Effectiveness of the PRO-SPORT™ Device With Chronic Pain in a Single Outpatient Visit

Subtitle: Effectiveness of Microcurrent Treatment with Tissue Reaction Readings for Chronic Pain in a Single Outpatient Visit

Thomas Lenahan, D.C., Darcy Brunk, D.C., Arielle Lafond, Avazzia Inc., Devyn Pontzer, Avazzia Inc.
Avazzia Inc., 13140 Coit RD, Dallas, TX 75240
(t) 214-575-2820
(f) 214-575-2824
(e) alafond@avazzia.com

Conflicts of Interest and Source of Funding:
Darcy Brunk, D.C., Achieve Chiropractic (Garland, TX), owner and member of Electrical Medicine Foundation, and Thomas Lenahan, D.C., Cornerstone Wellness Center (Plano, TX) provided the clinical facilities and patients that participated in this study. No additional funding or additional resources from other sources were provided for this study. Arielle Lafond and Devyn Pontzer, authors of this publication, are employed fulltime by Avazzia, Inc., Dallas, TX. Avazzia developed, manufactures and sells the PRO-SPORT™, the microcurrent devices used to conduct this study. Avazzia provided the clinician-investigators in this study the PRO-SPORT™ and all accessories for this study free of charge. The clinicians also were provided all necessary study documentation paperwork. The clinician-investigators were not further compensated for this study. Study-patients were not compensated for participation in the study.

ABSTRACT

Objectives

Microcurrent electrical stimulation for pain has been researched and reported effective in a number of recent studies. The aim of this study was to determine the effectiveness of the Avazzia PRO-SPORT™ device, a non-invasive hand-held microcurrent device that utilizes microchip and biofeedback technology to produce an electrical current with the skin as a conduit, in reducing self-reported chronic pain levels in a diverse population of patients with varying degrees of chronic pain.

Methods

Eighteen patients with a treatment diagnosis consistent with chronic pain and presented with other symptoms and diagnoses consistent with pain participated in this study. Each of the patients presented from two chiropractic clinics in the Dallas/Fort Worth area. The patient population varied by age, gender and reported pain level. Each patient received four microcurrent therapies using the PRO-SPORT™ device. Outcomes measured were self-reported pain levels prior to treatment using numeric visual analog scales, initial reaction and ongoing reaction data obtained using the PRO-SPORT™ device during treatment, and self-reported pain levels post-treatment using numeric visual analog scales.

Results

The average pain reduction experienced, as reported in the pain scores, went from 4.93 out of 10 to less than 2 out of 10. The results represented an average reduction in pain scores of 63%.

Discussion

The Avazzia PRO-SPORT™ device can reduce pain levels in patients with various degrees of chronic pain. The statistically significant reduction in pain of this degree in a single treatment indicates there is a high probability (>90%) of these results being replicable over a larger pain population and an increased reduction of chronic pain with extended use.

Key Words

Microcurrent technology, chronic pain, alternative medicine, neurostimulation, biofeedback.

INTRODUCTION

Microcurrent electrical stimulation for pain has been researched and reported effective in a number of recent studies. [1,2,3,4,5] Despite its efficacy in treating pain, it is seldom used as a therapy for chronic pain.

In recent years, the use of opioids in the U.S. to manage pain has grown to alarming levels.[6] The U.S. makes up 4.6% of the world's population yet consumes 80% of the world's pain pills[7,8]. In addition to the U.S. federal government looking for ways to manage the spike in these often addictive drugs[9], many local governments also aim to manage the use and abuse of these prescriptions[10] as well as the future increase in long-term costs of prescription medications.

Microcurrent electrical stimulation offers an appealing alternative to pharmaceutical treatment for pain. The cost is a single payment for the device rather than ongoing drug costs. It also requires minimal training in which virtually all patients can self-administer effective treatment and offers reduced risk of injury due to improper use. There is no risk for addiction, which is especially important in populations where addiction risk is high, and, unlike opioid prescription drugs, the device has no "street value."

Microcurrent is often compared to TENS (transcutaneous electrical nerve stimulation) technology. The TENS technology, which focuses on blocking pain signals to the brain, limits use largely to acute injuries and becomes ineffective once the patient's body "accommodates" the signal. Microcurrent technology, as found in the Avazzia PRO-SPORT™ device, advances TENS technology with the use of low-level electrical currents (10^{-6} amperes) and biofeedback technology to treat nerve and muscle pain, inflammation and other health challenges. Each type of tissue in the human body has an electrical frequency which may be disrupted by injury. Microcurrent restores normal frequencies within the cells, resulting in remarkable improvements in pain, inflammation and function. [11]

PRO-SPORT™ reaction data readings are used to measure each output pulse, and monitor relative tissue conductance and rate of change of the readings from the body. This includes Initial Reaction (IR) and Ongoing Reaction (OR) information on how the tissue reacts to treatment thus providing the operator data about its effectiveness.

Therefore, we speculate that microcurrent treatment using the Avazzia PRO-SPORT™ device is an effective stand-alone treatment for varying degrees of chronic pain over a diverse population as seen in a single visit. We conducted an open-label clinical study to support our hypothesis.

MATERIALS AND METHODS

Eighteen patients of Thomas Lehanan, D.C., and Darcy Brunk, D.C., were enrolled in our study. Each clinician has experience with microcurrent therapy. Patients at least 18 years of age and who had been diagnosed with chronic pain were eligible to participate. Each patient had a treatment diagnosis ICD-9 code consistent with chronic pain. Each patient also presented with other symptoms and diagnoses consistent with their chronic pain in various locations of the body. All patients that participated in this study presented with a history of chronic pain of at least six months. Patients with an implanted pacemaker, defibrillator or neurostimulator or who were pregnant or nursing were excluded from the study. All patients signed a written informed consent to participate in the study before any treatment was administered. See Table 1 for details of patient demographics.

The equipment used in this study was the Avazzia PRO-SPORT™ device, a prescription electro-stimulation biofeedback medical device (Avazzia Inc., Dallas, TX, USA). The PRO-SPORT™ device delivers a pulsed, damped, biphasic sinusoidal waveform with frequencies ranging from 0.5Hz to 1,524Hz and variability of power intensity. The clinician can control the power intensity, frequency, number of pulses per output and waveform damping. The device is equipped with electrodes on the back face of the device to be used for administering treatment. The clinician was also given a Y-electrode

accessory attachment, an electrode attachment that contains two stainless steel electrode balls attached to an eight inch handle, to be used to administer treatment. The Y-electrode tool differs from traditional TENS technology in which self-adhesive, conductive electrode pads are applied for treatment. The Y-electrodes enable tissue conductance impedance monitoring as opposed to the TENS pads that provide false hydration and override the actual subtle tissue conductivity characteristics.

The study was designed as an open-label clinical trial. The patients were seen over a single 60 minute visit at the office of Thomas Lehanan, D.C., or Darcy Brunk, D.C. Eligible participants completed a medical history and study intake form to further detail their chronic pain conditions and their current state. Prior to treatment being administered, each patient described their pain by rating their pain level on a numerical visual analog scale (VAS) from 0 to 10, with 10 meaning the patient was currently experiencing unbearable pain and 0 meaning no pain, and identifying the location of where they were experiencing pain on a diagram of the male or female body based on gender.

At each visit, the clinician administered treatment with the following designed protocol to address the local pain site and nerve regions:

1. Major scars reported by the patient through continuous painting motion of the device electrodes over and around the area of the scar set at comfortable power intensity as determined by the patient. The settings used varied frequency in a range from 30 Hz to 121 Hz with and without damping.
2. The point of pain, as indicated by the patient, and four to eight points directly surrounding the point of pain that is no more than two inches apart with treatment emphasis at locations with reaction readings indicating higher conductivity. Power was set at a comfortable intensity as determined by the patient. The contralateral side of the point of pain (same position, opposite side of body) was then treated using the same method.

3. Vertebras C5 through L4 along the spine and the corresponding left and right spinal nerves with the placement of the electrodes at each vertebrae and the device set at a comfortable power intensity as determined by the patient.
4. The vagus nerve and sternocleidomastoid muscle with the device set at a frequency of 120Hz with power intensity modulation.

Changes in the tissue impedances were displayed with numerical values on the Avazzia PRO-SPORT™ device.

At the end of the visit, each patient detailed their current pain level by rating on a numerical visual analog scale (VAS) from 0 to 10, with 10 meaning the patient was currently experiencing unbearable pain and 0 meaning no pain.

RESULTS

Eighteen participants were recruited and completed the single session. Before treatment, six (33%) patients reported a pain level between 0 and 3, associated with mild pain, eight (44%) patients reported a pain level between 4 and 6, associated with moderate pain, and four (22%) patients reported a pain level greater than 7, associated with severe pain. After the microcurrent treatment was administered, sixteen (89%) patients reported a pain level between 0 and 3, two (11 %) reported a pain level between 4 and 6 and none of the patients reported pain levels greater than 7. The average pain score rating was 4.93 ± 2.39 before treatment and 1.97 ± 1.87 after, yielding an average decrease in pain score of 3.06 ± 1.95.

Table 1 shows detailed average pain scores before and after treatment and average pain reduction (%). The pain scores post-treatment were collected approximately 5 to 10 minutes after the end of the treatment session. Overall, 5 (28%) patients experienced less than 40% pain relief, 4 (22%) experienced 41% to 60% pain relief and 9 (50%) experienced more than 60% pain relief. There were no adverse side

effects reported with the use of this treatment. Less than 2% reported no pain relief achieved with the single-session treatment. See Figures 1 through 4 for illustrations of results.

DISCUSSION

This study investigated the effectiveness of microcurrent technology using the Avazzia PRO-SPORT™ device as treatment for varying degrees of chronic pain over a diverse population as seen in a single visit. With the majority of the patients experiencing pain relief greater than 40% and an average decrease in self-reported pain score of 3.06 ±1.95, it is concluded that in a single visit, the treatment safely and effectively reduced the self-reported pain levels of chronic pain patients.

The patient population included in this study varied by age, gender, specific location of their chronic pain and the length of time of their chronic condition. By conducting the study over such a diverse population, we are able to assess its applicability over pain populations versus a single condition. However, the sustainability of the beneficial effect over an extended period of time and larger population[12] will need to be considered to further conclude the effectiveness of this treatment.

The use of the numerical, absolute VAS pain scale, as used in this study, in the assessment of levels of chronic and acute pain has been proven in previous studies to be less sensitive to bias. The use of the absolute type of VAS scale, only assessing current pain levels as opposed to a comparative scale, reduces the risk of patient bias affecting the data. In later studies assessing the efficacy of treatment, additional complementary indices of pain relief should be assessed to add additional validity to the data.

Extended research on biofeedback will provide more clarity on how it can be further incorporated in treatment of pain and help identify the source of pain throughout the body.

CONCLUSIONS

The Avazzia PRO-SPORT™ device safely and effectively improves pain levels in diverse patient populations with various degrees of chronic pain. The statistically significant reduction in pain (>40%)

and average decrease in pain score of 3.06 ±1.95 in a single treatment indicate there is a high probability (>90%) of these results being replicable over a larger pain population and an increased reduction of chronic pain with extended use.

REFERENCES

1. Chapman-Jones D, Hill D. "Novel microcurrent treatment is more effective than conventional therapy for chronic Achilles tendinopathy: randomised comparative trial". *Physiotherapy*. 2002, 88:471-480.
2. Park RJ, Son H, et al. "The effect of microcurrent stimulation on the foot blood circulation and pain of diabetic neuropathy". *Journal of Physical Therapy Science* 2011, 23: 515-518.
3. Oh HJ. "The effects of microcurrent stimulation on recovery of function and pain in chronic low back pain". *Journal of the Korean Physical Society*. 2008, 20: 67-73.
4. Jung YJ, Yu HY, Go SJ, et al. "Effects of Transcutaneous Electrical Nerve Stimulation and Microcurrent Electrical Neuromuscular Stimulation on Delayed Onset Muscle Soreness". *Physical Therapy Korea*. 2000, 7: 76-87.
5. McMakin, Carolyn R, M.A, D.C. "Microcurrent therapy: A Novel Treatment Method for Chronic Low Back Myofascial Pain". *Journal of Bodywork and Movement Therapies*. 2004, 8: 143-153.
6. Centers for Disease Control. "Vital Signs: Prescription Painkiller Overdoses in the U.S." November 2011. Available at: http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html.
7. U.S. Office of National Drug Control Policy. "Prescription Drug Abuse". 2011. Available at : http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf.
8. American Society of Interventional Pain Physicians. "Fact Sheet". 2012. Available at: http://www.asipp.org/documents/ASIPPFactSheet101111.pdf.

9. U.S. Department of Health and Human Services. "Opioid Overdose Toolkit". August 2013. Available at: http://store.samhsa.gov/product/SMA13-4742.
10. Hartocollis, Anemona."New York City to Restrict Prescription Painkillers in Public Hospitals' Emergency Rooms". *New York Times*. Jan. 10, 2013.
11. Whitaker, Julian, MD. "What Is Microcurrent Therapy?" Dr. Julian Whitaker. 14 Feb. 2014. Web. 11 May 2014. http://www.drwhitaker.com/what-is-microcurrent-therapy.
12. U.S. Department of Health and Human Services. Summary Health Statistics for U.S. Adults. National Health Interview Survey. 2009: 7.