

Electrical stimulation therapy for wound-related pain: a WHAM evidence summary

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CLINICAL QUESTION

What is the best available evidence for electrical stimulation therapy (EST) for reducing wound-related pain?

SUMMARY

Electrical stimulation therapy is a biophysical modality through which an electromagnetic current is delivered to the wound with the intention of promoting wound healing. The electrical current is thought to influence healing by increasing blood flow to the wound bed. *Level 1* evidence¹⁻⁴ indicated mixed results for EST applied via microcurrent amplitudes using various electroceutical devices in reducing wound-related pain. In some studies, EST was associated with statistically significant reduction in wound-related pain.^{1, 4} In other studies, there was no significant difference in impact on pain of EST versus placebo or standard care.^{2, 3} The evidence was generally at moderate-to-high risk of bias, pain scores were often not high at baseline,¹ and the level of pain reduction achieved was of questionable clinical significance in some studies.^{1,4} Only one study³ used a multidimensional pain assessment tool and none of the studies included pain assessment techniques that might identify nociceptive pain. *Level 3 and 4* evidence from observational studies reported benefits of EST for wound-related pain.⁵⁻⁷ Using EST as an adjunct to best practice wound treatment is associated with improved wound healing outcomes,⁸ and this might contribute to reduction in wound-related pain for some people.

CLINICAL PRACTICE RECOMMENDATIONS

All recommendations should be applied with consideration to the wound, the person, the health professional and the clinical context.

There is insufficient evidence to recommend electrical stimulation therapy primarily to manage wound-related pain. Pain management might be experienced when using electrical stimulation therapy to promote wound healing in hard-to-heal wounds that have not responded to best practice wound treatment.

SOURCES OF EVIDENCE

This summary was conducted using methods published by the Joanna Briggs Institute.⁹⁻¹² The summary is based on a systematic literature search combining search terms related to wounds and EST. Searches were conducted in Embase, Medline, Cochrane Library and Google Scholar with inclusion limited to evidence published from January 2013 to December 2023 in English. Levels of evidence for intervention studies are reported in the table below.

BACKGROUND

Electrical stimulation therapy involves applying an electrical current to the wound. The current is generally generated by a battery-type device at various electrical frequencies, amplitudes, polarities, and either in a direct, alternating or pulsed (monophasic or biphasic) current. The electrical

Level 1 evidence	Level 2 Evidence	Level 3 Evidence	Level 4 Evidence	Level 5 Evidence
Experimental designs	Quasi-experimental Designs	Observational – Analytic Designs	Observational – Descriptive Studies	Expert Opinion/ Bench Research
1.a Systematic review of RCTs ^{13, 14} 1.b Systematic reviews of RCTs and other designs ^{15, 16} 1.c RCTs ¹⁻⁴	None	3.e Observational study without control group ^{5, 6}	4.c Case series ^{7, 17}	5.a Expert consensus and literature reviews ^{18, 19}

stimulation is applied by placing at least two electrodes on the skin (with at least one applied to either the wound bed or the peri-wound skin) to conduct the electrical current through the wound tissue.

Electrical stimulation therapy can be broadly categorised based on the response the amplitude elicits in the individual. Higher amplitudes (300-400 milliamps [mA]; e.g. electrical muscle stimulation [EMS]) generate a motor response (e.g., muscle contraction); however, this level of stimulation is generally not required in wound care.¹⁸ Electrical stimulation therapy at an amplitude of 150-250 mA (e.g., trans-epidermal nerve stimulation [TENS]) leads to a sensory response (e.g., tingling or prickling) and at less than 100 mA the stimulation is sub-sensory (i.e., the recipient does not sense the stimulation).¹⁸ Sub-sensory electrical stimulation at the lowest of amplitude (e.g., below 60 mA) is referred to as microcurrent stimulation.¹⁸ Most EST is delivered in sessional treatments and using a range of regimens (regularity, duration, etc.).

Electrical stimulation therapy is used to promote wound healing and to reduce wound pain. The mechanism through which electrical current might promote wound healing is suggested to be promoting increased blood flow and reducing tissue oedema, which positively influences tissue oxygenation and cell proliferation.^{13, 19, 20} Any reduction in wound pain that might be achieved is likely to be associated with the stimulation of cell activity and reduction in tissue oedema that leads to wound healing.^{18,19} Because higher amplitude EST elicits motor response and sensations that are often described as tingling or uncomfortable, EST at lower amplitudes (i.e., TENS or microcurrent stimulation) is more often associated with pain relieving outcomes.¹⁸

CLINICAL EVIDENCE

The best clinical evidence on EST used to address wound-related pain comes from small trials that investigate electroceutical devices delivering microcurrent EST directly to the wound bed. The studies assessed pain using a unidimensional pain assessment tool to evaluate pain intensity or severity. Only one study³ also included a multidimensional pain assessment tool, and none of the studies included an evaluation of pain quality that might identify characteristics of nociceptive, neuropathic and or mixed pain experience. The different regimens are summarised in Table 1. *Level 1* evidence comes from four RCTs¹⁻⁴ with mixed findings on the impact of EST on pain:

- An RCT³ at low risk of bias compared EST to placebo therapy for VLU, with pain as one of the patient-reported outcome measures. The EST was applied with an electroceutical device (Accel-Heal) for 12 days, with outcomes measured at various intervals up to 24 weeks for the 90 participants. There were no statistically significant differences in visual analogue scale (VAS) scores or McGill Pain Questionnaire scores at any time

point between people who received the EST device and those receiving a placebo device. Mean pain scores decreased over time in both groups³ (*Level 1*).

- An RCT¹ at moderate risk of bias found a significant effect for Frequency, Rhythmic Electrical Modulation System (FREMS) in reducing pain associated with chronic leg ulcers (n = 60, different aetiologies). The FREMS EST was applied via electrodes at five different locations on the lower limb, including the peri-wound skin. Pain intensity was measured at 2-week intervals using a 0-10 mm VAS. Compared with no treatment, the FREMS regimen was associated with a significantly greater reduction in VAS scores, with statistical significance noted for all time intervals after the first treatment cycle¹ (*Level 1*). However, the mean pain intensity score was 3 mm at study commencement, suggesting pain was not a major concern for the participants.
- Another small RCT² at moderate risk of bias explored EST for managing pain at skin graft donor sites. The EST was applied using the Neurodyn High Volt (IBRAMED) device. Participants (n = 30) received either EST or sham therapy. Pain was measured using a VAS (score 0-10) before and after treatment, each day for 7 days. The same pain experience pattern was observed in both groups, with pain intensity at its highest immediately following donor site harvest and decreasing over time, to a negligible pain level at day 3 in the EST group and by day 7 in the sham therapy group² (*Level 1*).
- An RCT⁴ at high risk of bias explored pulsed EST using an electroceutical device (Dermapulse®). Participants with VLUs (n = 39) of at least 3 months' duration received either the EST or placebo therapy. Pain was scored monthly using a 5-point scale. At month 4 there was a statistically significant (p = 0.049) difference in pain reduction between the groups, favouring the EST⁴ (*Level 1*). However, the average reduction in pain was approximately 1-point on the scale, which might not have been clinically significant.

Four observational studies^{5-7, 17} provided additional evidence that EST can reduce wound pain, but this evidence is at moderate-to-high risk of bias, the studies are small and positive results are sometimes negligible:

- A cost effectiveness study⁵ at high risk of bias compared clinical and cost outcomes for people with chronic venous leg ulcers (VLUs, n = 30) over the 12 months prior to EST and 12 months with EST added to the standard regimen. The EST was applied with an electroceutical device (Accel-Heal). Pain scores on a 0-10 VAS after 12 months of EST significantly decreased (mean pain score before therapy 3.6, 95% confidence interval [CI] 2.4 to 4.8 versus mean pain score after therapy 0.63, 95% CI 0 to 1.3, p < 0.001)⁵ (*Level 3*). However, there was no control for change over time that might be expected over 12 months of treatment.

Table 1. Electrical stimulation therapy regimens

Study	Amplitude	Description of therapy	Regularity and frequency	Session duration	Pain assessment
Gomes 2018 ²	Microcurrent: 50–1,000 mA	Cathodic stimulation, frequency of 100 Hz, twin pulse monophasic, individualised dosage (minimum 100 V)	Daily for 7 days	50 minutes	Pain intensity using VAS (0 to 10)
Guest 2018 ³	Not stated	Pre-programmed electroceutical device	6 active units of therapy (each unit for 2 days) for 12 days	Continuous	Multidimensional evaluation (sensory intensity, cognitive pain evaluation and emotional impact of pain) using McGill Pain Questionnaire Pain intensity using VAS (0 to 10)
Guest 2015 ⁵	Microcurrent: 40–500 µA	Pre-programmed electroceutical device at frequency from 10–900 Hz	6 active units of therapy (each unit for 2 days) for 12 days	Pre-programmed in device	Pain severity using a 10cm horizontal VAS
Jünger 2008 ⁴	Microcurrent: 300 µA	Low frequency (128 Hz) pulsed current using an electroceutical device	Twice daily for 10 days	30 minutes	Sense of pain measured on a five-point scale (from 0 for no pain to 5 for very strong pain)
Leloup 2015 ⁶	Microcurrent: up to 300 µA	Low-voltage, monophasic, pulsed current with either positive or negative polarity	Pre-programmed in device, twice daily for 7-9 days	Pre-programmed in device, 20–30 minutes	Level of pain on a numerical rating scale (NRS)
Magnoni 2013 ¹	Set to individual tolerance	Biphasic, asymmetric pulse with negative voltage spike (–300 V) of short duration (10–100 µsec)	Three times per week (i.e. 6 sessions in a 2-week block). Consecutive cycles, each cycle for 4 weeks (2-week treatment followed by 2-week rest); repeated until healed (usually 1–2 cycles)	At least 20 minutes	Pain intensity using a 0–10mm VAS with a 10-point Likert scale (0 = no pain and 10 = worst pain imaginable)
Nair 2018 ⁷	Microcurrent: 0–1200 µA, set to individual tolerance	Pulsed high voltage (20–500 V)	Weekly in the clinic then three times daily in the home for a total of 4 weeks	20 minutes	Pain intensity using VAS (0 to 10)
Ovens 2019 ¹⁷	Not stated	Pre-programmed electroceutical device	Unknown frequency for 12 days	Not stated	Pain intensity using a VAS (scores not defined)

• In an observational study⁶ at high risk of bias, people (n = 73) with hard-to-heal wounds (median duration 12 months, different aetiologies) were treated with electrical stimulation therapy delivered with an electroceutical device (WoundEL®). Pain was measured using a numeric rating scale (NRS) at commencement of EST, at day 3 and at conclusion of treatment (day 7 or day 9). Median

NRS score decreased significantly over time from day 0 (median 6, SD 3.3), to day 3 (median 3, SD 2.8; p < 0.001) and to day 7 or 9 (median 2, SD 2.2; p < 0.001). The decrease in pain was also associated with a decrease in analgesic treatment (Level 3). However, there was no comparison group in this study⁶.

- A case series⁷ at moderate risk of bias reported the use of pulsed EST as an adjunct to standard care for 100 chronic wounds, primarily DFUs of more than 12 months' duration. The EST in this study was a pulsed microcurrent delivered using a system (BEST, Biofeedback Electro-Stimulation Technology) that allowed application of the electrical stimulation wirelessly without touching the skin (i.e., therapy was delivered through clothes and bandages). The EST was delivered weekly in the clinic at the time of wound dressing changes, and three times daily at home. Of those reporting wound pain at baseline (n = 89), there was a statistically significant reduction in the mean VAS score from a pre-treatment mean score of 6.0 ± 1.75 to post-treatment score of 2.2 ± 1.47 (p < 0.001). Over the course of the 4-week study, 59% of these participants experienced at least a 50% reduction in pain score⁷ (Level 4). This is likely to have been clinically significant.
- In a small observational study¹⁷ at high risk of bias, EST was applied with an electroceutical device (Accel-Heal) for 12 days to VLU (n = 8). Progress was followed for up to 20 weeks. Of the three VLUs reported as painful at the commencement of the study, all three reported rapid reduction in pain, with a mean reduction of 84% observed in the first two weeks and pain resolution within eight weeks for all VLUs¹⁷ (Level 4).

CONSIDERATIONS FOR USE

- Electrical stimulation therapy should not replace best standard of wound care.²¹
- Reduction in wound pain is associated with other positive clinical outcomes, including reduction in use of analgesia and improved sleep quality.⁷
- Evaluate the capacity of the individual to adhere to treatment when selecting adjunct therapies, therapy device and the treatment regimen.¹⁸
- Standards of wound practice²² and evidence-based clinical guidelines^{23, 24} outline that health professionals should collaborate with an interdisciplinary team when selecting adjuvant therapies, and have appropriate education and training before selecting or delivering EST, or teaching individuals to self-administer.

ADVERSE EFFECTS AND COMPLICATIONS

- Some complications/adverse events are associated with treating wounds with EST. A small number of people treated with electrical stimulation therapy reported dizziness and delusions, but these were not attributed to the EST intervention.^{13,14} Skin redness, irritation, slight discomfort, tingling or burning sensations have also been reported^{13,14,16}, but the certainty that these events were associated with EST is low.¹³ A minor burn has also been reported in one person.¹⁴

- Use caution when applying high voltage monophasic pulsed current (HVPMC) to wounds in people with Raynaud's syndrome.¹⁵ Increased wound pain has been reported but more research is required on this potential adverse event.¹⁵

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CONFLICTS OF INTEREST

The author declares no conflicts of interest in accordance with International Committee of Medical Journal Editors (ICMJE) standards.

ABOUT WHAM EVIDENCE SUMMARIES

WHAM evidence summaries provide a summary of the best available evidence on specific topics and make suggestions that can be used to inform clinical practice. Evidence contained within this summary should be evaluated by appropriately trained professionals with expertise in wound prevention and management, and the evidence should be considered in the context of the individual, the professional, the clinical setting and other relevant clinical information.

WHAM evidence summaries are developed using methodology consistent with that published by Joanna Briggs Institute⁹⁻¹². Evidence underpinning a WHAM recommendation is identified via a PICO search strategy, assigned a level of evidence and evaluated for risk of bias. All WHAM evidence summaries are peer-reviewed by an international Expert Reference Group. For more information on the methods and the WHAM Expert Reference Group, visit the website: www.WHAMwounds.com.

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Research Grants

Wounds Australia is offering three research grants – two worth \$5,000 and one worth \$10,000 to support wound care research as part of the mission to improve wound care for more Australians. Wounds Australia members are invited to review the grant guidelines and apply at https://woundsaustralia.org/#action=check_bulletin&code=&message=103_1708648758&bulletin_name=news_bulletin_1&category=

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Judged by the Editorial Board of *Wound Practice and Research* annually, one award per category is given based on published articles in the calendar year.