ENERGY ENHANCER®

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. December 2010

Pursuing Publication

Safety:

- 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 LifeWave Energy Patch for one hour.
- One subject complained of nausea that passed within minutes and she was able to continue testing with the Energy Enhancer patches. No other adverse effects were reported.

Patch instructions and study procedures:

- Acupoints tested:
    A. Lung 1 (Lu 1)
- 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 inches to 16.88 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.

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

	Baseline					With Patches			
	N	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum
Bicep Curls Max Weight	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	12	130.83	63.35	65	250	133.33	62.47	65	250
L Hand Strength	11	74.09	24.22	31	100	83.27	18.01	59	104
R Hand Strength	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	Minimum	Maximum	p-value
Bicep Curl Max Weight	**10**	**1.5**	**1.31**	**0**	**3**	**0.0056***
Max Repetitions	**10**	**4**	**3.53**	**0**	**10**	**0.0059***
Stretch and Reach	**12**	**1.1**	**0.76**	**0**	**2.5**	**0.0004***
Lat Pull Down	**12**	**2.5**	**2.38**	**0**	**5**	**0.0039***
L Hand Strength	**11**	**17.36**	**8.87**	**2**	**28**	**0.00642***
R Hand Strength	**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***

*** 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 LifeWave Energy 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**	**Minimum**	**Maximum**	**N**	**Mean**	**SD**	**Minimum**	**Maximum**
Average Speed	**5**	**16.91**	**2.42**	**14.00**	**20.09**	**5**	**18.22**	**2.48**	**14.55**	**21.21**
Peak Speed	**5**	**19.53**	**4.11**	**15.22**	**24.96**	**5**	**21.20**	**4.60**	**15.42**	**26.08**

Average Power	**5**	**139.42**	**53.87**	**79.63**	**205.80**	**5**	**159.69**	**55.96**	**84.93**	**229.72**
Peak Power	**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	**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 LifeWave Energy 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 while wearing LifeWave Energy Patches were statistically significant ($p<0.05$).
- Results of this pilot study demonstrate that LifeWave Energy 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 LifeWave Energy 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.

Budzynski T, Budzynski H, Tang HY. Acuscope and Skin Conductance along Meridians: Before and After LifeWave Energy Patches. May 2010

Pursuing Publication

Safety:

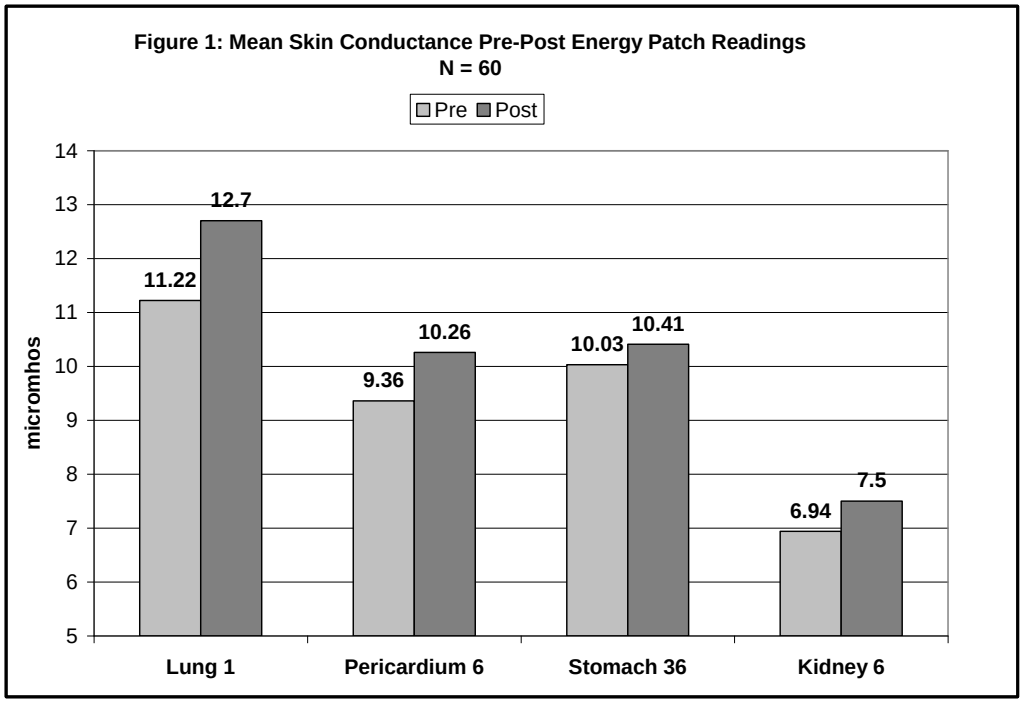
- 60 subjects between the ages of 18-65, without debilitating illnesses were tested using Energy Enhancer Patches to test meridian conductance at four different acupuncture points.
- A sub-group of 29 subjects will be tested using a second biofeedback instrument for deeper tissue changes.
- Subjects wore patches for 3 hours during testing.

Patch instructions and study procedures:

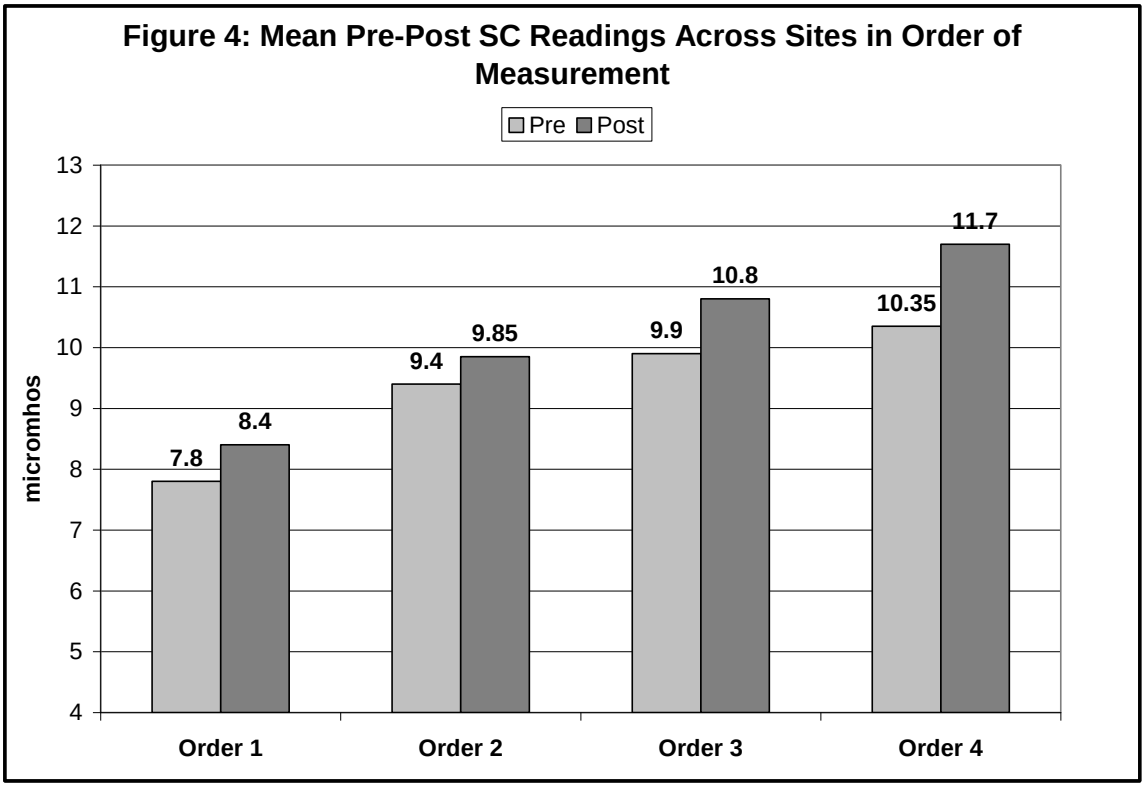
- **Acupoints Tested:** The Energy patch was tested by measurements at the following bilateral acupuncture sites:
    A. Stomach 36 (ST 36)
    B. Pericardium 6 (P 6)
    C. Lung 1 (Lu 1)
    D. Kidney 3 (Kd 3)
- The study compared a baseline measure with after-treatment measurements following the application of LifeWave Energy Enhancer patches that were sequentially moved between 4 different acupuncture sites. At testing time, the sequential order of measurement of these sites were randomly chosen to check whether time /order played a factor in the measure of conductance at a particular acupuncture point.
- 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 measurements. Two-tailed t-tests showed significant Pre-Post differences for Lung, Pericardium and Kidney with only the Stomach site not reaching significance.
    A. Lung 1 had a $p<0.0005$
    B. Pericardium 6 $p<0.02$
    C. Stomach 36 $p<0.17$
    D. Kidney 6 $p<0.03$



- 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.



- In contrast to the skin conductance measurement, the 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 an 0.05 level of significance, one-tailed.

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:

- 10 healthy male subjects ranging from 19.2 to 43.3 years old were recruited and tests were conducted "before patches" and "with patches" applying 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.
- There were no negative reports or adverse reactions reported in the group.

Patch instructions and study procedures:

- Acupoints tested:
    A. Kidney 1 (Kid 1)
- 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" and "after" 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 tend 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. 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 do generate measurable changes in both biophoton emission intensities and 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 “with patches” and “before 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 ($p=4.2x10^{-24}$). 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”.

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

Safety:

- 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 LifeWave Energy Enhancer patches or placebo patches.
- **There were no negative reports or adverse reactions reported in the group.**

Patch instructions and study procedures:

- The objective of this study was to test whether proprietary nanotechnology skin patches (LifeWave Energy Enhancer patches) produced for the purpose of increasing energy are also capable of modulating certain of the resonant frequencies of the body, promoting greater autonomic nervous system balance as reflected in heart rate variability (HRV).
- 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.
- Both experimental and control group had the energy or placebo patches applied over the lung meridian (just below the location where the collarbone and the shoulder bone meet).
- Acupoints tested:
    A. Lung 1 (Lu 1)

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=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.
- LifeWave Energy Patches appear to act on the autonomic cardiovascular factors influencing heart rate variability in the hypothesized direction. LifeWave Energy 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.

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:

- 20 subjects used LifeWave Energy Enhancer patches in a double-blind placebo controlled study during rest and after mild exercise.
- There were no negative reports or adverse reactions reported in the group.

Patch instructions and study procedures:

- The individuals were tested with no patches, and then in a double-blind crossover with placebo and active patches.
- Acupoints tested:
    A. Pericardium 6 (P 6)
    B. Lung 1 (Lu 1)
    C. Stomach 36 (St 36)
    D. Kidney 3 (Kid 3)
- *Heart Rate Variability (HRV) signal* refers to beat-to-beat variation of heart rate and represents the cyclical changes in 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 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. 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.
- 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**) f*or p <0.01.*
- Based on these observations it could be concluded that both during Rest and immediately after 5 minutes of mild Exercise, the Energy patches elicited an enhanced parasympathetic response which could be quantified by a reduction in normalized LF/HF. The statistical results revealed that the Energy 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.

Woolley LG, Haltiwanger S. BioCoherence and Lifewave Energy Enhancement Patches Utilizing Bionetic-Feedback Assessment. NuVisions for Wellness (2006).

Safety:

- Over two hundred people were tested.
- There were no negative reports or adverse reactions reported in the group.
- Duration of testing was 30 minutes.

Patch instructions and study procedures:

- **Acupoints Tested:** The Energy patch was tested by measurements at the following bilateral acupuncture sites:
    E. Stomach 36 (ST 36)
    F. Pericardium 6 (P 6)
    G. Lung 1 (Lu 1)
    H. Kidney 3 (Kd 3)
- 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 the ranges from between 11-30% in over 94% of all test subjects.

Shallenberger F, Nazaran H. The Effect Of A Non-Transdermal Surface Patch On Mitochondrial Function. LifeWave Study 2006

Safety:

- The subjects included 30 men and women between the ages of 18 and 65 years.
- Subjects wore either LifeWave Energy Enhancer patches or placebo patches for one hour during testing and daily for 7 days before testing.
- **There were no negative reports or adverse reactions reported in the group.**

Patch instructions and study procedures:

- Acupoints tested:
    E. Pericardium 6 (P 6)
    F. Lung 1 (Lu 1)
    G. Stomach 36 (St 36)
    H. Kidney 3 (Kid 3)
- A 2-week placebo controlled single-blind research study that measured respiratory oxygen uptake and carbon dioxide production under both resting and exertional conditions before and after application of the LifeWave 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.
- 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 (Figures 1-2). The subject was blinded to which patches ar placebo and which are 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 LifeWave 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 LifeWave 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.

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. Conf Proc IEEE Eng Med Biol Soc. 2005; 5:5563-7.

Safety:

- 10 subjects used LifeWave Energy Enhancer patches in a single-blind placebo controlled crossover study during rest and after mild exercise.
- **There were no negative reports or adverse reactions reported in the group.**

Patch instructions and study procedures:

- Acupoints tested:
  A. Pericardium 6 (P 6)
- 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 LifeWave energy patches on HRV signals, pilot data from 10 healthy volunteers were collected under three different conditions during rest and exercise using a BIOPAC system. 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* 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). Based on these preliminary observations it could be concluded that both during both 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 LifeWave energy patches have significant and clearly distinguishable effects on these important HRV signal features.

McGill RE. Investigative Study of Long Term Effects of LifeWave Energy Enhancer Patches Using Electro Meridian Analysis System (EMAS). September 2005

Safety:

- Seven subjects were enrolled in this double-blind placebo controlled pilot study using cross-over design for a 7 week period.
- The subjects acting as their own control were randomly assigned to wear LifeWave Energy Enhancer patches for three weeks on (Monday, Wednesday and Friday) or the placebo patches on (Monday, Wednesday and Friday) for three weeks, one week without any patches active or placebo, and then three weeks with the opposite type of patches - active to placebo or placebo to active.
- Duration of time subjects wore active LifeWave Energy Enhancer patches was (M, W, F) for three weeks.
- No adverse effects were reported.

Patch instructions and study procedures:

- **Acupoints Tested:**
    A. Triple Burner 5 (TB 5)
    B. Kidney 4 (Kd 4)
- A technician who was experienced with using the Electro Meridian Analysis System (EMAS), but who was blind to active or placebo patches conducted the EMAS measurements weekly and collected the daily logs weekly.
- A Visual Analog Scale (0-10) was used to collected data on perceived energy. 0 being no energy and 10 being the best energy they could imagine.
- Weekly measurements using the Electro Meridian Analysis System (EMAS) and daily logs kept by subjects to access perceived energy levels. The aim of this study was to investigate the ability of the Energy Enhancer patches to change or balance the energy in the meridians, channels of energy, sufficiently and to measure that change both objectively and subjectively.
- The EMAS was chosen because of its 50+ years of use and development by Dr. Yosio Nakatani and others. When initially investigating the phenomena of electroconductibility in the channels, he found it to be higher when there was disease related to that channel. For example, if there was kidney disease the skin resistance on the Kidney Channel was higher. This same pattern prevailed in the other 11 channels when there was disease of the organ related to that channel. He named this process *Ryodoraku*.
- Nakatani stated this mechanism could be explained by the viscero-skin sympathetic nerve reflex. Impulses from the viscera radiate to the spinal cord; the reflex zones are then reflected into the skin surface via the efferent sympathetic nerves and appear as a longitudinal connecting system, the meridian lines. According to this theory abnormalities on each meridian can be observed objectively by the measurement of elector-conductivity of certain points on the skin. By stimulating these points homeostasis ensues and abnormalities are regulated. EMAS found that it was possible through the use of computer programming to quickly compute the actual energy measurement (skin resistant/voltage) and display it as a bar graph and a specific numerical measure. These last 2 complexities were overcome with the use of a constant pressure probe and high speed mathematical computations achieved by the computer.

Efficacy of patches in this study:

- Reported and recorded energy increases ranged from 18% to 50%.

- Study results indicated a substantial and sustained increase in perceived energy during the three weeks participants were wearing the active LifeWave Energy Enhancer patches.
- The results of this pilot study show that subjects, using a combined self-assessment and obtained EMAS readings correlated to a significant degree with each other. Overall there was a combined 38% increase in body energy when compared to placebo.

Montgomery M. Fenestra Research - LifeWave Products Pure Energy Patches 60-Subject Test: Final Report 2004

Safety:

- This 30 day study involved 60-subjects of various age, exercise levels, race, sex, and health levels.
- Use of the LifeWave Energy Enhancer patches for 30 days did not result in any reported negative side effects or interactions for the length of this study. 100% of these subjects tolerated the patch test well.
- No allergic reaction on or around the area of placements were seen or reported during this study.

Patch instructions and study procedures:

- 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 30+ tests run on non-fasting urine and non-fasting saliva.
- 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.
- Acupoints tested:
    A. Pericardium 6 (P 6)
    B. Lung 1 (Lu 1)
    C. Stomach 36 (St 36)
    D. Kidney 3 (Kid 3)

Efficacy of patches in this study:

- Upon completion of the 60-subject groups 30-day testing and intake these significant measurements were found:
- 30% of subjects reported an increased since 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 Energy Patches by LifeWave Products 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

Goodson JA, Schmidt D. LifeWave Strength Test 2003

Safety:

- 44 male college athletes from the Morehouse College football team volunteered to participate in this double-blind placebo controlled study testing LifeWave Energy Enhancer patches.
- No information on adverse reactions was reported.

Patch instructions and study procedures:

- 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 95F. 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.
- Based on the data collected and the results obtained it was demonstrated that the LifeWave 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.

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:

- 25 male subjects, ages 18 to 22 years, volunteered to participate in this double blind randomized placebo controlled study testing Energy Enhancer Patches.
- No information on adverse reactions was reported.
- Subject wore the patches for 30-60 minutes.

Patch instructions and study procedures:

- The primary goal of this study was to determine whether LifeWave Energy Enhancer patches are a means by which an individual may substantially increase their net strength endurance within as quickly as 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 LifeWave 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 nontransdermal patches that contained the LifeWave technology. The Placebo group was provided with nontransdermal 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 in the above table, 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.
- 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.

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:

- This was an open label study of LifeWave Energy Enhancer patches.
- 142 were evaluated. Four horses did not demonstrate back pain, and were not evaluated further.

Patch instructions and study procedures:

- Acupoints Tested:
    C. Urinary Bladder 23 (UB 23)
- The objective of this study was to explore the use of acupuncture point palpation and application of LifeWave Energy Enhancer patches to specific points on the skin of horses. The goal was to see if LifeWave 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 of the remaining 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 LifeWave Energy Enhancer patches.
- In conclusion LifeWave Energy Enhancer patches when placed according to the technique outlined in this paper, consistently alleviated back pain in horses, as assessed by acupuncture palpation.

Brown, R. S. Patch permeability. Report of results: MVA6158. La Jolla, CA: Lifewave Products. November 2004

Two "patch" products, one brown patch and one white patch, were delivered to be evaluated by MVA Scientific Consultants to determine whether or not the adhesive-backed polyethylene film allowed the water soluble compounds contained in the patch products to migrate out of the patch product where they could potentially be absorbed into the skin of a person wearing a patch product.

- The patches were examined utilizing a combination of reflected brightfield microscopy, reflected darkfield microscopy, transmitted brightfield microscopy, scanning electron microscopy (SEM) and Fourier transform infrared microspectroscopy (FTIR).
- A reagent was chosen, based on information provided by the manufacturer, that would react with substances present in the brown (glucose) patch and in the white (glycerin) patch. The reagent chosen reacts with glycerin and with glucose to form a white precipitate.
- Sample patches at room temperature, sample patches heated to 40 degrees Centigrade for one hour and sample patches exposed to approximately 500 millitor of vacuum were tested by applying reagent to the adhesive side of the patch after removal of the release paper. The presence of a white precipitate would indicate that water soluble components contained in the blister area of the patch had migrated across the polyethylene-adhesive film and were available for absorption by the skin of a person wearing the patch.
- Based on examinations and testing of the construction of the white and brown patch products, **it was determined that it would not be expected that the water soluble components that reside within the patch products to migrate across the polyethylene film and be available for absorption through the skin of a person wearing the white or brown patch product**.

Clark D. The LifeWave Nanotechnology Energy Patch. May 2005

Safety issues:

- This study was performed on 36 random individuals ranging in age from 22 to 72 using infrared imaging as a method of measuring thermal changes that occurred when LifeWave Energy Enhancer patches were placed on the body.

Patch instructions and study procedures:

- Patches were worn for three consecutive days, 24 hours a day changing each set of patches every day until the set of 3 patches was gone. Next, the patient was asked to return in 48 hours to measure the residual effect of the patches.
- The patches were placed on hyperthermic (warm) areas of the body that were identified with infrared imaging.
- The objective was to first place the patches on the body and make the first infrared measurement to determine if an immediate response occurred at five minutes. Digital thermal measurements were performed over the patch site before and after the five minute period and the thermal differences recorded.
- The second measurement was done after the patches were applied for three consecutive days and measurements were taken two days after the last patch was administered.
- Infrared Imaging Measurements were performed with a highly sophisticated Computerized Thermal Imaging Infrared Camera. 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. It is a pure measure of a persons' health without causing any harm to the patient which is required in this application.
- 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 <u>both locally and distal from the site of application.</u>
- The measured response of the patches is proof that the patches create an effect on the body to cause a hyperthermic region to cool.
- This can only be explained by the patches creating an influence on the autonomic nervous system via the subcutaneous vascular beds. This study confirmed with a different technology (infrared imaging) that changes occurred in the autonomic nervous system. Changes in the autonomic nervous system were also observed by Dr. Nazeran when he did his HRV study.

- 36 subjects underwent specific thermal measurements as to the effects of the LifeWave Energy patches in a three day active use trial. Overall thermal changes from the first set of measurements to the second set of measurements were calculated. The average temperature was used to calculate delta T comparing series one thermal measurements was baseline and series two was noted to be the second set of measurements.
- The average thermal temperature in the first set of measurements in series one equals 32.2389 and 30.7556 in series two. This equals a 1.5833 delta T difference. In any thermal skin readings a .05 difference is considered significant to determine normal from abnormal.®