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NANOSCALE WEARABLE DEVICES REDUCE QUANTITATIVE AND QUALITATIVE MEASURES OF NEUROMUSCULAR PAIN

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In this pilot investigation with IceWave patches, an Electro-Acuscope was used to monitor nerve conduction between two electrodes as a quantitative measure of pain. Qualitative measure of pain severity was assessed by using a visual analog scale (VAS). Pain data from a cohort of 30 volunteers: 14 females and 16 males, 26-72 years old were analyzed. The subjects presented with a variety of neuromuscular pain: arthritic, lower back, neck, shoulder, sciatic, sports-related, car accident-related, scapular, and knee pain, with back pain being the most prevalent. The Electro-Acuscope was used to monitor pain "intensity" before and after wearing the IceWave™ patches. The VAS tool was used to assess the perception of pain severity pre- and post-application of the patches. These devices were applied to pre-designated acupuncture points according to instructions from the manufacturer. The measurements before wearing the patches were used as baseline. Subjects were instructed to keep well hydrated while wearing the patches. Subjects served as their own control. The hypothesis to be tested was: IceWave patches reduce quantitative and qualitative measures of neuromuscular pain. Statistical analyses were carried out to compare both the Electro-Acuscope readings and VAS markings pre- and post-application of the IceWave patches. The results showed that there was a highly significant ($p < 0.001$) reduction in both Electro-Acuscope readings and VAS markings post-application of the IceWave patches compared to the corresponding values pre-application of these patches. Therefore, application of these nanoscale wearable devices had a highly significant effect in reducing intensity and perception of severity of pain. The statistical power considering the effect size (% reduction in pain), sample size, and level of significance for the Electro-Acuscope data was at least 90%, while the statistical power for the VAS markings was at least 99%. Based upon these observations, the hypothesis was accepted as true.

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Nanoscale Wearable Devices Reduce Qualitative and Quantitative Measures of Neuromuscular Pain

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Abstract—**In this pilot investigation with IceWave patches, an Electro-Acuscope was used to measure nerve conduction between two electrodes as a quantitative measure of pain. Qualitative measure of pain severity was assessed by using a Visual Assessment Scale (VAS). Pain data collected from a cohort of 30 volunteers: 14 females and 16 males, 26-72 years old were analyzed. The subjects presented with a variety of neuromuscular pain: arthritic, lower back, neck, shoulder, sciatic, sports-related, car accident-related, scapular, and knee pain, with back pain being the most prevalent. The Electro-Acuscope was used to monitor pain "intensity" before and after wearing the IceWave™ patches. The VAS was used to assess the perception of pain severity pre- and post-application of the patches. These devices were applied to pre-designated acupuncture points according to instructions from the manufacturer. The measurements before wearing the patches were used as baseline. Subjects were instructed to keep well hydrated while wearing the patches. Subjects served as their own control. The hypothesis to be tested was: *IceWave patches reduce quantitative and qualitative measures of neuromuscular pain.* Statistical analyses were carried out to compare both the Electro-Acuscope readings and VAS markings pre- and post-application of the IceWave patches. The results showed that there was a *highly significant* ($p < 0.001$) reduction in both Electro-Acuscope readings and VAS markings post-application of the IceWave patches compared to the corresponding values pre-application of these patches. Therefore, application of these nanoscale wearable devices had a *highly significant* effect in reducing intensity and perception of pain severity. The statistical power considering the effect size (% reduction in pain), sample size, and level of significance for the Electro-Acuscope data was at least 90%, while the statistical power for the VAS markings was at least 99%. Based upon these observations, the hypothesis was accepted as true.**

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I. Introduction

PAIN, as defined by the International Association for the Study of Pain, is "an unpleasant sensory and emotional experience usually associated with actual or potential tissue damage, or described in terms of such damage". In 2001, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) recommended pain as the fifth vital sign (in addition to patient's temperature, blood pressure, heart rate, and respiratory rate). In the medical, as well as physical medicine and rehabilitation (PM&R) settings, pain is considered as one of the most common reasons for patients seeking care. In North America, the estimated costs of chronic pain, including direct medical expenses, lost income, lost productivity, compensation payments, and legal charges, are approximately $90 billion a year." [1].

It is clear that pain is a significant problem worthy of study and that safe and effective attenuation and treatment of pain can be beneficial for both the patient and the society. According to Jackson C. Tan, musculoskeletal pain can be divided into acute and chronic categories. Acute pain can be treated by many modalities such as rest, thermal therapies, transcutaneous electrical nerve stimulation (TENS), *acupuncture* and medications, such as non-steroidal anti-inflammatory drugs (NSAIDS), opioids, and muscle relaxants [1]. Chronic musculoskeletal pain could consist of categories such as chronic low back pain, non-inflammatory arthritis (e.g., osteoarthritis), inflammatory arthritis (e.g., rheumatoid arthritis), fibromyalgia and myofacial pain syndrome. Chronic pain treatments also include TENS, *acupuncture*, thermal therapies, lasers, and drugs such as antidepressants, NSAIDS, opioids, and other medications [1]. Nowadays therapies involving infrared heat, nonthermal infrared treatments with low energy lasers, *acupuncture* and electronic modalities such as micro-current devices are all accepted treatments for musculoskeletal pain.

It is well established that temporary pain relief may be achieved through the use of non-heating or low-heating infrared light therapies and micro-current devices. Typical infrared systems consist of non-thermal infrared diodes, lasers, *patches* containing metallic ions and infrared heating elements as the source of infrared light. At the present time low-energy laser therapy is being used to control the pain of many different types of diseases, but its mechanism of action is not known [2]. The energy delivered by low-energy laser therapy is too low to produce heat, but some data suggest that nerve transmission may be altered [3]. It is now well known that non-heating or low thermal pain relief may be achieved provided that a source of infrared light is available for therapy (Infrared light includes all radiations between wavelengths just beyond those of the deepest reds of the visible spectrum, 700 nm, up to the microwave range of ~100 μm).

Although traditional methods of infrared therapy have typically utilized infrared lamps, lasers and diodes as the source of infrared light, it is now well known that many *naturally occurring materials* are capable of reflecting or filtering the infrared light produced by the human body. These materials include silicon dioxide, titanium, aluminum

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oxide, several forms of carbon, jade, various *organic compounds and water.*

This is the first study to investigate *the effect of the IceWave patches* on quantitative and qualitative measures of pain. Pain data collected and complied in a database in 2009 from a cohort of 30 volunteers: 14 females and 16 males, 26-72 years of age, were retrospectively analyzed by the authors in 2011. The subjects presented with a variety of pain such as: arthritic, lower back, neck, shoulder, sciatic, sports-related, car accident-related, scapular, and knee pain, with the back pain being the most prevalent symptom. An Electro-Acuscope was used to monitor the "intensity" of pain before and after wearing the IceWave patches. The measurements before wearing the IceWave patches were used as baseline. The VAS tool was used to assess the *perception* of severity of pain pre- and post-application of the IceWave patches. Subjects were instructed to keep well hydrated. All subjects served as their own control. The hypothesis to be tested was: *IceWave patches reduce quantitative and qualitative measures of neuromuscular pain.*

II. Methods and Materials

A. Experimental Protocol

A simple experimental protocol was used by the pain assessment, patch application, and data collection team. After giving informed consent, the patients pointed out their area of significant pain or discomfort. The area was then palpated to determine if there was swelling associated with acute pain or constriction associated with chronic muscular problems. Using an Electro-Acuscope [4] (80 L, Biomedical Design Instruments, Burbank, California, USA), the Gain Spectrum was set to 85 to determine a median level of conductivity, which was set for each patient. An average Gain Spectrum setting is 000-100 but it can go as high as 999. Then the 2 Electro-Acuscope electrodes (probes) were placed on the pain area approximately 2 to 4 inches apart to obtain conductivity readings between the two points. The electrodes were then moved around the specific area to determine differentiation in the conductivity two inches up and down or left and right depending on the area of pain; although, the recorded readings were obtained from the actual area of pain. This method of reading was adopted for better accuracy. The IceWave patches were applied based on instructions available from the manufacturer's booklet [7]. Overall, each patient had conductivity change in tissue after applying the IceWave patches within 2-5 seconds; where on average conductivity readings would change 20-30 points and significant subjective change would occur within 2-5 minutes. There were a few cases in particular where subjective change took a little longer (15-20 minutes) and this was mainly dependent on the overall health of the individual and postural balance where energy flow could be affected.

B. IceWave Patches

For this investigation, the IceWave patches (LifeWave, La Jolla, California, USA) were used (Fig. 1). The IceWave patches are described as "passive nano-devices". They are transdermal and no substance enters the body. "They only reflect energy back into the body and they do not generate energy. The organic molecules in the patches act like frequency specific mirrors or reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broad-band reflectors. These organic materials have liquid crystal properties similar to the liquid crystal properties of cell proteins." [5].

"Placing a patch containing an organic liquid crystal on the skin will allow the organic materials to passively absorb wide-band energy and reemit narrow-band energy back into the body. Infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy from the body and then reemit the energy across a wide energy band. LW patches contain organic materials, which only mirror back energy that the body is already emitting. The difference between LifeWave patches and infrared products is that LifeWave patches only mirror back a very narrow band of frequencies. In this context LW patches are not significantly different in mechanism of action than infrared wraps, socks, bandages, blankets, etc." [5].

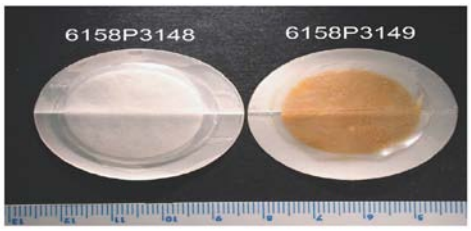

Fig. 1. The IceWave patches (Courtesy LifeWave LLC).

There are a number of recommended methods for efficient placement of IceWave patches on acupressure points by the manufacturer. Fig. 2 shows an example called the "*Bracketing Method*" [6].

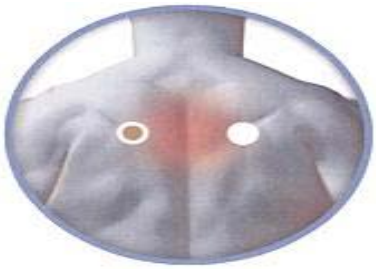

Fig. 2. Bracketing method of IceWave patch placement.

C. Instrumentation

An Electro-Acuscope, was used to monitor nerve conduction between two electrodes and provided a quantitative measure of pain level. This device works by using micro-current, low-voltage level, computerized feedback-controlled delivery of energy to the damaged tissue. This provided a quantitative measure of pain level on a conductance meter with a numerical scale of 0 to 100. Higher meter readings are indicative of higher bioelectrical conductance levels. The range and sensitivity of the conductance meter is controlled

by the Gain Spectrum dial on the device. For example, a Gain Spectrum of 100 represents a resistance range of 30K – 350K Ohms between two electrodes. Qualitative (subjective) measure of pain severity was assessed by using a visual analog scale (VAS) assessment tool [7], basically a 10 cm long line with numerals from 0 to 10 and three descriptors: 0 at the beginning designated as *No pain*: 5 in the middle designated as *Moderate pain* and 10 at the end designated as *Worst possible pain*.

Fig. 2. An Electro-Acuscope used in measurement of pain level [4].

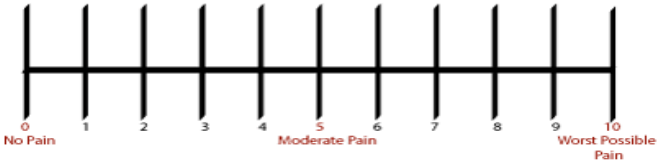

Fig. 3. A Visual Assessment Scale (VAS) similar to the one that was used in this study [8].

III. RESULTS

The Electro-Acuscope used in this study provided a quantitative measure of pain level on a conductance meter with a numerical scale of 0 to 100. Qualitative (subjective) measure of pain severity was assessed by using the visual analog scale (VAS) tool described above.

Electro-Acuscope readings and VAS tool numeral markings pre- and post-application of IceWave patches acquired from14 females and 16 males, 26-72 years of age (who presented with different types of pain such as arthritic, lower back, neck, shoulder, sciatic, sports-related, car accident-related, scapular, and knee pain, with the back pain being the most prevalent symptom) were analyzed in this investigation. Pain data were collected in 30 subjects (n=30) for this study. Table 1 shows summary of mean and standard deviation values for Electro-Acuscope readings as well as VAS tool numeral markings in all of the subjects.

TABLE I
SUMMARY OF MEAN AND STANDARD DEVIATION VALUES FOR ELECTRO-ACUSCOPE READINGS AND VAS TOOL MARKINGS, N = 30.

	Objective and Subjective Measures of Pain Level and Severity	
	Electro-Acuscope Conductivity Readings	**Visual Analog Scale Tool Markings**
Mean ±Std		
Pre-patch	**79.9 ± 11.0**	**5.5 ± 2.1**
Mean ±Std Post-patch	**59.1 ± 24.3**	**2.6 ± 1.9**

IV. DISCUSSION

Statistical analyses were carried out to compare both the Electro-Acuscope readings and VAS numeral markings pre- and post-application of the IceWave patches. The results showed that there was a *highly significant* reduction in the Electro-Acuscope readings as well as the VAS markings post-application of the IceWave patches compared to the corresponding values pre-application of these patches. This simply means that application of IceWave patches had a *highly significant* ($p < 0.001$) effect on 30 subjects wearing these patches in attenuating the intensity and perception of severity of pain. It is noteworthy that the average subjective effect size evaluated by the VAS tool was more pronounced than the average effect size measured by the Electro Acuscope. The statistical power considering the effect size (% reduction in pain, sample number, and level of significance) for the Electro-Acuscope data was at least 90%, while the statistical power for the VAS numeral markings was at least 99%.

V. CONCLUSION

The overall results showed that there was a *highly significant* ($p < 0.001$) reduction in both Electro-Acuscope readings and VAS markings post-application of the IceWave patches compared to the corresponding values pre-application of these patches. Therefore, application of these nanoscale wearable devices had a *highly significant* effect in reducing intensity and perception of pain severity. The statistical power considering the effect size (% reduction in pain), sample size, and level of significance for the Electro-Acuscope data was at least 90%, while the statistical power for the VAS markings was at least 99%. Based upon these observations, the hypothesis was accepted as true.

In future studies double-blind placebo-controlled protocols will be used to further investigate the efficacy of these devices on pain reduction.

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