

Study Report #1: Clark D. LifeWave IceWave Infrared Study Aug 29, 2006.

Safety issues:

- No adverse reactions were reported.

Patch instructions and study procedures:

- "Infrared studies were completed on 30 people with active IceWave patches. The infrared data shows that the IceWave patches consistently create an overall nervous system response to generally cool a (hot) hyperthermic region when measured with precise infrared technology. Conversely, when a region is hypothermic (cold) the IceWave patches will have the opposite effect on the area, and influence by warming the localized region."
- Acupoints used:
 - Patches were placed using the Cross Method (see Appendix).
- The Computerized Thermal Imaging Processing Camera ("TIP") was used to measure the 8-12 nanometer range of infrared output of the human body. This is the most common range of infrared output by the body. The use of infrared imaging is a unique, non-invasive diagnostic imaging procedure which detects and records surface skin temperatures by measuring the variations in heat that is spontaneously emitted from body surfaces. This specific imaging accomplishes this by scanning the subject with a highly sensitive infrared camera that can measure thermal differences to a one-hundredth of a degree. The surface skin temperatures are affected by the individual's physiological responses. Specifically, the autonomic nervous system of the body controls the thermal response. The external skin temperature creates a "thermal map" that is an objective measure of normal as well as abnormal physiologic function. The infrared evaluation, as a diagnostic procedure in evaluating normal physiologic function, is an accurate and objective evaluation. It is a pure measure of a persons' health without causing any harm to the patient which is required in this application.
- After the calibration period, baseline infrared images were collected and reviewed to identify hyperthermic/hypothermic regions. Patches were then applied over specific hyperthermic regions and then after an interval of five to twenty minutes after the application of the patches, the infrared imaging measurements were performed again. Computerized thermal measurements were performed over the patch site before and after the five to twenty minute period and the thermal differences recorded.

Efficacy of patches in this study:

- "Infrared Imaging clearly shows that LifeWave IceWave patches provide a thermoregulating effect to the body causing the nervous system to respond by normalizing the anomalous region of the body. Symptomatic changes seen with the IceWave patches in my study included such things as pain relief, improved range of motion, changes in stiff joints, and reports of energy improvement."
- "The study design was to first obtain a baseline measurement without patches and then to place the IceWave patches on the body over an identified hyperthermic area and measure the immediate response after five to twenty minutes. The body's response after placing the patches

in a hyperthermic region, as measured by the infrared imaging, proved a cooling response to the skin temperature readings both locally and distal from the site of application."

- "Thermal changes were seen in all 30 subjects. The average thermal temperature pre patch is 31.94°C. The average thermal temperature post patch is 30.85 °C. The average Delta T is 1.09°C. The minimum Delta T is 0.15°C. The maximum Delta T is 8.20°C. Using a student t-test, a p value of 0.008 is obtained. Since the p (probability) value of .008 in this study is a p value < 0.05 this indicates that the thermal temperature changes when IceWave patches are used are statistically significant."
- An example of an infrared image from the clinical trial is shown below in **Figure 2**.

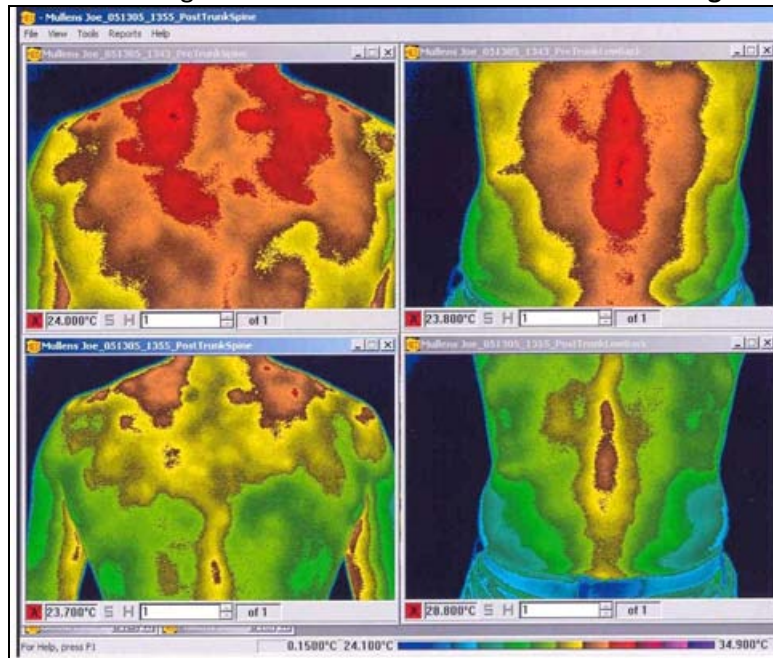


Figure 2: (Top) Infrared Images taken before the LifeWave pain relieving devices were applied to the participant. (Bottom) Infrared Images taken 5 minutes after the LifeWave devices were applied. It can be seen that LifeWave caused the hot inflamed areas (red color) to cool (green color).

Assessment: *This infrared study demonstrated both local and whole body effects occur as demonstrated by thermal changes both locally and distal to the site of application of the patches. The IceWave® Infrared Study performed on August 29, 2006 also showed that pain relief, improved range of motion, changes in stiff joints, and energy improvement also occurred. This study also showed that reduction in temperature and inflammation was noticeable within 5-20 minutes demonstrating rapid pain relief.*

Study Report #2: DeRock JL, Clark D, Nazeran H. Infrared Thermal Imaging Quantifies the Efficacy of IceWave Patches in Musculoskeletal Pain Relief in Horses. Published in *Journal of the American Holistic Veterinary Medical Association* (Vol. 30, No. 1, 2011).

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- A pain study focused on horses experiencing musculoskeletal pain. 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, myofascial pain syndrome and others.
- A total of 38 horses were evaluated by a licensed veterinarian and were diagnosed using a combination of acupuncture palpation and infrared imaging. Icewave® patches were placed on the area of pain as determined by acupuncture palpation and infrared imaging and worn for a 24 hour period then re-evaluated. Effectiveness of the treatment was based on several factors, including the ease of normal activities, palpation source of inflammation and infrared imaging.

Efficacy of patches in this study:

- "Statistical analysis of infrared thermal imaging data revealed a highly significant ($p < 0.0001$) effect due to wearing the IceWave patches in the affected (painful) areas in all horses with a statistical power of 100%."
- "Statistical analysis of acupuncture palpation data as assessed by the veterinarian based on the 1-10 point pain scale also revealed a highly significant ($p < 0.0001$) reduction in pain level due to wearing the IceWave Patches in the affected (painful) areas in all horses with a statistical power of 100%. This result further confirmed that there was excellent overall agreement between the experiential acupuncture palpation method used by the veterinarian in her clinical practice as a subjective measure of pain evaluation and infrared thermal imaging data as an objective measure of pain. Based upon these findings, the data clearly reveals the IceWave Patches produce a highly significant cooling effect (pain reduction) in the areas affected by pain in horses. It was also observed that the IceWave Patches exert a warming effect due to increased perfusion in hypothermic (cold) areas affected by abnormal circulation."
- "The LifeWave Patches produced a highly significant cooling effect in the areas affected by pain in horses of varying ages and breeds. We were very pleased with the positive feedback from most of the horse owners. They noticed changes in their horses, in some, very profound positive changes and better attitude. Almost all of the owners mentioned that their horses were calmer and seemed happier the next day. The IceWave technology promises to have a very profound effect in helping horses with their everyday aches, pains and distress. This drug-free pain management too will improve performance in many cases and seems to give very elderly horses' greater energy and relief from painful conditions."

Assessment: *This horse study demonstrated a reduction in back pain in 38 horses with a confirmation of a reduction in inflammation by an objective test called infrared thermal imaging. Infrared thermal imaging, also known in the literature as medical infrared thermal imaging, is a non-invasive diagnostic imaging procedure which detects and records surface skin temperatures by measuring the variations in heat that is spontaneously emitted from body surfaces. Since heat dissipation through the surface skin is mainly in the form of infrared radiation, infrared thermal imaging offers an effective way to study the physiology of thermoregulation and the thermal dysfunction associated with pain (Hobbins, 1984; Herry and Frize, 2004).*

Study Report #3: Nazeran H, Haltiwanger E. “Nanoscale Wearable Devices Reduce Qualitative and Quantitative Measures of Neuromuscular Pain.” Published in *International Journal of Medical Implants & Devices* (Vol 5. Number 2, 2011).

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- A total of 30 subjects with pain, 26-72 years of age participated in this open-label cross over design study.
- 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 back pain being the most prevalent symptom.
- The Cross Method (see Appendix) was used to apply the patches.
- The Electro-Acuscope was used to monitor the “intensity” of pain before and after wearing the IceWave® patches. The Electro-Acuscope, which uses micro-current, low-voltage level, computerized feedback controlled delivery of energy to the damaged tissue, was used to monitor nerve conduction between two electrodes. This device provided a quantitative measure of pain level on a conductance meter with a numerical scale of 0 to 100 before and after patches were applied to the skin.
- The Visual Analog Scale (VAS) tool was used to assess the perception of severity of pain pre- and post- application of the IceWave® patches. The hypothesis to be tested was: “The IceWave patches applied to pre-designated acupuncture points reduce the quantitative and qualitative measures (intensity and perception) of pain.”
- In this study the patients pointed out their area of significant pain or discomfort. Then the two Acuscope electrodes (probes) were placed on the pain area approximately 2 to 4 inches apart to obtain pretest conductivity readings between the two points.
- The IceWave® patches were worn based on instructions available from the manufacturer’s booklet (as seen in the Appendix). Following placement of the patches, a second post-application conductivity reading was obtained.
- Overall, each patient had conductivity change in tissue after applying the IceWave® patches within 2-5 seconds. On average, conductivity readings changed 20-30 points and significant subjective change would occur within 2-5 minutes.
- Statistical analyses were carried out to compare both the Electro-Acuscope readings and qualitative measure of pain severity was assessed by using VAS pre- and post-application of the IceWave® patches.

Efficacy of patches in this study:

- The results showed that there was a highly significant change in conduction in the Electro-Acuscope readings, as well as, 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 in reducing their 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 markings was at least 99%.

- In summary, the overall data in this study demonstrated that IceWave® patches, when applied to pre-designated acupuncture points, produced a highly significant ($p < 0.001$) reduction in the quantitative and qualitative measures of pain with an average statistical power of at least 94%. Therefore, the hypothesis that “The IceWave patches reduce the quantitative and qualitative measures (intensity and perception) of pain” was accepted as true.

Assessment: *This study showed the effectiveness of IceWave® patches in a number of diverse pain conditions ranging from: arthritic, lower back, neck, shoulder, sciatic, sports-related, car accident-related, scapular, and knee pain.*

Study Report #4: *Miller TF, Hollenback AE. A DOUBLE-BLIND, PLACEBO CONTROLLED CLINICAL EFFICACY EVALUATION OF A PATCH TO SOOTHE KNEE PAIN. Essex Testing Clinic, Inc. March 15, 2010.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this study, 62 subjects aged 35-75 years used IceWave® patches in a double-blind, placebo-controlled study over two days of patch use. One-half of the participants used the active test patches and the remaining half used a placebo patches.
- Acupoints tested:
 - A. Urinary Bladder 53 (UB 53)
 - B. Kidney 10 (Kid 10)
- A sufficient number of subjects meeting the inclusion/exclusion criteria were enrolled so that approximately 60 subjects completed the test procedure. (30 subjects in active cell (Patch X); 30 subjects in placebo cell (Patch Y).
- Individuals enrolled had to have a minimum, self-perceived arthritic pain level of “5” according to a ten-point scale (0=no pain; 9=severe pain in one knee).

Efficacy of patches in this study:

- A clinical efficacy study conducted with 62 subjects (31 subjects using Test Article: IceWave® X and 31 subject using Test Article: IceWave® Y) showed: self-perceived, arthritic knee pain was significantly improved ($p < 0.001$) during 2 days of use with IceWave® patches.
- Self-perceived, arthritic knee pain was significantly improved during 2 days of use ($p < 0.001$ on first day of use; $p < 0.05$ on second day of use) with placebo patches.
- During the course of the study, IceWave® patches were associated with a higher percentage of subjects reporting a reduction in overall pain levels. Additionally, there was a statistically significant difference observed between the test articles on the second day of use, with IceWave® patches exhibiting a greater decrease in pain levels than placebo patches.

Assessment: *This study showed the effectiveness of IceWave® patches being greater than placebo in reducing knee pain.*

Study Report #5: *Brandimarte B, Micarelli A, Alessandrini M, La Bella L, Pietropaoli G. LIFEWAVE SCIENTIFIC STUDY BY MEANS OF AN NM4 GAUGE LifeWave Study Italy, 2010.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this open-label study, 117 subjects male and female were tested with IceWave® patches.
- The NM4 device was used to collect objective measurements of neuromuscular potentials, in a non-invasive manner, both before and immediately after the application of the IceWave® patches. The NM4 is a device for the measurement of neuromuscular potential. It has 4 measurement channels with dual input that, by way of two measurements and one reference electrodes, allow the elimination of noise and external interference.
- Electromyography (EMG) is the recording of the electric activity of the muscles. Superficial EMG uses surface electrodes for recording, instead of needle electrodes, and it is therefore a non-invasive detection technique.
- The purpose of this scientific study was to demonstrate the efficacy and effect of the LifeWave pain patches with scientifically proven data and values under varying degrees of pain, inflammation, contracture and muscular tension availing itself of both subjective (patient) data, as well as more objective findings supplied by way of use of the generation muscular potential gauging device called NM4.
- Acupoints Used:
 - The IceWave® patches were applied using the Clock Method (as seen in the Appendix).

Efficacy of patches in this study:

- It has been demonstrated that the use of the IceWave® patches for pain control have a very important and almost immediate effect on the moderation of the muscular contractions and tensions, as well as, associated pain.
- All microvolt measurements showed a considerable improvement of the range of motion of the joint and of the various movements whose range returned to normal thanks to the solution of the various problems.
- In conclusion, the instrumental methodology implemented was useful to obtain objective data that confirm the effectiveness of the application of the LifeWave patches both in the acute phase of the pain in which the collected results have provided important scientific evidence, as well as, in the chronic phase in which the moderation of the pain felt by the patient was proportional to the results obtained with the NM4 device.

Assessment: *This study showed the effectiveness of IceWave® patches in subjects with pain, inflammation, contracture and muscular tension. Improvements in range of motion and an almost immediate effect were noted. Improvements were noted in subjects with neck pain (cervical), back pain (lumbar), shoulder pain, knee pain, foot pain, toe pain, and eye pain.*

Study Report #6: Streeter T, Nilkanth B, Dandekar S, et al. LifeWave Research Study. World Peace Centre, MIT College, Pune, India - Sept-Dec 2009. The Centre for Biofield Sciences.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- A total of 120 people participated in this double-blind, placebo-controlled study with 50 people in the IceWave® experimental group, 50 people in the Glutathione patch experimental group, and 20 people were in the placebo-control group.
- Acupoints used: Subjects randomized to the IceWave® group were asked to adhere the patches on the area of pain as determined by the three scans using the Cross method as shown in the LifeWave® handout “Patch Instructions” (as shown in the Appendix) for 12 hours.
- Participants randomized to the Glutathione group were asked to place the patch on a specific acupuncture point located on the wrist of the right hand known as Pericardium 6 (P6 – see Appendix). The same scans were repeated after 24 hours.
- The purpose of this study was to validate the efficacy of the IceWave® patch as a pain reliever and investigate the effectiveness of the Glutathione patch as a pain reliever and antioxidant by observing changes in the human biofield. Polycontrast Interference Photography (PIP), Gas Discharge Visualization (GDV) and Electro-Interstitial Scan (EIS) were the devices utilized before and after using LifeWave Patches.
- The Polycontrast Interference Photography (PIP) scan illustrates the subject’s biofield using a spectrum of colors to represent the positive and negative energy throughout the body based on changes in light intensity. Low/Negative energy areas are represented by red or orange colors, whereas, high/positive energy areas are represented by green, pink, or purple colors. The PIP scan was used to help identify congested areas of red, negative energy where an IceWave® or Glutathione patch should be placed on the subject.
- Gas Discharge Visualization (GDV) illuminates the energy leaks based on biophotonic (light) emissions from acupuncture points around the fingertips (Su Jok acupuncture system) which shown areas of pain, inflammation, or disease. A healthy, positive state would be illustrated as vibrant and symmetrical, whereas a negative energy state would be seen as dull and asymmetrical. The GDV scan will be used to evaluate where energy leaks are located on the body and help determine Life wave patch placement.
- Electro-Interstitial Scan (EIS) is a programmable electro-medical system scientifically proven and clinically validated. It is an efficient, non-invasive medical device that measures physiological parameters and produces detailed reports with 89% repeatable accuracy. The EIS measures conductivity of interstitial fluid between the cells. Its bio-impedance technology is similar to ECG and EEG, but rather than supplying information for only the brain or heart, the EIS measures electro physiological properties of 22 different volumes within the body and describes 69 different physiological parameters.

Efficacy of patches in this study:

- Almost 90% of subjects in the IceWave® experimental group displayed a positive change after using the IceWave® patch. Maximum changes were seen in the muscles of the hand, mid and lower back, and neck along with a significant positive change in the biofield with respect to the solar and naval chakras.
- Approximately 80% of subjects in the Glutathione patch experimental group have shown a positive change in the three energetic scans after wearing the Glutathione patch for 12 hours. The results for the control group were that 80% of subjects showed no improvement.
- Since no changes were observed in the control group; and remarkable positive changes were seen in both experimental groups, it can be concluded that both the IceWave® and Glutathione patches produce beneficial energetic effects.

Assessment: This study showed the effectiveness of IceWave® patches in almost 90% of subjects. Maximum changes were seen in the muscles of the hand, mid and lower back, and neck. These are the same locations that subjects in other studies have experienced pain relief. Use of these objective instruments demonstrates that physiological changes are being measured when IceWave patches are worn.

Study Report #7: Toneguzzi D, Carlovich S, Gini G. *INVESTIGATIVE STUDY OF BIOCHEMICAL EFFECTS OF LIFEWAVE PATCHES USING BIO-EXPLORER TECNOLOGY.* Italy, 2010.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- This was a study of ten people, between the ages of 33-70, suffering from chronic low back pain who were monitored for over 12 weeks. During the first eight weeks IceWave Patches for 24 hours per day.
- The IceWave® patches were applied using the Clock Method (see Appendix). At night, they were worn on Kidney 1, an acupuncture point on the soles of the feet.
- The Bioexplorer method is a non-invasive detection technology developed by Biophysics Research – Rome. The Bioexplorer method has been devised to provide an instrumental, non-invasive assessment of active biochemical processes occurring both in the cerebrospinal areas and in the inner organs of the human body before and after patch application.

Efficacy of patches in this study:

- "The obtained results from this pilot study confirm the efficacy of LifeWave IceWave products as pain personal perception obtained in other previous studies and they underline specific modifications from the biochemical point of view: as concerns the molecules typically involved in the chronic inflammatory process, it was verified meaningful reduction of COX-2, PGE-2, PGF-2, IL-1 and lactic acid. It was highlighted also important reduction of neuropeptides Substance P and Vasoactive Intestinal Peptides (VIP). This pilot study suggests that the clinical effectiveness of IceWave Patches arises from real biohumoral changes induced by this products and it highlights a specific action of IceWave on the inflammation biochemical processes."
- Reductions occurred within the first 3-4 weeks, then maintained throughout the 12 week period, even after the patches had been removed for the final 4 weeks.
- This pilot study suggests that the clinical effectiveness of IceWave® patches arises from real biohumoral changes induced by this product and it highlights a specific action of IceWave® on the inflammation biochemical processes.

Assessment: This study showed the effectiveness of IceWave® patches on chronic back pain and demonstrating an anti-inflammatory response.

Study Report #8: Dharia R, Piven E. *Effect of IceWave® Organic Nanoscale Patches on Reduction of Musculoskeletal Pain.* Palm Beach Internal Medicine, 2010.

Safety Issues:

3 subjects dropped out.

- One for non-response;
- One for withdrawal effects from narcotics;
- One for headache, attributed to detoxification effects.

All events resolved within 24 hours.

Patch instructions and study procedures:

- Open label, multi-site study with 40 subjects suffering from musculoskeletal pain.
- Initial patch placement was decided by the origin of pain and the Clock Method was used.
- Subjects rated their pain using the Universal Pain Scale before patch placement and then again after 1 hour and at the 3 hour mark.
- Subjects wore the patches for 24 hours for a 5 day period and rated their pain daily on Days 2-5 after 1 hour.

Efficacy of the patches in study:

- 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, Hour 1.
- At all subsequent time points, the means ranged from 1.40 to 2.15.
- The percentage of subjects with at least a 2-point improvement ranged from 90% to 95% with 85% or 34 people achieving reduction of 4 or more points by Day 5 Hour 1.
- By Day 1, 100% of subjects experienced some pain relief one hour after application. By Day 5, 77.5% experienced reduced pain ≥ 4 levels one hour after application and the mean pain score was 1.4, suggesting that almost everyone had no pain.

Assessment: *This study clearly showed that use of the IceWave patch decreased subject's perception of pain as soon as one hour after application.*