-standing record of achievement in wound healing. Even with average healing rate for VLUs of 5.7 weeks, it continues to strive for new, innovative ways to enrich our treatment programmes and improve outcomes for its patients. At Bromley Healthcare, leg ulcer management is provided in our award-winning tissue viability clinics, a Leg Club, and also by our District Nursing Service.

Box 1. Electroceuticals (www.accelheal.com).

Unlike the universal term 'electrical stimulation' previously used to describe devices such as Accel-Heal, electroceutical implies a more accurately targeted clinical application more akin to its pharmaceutical equivalent. Neural circuits communicating via electrical impulses regulate practically all of the body's organs and physiological functions. It is, therefore, possible to interpret the electrical language of health and disease from the level of gene expression upwards. It is now possible to inhibit or change a malfunctioning pathway in order to correct a potential defect.

TERESA GREAVES
Tissue Viability Nurse, The Willows Clinic, Bromley Healthcare CiC, Kent

Box 2. Ankle brachial pressure index (ABPI).

The ABPI is the ratio of the highest ankle to brachial artery pressure. It is used to determine the presence or absence of arterial disease. An ABPI of 0.8–1.2, in combination with the type of sounds present in the vessel and a holistic and limb assessment, is considered normal (free from significant peripheral artery/vascular disease). Such patients are suitable for compression therapy. An ABPI <0.8 may indicate some arterial disease requiring further investigation. An ABPI >1.2 suggests calcification of the walls of the arteries and incompressible vessels, which may require further investigation to eliminate peripheral arterial disease (Ovens, 2014).



Figure 1. Mrs SB's leg ulcer at the start of treatment.



Figure 2. Mrs SB's ulcer 3 days after the commencement of treatment with Accel-Heal.

ACCEL-HEAL

Accel-Heal® is a 12-day electroceutical Class IIA medical treatment that has been demonstrated to be effective in wound healing (Tadej et al, 2010; Taylor et al, 2011) (*Box 1*). The treatment consists of six 48-hour single-use units, to be applied consecutively, and electrode pads. The pre-programmed units manipulate gene expression in order to modify specific functions in dermal tissue (www.accelheal.com). Treatment

Box 3. Visual Analogue Scale.

A tool used to help a person rate the intensity of certain sensations and feelings, such as pain. The visual analogue scale for pain is a straight line measuring 10cm where 0 cm means no pain and 10 cm meaning the worst pain imaginable. A patient marks a point on the line that matches the amount of pain he or she feels.

is delivered via electrode pads placed on the healthy skin either side of the wound during a dressing change. As an adjunct treatment, Accel-Heal is applied alongside the patient's standard wound therapy regimen and can be used under compression bandaging.

The tissue viability team at Bromley Healthcare has successfully used Accel-Heal on many patients with complex wounds. For the purpose of these case studies, the patients were selected due to unresolved pain and non-healing ulceration. The patients all underwent full comprehensive leg ulcer assessments, ankle brachial pressure index (ABPI, see *Box 2*) measurement and the recording of all relevant medical history, medication and allergies. This was because it is important to identify all comorbidities that can potentially impact on the healing process. The patients were advised prior to the commencement of treatment that Accel-Heal is not designed to heal the ulcers within the 12-day course, but that it works to induce the healing process with best practice leg ulcer management.

CASE STUDY 1

Mrs SB is a 57-year-old lady who is married with three children and works full time as a children and families social worker. She is usually an active member of her church community and likes to socialise with her family and friends.

Mrs SB reported the effects of living with her ulceration as “utterly debilitating” and “the most stressful experience of my life”. She described her overall quality of life as “the worst possible” due to the physical symptoms that affected her daily life. Mrs SB experienced constant pain that prevented her from sleeping and that she described as “much worse than labour pains because it hurt just as much but unlike labour pains was constant”. She reported feeling extremely anxious and stressed, as she was unable to work because of the pain and

the side effects of the analgesia, which made her feel very drowsy. As a result of the ulceration, she was unable to attend her regular church services or get involved in her usual social activities. She found this “deeply upsetting” as she felt removed from her church community, which she described as her “support circle outside the family”. The ulceration also impacted on her ability to perform her activities of daily living and she had to rely on her husband for assistance, which made her feel a “burden” to him.

Assessment and treatment prior to commencing treatment with Accel-Heal

Mrs SB presented to the Leg Ulcer Clinic with spontaneous right lateral malleolus ulceration of 3 weeks’ duration. The wound bed was 100% sloughy, shallow with macerated edges, and malodorous, with erythema to the periwound skin. Her ABPI was 0.88 and her pain was 10/10 on the Visual Analogue Scale (VAS, see *Box 3*). Following antibiotic therapy and 3 weeks of full compression therapy, the ulcer failed to progress and increased in size to 12.2cm². The possibility of using Accel-Heal was discussed with Mrs SB and a decision was made to commence the treatment with the objective of reducing the pain and inflammation.

Medical history

Mrs SB had been diagnosed with the following:

- ▶ Sickle cell trait (1984)
- ▶ Essential hypertension (1999)
- ▶ Thyrotoxicosis (2008)
- ▶ Graves’ disease (2009)
- ▶ Right leg laser ablation to treat varicose veins (2011).

At the time of presentation, Mrs SB was being prescribed atenolol 50 mg daily, enalapril 5 mg daily, amlodipine 10 mg daily, tramadol 50 mg three times a day, co-codamol and antibiotics. She had no reported allergies

Treatment and outcome

Accel-Heal treatment was commenced on 8 April 2014 (*Figure 1*) for 12 days alongside her compression therapy. Mrs SB was trained to independently change the device every 48 hours. On 11 April, significant improvement was noted with the wound bed debriding (*Figure 2*) and Mrs



Figure 3. Mrs SB’s ulcer on completion of treatment.



Figure 4. Full healing of the ulcer after 2.5 months.

Table 1. Accel-Heal treatment summary for case study 1.

Date	Wound size (cm ²)	Pain level (Visual Analogue Scale)
8 April	12.2	10/10
11 April	12.2	6/10
6 May	10.1	0/10
23 May	4.0	0/10
20 June	0.0	0/10

SB’s pain score had reduced to a VAS score of 6/10. By 17 April, granulation buds were developing and the inflammation was reducing. Accel-Heal treatment was completed on 20 April (*Figure 3*), and by this date the wound bed had undergone significant changes, with the development of further granulation buds and reduced exudate. Mrs SB reported a further reduction in pain at this time, having a VAS score of 0–4/10. The wound continued to reduce in



Figure 5. Mrs EY's ulcer at initial presentation.



Figure 6. A 10% reduction was noted 3 days after commencing treatment with Accel-Heal.



Figure 7. Mrs EY's ulcer 1 week after starting treatment.



Figure 8. Mrs EY's ulcer had completely healed on 14 November following compression therapy.

size and tramadol was discontinued. On 29 April, Mrs SB was able to return to work on reduced hours. Full healing was achieved on the 20 June 2014 (Figure 4). For an overview of her treatment, see Table 1.

During the Accel-Heal treatment, Mrs SB reported that “the pain started to get less and less and I could see the wound healing, which was wonderful”. When her ulcer had healed completely, she said: “I feel that I now have my life back and can function normally without being a burden on my family,” and “I am delighted because I am no longer in pain” and “not having to take lots of medication”.

CASE STUDY 2

Mrs EY is an 81-year-old widow with two sons and six grandchildren. She is a retired teacher. She was a keen golfer, and although unable to play anymore following hip replacement surgery, she remains an active member of the golf club's social club. She is also a regular bridge player.

Mrs EY had her leg ulcer for 12 months before being referred for treatment to the Leg Ulcer Service. She reported that “looking after the wound took over my diary” due to regular appointments with the practice nurse for treatment at her GP surgery. The ulceration also impacted on her activities of daily living, such as showering and getting dressed. She stated that these activities “took much longer”, which impacted on her ability to function properly in terms of physical wellbeing. She also had to organise her shopping trips for quieter times of the day due to “anxiety about bumping the wound site, especially in supermarkets”.

Assessment and treatment prior to commencing Accel-Heal

Mrs EY attended her first appointment at the leg ulcer clinic on 29 September 2013. She had chronic ulceration in the gaiter region of the right lateral leg of 12 months' duration. The onset of her first ulcer was 10 years previous and she had experienced approximately two episodes of ulceration per year since that time. Erythema and oedema of the periwound skin was noted. Her ABPI was 1.1 and she had a high pain score of 8–10/10 on the VAS scale.

Table 2. Accel-Heal treatment summary for case study 2

Date	Wound size (cm ²)	Pain level (Visual Analogue Scale)
8 October	10.5	10/10
11 October	10.1	6/10
15 October	7.9	5/10
22 October	4.5	2/10
14 November	0.0	0/10

Full compression bandaging was commenced but due to her high pain score and episodes of reoccurrence, Accel-Heal was discussed with Mrs EY and a decision was made to commence treatment with the objective of reducing the pain and inflammation, and to reducing the risk of reoccurrence in the future.

Medical history

Mrs EY had been diagnosed with atrial fibrillation, ocular hypertension, hypothyroidism and osteoarthritis. She was prescribed warfarin therapy, paracetamol 1g four times a day, travatan 40cg/ml and levothyroxine 150µg daily. The patient had no reported allergies.

Treatment and outcome

Figure 5 shows the patient’s ulcer at the time treatment with Accel-Heal was commenced on 8 October 2013. Treatment ran for 12 days alongside the patient’s compression therapy. Mrs EY was trained to independently change the device every 48 hours. By 11 October, the ulceration had decreased in size by 10% (Figure 6). The exudate level had reduced, and periwound erythema and oedema had resolved. Mrs EY reported a reduction in pain, measuring 6/10 on the VAS scale. On 15 October, the ulcer had reduced in size by 20% (Figure 7) and the patient’s pain was 5/10 on the VAS scale. By 18 October, the ulcer had shrunk by approximately 30% since 8 October. Accel-Heal

treatment was completed on 22 October. Since the commencement of treatment, the ulcer had shrunk in size by 40%. At this time, the patient reported a pain score of 2/10.

Three weeks post Accel-Heal treatment, the ulcer had reduced in size by 80% and patient’s pain was 0/10 on the VAS scale. The Accel-Heal treatment had successfully achieved its objectives of reducing the pain and inflammation, and as a result the patient was able to tolerate compression therapy. The ulcer progressed to full healing on 14 November (Figure 8). For an overview of Mrs EY’s treatment, see Table 2.

During the Accel-Heal treatment, Mrs EY stated that “I could see my wound improving almost immediately and for the first time in a year I felt hopeful that it would heal”. With her ulcer now healed, Mrs EY feels that she has her life back and can “shop when I want to”.

CASE STUDY 3

Mrs DS is an 83-year-old widow who suffers from dementia but has a very supportive daughter. The patient gave consent for her daughter to explain how the ulceration affected her personally and the impact it had on their family unit. Mrs DS is an elegant woman who takes great pride in her appearance and is also a private person. She enjoys spending time with those closest to her, her daughter and her family, taking part in family outings and going out for coffee and shopping. Her daughter is married, works full time and has a grown-up son and an 11-month-old granddaughter.

Mrs DS lives independently, but depends on support from her daughter. Her daughter described the effects of her mother’s ulceration as a “living nightmare” for both her mother and the family. Mrs DS found the physical symptoms of her condition distressing and extremely stressful. The pain disturbed Mrs DS’ sleep, as “even the weight of a sheet touching the leg causes extreme pain.” The high levels of uncontrolled exudate also caused Mrs DS significant upset, with the exudate seeping through the dressings and often “into her shoes and staining her clothing.” Malodour from the ulcer, which the daughter described as “so bad that we have to open windows”, caused Mrs DS to become more withdrawn and abandon her regular trips out with her daughter. As a result, Mrs DS withdrew

from family contact, becoming a “virtual recluse” and only allowing her daughter to visit regularly. She was “extremely embarrassed by the smell” and “kept apologising” to her daughter.

The patient’s daughter said: “People didn’t realise the impact that mum’s chronic wound had on my life. Due to the care that mum needed and all the appointments, it felt like my life wasn’t my own anymore. It all revolved around mum and I was trying to juggle all my responsibilities and felt unable to get on with my own life. It placed a huge strain on my marriage and at many times I felt like I couldn’t cope anymore.

“It was awful watching mum go through this hell with no improvement; sobbing in pain, being embarrassed by the smell from her wound and withdrawing from life; and not being in position to help her in any real way was truly awful.

“Mum has always taken great pride in her appearance and was mortified when the exudate would seep through her clothes. Along with the really vile smell coming from her wound and the fact that she could not find any suitable footwear to accommodate the dressings and having to resort to wearing a pair of baseball boots, Mum’s already fragile self-confidence dwindled even further. She got to a point where she didn’t want to have contact with the wider family, missing out on seeing her baby great granddaughter, and she spent most of her time isolating herself. Her condition affected every aspect of our life as a family.”

Assessment and treatment prior to commencing Accel-Heal

Mrs DS attended her first appointment at the leg ulcer clinic on 17 September 2013 following a referral by her GP. She had a 2-year history of spontaneous ulceration in the gaiter region on her left leg which had remained unhealed and was her second episode of ulceration in 6 years. During this period, the patient underwent compression therapy but it was discontinued for reasons that remain unknown. Her wound bed was 100% slough with peri-wound oedema. Her ABPI was 0.92 and her pain was 7/10 on the VAS.

Due to the chronicity of the ulceration, treatment with Accel-Heal was discussed with the patient and her daughter and consent obtained. It was agreed

Table 3. Accel-Heal treatment summary for case study 3.

Date	Wound size (cm ²)	Pain level (Visual Analogue Scale)
4 October	10.0	7/10
8 October	8.0	4/10
11 October	7.0	1-4/10
15 October	6.0	1-4/10
22 October	4.0	1-2/10
1 November	1.0	0/10
8 November	0.0	0/10

that her daughter would be taught how to change the units every 48 hours. The main objectives for using Accel-Heal were to induce the healing process and reduce the pain.

Medical history

The patient had the following conditions:

- ▶▶ Type 2 diabetes
- ▶▶ Dementia
- ▶▶ Degenerative spondylolisthesis
- ▶▶ Diverticular disease
- ▶▶ Right partial parotidectomy
- ▶▶ Essential hypertension.

Mrs DS had been prescribed metformin 500mg twice daily, one to two co-codamol 8mg/500mg tablets four times a day, paracetamol 1g four times a day, atorvastatin 40mg at night, furosemide 40mg once daily, omeprazole 20mg once daily, amlodipine 5mg once daily, levothyroxine 10µg once daily, two to three sachets of Macrogol compound oral powder daily, two puffs of Symbicort 200/6 Turbo inhaler twice daily and 3.5-g ispaghula husk sachets. The patient had no reported allergies.

Treatment and outcome

Accel-Heal treatment was commenced on 4 October 2013 for 12 days alongside her compression therapy. On commencement, the total wound area



Figure 9. On 8 October, at the start of treatment, Mrs DS’ ulcer measured 10cm² and had a sloughy bed..



Figure 10. The wound had reduced in size by 30% 3 days after treatment with Accel-Heal had commenced..



Figure 11. By 15 October, epithelialisation tissue had formed and the wound had reduced in size by 40%.



Figure 12. Mrs DS' ulcer was fully healed within 5 weeks of starting treatment with Accel-Heal.

measured 10cm² and there was a 100% sloughy wound bed (Figure 9). On 8 October, the wound had reduced in size by 20% and granulation tissue had formed. Mrs DS reported reduced pain (4/10 on the VAS scale). By 11 October, the wound area was 30% smaller than at the start of treatment (Figure 10). The wound bed continued to develop granulation buds and decrease in size. Mrs DS' pain score had reduced to 1–4/10. On 15 October, the wound area had reduced in size by 40%, with epithelialisation tissue appearing (Figure 11). The pain score remained at 1–4/10 on the VAS. Treatment was completed on 16 October. For an overview of Mrs DS' treatment, see Table 3.

Post treatment, on 22 October, the wound area had decreased by 60% and her pain had reduced to 0–2/10. On 1 November, the wound had decreased in size by 90% and the pain had completely resolved. Full healing was achieved on 8 November (Figure 12), which was within 5 weeks of beginning treatment with Accel-Heal.

During the Accel-Heal treatment, Mrs DS' daughter stated: "It felt like we were witnessing a miracle. Mum's pain diminished and within days we could see the wound getting smaller. The exudate got less and less and wasn't smelly anymore and it was so nice to see Mum begin to enjoy life once again. With the wound now healed Mum enjoys spending time with her great-granddaughter and we can enjoy our trips out again without having to have all the car windows open, and without the stress or worry of whether the exudate will leak out again when we are out in public. I, on the other hand, feel like I have my life back now that the pressure of caring for mum's wound has gone. It's great." She added that "More needs to be done to ensure that patients, their carers, relatives and clinicians are made aware of all the treatment options available. We were lucky in the end. Wounds like Mum's ruin lives — it's not just the wound that is affected — it is the whole person that's affected, and their family as well."

CONCLUSION

Complex wounds such as leg ulcers present many challenges to health professionals. They also have a detrimental impact on the patient's emotional, physical and social wellbeing and quality of life, as the case studies have demonstrated. Advanced modalities, such as Accel-Heal, used alongside

standard treatments have been proven to promote positive clinical changes in complex wounds in these case studies as well as in previous clinical studies (Tadej et al, 2010; Griffin, 2013; Ovens, 2014). The three case studies in this paper demonstrate the clinical effectiveness of this therapy in acute cases as well as in complex wounds that have become chronic.

While significant improvement in clinical outcomes is clearly beneficial, as it removes the physical factors associated with a complex wound, the improvement in the quality of life and wellbeing of patients as a result of using advanced modalities such as Accel-Heal cannot be underestimated. Given the range of clinical and socio/psychological evidence, where appropriate, advanced modalities such as Accel-Heal should be considered for use as soon as possible if appropriate to enable patients to regain their quality of life and improve their wellbeing.

Complex wound management is not just about healing/managing the wound. It is also crucial for clinicians to ensure that all interventions address the person as a whole and are timely, appropriate and lead to improvement in overall quality of life and wellbeing.

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