

Y-AGE® GLUTATHIONE

Study Report #1: Connor MH, Maret K. *Gas Discharge Visualization Testing of LifeWave Glutathione Patches*. Presented at 21st Annual ISSSEEM Conference June 24, 2011

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- The focus of this study was to discover if there are specific physiological changes produced by the application of the Y-age Glutathione.
- Additional interest was in whether there would be changes in the levels of focus of individuals participating which would be consistent with changes in glutathione production in relation to dopamine and if there would be changes consistent with recognized anti-oxidant effects on the liver, kidney, and nervous system including the spine.
- This was a double-blind, placebo-controlled, randomized, pilot study of 10 active and 10 control healthy subjects aged 30 and above using the LifeWave Glutathione patch.
- Subjects were tested using Gas Discharge Visualization (GDV), which was developed as a way of photographing and measuring the spectrum of gas emission from the fingertips and the potential biophoton emission.
- Focus was assessed by the Visual Analogue for Focus (fVAS).
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)

Efficacy of patches in this study:

- For the control subjects, there was thus no difference shown in GDV between the initial and final runs using the placebo patches while there were significant changes after one hour of wearing the glutathione patches. These changes are in keeping with known effects of glutathione on the liver and kidneys supporting known antioxidant effects.
- The $p < .006$ findings of impact on solar plexus region and specifically on the liver, kidney, and nervous system suggest that there may be a physiological effect of the LifeWave Glutathione patch consistent with recognized clinical effects of glutathione when placed at the CV6 acupuncture point.
- Further, using the GDV software analysis program, the active group showed clear changes in the oscillation patterns of gas emission over a period of one hour, these findings are consistent with the non-linear dynamical theory of homeopathic remedies presented by Bell et al (2004, 2006, 2009). Control group in contrast shows normalizing consistent with previous GDV studies of healthy individuals.
- These changes are in keeping with known effects of glutathione on the liver and kidneys supporting known antioxidant effects.
- Subject self-assessment using the Visual Analogue for Focus (fVAS) showed improvement in cognitive focus in both groups with an average of 16% change in the active group and 19% change in the control group. fVAS data on the changes in focus levels are supported by matched pattern of change of the nervous system in the GDV data on the active group but not to a level of significance as the change was distributed across the body and not located in a single area.

Assessment: *This study provides supportive evidence that stimulation of an acupuncture point (Conception Vessel 6) by Y-Age Glutathione patches creates physiological changes consistent with recognized clinical effects of glutathione when placed at the CV6 acupuncture point.*

Study Report #2: *Miller TF, Erienne JA, Hollenback AE, DeNisco N. Clinical Evaluation of an Anti-Acne Test System of Glutathione Patches and LifeWave Homeopathic Spray. Essex Testing Clinic, Inc. January 15, 2010.*

Safety issues:

- Three subjects reported mild itchiness under the patch, but not to the extreme where they had to remove the patches.

Patch instructions and study procedures:

- In this study 40 subjects (age 12-35 years) with mild to moderate acne as characterized according to the Cook's acne scale, used the Y-age Glutathione patch for 6 weeks, along with the LifeWave Y-age Plus spray, a homeopathic product taken orally, daily.
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)
 - B. Conception Vessel 17 (CV 17)
- Subjects who met the screening criteria based on medical history were evaluated by a Board-Certified Dermatologist to determine the grade of acne based on the Cook's scale. Acne lesions on the cheeks, chin and forehead were counted and graded at baseline. Photos were taken with a Visia CR Imaging System.
- Mean acne grade at baseline was based on number of lesions and types (open and closed comedones, pustules) and skin irritation.
- Subjects were given instructions on the proper use of the Glutathione patches and spray and given test products to take home.
- Follow-up digital photos and evaluations of acne, and open and closed comedones were performed by a trained technician or Board Certified Dermatologist after 1, 2, 3, 4, and 6 weeks of use. At the 6 week final visit, a Board-Certified Dermatologist performed all the final evaluations.

Efficacy of patches in this study:

- When acne scores taken after 1, 2, 3, 4, and 6 weeks of use were compared to baseline, there was no change after 1 week of product use. There was a 7.1%, 21.4%, 28.6% decrease (improvement) in the acne grade after 2, 3 and 4 weeks of product use, respectively.
- The improvements after 3 and 4 weeks of product use were statistically significant when compared to baseline.
- Open Comedones were significantly improved after 2, 3 and 4 weeks of product use. There were 69.2%, 84.6%, 92.3% and 46.2% improvements after 2, 3, 4 and 6 weeks of product use, respectively.
- Closed Comedones were significantly improved after 2, 3, 4 and 6 weeks of product use. There was an 83.3% improvement after 3 weeks and 93.3% and 66.7% improvements after 4 and 6 weeks of product use, respectively.

Assessment: *This study provides supportive evidence that stimulation of acupuncture points by Y-Age Glutathione patches and the homeopathic spray together creates a physiological change in the*

skin, resulting in a reduction in acne. Although minor skin irritation occurred in three participants, the adverse events were not significant enough to remove the patch and produced beneficial results.

Study Report #3: Blake-Greenberg S, Nazeran H. "Nanoscale Glutathione Patches Improve Organ Function." Presented at *International Federation for Medical & Biological Engineering Proceedings Series* (2010).

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this study, 30 healthy subjects participated in this 4-week, open-label study of LifeWave Glutathione patches.
- Acupoints tested:
A. CV6
- Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from two cohort volunteers after giving informed consent. The EIS is approved for use as a monitoring tool as set out in the TGA certificate for its intended use.
- Cohort 1 comprised of 10 subjects: 1 male and 9 females, 18-86 years of age while Cohort 2 were 20 subjects: 4 males and 16 females, 18-86 years of age. All subjects served as their own control.
- Cellular physiological function in subjects was evaluated in 8 organs (1.pancreas, 2.liver, 3.gallbladder, 4.intestines, 5.left adrenal gland, 6.right adrenal gland, 7.hypothalamus and 8.pituitary gland) while wearing the glutathione patch for a period of 4 weeks.
- Cohort 1 wore the patches for 12 hours daily during the four weeks; Cohort 2 wore the patches for 12 hours per day each weekday, equaling 5 out of the 7 days for the four week period.
- Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the glutathione patch was worn and repeated each for the study duration.

Efficacy of patches in this study:

- Statistical analyses were carried out in both cohorts comparing the cumulative averages of the net changes in cellular physiologic functional status of each organ at the end of the study period with corresponding baseline data. The results in Cohort 1 showed a highly significant ($p < 0.001$) improvement in physiologic functional status of all organs tested except in pancreas that showed a very significant improvement ($p < 0.01$). Average statistical power considering the effect size (percent improvement in physiologic function, sample number, and level of significance) was at least 72% in Cohort 1.
- The results in Cohort 2 showed a significant ($p < 0.05$) improvement in physiologic functional status of four organs (adrenal glands, hypothalamus and pituitary gland). Average statistical power considering the effect size (percent improvement in physiologic function, sample number, and level of significance) for these organs was at least 76% in these tests. No significant improvement in cellular physiologic status was observed in pancreas, liver, gall bladder and intestines in Cohort 2. This could be attributed to the fact that by not using the patches for 2 days in a week (about 30% less exposure to glutathione), the subjects in Cohort 2 did not achieve adequate stimulated detoxification in all organs by glutathione over the study period.

- In summary, the overall data in Cohort 1 demonstrated that the glutathione patch worn 12 hours daily over a period of 4 weeks produced a highly significant improvement in physiologic functional status of liver, gall bladder, intestines, adrenals, hypothalamus and pituitary gland and a very significant improvement in the pancreas with a statistical power of at least 72%. Stated differently, it could be concluded that the glutathione patch caused a significant improvement in cellular physiologic functional status of pancreas, liver, gall bladder, intestines, adrenals, hypothalamus and pituitary gland with a statistical power > 91%. Therefore, the hypothesis that: The glutathione patch worn 12 hours daily for 4 weeks significantly improves cellular physiologic functional status in different organs, was accepted as true.

Assessment: *This study provides supportive evidence that stimulation of an acupuncture point (CV6) by Y-age Glutathione patches improves the physiological functional status of 7 organs as measured by an Electro Interstitial Scanning (EIS) system. Improvement in organ function is supportive of an anti-aging claim. Specifically, this study provides data indicative of the Y-age Glutathione patch is more effective in improving cellular organ function, when worn daily instead of only five days per week.*

Study Report #4: *Tully L, Lange A, Shade C. Report for Human Clinical Pilot Study LifeWave Glutathione Patch. Energy Medicine Research Institute. January 28, 2010.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this study, nine (9) subjects participated in an open label clinical study to examine the effectiveness of the Glutathione Patch to increase blood glutathione (GSH) over a four-day period of wearing the patches .
- The secondary aim was to determine if detoxification was improved, by testing the urine mercury output.
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)
 - B. Conception Vessel 17 (CV 17)
- Samples of whole blood Glutathione (GSH), GSH enzyme activities and urine mercury levels were collected at a Lab Corp located in Boulder, CO.
- These samples were collected at days 1, 4 and 7 before patches were applied to establish a baseline.
- Following baseline measurements, the patches were applied every 12 hours and rotated between acupuncture points CV6 and CV17.).
- Subsequent identical measurements were repeated on days 9, 11, 13 and 15. Urine samples for mercury determination were collected on days 4, 7 (baseline), 13 and 15. Samples were frozen until assayed.
- This study also measured enzymes of the glutathione pathway (Glutathione S-transferase and Reductase) to determine possible mechanisms of action of the patch.

Efficacy of patches in this study:

- Results indicate that LifeWave Glutathione patches significantly increased blood glutathione and had no overall effect on GSH enzymes.

- Urine mercury was elevated in some of the subjects.
- Results show there was a trend toward an increase in blood GSH. When comparing averaged baseline to each day after patch application, all of the measurements after patch placement were higher than baseline.
- Results of this pilot study demonstrate that the LifeWave GSH Patch increases blood GSH significantly in several of the subjects. Although there was variability in baseline GSH measurements, all of the averaged measurements after patch placement for each time point were above 264.6%, and more importantly, above the average baseline measurement benefit of LifeWave GSH patches. Furthermore, when comparing the lowest baseline value to post-patch values, the increase was as high as 454%.
- The GSH increases are substantial in subjects with a lower GSH baseline value, indicating that LifeWave GSH patches are more beneficial for individuals that are deficient in GSH. Another potential benefit for the LifeWave GSH Patches is that they do not over stimulate the GSH system, which could potentially cause harm.
- There were no appreciable changes in either GSH Reductase, or GSH S-Transferase, suggesting that this study did not demonstrate that these enzymes are involved in the actions of LifeWave GSH Patches.
- There were some spikes in urine mercury levels in some of the subjects, indicating that a consequence of increased GSH levels is an enhanced detoxification. However, the changes in GSH and mercury were not tightly correlated, which does not demonstrate conclusively that LifeWave GSH Patch induced increases in GSH are related to changes in mercury. Further characterization of the amount of GSH needed to change mercury levels and the timing of increases in GSH and mercury are needed. However, the LifeWave Patches are altering mercury levels, which likely means they are contributing to detoxification of heavy metals. This is another important benefit of LifeWave GSH Patches.

Assessment: *This study provides supportive evidence that stimulation of acupuncture points (CV6 and CV17) by Y-age Glutathione patches creates physiological changes supporting the claim that they create an antioxidant effect as measured by an increase in glutathione levels.*

Study Report #5: *Haltiwanger S. A New Way to Increase Glutathione Levels in the Body. Published in Hippocrates 2006; Vol 28 Issue 1:48-49.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- This is a 15 person, open-label, human clinical pilot study of the effects of LifeWave Glutathione Patch on blood glutathione levels.
- Subjects were tested over a five-day period
- Baseline data was collected on all subjects and glutathione levels were measured in whole blood in $\mu\text{mole/L}$.
- Acupoints tested:
 - A. Conception Vessel 6 (CV 6)

- Each subject was required to return daily for blood collection. The subjects wore each LifeWave Glutathione patch for 24 hours and then the old patch was removed and a new patch was placed on CV6. This was repeated five times.
- Analysis of the data showed that all participants had increases in blood glutathione during the period of study (see **Table 1**).

Table 1: Glutathione data of 15 subjects in Glutathione pilot clinical trial

Subject #	Baseline (µmol/L)	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
1	1664	2256	2323	6481	7841	7158
2	1618	2430	2425	2500	8064	7953
3	1629	2370	2350	6226	6879	6499
4	1699	6693	2312	6948	8305	7532
5	1708	6868	6971	7096	7989	7601
6	2295	8619	8607	8403	10000	2270
7	2241	10000	2323	8645	8368	8546
8	2361	8033	10000	8692	10000	2238
9	2348	8042	2357	10000	2370	2265
10	2377	8150	8349	10000	2223	10000
11	2333	10000	10000	10000	10000	7992
12	1596	9553	8636	9276	2361	8100
13	1992	7787	10000	10000	9418	7645
14	2512	10000	10000	10000	10000	10000
15	1939	10000	10000	10000	8068	10000

Efficacy of the patches:

- All subjects showed an increase in blood glutathione levels compared to baseline.
- Average increases in blood glutathione were three to four times that of the baseline level.

Assessment: *This study provides supportive evidence that stimulation of an acupuncture point (CV6) by Y-Age Glutathione patches creates physiological changes supporting the claim that they create an antioxidant effect as measured by an increase in glutathione levels.*

Study Report #6: *Streeter T, Nilkanth B, Dandekar S, et al. LifeWave Research Study. The Centre for Biofield Sciences, World Peace Centre, Maharashtra Institute of Technology, Pune, India. Sept-Dec 2009.*

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this randomized, double-blind, placebo-controlled study, 50 people wore the Y-age Glutathione patch, 50 wore a different LifeWave patch and 20 people were in the control group.
- Acupoints used:
 - A. Pericardium 6 (P 6)

- The purpose of this study was to investigate the effectiveness of the Glutathione patch as a pain reliever and antioxidant by observing changes in the human biofield. Polycontrast Interference Photography (PIP), Gas Discharge Visualization (GDV) and Electro-Interstitial Scan (EIS) were the devices utilized before and after using LifeWave Glutathione patches.
- Polycontrast Interference Photography (PIP) scan illustrates the subject's biofield using a spectrum of colors to represent the intensity of light emitted from and around the body. Low light intensity areas are represented by red or orange colors, whereas, high light intensity areas are represented by green, pink, or purple colors. The PIP scan was used to help determine where a Glutathione patch should be placed on the subject based on low light intensity.
- Gas Discharge Visualization (GDV) illuminates the energy leaks which are a result of pain, inflammation, or disease. A healthy, positive state would be illustrated as vibrant and symmetrical, whereas a negative energy state would be seen as dull and asymmetrical. The GDV scan will be used to evaluate where energy leaks are located on the body and help determine LifeWave patch placement.
- Electro-Interstitial Scan (EIS) is a programmable electro-medical system scientifically proven and clinically validated. It is an efficient, non-invasive medical device that measures physiological parameters and produces detailed reports with 89% repeatable accuracy. The EIS measures conductivity of interstitial fluid between the cells. Its bioimpedance technology is similar to ECG and EEG, but rather than supplying information for only the brain or heart, the EIS measures electro physiological properties of 22 different volumes within the body and describes 69 different physiological parameters.
- The same scans were repeated after 24 hours.

Efficacy of patches in this study:

- Approximately 80% of subjects have shown a positive change in the three energetic scans after wearing the Glutathione patch for 12 hours. The results for the control group were that 80% of subjects showed no improvement.
- As no changes were observed in the control group and remarkable positive changes were seen in the all three measurements in the Glutathione experimental group, it can be concluded the patches produce beneficial energetic effects.
- During the use of the Glutathione patch, the chakras displayed calming frequencies displayed as positive green and subtle pink. Low energetic chakras are seen to open up and low energy and congested energy wer replaced by green and violent healing energy.

Assessment: *This study showed the effectiveness of LifeWave Glutathione patches in almost 80% of subjects. Use of these objective instruments demonstrate that physiological changes are being measured when Glutathione patches are worn.*