

**A PLACEBO-CONTROLLED RANDOMIZED STUDY ON THE EFFECTS OF ICEWAVE® PATCHES
ON THE REDUCTION OF PAIN**

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Abstract

The purpose of this study was to evaluate the effectiveness of the IceWave® patch for reducing pain. Specifically, the aim was to determine the immediate effectiveness of pain relief using IceWave patches compared with placebo.

This study extends the list of IceWave studies performed to examine the reduction of pain following the use of IceWave patches in painful musculoskeletal areas specified by the subject. It is known that changes in pain levels can include the placebo effect in any pain treatment study. In this study, the measure of the subjective level of pain in response to treatment was compared between control and treatment groups over time, thereby allowing the quantification of the placebo effect in relationship to the treatment effect.

The study consisted of an initial sample of 112 subjects complaining of musculoskeletal pain tested in two pain centers where acupuncture is used as a method of treatment. The ages ranged from 18 to 80 years. Pain medications (including over-the-counter drugs) were withdrawn from the subjects for a period of 5 days to 2 weeks prior to entry into the study. The subject was eligible if he/she expressed a level 3 or greater pain sensation on a 10-point visual analog scale (VAS). No pain medications were allowed during the study nor any physical pain relief modalities such as chiropractic adjustments, acupuncture, massage, physical therapy or machines designed for the reduction of pain (TENS units).

The subjects were randomly assigned to treatment and control groups through the use of a pre-assigned designation of treatment and control patches to which both investigators and subjects were blinded. The subjects were taught to “patch” the chosen pain area using a specific protocol during the initial visit and sent home with six more pairs of patches to be used for 12 hours daily for the next 6 days. They were instructed to record the sensation of pain before and after patching each day and to return their pain diary after the completion of the seventh day of patching.

105 subjects completed the study and the results of the study indicated that pain levels were reduced: The treatment group showed a significant difference in reduction of pain over the 7 days compared with the control group ($p < 0.0001$). The control group had a sharp reduction of pain sensation the first day most likely due to a placebo effect, although the reduction was not nearly as much as the treatment group (-33% vs. -57%). But thereafter on the following days of the study, the control group manifested a much smaller difference in pain level reduction than did the treatment group.

THE STUDY: A RANDOMIZED, PLACEBO-CONTROLLED STUDY ON THE EFFECTS OF ICEWAVE® PATCHES ON THE REDUCTION OF PAIN

Introduction

This study on the treatment of pain focuses on one of the most significant of health care problems worldwide. In 2001, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) recommended pain as the fifth vital sign (in addition to a patient's temperature, blood pressure, heart rate and respiratory rate) for determining diagnostic and treatment procedures. Pain is one of the most common reasons for patients to seek care. In North America, chronic pain, including direct medical expenses, lost income, lost productivity, compensation payments and legal charges, costs the nation upwards of \$635 billion per year, according to a recent report by the Institute of Medicine (IOM).¹ It is clear from this brief statistic that pain is a significant problem worthy of study and that finding effective treatments for pain can be beneficial for both patients and society.

Treatment approaches to chronic pain include multiple strategies which fall into six major categories: pharmacologic, physical medicine, behavioral medicine, neuromodulation, interventional and surgical.⁸ In addition to the known treatment strategies to treat chronic pain, one must also appreciate that in many patients, co-morbidities such as depression and pain medication addiction may exist. Opioid addiction, especially, is a common occurrence.⁹ Thus the effectiveness of novel pain relief strategies may also have a direct positive impact on these co-morbidities.

Therapies involving infrared heat, non-thermal infrared treatments with low energy lasers, acupuncture and electronic modalities such as microcurrent devices are all accepted treatments for musculoskeletal pain. These modes of treatment are tested by energy-driven measurements congruent with previous studies by LifeWave research. In these studies, normalization of infrared activity through testing by infrared thermal imaging occurred on both humans and horses after the use of IceWave patches.^{10,11} The use of the Acuscope and pain scales on humans following IceWave patching also produced positive results, as did the measure of veterinarian palpation with horses.^{12,13,14,15,16}

The invention of the IceWave patch for chronic pain treatment arises in convergence with new research in the field of energy medicine and the development of precise nanotechnological advancements. For over 5000 years through careful clinical observation, Traditional Chinese Medicine has been known to treat pain via acupuncture, a procedure that involves applying thin sterile needles into points along channels in the body called meridians. Through modern science, we can now verify the validity of this type of treatment and improve upon it by the creation of energy frequency-specific devices such as electromyography, laser and microcurrent applications as well as new scientific inventions such as the IceWave patch.

In order to explain the biological effects of acupuncture and thus newer energy therapies such as the IceWave patch, the introduction of this paper will include literature regarding: a) the discovery of the anatomic structure of the bioelectrical system; b) the development of energy medicine and other research/healing, using meridian stimulation as a means of symptom and pain reduction; and c) a brief discussion of LifeWave technology.

Discovery of Bonghan Ducts. A major breakthrough in Energy Medicine has been the discovery of anatomic energy structures in the human body that are composed of ducts (Bonghan ducts named after the Korean discoverer, Bonghan Kim) and fine webs of netting which are pervasive throughout organs as well as connective and fascial tissue^{17,18}. The findings by dye examination showed meridian pathways that closely follow those recorded in Traditional Chinese Medicine^{19,20}.

Connecting Anatomy with Current Energy Research to define “healing”. Recently in 1993, Oschman, a leader in energy medicine, connected the works of Burr, Becker and Selden in energy research^{21,22} with that of the 1964 work of Bonghan Kim in anatomy, posing this totality as the energy field upon which acupuncturists and energy medical practitioners could produce healing²³. Oschman had hoped to move acupuncture beyond the concept of subtle energies into measureable energy frequencies when he gave his presentation to the First Symposium of the Committee for Acupuncture Research in 1993, but the message was ignored. The next major synthesis proposing Kim’s disclosure of the anatomic structure for energy as a central dynamic finding was published by Van Wijk, Soh and Van Wijk (2007). These authors stated:

“Anatomic, cellular and molecular studies reveal the enormity and pervasiveness of such (energy) tissue from the highly structured, strong and dense fascia, via the Bonghan ducts and connections to skin and internal organs to the fine-structured extracellular matrix surrounding individual cells. Tracing coherent events from the macromolecular to the cellular level has improved the understanding of the processes of intercommunication and the system’s self-healing response”²⁴.

This incredibly fruitful knowledgebase can be extremely useful for developing a sub-discipline of healing that does not rely on pharmaceutical intervention to reduce or remove chronic symptoms.

Energy Medicine. Between 1915 and 1930’s, during the period of persecution of Dr. Royal Rife by the American Medical Association (AMA) and the Food and Drug Administration (FDA), only a few of the advanced optical engineering devices such as microscopes, which could view living viruses and disrupt their growth frequencies, managed to be saved from destruction by the FDA. The historical background thereafter as recorded by James Oschman (2000) has traced the emergence of careful research into the role of electricity in biochemical and cellular growth and functioning of tissues and energy pulsations during organ activity. Electro-biology, which the study area had been called in the early 20th Century, has eventually persevered in recording the electrical properties of every organ, tissue and active mechanism by which the body communicates within itself. Additionally, reams of discoveries of the resonating frequencies of viruses and bacteria were saved and they continue to expand to now play a part in present-day treatment of disease²⁵. Unfortunately, destruction of a tremendous volume of medical advancement remains a blot in medical history.

Frequency-Specific Actions of Each Body Activity. The knowledge of frequency-specific actions of cells and body substances, along with the careful recordings of pulsations during cellular

growth and functioning, allowed for a definition of “healing energy” which stimulates the repair of tissue and remission of symptoms of disease. At one time, only extremely low frequencies (ELF) were believed to produce the active mechanisms of such actions as growth and healing. Now the total spectrum of frequencies produced by electronic devices with its harmonics and sub-harmonics such as the infrared frequencies, X-rays and low frequency Hertz within the microcurrent power range are now viewed as having valid healing powers when used as stimulation. Frequencies that are accessible in various devices now range from 0.01 to as high as 999.0 HZ.

Notes Oschman (2000), activation of specific processes opens up not only the natural flow of energy and information, but also has led to the growing use of electrical devices (including LifeWave patches) that stimulate and direct healing by augmenting the biological rhythms of the body. Stimulation of the cellular structure of the body through the bioelectrical system can relieve pain and increase wound healing by regenerating injured tissue and improving protein synthesis, among other effects.²⁶

The total body is composed of rhythms – each system of body processes, each organ, each cell, each atom, each enzyme, all vibrate at their own pace and rhythm. All are powered by bioelectrical energy whose pulsations we use for measuring and recording. We measure heart rate, audiograms, electrocardiograms, electroencephalograms, blood pressure pulsations, all of which provide us with diagnostic information about organ activity, but do not in itself provide us with frequencies used for treatment of the organ. Although we do not commonly measure muscle (electromyography) or nerve conduction, electrodermal, or electroencephalographic activity, all these measures can help us redefine healing.

Mechanism of Action

Energetic Mechanism. The LifeWave patches are non-transdermal phototherapeutic patches that do not transfer any chemicals or drugs into the body. The varieties of LifeWave patches include patches for improving energy, pain, sleep and antioxidant levels. The product we used in this study is the one designed for pain relief called IceWave.

LifeWave patches work by stimulating acupuncture points on the body via infrared energy. LifeWave patches reflect energy back into the body, but they do not have internal power sources that generate energy. Increased electrical conductivity of the skin has been documented in other research using the LifeWave patches. LifeWave patches also work by stimulating the connective tissue network outside of direct acupuncture point stimulation. This study uses the latter mechanism for researching the treatment of pain.

The nontoxic materials in the patches act like frequency-specific reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broad band reflectors. Placing the LifeWave patch on the skin allows the patch to trap and passively absorb wide-band infrared energy and re-emit narrow-band infrared energy back into the body. By way of example, infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy

from the body and then re-emit the energy across a wide energy band. LifeWave patches contain materials, which mirror back the energy that the body is already emitting. The difference between LifeWave patches and other infrared products is that LifeWave patches only mirror back a very narrow band of frequencies depending on the patch product selected. In summary, LifeWave patches are designed to deliver infrared wavelengths to enhance the electrical conductivity of the skin and are a new method of stimulating acupuncture points and connective tissue networks.”²⁷.

Nanotechnologic Construction of LifeWave Patches. LifeWave patches contain nanostructured bio-molecular crystals (mostly amino acids and natural sugars) which when placed on the skin, use photonic and electric properties of the body to reflect back frequency-specific signals. These signals, upon reaching the biophysiologic response that is desired, will show measureable desired changes in the body. Through a proprietary nanotechnology process of designing different molecular structures, LifeWave has been able to construct frequency-specific patches, each with its own ability to induce a specific biophysiologic response.- In the case of the IceWave patch, photic receptors are formed with frequency-specific alterations that lower inflammatory processes, and in fascial tissue, result in the reduction of pain sensation.^{28,29}

Chronic Pain. The association of the use of stimulation of the energy pathways/fascial tissue when treating chronic pain can be better described here by examining the part of pain research having to do with the inflammatory process. It is known that pain often follows nerve pathways and is tied in many different ways to emotions and traumas occurring in concert with pain development and that the brain produces its own centers and triggers for pain leading to chronic pain. This study’s protocol uses mainly the fascial sites where pain is manifest, rather than the acupuncture points, myofascial trigger points or neural pathways. The following discussion of pain will briefly describe the immune system mechanisms and mast cell involvement with inflammatory processes which generate pain sensations.

Zeroing in on inflammation. An excellent review of mast cells – their early evolution as innate immune reactors and their collaboration in the more advanced antibody-mediated specific immunity responses -- can be found in the *British Journal of Hematology*³⁰. A succinct explanation of mast cell behavior is that, being a primitive cell found in many areas of connective tissue, skin and mucosa, mast cells become the initial responders for protective immunity, initiating the inflammatory reaction as a defense mechanism. Thereafter, the defensive collaboration with a secondary host defense, the adaptive immune system, elaborates the defense. As civilization has developed, successive allergic substances, parasites and bacterial/viral infections have produced more allergic diseases and more defensive structures. The importance of discovering the complexity of mast cell behavior is that beyond the initial life-saving inflammatory responses, there lies an emerging picture that mast cells are deeply involved in severe allergic and autoimmune diseases as well as chronic pain and inflammation³¹.

Study Questions

1. Are the IceWave patches more effective than placebo at reducing pain in a clinical setting?
2. Are there within-group differences, using paired (pre-post) means calculated for each day separately and for each group separately, simply to see if means changed from beginning of the patch application and the post period? (If changes are produced for both treatment and control group, it would indicate a large placebo effect apparent in both groups).
3. What other subgroup variables might affect pain levels? (i.e. age, weight, sex).
4. If effective, are IceWave patches a viable alternative to drugs in the treatment of pain given the safety profile (side effect profile)?

Study Design

This was a double-blind, placebo controlled, multi-site study. The primary study site was located in Lake Placid, NY. The second site was in Lakeside, AZ. Subjects were recruited from the surrounding areas. Eligible subjects were randomized to receive treatment X or Y. 112 eligible subjects were enrolled in the seven-day study.

Day 1: Baseline/Screening (Study Visit)

Individuals who responded to local recruitment notices were scheduled for an appointment for the informed consent process. After the consent was completed and signed, the screening was completed. If an individual was eligible, then they were assigned a Subject ID and randomly assigned to receive either treatment. The patches were packaged by the study Sponsor and coded so that the treatment category was unknown to both participants and investigators.

Since the screening required a pain level of 3 or higher on a ten-point visual analog (VAS) scale, this also became the baseline and first day of study.

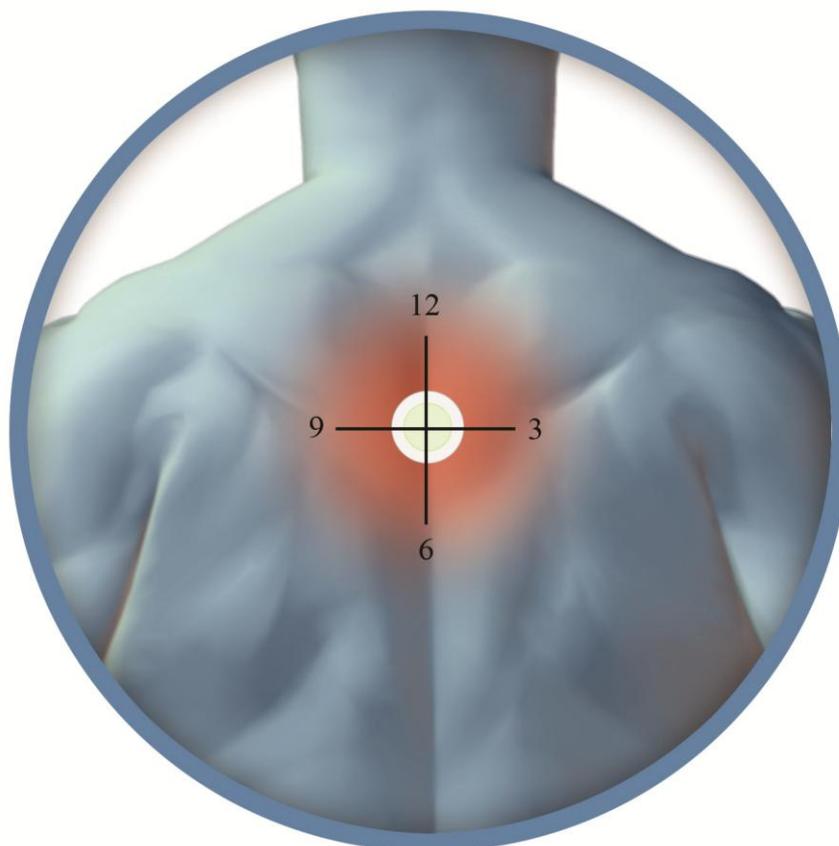
The subjects were instructed on how to apply the patches using the Cross Method developed by LifeWave (see below) as a guide for applying the patches, specific to the origin of the pain. The subjects were told to apply the dark-colored patch over the point of maximal pain and the white patch according to the Cross Method as demonstrated on Day 1 while at the clinic. They completed Day 1 of their pain diary while at the clinic. The subjects were then sent home with six additional sets of patches, instructions on how to apply patches, a 6-day pain diary, and a self-addressed, stamped envelope in order to return their diaries at the end of the study period. Subjects were taught to apply the patches daily and place them according to the origin of the pain at the time of application.

Days 2-7: The study required subjects to wear one set of the patches every day and take a baseline measurement of pain each day, then 10 minutes after patch application.

Day 8: Subjects mailed the completed pain diary to the investigator and completed their study participation.

IceWave Application Instructions

Application of patches: The dark patch was applied in the center of the maximal area of pain and the white patch was applied according to the Cross Method (also known as the Clock) pain relief protocol as shown below:



**Dark patch will be placed where pain is; this graphic just shows a light-colored patch just for clarity.*

STEP 1

Peel the plastic cover from one **DARK-colored** patch, and place it on the skin directly on the point where you have the most pain.

STEP 2

Now remove one half of the plastic cover on a **WHITE-colored** patch and place lightly onto your clothing at the 12 o'clock point someplace ABOVE the pain and where the DARK-colored patch is located. Wait 10 seconds and re-rate your pain on the 0–10 scale. Take note of the effect and go to step 3.

STEP 3

Move the WHITE patch to the 3 o'clock position in relation to the Dark patch. Wait 10 seconds and re-rate your pain on the 0–10 scale. Take note of the effect and go to step 4

STEP 4

Move the WHITE patch to the 6 o'clock position in relation to the DARK patch. Wait 10 seconds and re-rate your pain on the 0–10 scale. Take note of the effect and go to step 5

STEP 5

Move the WHITE patch to the 9 o'clock position in relation to the DARK patch. Wait 10 seconds and re-rate your pain on the 0–10 scale. Take note of the effect and now go back to the location that felt like it had the most effect and affix there. **THIS IS YOUR FINAL LOCATION AND YOUR PAIN ASSESSMENT SHOULD BE BASED ON THIS.** Remove all adhesive backings and stick firmly to skin.

Pain Diary (daily for 6 days after initial study visit):

Pain level BEFORE Patch Application: _____

Pain level AFTER 10 MINUTES OF Patch Application: _____

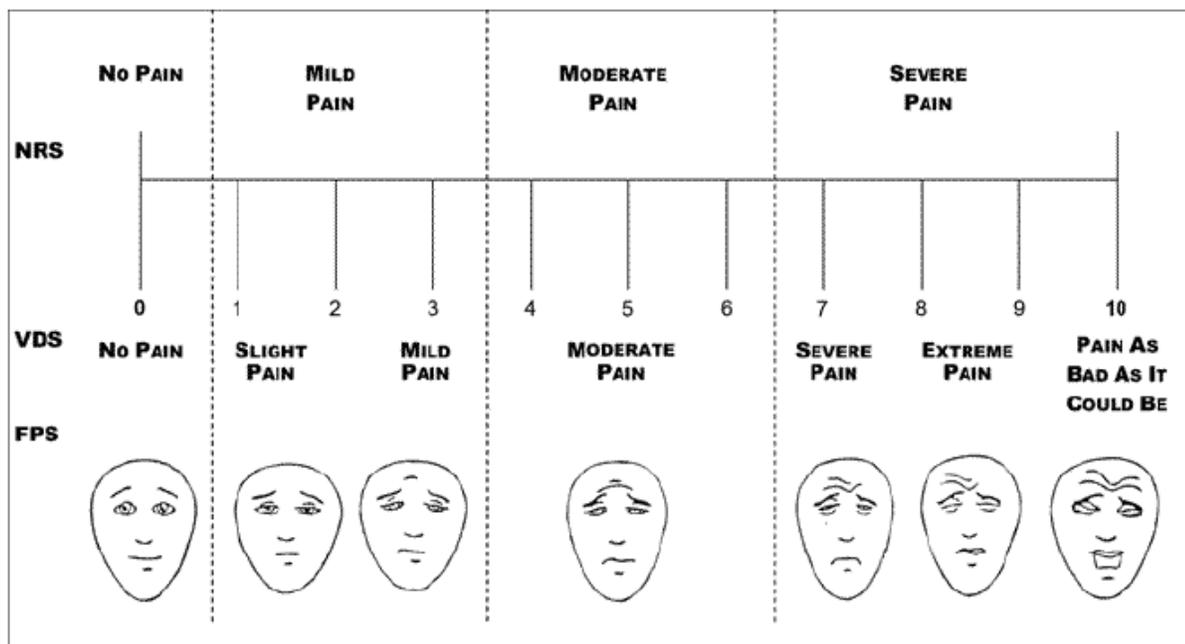


Figure. Numeric Rating Scale (NRS), Verbal Descriptor Scale (VDS), and Faces Pain Scale (FPS). *Source* (FPS): Bieri D, Reeve RA, Champion GD, Addicoat L, Ziegler JB. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: Development, initial validation, and preliminary investigation for ratio scale properties. *Pain*. 1990;41(2):139–50. [PMID: 2367140] Used with permission.

The pain scale selected for the pain diary is a combination of the Numeric Rating Scale, Verbal Descriptor and Faces Pain Scale and is a visual representation of an individual's level of pain.

Inclusion/Exclusion Criteria:

Eligible subjects were required to be relatively healthy individuals between 18 and 80 years of age with musculoskeletal pain for a minimum of 24 hours within the last week with a level of pain at least a 3 on a scale of 1-10. Potential subjects were deemed ineligible for the study if they were pregnant, nursing, unable to withdraw from pain medications for the study duration and/or unable to meet the minimum pain levels and durations. All subjects must have agreed to refrain from any pain treatment for the duration of their participation. These included prescription and over-the-counter pain medications, chiropractic adjustments, massage, acupuncture, physical therapy and TENS machines.

Changes to trial design

The original study design had an exclusion criterion of having used pain medication within the last two weeks (14 days) of baseline. Potential subjects either needed to have been off all medication for at least two weeks prior to the screening or needed to return after being off pain medication for a two week period. In addition, they would need to continue to be medication and treatment-free for the duration of the study.

With IRB approval, the protocol was amended to reduce the washout period of two weeks to five days.

Study Settings:

Subjects were recruited from the Lake Placid, New York and Lakeside, Arizona communities and surrounding areas by radio, newspaper, flyers hung in hospital lobbies, and from the current patient base of the investigators.

Safety: Subjects were required to report any potential adverse effects from using the patches in their pain diaries or any new symptoms that they felt might be relevant to the investigator.

Drop-outs/Withdrawn: Seven subjects withdrew from the study.

- Two for no immediate results with application of patch after 10 minutes*.
- One withdrew after Day 4, when subject took aspirin for pain.*
- Three were lost to follow-up and did not respond to phone-calls.
- One withdrew due to rash

*Note: after the treatment code was broken, it was discovered that these three were assigned placebo patches.

Adverse Events: Six subjects reported reactions during the treatment period of the study.

- Two reported a mild allergic reaction (itchiness) to the patches.
- Three reported detoxification effects; loose bowels and/or headache.

- One reported feeling warmth in the area where the patches were applied, after the application.

Of the six reported adverse events, one subject who experienced a rash, withdrew from the study. The rest continued to completion.

The study was concluded early by the Sponsor due to low enrollment and because recruitment strategies had been exhausted by the investigators. One of the greatest challenges in doing pain research is recruitment, because individuals in extreme pain are either unwilling to be weaned off existing interventions or their pain is not high enough to show a measureable difference from an investigational drug or device, such as the IceWave patch. The inclusionary criteria was changed early in the study to allow eligible subjects a 5-day washout period before intervention, instead of two-weeks, but even this was too much for some.

Data Analysis

The data was processed using MS-Excel and Statistical Package for Social Sciences (SPSS) version 20. Descriptive statistics were used to attain the mean, range, frequency and percentage of the surveyed variables. Pearson's correlation was used to explore the relationship between the variables. General Linear Model repeated measure and Independent T-test were used to determine pre-post and group differences. P values of <.05 were taken to be statistically significant in this data analysis.

Results

A total of 105 participants completed the study, with 54 participants in the control group, and 51 participants in the experimental group. Qualified participants were randomly assigned to either control (placebo) or experimental group. The two groups at the baseline were homogeneous in their demographic characteristics. The mean age of the control group was 54±12 (ranged 28-84 years old), and 52±13 (ranged 24-78 years old) for the experimental group. Both groups had similar male to female ratio. The baseline pain level was comparable (Table 1).

Table 1: Demographic Data

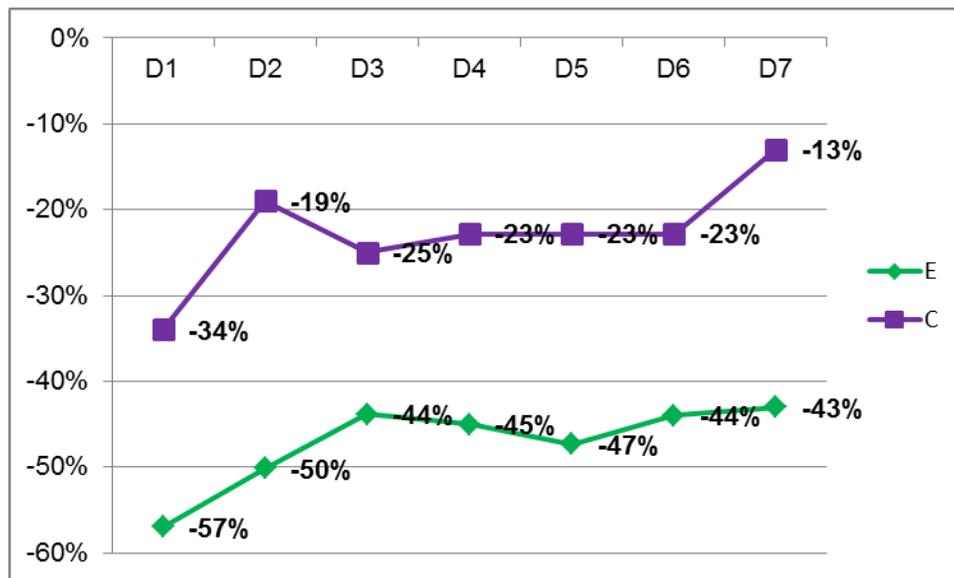
Groups	Sample Size	Age	Gender	Baseline Pain Level
Control Group	N=54	Mean/SD: 54±12 Ranged: 28-84 y/o	Male = 18 Female = 36	Mean/SD: 5.2±1.6 Ranged: 3-9
Experimental Group	N=51	Mean/SD: 52±13 Ranged: 24-78 y/o	Male = 13 Female = 38	Mean/SD: 4.9±1.5 Ranged: 3-9

The experimental group had more (nearly double) percentage of pain reduction compared to placebo group. By Day 3, the amount of pain reduction started to plateau (Table 2 & Figure 1).

Table 2: Percentage of Pain Reduction

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Control Group	-34%	-19%	-25%	-23%	-23%	-23%	-13%
Experimental Group	-57%	-50%	-44%	-45%	-47%	-44%	-43%

Figure 1: Percentage of Pain Reduction



The pre-post pain reductions (Paired Sample T-test) were statistically significant for both groups ($p < 0.0001$). Since pain is a highly subjective measure, the placebo effect may help to explain the perceived pain reduction of the control group. In this study, the percentage changes or the analysis of Generalized Linear Model (GLM-repeated measures) in the pain reduction between groups may be a better indicator of the effectiveness of the intervention.

General Linear Model Repeated Measure ANOVAs and Independent T-test were used to test the between group differences. There was a statistically significant group differences on pain reduction with repeated measures (GLM, $p < 0.0001$); as well as the between groups total pain reduction (Independent Sample T-test, $p < 0.005$). Similar results were observed when controlled for age and gender. There were no significant differences between male and female, age groups, gender or entering pain levels. Only one between-difference group is reported after the pain differences are described – that of obesity.

In this study, half of the sample was either overweight or obese. This demographic distribution mirrored the national data that 34% of people age 20 or older in the United States are obese, 34% of people are overweight, 32% of people are at a healthy weight, and 0.4% of people are

underweight. It has been noted in the literature that Body Mass Index (BMI) was associated with significant increases of physical pain in both youth and adults. The finding of this study was consistent with the literature that the higher the BMI, the greater the self-reported pain level at baseline (N=105, P<0.05) (Table 3).

The interesting phenomenon was that BMI was associated with the total pain reduction in the control group (the higher the BMI, the greater perceived pain) (N=54, p<0.05); however this relationship was not observed in the experimental group. The intervention seemed to minimize the correlation between BMI and perceived pain.

Table 3: Percentage of Pain Reduction

	Baseline Total Sample	Baseline Control Group	Baseline Experimental Group
Underweight	1 (0.9%)	0 (0%)	1 (2%)
Normal	41 (38.3%)	24 (43%)	17 (33.3%)
Overweight	35 (32.7%)	17 (30.9%)	18 (35.3%)
Obese	28 (26.2%)	14 (25.5%)	14 (27.5%)
<i>Total</i>	<i>105</i>	<i>54</i>	<i>51</i>
(underweight \leq 18.5; normal weight 18.5-24.9; overweight 25-29.9; obesity \geq 30)			

Discussion

This study indicates that treatments such as IceWave patches may occupy an important place in the non-drug management of pain. Alternatives to drugs are becoming increasingly sought after because of a number of problems generated by long term use of pharmaceuticals, including drug toxicities. Acetaminophen alone, for example, contributes to hepatic poisoning even at therapeutic doses as low as 4 grams/day, especially with consumption of alcohol.³² Use of opioids is undergoing careful analysis to deter tolerance or addiction.³³ Because of this risk and the long term chronicity of many cases of muscular/fascial tissue pain and non-malignant cancer pain; it seems all the more important that research into alternative treatments is pursued. Hence, research into the human energy system, now that knowledge of its healing attributes have become much more widespread, is an obvious step in elucidating non-drug alternatives.

A landmark analysis of Bonghan Kim's discovery (of an anatomic structure of the body's energy system) was reported by Soh.³⁴ He reported on the impact on electrical needling of acupuncture points, offering a glimpse of the mechanisms by which the Bonghan ducts provide healing. By studying the capacities of acupuncture points (AP) and acupuncture meridians (AM), more of their functions can be elucidated through study because they occupy central sites where blood vessels and nerve endings converge over myofascial and connective tissue. IceWave patches likely use this system for its pain reduction effect.

The electrical system of the body contains a wealth of opportunity for not only treatment of chronic illnesses, but also for the optimizing health. The rejuvenation of the energy systems of the body can become incorporated into health care services without the dangers of drug toxicity and addiction. Using the body's own electrical energy, especially in treatment of pain, seems to be safe and effective.

The relationship of pain to obesity can also be inferred by Soh's in-depth description of how the circulatory system of the Bonghan ducts (BHD) is anatomically woven into the circulating blood arteries and arterioles. It is apparent that fat deposits tend to group in these connecting AP's and AM's, and produce increased pain. Thus, the finding in this study of the association of higher pain with individuals with higher BMI is understandable. The fact that the correlation between BMI and perceived pain was less observable in the treatment group can also be explained by Soh's observations.

The adverse events noted in this study were minimal. The incidence of headache and loose bowels could be attributed to a detoxification effect of the IceWave patches. The incidence of skin irritation was apparently equal in both placebo and treatment groups. The feeling of warmth noted by one subject is not uncommon (as per clinical experience of both investigators) and is not considered a true negative adverse event. Only one subject did not complete the study due to the adverse reaction. The rest who dropped out did so for other reasons.

Summary

The problem with using pharmaceuticals for pain management is becoming increasingly formidable because of the increasing numbers of people now taking pain drugs. Not only are there increasing numbers of patients becoming addicted to prescription drugs, the drugs are losing their effectiveness. Furthermore, short and long-term side effects of pharmaceutical interventions for pain leave many healthcare providers and patients wondering whether there are effective drug-free alternatives for pain relief. In this study we have demonstrated the efficacy of IceWave patches in the drug-free management of pain. IceWave patches may be a safer alternative to drugs for many people seeking pain relief given its low side effect profile as demonstrated in this study.

Acknowledgement

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