

# GLUTATHIONE PATCHES IMPROVE CELLULAR PHYSIOLOGIC FUNCTIONAL STATUS IN DIFFERENT ORGANS

Sherry Blake-Greenberg ND, MA, HMD, and Homer Nazeran PhD, CPEng (Biomed.)\*

Health Integration Therapy, Palos Verdes Estates, California 90274, USA

\*Electrical and Computer Engineering, University of Texas at El Paso, El Paso Texas 79968, USA

## ABSTRACT

Glutathione, termed the “ultimate” or “master” antioxidant, is a vital intracellular tripeptide molecule and plays a central role in cellular physiologic functions. It is very important in cellular detoxification and protection from damage caused by free radicals, peroxides and toxins. Blood glutathione levels are indicative of overall health. Glutathione metabolism and its cause and effect relationship to diseases such as cancer, neurodegenerative diseases, cystic fibrosis, HIV, aging and others have been shown in biomedical literature. Currently the undeniable connection between glutathione and good health is very well established.

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. 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. Cellular physiologic function in subjects were evaluated in 8 organs (pancreas, liver, gall bladder, intestines, left and right adrenal glands, hypothalamus and pituitary gland) while wearing the glutathione patch for a period of 4 weeks. Physiologic function testing was repeated each week. Cohort 1 wore the glutathione patch for 12 hours/day *daily*, while Cohort 2 wore the glutathione patch for 12 hours/day on *weekdays*. Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the glutathione patch was worn. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control. The hypothesis to be tested was: *The glutathione patch worn 12 hours daily for four weeks significantly improves cellular physiologic functional status in different organs.*

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 (% 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 (% improvement in physiologic function, sample number, and level of significance) for these organs was at least 76% in these tests. No significance 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.

The overall data in Cohort 1 in this study demonstrated that glutathione patches worn 12 hours daily over a period of 4 weeks produced a *highly significant* improvement in physiologic functional status of *pancreas, liver, gall bladder, intestines, left and right adrenals, hypothalamus and pituitary gland* and *very significant* improvement in *pancreas* with a statistical power of at least 72%. Stated differently all organs achieved *significant* cellular physiologic functional status improvement compared to baseline with a statistical power of at least 91%.

**Keywords:** *Glutathione patch, Cellular physiologic function measurements, Electro interstitial scan (EIS) system*

## INTRODUCTION

Glutathione is a vital intracellular tripeptide molecule comprised of 3 nonessential amino acids: cysteine, glutamic acid and glycine (g-glutamyl-cysteinyl-glycine abbreviated as GSH). These 3 building blocks in turn are made from different combinations of essential amino acids. The –SH suffix in GSH (reduced form of glutathione) indicates that it contains a sulfhydryl group. This group comes from sulfur-containing amino acids cysteine and methionine. Glutathione is produced naturally in abundance in the body and circulates constantly in the bloodstream neutralizing *free radicals* (dangerous by-products of normal metabolic processes converting food to energy) and removing environmental poisons such as heavy metals, harmful waste products and toxins to protect cells against oxidative stress. Free radicals are unstable oxygen-containing molecules which are hungry for electrons to quench their insatiable desire for cell destruction. Glutathione is a powerful antioxidant (created by the same energy-producing processes that create free radicals) which serves as a built-in defense against the harmful effects of free radicals, by rapidly quenching the destructive free electrons in these molecules. The balancing act between free radicals and antioxidants could be easily disrupted for any reason such as when the body is under stress, fighting an infection or inflammation or healing from an injury, in which case more free radicals are generated. Free radicals are also created when the body is exposed to cigarette smoke, alcohol, ultraviolet light, heavy metals, air pollution, pesticides, food additives, and other environmental toxins. Free radicals are the underlying cause of a variety of illnesses in the body [1].

Lyons et al, described that glutathione serves diverse physiologic functions such as detoxification of xenobiotics, protection of cells from oxidative stress, and acts as a storage and a transport form of cysteine. They explained that reduced tissue levels of GSH are thought to compromise cell function, promote tissue damage, and increase morbidity under various disease conditions [2].

Wu et al, studied glutathione metabolism and its implications for health. They described that glutathione plays important roles in antioxidant defense, nutrient metabolism, and regulation of a variety of cellular events. They also explained that glutathione deficiency contributes to oxidative stress playing a key role in aging and the pathogenesis of many diseases. These diseases include: seizure, Alzheimer's, Parkinson's, liver disease, cystic fibrosis, sickle cell anemia, human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), cancer, heart attack, stroke, and diabetes. They emphasized the need for new understanding of the nutritional regulation of GSH metabolism as a critical step for development of effective health improvement and disease treatment strategies [3].

Townsend et al, provided an overview of the biological importance of GSH at cellular and organism level and showed cause and effect relationships between GSH metabolism and diseases such as cancer, neurodegenerative diseases, cystic fibrosis (CF), HIV, and aging. They also showed how the enzymes involved in GSH regulation and control influence susceptibility and progression of these conditions. They concluded that there seemed to be no harm in supplementing a diet with GSH as “perhaps the product will provide a supply of the constituent amino acids, where, in particular, cysteine may be useful in stimulating gastrointestinal synthesis of GSH” [4].

The current methods of oral supplementation with glutathione or its amino acid precursors have not been effective in significantly elevating the blood levels of this antioxidant due to stomach acid destruction of L-Glutathione and unpredictability of results with precursor amino acids. Direct daily injection of glutathione has been more effective in producing short term elevation of glutathione, however this approach is unreliable due to expense and inconvenience. Preliminary clinical data from blood and

urine samples collected every 24 hours over a period of 5 days from 15 volunteers wearing the glutathione patch have shown a 3 to 4 fold increase in blood levels of glutathione compared to baseline levels [5].

This is the first study of its kind to investigate the effect of the glutathione patch on organ physiologic function. Bioelectrical impedance data indicative of cellular physiologic function, using an EIS system, were acquired from two cohort volunteers. Cohort 1 comprised of 10 subjects: 1 male and 9 females, 18-86 years of age while Cohort 2 comprised of 20 subjects: 4 males and 16 females, 18-86 years of age. Cellular physiologic function in subjects were evaluated in 8 organs (pancreas, liver, gall bladder, intestines, left and right adrenal glands, hypothalamus and pituitary gland) while wearing the glutathione patch for a period of 4 weeks. Physiologic function testing was repeated each week. Each visit was approximately 1 hour in duration for the testing. Cohort 1 wore the glutathione patch for 12 hours *daily*, while Cohort 2 wore the patch for 12 hours/day on *weekdays* only. Physiologic function baseline data were acquired from all subjects at the beginning of the study period before the glutathione patch was worn. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control.

The overall data in this study demonstrated that glutathione patches worn 12 hours daily over a period of 4 weeks caused *highly significant* improvement in physiologic functional status of *pancreas, liver, gall bladder, intestines, left and right adrenals, hypothalamus* and *pituitary gland* and *very significant* improvement in pancreas with a statistical power of at least 72%. Stated differently all organs achieved *significant* cellular physiologic functional improvement with a statistical power of at least 91%.

## MATERIALS AND METHODS

For this investigation, the glutathione patch (LifeWave, La Jolla, California, USA) was used. The glutathione patch is described as “a new method for increasing glutathione levels by stimulating acupuncture points on the body with a combination of pressure and infrared energy. The LifeWave glutathione patch is a non-transdermal patch that does not put any chemicals or drugs into the body. The LifeWave glutathione patch contains natural nontoxic crystals that absorb body heat to generate infrared signals that cause the body to produce more endogenous glutathione. Clinical studies utilizing blood analyses indicate an average rise of more than triple the blood glutathione over a period of 24 hours” [5]. For a comprehensive discussion of the LifeWave glutathione patch please see reference [6].

An EIS (Electro Interstitial Scan, U.S. patent No. US 61/194,509) system was deployed to acquire bioelectrical impedance data indicative of cellular physiologic functional status in 8 organs. “The EIS provides an electrical signal corresponding to the status of a patient's physiological parameters: Na<sup>+</sup>/K<sup>+</sup>ATPase pump activity, tissue pCO<sub>2</sub>, sympathetic system activity and microcirculation blood flow.” [7]. The EIS System uses chronoamperometry based on Cottrell's equation [8]. It is based on bioelectrical impedance and physiology of the interstitial fluid. It introduces low intensity direct currents at 1.2 V into the body to measure only one compartment of the interstitial fluid. “The EIS System with world wide patents (No 06/09878 and 065217) is the only commercially available device utilizing a Direct Current, allowing in vivo analysis of the physiological parameters at the cellular level via the interstitial fluid. The 3 minute test is free of any operator bias. The EIS system using Chronoamperometry, models human body systems with measurements of physiological data.” [9].

The EIS is a hardware/software computerized system that applies precise algorithms and proprietary formulas to generate on-screen, 3-D modeling representations of the human body's systems;

with specific intended uses. EIS system is a French electrochemical device, classified as a medical device in Europe and the United States. Its main functions are to read the different processes going on in the body, hyper-activity and hypo-activity in the organs. EIS measures the biochemistry and hormone levels. It also measures pH, body composition and the sympathetic and parasympathetic system. Even emotional traumas can be detected by measuring the biochemistry and cellular activity in various areas of the brain. It is measuring by sending harmless, low voltage frequencies to and from 6 electrodes connected to the body. The computer software calculates everything based on the changes made to these signals on their path through the body. Most measurements are done based on the extracellular fluids, which is the environment of all cells. This is where the biochemistry is most important, and where cellular activity can be measured by looking at what goes into and out of the cells. EIS scans the whole body in 3 minutes. It is a biofeedback device in the United States with pending FDA approval.

Inclusion criteria for participation in this study were functional individuals who were willing to wear the glutathione patch and participate in the study for a period of four weeks. Participants also agreed to not commence with any other new therapy or methods of healing and/or make any major changes in their daily life that could alter the efficacy of the study. Subjects must not have worn the glutathione patch prior to the study. Subjects were recruited from the local area of Palos Verdes and may or may not have been previous patients of Health Integration Therapy. Two cohort of volunteer subjects participated in this study. Cohort 1 comprised of 10 subjects: 1 male and 9 females, 18-86 years old while Cohort 2 were 20 subjects: 4 males and 16 females, 18-86 years old. Cohort 1 wore the glutathione patch for 12 hours *daily*, while Cohort 2 wore the glutathione patch for 12 hours/day on *weekdays* only. After giving informed consent, cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the glutathione patch was worn and weekly afterwards for 4 weeks. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control. The subjects were instructed to place the glutathione patch 2 inches inferior to the navel (below belly button) or on CV<sub>6</sub>. Figure 1 shows the glutathione patch and figure 2 shows the anatomical position for wearing the glutathione patch.



Figure 1. The LifeWave glutathione patch.

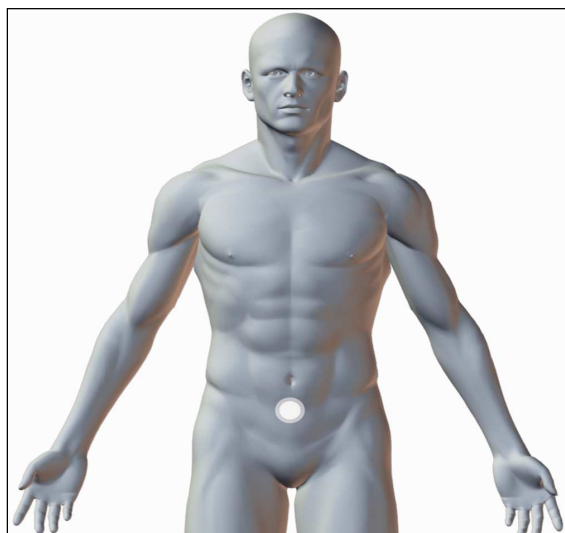


Figure 2. The anatomical position for wearing the glutathione patch (CV<sub>6</sub>).

## RESULTS

The Electro Interstitial Scan (EIS) System used in this investigation measured cellular physiologic function on a scale of -100 to 0 for under-function and 0 to +100 for over-function. A reading in the -20 to + 20 is range indicative of normal values for organ function.

Table 1 shows typical EIS System readings (cellular function physiologic status) for a female subject, while Table 2 shows typical EIS System readings for a male subject as examples. Functional status changes from week to week are noted as  $\Delta_1$ ,  $\Delta_2$ ,  $\Delta_3$  and  $\Delta_4$ , for the 4-week period showing cellular physiologic changes in the organs.  $\Delta_{avg}$  shows the average value of changes for the 4-week period, and  $\Delta_{total}$  represents the average total physiologic change after 4 weeks with respect to baseline readings. Table 3 shows the overall mean values and standard deviations for baseline and total change in physiologic function for each of the organs in Cohort 1 (n =10).

Table 1. Typical Electro Interstitial Scan (cellular function physiologic status) data for a female subject in Cohort 1.

Date	ORGAN NAME							
	Pancreas	Liver	Gall bladder	Intestine	R Adrenal	L Adrenal	Hypoth.	Pituitary
<b>Baseline</b>	<b>-70</b>	<b>-73</b>	<b>-73</b>	<b>-72</b>	<b>-65</b>	<b>-70</b>	<b>-46</b>	<b>-2</b>
<b>Week 1</b>	-42	-43	-43	-49	-34	-32	-22	0
<b>Week 2</b>	-38	-52	-52	-29	-27	-26	-25	0
<b>Week 3</b>	-58	-64	-64	-66	-49	-47	-27	0
<b>Week 4</b>	-55	-61	-61	-58	-32	-29	-26	0
$\Delta_1$	28	30	30	23	31	38	24	2
$\Delta_2$	4	-9	-9	20	7	6	-3	0
$\Delta_3$	-20	-12	-12	-37	-22	-21	-2	0
$\Delta_4$	3	3	3	8	17	18	1	0
$\Delta_T$	15	12	12	14	33	41	20	2
$\Delta_{T-base}$	<b>85</b>	<b>85</b>	<b>85</b>	<b>86</b>	<b>98</b>	<b>111</b>	<b>66</b>	<b>4</b>

Table 2. Typical Electro Interstitial Scan (cellular function physiologic status) data for a male subject in Cohort 1.

Date	ORGAN NAME							
	Pancreas	Liver	Gall bladder	Intestine	R Adrenal	L Adrenal	Hypoth.	Pituitary
<b>Baseline</b>	<b>-6</b>	<b>-7</b>	<b>-7</b>	<b>-19</b>	<b>-32</b>	<b>-34</b>	<b>-15</b>	<b>-2</b>
<b>Week 1</b>	16	2	2	27	-47	-45	-29	-21
<b>Week 2</b>	23	6	6	31	-43	-48	-26	-21
<b>Week 3</b>	32	0	0	28	-20	-21	-13	1
<b>Week 4</b>	22	14	14	21	14	-13	2	1
$\Delta_1$	22	-5	-5	46	-15	-11	-14	-19
$\Delta_2$	7	4	4	4	4	-3	3	0
$\Delta_3$	9	-6	-6	-3	23	27	13	22
$\Delta_4$	-10	14	14	-7	34	8	15	0
$\Delta_T$	28	7	7	40	46	21	17	3
$\Delta_{T-base}$	<b>34</b>	<b>14</b>	<b>14</b>	<b>59</b>	<b>78</b>	<b>55</b>	<b>32</b>	<b>5</b>

Table 3. Summary of mean and standard deviation values for EIS readings in 8 organs in Cohort 1, n = 10.

	ORGAN NAME							
	Pancreas	Liver	Gall bladder	Intestine	R Adrenal	L Adrenal	Hypoth.	Pituitary
<b>Avg</b> Baseline	-24.2	-30.9	-30.9	-18.6	-26.8	-30.1	-21.5	-0.8
<b>Avg</b> $\Delta$ Total	18.4	31	31	25	35.6	34.5	27.8	1.1
<b>Avg</b> Std Baseline	18.0	19.6	19.6	32.2	22.4	16.6	12.9	1.3
<b>Avg</b> Std $\Delta$ Total	29.0	27.1	27.1	38.8	52.2	39.2	22.3	2.64

## DISCUSSION AND CONCLUSION

Statistical analyses were carried out in both cohorts comparing the cumulative averages of the net changes in 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 (% 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 (% improvement in physiologic function, sample number, and level of significance) was at least 76% in these tests. No significance 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 discontinue use and not wearing the glutathione patch for 2 days in a week (about 30% less exposure to glutathione) the subjects in Cohort 2 did not have adequate stimulated detoxification in all organs by glutathione over the study period.

More detailed statistical analyses of the EIS data enabled us to make the following observations:

1. In Cohort 1 (n =10), the average statistical power was more than **72%** for all organs showing a *highly significant* ( $p < 0.001$ ) improvement in cellular physiologic function. The average statistical power without considering the pituitary gland was more than **82%**. The average statistical power, without considering pituitary and intestine was more than **90%**.
2. In Cohort 1 (n = 10), the average statistical power was more than **84%** for all organs showing a *very significant* ( $p < 0.01$ ) improvement in cellular physiologic function. The average statistical power without considering the pituitary gland was more than **91%**. The average statistical power without excluding the pituitary gland and intestine was more than **97%**.
3. In Cohort 1 (n = 10), the average statistical power was more than **91%** for all organs showing a *significant* ( $p < 0.05$ ) improvement in cellular physiologic function. The average statistical power without considering the pituitary gland was more than **96%**. The average statistical power without excluding the pituitary gland and intestine was more than **99%**.
4. In Cohort 2 (n = 20), 4 organs (adrenal glands, hypothalamus and pituitary gland) showed a *significant* ( $p < 0.05$ ) improvement in cellular physiologic function.

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 *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.

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