

ENERGY ENHANCER®

Study Report #1: Clark D. LifeWave Energy Patches Infrared Study. Dec 12, 2005.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this study, abnormal asymmetric infrared measurements were observed in each case which warranted discussion and consideration of patch placement. Our initial interest was the concept that by placing patches on abnormal thermal regions, it would allow us the ability to control abnormal physiological conditions, which in turn, would change the energies of the individual.
- The primary aim of this study was to demonstrate a physiological thermal response to the Energy Enhancer® patches within a five minute period.
- 36 healthy subjects were enrolled, between 22 to 72 years of age.
- A subset five subjects from the sample, was given placebo patches.
- Infrared Imaging Measurements were performed with a highly sophisticated Computerized Thermal Imaging Processing Camera ("TIP"). 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 physiological responses of the individual. 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.
- The Computerized Thermal Imaging Infrared Camera "TIP" was used to measure the 8-12 nanometer range of infrared output of the human body. This is the common range of infrared output by the body. The camera selected is the most detailed, focused and expensive on the current market. It also has proprietary software to capture, store and record the measured Infrared output of the body and record the data in a digital medium.

Efficacy of patches in this study:

- The response to the body by placing the patches in a region of hyperthermic state as measured by the infrared imaging proved a cooling response to the skin temperature readings both locally and distal from the site of application. This is a valuable corollary when understanding the measured response of the patches is proof that the patches emit some form of energy to the body to cause a hyperthermic region to cool. This can only be explained by the patches emitting a form of energy that influenced the autonomic nervous system via the subcutaneous vascular beds.
- "The average thermal temperature pre patch is 32.239°C. The average thermal temperature post patch is 30.756 °C. The average Delta T is 1.483°C. Since the p (probability) value of .00001 in this study is greater than p value < 0.05 this indicates that the thermal temperature changes that occur when Energy Enhancer® patches are used are statistically significant."

- The thermal images shown in **Figure 2** demonstrate the local and distal cooling effects created by the reflected IR energy from the Energy Enhancer® patches. The temperature gradients clearly show the distal cooling effects. The color palette shows the hottest temperatures as red, balanced temperature as green, and cooler temperatures as blue. The beneficial cooling effect of the patches can be seen in blue and green colors far away from point of application of the patches. A drop in skin temperature initiates an autonomic response in favor of parasympathetic arm of the ANS.

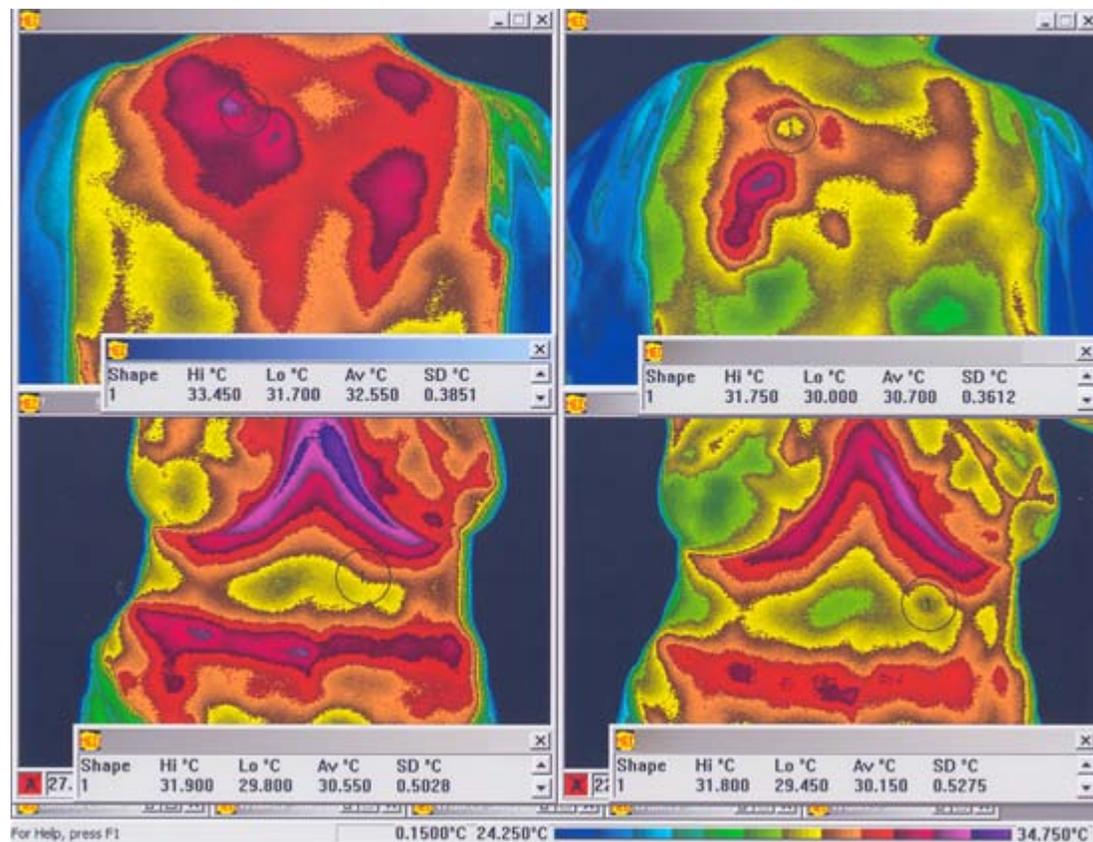


Figure 2: The above images were taken with a Computerized Thermal Imaging Processing Camera "TIP" measuring the spontaneous emitted heat patterns of the skin before and after LifeWave patches were applied (Clark, 2005). The circles represent the placement of the patch. This image represents a significant change has occurred in the autonomic nervous system.

- "Results: The majority of the participants revealed a thermal response to the patches within a five-minute period. The group also responded beyond the placebo effect, as evidenced by the number of individuals that experienced a significant physiological response. A greater than 80% favorable response rate was observed by the individuals in the study. This study offered one of the first measurements of physiological changes."

- Placebo patches on five other random people did not offer any measurable physiological infrared response, nor were there any overall body responses. Due to the overwhelming response and measured outcomes of the patches after 5 minutes it is very conclusive that the energy of the patches affected the people in this study in a very significant way ($p < 0.00001$). Therefore, the hypothesis that the Energy Enhancer® patches create a cooling response in hyperthermic skin areas is accepted to be true.

Assessment: *This infrared study demonstrates both local and whole body effects occur as demonstrated by thermal changes both locally and distal to the site of application of the patches. This study also showed that reduction in temperature and inflammation was also measurable within five (5) minutes. This study is supportive of a device that modifies physiological processes in the body. This study also provides support that the Energy Enhancer® patches have a physiological response on the autonomic nervous system.*

Study Report #2: Nazeran H, Chatlapalli S, Krishnam R. Effect of Novel Nanoscale Energy Patches on Spectral and Nonlinear Dynamic Features of Heart Rate Variability Signals in Healthy Individuals during Rest and Exercise. Published in *Conference Proceedings IEEE Eng Med Biol Soc. 2005; 5:5563-7.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - Pericardium 6 (P 6)
- In this study, 10 subjects used Energy Enhancer® patches in a single-blind placebo controlled crossover study during rest and after mild exercise.
- Heart rate variability refers to the beat-to-beat variation in heart rate (HR) and is modulated largely by the autonomic nervous system via changes in the balance between parasympathetic and sympathetic influences. Since short-term variations in HR reflect sympathetic nervous activity, they provide useful non-invasive markers for assessing autonomic control under various physiologic states and conditions.
- To evaluate the effect of Energy Enhancer® patches on HRV signals, pilot data from 10 healthy volunteers were collected under three different conditions during rest and exercise using a BIOPAC system. Each subject was tested at rest and after exercise, at baseline, wearing the Energy Enhancer® and then lastly wearing the placebo patches.
- The HRV signal was derived from preprocessed ECG signals using an Enhanced Hilbert Transform (EHT) algorithm with built-in missing beat detection capability for reliable QRS detection. Autoregressive (AR) modeling of the HRV signal power spectrum was achieved and different parameters from power spectrum as well as approximate entropy were calculated for comparison. Poincaré plots were then used as a visualization tool to highlight the variations in HRV signals before and after exercise under normal conditions and under the influence of placebo and energy patches.

Efficacy of patches in this study:

- The results show some interesting changes in the spectral and nonlinear dynamics parameters of the HRV signals when wearing the *Energy* patches compared to these values when wearing the *Placebo* patches. They showed that during rest, there was a slight decrease in LF (<1% in the male and <3.5 in the female) as well as in the ApEn (<3.5% in the male and < 1% in the female). There was a large increase in HF (30% in the male and 108% in the female). The LF/HF for the

resting condition showed a large reduction (24% in the male and 54% in the female). The results also demonstrated that after 5 min exercise, while wearing the *Energy Enhancer*[®] patches, there was a slight decrease in LF (<3.5% in the male and <1% in the female) as well as in the ApEn (7% in the male and almost 0% in the female).

- There was a large increase in HF (62% in the male and 31 % in the female). The LF/HF showed a large reduction (63% in the male and 24% in the female).

Assessment: *Based on these preliminary observations, it could be concluded that both during rest and after 5 min of exercise, the Energy patches enhanced the relaxation level as they reduced the LF/HF. This is a very desirable effect as a reduced sympatho-vagal balance during rest has an enhancing relaxation effect and during exercise has an enhancing activity effect. The results demonstrate that Energy Enhancer[®] patches have significant and clearly distinguishable effects on these important HRV signal features.*

Study Report #3: *Nazeran H. Heart rate variability signal parameters quantify skin cooling effect of Energy Patches during rest and exercise in young healthy individuals. Biomedical Engineering Recent Developments. Otto C. Wilson, Binh Q. Tran, Jafar Vossoughi, Editors. 2007:13-19.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - Pericardium 6 (P 6)
 - Lung 1 (Lu 1)
 - Stomach 36 (St 36)
 - Kidney 3 (Kid 3)
- For this study, HRV data was acquired from 20 young healthy volunteers (10 males and 10 females, 19-25 years of age), in a double-blind placebo-controlled study, and used to evaluate the skin cooling effect of the *Energy Enhancer*[®] patches on the ANS during rest and immediately after mild exercise while wearing active (**A**) and placebo (**P**) patches.
- *Heart Rate Variability (HRV) signal* refers to beat-to-beat variation of heart rate and represents the cyclical changes in heart rate (HR). As HR is modulated by both parasympathetic and sympathetic inputs, HRV can be utilized as an indirect and non-invasive marker of autonomic regulation and control under different physiological conditions. High HRV reflects an autonomic nervous system (ANS) that is adaptable and dynamically responsive to change whereas reduced HRV is indicative of an abnormal or restricted ability of the ANS in maintaining homeostasis.
- ECG signals were acquired, filtered and further processed to derive the HRV signal. The low frequency (LF), high frequency (HF), and their ratio LF/HF were calculated to assess the parasympathetic dominance or the skin cooling effect of a set of nontransdermal *Energy Enhancer*[®] patches on young healthy individuals during rest and immediately after mild exercise.

Efficacy of patches in this study:

- Data from condition (**A**) and condition (**P**) were compared using statistical analysis (one-sample inference). The LF/HF decreased *significantly* both during rest and immediately after mild exercise in condition (**A**) compared to condition (**P**) for $p < 0.01$.

Assessment: *Based on these observations it could be concluded that both during rest and immediately after 5 minutes of mild exercise, the Energy Enhancer[®] patches elicited an enhanced*

parasympathetic response which could be quantified by a reduction in normalized LF/HF. The statistical results revealed that the Energy Enhancer® patches showed a very significant effect ($p < 0.01$) compared to Placebo patches in reducing the normalized LF/HF during rest and even further after 5 minutes of mild exercise with a statistical power of at least 85% in this sub-population.

Study Report #4: Budzynski T, Budzynski H, Maret K, Tang HY. (2008). Heart rate variability enhancement through nanotechnology: A double-blind randomized-control pilot study. Published in *Journal of Neurotherapy*, 12(1), 45-55.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - Lung 1 (Lu 1)
- The objective of this study was to test whether proprietary nanotechnology skin patches (Energy Enhancer® patches) produced for the purpose of increasing energy are also capable of modulating certain resonant frequencies of the body, promoting greater autonomic nervous system balance as reflected in Heart Rate Variability (HRV).
- Forty (40) adult participants were chosen and divided randomly into two groups of 20 participants each. The study used double-blind and randomized control design. Subjects wore the Energy Enhancer® patches or placebo patches.
- The HRV measures were obtained prior to and 15 min after the patches had been applied. The HRV was measured with a BioCom HRV system.

Efficacy of patches in this study:

- Analysis of the two groups indicated that when the experimental group HRV data were examined for pre–post differences, the low frequency to high frequency (LF/HF) ratio decreased significantly ($p < .01$, one-tailed t-test), the very low frequency (VLF) decreased significantly ($p < .05$), the LF decreased ($p = .011$), LF norm decreased ($p < .05$), and HF norm increased ($p < .05$).
- It should be noted that the normalized LF and HF parameters represent relative values of each power component in proportion to total power minus the VLF component. This emphasizes the controlled and balanced behavior of the two branches of the autonomic nervous system. It tends to minimize the effect of change in total power on the values of LF and HF components (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996).
- The control group, however, showed no significant pre-post changes in these parameters. Comparisons between energy and placebo patch groups reached statistical significance ($p < .05$) only in the VLF parameter.
- Energy Enhancer® patches appear to act on the autonomic cardiovascular factors influencing heart rate variability in the hypothesized direction. Energy Enhancer® patches can result in a decrease of sympathetic drive to the heart. This technology can be used to augment neurotherapy especially in cases characterized by chronic stress or fatigue factors.

Assessment: *Study Reports #2, 3 and 4 of HRV demonstrate that the Energy Enhancer® patches have an effect on the autonomic nervous system. This is more evidence that the LifeWave patch devices are able to modify a physiological process. In addition, these HRV studies also support the findings of the infrared study, which showed a physiological modification of thermal energy distribution in the body by cooling hyperthermic regions of the body.*

Study Report #5: Shallenberger F, Nazaran H. The Effect Of A Non-Transdermal Surface Patch On Mitochondrial Function. LifeWave Study 2006. Revised March 12, 2011.*

**Note: As a result of the Therapeutics Goods Administration (TGA) concerns about this study, Dr. Homer Nazaran revised the report to incorporate a detailed description of the clinical study protocols including inclusion/exclusion criteria, primary and secondary endpoints, methods of assessment and validation testing data for the procedures used, as well as the statistical plan, calculations and significance of the procedures to assess the device clinical performance. It also includes info on the device mode of action and scientific literature to support the device claim as an enhancer of the body's energy.*

Safety issues:

- There were no adverse events reported in the group.

Patch instructions and study procedures:

- Acupoints tested:
 - Pericardium 6 (P 6)
 - Lung 1 (Lu 1)
 - Stomach 36 (St 36)
 - Kidney 3 (Kid 3)
- A 2-week, placebo-controlled, single-blind research study which measured respiratory oxygen uptake and carbon dioxide production under both resting and exertional conditions before and after application of the Energy Enhancer® patch. The data obtained was then analyzed by a computerized program (Bio-Energy Testing®) to determine the following metabolic parameters: maximum aerobic ATP, maximum ATP from fatty acid metabolism, resting ATP, resting ATP from fatty acid metabolism, and maximum aerobic work.
- The subjects included 30 men and women (age range 40 - 61 years). Criteria for participation in this study included: a) the ability to complete all test protocols; b) freedom from chronic illness; c) absence of any medications that may alter metabolism; and d) being a non-smoker. All participation was voluntary in nature and subjects could terminate their participation in the study at any time they wished without any consequences
- Subjects wore either Energy Enhancer® patches or placebo patches for one hour during testing and daily (12 hours) for 7 days before testing.
- Each subject reported to The Nevada Center, Inc. for a total of three (3) visits. The first visit included an explanation of what is involved in the Bio-Energy Testing® procedure, an orientation with the laboratory equipment, and the initial test. The remaining laboratory visits involved subject testing and will be referred to as a testing session. Each testing session was approximately 1 hour in duration and testing sessions were be separated by 1-week (7 days). Tests were performed in the morning, and subjects were be asked to avoid foods and beverages (except for water) and all forms of mental or physical exertion on the morning of testing.
- Week 1 Testing Session: The week 1 testing session served as the baseline measurement for the study. Following this test, the subject was instructed regarding the correct placement on the skin of the LifeWave patches as directed by the product manufacturer. When the patches were positioned correctly, the subject was then given a placebo set of LifeWave patches, and was instructed to begin a daily application of these patches.
- Week 2 Testing Session: The week 2 testing session served as the placebo effect measurement for the study. The test was performed while the subject was wearing the placebo LifeWave

patches. Following this test, the subject was given an active set of LifeWave patches, and was instructed to begin a daily application of these patches as directed by the product manufacturer. The subject was blinded to which patches were placebos and which were active. Both placebo and active patches were identical in appearance.

- Week 3 Testing Session: The week 3 testing session served as the active effect measurement for the study. The test was performed while the subject was wearing the active LifeWave patches. Following this test, the subject was given a copy of all three testing results. The subjects was not advised as to what patches were active or placebo until the completion of the study.

Efficacy of patches in this study:

- Application of the Energy Enhancer® patches produced a significant increase in maximum aerobic ATP, maximum ATP from fatty acid metabolism, resting ATP, and maximum aerobic work. There was no significant effect on resting ATP from fatty acid metabolism.
- Results showed that
 - A. Maximum aerobic work improved in 50% of subjects.
 - B. Maximum aerobic from fatty acid metabolism improved in 36% of subjects.
 - C. Maximum aerobic ATP improved in 46% of subjects.
 - D. Resting ATP improved in 23% of subjects.
 - E. Resting ATP from fatty acid metabolism improved in 40% of subjects.
- Results: application of the Energy Enhancer® patch has significant metabolic effects which confirm the manufacturer's claim that it increases energy, stamina, and performance. These findings provide a rationale for using the patch in conditions in which increased metabolic performance is desired.
- The results of this single-blind, placebo-controlled study show that applying the Energy Enhancer® patches on the four described acupuncture points has statistically significant metabolic effects on a subset of subjects. The responders produced greater amounts of resting ATP (basal metabolism), greater amounts of maximal aerobic ATP (aerobic capacity), greater amounts of ATP from fatty acid metabolism, and higher levels of aerobic work capacity. The range of improvement was from a modest 15% to a dramatic 70% improvement in several cases.

Assessment: *This study supported the claim that the Energy patches increased energy in a subset of users. Furthermore, the responders frequently showed increases in all of the metabolic parameters measured, rather than in just a few parameters. Likewise, the non-responders failed to show any improvement in any parameter measured. This observation tends to confirm that the patches directly impact mitochondrial function, which is a physiological change and supports the claim that wearing the Energy Enhancer® patches improves energy.*

Study Report #6: Budzynski T, Budzynski H, Maret K, Tang HY. *Acuscope and Skin Conductance along Meridians: Before and After LifeWave Energy Patches. Dec. 2009.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedure:

- Acupoints used:
 - Stomach 36 (ST 36)
 - Pericardium 6 (P 6)
 - Lung 1 (Lu 1)
 - Kidney 3 (K 3)

- Sixty subjects (ages 18-65) without debilitating illnesses participated in this study with the aim to examine the effect of the Energy Enhancer® patches on meridian conductance at four different acupuncture points measured by a biofeedback instrument. Also, with an awareness that the changes in conductance might differ at the skin level and in the deeper 4 tissues, two measurements were performed using skin conductance for skin surface changes and Electro-Acuscope conductance for examining deeper tissue changes. This study was based on the premise that energy flow throughout the body is transmitted through the meridian pathways and aims to show that skin conductance increases with the application of the Energy patch. A sub-group of thirty subjects was also measured using two different biofeedback instruments to further validate the findings of the first instrument.
- The study compared a baseline measure with after-treatment measurements following the application of Energy Enhancer® patches that were sequentially moved between 4 different acupuncture sites. At testing time, the sequential order of measurement of these sites was randomly chosen to check whether time/order played a factor in the measure of conductance at a particular acupuncture point.
- Subjects wore patches for 3 hours during testing.
- All 60 subjects were measured with the Thought Technology Biofeedback skin conductance (SC). A later measure was added using the Electro-Acuscope (AC) on roughly half of the original sample (29) who were called back to compare the possible differences in conductance at what may be the deeper levels of tissue below the skin.

Efficacy of patches in this study:

- Results of the skin conductance measurement showed that at the 4 acupuncture sites (lung, pericardium, stomach and kidney), the means show an increase in conductance after application of the energy patches using the skin conductance measurement as compared to baseline. Two-tailed t-tests showed significant pre-post differences for lung, pericardium and kidney with only the stomach site not reaching significance as shown in **Figure 3**.
 - A. Lung 1 had a $p < 0.0005$
 - B. Pericardium 6 $p < 0.02$
 - C. Stomach 36 $p < 0.17$
 - D. Kidney 6 $p < 0.03$

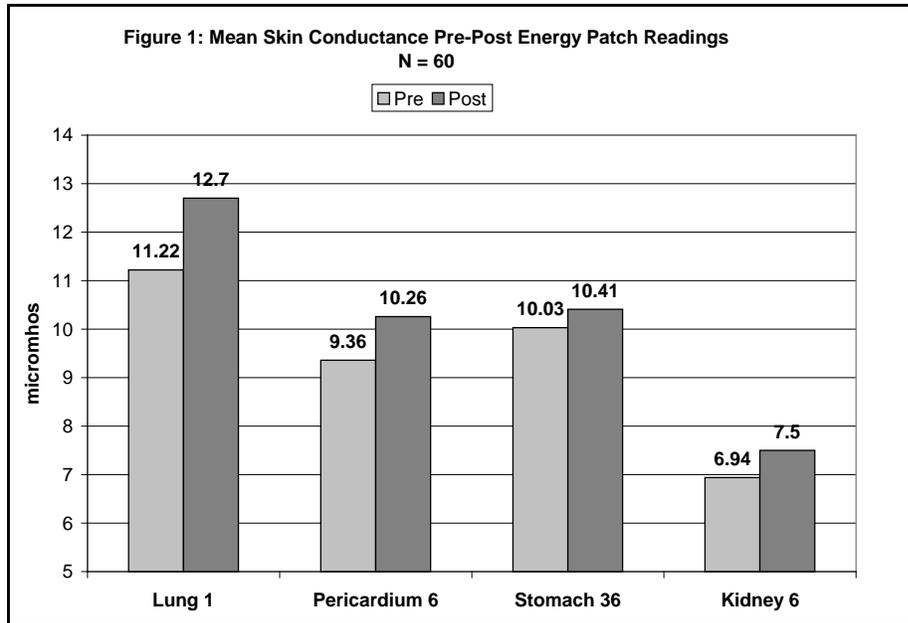


Figure 3: Comparison of mean skin conductance pre- and post-patch placement *Note: Graph denoted as Figure 1 in original research report.

- In the case of the skin conductance, each successive measurement had added to the level of skin conductance, probably as a result of the fact that measurement of skin conductance instills a small stimulation into the meridians. But more importantly, each time a set of energy patches were placed on the body, even though those patches were removed as the patch set was moved to the next site, the level of skin conductance seemed to increase with each application, as can be seen in **Figure 4**.

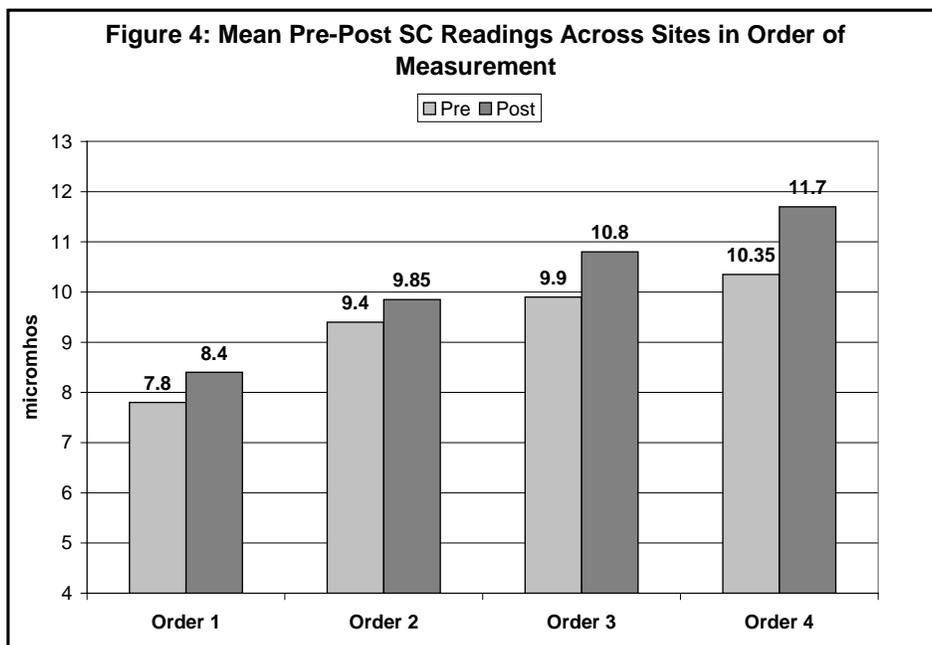


Figure 4: Sequential skin conductance measurements with four patch placements

- In contrast to the skin conductance measurement, the Electro-Acuscope means increased only slightly in the Pericardium and Stomach areas. Whereas the Lung and Kidney means decreased with patch application. Only the Kidney measure showed a 0.05 level of significance, one-tailed.

Assessment: *This study examined the effect of the Energy Enhancer® patches on meridian conductance at four different acupuncture points measured by a biofeedback instrument. This study was based on the premise that energy flow throughout the body is transmitted through the meridian pathways. The study did show that skin conductance increases with the application of the Energy patch device to acupuncture points. Increasing skin conductance is evidence of a physiological change in the body. This study provides support that one of the effects (mechanism of action) of the LifeWave Energy patch is to stimulate acupuncture points and increase energy flow through the acupuncture meridian system.*

Study Report #7: *Harada T, Tsuchiya K, Maret K. Effects of LifeWave Patches on Acupuncture Meridians & Biophoton Emission in Human Subjects (A Pilot Study). Dec 16, 2009. Dove Health Alliance and California Institute for Human Science.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - Kidney 1 (Kid 1)
- Ten (10) healthy male subjects (ages 19 to 43 years) were recruited and tests were conducted prior to and during use of the Energy Enhancer® Patches.
- This open-label pilot study aimed to determine if there is any detectable change in the conditions of the human acupuncture meridian system and bio-photon emission (BE) patterns that can be attributed to the Energy Enhancer® patches. Females were excluded in this initial study in order to remove the influence of the menstrual cycle in detection of subtle changes.
- Continuous AMI and Snapshot AMI devices were used to monitor the energetic conditions of the acupuncture meridian system, and photon counting system was used to detect biophoton emission from subject's right hand. Heart rate from electrocardiography (ECG), pulse rate from photoplethysmography (PPG) and respiration were also monitored from a Polygraph system (Polygraph) along with continuous AMI measurements to acquire supplementary information.
- Tests were conducted in the following order: (1) Blood pressure and heart rate; (2) Snapshot AMI; (3) Biophoton emission (4) Continuous AMI with Polygraph (15 min control period, no patch); (5) Continuous AMI with Polygraph (30 minutes continuous monitoring with patches); (6) Biophoton emission (with patches); (7) Snapshot AMI (with patches); (8) Blood pressure and heart rate. Results were processed and observed changes between "before patches" and "with patches" were extracted for analysis.

Efficacy of patches in this study:

- Results: Possibly as effects of wearing the Energy Enhancer® Patches on the soles, it was found that:
 - A. The application of the Energy Enhancer® patches to the Kidney 1 points on the soles tends to cause the biophoton emission from the palm of the right hand to decrease. The decrease in biophoton emission may be interpreted as a shift to a more desirable health condition.

- B. The body's energetic functions (Ki-energy, sympathetic nervous system & immune system activities) tend to shift to the lower half of the body.
 - C. Immune system activities tend to be enhanced in the entire body.
 - D. No common patterns were evident in individual meridian left-right balance.
 - E. Autonomic nervous system function, from measurements of heart rate variability (HRV) and respiratory frequency, tends to shift toward a parasympathetic dominant state.
- Statistically significant results were obtained strongly indicating that the Energy Enhancer® patches generate measurable changes in both biophoton emission intensities and the body's energetic condition. With generally healthy subjects, the changes induced appear to be in the desirable direction (i.e. improvement in body functions and a more relaxed state).
 - Of the 10 subjects, only two were marginally positive or negative with virtually no significant change between "before patches" and "with patches." All other subjects showed a decrease in BE with the patches on for about 40 minutes. The rate of decrease varied from 15% to 90% depending on the subject.
 - When a t-test was applied to the [(Aft-M)-(Bef-M)] data sets of the two groups, with $p=0.05$ as the preset significance level, the result turned out to be significant with $p=0.043$. A second method of analysis found that of the 10 subjects, 7 subjects showed a statistically significant decrease in biophoton emission (BE) with p-values ranging from significant ($p=0.0062$) to extremely significant ($p=4.2 \times 10^{-24}$). Of the remaining 3 subjects, one showed a decrease with $p=0.052$, close to the preset criteria ($p=0.05$). No statistical significance was found with the other two subjects. Although the choice of data segments and the approach of analysis were different, the results obtained by the two methods of analysis were found to be largely consistent with each other. Seven subjects out of ten showed a statistically significant decrease in BE between "before patches" and "with patches".

Assessment: *This study examined the effect of the Energy Enhancer® patches on energetic shifts in the body's meridian system as measured by a different biofeedback instrument than the one used in Study Report #6. This study was also based on the premise that energy flow throughout the body is transmitted through the meridian pathways. The study did show energetic shifts in the meridian system when the energy patch was applied to acupuncture points. This study also provides support that one of the effects (mechanism of action) of the LifeWave Energy patch is to stimulate acupuncture points and shift energy flow through the acupuncture meridian system. In addition, this is another study that confirmed that the energy patch had a physiological effect (mechanism of action) on the autonomic nervous system moving toward a parasympathetic dominant state confirming the results seen in Study Reports #2, 3 and 4.*

Study Report #8: Montgomery M. Fenestra Research - LifeWave Products Pure Energy Patches 60-Subject Test: Final Report 2006.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - A. Pericardium 6 (P 6)
 - B. Lung 1 (Lu 1)
 - C. Stomach 36 (St 36)
 - D. Kidney 3 (Kid 3)

- This 30-day study involved 60 subjects of various age, exercise levels, race, sex, and health levels.
- Subjects followed the standard protocol in the LifeWave brochure of rotating through 4 placements every other day after initially wearing the patches daily for the first 3 days.
- Subjects were tested at baseline and then again at the end of the second and fourth weeks of the study by the Optimal Wellness Test, which runs a combination of 3
- 0+ tests run on non-fasting urine and non-fasting saliva.

Efficacy of patches in this study:

- Upon completion of the 60 subject, 30-day testing and intake, these significant measurements were found:
 - 30% of subjects reported an increased sense of well-being while wearing the patches.
 - Five subjects reported a weight loss of at least 6 pounds during this study.
 - It was reported that the daily use of the LifeWave Energy Enhancer® Patches did improve the energy levels in 100% of our test subjects.
 - An average of 22.3% increase in the subject's ability to convert fat into energy was measured when the energy patches were applied to the subjects

Assessment: *This study showed increased energy from fat burning which is the same mechanism of action tested in Study #5. This study supports the claim that the Energy Enhancer® patches improve energy.*

Study Report #9: *Tully L. Open-label pilot study to determine the efficacy of the LifeWave Energy Patch in improving fitness, strength, endurance and balance in 10 healthy humans. Energy Medicine Research Lisa Tully, PhD December 2010. Presented at 21st Annual ISSSEEM Conference June 24, 2011.*

Safety issues:

- One subject complained of nausea that passed within minutes and continued testing with the Energy Enhancer® patches. No other adverse effects were reported.

Patch instructions and study procedures:

- Acupoints tested:
 - Lung 1 (Lu 1)
- In this pilot study, tests were conducted that measure flexibility, strength and endurance in 10 healthy humans (6 male and 4 female) ranging from 18-65 years of age with no history of disease, pregnancy, drug or alcohol use, or on any medications. All subjects were in good general health and did not have a high level of fitness.
- Subjects were measured before and after wearing the Energy Enhancer® patch for one hour.
- Various tests were used for strength and endurance to determine the most efficacious test for these parameters. Tests conducted included: stretch and reach, hand strength, bicep curl and latissimus dorsi pull down maximum weight, bicep curl repetition to failure and various outcome measures with an ergometer bicycle (peak and average power, average and peak speed, heart rate, distance, speed, and calories).

Efficacy of patches in this study:

- In the flexibility tests, the mean stretch and reach measure rose from 15.77 to 16.88 inches and this increase was significant with $p < 0.05$.
- In strength tests, mean bicep curl maximum weight rose from 16 to 17.5 pounds, the mean value for lat pull downs rose from 130.83 to 133.33 pounds and the mean value for peak watts per pound rose from 232.22 to 273.22.

- Outcomes from the study measurements are shown in **Table 1**.

Table 1: Summary statistics for all outcome measure for baseline and with patches assessments.

	Baseline					With Patches			
	N	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.
Bicep Curls Max Weight (lbs)	10	16	7.38	5	27.5	17.5	7.48	7.5	30
Max Reps	10	20.7	7.65	6	35	24.7	8.26	8	35
Lat Pull Down (lbs)	12	130.83	63.35	65	250	133.33	62.47	65	250
L Hand Strength (kgs)	11	74.09	24.22	31	100	83.27	18.01	59	104
R Hand Strength (kgs)	11	87.09	19.35	57	118	93.36	15.7	69	122
Stretch and Reach	12	15.77	2.23	12	18.75	16.88	2.32	13	20.25
Peak Watts/lbs	9	232.22	96.98	116	394	273.22	106.03	140	460
Average Watts/lbs	9	106.81	38.19	46.45	150.7	130.67	47.1	61.8	204.6

- **Table 2** shows that all of the strength tests showed significant improvements.

Table 2: Analysis of absolute change of all outcome measures from baseline to post-treatment.

	N	Mean	SD	Min.	Max.	p-value
Bicep Curl Max Weight (lbs)	10	1.5	1.31	0	3	0.0056*
Max Repetitions	10	4	3.53	0	10	0.0059*
Stretch and Reach (in.)	12	1.1	0.76	0	2.5	0.0004*
Lat Pull Down (lbs)	12	2.5	2.38	0	5	0.0039*
L Hand Strength (kgs)	11	17.36	8.87	2	28	0.00642*
R Hand Strength (kgs)	11	6.27	5.97	-1	21	0.0059*
Stretch and Reach	12	1.1	0.76	0	2.5	0.0004*
Peak Watts/lbs	9	41	31.3	-6	106	0.0044*
Average Watts/lbs	9	23.86	14.72	10.71	53.9	0.0013*

*Note: p<0.05

- During the five-minute bicycle test, **Table 3** shows that all outcome measures were increased. The mean value for average speed increased from 16.91 to 18.22, peak speed rose from 19.53 to 21.2, peak power rose from 208.38 to 259.56, peak heart rate rose from 164.2 to 169,

distance increased from 1.44 to 1.55 miles, calories burned increased from 43.84 to 50.04, and peak watts per kilogram increased from 2.82 to 3.24. Increases in peak speed and power, distance and peak watts per kilogram while wearing Energy Enhancer® patches were statistically significant ($p < 0.05$).

Table 3: Summary statistics for all outcome measure for baseline and post-treatment assessment.

	Baseline					Post-Treatment				
	N	Mean	SD	Min.	Max.	N	Mean	SD	Min.	Max.
Average Speed (MPH)	5	16.91	2.42	14.00	20.09	5	18.22	2.48	14.55	21.21
Peak Speed (MPH)	5	19.53	4.11	15.22	24.96	5	21.20	4.60	15.42	26.08
Average Power (watts)	5	139.42	53.87	79.63	205.80	5	159.69	55.96	84.93	229.72
Peak Power (watts)	5	208.38	111.45	105.00	382.00	5	259.56	132.10	120.00	451.00
Ave HR	5	150.00	5.39	141.00	154.00	5	156.20	12.99	139.00	174.00
Peak HR	5	164.20	5.93	159.00	173.00	5	169.00	14.30	149.00	187.00
Distance (miles)	5	1.44	0.21	1.17	1.63	5	1.55	0.23	1.21	1.77
Calories	5	43.84	16.15	26.00	61.80	5	50.04	16.81	26.20	70.80
Av Watts/kg	5	1.86	0.59	1.30	2.60	5	2.12	0.58	1.30	2.80
Peak Watts/kg	5	2.82	1.01	1.70	4.20	5	3.24	1.25	1.90	5.00

- In endurance tests, the mean value for average watts per pound (a measure of the ability to keep physical power up over time, thus endurance) rose from 106.81 to 130.67 and this was a significant improvement ($p < 0.05$).
- An additional endurance test was conducted and more outcome measures are reported. There were increases in mean values for all outcome measures after subjects wore Energy Enhancer® patches for one hour. Average power increased from 139.42 to 159.56, average heart rate increased from 150 to 154, average watts per kilogram rose from 1.86 to 2.12. Changes in average speed of MPH while wearing LifeWave Energy Patches were statistically significant ($p < 0.05$).
- Results of this pilot study demonstrate that Energy Enhancer® patches produce a significant increase in performance for all tests of strength, flexibility and endurance that were conducted. Most of the subjects demonstrated an increase in performance in every test, leading to a significant increase in performance for every test. Although these absolute changes seem small for some of these tests, such as the weight strength tests (bicep curl and lat pull downs), they are large changes when one takes into account the importance of lifting a weight that is only a

few pounds heavier. The same conclusion is true for the stretch and reach test, using distance as the endpoint rather than weight lifted.

- For the endurance tests, several outcome measures were substantially improved. For the three mile course, both peak and average watts per pound were significantly increased by the Energy Enhancer® patches. Results for the second endurance test were more dramatic. With only a sample size of five, statistical significance was achieved for an increase in average and peak speed, peak and average power, distance and peak watts per kilogram. A larger study is planned.

Assessment: *This was a pilot study that demonstrated that wearing the Energy Enhancer® patches on acupuncture points produced a significant increase in performance for all tests of strength, flexibility and endurance which were conducted. This study supports the claim that the energy patches improve energy and performance.*

Study Report #10: *Tully L. Report for Human Clinical Study of the Efficacy of LifeWave Energy Patch in Improving Flexibility, Strength and Endurance. Submitted by Energy Medicine Research Institute, June 2, 2011.*

Safety issues:

- One subject stated their wrist hurt during the testing with the placebo patch.

Patch instructions and study procedures:

- Acupoints tested:
 - Pericardium 6
- A human double blind crossover clinical study examined the efficacy of the LifeWave Energy Patch to increase flexibility, strength and endurance in 60 healthy subjects.
- Subjects were measured before and after wearing the Energy Enhancer® patch for one hour.
- Various tests were used for strength and endurance to determine the most efficacious test for these parameters. Tests conducted included: stretch and reach, hand strength, bicep curl and latissimus dorsi pull down maximum weight, bicep curl repetition to failure and various outcome measures with an ergometer bicycle (peak and average power, average and peak speed, heart rate, distance, speed, and calories).

Efficacy of patches used in the study:

- Results of this study demonstrate that Energy Enhancer® patches produce a significant increase in performance for all but one of the tests of flexibility, strength and endurance that were conducted. Many of the subjects demonstrated an increase in performance in every test and outcome measure, leading to a significant increase in performance for these tests.
- Although the absolute changes seem small for some of these tests, such as the weight strength tests (lat pull downs), they are large changes when one takes into account the importance of lifting a weight that is only a few pounds heavier. The same conclusion is true for the stretch and reach test, using distance as the endpoint rather than weight lifted.
- Factors that can influence the outcome were analyzed and found not to have any effects. All of the subjects were properly randomized, as shown by the lack of difference between baseline measures between the active and placebo groups. Additionally, there was no learning effect that can occur as a result of repeating a test, regardless of the length of the washout period.

- The reported increased energy levels correlated with the increased performance indicates that the Energy Enhancer® patches are increasing energy levels. The increase in athletic performance observed in this study is substantial. Furthermore, it should be noted that in this study, the patches were only worn for an hour. It is likely that a longer application, which occurs during normal use, will produce greater effects.
- The tests utilized in this pilot study are objective measures of flexibility, strength and endurance that are used in standard athletic testing. They are academically credible and superior to applied kinesiology tests that are commonly used to demonstrate the efficacy of products that increase athletic performance.

Assessment: *Results of this study demonstrate that Energy Enhancer® patches produced a significant increase in performance for all but one of the tests of flexibility, strength and endurance that were conducted (stretch and reach, latissimus dorsi maximum weight lifted, left hand strength, peak and average speed, peak and average watts per kilogram, distance and calories). Many of the subjects demonstrated an increase in performance in every test and outcome measure, leading to a significant increase in performance for these tests. This double blind crossover clinical trial showed that Energy Enhancer® Patches produce a significant increase in several tests of flexibility, strength and endurance in healthy humans. The tests utilized in this study are objective measures that are used in standard athletic testing and substantiate the claim and mechanism of action is that Energy Enhancer® patches increase energy.*

Study Report #11: Goodson JA, Schmidt D. *LifeWave Strength Test 2003.*

Safety issues:

- No adverse reactions were reported.

Patch instructions and study procedures:

- In this study, 44 male college athletes from the Morehouse College football team volunteered to participate in this double-blind, placebo-controlled study testing Energy Enhancer® patches.
- The study was conducted so that both baseline and comparative data were collected after the athletes had been fatigued by a 60-minute heavy weight training workout. In addition, it was also decided to test the athletes while under heavy physical trauma; the athletes performed the workout and tests starting at 4:30am in a weight training room where the temperature was maintained in excess of 95°. The standardized exercise that was chosen for this test was a 185lb or 225lb Bench Press. Baseline data was collected on Monday and comparative data collected on Thursday.
- Using a double-blind, randomized, placebo-controlled study, a total of 44 subjects, ages 18 to 30 years, volunteered to participate for this 2 day test study. Subjects' baseline bench press data was collected after a normal prescribed off-season football upper body 60 minute workout session. Subjects were asked to bench press a fixed weight until failure. In the next session, subjects were randomized into three groups using a numbering system that labeled participants as experiment group, placebo group or control group members with 44 completing this two session study.

Efficacy of patches in this study:

- The average percentage change in strength endurance in the Control group was a decrease in performance of 3.1% from the baseline tests to the comparative tests; (2) The average percentage change in strength endurance in the Placebo group was an increase in performance

of 3.6% from the baseline tests to the comparative tests; (3) The average percentage change in strength endurance in the Experiment group was an increase in performance of 33.9% from the baseline tests to the comparative tests.

- Results demonstrated that the Experimental group showed the highest percentage of improvement in strength endurance when averaging all members, the highest percentage of improvement in strength endurance when averaging only those members who showed an improvement, and the lowest percentage of decreased performance when averaging only those individuals who showed a decline in performance.

Assessment: *Based on the data collected and the results obtained it was demonstrated that the Energy Enhancer® patches are a method for the improvement of athletic performance, and more particularly a means by which an individual may increase their net stamina/strength endurance output.*

Study Report #12: *Schmidt D, Shaughnessy R. A double blind placebo controlled study of the LifeWave technology as it relates to the improvement of strength endurance in high performance college athletics. 2003.*

Safety issues:

- No adverse reactions were reported.

Patch instructions and study procedures:

- Subject wore the patches for 30-60 minutes.
- Twenty-five (25) male subjects, ages 18 to 22 years, volunteered to participate in this double-blind, randomized, placebo-controlled study testing Energy Enhancer® patches.
- The primary goal of this study was to determine whether Energy Enhancer® patches are a means by which an individual may substantially increase their net strength endurance within the first use of the product. Subjects were divided into three groups: Control, Placebo and Test.
- A standardized test was selected to measure net gains in strength endurance, and in this case the exercise that was performed by all athletes was a 225 lb. flat Bench Press.
- The baseline data for this test was collected on Thursday June 26, 2003. The comparative data was collected on the following Wednesday July 2, 2003. All subjects were blind as to whether they were wearing Energy Enhancer® patches or placebo patches. The test was performed within 10 minutes of first applying the patches to the athletes
- Subjects' baseline bench press data was collected after a brief warm up period. Subjects were asked to bench press a fixed 225 lb. weight until failure. In the next session, subjects were randomized into three groups using a numbering system that labeled participants as test group, placebo group or control group members with 25 completing this two session study. The test group was provided with non-transdermal patches that contained the LifeWave technology. The Placebo group was provided with non-transdermal patches that contained water. A collection team independent of the players collected and monitored data throughout the study process.

Efficacy of patches in this study:

- From the raw data collected, and by removing the highest and lowest scores from each group, it was determined that: (1) The average percentage change in strength endurance in the Control group was an increase in performance of 8.9% from the baseline tests to the comparative tests (average 0.875 rep improvement); (2) The average percentage change in strength endurance in the Placebo group was an increase in performance of 13.8% from the baseline tests to the comparative tests (average 1.67 rep improvement); (3) The average percentage change in

strength endurance in the Test group was an increase in performance of 43.2% from the baseline tests to the comparative tests (average 2.6 rep improvement).

- Results demonstrated that the Test group using the LifeWave technology showed the highest percentage of improvement in strength endurance when averaging all members, the highest percentage of improvement in strength endurance when averaging only those members who showed an improvement, and the lowest percentage of decreased performance when averaging only those individuals who showed a decline in performance.

Assessment: *Based on the data collected and the results obtained it was demonstrated that the LifeWave technology is a method for the improvement of athletic performance, and more particularly a means by which an individual may increase their net stamina/strength endurance output.*

Study Report #13: DeRock JL. Responsiveness of Horses to Biofrequency Modulation after Acupuncture Palpation. Journal of the American Holistic Veterinary Medical Association (JAHVMA) 2005 Oct-Dec; 24(3):11-14).

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints Tested:
 - Urinary Bladder 23 (UB 23)
- This was an open label study of Energy Enhancer® patches.
- One hundred thirty-eight (138) horses were enrolled, after an acupuncture palpation evaluation by PI, a licensed veterinarian. Owners brought in horses showing signs of discomfort. A subset of seven of the 138, were given a placebo patch.
- The objective of this study was to explore the use of acupuncture point palpation and application of Energy Enhancer® patches to specific points on the skin of horses. The goal was to see if Energy Enhancer® patches would relax the back and relieve back discomfort in horses.
- The study was led by a licensed veterinarian with training in acupuncture, which she uses in her private practice focused on equine acupuncture. The veterinarian applied her techniques to palpitate the animal and consistently diagnose the source of pain. This technique is based on the Chinese technique called *Association* or “Back-Shu” Points and *Alarm* or “Front-Shu” Points. An acupuncture modulation scale was used to measure before and after levels of discomfort to assign a sensitivity score.

Efficacy of patches in this study:

- One hundred thirty-five (135) of the 138 horses with back pain showed elimination of back pain after patch placement for five minutes. Two horses who failed to respond initially showed elimination of back pain after reversal of patch position. One horse failed to respond.
- The more severe the back pain, the more dramatic were the effects. The seven horses who initially received placebo patches did not show any change in their sensitivity score when reassessed after placement.
- The lack of perceived improvement after placement of the placebo patches, to which the investigator was blinded, likely confirms the legitimacy of the perceived therapeutic response to Energy Enhancer® patches.

Assessment: *In conclusion, Energy Enhancer® patches when placed according to the technique outlined in this paper, consistently alleviated back pain in horses, as assessed by acupuncture palpation.*

Study Report #14: McGill R. *Investigative Study of Long Term Effects of LifeWave Patches Using Electro Meridian Analysis System ®(EMAS).* Presented at LifeWave Convention in Las Vegas, NV. Sept. 2005.

Safety issues:

- No adverse reactions were reported.

Patch instructions and study procedures:

- The aim of this 7- person pilot study was to test the ability of the Energy Enhancer® patches to change or balance the energy of the meridians and measure that change.
- Measurements were tested by use of the EMAS system to measure changes in energy. A secondary subjective measure was recorded by subject.
- The seven week study used a cross over design; first, subjects were randomly assigned to receive either placebo or Energy Enhancer® patches, then a one week washout period before wearing the second treatment.
- Acupoints used together (Yin and Yang):
 - Triple Burner 5
 - Kidney 4
- Patches were worn 3 days per week.

Efficacy of patches in the study:

- Self assessed energy levels correlated correctly to the blinded patch assignment.
- One subject reported no change in energy levels from placebo to active.
- Four subjects had increases in energy recorded by self and EMAS.
- Two subjects had a decrease in energy (3% and 13%).

Assessment: *This early pilot study showed the trend toward energy levels increasing in the meridians with use of Energy Enhancer® and decreasing when using placebo.*

Study #15: Maret K, Chevalier G, Harada T, Tsuchiya K. *Effects of Lifewave Patches on Acupuncture Meridians, Biophoton Emission and Heart Rate Variability In Human Subjects (A Double Blind Study).* Dove Health Alliance. Sept. 2011.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoints used:
 - Kidney 1
- 15 male subjects were randomized to receive either placebo or Energy Enhancer® patches
- The focus of this study was to compare the effects of both the Energy Enhancer® and placebo patches on biophoton emission, heart rate variability and acupuncture meridian functions.
- Continuous AMI and Snapshot AMI were used to monitor the energetic condition of the acupuncture meridian system. A photon counting system with photomultiplier (PMT) head was used for biophoton detection. EKG and respiration were recorded by the ProComp 5 Encoder

(Thought Technology Ltd) for off-line HRV analyses. Body impedance was also measured by the RJL Body Composition Analysis System to provide auxiliary information on the subjects.

Efficacy of patches in this study:

- Biophoton emission data was not statistically different when comparing both treatment groups.
- Statistically highly significant differences were found in time-domain HRV metrics (SDNN, RMSSD, Variability) indicating that the Energy Enhancer® patch enhanced the parasympathetic tone more distinctively than the placebo patch.
- Variance analysis of Continuous AMI signals showed the opposite increase/decrease patterns between patches, indicating that the Energy Enhancer® patch increased the dynamic range of Ki-energy activities more strongly than the placebo patch.

***Assessment:** Based upon the results and their implications derived from detailed analyses of measured bio-energetic variables it is reasonably evident that more functionally desirable changes were found with application of the Energy Enhancer® patch than with the placebo patch.*

Study Report #16: Woolley, Lee., Haltiwanger, Steve. BioCoherence and Lifewave Energy Enhancement Patches Utilizing Bionetic-Feedback Assessment (2006). NuVisions for Wellness.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- The Energy patch was tested by measurements at the following bilateral acupuncture sites:
 - Stomach 36 (ST 36)
 - Pericardium 6 (P 6)
 - Lung 1 (Lu 1)
 - Kidney 3 (Kd 3)
- Two hundred subjects sampled and each was tested for 30 minute period.
- BioCoherence Analysis (BCA) is an emerging complex science that records and analyzes unique bioelectrical information from the body by measuring micro-voltage readings detected on the skin's surface. The bioelectrical information is converted mathematically through specific algorithms through FFT analysis which specifically extracts meaningful information from within the core data isolated by specialized SsEMG equipment at specific and unique bandwidths.
- The data sampling times included over 90% of the tests using 2.5 minutes and only 10% of the tests using a testing time of 4.5 minutes. The variables for sampling duration showed increases in modulations only due to the increase of modulations which were time based and that 3-5 modulations per 2.25 minutes in the selected frequency bandwidths was average. Shorter tests showed consistent readings noting that the highest amplitudes would appear within the first two minutes of the sampling and would also re-appear within the 4.5 minute sample. The characteristics of these long waves differ from short waves, however for our discussion in this paper the measured frequencies were in the 0-10 KHz range. The highest amplitudes show ranges between .01 and 5.8. The average amplitudes show ranges between .00 and 1.3. Modulation ranges for signal strength between 0-13. Coherence ranges include a matched number of modulations, similar amplitudes, and no frequency going out of range. In the most coherent of subjects, the averages also demonstrated 50% of the highest amplitude at any given time. Those subjects who were adequately hydrated, had been eating quality nutrition, and who also practiced meditation, showed significant differences in the BioCoherence readings

Efficacy of patches in this study:

- Average readings of amplitude carried the significance in the data, and in every test case an increase in overall average amplitude range and/or a normalizing in frequency bandwidths were detected. These effects exemplified an overwhelming success in increasing the overall BioCoherence in over 94% of all test subjects.

Assessment: *Overall changes in modulation, amplitudes, and energy distribution were noted in this study. Comparison between initial reading and final readings when patches were worn demonstrated shifts in available energy potentials between 18-33% over baseline data for all test subjects. In summary, Energy Enhancer® patches did promote a renormalization or increase in BioCoherence.*

Study Report #17: Connor, M., Baldwin, A., and Eickhoff, J. Hormonal and Doppler Laser Perfusion Testing of the Lifewave Energy Enhancer Patches (2102). Optimal Healing Research.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Double-blind, placebo controlled study pilot study of 20 healthy adults, 10 who wore the active patch and 10 who wore the placebo patch to assess physiological changes of the sealed FDA registered homeopathic Energy Enhancer® patch.
- Subjects were consented and then the first baseline saliva sample collected for hormonal testing. Three more saliva samples were provided over the ensuing 24 hours. On day two, subjects entered the laboratory at 8:00 am for the first laser Doppler scan to evaluate baseline blood perfusion of the fingertips (index, middle and ring fingers) of both hands. The Energy Enhancer® patches were applied (white patch to point TB5 on the right wrist, 3-4 finger widths from the crease in the palm side of the wrist, and tan patch to P6 on the left wrist). Scans were then taken immediately after, and 10 minutes after, patch application. Subjects were asked to leave the patches on all day and return to the lab at noon and at 4 pm for further scans and then the patches were removed. The same process was repeated on the subjects the next day using new patches, and a second set of saliva samples were collected.
- The Marlowe-Crowne Social Desirability scale was administered to determine if social responses showed a tendency to support a placebo effect. Global Mode Scale and Hassles and Uplift scales were administered to determine if there were any significant changes of mood with patch application. The Tellegen Absorption scale was administered to determine if subjects were producing a high level of absorption showing a possibility of self-hypnosis. eVAS for Energy was administered to determine if there was a change in the subject's perception of their level of energy.

Efficacy of Patches in this Study:

- During the baseline assessment, no statistically significant differences in cortisol levels were detected between groups. Significantly higher cortisol levels were in the active group compared to placebo group at noon, (2.39±0.17 ng/mL versus 2.15±0.27 ng/mL, p=0.036) and at 4pm (2.02±/-0.24 ng/mL versus 1.67±/-0.31 ng/mL, p=0.0156).
- The DHEA levels were significantly lower at baseline 8am and 8pm in the placebo group when compared to the active group. Significant differences were observed for the changes in DHEA levels baseline to treatment day in DHEA levels between the active and placebo groups at 8pm p=0.032 and at midnight p=0.0464. DHEA in the active group decreased on the treatment day, whereas DHEA in the placebo group was not affected.

- There were no significant differences detected for the changes from the baseline to treatment day assessment between groups for estradiol, progesterone, or testosterone.
- There was no significant difference in the Marlowe-Crowne Social Desirability Scale total scores, eVAS total scores, or the Telegen Absorption Scale Total scores detected between groups.

Assessment: *DHEA and Cortisol testing showed significance differences between placebo and active groups, which warrants further testing. Placement of patches, per se, may cause a temporary relaxation of subcutaneous blood vessels. Placement of active patches causes a small, delayed microvascular relaxation in healthy subjects at room temperature. Experiments performed at lower temperatures may produce more definitive results in Laser Doppler Perfusion imaging. There was a statistically significant decrease in the placebo group's energy level between day one and day two while the active group maintained their perception of their energy level. In addition, there was a significant difference for the change from baseline to treatment day 1 in the Global Mood Scale Positive Affect score between active and placebo groups, ($p=0.0167$), the active group showing very little change and the placebo group showing a significant decrease.*