PILOT STUDY

Effects of Energy Enhancer Patches on Cortisol Production, Peripheral Circulation, and Psychological Measures: A Pilot Study

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ABSTRACT

Context • LifeWave Energy Enhancer (LEE) patches (LifeWave Corp, San Diego, CA, USA) on skin produce some changes that are consistent with increased energy production, but little is known about their effects on cortisol concentrations or the peripheral circulation.

Objective • The study intended to assess the effects of LEE patches on salivary cortisol, peripheral circulation, and psychological measures on healthy adults.

Methods • A double-blind, placebo-controlled, randomized pilot study was performed.

Setting/Location • Measurements were performed in Sabre Sciences Laboratory (Carlsbad, CA, USA). Participants collected some of the saliva samples at work or home.

Participants • To obtain pilot data, 20 healthy individuals with no chronic conditions were recruited—5 males and 15 females—aged 30-69 y.

Intervention • Participants completed baseline psychological questionnaires and provided saliva samples for hormonal analysis. The next day, fingertip microvascular perfusion was measured, LEE or placebo patches were applied to participants' wrists, and perfusion scans were repeated, first immediately after and then 10 min after application of the patch. Saliva samples were collected, and questionnaires were completed. Participants returned at noon and 4 PM for further scans, and at the end of that time, the patches were removed. The protocol was repeated the following day using new patches.

Outcome Measures • The research team analyzed the saliva samples for levels of cortisol and measured the percentage changes in cutaneous microvascular perfusion. The participants completed the energy visual analog scales (eVASs) and the Marlowe-Crowne Social Desirability survey.

Results • After the first patch application, the active group showed significantly higher cortisol concentrations than the placebo group, both at noon—2.39 ± 0.17 ng/mL vs 2.15 ± 0.27 (P = .0360), respectively—and at 4 PM—2.02 ± 0.24 vs 1.67 ± 0.31 (P = .0155), respectively. No consistent changes occurred in perfusion. The eVAS score decreased significantly compared with baseline in the placebo group but not in the active group.

Conclusion • Cortisol concentrations and eVAS scores showed significant differences between groups, which is consistent with the patches increasing energy production, warranting further testing. (*Adv Mind Body Med.* 2015;29(1):##-##.)

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The LifeWave Energy Enhancer (LEE) patch (LifeWave Corp, San Diego, CA, USA) is an FDA-registered, sealed, nontransdermal patch. The patches contain homeopathic materials that reflect low levels of light in the infrared and visible band and stimulate nerves and points on the skin when activated by body heat. The only known risk is a reaction to the patch adhesive in 1 of 300 000 people. Previous research has suggested that individuals can experience physiological changes that are consistent with increased energy production when they wear the patch. Shallenberger and Nazaran[1] showed that the LEE patch

significantly increased maximum aerobic adenotriphosphate (ATP), maximum ATP from fatty-acid metabolism, resting ATP, and maximum aerobic work. A randomized, double-blind, placebo-controlled, crossover clinical study by Tully[2] showed that LEE patches improved performance in tests of flexibility, strength, and endurance.

So far little is known about how LEE patches affect cortisol concentrations or how they influence the peripheral circulation, even though both of these parameters modulate energy levels. Increased cortisol production enhances oxidation of fatty acids, leading to a higher metabolic rate and, hence, to increased energy production in cells as they experience increased demands.[3] For this reaction to occur, free fatty acids and oxygen have to be transported to the cells by the peripheral circulation so that they can produce ATP and, therefore, energy. For this reason, a combination of increased metabolism and improved peripheral circulation facilitates cellular energy production. In the current randomized, controlled, double-blind pilot study with healthy, adult volunteers, the research team tested whether application of the LEE patch significantly increased salivary cortisol and enhanced peripheral circulation. The study investigated those effects as possible mechanisms for the energy-enhancing effect of the LEE patch.

METHODS

Participants

Participants were recruited by e-mail announcement, through radio announcements, and by word of mouth. Flyers were also placed on public access bulletin boards. Healthy individuals who had no chronic conditions, were not pregnant, and were older than 21 years were eligible to participate as long as they did not have any of the following psychological/physical conditions: (1) a history of psychological disorders; (2) a history of drug or alcohol abuse; and (3) a history of any major medical problems, such as epilepsy, stroke, Alzheimer's disease, Parkinson's disease, or major head trauma.

A computer randomization program was used to assign numbers, from 1 to 20, to envelopes in which the patches had been placed. All participants were assigned a number in order of recruitment, starting at 1 for the first person enrolled and 20 for the last person, and they received the envelope that matched his or her number. The authors were blinded as to group assignments and as to the identity of the groups as active or control until data collection was completed.

Application for permission to perform human studies was made to the internal review board of the National Foundation for Energy Healing (NFFEH), and the study was approved as NFFEH 10-17-11-18.

Procedures

Two groups of patches, one being the active LEE patches and the other being placebo patches, were assembled at LifeWave Corporation and sent to the research team. They were packaged as groups 1 and 2. The placebo patches for the control group were identical to the active patches but did not incorporate the active ingredients used by them. All patches were sealed so that none of the substances in the patch actually penetrated the skin. It is believed that the content of the patches communicates with the body through the human magnetic field. This is known as frequency modulation and resonant energy transfer. Cortisol was measured using samples of saliva taken during 24-hour periods before and after application of the patches. Saliva was sampled rather than blood because it is much more convenient to obtain, and the procedure is less invasive for participants.

Improvement of peripheral circulation, posited as a possible mechanism for the energy-enhancing action of the LEE patch, was assessed. A laser Doppler perfusion imaging system (PeriScan PIM II Imager, Perimed, Stockholm, Sweden) was used to evaluate changes in blood perfusion of the fingertips.[4] This instrument employs a low-energy laser beam that interacts with red blood cells flowing through cutaneous blood vessels, resulting in a frequency change in the laser beam that is dependent on the velocity of the red cells. The measurement is passive, and no known risks exist for this measurement process. An image of the finger is produced that shows color-coded areas of low-to-high cutaneous blood flow.

Using the energy visual analog scale (eVAS, Conner, under development and previously tested on 160 subjects), participants rated their overall sense of focus at the time of testing. When performing this assessment, participants were instructed to consider their physical, mental, emotional, social, and spiritual condition. The Marlowe-Crowne Social Desirability scale (MCSDS) assesses political correctness and was used to assess whether respondents were responding truthfully or misrepresenting themselves to manage their self-presentation. This scale has been normalized and is well established.[5] Participants also completed a demographic questionnaire.

Intervention

Day 1 (Baseline). Participants were invited to sign informed consent forms after being provided with information about the experiment and having their questions answered. They were asked not to consume caffeine-containing drinks during the experiment. The baseline eVAS and MCSDS questionnaires were administered. Each participant then provided a saliva sample in a labeled vial that was then refrigerated.

Next, each participant was asked to provide saliva samples in supplied, numbered vials, obtaining them during the day wherever they were at 12 noon, 4 PM, 8 PM, and midnight of the current day and at 4 AM of the following morning. They were instructed to refrigerate these samples immediately and to return them to the laboratory the next morning. Participants were requested to drink 4 to 6 glasses of water during the day, as advised by the patches' manufacturer.

Day 2 (First Application of Patches). Participants entered the laboratory at 8:00 AM and returned the saliva vials from the previous day for freezing. Participants were

provided with a second set of saliva vials and produced 1 sample for immediate refrigeration. After participants had been sitting in the temperature controlled room (24°C) for 10 minutes, they were reseated comfortably at the apparatus table, and baseline scanning of the dorsal surfaces of the index, middle, and ring fingertips of both hands was performed with the Doppler laser perfusion imager.

The scanning took 3 minutes for each hand. Four scans of 75s each were taken of each hand, focusing on the index, middle and ring fingers, and later, in each case, the 4 scans were digitized and averaged for greater accuracy. Outside distraction was minimized through use of dim lighting and closed window blinds. The LEE patches were then applied as follows: (1) the white patch to acupuncture point TB5 on the right wrist, 3 to 4 finger widths from the wrist crease closest to the palm, and (2) the tan patch to the corresponding location on the left wrist at acupuncture point P6. Scans were taken immediately after application and again 10 minutes later. Participants were asked to leave the patches on all day, drink 4 to 6 glasses of water, and return to the lab at noon and 4 PM for further scans and saliva samples. The patches were removed after the scan at 4 PM; the eVAS was administered; and the participants were reminded to produce saliva samples at 8 PM and midnight of the current day and at 4 AM on the following morning.

Day 3 (Second Application of Patches). Participants returned the 3 saliva vials from the prior day for freezing, and then their fingertips were scanned before, immediately after, and again 10 minutes after applying a new pair of patches. The participants returned at noon and 4 PM for additional scans. After the last scan, the patches were removed, and the eVAS questionnaire was administered. On completion of measurements for each participant, the saliva tests were sent to Sabre Sciences Laboratory (Carlsbad, CA, USA) for analysis.

Outcome Measures

Salivary Cortisol. Sabre Sciences Laboratory provided absolute values of salivary cortisol concentration (ng/mL) for the 6 time points on day 1 (baseline) and day 2 for each subject. The values for each subject for a given time point on a given day were averaged and statistically compared between the two groups.

Cutaneous Microvacular Perfusion. For the perfusion analysis, each scanned image was observed on the computer screen and 3 regions of interest (ROIs), coinciding with the 3 fingertips, were drawn on each image using a cursor. The digital, pixilated data from each scan for each ROI were automatically averaged, using the supplied LDPIwin software (author, please provide manufacture name and location) and, the means and standard deviations exported to an Excel spreadsheet (Microsoft, Redmond, WA, USA). These values reflected the average perfusion for each scan for a given ROI. No current laser Doppler instrument can provide absolute perfusion values (eg, mL/min/100 g of tissue). Rather, measurements are expressed in arbitrary perfusion units. The mean overall perfusion for each ROI was calculated by averaging the 4 scans taken for a given session, and then the mean values for the 3 ROIs were averaged for each hand.

Energy Visual Analog Scale. The eVAS is a 100-mm line on which the participant marks their self-assessed level of focus, from no ability to focus (start of line) to their total focus (end of line). The distance of the mark from the start of the line is measured directly and is used as the eVAS score

Marlowe-Crowne Social Desirability Survey. The MCSDS consists of 33 items using a true/false response format and has no subscales. A score of 9 to 19 is considered a moderate score, and 20 to 33 is considered high.

Statistical Analysis

Hormonal parameters and scores on psychological questionnaires were summarized in terms of means±standard deviations, stratified by group. The comparisons of baseline characteristics of participants in the active and controls groups were conducted using a 2-sample *t* test for age, weight, height, body mass index (BMI), cortisol levels, eVAS, and MCSDS or using a Fisher's exact test to test for significant differences between groups in the numbers of males versus females in each group. Absolute changes from baseline were calculated within each group using a paired *t* test. The comparison of absolute values and absolute changes from baseline between groups was conducted using a 2-sample *t* test. Normal probability plots and the Shapiro-Wilk test, which uses the null-hypothesis principle to check whether a sample comes from a normally distributed population, were used to verify the normality assumption for each outcome measure.

Repeated measures analysis of variance followed by pair-wise multiple comparisons were used to determine significant differences between average blood perfusion in the fingertips when compared between each stage of the experiment (eg, at baseline versus immediately after patch application). These values were repeated measures on the same person, and each person was his or her own control. Although people in the control group did not receive active patches, it was still possible that the mechanical application of the patch to the skin could cause changes in fingertip perfusion. Therefore, changes in perfusion for participants in the control group were analyzed in the same way. The data for each group were tested for normality and equal variance. If the data failed either test, an equivalent nonparametric test was performed, such as the Wilcoxon signed-test, which is still valid when the population cannot be assumed to be normally distributed. It was hypothesized that participants in the active groups would show significantly greater changes in perfusion after application of the patches than would the control participants. A probable value of $P < .05$ was considered to be statistically significant.

RESULTS

Participants

Twenty eligible participants were randomly assigned to the experimental (active) and control (placebo) groups, 9 to the first and 10 to the second. Nineteen participants (95%)

Table 1. Cortisol Concentrations at Each Time for Day 1 at Baseline and for Day 2 During First Patch Session

Parameter	Time	Day	Active (n = 9)		Placebo (n = 10)		*P* Value[a]
			Mean	SD	Mean	SD	
Cortisol	8 AM	Baseline	4.41	1.02	4.61	0.73	ns
(ng/mL)	Noon	Baseline	2.35	0.40	2.32	0.29	ns
	4 PM	Baseline	1.87	0.31	1.90	0.33	ns
	8 PM	Baseline	1.12	0.40	1.27	0.37	ns
	Midnight	Baseline	1.18	0.06	1.18	0.09	ns
	4 AM	Baseline	1.85	0.10	1.82	0.13	ns
	8 AM	During	4.59	0.61	4.34	0.57	ns
	Noon	During	2.39	0.17	2.15	0.27	.0360[b]
	4 PM	During	2.02	0.24	1.67	0.31	.0155[b]
	8 PM	During	1.23	0.21	1.18	0.14	ns
	Midnight	During	1.12	0.11	1.09	0.08	ns
	4 AM	During	1.56	0.22	1.68	0.20	ns

Abbreviations: SD, standard deviation; ns, nonsignificant.

[a] *P* value for comparison between groups.
[b] $P < .05$

Table 2. Energy Visual Analogue Scale (Absolute Scores)

Day	Time	Active (n = 9)		Placebo (n = 10)		*P* Value[a]
		Mean	SD	Mean	SD	
1		80.67	17.68	95.50	13.92	.0569
2	AM	71.67	19.42	79.40	20.55	ns
2	PM	80.00	20.66	84.80	22.03	ns
3	AM	72.11	21.36	86.20	14.37	ns
3	PM	78.89	18.80	89.40	26.48	ns

Abbreviations: SD, standard deviation; ns, nonsignificant.

[a] *P* value for comparison between groups.

completed the baseline and follow-up assessments. When comparing groups, no statistically significant differences existed in mean BMI, height, weight, or age. The mean ages of the active and placebo groups were 46.6 and 55.1 years, respectively. The active group included 5 females and 4 males, and the placebo group included 9 females and 1 male.

Cortisol Concentrations

Baseline values for cortisol did not significantly differ between the 2 groups (Table 1). However, on day 2, cortisol concentrations at noon and 4 PM were significantly higher for the active group than for the placebo group.

Psychological Questionnaires

Energy Visual Analog Scale. The eVAS scores did not differ significantly between groups on days 1, 2, and 3, but the eVAS was marginally lower on day 1 for the active group compared with the placebo group (Table 2). Within the placebo group, a significant decrease in the eVAS score was detected between baseline on day 1 and the morning of day 2, -16.1 ± 19.11 ($P = .02587$), and a marginally significant decrease between baseline on day 1 and the morning of day 3, -9.3 ± 13.2, $P = .05287$ (Table 3). Within the active group, no significant changes in eVAS occurred from baseline values. These results suggest that the placebo group perceived a reduction in their energy levels for the mornings of days 2 and 3 compared with baseline on day 1, but the active group did not.

Marlowe-Crowne Social Desirability Scale. No significant differences in the total scores for the MCSDS were detected between groups, 17.44 ± 3.84 (SD) for the active group vs 15.70 ± 3.16 for the placebo group. The lack of significance in the MCSDS test would suggest that both groups were consistent in providing correct answers rather than providing answers that were motivated by a need to perform on the tests in a particular way.

Laser Doppler Perfusion Imaging

Results for the laser Doppler perfusion scanning are shown in Table 4. On day 3, participants in the active group showed a significant increase in left-hand perfusion at noon compared with baseline when the patches were applied at 8:30 AM ($P = .0350$), whereas control participants showed no changes throughout the day. However, these results must be treated with caution because the data from the small number of participants showed insufficient statistical power.

Table 3. Energy Visual Analogue Scale (Changes in Scores)

	Active (n = 9)			Placebo (n = 10)			
Change	**Mean**	**SD**	***P* Value**[a]	**Mean**	**SD**	***P* Value**[a]	***P* Value**[b]
Day 1 to Day 2, AM	-9.00	18.22	ns	-16.10	19.11	.02587[c]	ns
Day 1 to Day 2, PM	-0.67	26.54	ns	-10.70	16.30	ns	ns
Day 1 to Day 3, AM	-8.56	27.92	ns	-9.30	13.20	.05287	ns
Day 1 to Day 3, PM	-1.78	24.87	ns	-6.10	20.50	ns	ns

Note: Changes in scores are from day 1 to day 2 (AM and PM) and day 3 (AM and PM).

Abbreviations: SD, standard deviation; ns, nonsignificant.

[a] *P* value within each group, for evaluating changes from baseline to a period during which participants were wearing a patch.
[b] *P* value between groups for comparing changes from baseline to a period during which participants were wearing a patch.
[c] $P < .05$.

Table 4. Microvascular Perfusion of Fingertips (Arbitrary Perfusion Units)[a]

Active Patches

Day	Hand	Baseline	10 Min	Noon	4 PM
2	Left	1.94 ± 0.60	1.83 ± 0.42	1.94 ± 0.28	1.95 ± 0.18
	Right	1.86 ± 0.42	1.82 ± 0.37	1.83 ± 0.26	1.99 ± 0.28
3	Left	1.71 ± 0.37	1.86 ± 0.31	1.87 ± 0.34[b]	1.81 ± 0.27
	Right	1.75 ± 0.43	1.93 ± 0.35	1.85 ± 0.37	1.87 ± 0.28

Placebo Patches

Day	Side	Baseline	10 Min	Noon	4 PM
2	Left	1.98 ± 0.25	2.09 ± 0.18	1.92 ± 0.33	2.00 ± 0.17
	Right	1.93 ± 0.29	2.05 ± 0.33	1.90 ± 0.43	1.95 ± 0.25
3	Left	1.85 ± 0.25	1.97 ± 0.31	1.86 ± 0.30	1.97 ± 0.30
	Right	1.76 ± 0.31	1.96 ± 0.35	1.70 ± 0.32	1.99 ± 0.31

[a] In this table, *baseline* means the point at which the patch was applied on days 2 and 3 of the study, which was approximately 8:30 AM. *10 Min* refers to values 10 min after patch application.
[b] $P = .0350$ for change from baseline to noon for left hand on day 3.

DISCUSSION

This pilot study demonstrated that salivary cortisol concentration increased significantly in participants who wore the LEE patch when compared with the placebo group. Baseline cortisol concentrations for the 2 groups were not significantly different. The cortisol difference between groups after the first patch application (day 2) was a combination of a small increase compared with baseline (12 noon: 2.39 vs 2.35; 4 PM: 2.02 vs 1.87) for the active group and a small decrease compared with baseline (12 noon: 2.15 vs 2.32; 4 PM: 1.67 vs 1.90) for the placebo group (Table 1). Although the mechanisms of action are not yet understood and the sample size was small, the increase of cortisol levels in the active group compared with the placebo group was consistent with cortisol being an energy source mediated through higher carbohydrate metabolism. All the cortisol concentrations observed in participants were within the normal range[6] (ie, 3.7-9.9 ng/mL at 8 AM and 0.8-1.5 ng/mL at 8 PM) and were not high enough to indicate an increased state of stress. As an example of salivary cortisol concentrations in people under stress, the average value for salivary cortisol measured in a group of nurses on a typical workday was 564 ng/mL.[7]

Whereas the active group's perception of their energy levels after patch application stayed stable, the placebo group's

showed a significant reduction. One reason for this response could be that they had suffered from the effects of sleep interruption during saliva sampling, and the slight decrease in cortisol concentrations provided them with a lower amount of energy compared with that for the members of the active group, who were able to maintain their perceived energy. A link between salivary cortisol concentrations and perceived energy has been observed previously in office workers.[8]

The possible confounding effect of sleep deprivation was a limitation in this study. Because no differences were observed in salivary cortisol concentrations between groups at midnight and 4 AM, future experiments can be designed to omit the nightly saliva sampling and consequential sleep interruption. Another limitation was that increases in peripheral circulation, which would be expected to accompany enhanced metabolism, may have been masked due to existing preactive vasodilatation resulting from the summer heat in southern Arizona where the experiments were performed. Further experiments performed at different temperatures, on larger numbers of people, may produce more definitive results.

CONCLUSIONS

Cortisol concentrations and eVAS scores showed significant differences between placebo and active groups, which is consistent with the patches increasing energy production in the active group. The small, delayed increase in peripheral circulation in the active group is also consistent with increased energy production in the body. These preliminary findings indicate that the efficacy of the energy enhancer patches warrants further testing.

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