The Effect Of A Non-Transdermal Surface Patch On Mitochondrial Function

By Frank Shallenberger, MD, Homer Nazaran, Ph.D.

Abstract

Background
This investigation will examine the effect of applying a commercially available non-transdermal surface patch containing amino-acids (proteins) on ATP production, substrate utilization, and strength. The manufacturer of this product claims the benefits of using the LifeWave™ Energy Enhancer patches include: a) increased energy, b) increased stamina, and c) increased performance.

Methods
This 2-week placebo controlled single-blind research study will measure 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 will then be 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.

Results
Application of the LifeWave™ Energy Enhancer patch 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.

Conclusions
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.

This investigation will examine the effect of applying a commercially available non-transdermal surface patch (LifeWave LLC, Suwanee GA) containing amino-acids (proteins) on ATP production, substrate utilization, and strength. The manufacturer of this product claims the benefits of using the LifeWave™ Energy Enhancer patches include: a) increased energy, b) increased stamina, and c) increased performance; all within 20 minutes of application.

The membrane of the patches is made of a non-porous polyethylene with an acrylic adhesive; therefore, nothing is directly transferred from the patch into the body (see attached report from MVA Scientific Consultants). Within the patches is a combination of amino acids, water, oxygen, and organic substances bound to a polyester substrate and all compounds are recognized as safe (FDA 21 CFR) (LifeWave information brochure).
The theoretical basis for the mechanism of action is through frequency modulation and resonant energy transfer. Simply, the protein combination contained within the patches interacts with the naturally occurring magnetic field of the human body. The manufacturer suggests that the application of the patches to the skin (exposing the patch to the naturally occurring magnetic field of the body) causes the contents of the patch to vibrate (resonant energy transfer) and transmit a signal to the cells (frequency modulation with biological energy field). Through signal transduction, the cells interpret the signal initiated from the patch stimulating an increase in fatty acid metabolism.

The implication for a non-pharmacologic method of stimulating ATP production, and specifically fatty acid utilization, are great. Therefore, the purpose of this investigation is to evaluate the short-term regular use of the LifeWave™ Energy Enhancer patches on 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.

Methods and Procedures

This research study was conducted by Frank Shallenberger, MD and The Nevada Center, Inc., a general medical clinic located at 1231 Country Club Dr., Carson City, NV 89703. Prior to any data collection, all study procedures were thoroughly explained by an investigator and each subject provided written consent to participate in the study.

Subjects

The subjects include 30 men and women between the ages of 18 and 65 years. Criteria for participation in this study include: a) being able to complete all test protocols; b) being free of chronic illnesses; c) not taking any medications that may alter metabolism; and d) being a non-smoker. All participation is voluntary in nature. Subjects were paid $200 upon completion of their arm of the study.

Recruitment of subjects will occur throughout northern Nevada and the surrounding communities as a result of applications sent to the patient database of The Nevada Center, Inc. Subjects may or may not be patients of The Nevada Center, Inc.

Bio-Energy Testing®

The Bio-Energy Testing® protocol uses an FDA approved pulmonary gas analyzer and computerized ergometer (Medical Graphics Corporation, 350 Oak Grove Parkway, St. Paul, Minnesota 55127 U.S.A.) that analyzes oxygen to carbon dioxide conversion rates and work in watts, a bio-impedance body fat analyzer (Omron Healthcare, Inc., 1200 Lakeside Drive, Bannockburn, Illinois 60015), a heart rate monitor, (Polar Electro Inc. 1111 Marcus Avenue, Suite M15, Lake Success, NY 11042-1034), and computer software (Bio-Energy Testing, LLC, 1231 Country Club Dr. Carson City, NV, 89703) to determines a subject’s mitochondrial efficiency. By that is meant, how much ATP a subject’s mitochondria are capable of producing, and what percentage of substrate is fat or glucose.

Almost all of the oxygen that is consumed in the human body is consumed in the mitochondria to produce energy. Although a small percentage is used as part of the oxidative burst of the activated immune system and also as part of the P450 detoxification systems in the liver, as long as the subject’s immune system is not actively fighting an infection, and as
long as there is no acute toxicity, it can be safely assumed that in a fasting individual all oxygen consumed is being consumed in the mitochondria.

Thus, ATP can be measured as a function of oxygen uptake as follows:

\[
\text{Fatty Acid} + 23\text{O}_2 \rightarrow 16\text{CO}_2 = 16\text{H}_2\text{O} + 130\text{ATP}
\]

\[
\text{Glucose} + 6\text{O}_2 \rightarrow 6\text{CO}_2 + 6\text{H}_2\text{O} + 36\text{ATP}
\]

Thus when fatty acids are metabolized by oxygen, there is a ratio of 5.6 (130/23) molecules of ATP produced per molecule of oxygen consumed. By measuring oxygen consumption, the amount of ATP being produced can be easily determined by multiplying this amount by 5.6.

In the case of glucose, there is a ratio of six molecules of ATP being produced per molecule of oxygen being consumed (36/6). By measuring oxygen consumption, the amount of ATP being produced can be easily determined by multiplying this amount by 6.

The ratio of glucose metabolism to fatty acid metabolism is a linear relationship, and can be determined by the ratio of CO2/O2.

Thus, the Bio-Energy Testing® software can determine at any point in time how much ATP is being produced, and what percentage is being produced from fatty acids and from glucose.

ATP produced from anerobic production is not measured because all determination of oxygen consumption is stopped as soon as lactic acid threshold is reached. This point can be determined by the point at which the ratio of CO2/O2 suddenly accelerates above 1.0.

These determinations are made in the morning after an overnight fast. The first measurements are taken while the subject is resting in a reclined position for eight minutes at his predetermined resting heart rate. The subject then exercises on a cycle ergometer using a ramping protocol that is determined by his age and level of fitness. All measurements are stopped when the subjects reaches his lactic acid threshold. This form of analysis can be used to determine a patient’s mitochondrial functional dynamics, including:

1) Total Resting ATP production (resting metabolism).
2) Resting ATP production from fatty acid metabolism.
3) Maximal ATP production from fatty acid metabolism.
4) Maximal aerobic ATP production (aerobic capacity).
5) Maximal aerobic work.

**Study Design**

This was 2-week placebo controlled single-blind research study. 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® 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 (Figures 1-2). 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 are 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 and a check for $200. The subjects was not advised as to what patches were active or placebo until the completion of the study.

**Follow-up Consultation:** An investigator contacted each subject 7 days following the week 3 testing session via telephone or e-mail (at the discretion of the subject) to inquire about any perceived residual effects from the patches.

**Treatment Patches**

The efficacy of the LifeWave Energy Enhancer patches is the primary focus of this study. The nonporous membrane of the patches is made of polyethylene and one side of the patch is coated with an acrylic adhesive (Figure 1). When applied to the surface of the skin, there is no direct transfer of material from the patch to the body (non-transdermal).

A single patch has a centralized blister pocket 32mm in diameter encompassed by an edge approximately 4.5mm wide for a total diameter of 41mm. The blister pocket of a patch contains a synthetic fiber disc 28mm in diameter and all of the compounds used in the composition of the patches are recognized as safe (FDA 21 CFR).

The synthetic fiber disc is composed of a polyester substrate matrix containing a combination of amino acids, water, oxygen, and organic substances. A patch has either a brown color (glucose patch) or a white color (glycerin patch). Patches are worn in pairs and applied bilaterally over one of four possible anatomical landmarks with the white patch worn on the right side of the body and the brown patch worn on the left side of the body (Figure 2).

Each subject was instructed to wear a pair of patched (brown & white) every day of both the treatment and the placebo cycles, and to be sure to apply the patches at the same locations for the duration of the study. To clarify, each subject was provided a diagram similar to Figure 2 labeling the location and date of patch application. Further, each subject was instructed how to apply the patches and the exact anatomical locations of patch application was identified on each subject’s body. For the duration of each treatment cycle, subjects were instructed to consume a minimum of two liters of water each day because the
patch manufacturer suggests an enhanced efficacy of the patch with this minimum volume of fluid consumption.

*Source of Treatment Patches*

For this study, LifeWave Products, LLC (Suwanee, GA) provided the LifeWave™ Energy Enhancer patches and the placebo patches. The placebo patch was designed to have all of the physical appearance characteristics of the LifeWave patch.

*Statistical Analysis*

For each of the 5 sets of responders, we are testing the null hypothesis that the means of the response variable are the same across the 3 groups (or times as Base, Control and Active) versus the alternative hypothesis that at least 2 of the 3 means are different. To test these hypotheses, we use the General Linear Mixed Model Analysis which is a generalization to the Analysis of Variance for repeated measures over group. When the group effect is significant, further testing using the Tukey post-hoc procedure is employed to see where the differences lie. The significance level of 0.05 is used for all tests.

1. **Effect of Energy Patches on Maximal Aerobic Work Responders**

   There is a significant difference in the mean FF for the 3 groups (p-value = 0.0032). From the Tukey post-hoc procedure, the Active mean FF (mean = 91.7) is significantly
higher than the Base mean FF (mean = 77.0, p-value = 0.0031) and the Control mean FF (mean = 80.8, p-value = 0.0197).

2. **Effect of Energy Patches on Total Resting ATP Production Responders**
   There is a significant difference in the mean MF for the 3 groups (p-value = 0.0443). From the Tukey post-hoc procedure, only the Active mean MF (mean = 99.3) is significantly higher than the Base mean MF (mean = 85.5, p-value = 0.0373).

3. **Effect of Energy Patches on CF (Resting ATP Production from FAT) Responders**
   There is a significant difference in the mean CF for the 3 groups (p-value = 0.0002). From the Tukey post-hoc procedure, the Base mean CF (mean = 60.1) is significantly lower than the Control mean CF (mean = 80.7, p-value = 0.0042) and the Active mean CF (mean = 91.6, p-value = 0.0001).

4. **Effect of Energy Patches on FBF - Maximal Aerobic ATP Production from Fat Responders**
   There is a significant difference in the mean FBF for the 3 groups (p-value = 0.0048). From the Tukey post-hoc procedure, the Active mean FBF (mean = 131.8) is significantly higher than the Base mean FBF (mean = 90.8, p-value = 0.0050) and the Control mean FBF (mean = 100.2, p-value = 0.0204).

5. **Effect of Energy Patches on EQ - Maximal Aerobic ATP Production Responders**
   There is a significant difference in the mean EQ for the 3 groups (p-value = 0.0001). From the Tukey post-hoc procedure, the Active mean EQ (mean = 121.6) is significantly higher than the Base mean EQ (mean = 94.2, p-value < 0.0001) and the Control mean EQ (mean = 106.5, p-value = 0.0194).

**Results**

Application of the LifeWave™ Energy Enhancer patch produced a significant increase over placebo 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. There were no significant side effects from the patch.

**Discussion**

This study demonstrates a statistically significant improvement from the LifeWave™ Energy Enhancer patch in responders in all metabolic markers except resting fatty acid metabolism. In some cases very dramatic improvements were noted. These results coincide with other performance related studies using the patch. The implications are that the patches would be valuable in a selected subset of individuals seeking improved metabolic performance and/or help with weight control.

However, it is important to note that not all subjects responded to the patch application. Specifically:

1. Maximum aerobic work improved in 50% of subjects.
2. Maximum aerobic from fatty acid metabolism improved in 36% of subjects.
3. Maximum aerobic ATP improved in 46% of subjects.
4. Resting ATP improved in 23% of subjects.
5. Resting ATP from fatty acid metabolism improved in 40% of subjects.

A possible explanation for a failure to improve in the non-responders may be patch location variability. It may be that there is a certain amount of individual variation in the locations of patch placement that will be effective.

Another reason may be that diet was not controlled for. The carbohydrate content of the diet during the 4-5 days before an CO2/O2 evaluation has been shown to skew the CO2/O2 ratio such that in a resting state glucose metabolism becomes greater than fatty acid metabolism. This latter fact may explain why there was no consistency found in the responders regarding resting fatty acid metabolism, while there was consistency in exertional fatty acid metabolism.

References


(57) Levine SA, Kidd PM. Antioxidant Adaptation – Its Role In Free Radical Pathology. 1985, Biocurrents Division, Allergy Research Group, 400 Preda St., San Leandro, CA 94577.