Transcutaneous Electrical Nerve Stimulation to Manage a Lower Extremity Wound Complicated by Peripheral Arterial Disease: A Case Report

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Abstract
Transcutaneous electrical nerve stimulation (TENS) is used to alleviate muscle pain, and there is some evidence it may affect healing in chronic wounds. An 80-year-old male patient with a chronic left lower extremity wound and a history of peripheral arterial disease, type 2 diabetes, hypertension, chronic obstructive pulmonary disease, and lung cancer presented for treatment. Previous protocols of care, mainly consisting of sharp debridement and daily dressing changes, had not resulted in a decrease in wound size. The patient had right and left iliac artery stenosis — not amenable to surgical intervention — and an ankle brachial index (ABI) of 0.63 on the left and 0.59 on the right lower extremities. On presentation, the wound measured 3.0 cm x 2.0 cm with a depth of 0.3 cm and a 0.5-cm tract at the 5 o’clock position. Treatment was changed to application of an ionic silver-containing Hydrofiber™ dressing and low-frequency TENS. Electrodes were applied 2 cm superior and inferior to the wound margin at a frequency of 2 Hz with a pulse width of 250 microseconds and amplitude of 33 mA. Treatment time was 45 minutes, twice daily, for 3 months, performed at home by the patient and his caregiver. After 4 weeks, wound dimensions decreased by 1.51% per day, and the wound was completely healed (100% epithelialized) after 12 weeks. At that time, the ABI of the left (treated) leg had increased to 0.71. Research is needed to determine the efficacy and effectiveness of low-frequency TENS to help clinicians provide evidenced-based treatment for wounds complicated by decreased blood flow.

Keywords: case study, peripheral arterial disease, wound, leg ulcer, transcutaneous electrical nerve stimulation

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Transcutaneous electrical nerve stimulation (TENS) has long been used to control and/or alleviate muscle pain during acute, specifically muscular, injuries; it also is effective in chronic conditions such as fibromyalgia and cases of chronic low back pain. TENS is provided via a small, portable unit and may be self-administered with proper training; it is usually purchased for home use and covered by most insurance carriers. A typical setting for TENS for pain control would be a symmetric, biphasic wave form at a frequency of 180–200Hz with a modulated pulse width of 20–100 microseconds for a treatment time as needed, which may range from minutes to hours.1 Electrode configuration is over or around the painful area.1

In the wound care arena, TENS is not usually a modality of choice for treating chronic, nonhealing wounds. Electrical stimulation, specifically high-volt pulsed current (HVPC), has been shown to facilitate healing of chronic wounds. However, HVPC and TENS are two completely different types of electrical stimulation. HVPC typically has a twin-peaked monophasic waveform.2 The pulse rate most frequently used in wound healing is 50–120 pps (0.83–1.25 msec).3 Voltage may be selected with intensity between 100 V and 500 V.2 The amplitude selected for wound healing is usually between 80 V and 200 V, and the polarity and pulse rate are varied.2 The high-voltage stimulation has a high peak current that provides greater penetration into tissue, allowing for stimulation of deep motor points.1 HVPC has been...
shown to improve blood supply and decrease edema with use of the negative pole.\textsuperscript{4,5} Treatment programs with HVPC are usually performed in a clinic or facility at a frequency of five to seven sessions per week with a treatment time of 60 minutes. In contrast to HVPC, TENS has a balanced, symmetric or asymmetric waveform that has been shown beneficial, albeit in limited research, for pain modulation.\textsuperscript{1}

Multiple studies have demonstrated the efficacy of electrical stimulation in wound healing in both animals and humans. Electrical stimulation may be provided via direct current and HVPC. Several case series and controlled clinical studies\textsuperscript{6-8} involving human participants showed low-intensity, continuous direct current of 0.2–1.0 mA applied from the anode 4 to 6 hours daily promoted healing of dermal ulcers. In animal studies with rats,\textsuperscript{4} HVPC with negative polarity increased blood flow volume nearly instantaneously at the pulse rates tested — 2, 20, 80, and 120 pps — with blood flow velocity remaining elevated from 4 to 20 minutes after treatment.

In a randomized controlled trial, Kloth and Feedar\textsuperscript{9} examined 16 patients ages 20–89 years with Stage IV pressure ulcers. Patients in the treatment group (n = 9) received daily electrical stimulation from a commercial high-voltage generator, and patients in the control group (n = 7) had the electrodes applied daily but received no stimulation. Results of the study showed a mean healing time of 44.8% a week and healed 100% over a mean period of 7.4 weeks in the treatment group. The ulcers of patients in the control group increased in area an average of 11.6% a week and increased 28.9% over a mean period of 7.4 weeks. Positive polarity was used initially then switched to negative polarity if wound healing plateaued. Treatment frequency was 5 to 7 days per week for 45 to 60 minutes.

In a controlled animal study, Khalil and Merhi\textsuperscript{10} demonstrated the group that received low-frequency TENS (20V, 5Hz for 1 minute) had a substantial improvement in wound healing as compared to the sham treatment in aged rats. The authors concluded wound healing in aged rats can be accelerated by peripheral activation of sensory nerves using low-frequency parameters. Cramp et al\textsuperscript{11} compared the sensitivity to change in blood perfusion during treatment with TENS using laser Doppler imaging (LDI) and a skin thermometer. In a double-blind study, low- and high-frequency (4 Hz and 110 Hz, respectively) TENS was applied to the forearm skin of 30 healthy human volunteers. Blood flow and temperature readings were recorded before, during, and for 15 minutes after TENS application. Analysis showed substantial increases in blood perfusion during the treatment period in the low-frequency group when compared with the other two groups, and no significant changes in skin temperature.

In a case series, Wikstrom et al\textsuperscript{12} quantified blood flow changes at two different frequencies (2 Hz, 100 Hz) and to sham when TENS was applied to nine healthy adults. Changes in blood flow were measured using LDI every 5 minutes. Results showed mean blood flow increases of 40% during low-frequency TENS, compared with a 12% increase in high-frequency with no change during sham stimulation.\textsuperscript{12} In another case series by Cosmo et al,\textsuperscript{13} 15 adult patients (mean age of 73 years) with chronic leg ulcers (12 venous ulcers, two arterial ulcers, and one vasculitis) with a history of 3 months to 16 years were provided low-frequency TENS (2Hz, 10-45 mA) for a 60-minute period. The changes in blood flow were measured every 5 minutes with LDI. After the treatment, mean blood flow to the ulcer had increased 35% and 15% in the intact skin surrounding the ulcer. Mean blood flow increases of 29% in the ulcer and 9% in the skin were measured 15 minutes after the cessation of TENS.

Precautions. Precautions regarding TENS use include a tingling sensation under the electrodes and potential skin irritation.\textsuperscript{2} Contraindications for the use of TENS include the presence of demand-type cardiac pacemakers; application over the carotid sinus; near areas of venous or arterial thrombosis, thrombophlebitis, or malignancy; and in the presence of osteomyelitis.\textsuperscript{1,2} In addition, topical substances containing metal ions (ie, povidone iodine, zinc, Mercurochrome, and silver sulfadiazine) should be completely removed before electrical stimulation is applied. Direct current electrical stimulation has the ability to transfer ions into the tissues by iontophoresis. Heavy metal ions may have toxic properties when introduced into the body.\textsuperscript{3} However, TENS is not a form of direct current electrical stimulation. In addition, utilization of nonmetallic silver (ie, ionic silver) does not affect conductivity and is safe to use with electrical stimulation (Personal correspondence received from Mike Walker, PhD, CBiol. FSB, Senior Research Advisor, ConvaTec, Inc, Skillman, NJ).

The role of peripheral arterial disease (PAD). All lower extremity chronic wounds are challenging to heal, especially in the presence of PAD. The negative impact of PAD and the
frequency with which it is encountered in clinical practice in-crease with the age of the patient; PAD is equally common in men and women and may occur in any blood vessel, but it is more common in the legs than the arms. According to the Centers for Disease Control and Prevention, in 2013 approximately 8 million people in the United States had PAD (including 12% to 20% of individuals older than 60 years). As the population ages, the prevalence could reach 9.6 to 16 million in persons ages 65 years and older and 19 million overall by 2050 (based on 2004 statistics). The key to successful wound healing in this patient population is vascular intervention. Technological advancements have allowed many patients with critical limb ischemia to have endovascular procedures to restore or improve blood supply in the lower limbs. However, even if nonsurgical means have been successful in the past, the patient may now require more invasive surgical interventions/vascularization. In some cases, patients may not be candidates for surgical revascularization due to the progressive nature of the disease process as well as complex comorbidities (ie, congestive heart failure, diabetes, renal failure, respiratory diseases) that substantially reduce the potential for a positive surgical outcome. Therefore, patients with PAD and chronic wounds who do not have revascularization options are at an increased risk for amputation and mortality.

This case study describes the treatment of a patient with a chronic lower extremity wound and several concomitant diagnoses, including PAD, lung cancer, chronic obstructive pulmonary disease (COPD), and coronary artery disease (CAD). The patient had a history of chronic tobacco use, and surgical vascular intervention was not an option.

Case Report

Mr. E is 80 years old. He presented to the author’s wound clinic with a chronic, nonhealing ischemic wound on his left lateral lower extremity that had been present for 4 months after he sustained a fall. His medical history included type 2 diabetes for 14 years (HgbA1c 7.5%). He also had hypertension, COPD, PAD, and lung cancer in remission. Mr. E initially was treated in a different wound clinic, but after 2 months, he was referred to the author’s wound clinic for continued wound care.

Previous treatment. At the first wound clinic, Mr. E’s wound initially measured 3.5 cm x 2.6 cm with a depth of 0.2 cm. Daily dressing changes consisted of 0.9% normal saline-soaked cotton gauze. After 4 weeks of treatment, Mr. E was referred to a vascular surgeon for assessment, which revealed the absence of pulses in bilateral posterior tibial and dorsalis pedis arteries as well as diminished bilateral popliteal pulses. A pulsed volume recording (PVR) demonstrated right and left iliac artery stenosis. Mr. E’s ankle brachial index (ABI) was 0.63 on the left lower extremity and 0.59 on the right lower extremity. He underwent an angiogram, but lesions in the iliac arteries were not amenable to intervention. Results from the vascular assessment included a strong recommendation against surgical intervention except as a last resort, secondary to Mr. E’s complex comorbidities and his inability to endure the physical demands of surgery. As a result, if his wound did not heal, his only option was a below-knee amputation of the left lower extremity.

After 6 weeks of treatment consisting of sharp debride-ment with daily dressing changes with 0.9% saline, Mr. E’s wound increased to 4.1 cm x 2.6 cm with a depth of 0.9 cm, with two tracts at 6 o’clock and 7 o’clock measuring 0.8 cm and 1.6 cm, respectively. A swab culture of the wound surface was performed at this point and the primary dressing was changed to a Hydrofiber™ (Aquacel Ag, ConvaTec, Skillman, NJ) dressing containing ionic silver. Mr. E’s caregiver performed daily dressing changes at home. After 2 weeks, the primary dressing was changed to 0.1% gentamicin sulfate, applied three times daily and covered with an appropriate secondary dressing, due to identification of Staphylococcus aureus from the wound culture. Mr. E then was referred to the author’s wound clinic for continued care.

Study treatment. During the initial visit to the author’s clinic, Mr. E’s wound measured 3.0 cm x 2.0 cm with a depth of 0.3 cm, and a tract at the 5 o’clock position measuring 0.5 cm; all previous treatment notes were reviewed. Mr. E was performing dressing changes at home as previously directed by his initial wound clinic. A swab culture of the wound surface at his initial visit to the author’s clinic showed no evidence of S. aureus on the wound surface, so gentamicin sulfate ointment use was discontinued 1 week later. At this point, Mr. E was assessed by a plastic surgeon for a potential skin graft, but he was deemed “not an appropriate candidate” for intervention secondary to his extensive circulatory impairments.

Using the treatment chart notes, percent change in wound area during the previous 4 months was calculated (initial area – follow up area/initial wound area x 100%). Because wound response during hydrofiber treatment was most encouraging (see Table 1), the hydrofiber dressing with ionic silver was started as the primary dressing. In addition, after 2 weeks TENS therapy was initiated. Figure 1 depicts Mr. E’s wound at the initiation of TENS treatment 2 weeks after the initial assessment at the authors’ wound clinic. Wound measurements had remained unchanged as compared to measurements at his initial visit, and due to the formation of a thick layer of adherent devitalized tissue, the wound’s depth and the previously mentioned tract at the 5 o’clock position were obscured.

Because of the poor level of perfusion in Mr. E’s left lower extremity, TENS was chosen as the only potential treatment available to increase blood flow to the wound and surrounding area, as evidenced in the findings published by Cosmo et al. In keeping with these findings, treatment settings were selected to match published settings as much as possible. The LogiSTIM® TN-11 unit (US Medical Minnetonka, MN, see Figure 2) was set to deliver a 2Hz biphasic, symmetric wave-
Transcutaneous Nerve Stimulation

Form through the periwound area at an amplitude of 33mA with a pulse width of 250 microseconds. The TENS unit allows settings, such as the signal frequency of 2Hz and the biphasic, symmetric waveform, to be “fixed” and remained unaltered by the patient. Only the amplitude could be adjusted to control the current flowing from electrode to electrode, rendering the patient responsible for the correct settings.

To ensure uniform treatments and proper machine settings, Mr. E received extensive initial training that included machine function, construction, basic maintenance, and required settings. The initial phase of patient training provided by the physical therapist involved the following steps:

1) demonstrating how electrodes were placed 2 cm superior and inferior to the wound margin by outlining the desired location on the lower extremity with a skin pen; 2) turning the TENS unit on and setting the signal amplitude to the desired parameter of “33” as seen on the TENS unit display (accomplished through simple push button manipulation); and 3) turning the unit off and disconnecting the leads from the electrodes. At this point, the electrodes remained fixed at their designated location for the initial phase of training.

Phase two of Mr. E’s training involved the patient repeating each of the previous steps he had been shown to ensure he would be able to administer treatments correctly at home. He repeated this process four times until he was able to complete all steps correctly and without hesitation. Mr. E then was required to teach the entire process to his caregiver with clinician supervision, from electrode installation through treatment and after care. The therapist evaluated the caregiver’s aptitude to ensure there were no gaps in the caregiver’s knowledge. This allowed two sets of trained eyes to verify each treatment, including those given at home. Effectiveness of this phase was measured by repeat demonstration across several visits at the clinic. As the education and treatment process progressed, Mr. E and the caregiver were trained in after-care instructions, safety precautions, and how to recognize atypical signs and symptoms of treatment.

The treatment protocol was reviewed at each clinical visit to ensure the parameters of treatment were being followed correctly. Treatment time was 45 minutes, twice per day. The waveform was biphasic and symmetric; therefore, positive/negative electrode placement was inconsequential. Electrode connectors were accessible on the exterior of the dressing for ease of connection to prevent dressing from being disturbed.

The wound dressing was changed and the electrodes were removed to allow for skin inspection during Mr. E’s weekly clinic visits. New electrodes were applied to ensure proper electrical contact was maintained and to reduce the potential for infection. Treatment consisted of wound irrigation with 0.9% normal saline with pulsatile lavage (8 psi) and concurrent suction (160 mm Hg). This approach was used to irrigate the wound base and wound margin and to loosen devitalized tissue in preparation for conservative, sharp, selective debridement. The requirement for conservative, sharp, selective debridement was determined on a visit-by-visit basis and was provided only as required in order to maintain a wound bed free of devitalized tissue that could hinder the wound’s ability to contract and heal. At each visit, the hydrofiber silver dressing was re-applied with an appropriate secondary dressing for exudate management and conformal gauze.

Pain was assessed at each treatment session using the visual analog scale. Pain was assessed as an adjunct to wound healing and while it gave no specific indication of wound status, a reduction in pain was viewed as an overall positive sign.

A reduction in wound size of length, width, and depth was noted at Mr. E’s fourth treatment visit. Further reduction in
Once the wound was deemed closed, an ABI was performed with a result of 0.71 on the left lower extremity and 0.57 on the right lower extremity. An ABI also was performed at Mr. E’s 1-month follow-up with a result of 0.80 on the left and 0.57 on the right side. At the 1-month follow-up assessment, Mr. E was provided a light compression stocking (10–12 mm Hg) to prevent edema and decrease the potential for wound recurrence and TENS was discontinued. As of his 6-month assessment, Mr. E has no wounds and has continued use of light compression. With continued routine medical assessments, his prognosis is positive.

**Discussion**

Wounds related to or complicated by PAD are difficult to manage successfully. This particular patient’s case was extremely challenging due to the inability to revascularize his lower limbs. When his wound did not show any clinical improvement with initial care, the treatment was changed by adding low-frequency TENS based on treatment parameters discussed in research by Cosmo et al.13 Due to Mr. E’s compromised blood flow and disqualification as a surgical revascularization candidate, utilization of TENS was determined to be the best modality that may be able to overcome the limitations of healing imposed by PAD. In Mr. E’s case, his ABI increased in the left lower extremity from 0.63 to 0.71 with the addition of TENS and with continued use of TENS after the wound was closed, his ABI increased to 0.80 at his 1-month follow-up. Mr. E also reported no pain in his left lower extremity through his 6-month follow-up assessment. TENS treatment was not performed on his right lower extremity, which showed no relevant change.

Initial wound healing was noted while maintaining a moist wound environment using the hydrofiber dressing containing ionic silver (see Table 1) with a change in wound size of 0.90% per day. Addition of TENS increased this rate to 1.51%. Although debridement of stable eschar in a wound due to arterial insufficiency is contraindicated, Mr. E’s wound presented with loose slough that after pulsatile lavage was able to be removed as needed with sharp, selective, conservative debridement at each clinic visit. Electrode placement addressed any potential iontophoresis effects; the electrodes were placed in an area (2 cm superior and inferior to the wound margin) where no potential ionic or metallic agents were applied. In addition, the waveform selected by the TENS unit was biphasic and symmetric, which has zero net charge under each electrode, thus eliminating the possibility of any substance transfer into the tissue. The hydrofiber dressing contains silver that remains neutral until wound exudate makes the silver available inside the dressing, where it acts in an antimicrobial fashion in solution; this is beyond the path of current created by the TENS treatment. In this particular case study, no problems were identified with utilization of the silver-containing hydrofiber dressing, but if ionic silver is not deemed necessary, a hydrofiber dressing without nonionic
DO NOT DUPLICATE

Reduced risk of build-up of H+ and/or OH− ions at the fixed metric waveform, facilitating longer-term application with a costs. TENS also offered the added benefit of a biphasic, symmetrical waveform, allowing treatment more frequently in the comfort of his home instead of the practice of wound care.

Utilization of TENS allowed Mr. E to perform electrical stimulation treatments in the comfort of his home instead of the practice of wound care, thus decreasing his healthcare and transportation costs. TENS also offered the added benefit of a biphasic, symmetric waveform, facilitating longer-term application with a reduced risk of build-up of H+ and/or OH− ions at the fixed electrode location that could lead to potential skin damage. The treatment time of 45 minutes, twice daily, was different from the referenced treatment parameters described by Cosmo et al.13 (60 minutes once per day) to accommodate patient and caregiver concerns regarding protocol adherence; through conversation with Mr. E and his caregiver, it was determined that patient ability to complete the treatment would be improved with treatment intervals of 45 minutes twice daily.

The research available describing the use of low-frequency TENS in wounds is limited. Prospective, randomized controlled clinical studies are needed to determine the efficacy of this treatment and its effect on perfusion in patients with lower extremity ulcers and PAD when revascularization is not an option.

Conclusion

TENS has long been used in the treatment of muscle pain and discomfort, and there is some evidence that it may be beneficial for healing chronic wounds. The results of this case study were encouraging. Despite the presence of extensive PAD, wound healing of a lower leg ulcer was achieved with the use of an ionic silver-containing hydrofiber dressing and low-frequency TENS. In addition, perfusion in the treated limb improved as evidenced by an improvement in ABIs. The patient's ABI in the untreated leg remained unchanged. Future research is needed to further strengthen the evidence of use of TENS in patients with compromised perfusion in order to determine optimal strategies for wound healing with this form of electrical stimulation.

Table 1

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<thead>
<tr>
<th>Treatment method (IC)</th>
<th>Percent change in wound area per daya</th>
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</thead>
<tbody>
<tr>
<td>Hydrogel and gauze</td>
<td>0.19%/day</td>
</tr>
<tr>
<td>Saline and gauze</td>
<td>-1.23%/day</td>
</tr>
<tr>
<td>Hydrofiber with ionic silver</td>
<td>0.90%/day</td>
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<table>
<thead>
<tr>
<th>Treatment method (AC)</th>
<th>Percent change in wound area per daya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrofiber with ionic silver/TENS</td>
<td>1.51%/day</td>
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</tbody>
</table>

a Percent change in wound area was calculated retrospectively based on wound care notes (IC) and prospectively at weekly visits (AC) as: wound area=wound length*wound width; % change in area = ((previous visit wound area-current wound area)/previous wound area) x 100%

References