Surface Acoustic Wave Patch Therapy Affects Tissue Oxygenation In Ischemic Feet

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Abstract: Background. Transcutaneous oxygen pressure (TcPO2) less than 30 mm Hg at the toe leads to local tissue hypoxia and nonhealing wounds. Studies regularly illustrate that TcPO2 values are strong predictors of healing and can accurately demonstrate altered levels when extremities have restricted blood flow. The objective of this study was to evaluate the effectiveness of surface acoustic wave (SAW) in ischemic feet on local tissue oxygenation. Methods. Ten patients, ranging from 40-75 years of age and suffering from critical limb ischemia (CLI) were selected from a vascular surgery clinic to undergo evaluation with a PainShield SAW Patch device (NanoVibronix Inc, Melville, NY). Patients were treated once with 96 Khz of SAW for 30 minutes. All patients had an ankle brachial index of < 0.4 mm Hg. Two patients (patients 1 and 8) had necrosis of at least 2 toes on the affected limb and were given the device for nightly use for 1 month. Results. Through usage of SAW there was a significant increase in all patients’ saturation values. The recorded baseline in both patients with necrotic toes almost doubled and during usage there was still a measurable increase in oxygen saturation. In both of these patients the subjective pain measures dropped significantly. Pain, as assessed by the Visual Analog Scale, dropped from 9 to 2 for patient 1 and from 8 to 3 for patient 8. Patient 1 went from 5 methadone treatments per day to only 1 per day starting in week 3. Patient 8 did not change their pain medication regimen. Conclusion. Surface acoustic waves as delivered in this study had a positive effect on tissue oxygenation and saturation in ischemic feet. In lower extremities that are not surgical candidates or are either in the pre- or postsurgical environment, an SAW patch device is a good therapy in elevating the extremities’ O2 saturation.

Key words: chronic ulcers, diabetic ulcers, lower extremity wounds, ultrasound, surface acoustic wave

H ealing of chronic wounds is dependent on many factors including type of wound, etiologies, depth, and comorbidities of the patient. According to Mustoe et al,1 billions of dollars are spent annually in the United States due to chronic wounds. Chronic wounds do not follow the typical hemostasis, inflammation, proliferation, and remodeling found in
Critical limb ischemia and its sequelae have restricted blood flow. Peripheral artery disease (PAD), which can eventually lead to CLI, can be treated in numerous ways. Terminal health conditions caused by CLI relate to decreased oxygen perfusion to tissues. The least invasive way to treat PAD and its symptomatology, which is completely patient dependent and supported by the literature, includes exercise training. Haas et al stated that the most significant long-term treatment for PAD is extended exercise programs, such as walking. Nonetheless, modifying cardiovascular risk factors, surgical intervention, and pharmaceuticals can also be utilized, but with a decreased chance of success. Haas et al stated that many clinical trials demonstrate the benefits of exercise therapy, both clinically (ie, longer walking duration before claudication) as well as chemically (ie, modified markers of ischemia in the blood and structural adaptations in the limb such as improved walking tolerance, modified inflammatory and hemostatic markers, and enhanced vasoresponsiveness), and adaptations within the limb (ie, angiogenesis, arteriogenesis, and mitochondrial synthesis) that enhance oxygen delivery and metabolic responses, potentially delaying progression of the disease, enhancing quality of life indices, and extending longevity.

Holdich et al performed a study of 10 patients with claudication monitoring TcPO$_2$ during exercise. The authors found that TcPO$_2$ at the beginning of claudication fell by 16% and reached 32% at the maximum distance each individual was able to walk, and the findings were easily reproducible.

Cullum et al performed a systemic review of randomized control trials examining wound care management,
including compression, laser therapy, electrotherapy, and ultrasound. The wounds included leg ulcers, pressure ulcers, diabetic foot ulcers, and ischemic wounds. Ultrasound was specifically utilized in the randomized control trials for chronic wounds. The evaluation determined there was not sufficient evidence to draw conclusions about the relationship between ultrasound and chronic wound healing.

Therapeutic ultrasound operates from a range of less than 1 MHz to 3 MHz. Hanson et al. noted that ultrasound has shown to aid in wound healing by various means in pressure ulcers and leg and foot ulcers. They noted an abstract which utilized a low-frequency ultrasound modality that was clinically effective in encouraging healing and tissue granulation within wounds via cavitation and acoustic microstreaming.

Surface acoustic wave (SAW) therapy utilizes a different acoustic wave than traditional ultrasound. While ultrasound therapy is usually a focused beam starting at the diameter of the probe that penetrates deeply with almost no energy on the surface of the skin or tissue, SAW is a very scattered beam whose energy is almost totally absorbed in the surface of the tissue. The SAW device has a maximal penetration of 4 cm, while traditional ultrasound penetrates to approximately 10 cm. Further, SAW spreads across a wide area, in the case of this device, approximately 20 cm.

Kavros and Schenck performed a case series examining the use of noncontact low-frequency (NCLF) ultrasound in the treatment of chronic foot and leg ulcers. The study included 51 patients with numerous conditions, including limb ischemia, and found that utilizing NCLF ultrasound improved the rate of healing and closure in recalcitrant lower-extremity skin ulcerations. Moreover, Kavros et al. performed a study examining NCLF ultrasound in nonhealing leg and foot ulcers with chronic CLI. In this randomized controlled trial, 35 patients received both ultrasound therapy and local wound care, while a control group received wound care without ultrasound therapy. Transcutaneous oximetry pressures in both the supine and dependent position were measured. Patients who received both ultrasound and local wound care achieved > 50% wound healing at 12 weeks compared to the control group that received only local wound care. Nevertheless, the study noted that most of the patients from both the treatment and control groups who did not successfully have 50% wound healing in the 12-week period had baseline dependent TCPO2 values < 20 mm Hg. The effectiveness of ultrasound in ischemic feet and local tissue oxygenation ranges remains a subject requiring increased study, leading to the development of this evaluation.

**Methods**

Ten patients with CLI were selected from a vascular surgery clinic at the Multidisciplinary Wound Care Center at Shaarei Zedek Medical Center, Jerusalem, Israel to undergo evaluation with the PainShield Surface Acoustic Wave Patch Diathermy device (NanoVibronix Ltd, Melville, NY) (Figure 1). Six patients were females and 4 were males. Patient age ranged from 40-75 years. All patients reported pain while resting and had a documented ABI of < 0.4 mmHg. None of the patients had open wounds at the time, but 2 had necrosis of at least 2 toes on the affected limb. These 2 patients were given the device for follow-up use for 1 month.

Patients were brought into the clinic and seated in a comfortable prone position with their legs extended. Patients were advised that they would be in this position for approximately 1 hour. After 5 minutes of rest, a
TcPO$_2$ monitor was applied on the dorsal center of the foot just proximal to the metatarsophalangeal joints. Transcutaneous oxygen pressure was allowed to stabilize for 15 minutes and, after reaching a stable baseline, was left undisturbed for 5 additional minutes. An SAW patch was placed just proximal to the TcPO$_2$ lead. The SAW device was activated and the TcPO$_2$ was monitored and recorded over the next half hour. The SAW device has a fixed setting of 96 Khz and runs cycles of 30 minutes of active treatment and 30 minutes of idle treatment.

At the end of the half hour of active SAW therapy the device was shut off and the TcPO$_2$ was monitored for another 15 minutes to evaluate the drop-off in oxygenation after use.

The 2 most severe patients were given the device for home use for 1 month. They were advised to use the device at night while sleeping. The device typically runs on cycles of 30 minutes of active SAW and 30 minutes of idle for 6.5 hours. These 2 patients were spoken with almost daily to ensure that they were using the device and there were no complications. At the end of the month, these 2 patients returned to the clinic and again underwent TcPO$_2$ evaluation, both to establish a baseline and to evaluate with additional SAW usage.

Table 1

<table>
<thead>
<tr>
<th>Patient number (Age)</th>
<th>Baseline (mmHg)</th>
<th>High during treatment (mmHg)</th>
<th>Percent change during treatment</th>
<th>Value after rest (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (65)</td>
<td>19</td>
<td>31</td>
<td>63.15</td>
<td>30</td>
</tr>
<tr>
<td>2 (40)</td>
<td>43</td>
<td>57</td>
<td>32.56</td>
<td>53</td>
</tr>
<tr>
<td>3 (73)</td>
<td>36</td>
<td>56</td>
<td>55.56</td>
<td>55</td>
</tr>
<tr>
<td>4 (68)</td>
<td>31</td>
<td>36</td>
<td>16.12</td>
<td>36</td>
</tr>
<tr>
<td>5 (70)</td>
<td>11</td>
<td>19</td>
<td>72.72</td>
<td>17</td>
</tr>
<tr>
<td>6 (75)</td>
<td>16</td>
<td>43</td>
<td>168.75</td>
<td>43</td>
</tr>
<tr>
<td>7 (71)</td>
<td>49</td>
<td>56</td>
<td>14.29</td>
<td>54</td>
</tr>
<tr>
<td>8 (71)</td>
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<td>33</td>
<td>43.47</td>
<td>31</td>
</tr>
<tr>
<td>9 (68)</td>
<td>40</td>
<td>55</td>
<td>37.5</td>
<td>54</td>
</tr>
<tr>
<td>10 (62)</td>
<td>28</td>
<td>37</td>
<td>32.14</td>
<td>34</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Patient</th>
<th>Original baseline (mmHg)</th>
<th>End of treatment (mmHg)</th>
<th>1-month baseline (mmHg)</th>
<th>End of treatment (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>43</td>
<td>34</td>
<td>49</td>
</tr>
<tr>
<td>2</td>
<td>23</td>
<td>33</td>
<td>40</td>
<td>50</td>
</tr>
</tbody>
</table>
Table 2 demonstrates the changes that occurred with the 2 patients (patient 1 and patient 8) who received the device for a month. The recorded baseline in both patients almost doubled and during usage there was still a measurable increase in oxygen saturation. In both of these patients, subjective pain measures dropped significantly. Pain VAS dropped from a score of 9 to 2 for patient 1, and from a score of 8 to 3 for patient 8. Patient 1 went from 5 methadone treatments per day to only 1 per day starting in week 3. Patient 8 did not change their pain medication regimen which consisted of nonsteroidal anti-inflammatory drugs before sleep. Both patients related feeling much better overall, with a better ability to walk or stand.

Discussion

Tissue hypoxia is both a subjective and objective disaster. Patients relate significant pain, develop ulcerations, and the condition often progresses to a point where amputation is necessary. Ultrasound has been known to relieve pain in a variety of clinical settings including chronic wounds and leg ischemia. Further double-blind studies are required to test the efficacy and safety of SAW therapy on tissue oxygenation compared to a properly blinded placebo device believed by participants, investigators, and patients to be active.

Conclusion

Although more investigation needs to be conducted, it is clear that SAW as delivered by the device evaluated in this study has a positive effect on tissue oxygenation and saturation in ischemic feet. In lower extremities that are not surgical candidates, or in the pre- or post-surgical environment, the device is a good therapy for elevating the oxygen saturation in the legs. This study shows that use of an SAW patch diathermy device increases tissue oxygenation and can help to treat both the subjective symptoms and objective signs and complications of CLI.

References