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Original Article

Effect of IceWave® organic nanoscale patches on reduction of musculoskeletal pain

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ABSTRACT

In this pilot dual-site study with LifeWave IceWave® patches, using subjects as their own controls, data were acquired from a convenience sample of 16 males and 24 females, 50% Caucasian-Americans, 50% Hispanic-Americans, ages 20 - 85 with neuromuscular pain. The hypothesis was: the application of IceWave® patches to the skin will reduce one's perception of pain. Subjects were tested at baseline (without any patches), and then at 1 and 3 h on day 1 and at 1 h on days 2 - 5 after patch application. At every time point, the mean change, indicative of one's perception of pain, was highly significantly ($p < 0.0001$) reduced, with a statistical power of 100% compared to baseline. Based on these findings, the hypothesis was accepted as true.

Keywords acupuncture, organic nanotechnology, pain management

INTRODUCTION

Pain is a subjective and personal experience. Some people go through life escaping pain, but most know how distressing and how hurtful it can be. One hundred million Americans were affected by acute and chronic pain associated symptoms in 2011.

Pain comes at a tremendous price. Pain causes missed work, loss of sleep, reduced productivity and lowered wages. It challenges all areas of function. The emotional burden on the people with pain and their families is considerable (http://www.painmed.org/patient/facts.html). In 2004, the World Health Organization (WHO) asked practitioners and researchers to find better sources of relief for people in pain (WHO, 2004).

In the USA, acupuncture has been widely used by thousands of mainstream and complementary medicine practitioners for pain relief, according to the 2007 National Health Interview Survey (Barnes et al., 2008). Still, many people in pain choose analgesics, prescription anti-inflammatories or narcotics that may cause serious toxic side effects in some of them, which makes pursuit of a non-toxic approach to pain management highly desirable.

Other methods of treatment of pain include behavioral approaches and physical medicine approaches, such as acupuncture, and electronic modalities such as biofeedback, microcurrent units and transcutaneous nerve stimulation units (TENS).

This current study was undertaken as an open-label dual-site pilot study to investigate the effect of the IceWave® organic nanoscale patches on pain control in individuals needing pain management for persistent or acute conditions, and to determine the immediate and long-term effectiveness of the pain control.

Photobiomodulation is an emerging branch of science that typically utilizes a low energy level laser or light emitting diodes to produce specific biochemical effects within humans or animals. As an example, research funded by the U.S. Defense Advanced Research Projects Agency conducted by Whelan revealed that there were specific wavelengths of light that could initiate an elevation of mitochondrial energy (Whelan et al., 2001a, 2001b). This is important because the mitochondria provide ATP, the basic chemical unit of energy for cells. In the context of this paper, which is pain management, ATP is an important chemical responsible for energy release in the cells, and is involved in injury repair and pain relief. It has been shown in this regard that specific wavelengths of infrared light can both elevate ATP production and produce pain relieving effects (Whelan et al., 2001a, 2001b).

When any of the LifeWave patches are placed on the skin, they safely transmit specific wavelengths of light to optimize certain biological functions, such as pain control. These devices have photonic and electrical properties. They are essentially a passive, wireless nanotechnology that relies on non-toxic organic crystals. The crystals absorb infrared frequencies (body heat) in the range of 1000 - 20,000 nanometers and emit light in the infrared and visible spectra back into the body.

Traditional Chinese medicine reveals more than 2,000 acupuncture points on the human body that are connected by 12 main and 8 secondary pathways. Bonghan first named and described the "Bonghan ducts" that are interconnected by a fine netting of webs that are found in organs, and connective and fascia tissues (Soh, 2009). Van Wijk, Soh and Van Wijk (2007) linked the Bonghan ducts with energetic tissue from dense fascia with the skin in internal organs to an extracellular maxtrix that encompasses each cell. Although IceWave Patches® have been reported to be used by acupuncturists to stimulate specific meridian points, these patches also tap into the larger bioelectrical system composed of semiconducting proteins, such as collagen, which utilize their electrically conducting properties to move energy from one location to

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another (Becker, 1990; Becker and Selden, 1985).

Collagen, the most abundant protein in the human body, forms the bulk of connective tissues that are associated with bound water and ions to produce a hydrated state. The combination of collagen and water creates an electrically conductive continuum that extends throughout the body, even into the interior of cells (Ho, 1998). Collagen is a regular repeating protein that possesses the biophysical properties of being both piezoelectric and pyroelectric (Fukada, et al., 1976). It has also been proved by experimental evidence that the piezoelectric and pyroelectric properties of collagen will vary with temperature and level of hydration (Netto et al., 1975). Research on LifeWave patches has demonstrated that these patches will increase electrical conductivity of acupuncture points and collateral regions (Budzynski et al., 2009; Nazeran et al., 2011).

LifeWave research has been tested by quantifiable energy-driven measurements to demonstrate the safety and efficacy of its products. The conventional diagnostic methods utilized to evaluate the LifeWave IceWave ® pain relieving patches include: Medical Infrared Imaging (Thermography), Thought Technology Biofeedback Skin Conductance, Electromyography, Electro-Acuscope, and Self-perceived pain questionnaires. Non-conventional methods for diagnosing both the safety and efficacy of the IceWave®pain relieving patches include: biophoton emission, Bioexplorer method, electro-interstitial scanning (EIS), Gas Discharge Visualization (GDV), and Polycontrast Interference Photography (PIP). All of the following studies have used the Clock Method described in the methods section below for patch application for pain.

De Rock et al. (2011) used infrared digital thermal imaging and acupuncture palpation evaluation by a veterinarian on 38 horses to evaluate the efficacy of IceWave® patches on pain reduction. The horses in this study had mild to severe back pain. Statistical analysis of both the thermal imaging data and veterinarian palpation of painful areas had a highly significant effect ($p < 0.0001$) with a statistical power of 100%, when patches were placed on affected painful areas on each horse. The study proved that IceWave® patches produced a highly significant cooling effect in painful areas and a warming effect in hypothermic areas where there was abnormal sensation.

Toneguzzi et al. (2010) in an unpublished study examined the biohumoral inflammatory response to IceWave® patches using a technique called Bioexplorer that was developed by the Institute of Biophysics in Rome, Italy. In this pilot study, researchers used an Italian pain questionnaire and symptom checklist to show changes in pain in a convenience sample of 10 subjects, where subjects served as their own control. They found a reduction of inflammation in the seven markers was concurrent with a sustained reduction of pain one month following IceWave® patch application for 10 days. They confirmed the reduction of inflammation markers of COX-2, PGE-2, PGF-2, IL-1 and lactic acid that occurred in the first 3 - 4 weeks and sustained for 12 weeks following patch usage. The study highlighted an important reduction of neuropeptides Substance P and Vasoactive Intestinal Peptides (VIP).

In a pilot study by Nazeran and Haltiwanger (2011), IceWave® patches were evaluated by measuring electrical conduction between two points using an Electro-Acuscope for quantitative assessment, as well as the Visual Analog Pain Scale (VAS) for qualitative pain assessment (Wewers and Lowe, 1990). The convenience sample consisted of 30 male and female subjects with a wide variety of neuromuscular pains. Measurements were done before and after patch application. Results were highly significant at the $p < 0.001$ levels, indicating that IceWave® patches effectively reduced the subjects' perception of the severity and intensity of pain. Statistical power of these tests was 99% for the VAS and 90% for Electro-Acuscope measurements.

Streeter, et al. (2009), conducted a double-blind, placebo controlled study on 120 people with two experimental groups and one control group. The study purpose was to validate IceWave® patch efficacy compared to Glutathione ® patch efficacy for pain with the third group using placebo patches. Polycontrast Interference Photography (PIP), Gas Discharge Visualization (GDV) and Electro-Interstitial Scan (EIS) were the devices utilized before and after using LifeWave Patches. GDV scanning was used to assist with optimal patch placement by biophotonic emissions from acupuncture points. EIS measured conductivity of interstitial fluid between cells by measuring the electro-physiological properties of 22 different volumes in the body along 69 parameters. Both IceWave® and Glutathione® patches were found to create beneficial energetic effects.

MATERIALS AND METHODS

Description of materials

LifeWave produces a variety of patches for different purposes that fall under the category of a new energy modality. The majority of product research has shown their patches are innovative, non-transdermal devices that improve the electrical conductivity of connective tissues in the skin as well as stimulating specific acupuncture points for improving flow of energy without the use of acupuncture needles. These patches contain nanostructured bio-molecular organic substances that are GRAS (Generally Recognized as Safe) approved by the Federal Drug Administration in the U.S.A. The IceWave® patches are 3.5 cm diameter discs that cover 9.6 (cm^2) of surface area ($A = pi/4*d^2$). Using a proprietary process, LifeWave has constructed seven different types of patch products, each with unique molecular structures that create a specific biophysiologic response when applied to the skin, which have been tested by ten years of empirical experimentation.

Since the skin contains so many electrically conductive points, when one IceWave® patch is moved around a central patch to different sequential locations, the user will invariably find an acupuncture point within four to six different moves that creates an electrical circuit on the skin to relieve pain.

The Clock Method (also referred to as the Cross Method) was developed for IceWave® as a guide for patch placement for use when people have little or no knowledge of acupuncture points and meridians. The method uses the hydration and the electrical conductivity properties of the skin to make contact with acupuncture points and meridians.

One begins by placing the tan patch on an identified pain spot, which would represent the center of the clock. Next, the person moves the white patch in a series of different locations that correspond to the numbers on the clock face, leaving the white patch on for 10 to 20 seconds to see if any pain relief has occurred in each position. The first location is above the tan patch, then below the tan patch, then to the right of the tan patch and then to the left of the tan patch. Unpublished research confirms that this method produces some reduction of pain 90% of the time.

LifeWave research purports that IceWave® patches provide a noninvasive, drug-free method for quick pain reduction. The patches contain natural nontoxic organic crystals that absorb body heat and generate infrared signals. IceWave® patches have recently been approved as a beneficial medical device for pain reduction in France and the European Union, altering the patch classification in Europe.

Table 1. Summary statistics for pain scores at each time point

Time Point		Mean	SD	Median	Min	Max
Baseline		6.08	1.62	6.0	4	10
Day 1	Hour 1	3.03	2.29	3.0	0	10
	Hour 3	1.68	1.79	2.0	0	7
Day 2	Hour 1	2.15	1.94	2.0	0	7
Day 3	Hour 1	1.90	2.10	2.0	0	9
Day 4	Hour 1	1.70	2.14	1.0	0	9
Day 5	Hour 1	1.40	1.84	1.0	0	8

Hypothesis

The hypothesis was that application of IceWave® patches on the skin will reduce one's perception of pain.

Design and Subjects

This was an open label, pretest-posttest study using subjects as their own controls. A convenience sample of 16 male and 24 female subjects (n = 40) between the ages of 30 - 84 years were recruited from two sites in Palm Beach County, Florida: a physician's outpatient clinic and an assistive living facility. Each subject reported musculoskeletal pain during the week before data collection. Subjects were required to: 1) score ≥ 4 on the self-described Universal Pain Assessment Tool (UPAT); 2) score ≥ 3 on the MiniCog Assessment form to establish comprehension to sign the informed consent and HIPAA authorization forms; 3) have used some form of pain medication routinely for persistent or chronic pain management; 4) and be seeking an alternative to pain medication for inclusion in the study. Subjects were excluded if they: were pregnant or breast-feeding, had sensitivity to medical adhesives, had a pacemaker, had used pain medications within a 24 h period prior to start of study, were in litigation, had cognitive deficits, or were unable to refrain from using pain medication during the course of the study.

Procedures

The Independent Investigational Review Board, Inc. of Plantation, Florida approved the research protocol and informed consent was obtained. The study was funded by LifeWave, LLC, in 2010 with a small grant. Subjects were screened against the inclusion criteria. Queries about medications and medical history were completed. Subjects were encouraged to stay well-hydrated during the study period. Placement of patches followed the Clock Method instructions described earlier, as a way of finding the best location for placement. Subjects rated the effectiveness of the pain relief on the scale of 1 - 10 in the seconds following patch placement. Subjects were instructed to reapply patches to the same anatomical positions daily every 12 h. Baseline UPAT scores were assessed for 5 days before and after patching. Researchers were trained in patch placement by a LifeWave consultant. Two-sided paired t-tests were used to evaluate the data and disprove the null hypothesis.

Statistical analysis

A non-parametric approach was used to compare the cumulative averages of the net changes in the post-patch assessment period with corresponding baseline data obtained in the pre-patch assessment. Data showed that subjects wearing IceWave® organic nanoscale patches experienced a highly significant ($p < 0.0001$) reduction in perception of pain intensity compared to baseline (while wearing no patches) following repeated application of these patches to the painful areas. Based upon the effect size for reduction of pain, number of subjects, and level of significance for this study, the statistical power for each test at all of the time points was found to be 100%. By day 1, 100% of subjects experienced some pain relief 1 h after application. By day 5, 77.5% experienced reduced pain ≥ 4 levels one h after application and the mean pain score was 1.4, suggesting that almost everyone had no pain.

RESULTS

Forty subjects completed the study: 16 males and 24 females. Three subjects were dropped from the study by the researchers. Two people had mild withdrawal reactions from stopping analgesic drugs such as headache or diarrhea and one person could not do without pain medication. The null hypothesis was rejected. Table 1 displays summary statistics for the pain scores at each time point: the mean, standard deviation (SD), median, minimum value, and maximum values.

At baseline, the pain scores ranged from 4 to 10 with a mean of 6.08 and a median of 6.0. The mean score was reduced to 3.03 at day 1, 1 h At all subsequent time points, the means ranged from 1.40 to 2.15. Table 2 displays summary posttest statistics for the changes from baseline and reports the p-values from the two-sided paired t-tests, demonstrating the mean change is equal to zero. The mean change from baseline was smallest at Day 1, 1 h (-3.05 points). At all subsequent time points, the mean improvements ranged from changes of -3.93 to -4.68. At every time point, the mean change compared to baseline was highly significant ($p < 0.0001$).

Table 3 summarizes the results from each post-baseline time point in terms of the percentage of subjects who achieved a specified magnitude of reduction (or greater) from the baseline pain score at each post-baseline time point. The percentages of subjects with reductions of at least 1 point, of at least 2 points, of at least 3 points, and of at least 4 points are displayed. At all time points subsequent to day 1, 1 h, and the percentage of subjects with at least a 1 -point improvement

Table 2. Summary statistics for pain score changes from baseline at each time point

Time Point		Mean	SD	Median	Min	Max	p-value
Day 1	Hour 1	-3.05	2.24	-3.0	-8	2	<0.0001
	Hour 3	-4.40	1.98	-4.0	-8	1	<0.0001
Day 2	Hour 1	-3.93	2.22	-4.0	-10	2	<0.0001
Day 3	Hour 1	-4.18	2.18	-4.0	-10	0	<0.0001
Day 4	Hour 1	-4.38	2.29	-4.0	-10	2	<0.0001
Day 5	Hour 1	-4.68	2.13	-4.0	-10	0	<0.0001

Table 3. Percentages of subjects with improvements from baseline of at least 1, 2, 3, and 4 points on the pain scale

Time Point		Improvement (%)			
		1+	2+	3+	4+
Day 1	Hour 1	82.5%	80.0%	65.0%	32.5%
	Hour 3	100.0%	95.0%	85.0%	60.0%
Day 2	Hour 1	97.5%	92.5%	75.0%	55.0%
Day 3	Hour 1	95.0%	90.0%	82.5%	57.5%
Day 4	Hour 1	95.0%	90.0%	82.5%	72.5%
Day 5	Hour 1	97.5%	92.5%	85.0%	77.5%

ranged from 95% to 100%. Similarly, the percentage of subjects with at least a 2-point improvement ranged from 90% to 95% with 85% or 34 people achieving a reduction of 4 or more points by the 5th day. Visual inspection of pain ratings after baseline revealed that 5 subjects rated their pain as 1; 2 subjects rated their pain as 2; 4 subjects rated their pain as 3; 1 subject experienced pain at level 5 and one outlier only had slight improvement moving from level 9 to level 8.

DISCUSSION

This study reveals the potential of IceWave® patches to provide sustainable non-drug management of pain. Alternative treatments are increasing in popularity, due to the drug toxicities and the negative consequences of pharmaceuticals. Patches can be used to create multiple circuits on the skin to address the numerous areas of pain.

Hydration levels are a factor influencing the efficacy of IceWave® patches. Some people have anecdotally reported up to 24 h of pain relief after wearing these patches, which may be related to their levels of hydration. The subject in this study, who experienced very little relief, may have not been following the specific recommendations to drink water.

IceWave® patches have been utilized with animals and humans. They have not been tested with pregnant women. IceWave® patches could offer practitioners, such as physicians, occupational and physical therapists, and acupuncturists, strategies for the provision of quick pain relief for patients/clients. These practitioners may be in a position to conduct experimental research studies that compare IceWave® patches with other modalities typically used for pain reduction such as hotpacks, iontophoresis, ultrasound, TENS units and acupuncture, to demonstrate sustainability of pain relief with each method. These practitioners work with a wide variety of people with neuromuscular, orthopedic, and neurological problems with pain, who could be evaluated.

The Clock Method for easy placement of IceWave ® patches enables the practical everyday use by average people. There were no adverse events reported in this study. Mild effects of diarrhea and headaches may have been related to withdrawal from analgesic medications or a detoxification effect of IceWave® patches.

One limitation of the study was that subjects did not keep hydration records for statistical comparison. This study was also limited by the lack of usage of a placebo patch, the convenience sample and using subjects as their own controls. To advance this science, future studies must be undertaken with a larger random sample using double-blind placebo controlled trials with waiting-control groups.

CONCLUSION

This pilot study adds value to the literature on pain management, providing another option for non-invasive pain management. It offers people with acute and chronic neuromuscular pain a complementary alternative to pain management with drugs, without any adverse side effects.

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CONFLICT OF INTEREST

All authors declare that there is no conflict of interest.

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