Y-AGE® CARNOSINE

Study Report #1: Nazeran H, Blake-Greenberg S. "Nanoscale Carnosine Patches Improve Organ Function." Presented at *International Federation for Medical & Biological Engineering Proceedings Series* (2010). In: K.E. Herold, W.E. Bentley, and J. Vossoughi (Eds.): SBEC 2010, IFMBE Proceedings 32, pp. 138–141, 2010.

Safety issues:

No adverse events were reported.

Patch instructions and study procedures:

- Twenty healthy subjects in this pilot study were tested to determine the effectiveness of the LifeWave Carnosine patch for improving the physiologic functional status in the organs in a twoweek period.
- The LifeWave Carnosine patch was worn 12 hours daily on alternate days (3 days a week: Tuesdays, Thursdays, and Saturdays) over a period of 2 weeks.
- Acupoints tested:
 - A. Conception Vessel 6 (CV6)
 - B. Conception Vessel 17 (CV17)
- Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from twenty volunteers (7 males and 13 females, 19-83 years of age). All subjects served as their own control.
- Cellular physiologic function was evaluated in 10 organs (1.pancreas, 2.liver, 3.left kidney, 4.right kidney, 5.intestines, 6.left adrenal gland, 7.right adrenal gland, 8.hypothalamus, 9.pituitary and 10.thyroid glands) while wearing the Carnosine patch for a period of 2 weeks.
- Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before application of the Carnosine patch and repeated each week.

Efficacy of patches in this study:

• The overall data in this study demonstrated that the LifeWave Carnosine patch worn 12 hours daily on alternate days (3 days a week: Tuesdays, Thursdays, and Saturdays) over a period of 2 weeks produced a very significant (p < 0.01) improvement in the physiologic functional status of the pancreas, liver, right kidney, left and right adrenals, hypothalamus, pituitary and thyroid glands with an average statistical power of at least 95%.

Assessment: This study provides supportive evidence that stimulation of an acupuncture points (CV6 and CV17) by Y-Age Carnosine patches improve the physiological functional status of 8 organs as measured by an Electro Interstitial Scanning (EIS) system. Improvement in organ function is supportive of an anti-aging claim.

Study Report #2: Tully L. Report for Pilot Human Clinical Study of the Efficacy of the LifeWave Carnosine Patch in Improving Flexibility, Strength, and Endurance in Healthy Humans. Energy Medicine Research Institute. Boulder, Colorado, USA. April, 2011.

Safety issues:

No adverse events were reported.

Patch instructions and study procedures:

- Results demonstrate that the LifeWave Carnosine Patch significantly increases performance in a flexibility test and 12 different tests of strength and endurance.
- Ten healthy individuals (five male and five 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 open label pilot study. Tests conducted included: stretch and reach, hand strength, maximum sit ups in 30 seconds, maximum push-ups in 30 seconds, maximum bicep curl weight, maximum bicep curl repetitions and 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.
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)
 - B. Conception Vessel 17 (CV 17)

Efficacy of patches in this study:

- Results of this pilot study demonstrate that wearing the LifeWave Carnosine patch for one hour
 produces a significant increase in performance in five of the tests of flexibility, strength and
 endurance that were conducted. Wearing the LifeWave Carnosine patch for one week
 produced a significant improvement in all but two of the tests. Furthermore, there were
 significant differences in all but three of the tests between the two time points, indicating that
 wearing the patch for longer times produces larger changes. All subjects tolerated the patches
 well and no adverse effects occurred.
- 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.
- This pilot clinical trial shows that the LifeWave Carnosine patch produces a significant increase in over a dozen tests of flexibility, strength and endurance in healthy humans when worn for one week.
- **Table 2** shows the same outcome measures after wearing the Carnosine patch for one week. As shown, there were statistically significant improvements from baseline for every outcome measure except left hand strength and maximum sit ups in 30 seconds.

Table 2: Absolute Changes from Baseline for Outcome Measures After Wearing the LifeWave Carnosine Patch for One Week

| Measure | Mean | Std. Dev. | Median | Minimum | Maximum | p-value |
|----------------------------------|------|-----------|--------|---------|---------|----------|
| Stretch and Reach (inches) | 1.26 | 0.66 | 1.21 | 0.09 | 2.09 | 0.0002** |
| L Hand Strength (lbs) | 5.60 | 7.16 | 1.50 | -14.00 | 10.00 | 0.0614 |
| R Hand Strength (lbs) | 7.70 | 5.96 | 7.50 | 1.00 | 19.00 | 0.0027* |
| Bicep Curl Max. Wt. (lbs.) | 3.10 | 2.17 | 3.75 | 0.00 | 5.00 | 0.0015* |
| Bicep Curl Repetition to Failure | 7.10 | 7.19 | 5.00 | 0.00 | 20.00 | 0.0122* |
| Maximum Sit Ups in 30 sec. | 1.60 | 6.62 | 0.00 | -4.00 | 20.00 | 0.464 |
| Maximum Push Ups on 30 sec. | 4.50 | 3.92 | 4.00 | -1.00 | 14.00 | 0.0055* |
| Average Speed (mph) | 1.67 | 0.81 | 1.85 | 0.06 | 2.99 | 0.0001** |
| Peak Speed (mph) | 1.76 | 1.62 | 1.70 | -1.06 | 5.00 | 0.0073* |

| Average Power (Watts) | 17.65 | 9.25 | 14.83 | 6.64 | 29.98 | 0.0002* |
|-----------------------|-------|-------|-------|-------|-------|----------|
| Peak Power (Watts) | 37.78 | 34.33 | 34.35 | -8.00 | 95.00 | 0.0069* |
| Average Watts/Kg | 0.33 | 0.18 | 0.35 | 0.10 | 0.70 | 0.0002* |
| Peak Watts/Kg | 0.46 | 0.49 | 0.35 | -0.20 | 1.40 | 0.016* |
| Distance | 0.14 | 0.07 | 0.15 | 0.02 | 0.30 | 0.0002** |
| Calories | 7.64 | 4.08 | 8.10 | 2.00 | 14.70 | 0.0002* |

(Note: * denotes p<0.05; ** denotes p<0.001)

Assessment: This study provides supportive evidence that stimulation of acupuncture points (CV6 and CV17) by Y-Age Carnosine patches improves the physiological function of the body to increase athletic performance.

Study Report #3: Budzynski T, Budzynski H, Tang HY. Testing Anti-aging Carnosine Patches: Reducing Mental Decline Due to Glycosylation and Oxidative Stress.

Safety issues:

- Four participants were removed from the study:
 - A. Participant #1 did not return for 6 weeks.
 - B. Participant #2 was thought to be a controlled diabetic, but suffered a severe hyperglycemic event just before post-testing.
 - C. Participant #3 came for post-testing but was quite emotionally overwhelmed for reasons unrelated to the study.
 - D. Participant #4 was obviously overwrought, but did not express the reason why.
- It was concluded that these issues were un-related to wearing the Carnosine patches, since the diabetic had a prior history of hyperglycemic reactions.

Patch instructions and study procedures:

- In this double-blind randomized study, 20 treatment and 20 control subjects ages 40 and older, who were not incapacitated by an acute disorder, to test whether the Y-age Carnosine patches would reverse changes in the aging process over a month's time through wearing of the patches five days per week.
- The study examined the improvement of memory and other brain activities such as information
 processing speed, cognitive functioning and cognitive proficiency using Electroencephalography
 (EEG) and computerized standardized test of the functioning of the mental processes
 (MicroCog).
- Secondarily, the study examines the reduction of stress (by balancing of the sympathetic and parasympathetic contribution to the heart beat action) tested by measuring heart rate variability (HRV).
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)
 - B. Governing Vessel 24.5 (GV24.5)

Efficacy of patches in this study:

- HRV testing showed that the treatment group who used the Carnosine patches had changed significantly to improve their parasympathetic measure, showing lower stress effects on the heart beat.
- In the cognitive testing the treatment group who used Carnosine patches achieved significant improvement in cognitive functioning. The Microcog testing showed improvements in attention,

- reasoning, memory, processing speed, general cognitive functioning and general cognitive proficiency. In this study it was notable that the more complex thought processes were most effectively improved.
- The sample was evenly dispersed by age: the average age of the treatment group was 57 years and the control group, 61. By gender, the treatment group averaged 35.2% male and 64.71% female; the control group averaged 36.8% male and 63.1% female.
- The Microcog differences between Treatment and Control group are presented in **Table 3** including levels of significance. All differences were significant (p<0.05) with the exceptions of Spatial Processing, Reaction Time and Processing Accuracy, the latter of which almost reached a significance of p>.05.

Table 3: Carnosine Study Report - Microcog Differences between Treatment and Control Groups (Treatment=17; Control=19)

| Subtest | Pre-Test Mean | | Post-Test Mean | | Differences | | Probability |
|-------------------------------|---------------|---------|----------------|---------|-------------|---------|-------------|
| | Treatment | Control | Treatment | Control | Treatment | Control | |
| Attention | 99 | 99.7 | 107.33 | 99.9 | 8.35 | 0.3 | 0.022* |
| Reasoning | 109.5 | 108.3 | 116.5 | 109.5 | 7.2 | 1.26 | 0.051 |
| Memory | 98.1 | 107.6 | 109.2 | 107.7 | 10.82 | 0.52 | 0.0095* |
| Spatial Processing | 107.5 | 110.7 | 113.9 | 111.8 | 6 | 1.11 | 0.12 |
| Reaction Time | 97.3 | 97.8 | 101.5 | 92.6 | 2.94 | -5.31 | 0.131 |
| Processing Speed | 99.4 | 98.8 | 105.4 | 98.2 | 5.7 | -0.63 | 0.001* |
| Processing Accuracy | 101.6 | 108.6 | 113.4 | 113.89 | 11.76 | 5.26 | 0.063 |
| Gen. Cognitive Function | 100.4 | 104.3 | 112.4 | 107.6 | 12 | 3.31 | 0.0004* |
| Gen. Cognitive Proficiency | 97.9 | 101.4 | 112.9 | 105.7 | 15.05 | 4.36 | 0.0016* |

(Note: * denotes p-values < 0.05)

Assessment: This study provides supportive evidence that stimulation of an acupuncture point (CV6) by Y-Age Carnosine patches has physiological effects of increasing parasympathetic activity of the autonomic nervous system and improving cognition.

Study Report #4: Tully. L. *Pilot Clinical Study of LifeWave Carnosine Patch in Lowering Blood Lactate Levels.* Energy Medicine Research. August 2011.

Safety issues:

No adverse events were reported.

Patch instructions and study procedures:

• A pilot clinical study conducted to determine the efficacy of the LifeWave Carnosine Patch in lowering lactate threshhold (LT) by measuring blood lactate at increasing power levels while riding a three mile road course on an ergonometer stationary bicycle. Heart rate at the lactate threshold was also monitored. Ten healthy athletes were tested after one hour of wearing the patch on the

stationary bike, increasing the work load every 3 minutes by 25 Watt increments and retesting for lactate until the subject reaches 4 mmoles per liter lactate (threshold). Subjects were retested after wearing the patches daily for one week.

- Acupoints used:
 - Conception Vessel 6 (CV6)
 - Conception Vessel 17 (CV17)

Efficacy of the patches in this study:

- The Carnosine patch for one hour significantly decreased LT from baseline for both the 1 hour length of patch application (significance level .004) and the 1 week time length (.0001).
- There was also a significant decrease in LT between the two treatment time lengths (p=.037).
- There was a significant increase between baseline and both treatment groups. As observed in for the LT testing, the treatment group that wore the patch for a longer length of time achieved a higher significance level (p=.01 and p=.005, respectively for the 1 hour and 1 week treatment groups).

Assessment: The results demonstrate that the Carnosine patch significantly decreases the lactate threshold and heart rate at lactate threshold. This means that the Carnosine patch can improve endurance in athletic performance.

Study Report #5: Tully L. *Efficacy of LifeWave Y-Age Carnosine Patch in Improving Flexibility, Balance, Strength and Endurance in Healthy Humans*. Energy Medicine Research Institute. Jan. 2012.

Safety issues:

No adverse events were reported.

Patch instructions and study procedures:

- Aim of this double-blind, placebo controlled study was to utilize standardized, academic athletic
 tests to evaluate the efficacy of LifeWave Y-Age Carnosine patches in improving strength,
 endurance, balance and flexibility.
- Tests to measure strength, flexibility, and balance were stretch and reach, length of time balancing on one foot, left and right hand strength, bicep curl maximum weight and repetitions to failure, maximum push-ups in 30 seconds, maximum sits ups in 30 seconds, 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.
- The 30 subjects were randomized into the Carnosine or placebo groups for one week and then after a two-week wash-out period, crossed over into the second group for another week. Testing was done at baseline, post week 1, then again post week 4.

Efficacy of patches in this study:

- Highly significant increases from baseline to week one were observed for the group wearing the active patch for every outcome measure (p<0.001, for balance, p=0.005, for WPKG p=0.014). These increases ranged from 0.2 watts/kg (average power) to 29.6 watts (peak power).
- No significant changes from baseline to week one were observed for the placebo group (except for maximum push-ups, p=0.003, but it was a negative change). The placebo group did an average of 0.5 less push-ups than they did at baseline. The other tests that produced a negative

- change from baseline for the placebo group were right hand strength and peak WPKG (-0.3 PSI and -0.1 watt/kg, respectively and these changes were not significant).
- Significant differences in the changes from baseline to week one were observed between the placebo and active groups for all study outcomes (p<0.001, for balance p<0.010).
- Although the absolute changes seem small for some of these tests, such as the weight strength
 tests, 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 observed with
 the active patch had a high level of significance, demonstrating the efficacy of the active patches
 in the tests.

Assessment: This double-blind crossover placebo-controlled clinical trial shows that LifeWave Carnosine Patches produce a significant increase in several tests of flexibility, balance, strength and endurance in healthy humans when worn for one week and this effect is further enhanced by wearing the patch for three weeks. The increase in performance for the active patch ranged from 14.9% to 125% for strength and endurance tests, 28.8% for the flexibility test and 100.2% for the balance test. These changes are dramatic and it is likely that the patches will produce greater or sustained effects when worn for longer periods.