

Report for Human Clinical Pilot Study of the Efficacy of LifeWave Energy Patch in Improving Flexibility, Strength and Endurance

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Abstract: A pilot human clinical study examined the efficacy of the LifeWave Energy Patch to increase flexibility, strength and endurance in ten healthy subjects. Results indicate that Life Wave Patches significantly increase performance in one flexibility test and three different tests of strength and endurance. A larger study is planned.

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.

In this pilot study, tests were conducted that measure flexibility, strength and endurance in 10 healthy humans. 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, calories, Results demonstrate that the LifeWave Energy Patch improves performance in several different tests of flexibility, strength and endurance in healthy humans.

Methods

Ten healthy individuals (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 were subjects in this pilot study. 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. Each testing session followed a five-minute warm up on the Elliptical machine. The subjects were instructed to remain well hydrated when reporting for testing. One flexibility test and three different strength and endurance tests were conducted. The tests are described below.

Institutional Review Board approval was obtained for this study.

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 Shapiro-Wilk test.

All p-values are two-sided, with $p < 0.05$ indicating statistical significant differences. The data analysis was performed using SAS[®] version 9.2 software (SAS Corp., Cary, NC).

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 in 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) Bicep Curl Maximum Weight

Bicep Curl maximum weight was determined by having the subject perform a bicep curl with a five pound free weight for five repetitions. The weight was increased by five pounds until the subject could no longer perform five repetitions with proper form. If the subject was unable to lift five repetitions with a weight, one and two pound weights were used as increments to determine the maximum weight that can be lifted for five repetitions and this weight was recorded.

Endurance

A) Three Mile Road Course

Subjects pedaled a three mile road course on a stationary bicycle with an electronic ergometer (www.computrainer.com) in “competition” with three others. Peak and average speed and wattage per pound and time to finish was recorded. Heart rate was also monitored.

B) Five Minute Road Course

Subjects were asked to pedal on a stationary bike at their peak performance for five minutes. Distance, peak and average watts, peak and average heart rate and calories were measured.

C) Bicep Curl Repetition to Failure

For the repetition to failure bicep curl test, the arm that was not used for the maximum bicep curl maximum weight test was used to curl 70% of the maximum weight to failure and this number was recorded.

Results

As seen in Table 1, there was an increase in performance for all of the tests in subjects wearing LifeWave Energy Patches, compared to their baseline measures. Table 2 shows a comparison of the absolute changes of all outcome measures. There was a significant increase in performance for every test that was conducted ($p < .05$).

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

| | N | Mean | Baseline | | With Patches | | Minimum | Maximum | |
|----------------|----|--------|----------|---------|--------------|--------|---------|---------|-------|
| | | | SD | Minimum | Maximum | Mean | | | SD |
| 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 | 12 | 15.77 | 2.23 | 12 | 18.75 | 16.88 | 2.32 | 13 | 20.25 |
| Reach | | | | | | | | | |
| 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 |
| Time to Finish | 6 | 19.2 | 2.5 | 15.4 | 22.7 | 16.8 | 2.4 | 12.9 | 19.8 |

Flexibility Test

Table 1 shows that the mean stretch and reach measure rose from 15.77 inches to 16.88 and this increase was significant (Table 2, $p < 0.05$).

Strength Tests

As seen in Table 1, 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 2 shows that all of the strength tests showed significant improvements. Of particular note is the change in the time to finish in the ergometer bicycle competition. As seen in Table 1, the maximum decrease in finish time was 3.2 minutes, which is very dramatic. Table 2 shows a significance level for this measure of $p < 0.001$, which is impressive for a sample size of six (some of the subjects chose not to complete the three mile road course). One of the subjects chose to do a one mile road course and their time to finish decreased from 4:07 to 2:56 minutes. This is a substantial change.

Table 2: Analysis of absolute change of all outcome measures from baseline to with patches.

| | 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* |
| Time to Finish | 6 | -2.4 | .8 | -.8 | -3.2 | <.001** |

• $p < 0.05$
 ** $p < 0.001$

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. Table 4 shows that increases in peak speed and power, distance and peak watts per kilogram while wearing LifeWave Energy Patches were statistically significant ($p < 0.05$).

Endurance Tests

As seen in Table 1, 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 (Table 2, $p < 0.05$). Due to compliance issues, an additional endurance test was conducted and more outcome measures are reported. As seen in Table 3, 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. Table 4 shows that changes in average speed while wearing LifeWave Energy Patches were statistically significant ($p < 0.05$).

Table 3. Summary statistics for all outcome measure for baseline and with patch assessment for the five minute ergometer bicycle test.

| | Baseline | | | | | With Patches | | | | |
|---------------|----------|--------|--------|---------|---------|--------------|--------|--------|---------|---------|
| | 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 |

Table 4. Analysis of absolute change of all outcome measures from baseline to post-treatment for five minute ergometer bicycle test.

| | N | Mean | SD | Minimum | Maximum | p-value ¹ |
|------------------|---|-------|-------|---------|---------|----------------------|
| Average Speed | 5 | 1.31 | 0.62 | 0.55 | 2.23 | 0.0090* |
| Peak Speed | 5 | 1.67 | 1.33 | 0.20 | 3.45 | 0.0487* |
| Average Power | 5 | 20.26 | 11.44 | 5.30 | 34.62 | 0.0167* |
| Peak Power | 5 | 51.18 | 34.36 | 15.00 | 94.00 | 0.0291* |
| Average HR | 5 | 6.20 | 11.43 | -2.00 | 25.00 | 0.2920 |
| Peak HR | 5 | 4.80 | 14.82 | -10.00 | 28.00 | 0.5091 |
| Distance | 5 | 0.12 | 0.06 | 0.04 | 0.19 | 0.0107* |
| Calories | 5 | 6.20 | 5.61 | 0.20 | 14.20 | 0.0688 |
| Average Watts/kg | 5 | 0.26 | 0.22 | 0.00 | 0.60 | 0.0568 |
| Peak Watts/kg | 5 | 0.42 | 0.27 | 0.20 | 0.80 | 0.0249* |

* p<0.05

Discussion

Results of this pilot study demonstrate that LifeWave Energy Patches produce a significant increase in performance for all tests of flexibility, strength and endurance that were conducted (stretch and reach, bicep curl and latissimus dorsi maximum weight lifted, peak and average watts per pound, bicep curl repetitions to failure. LifeWave Energy Patches also produced a significant increase in other outcome measures (time to finish and distance). Most 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 (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. The most striking change observed was a mean decrease in finish time of 2.4 minutes (the maximum decrease was 3.2) with a sample size of six. This is a large amount of time to decrease for a finish time in a three mile road course. Also, in a one mile road course test, the finish time was reduced by 25%. These results are dramatic.

Results for the second bicycle endurance test were also impressive. With only a sample size of five, statistical significance was achieved for an increase for nearly every measure: average and peak speed, peak and average power, distance and peak watts per kilogram. Also, the heart rate did not rise much during this test, indicating that the subjects were increasing their efficiency in performance. These are impressive results.

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 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. Additionally, a high level of statistical significance was achieved considering the small population size, especially for the five minute bicycle test. A larger population size is likely to produce a higher level of statistical significance in these tests.

Conclusions

This pilot clinical trial shows that LifeWave Energy Patches produce a significant increase in flexibility, strength and endurance in healthy humans. The tests utilized in this study are objective measures that are used in standard athletic testing. Statistically significant improvements in several parameters of athletic performance induced by the energy patches were observed, demonstrating that LifeWave Energy Patches improve flexibility, strength and endurance. A larger study is planned to further demonstrate these effects.

Research Team

Research was conducted by Lisa Tully, PhD, owner of Energy Medicine Research Institute and Ryan Shilling, owner of Watts Up. Both companies are based in Boulder, Colorado. This study was sponsored by LifeWave Inc.

Dr. Lisa Tully received her PhD in Pharmacology and Toxicology from the Indiana University School of Medicine. Dr. Tully has several publications in peer-reviewed medical journals and has presented her research at international scientific conferences. Following her postdoctoral fellowship, Dr. Tully shifted from academic medical research to pursuits in integrative medicine and has attended many international medical conferences over the past decade, evaluating low cost and effective health care. Dr. Tully is currently on the Scientific Advisory Board of several companies and non-profit organizations and is founder of the Energy Medicine Research Institute, whose mission is to assess the efficacy of vibrational medicine technologies and therapies.

Ryan Shilling, owner of Watts Up, a company that specializes in athletic training, has professionally tested athletes for a decade. He has performed testing for Athletic Republic, a company that trains athletes. He has conducted field tests on athletes specific to running and cycling. He specializes in testing athletes for strength, flexibility and endurance for training purposes.