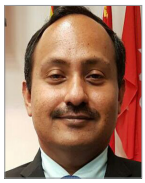
Powering the progression of hard-to-heal wounds with electrical stimulation: observational analysis of wounds treated with Accel-Heal



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Electrical stimulation therapy (EST) is known to accelerate healing and reduce the pain associated with chronic wounds. Widespread adoption of the therapy has been slow, thought to be due to the practical challenges associated with using the technology. A new, wearable, easy to use EST device designed to overcome these challenges (Accel-Heal, Accel-Heal Technologies Ltd, UK), was assessed in Malaysia, in ten patients with hard-to-heal and painful wounds. Findings support the wider literature, that EST can reduce wound pain and kick-starts the healing process, even in the very challenging wounds chosen for this evaluation.

Key words:

- *Accel-Heal*
- *Chronic wounds*
- *Electrical stimulation*
- *Wound pain*

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Globally, chronic wounds are a substantial clinical, social, and economic challenge and it is expected that the size of the burden will continue to grow as populations age, and factors that increase the risk of chronicity (e.g. obesity, diabetes) grow more prevalent (Sen, 2021). The burden of chronic wounds in South-East Asia is considerable; a study in Singapore identified that the incidence of any chronic wound was 296 per 100,000 individuals (Goh et al, 2020).

Best practice wound care, for example employment of principles like wound bed preparation (WBP; Schultz et al, 2004) and advanced wound dressings, has been widely recognised and adopted, but despite best practice, around half of chronic wounds remain unhealed after 12-months of treatment despite receiving standard care (Guest et al, 2020). New technologies are needed to improve outcomes that can be adopted in addition to the basic standards of wound care. However, other than the advent of negative pressure wound therapy (NPWT), no transformative technologies have been widely adopted over the past several decades (Fletcher, 2021).

One treatment modality with great potential is electrical stimulation therapy (EST). Movement of electrical charge, in the form of ions, predominantly calcium (Ca^{2+}), chloride (Cl^{-}), potassium (K^{+}) and sodium (Na^{2+}), present in blood and interstitial tissues, is a basic tenet of human physiology that drives bioelectric cell signalling (Milne et al, 2021). EST is designed to harness the ability of cells to recognise and respond to electrical charge, to drive a healing response via healing-related bioelectric signalling processes (McCaig et al, 2005). In normal wound healing, any break in the epidermis causes a small 'current of injury', (i.e., flow of ions from positively charged areas to negatively charged areas), which skin cells respond to by activating healing behaviours, such as proliferation, migration, growth factor production and collagen production (Martin-Granados and McCaig, 2014; Hunckler and de Mel, 2017, Milne et al, 2021). The current of injury can dissipate over time, meaning that in a chronic wound, this aspect of the body's healing mechanism may no longer be functional. By applying an appropriate electrical current to the wound, in the form of EST, there is evidence that the inflammatory phase, proliferative phase and remodelling phases of healing can be stimulated (***Figure 1***; Martin-Granados and McCaig, 2014; Hunckler and de Mel, 2017; Milne et al, 2021).

The clinical benefits of EST have been widely explored in numerous randomised controlled trials (RCT), the data from which have been analysed in a series of meta-analyses. Results widely agree that EST improves wound-related outcomes in hard-to-heal wounds (Barnes et al, 2014; Lala et al, 2016; Girgis and Duarte, 2018; Chen et al, 2020; Arora et al, 2020; Avendaño-

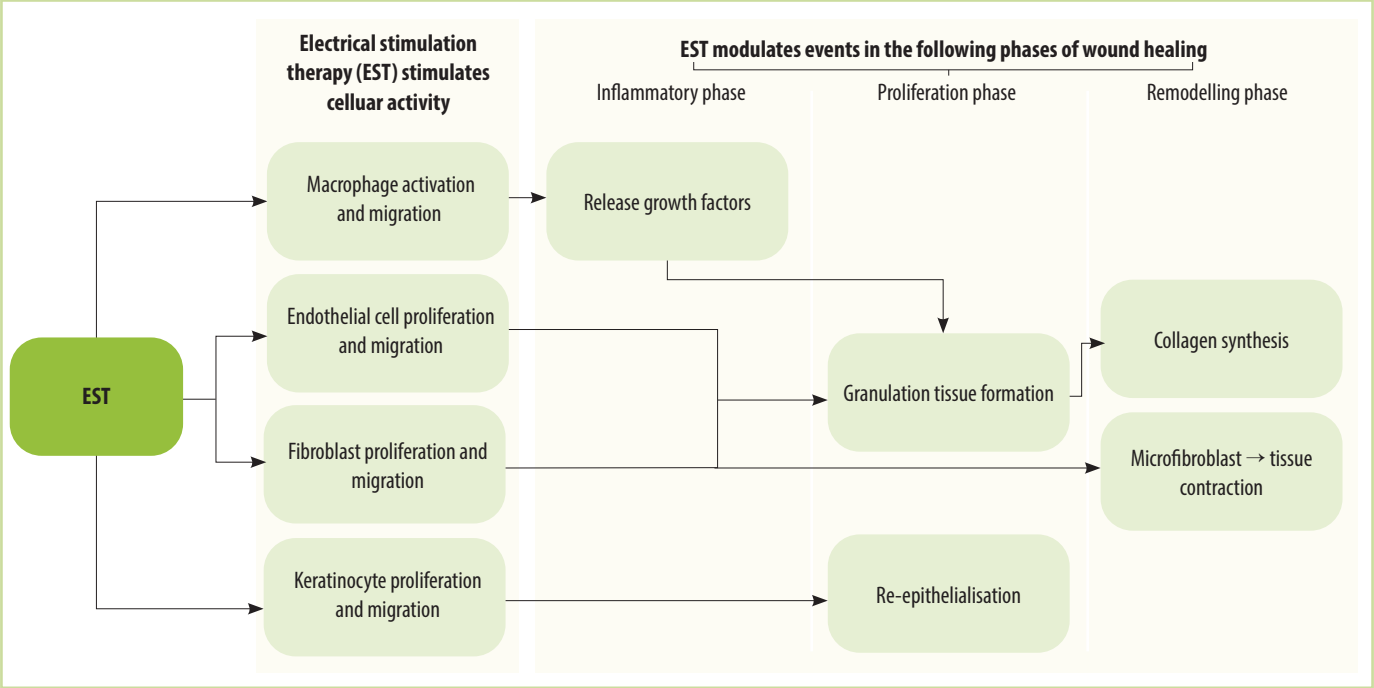

Figure 1. The role of electrical stimulation therapy (EST) in wound healing. In a wound environment, EST can stimulate cellular activity that is relevant to many stages of wound healing. In the inflammatory phase, EST can activate macrophages and stimulate the production and release of growth factors. In the proliferative phase, EST can stimulate the proliferation and migration of many cell types including fibroblasts, endothelial cells and keratinocytes, important for the angiogenesis, granulation tissue formation and re-epithelialisation. In the remodelling phase of healing, EST can stimulate collagen matrix formation as well as wound contraction and cellular differentiation, and organisation of the extracellular matrix (McCaig et al, 2005; Martin-Granados and McCaig, 2014; Hunckler and de Mel, 2017; Milne et al, 2021)

Coy et al, 2021). However, despite this clinical efficacy, the technology has not been widely adopted to date. This is thought to be because in the past, EST has been delivered via large and complex devices, and was designed to be delivered during wound dressing changes in a clinic or hospital setting. This made the technology inconvenient for both patients and healthcare professionals (Piaggesi et al, 2018; Atkin et al, 2020). Another possible reason is that EST is a generic term that covers a wide range of electrical stimuli. Some devices deliver stimuli that are unpleasant or even painful for patients (e.g. pins and needles sensation) making patients less willing to comply with treatment regimes (Draper et al, 2012; Atkin et al, 2020).

Many existing devices are complex to set up, with multiple varying treatment options making application difficult (Piaggesi et al, 2018).

A new EST device (Accel-Heal, Accel-Heal Technologies Ltd, Kent, UK), designed to overcome these barriers to adoption, is now available in Malaysia, having been available in Europe for several years. This device delivers an uninterrupted, pre-programmed, subsensory electrical stimulation for a treatment duration of 12-days with the intention that it can be managed by patients in their own homes (Atkin et al, 2020). It is a wearable device, designed to be used within existing wound care pathways and along-side standard and advanced wound dressings for a 12-day treatment duration; it

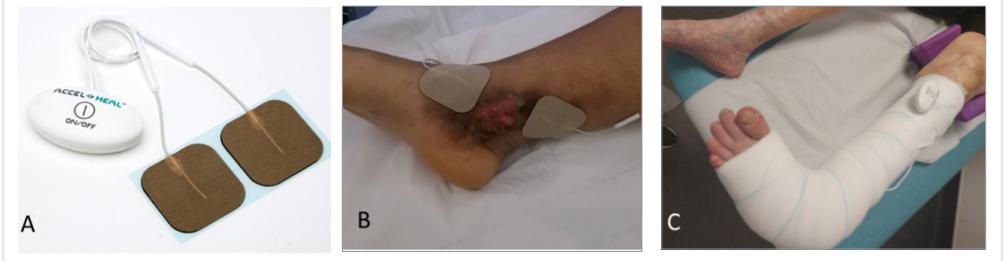

Figure 2. Accel-Heal device. The Accel-Heal device and electrode pads (A) can be applied to periwound skin (B). Usual wound dressings can then be applied (C).

can be used underneath compression stockings and bandages and does not impede the use of advanced wound dressings (*Figure 2*). Because it is subsensory, patients typically cannot feel any sensation when it is applied. The treatment is designed to kick-start healing in otherwise non-healing wounds. After the 12-day treatment period, during which time wounds are typically expected to improve, progression continues for several subsequent weeks.

Aim

The objective of this study was to evaluate the effect of Accel-Heal on a series of patients with complex, painful, non-healing chronic wounds, and specifically to monitor changes in wound pain and wound dimensions in response to the treatment. Specifically, an observational assessment was undertaken to explore the efficacy of Accel-Heal on wounds with different characteristics; challenging hard-to-heal wounds (large, highly complex, infected and sloughy) and clean, well-prepared hard-to-heal wounds.

Methods

A non-comparative, observational study was undertaken in Kuala Lumpur General Hospital in Malaysia, using a portable EST device (Accel Heal, Accel-Heal Technologies Ltd, Kent, UK) for patients with stalled wounds.

The Accel-Heal device was applied for the 12-day treatment cycle alongside standard therapy according to local protocol. In some cases, where it was deemed of clinical value, or where patients specifically requested a continuation of EST, additional 12-day Accel-Heal treatments were permitted. Outcome measures relating to wound dimensions (maximum length, width and depth) and wound pain (measured using the numerical visual analogue score (VAS) 0–10 scale, where a score of zero indicated no pain and a score of 10 indicated the worst possible pain) were recorded at baseline (immediately before the first application of the device) 1-week and 2-weeks after initiation of therapy and at one other follow up visit; this last visit could occur at varying intervals as deemed clinically appropriate.

All patients had very challenging wounds (large, often of long duration) with high levels of wound pain at baseline. Initially, patients in whom the process of WBP was on-going, but where a clean wound bed had not yet been achieved, were chosen for treatment; six such patients were categorised as group 1. We subsequently hypothesised that patients may benefit to a greater extent from EST if a clean and well-prepared wound bed could be achieved before EST was applied, and that multiple applications of EST may extend or improve pain remission and accelerated healing. This approach was adopted for four patients, categorised as group 2, all of which had 'clean', well-prepared wounds at baseline and who were given two successive 12-day cycles of EST treatment, sometimes with a short gap in between.

Data analysis

Wound area (length x width) and wound volume (area x depth) were calculated at baseline and all subsequent time points and reduction was calculated as a percentage of baseline dimensions. For wound pain, where a range in pain was reported by the patient for example 6–7, a mid-point was used i.e. 6.5.

Because of the relatively small numbers of patients in this assessment, any comparisons between sub-groups were considered to be purely observational. As this was a non-comparative observational study, no comparison group was available to compare outcomes with. In lieu, the change in wound area was assessed against a widely adopted benchmark that states that a 10-15% reduction in wound area per week (or approximately 50% over 4-weeks) is representative of good progress (Lavery et al, 2008; Gottrup et al, 2010).

Results

Patients

We evaluated 10 patients, each with one wound. Demographic and wound details are shown in *Table 1*. The majority of patients (n=7) were female; 80% of wounds had been present for between 2–7 months. The majority of patients (n= 8) had comorbidities, including diabetes, hypertension, heart disease and renal transplant.

Various chronic wound aetiologies were represented in the study. Of the wounds six (60%) were diabetic foot ulcers (DFU) and two (20%) were venous leg ulcers (VLU), where the patients received compression therapy as part of their treatment. One wound was a surgical foot wound following orthopaedic surgery for a leg lengthening procedure, needed as a result of an accident which had occurred 20 years previously and one wound developed to the shin following cellulitis and was further complicated by diabetes and hypertension. The wound was deep and punched out with periwound oedema.

Treatment with Accel-Heal

All ten patients received at least one application

Table 1. Patient demographics and wound characteristics at baseline		
Demographics	Female, n (%)	7 (70)
	Age, years, mean (range)	61 (38–84)
Comorbid conditions	Any comorbidity, n (%)	8 (80)
	Diabetes Hypertension Renal transplant Heart disease	7 4 1 1
Wound characteristics	Wound duration, months, mean (range)	12 (2–72)
	Wound aetiology, n (%) Diabetic foot ulcer Venous leg ulcer Postsurgical Cellulitis	 6 (60) 2 (20) 1 (10) 1 (10)
	Mean area, cm^2 (range)	66.4 (5.3 – 133.0)
	Mean wound pain, visual analogue scale (VAS; range)	6.8 (10 – 4.0)

Table 2. Wound-related outcomes at baseline, week 1, week 2 and follow up

Group*	Patient	Indication	Wound area, cm^2 (% reduction from baseline)				Wound pain, visual analogue scale (% reduction from baseline)			
			Baseline	Week 1	Week 2	Follow-up	Baseline	Week 1	Week 2	Follow-up
1	1.1	DFU	133.0 (100.0)	114.0 (14.3)	120.3 (9.6)	42.0 (68.4)	8.5 (100.0)	6.5 (23.5)	6.0 (29.4)	0 (100.0)
	1.2	VLU	132.0 (100.0)	110.2 (16.5)	82.5 (37.5)	102.0 (22.7)	6.0 (100.0)	4.5 (25.0)	4.5 (25.0)	1 (91.7)
	1.3	DFU	105.0 (100.0)	97.5 (7.1)	95.0 (9.5)	40.0 (61.9)	4.0 (100.0)	2.0 (50.0)	2.0 (50.0)	1 (75.0)
	1.4	DFU	48.1(100.0)	25.0 (48.1)	24.0 (50.0)	0.5 (99.0)	7.0 (100.0)	5.0 (28.6)	5.0 (28.6)	0 (100.0)
	1.5	DFU	27.0 (100.0)	27.0 (0.0)	18.0 (33.3)	10.5 (61.1)	5.0 (100.0)	0.0 (100.0)	0.0 (100.0)	0 (100.0)
	1.6	VLU	31.2 (100.0)	–	31.2 (0.0)	16.5 (47.1)	5.5 (100.0)	–	4.0 (27.3)	1 (81.8)
	Mean (%)		**79.4 (100.0)**	**74.7 (5.9)**	**61.8 (22.1)**	**35.3 (55.6)**	**6.0 (100.0)**	**3.6 (40.0)**	**3.6 (40.3)**	**0.4 (93.1)**
2	2.1	Cellulitis	5.3 (100.0)	5.3 (0.0)	3.0 (42.9)	2.5 (52.4)	6.5 (100.0)	2.5 (61.5)	1.0 (84.6)	1 (84.6)
	2.2	DFU	93.5 (100.0)	52.3 (44.1)	34.5 (63.2)	17.0 (81.8)	8.0 (100.0)	5.0 (37.5)	5.0 (37.5)	3 (62.5)
	2.3	DFU	82.5 (100.0)	45.5 (44.8)	36.0 (56.4)	22.0 (73.3)	10.0 (100.0)	5.0 (50.0)	3.0 (70.0)	4 (60.0)
	2.4	Postsurgical	6.0 (100.0)	5.0 (16.7)	4.0 (33.3)	2.7 (55.0)	7.0 (100.0)	0.0 (100.0)	0.0 (100.0)	0 (100.0)
	Mean (%)		**46.8 (100.0)**	**27.0 (26.4)**	**19.4 (48.9)**	**11.1 (65.6)**	**7.9 (100.0)**	**3.1 (60.3)**	**2.3 (71.4)**	**2.0 (74.6)**
Overall (n=10)	**Mean (%)**		**66.4 (100.0)**	**53.5 (21.3)**	**44.8 (33.6)**	**25.6 (62.3)**	**6.8 (100.0)**	**3.4 (49.8)**	**3.1 (54.8)**	**1.1 (84.4)**

DFU=diabetic foot ulcer; VLU=Venous leg ulcer; *Some patients had more than one comorbidity

of Accel-Heal, while four patients received two, consecutive, 12-day cycles of Accel-Heal, as opposed to a single cycle. All assessments were carried out for all patients with no missing data, including baseline, week 1, week 2 and final (follow-up) assessments. The final assessment was carried out at different time points as convenient to both patient and the healthcare professionals. Follow-up data were obtained between 5–16 weeks, with a mean of 12 weeks. No adverse effects were observed that were linked to treatment with Accel-Heal. After the end of their first session of EST and because of the excellent progress made, three patients specifically requested to receive additional rounds of therapy. No patients asked to be removed from the therapy.

Wound outcomes

Wound-related outcomes for all patients are shown in *Table 2*. The change in wound area was measured at baseline, week 1, week 2 and at one further follow-up visit that took place on average 12 weeks after the start of the study. Wound area reduced from an average of 66.4cm^2 at baseline to 53.5cm^2 at the end of week 1, 44.8cm^2 by the end of week 2 and 25.6cm^2 by the final follow-up assessment.

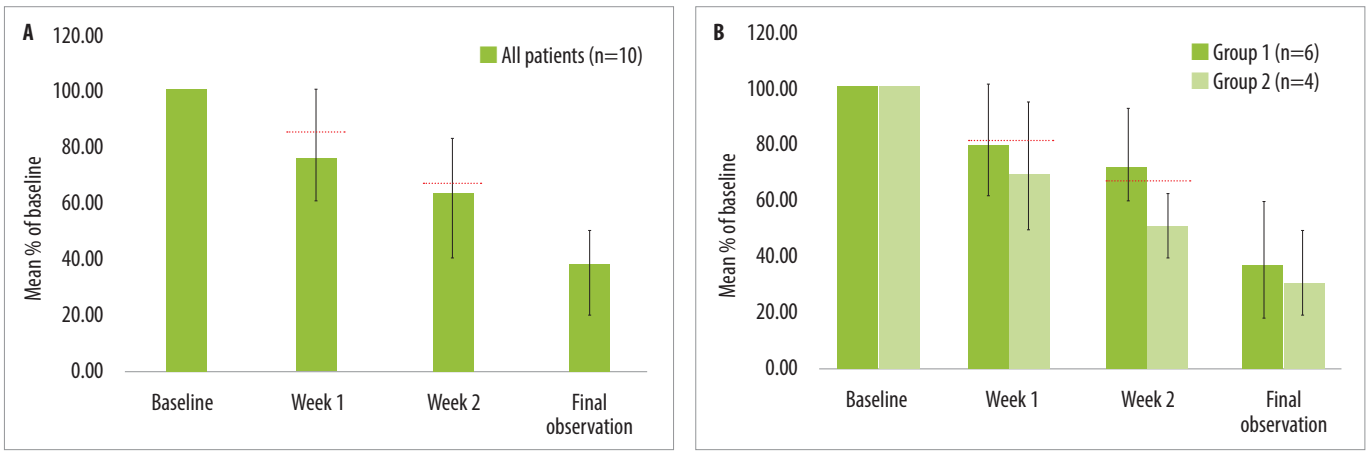

Figure 3. Reduction in wound area following treatment with Accel-Heal. All patients represented in A (n=10); groups 1 (n=6, in whom wound bed preparation was not complete) and 2 (n=4, well prepared, clean hard-to-heal wounds) represented in B. ± standard deviation. Dotted line represents a 15% reduction per week in wound area, the benchmark against which wound progress is commonly assessed (Lavery et al, 2008; Gottrup et al, 2010)

The mean percentage change in wound area was calculated, compared with baseline (100%). Results are shown in *Figure 3*. Within the first week, wound area reduced in size by 21.3% and by around a third within 2-weeks (33.6%). At both of these time points, the weekly, average reduction in wound area had exceeded the 15% per week benchmark, commonly agreed to denote a good level of progress per week (Gottrup et al, 2010) (as denoted in *Figure 3* by the dotted line). On average, by the time of the final follow up assessment, wound area had reduced by nearly two-thirds (62.28%).

When patients in group 1 and 2 were evaluated separately (*Figure 3B*), there appeared to be a slightly larger reduction in wound area in the wounds which were clean and well-prepared before treatment with Accel-Heal (group 2; *Figure 3B*). The average wound area reductions for this subset at week 1 and week 2, exceeded the benchmark of 15% per week wound area reduction. However, the wound size reduction was slightly less marked for patients in group 1 (with highly complex and suboptimally prepared wounds). In this group, average wound area reduction achieved >15% reduction overall in the first week of treatment, but not in the second week of treatment. No robust conclusions can be drawn because of the very small numbers of patients in these subgroups.

Within the whole cohort (n=10), at baseline, overall wound pain was 'high' with a mean pain score of 6.75 (out of a maximum of 10, *Figure 4A*); 7/10 patients reported a 'high' pain score at this time point (defined as ≥6 out of 10; *Table 2*). Wound pain was markedly

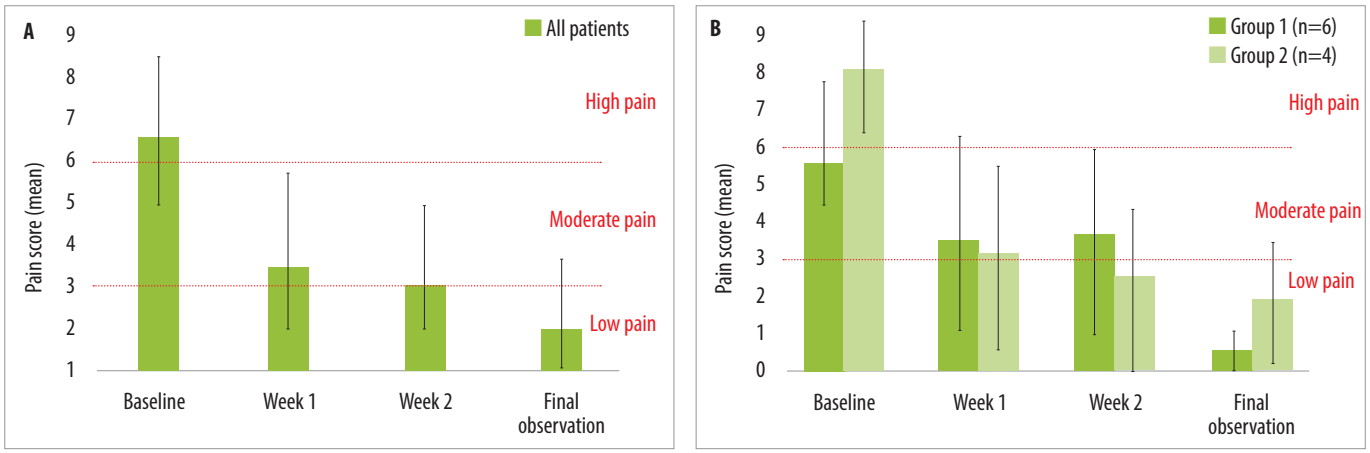

Figure 4. Wound pain following treatment with Accel-Heal. Measured using the visual analogue scale VAS (0–10) scale. All patients represented in A (n=10); groups 1 (n=6, in whom wound bed preparation was not complete) and 2 (n=4, well prepared, clean hard-to-heal wounds) represented in B. ± Standard deviation. Dotted line represents categories of high (6–10), moderate (3–6) and low/no (0–3) pain

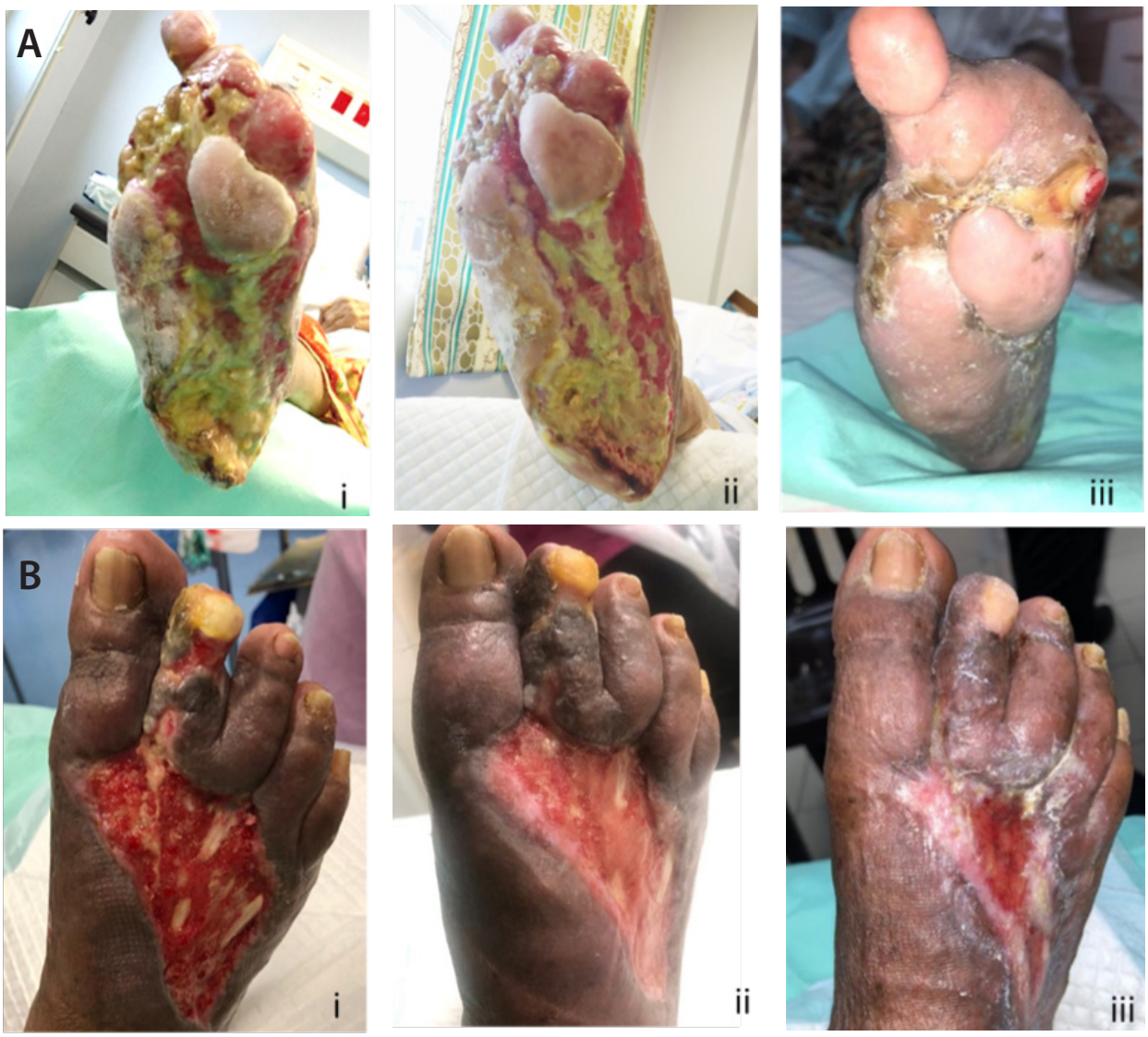

Figure 5. Case studies, showing wound images at baseline (i), after Accel-Heal treatment (ii) and at the final follow-up visit (iii). A – Patient 1.1 was an 80-year old female receiving treatment for an extensive and painful diabetic foot ulcer (DFU), measuring 133cm^2 in area, who reported a pain score of 8.5/10 at the beginning of treatment with Accel-Heal (Ai). Wound condition improved after 2-weeks and pain was reduced (Aii). The final visit was 14-weeks after baseline, at which point wound pain was 0 and wound size was 42cm^2, a 68% reduction (Aiii). B – Patient 2.2 was a 72-year-old female with an extensive and painful DFU, measuring 94cm^2 in area and a pain score of 8/10 at the beginning of treatment (Bi). This patient had two sequential 12-day cycles of treatment with Accel-Heal, after which a marked reduction in wound size (to 35cm^2) and reduction in wound pain (to 5/10) was observed (Bii). The final visit was 13-weeks after baseline, at which point wound pain was 3 and wound size was 17cm^2, an 82% reduction compared with baseline (Biii).

reduced within the first week of application of Accel-Heal (*Figure 4A*). By the end of the first week wound pain halved to an average score of 3.4, representing a 49.8% reduction. Wound pain dropped further to 3.1 (a 54.8% reduction compared with baseline) by the end of the second week. This represents an overall reduction in wound pain from high to moderate within 1 week of treatment that further improved by week 2 (*Figure 4A*). This reduction in pain was maintained over subsequent weeks with mean pain levels at the follow-up assessment reported as 1.1 (categorised as 'low' as denoted by the dotted line in *Figure 3A*); at this time point, 4/10 patients reported no wound pain (score of 0; *Table 2*). One patient with a pain score of 8.5 at the start of therapy, had their pain score reduced sufficiently so that they were able to stop taking regular tramadol and paracetamol and needed only occasional

paracetamol. One patient with a pain score of 10 at the start of therapy, had their pain score reduced to 3 on completion of the therapy.

Analysis of the pain scores in groups 1 and 2 showed that overall, patients in both groups showed meaningful reductions in wound pain during the Accel-Heal treatment (*Figure 4B*). Patients in group 2, may have experienced a more marked reduction in wound pain; the baseline scores in this group were higher than in group 1 and pain scores throughout subsequent treatment fell, overall, to 'low' levels (mean 2.3 by week 2). The low numbers in these subgroups mean that it is not possible to draw robust conclusions.

Figure 5A shows a patient from group 1, where WBP was incomplete at the point when Accel-Heal was applied. An 80-year-old female with diabetes mellitus and hypertension was diagnosed with an extensive DFU of her right foot, which had been present for 5 months and measured 133cm^2. At baseline, the wound was pale yellow and sloughy and producing large volumes of foul, purulent exudate. Antibiotics were prescribed. Wound pain was 8–9/10 requiring pain relief (tramadol and paracetamol) on a daily basis. Accel-Heal was commenced for 12-days and was applied along-side a charcoal/silver based primary dressing (Vliwaktiv Ag Wound Dressing, Lohmann Rauscher) and a hydrogel dressing (Hylogel, Mil Laboratories Pvt Ltd). At the 2-week time point, wound pain had reduced to 6 and the patient now no longer required tramadol to manage the pain. A small decrease in wound size was observed at this stage, to 114cm^2 but the condition of the wound was much improved. The patient was followed up to 14-weeks following baseline. By the end of the follow-up period, wound pain had reduced to 0 and the patient only needed to take paracetamol occasionally. A good healing rate was observed, with 68.4% of the baseline area healed.

Figure 5B shows a patient from group 2, whose wound was clean before commencement of treatment with Accel-Heal. A 72-year-old female with diabetes mellitus and hypertension was referred to the wound care unit for non-healing sloughy wound DFU on the right foot with a duration of 2 months. At baseline, the wound was red and granulating with minimal slough, moderate, serous exudate level, with no odour, and measured 93.5cm^2. The patient reported a pain score of 8/10. Accel-Heal was initially applied along-side an organic wound ointment (Wound Kreme, Feuilleorganix Sdn Bhd, Malaysia) and a low adherence secondary dressing (Melolin, Smith & Nephew, Hull, UK). Within one week of treatment with Accel-Heal, wound pain had reduced to 5/10 and the wound area had reduced to 52cm^2. This patient was treated with 2 cycles of Accel-Heal. After both treatment cycles had completed (3 weeks from baseline, *Figure 5Bi*) the wound size had more than halved (34cm^2), wound pain had reduced further to 3/10 and the wound condition had improved, with healthy granulation tissue, epithelialisation and minimal exudate reported. This patient was followed up for a total of 13-weeks post-baseline. By the end of this follow-up period wound size had reduced to 17cm^2, a reduction of 82% compared with baseline and wound pain had reduced to 3/10.

Discussion

The effect of EST on wound healing has been shown in a number of high quality RCTs that have been amalgamated in several meta-analyses (Barnes et al, 2014; Lala et al, 2016; Girgis and Duarte, 2018; Chen et al, 2020; Arora et al, 2020; Avendaño-Coy et al, 2021). Briefly, compared with standard wound care, EST has been shown to decrease wound area (Barnes et al, 2014; Girgis and Duarte, 2018; Avendaño-Coy et al, 2021), accelerate healing (Arora et al, 2020; Chen et al, 2020), increase chance of healing (Lala et al, 2016; Girgis and Duarte, 2018) and decrease wound pain (Avendaño-Coy et al, 2021). The reason why this technology has not been more widely adopted in daily practice is believed to be due to practical obstacles to its use, such as complexity of devices, the need to periodically remove wound dressings to apply EST and treatment via clinic-based devices which is inconvenient for both patients and clinicians (Piaggesi et al, 2018; Milne et al, 2021).

This is believed to be the first published record of the use of this EST device in Asia. Overall results showed positive outcomes associated with the use of the device. The average reduction in wound area within the first week of treatment was 21%, increasing to 34% by the end of the second week. A commonly used benchmark to assess wound progress, is whether a wound has decreased in area by more than 10–15% per week (Lavery et al, 2008). The fact that, on average, wounds treated with Accel-Heal performed well against this benchmark, in the first 2 weeks of treatment, is positive and is evidence to suggest that Accel-Heal may be able to kick-start the healing process. These observations are consistent with previously published studies that have reported that over 80% of non-healing wounds treated with Accel-

Heal go on to Heal within 20-weeks after one 12-day treatment with Accel-Heal, subsequently stepped down to standard wound care (Turner and Ovens, 2017; Ovens, 2018).

In this evaluation, data relating to wound pain was also captured. Wound pain can be a major burden to patients and a major barrier to compliance with standard wound treatments. Over two-thirds of people living with a chronic wound have reported that wound pain is the worst aspect of their condition (Hofman et al, 1997). Wound pain can reduce quality of life, mental health, quality of sleep as well as impacting on mobility (Atkin et al, 2020). Wound pain can also affect the chance of wound healing; pain can be a reason for non-compliance to some gold standard treatments such as compression, or other wound treatments and failure to comply to gold standard treatments is likely to reduce the likelihood of healing (Atkin et al, 2020). In this cohort of highly painful wounds, pain was managed quickly and effectively; overall, wound pain was found to be halved within the first week of treatment with Accel-Heal, reduced from an average score of 6.8, out of a maximum score of 10, classed as 'high' pain, to an average score of 3.4, classed at the lower end of 'moderate' pain, after one week of treatment with Accel-Heal. After the second week of treatment, wound pain decreased further to an average of 3.1/10 and that this was maintained after the end of the 12-day treatment programme with very low levels of pain (1.1/10) being reported at the end of the follow up period. The ability of EST to reduce wound-related pain has been previously reported (Milne et al, 2021), including in studies that specifically investigated the effects of Accel-Heal (Turner and Ovens, 2017; Guest et al, 2018). Turner and Ovens (2018) reported that wound-related pain reduced by 83% within 2-weeks of starting treatment with Accel-Heal, from a mean VAS score of 6.9 to 0.9; these values represent a clinically meaningful reduction in pain (Turner and Ovens, 2017). The reduction in wound-related pain observed after starting treatment with EST has been previously reported to have a major impact of patient quality of life (Milne et al, 2021). While the evaluation described here did not explore the impact of treatment of quality of life, we did observe a reduction in the amount of analgesia needed to control wound pain, in some cases a complete cessation of painkillers like tramadol.

The initial hypothesis was to explore the effect of Accel-Heal on some of the most challenging wounds in the clinic. Following encouraging outcomes in the first six patients, with wounds that had not achieved ideal WBP, a new hypothesis was explored — if good wound bed preparations were made before application of the first therapy, then multiple applications of EST may extend or improve pain remission and accelerated healing. Good outcomes were also reported in this second group; although the small numbers involved make it difficult to draw robust conclusions, this approach merits further exploration.

Limitations

This study had several limitations: firstly, the relatively small size and non-comparative nature of the study means that any conclusions made regarding the efficacy of the device can only be considered observational. Secondly, data captured at follow-up varied in terms of the timing of the follow up assessment, which varied from week 5 to week 16 after the initiation of Accel-Heal treatment. These follow-up assessments were pooled, which may be a confounding factor when interpreting these data, given that wounds would have progressed to different extents at these different timepoints.

Conclusions

Outcomes from this single-centre, observational study, are believed to be the first published use of Accel-Heal in Malaysia. This study supports the use of EST to kick-start healing and relieve pain in a wide range of hard-to-heal wound types including DFUs, VLUs and postsurgical wounds. Pain was managed quickly and effectively. The use of two sequential 12-day treatment cycles is a new concept with great potential that requires further exploration. Further high-level clinical evidence is needed to further investigate the impact of Accel-Heal on a range of hard-to-heal wounds. WAS

Declaration of interest:

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