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Human Clinical Study of the Efficacy of LifeWave Energy Patch in Improving Flexibility, Strength and Endurance in Healthy Humans

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ABSTRACT

[[SUBSTITUTE THE PARAGRAPH BELOW
This double-blind crossover placebo-controlled clinical trial demonstrates that LifeWave Energy Patches produce a significant increase in several tests of flexibility, strength and endurance in healthy humans when worn for one hour. This increase is correlated with a subjective increase in energy levels.]

In this double-blind crossover placebo-controlled clinical trial, tests were conducted that measure flexibility, strength and endurance in 60 healthy humans. Tests conducted included: stretch and reach, hand strength, latissimus dorsi pull down maximum weight, outcome measures with an ergometer bicycle (peak and average power and watts per kilogram, average and peak speed and speed per kilogram, distance and calories. These results demonstrate that the LifeWave Energy Patch improved performance in several different tests of flexibility, strength and endurance in healthy humans. In addition, one third of the subjects reported an increase in [[subjective] energy levels while wearing the active patch and no change in energy while wearing the placebo. In contrast, [[only] one of 60 reported that the placebo produced an increase in energy and no energy change with active patch.

Key Words: energy medicine, energy enhancement, strength, flexibility and endurance tests

Introduction

The LifeWave Energy Patch is a non-transdermal patch system that utilizes innovative technology to gently stimulate acupuncture points – improving the flow of energy in the body to produce drug-free energy enhancement. The LifeWave Energy Patch contains natural nontoxic crystals that absorb

body heat and generate infrared signals that cause the body to produce energy, as explained below.

There is a growing number of energy enhancement products being marketed. However, there is little, if any research being conducted to evaluate their efficacy. Many of the products are assessed through applied kinesiology. When enhanced muscle strength is demonstrated with the products, it is assumed that a positive effect has been generated. However, results of these "tests" can be biased (consciously or unwittingly by the person administering the test. The purpose of this study was to utilize standardized, academic athletic tests to evaluate the efficacy of LifeWave Energy Enhancer patches.

LifeWave Energy Enhancer Patches

For this investigation, Energy Enhancer patches produced by LifeWave (LW) in La Jolla, CA, were used. The patches are non-transdermal (Brown, 2004), which means that no substance enters the body. LifeWave self-adhesive patches have been proven to be a safe and effective technology capable of gently stimulating acupuncture points without the use of needles (LifeWave research). LifeWave's patches utilize an innovative technology to stimulate acupuncture points on the body and improve the flow of energy in the acupuncture meridians. The patches are designed to stimulate acupuncture points by several mechanisms that involve both acupressure and energetic principles.

LifeWave Energy Enhancer patches are comprised of nontoxic materials that do not generate energy, but rather reflect it back into the body when placed on acupuncture points. The materials in the patches act like frequency specific reflectors (narrow-band), comparable to the ceramic fibers found in infrared (IR) products, which are broad-band reflectors that reflect wavelengths from .74 μm to 300 μm). Placing a LifeWave patch on the skin will allow the patch to trap and passively absorb wide-band IR energy and re-emit narrow-band IR energy back into the body. By way of example, other IR wraps that are used to relieve pain and inflammation from injuries contain inorganic ceramic fibers. These inorganic fibers absorb IR energy from the body and then reemit the energy across a wide energy band. LifeWave patches contain materials which mirror back the energy that the body is already emitting. The difference between the LifeWave patches and other IR products is that the LifeWave patches only mirror back a very narrow band of frequencies, depending on the patch product selected. In summary, LifeWave patches are designed to deliver IR wavelengths to enhance the electrical conductivity of the skin and are a new method of stimulating acupuncture points (LifeWave Research).

[[A Literature review shows promising IR effects.] Several types of infrared emitters are described in the literature that create biological effects when exposed to the temperature range of body heat. Materials that absorb IR energy from the body can then reemit the energy to exert biological effects. Accumulated evidence indicates that far-IR [radiation] is biologically active. A study by Inuoue and Honda (1986) showed a significant increase in weight of rats exposed to IR emitting discs on cage floor. Chronic IR exposure in rats produced a significant ($p<0.01$) increase in slow wave sleep and wakefulness (Honda and Inuoue, 1988). In another study, sleeping on mattresses imbedded with IR discs resulted in a subjective assessment of slightly longer and deeper sleep and fewer wakeful episodes during the night, compared to controls and an insomniac reacted positively to IR, (Kotorii et. al., 1988).

Bioceramics are an infrared emitter incorporated in clothes (gloves, shorts, dressings) that have been shown to produce biological effects (pain reduction and improved sleep) when exposed to body heat (Masuda et. al., 2005, Silva et. al., 2009).

Here are further examples of IR effects from this research literature. Skin microcirculation (measured by continuous laser Doppler flowmeter) in rats is significantly increased soon after removal of the FIR emitter. The stimulating effect on skin blood flow was more significant in the rats treated with FIR for 45 minutes and could be sustained as long as 60 minutes. Ise et al. (1987) detected a significant enhancement of forearm blood flow in 6 out of 9 subjects as measured by plethysmography after a 20 minute exposure of forearms to ceramic radiator disks arranged in series.

A double-blind study of 60 patients with Raynaud's Disease documented significantly increased blood volume and flow with impedance plethysmography. This was significant for the active limb versus the control side with30 minutes of wear for the lower leg ($p< 0.01$) and for the forearm ($p<0.05$). Furthermore, clinical effectiveness for pain (arthritis, peripheral vascular disease) was correlated with the duration of use per day. Significant improvements were documented in both subjective measures of pain and discomfort and in objective measures of temperature, grip, and dexterity Improvements were noted in the visual analogue scale rating ($P=0.001$), DASH score ($p=0.001$), Jamar grip strength ($p=0.002$), infrared skin fingertip temperature ($p=0.003$), Purdue hand dexterity test ($p=0.0001$) and a Likert scale ($p=0.001$) with ceramic gloves vs. placebo cotton gloves. (Ko and Burbreyer, 2002)

In a ransomized study done by Chang et al (2009) of 70 inpatients with the clinical diagnosis of depression with sleep disturbance, an infrared emitter composed of a patch-like sticker reflecting far-infrared was applied to the acupuncture points PC6, HT7 and SP6 for a period of 15 minutes twice a week. In the experimental group, there was an increase in serum serotonin levels ($p<0.01$) and a reduction in the serum levels of the free-radical malondialdehyde (MDA, $p<0.001$), compared to controls. The results of MDA data in this experiment are in agreement with the current hypothesis that in contrast to to serotonin, MDA revealed a higher serum level in the chronic stress or depression equivalent condition (Li *et al*., 2003). The reversed MDA level followed by the treatment of SSRI support the above working hypothesis (Ozcan *et al*., 2004).

In summary, LifeWave patches are specifically designed to passively reflect back into the body a portion of the electromagnetic frequencies that they are exposed to when placed on the body. This process elicits specific responses, depending on the product.

Subjects

Sixty healthy individuals (26 male and 34 female) ranging from 18-65 years of age with no history of disease, pregnancy, drug or alcohol use, or on any medications, were subjects in this pilot study. Subjects were in chosen with the following inclusion and exclusion criteria:

Inclusion Criteria:

1. Subjects who have signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
2. Subjects were 18-65 years of age, either sex.
3. Subjects who were able to follow the protocol as designed by the Energy Medicine Research Institute
4. In generally good health.

Exclusion Criteria:

1. History of serious diseases or illness diagnosed at this time, including cancer, or undergoing chemotherapy.
2. Subjects currently taking Tylenol, haloperidol or any prescribed or non-prescribed medication that may, in the opinion of the researchers, alter testing results.
3. History of alcohol addiction or currently consuming more than four drinks per day.

4. Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
5. Subjects with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.
6. Subjects with a high fitness level.

Institutional Review Board approval was obtained for this study (National Foundation for Energy Healing, AZ). Informed consent was obtained from all participants prior to testing.

Methods

In this clinical study, tests were conducted that measure flexibility, strength and endurance. Tests conducted included:

- stretch and reach
- hand strength
- latissimus dorsi pull down maximum weight
- outcome measures with an ergometer bicycle (peak and average power and watts per kilogram, average and peak speed and speed per kilogram, distance and calories.

A baseline measurement was conducted utilizing one flexibility test and ten different strength and endurance tests, described below. Each testing session followed a five-minute warm up on the Elliptical machine.

Subjects were asked to return to repeat the testing after one week (to allow recovery time) while wearing either the placebo or active patch. Subjects were randomized and the study was double blind. Following another one week period to allow recovery time and wash out any effects of the patch worn during the second test, a third test was done to test the patch that was not tested in the second test. Subjects were instructed to place either a placebo or an active patch one hour before testing on the pericardium 6 acupuncture points of each wrist. \ The subjects were instructed to remain well hydrated when reporting for testing.

Data was collected at Mountain Edge Fitness Center, Boulder, CO.

Flexibility Test

Subjects were asked to sit on the floor against a wall with feet against the stretch and reach measuring device (http://www.fitnessgiant.com/noname16.html) and reach as far forward as they can. The distance reached was measured three times and the highest value recorded

Strength Tests:

A) Digital Hydraulic Hand Grip Dynamometer Subjects were instructed to squeeze the dynamometer (http://www.topendsports.com/testing/store-strength.htm) as hard as they can with each hand. Two measurements with each hand were recorded and the highest score was recorded.

B) One Repetition Maximum Test to Measure Maximum Strength of the Latissimus Dorsi Muscles.

One repetition maximum test is a measure of the maximal weight a subject can lift with one repetition. For these tests, a latissimus dorsi (lat) pull down weight machine (http://www.cybexintl.com/products/strength/11130/intro.aspx) was used. After a warm up, an achievable weight was chosen. Then after a rest of at least several minutes, the weight was increased by 5 pounds and the test repeated. This was continued until the subject could only repeat one full and correct lift of that weight. The maximum weight lifted was recorded. The sequence of lifts was recorded and was used in subsequent tests in determining the lifts to attempt.

C) Five Minute Road Course Ergomometer Measurements: Peak Speed and Watts
Subjects were asked to pedal on a stationary bike with an ergomometer at their peak performance for five minutes. Peak speed and watts and peak watts per kilogram were recorded.

Endurance
A) Five Minute Road Course Subjects were asked to pedal on a stationary bike at their peak performance for five minutes. Distance, average watts speed, distance, calories and peak watts per kilogram were recorded.

Statistical Methods

Descriptive statistics were generated to summarize all outcome measures. Specifically, all measures were summarized in terms of number of means, standard deviations and ranges for each measurement time point (baseline, post-treatment). Absolute changes of all study outcomes were computed and summarized in terms of means, standard deviations and ranges. Changes from baseline were computed using a paired t-test. The normality assumption for all outcome measures were verified using normal probability plots and by conducting the Shaprio-Wilk test. All p-values are two-sided, with $p<0.05$ indicating statistical significant differences.

Data analysis was performed using SAS® version 9.2 software (SAS Corp., *Cary*, NC). The Grizzle model for 2 X 2 cross over study designs was used to evaluate the carry over or learning effect

Results

Baseline comparisons of randomized subjects are shown in Table 1, Summary statistics and comparison of subjects who were first randomized to placebo arm versus subjects who were first randomized to active arm are compared. The p-values refer to the comparisons of the baseline values between the two groups. There were no significant differences between the groups that received placebo versus active first in the testing protocol, indicating that the subjects were properly randomized.

Table 1. Baseline Comparison of Randomized Subjects.

	Placebo		**Active**		
Measure	**Mean**	**SD**	**Mean**	**SD**	**p value**
Lat Pull Down (lbs.)	103.55	45.59	83.62	32.95	0.0586
L Hand Strength (kgs)	77.03	32.33	69.24	23.24	0.2912
R Hand Strength (kgs)	82.26	30.03	73.72	24.05	0.2313
Peak Power (watts)	221.57	101.26	188.65	106.88	0.2254
Peak Speed (MPH)	19.06	3.99	17.7	3.91	0.1891
Average Power (watts	133.25	64.65	108.56	46.82	0.0975

Average Speed (MPH	16.47	3.71	15.03	3.13	0.1096
Peak Watts/kg	163.07	14.71	162.38	12.87	0.8488
Average Watts/kg	1.73	0.69	1.45	0.56	0.0816
Distance (miles)	1.38	0.3	1.23	0.27	0.0545
Calories	39.69	19.59	31.72	12.83	0.0693

[
Min.=minimum
Max.=maximum

Flexibility Test

Table 2 shows a comparison of the absolute changes of the flexibility measure. The mean increase of the stretch and reach distance 0.54 inches for the active patch and this value was significant (p=0.009), The absolute change for the placebo patch compared to control was 0.26 inches, which was not significant (p=0.189).

Table 2 Analysis of absolute change from baseline of stretch and reach measures for placebo and active patches.
[[needs table .jpg

	Active				Placebo				
Mean	**SD**	**Min.**	**Max.**	**p value**	**Mean**	**SD**	**Min.**	**Max.**	**p value**
0.54 in.	1.46	-3.25	3.58	0.009*	0.26	1.39	-2.41	5.51	0.189]

Strength Tests
As seen in Table 3, all of the strength tests resulted in significant differences (between p<0.05 and 0.001) favoring the active patch except for the right hand strength, while only the lat pull down test was significant for placebo. However, there was a trend for this measure to be increased (absolute change of 1.36 for the active patch, versus -1.02 for placebo. The lat pull down absolute change from baseline value was 5.09 and 2.86 pounds for active and placebo patch, respectively. The absolute changes for both were significantly different (p<0.001), although the change for the active patch was nearly twice the change produced by the placebo patch. The left hand strength absolute change from baseline for the active and placebo patches were 2.87 (p<0.05) and -1.33 kilograms, respectively. The right hand strength absolute change from baseline for the active and placebo patches was 1.36 and -1.02 kilograms, respectively. The peak speed absolute change from baseline for the active and placebo patches was 11.24 (p<0.001) and .11 miles per hour, respectively. The peak watts absolute change from baseline for the active and placebo patches was 41.45 (p<0.05) and -5.05 watts, respectively. The peak watts per kilogram absolute change from baseline for the active and placebo patches was 0.22 (p<0.05) and -0.09, respectively.

Three of the tests with the placebo patch produced negative changes (a decrease in performance). However, these decreases were smaller than the corresponding increases in performance with the active patch and the decreases were not significantly different.

Table 3. Analysis of absolute change from baseline of strength measures for placebo and active patches.

	Active					Placebo				
Measure	**Mean Diff**	**SD**	**Min.**	**Max**	**p-value**	**Mean Diff**	**SD**	**Min.**	**Max.**	**p-value**
Lat Pull Down (lbs)	5.09	4.95	-10.0	15.0	<0.001*	2.86	5.59	-20.0	15.0	0.001**
L Hand Strength (kg)	2.87	8.99	-28.0	24.0	0.024*	-1.33	10.32	-40.0	25.0	0.373
R Hand Strength (kg)	1.36	7.20	-22.0	16.0	0.176	-1.02	9.13	-30.0	19.0	0.438
Peak Speed MPH)	1.24	1.87	-2.80	6.65	<0.001*	0.11	1.53	-4.80	4.32	0.607
Peak Watts	41.45	141.6	-111.0	977.0	0.038*	-5.05	46.29	-207.00	76.00	0.059
Peak Watts/kg	0.22	0.63	-1.60	1.6	0.016*	-0.09	0.69	-2.40	1.00	0.351

* p<0.05 ** p<0.001

Endurance Tests

Table 4 shows that for all of the endurance measures there were significant changes (p<0.001) from baseline after wearing LifeWave Energy Patches. There was a significant increase in the average speed with the placebo patches (p<0.05), although this change was less than half of the change induced by the active patch. The average speed absolute change from baseline for the active and placebo patches was 1.15 and 0.37, respectively. The average watts absolute change from baseline for the active and placebo patches was 13.16 and 3.8, respectively. The distance absolute change from baseline for the active and placebo patches was 0.1 and 0.03 miles, respectively. The calories absolute change from baseline for the active and placebo patches was 4.43 and 1.74, respectively.

Table 4. Analysis of absolute change from baseline of endurance measures for placebo and active patches.

	Active					Placebo				
Measure	**Mean**	**SD**	**Min.**	**Max.**	**p-value**	**Mean**	**SD**	**Min.**	**Max.**	**p-value**
Average Speed (MPH)	1.15	1.46	-2.56	4.56	<0.001**	0.37	1.21	-4.49	2.83	0.035*

Average Watts	13.16	18.44	-56.67	62.02	<0.001**	3.80	15.42	-31.18	41.34	0.091
Average Watts/kg	0.25	0.31	-0.60	0.9	<0.001**	0.05	0.25	-0.80	0.70	0.136
Distance (miles)	0.1	0.12	-0.21	0.36	<0.001**	1.74	6.8	-10.20	35.90	0.082

* p<0.05 ** p<0.001

Carryover effects

An analysis for evaluating the carry over was also conducted to ensure that for subjects who wore the [placebo patch first, there was no "learning" effect from repeating the tests. In this study, the order of patches worn for testing was randomized such that one half of the subjects wore the placebo patch first and the other half wore the active patch first.

Table 5 shows the p-values for all study measures evaluating the carry over effects. There is no evidence for a carry over effect for any of the endpoints.

Table 5. Carryover analysis shows no "learning" effect.

Measure	**p-value**
Stretch and Reach	0.539
Lat Pull Down	0.289
Left Hand Strength	0.323
Right Hand Strength	0.285
Peak Speed	0.234
Peak Watts	0.659
Peak Watts/kg	0.887
Average Speed	0.492
Average Watts	0.769
Average Watts/kg	0.709
Distance	0.705
Calories	0.712

Each subject was surveyed about whether they noticed any changes in energy while wearing the patches. As shown in Table 6, out of the 60 subjects, 20 reported an increase in energy with only the active patch. Five subjects reported an increase in energy with the placebo patch. Of these five, 2 noticed a slight energy change in only the placebo and three subjects observed a change in energy with both patches, but two of the subjects noticed that the active patch produced a stronger change. One subject stated that their wrist hurt during the testing with the placebo patch and they felt happy with the active patch. No one reported a decrease in energy while wearing the active patch and two subjects noticed a decrease in energy while wearing the placebo patch. Thirty-three subjects did not notice any change in energy with either the active or placebo patches.

Table 6. **Energy survey of study subjects**

Total	**Active patch**	**Placebo patch**

20	Increase	No change
2	No change	Increase
2	Increase	Increase (same as active)
1	Increase	Increase (smaller change than with active patch)
0	Decrease	
2		Decrease
33	No change	No Change

In summary, these results demonstrate that the LifeWave Energy Patch significantly improves performance in several different tests of flexibility, strength and endurance in healthy humans. In addition, one third of the subjects reported an increase in energy levels while wearing the active patch and no change in energy while wearing the placebo. In contrast, only one of 60 reported that the placebo produced an increase in energy and no energy change with active patch.

Discussion

Results of this study demonstrate that LifeWave Energy Enhance patches produce 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). Although the right hand strength test was not significantly different from baseline, for the active patch the change induced was nearly twice that of the change observed with the placebo. Conversely, for the only placebo test that showed a significant increase in performance (lat pull down) the change was less than half the increase of the active patch.

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. Furthermore, the increases obeserved with the active patch had a high level of significance, demonstating the efficacy of the active patches in the tests.

Factors that can infuence the outcome were analyzed and found to have no effects on the outcomes. 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).

It is important to note that one third of the subjects felt an increase in energy only while wearing the active patch and only two subjects felt an increase in energy only while wearing the placebo patch. The subjects who felt the increase in energy also performed better on the tests. This could explain a decrease in performance with the placebo patch for the subjects who wore the active patch first. If the subjects did not feel the energy increase with the placebo patch compared to the active patch, they might tend to not perform as well if they suspect that the placebo patch is indeed the placebo. Regardless, the decreases were not significantly changed from baseline.

The reported subjective increased energy levels which correlated with the increased performance demonstrate that the LifeWave Energy 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 is common 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.

The objective test used in this study, an energy survey, produced substantial results. One-third of the subjects reported an increase in energy with the active patches and conversely, only two subjects reported an increase in only the placebo. Again, more dramatic energy changes could be noticed after wearing the patches for longer than one hour. These results indicate that there is a detectable increase in energy with the LifeWave Energy Enhancer patches.

Conclusions

This double-blind crossover placebo-controlled clinical trial shows that LifeWave Energy Patches produce a significant increase in several tests of flexibility, strength and endurance in healthy humans when worn for one hour. This increase is correlated with a subjective increase in energy levels. It is likely that the patches will produce greater or sustained effects when worn for longer periods.

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