

## Surface Acoustic Wave Patch Therapy Affects Tissue Oxygenation In Ischemic Feet

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**Abstract:** *Background.* Transcutaneous oxygen pressure (TcPO<sub>2</sub>) less than 30 mm Hg at the toe leads to local tissue hypoxia and nonhealing wounds. Studies regularly illustrate that TcPO<sub>2</sub> 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' O<sub>2</sub> 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,<sup>1</sup> 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

**KEYPOINTS**

- Surface acoustic wave (SAW) ultrasound therapy 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.

acute wounds. Chronic wounds typically come in a variety of etiologies, including venous ulcers, arterial ulcers, pressure ulcers, and neuropathic ulcers, which all seem very different in etiology, but may have similar difficulties healing. One reason is impaired circulation resulting in local tissue hypoxia.<sup>1</sup>

Transcutaneous oxygen pressure (TcPO<sub>2</sub>) less than 30 mm Hg at the toe leads to local tissue hypoxia and non-healing wounds.<sup>1</sup> Local blood flow, affected by numerous etiologies such as impaired arterial inflow, arteriovenous pressures, capillary density, and local tissue consumption directly affect tissue partial oxygen pressures. Setacci et al<sup>2</sup> stated that the most common cause of ischemic feet is atherosclerotic peripheral arterial disease, such as that which occurs secondary to diabetes mellitus.<sup>2</sup> Mustoe et al<sup>1</sup> also points out that diabetic ulcers are closely related to atherosclerotic large vessel conditions and chronic ischemia. Large vessel disease is not typically found in venous and pressure ulcers. Nevertheless, previous ulcerations greatly increase the possibility of reulceration due to fibrosis and decreased tissue perfusion.<sup>1</sup> Moreover, other causes of ischemic feet include acute embolisms from the heart or arteries, thrombosis from procoagulative blood clots, arterial spasms, or injury from trauma and drug use.<sup>2</sup> Edema in surrounding skin has also been shown to lessen TcPO<sub>2</sub> in wounds.<sup>1</sup>

According to Davies,<sup>3</sup> 12% of the adult population in the United States have critical limb ischemia (CLI), defined symptomatically as ranging from no symptoms to intermittent claudication, atypical leg pain, rest pain, ischemic ulcers, or gangrene. Beard<sup>4</sup> states that about 150-200 people per 1 million progress to CLI with ischemic rest pain, ulceration, and/or gangrene. Critical limb ischemia costs approximately 200 million dollars a year in the United Kingdom.<sup>4</sup> Critical limb ischemia and its sequelae have significant social and economic impacts, with 25% of patients not surviving after 1 year, amputations occurring in approximately 30% of patients, and a mortality rate of 60% at 5 years.<sup>3</sup>

Ruangsetakit et al<sup>5</sup> prospectively examined 50 patients living with CLI with digital gangrene or chronic ischemic ulcers to determine the values of TcPO<sub>2</sub>, which predicts ulcer healing. Transcutaneous oxygen pressure was measured in the supine position while the patient was at rest with the leg elevated at 30 degrees. The mean age of participants in this study was 68 years and the mean ankle brachial index (ABI) was 0.75. In this patient population, TcPO<sub>2</sub> < 20 mmHg showed no improvements in ulcer healing, while patients with measurements > 40 mmHg had complete ulcer healing. Patients with a TcPO<sub>2</sub> between 20 mm Hg and 40 mm Hg varied between no healing and complete healing, with patients having greater than 10 mm Hg decreases upon leg elevation demonstrating less healing potential.<sup>5</sup> Studies regularly illustrate that TcPO<sub>2</sub> values are strong predictors of healing and can accurately demonstrate altered levels when extremities have restricted blood flow.<sup>6</sup>

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<sup>7</sup> states 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<sup>7</sup> states 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.<sup>7</sup>

Holdich et al<sup>8</sup> performed a study of 10 patients with claudication monitoring TcPO<sub>2</sub> during exercise. The authors found that TcPO<sub>2</sub> 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.<sup>8</sup>

Cullum et al<sup>9</sup> 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.<sup>9</sup>

Therapeutic ultrasound operates from a range of less than 1 Mhz to 3 Mhz.<sup>10</sup> Hanson et al<sup>10</sup> 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<sup>11</sup> performed a case series examining the use of noncontact low-frequency (NCLF) ultrasound in the treatment of chronic foot and leg ulcerations. 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<sup>12</sup> 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 TcPO<sub>2</sub> values < 20 mm Hg.<sup>12</sup> The effectiveness of ultrasound in ischemic



**Figure 1.** PainShield Surface Acoustic Wave Patch Diathermy device (NanoVibronix Ltd, Melville, NY).

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

**KEYPOINTS**

- Ten patients with critical limb ischemia 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 (SAW) Patch Diathermy device (NanoVibronix Ltd, Melville, NY) (Figure 1).
- 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.
- After 30 minutes of active therapy, the device was shut off and the transcutaneous oxygen pressure was monitored for another 15 minutes to evaluate the postintervention drop-off in oxygenation.

TcPO<sub>2</sub> 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<sub>2</sub> lead. The SAW device was activated and the TcPO<sub>2</sub> 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 treat-

ment. At the end of the half hour of active SAW therapy the device was shut off and the TcPO<sub>2</sub> 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<sub>2</sub> evaluation, both to establish a baseline and to evaluate with additional SAW usage.

**Results**

Table 1 represents the changes in oxygen saturation from baseline measurement through usage of the SAW patch device, as well as 15-minute post-usage measurements. There was a significant increase in all patients' saturation values. The rate of the drop off varied, but no patient's values returned to pre-device usage levels. No subjective measurements were collected, as 30 minutes of treatment was deemed too short for any real changes, and any that would be recorded were more than likely due to a placebo effect.

**Table 1.** Results of oxygen saturation during treatment with a surface acoustic wave device.

Patient number (Age)	Baseline (mmHg)	High during treatment (mmHg)	Percent change during treatment	Value after rest (mmHg)
1 (65)	19	31	63.15	30
2 (40)	43	57	32.56	53
3 (73)	36	56	55.56	55
4 (68)	31	36	16.12	36
5 (70)	11	19	72.72	17
6 (75)	16	43	168.75	43
7 (71)	49	56	14.29	54
8 (71)	23	33	43.47	31
9 (68)	40	55	37.5	54
10 (62)	28	37	32.14	34

**Table 2.** Results after 1 month of use of the surface acoustic wave device.

Patient	Original baseline (mmHg)	End of treatment (mmHg)	1-month baseline (mmHg)	End of treatment (mmHg)
1	16	43	34	49
2	23	33	40	50

**KEYPOINTS**

- The 2 most severe patients were given the device for home use for 1 month while sleeping.
- The typical cycle was 30 minutes of active surface acoustic wave (SAW) and 30 minutes of idle SAW for 6.5 hours.
- In both of these patients, subjective pain measures dropped significantly.

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.

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