A Randomized, Double-Blind Trial Evaluating the Safety and Efficacy of the PainShield® Surface Acoustic Wave (SAW) Device vs. Sham Device

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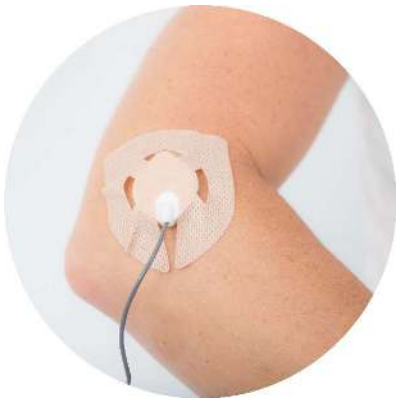
Background

Tennis elbow (lateral epicondylitis) is characterized by a pain or ache on the outside of the arm where the forearm meets the elbow. It is caused by repetitive motion of the muscles and tendons in the forearm that results in small tears of the tendons at the elbow. The tears can become inflamed causing pain and stress to the rest of the arm. Only about 3% of the population is affected by tennis elbow. It is a common injury that usually heals with minor treatment, but if left untreated the pain can intensify and become a chronic pain that can make the outside of the elbow too painful to touch and make it harder for a person to grip or lift things. Treatments for tennis elbow usually involve exercise, physical therapy, and pain/anti-inflammatory medications such as ibuprofen, naproxen, or aspirin, but longer lasting chronic pain can lead to patients taking stronger pain medications such as opioids. New treatments, such as ultrasound therapy, are being developed to give patients an alternative to pain medications.

NanoVibronix, Inc. has developed a device called PainShield® Surface Acoustic Waves to treat tennis elbow (Fig. 1). The device uses low intensity surface acoustic wave (SAW) technology. It is a wearable, battery-powered electronic unit that delivers localized therapeutic ultrasound waves to the affected area to relieve pain and promote soft tissue healing. It can be conveniently used by patients at home, school, or the office.



Methods

A randomized, double-blind study was conducted at Birmingham Orthopedic and Sports Specialists in Birmingham, AL to evaluate the safety and effectiveness of the PainShield® device. Patients, who had a history of tennis elbow with associated chronic elbow pain for more than 6 months, were randomized to either the PainShield® device or a Sham device. Both the patient and the clinician were blinded to the device assignment. Patients were instructed to wear the device for 6.5 hours per day for 30 days. They were not allowed to use opioids or have any type of injection in their arm for 30 days prior to the trial or during the trial, but standard over the counter pain medications such as ibuprofen or naproxen were

allowed. Patients were asked to keep a daily log during the study to record pain levels (scale 0-10), number of hours the device was worn, and any pain or anti-inflammatory medications taken. The investigator saw the patients in the clinic on a weekly basis to evaluate pain and tenderness at the lateral humeral epicondyle, range of motion, and adverse events.

Results

Twenty-seven patients being treated for tennis elbow by an orthopaedic surgeon were enrolled in the study upon signing an informed consent. Eleven (41%) males and sixteen (59%) females were evaluated and randomized to a device. The average patient age was 50 years (range 17-73). Fourteen patients were randomized to the PainShield® device (8 men, 6 women), and thirteen patients were randomized to the Sham device (3 men, 10 women). Twenty-one (78%) patients completed the study; 11 patients in the PainShield® device group and 10 patients in the Sham group. Six patients withdrew from the study (3 in each group).

Upon clinical evaluation, all patients had full range of motion throughout the study. No device-related skin infections, changes in skin, or other adverse events were noted in either group. Patients reported wearing the device an average of 6 hours per day. All patients had symptoms of pain and point tenderness at the beginning of the study, but 10 (91%) patients in the PainShield® group had complete or partial resolution of symptoms by the end of the study. One patient had no change in pain, and no patients reported an increase in pain. In the Sham group, 5 patients (50%) had complete or partial resolution of symptoms. Four patients had no change in pain, and one patient had an increase in pain. Seven patients (33%) overall reported over the counter pain or anti-inflammatory medication use. Pain scores indicated a significant change in pain during the study ($p<0.05$). In the PainShield® group, 65% of the patients had a reduced pain score to a 1 or less; 45% had a pain score reduction to 0.

Patient Satisfaction

Patients in both groups reported that they were very pleased with the results of the study. They thought the device was easy to use and would recommend it to other patients. In the PainShield® group, two patients had battery-related issues; one patient experienced a low battery on one day, and one patient had trouble charging the battery on the device and subsequently withdrew from the study due to no change in pain level. One patient did not wear the device for a couple days because of discomfort from the sun. One patient wore the device while sleeping. In the Sham group, 2 patients withdrew from the study because they could not tolerate wearing the device due to an increase in pain.

Conclusions

Overall, symptoms improved in 71% of the patients over a 30-day time period. In the PainShield® group, 91% of the patients improved with statistically significant changes in pain scores. Patients who wore the device and took over the counter pain/anti-inflammatory medications had a complete resolution of symptoms within 10 days. In the Sham group, 50% of the patients improved. It is believed that the placebo effect, the use of over the counter medications, and minimal pain levels all contributed to this result. The data from this study indicates that the PainShield® device is safe and effective in the treatment of tennis elbow.