The LifeWave ALAVIDA Non-transdermal Anti-aging Patch Improves Cellular Functional Status in Different Organs

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ABSTRACT

LifeWave (www.lifewave.com) develops, manufactures and sells non-transdermal patches for indications such as improving sleep, pain and energy by placement of these patches on acupuncture meridians. The patches when stimulated by the body's thermo-magnetic field; reflect low levels of light in the infrared and visible bands of the spectrum. FTIR (Fourier Transform Infrared) substantiates this phenomenon. When placed on the body like a band-aid, the patches stimulate nerves and points on the skin to produce health benefits not obtainable with any other product on the market today. ALAVIDA Patch (which is a temporary name until it is marketed) is a component of a skin care system that will be sold as an individual anit-aging product and is therefore consistent with LifeWave values on health and wellness.

Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from 10 healthy and functional volunteers (2 males and 8 females, 44-65 years of age, 126-188 lbs in weight, 4', 11" -6', 1" in height) after giving informed consent. The research protocol for this study was reviewed and approved by the National Foundation for Energy Healing Institutional Review Board (IRB). Cellular physiologic function in these subjects was evaluated (at the Health Integration Therapy Institute in Palos Verdes Estates, California in 2015) in 12 organs (left and right kidneys, left and right adrenal glands, left and right frontal lobes, pancreas, liver, intestines, hypothalamus, as well as pituitary and thyroid glands) while wearing the ALAVIDA Anti-aging Patch nightly for a period of 30 days. Physiologic function (EIS) testing was repeated each week. Cellular physiologic status baseline data were acquired from all subjects at the beginning of the study period before wearing a new ALAVIDA Patch nightly for 5 consecutive nights a week with 2 nights off during the 30 days study period. All subjects served as their own control. The hypothesis to be tested was: *Wearing a new ALAVIDA Anti-aging Patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period significantly improves cellular physiologic functional status in different organs.*

Statistical analyses were carried out comparing the *cumulative averages of the net changes* in cellular physiologic functional status of each organ at the end of the study period with respect to the corresponding baseline data. The results showed a *highly significant ($p < 0.001$)* improvement with a statistical power of at least 99% in physiologic functional status of the (right and left) frontal lobes and adrenal glands as well as liver, hypothalamus, pituitary gland and thyroid gland. There was a *very significant* ($p < 0.01$) improvement with an average statistical power of at least 90% in the functional status of (left and right) kidneys and pancreas. The intestines did not achieve statistical significance *($p < 0.05$)* over this period probably requiring more time for the ALAVIDA Patch to take effect in this organ.

In summary, the overall data in this study demonstrated that the wearing a new ALAVIDA Patch nightly for 5 consecutive nights a week with 2 nights off for a duration of 30 days produced a *highly significant ($p < 0.001$)* improvement in the physiologic functional status of the frontal lobes, hypothalamus, adrenals, thyroid gland, pituitary gland and liver with a statistical power of at least 99%. The frontal lobes exhibited the most remarkable effect size. The results also revealed a *very significant* improvement ($p<0.01$) with an average statistical power of at least 90% in the functional status of kidneys and pancreas. The intestines did not reach a significant ($p<0.05$) improvement in 10 subjects over a period of 30 days. With these findings we accept the *hypothesis as true*, that is: *wearing a new ALAVIDA Anti-aging Patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period significantly improves cellular physiologic functional status in different organs.*

Keywords: **LifeWave, *ALAVIDA Anti-aging Patch, Acupuncture points, Electro-interstitial scan (EIS), Cellular functional status.***

INTRODUCTION

LifeWave (www.lifewave.com) develops, manufactures and sells non-transdermal patches for indications such as improving sleep, pain and energy by placement of these patches on acupuncture meridians. The patches when stimulated by the body's thermo-magnetic field; reflect low levels of light in the infrared and visible bands of the spectrum. FTIR (Fourier Transform Infrared) substantiates this phenomenon. When placed on the body like a band-aid, the patches stimulate nerves and points on the skin to produce health benefits not obtainable with any other product on the market today. The ALAVIDA Patch is a component of a skin care system and therefore it is consistent with LifeWave values on health and wellness.

This is the first study of its kind to investigate the effect of the ALAVIDA Anti-aging Patch on organ physiologic function. This open-label, single-site pilot investigation enrolled 10 volunteers (2 males and 8 females, 44-65 years of age, 126-188 lbs in weight, 4', 11" -6', 1" in height) by applying careful inclusion and exclusion criteria. Measurements were performed using an Electro Interstitial Scanning (EIS) system at baseline, week 1, week 2, week 3, and week 4 to monitor the ALAVIDA Anti-aging Patch effects on physiological functional status of 12 organs: left and right kidneys, left and right adrenal glands, left and right frontal lobes, pancreas, liver, intestines, hypothalamus, as well as pituitary and thyroid glands while wearing the patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period.

Detailed statistical analyses of the data in this pilot investigation demonstrated that wearing a new ALAVIDA Patch for 30 days produced a *highly significant ($p < 0.001$)* improvement in the physiologic functional status of the frontal lobes, hypothalamus, adrenals, thyroid gland, pituitary gland and liver with a statistical power of at least 99%. The analyses also revealed a *very significant* ($p<0.01$) improvement with an average statistical power of at least 90% in the functional status of kidneys and pancreas. The intestines did not reach a significant ($p< 0.05$) improvement in 10 subjects over this study period. Overall the EIS results showed that the frontal lobes exhibited the most remarkable effect size, while the intestines did not produce any statistical significant improvements in 30 days. This pilot investigation enabled us to test the following hypothesis: *Wearing a new ALAVIDA Anti-aging Patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period significantly improves cellular physiologic functional status in different organs.* Based upon the study findings we accepted the *hypothesis as true.*

MATERIALS AND METHODS

For this investigation, the ALAVIDA Ant-aging Patch (LifeWave, San Diego, California, USA) was used. The research protocol for this study was reviewed and approved by the National Foundation for Energy Healing Institutional Review Board (IRB). The ALAVIDA Anti-aging Patch is intended to cleanse the skin from the inside by reducing the body's production of free radicals. The LifeWave Patches contain a blend of water and non-toxic organic materials applied to a disc of polyester fabric sealed within a polymer shell. The 3M medical-grade adhesive for the Patches is hypoallergenic, so skin irritations are unlikely.

Ten healthy and functional volunteers (2 males and 8 females, 44-65 years of age, 126-188 lbs in weight, 4', 11" -6', 1" in height) were recruited from the South Bay area of Los Angeles, California. The recruits were interested in practicing holistic health and energy medicine. The following inclusion and exclusion criteria were applied when recruiting subjects for a continuous experimental period of 30 days.

Inclusion Criteria:

1. Participants who signed a written informed consent consistent with the required guidelines of the protocol and met prior to participation in the trial.
3. Subjects who were able to follow the experimental protocol.
4. Subjects who were in generally good health.
5. Subjects with any condition that, in the opinion of the investigators or intake staff, would not jeopardize the safety of the subject nor affect the validity of the data collected in this study.

Exclusion Criteria:

1. History of serious diseases or illness diagnosed at the time of study, including liver or kidney disease, cancer, or undergoing chemotherapy.
2. Subjects who were abusing alcohol at the time of the study.
3. Subjects who were unable to keep to schedule for testing.
4. Subjects who were sensitive to medical adhesives.

The research participants were given a 30-day supply of X 29 Anti-aging Patch after enrolling in the study after giving an informed consent. For scheduling and consistency purposes, subjects were instructed to wear a new X 29 Patch consecutively for 5 nights per week, with two nights off for 30 days. They were informed to rotate wearing the ALAVIDA Patch between behind their necks and below their belly buttons; that is on CV7 (Figure 1) and CV4

(Figure 2) acupuncture points, respectively. They were also advised not to wear the ALAVIDA Patch for two days every week. Subjects were instructed to apply the ALAVIDA Patch before going to sleep and removing it upon waking up. It was emphasized that the Patch should be worn for no longer than 12 hours for best use and the used Patch could be disposed of in trash. It was clearly explained to the subjects to make a note on their Daily Log if they removed the ALAVIDA Patch during the previous night.

Bioelectrical impedance data indicative of cellular physiologic organ function (status) in these subjects were collected at the Health Integration Therapy Institute in Palos Verdes Estates, California in 2015. The scans were acquired in 12 organs (left and right kidneys, left and right adrenal glands, left and right frontal lobes, pancreas, liver, intestines, hypothalamus, as well as pituitary and thyroid glands) while wearing the ALAVIDA Anti-aging Patch nightly following the study protocol described above. The EIS system is a hardware/software-computerized system that deploys precise algorithms and proprietary formulas to generate on-screen, 3-D modeling representations of the human body's systems; with specific intended uses. The 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, namely the hyper-activity and hypo-activity in the organs. The EIS system measures the biochemistry and hormone levels. It also measures pH, body composition and the sympathetic and parasympathetic influences of the autonomic nervous system (ANS). Even emotional traumas can be detected by measuring the biochemistry and cellular activity in various areas of the brain. By application of harmless, low voltage signals with specific frequencies to 6 electrodes connected to the body, bioelectrical impedance (or its inverse tissue conductivity) measurements are made. The computer software calculates the organ responses to the stimulating signals based on changes made to these signals as they pass through the body. Most measurements are done on the extracellular fluids, which constitute 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. The EIS system scans the whole body in less than 5 minutes and the entire session should take no longer than half an hour. It is considered a biofeedback device in the United States with pending FDA approval.

LifeWave provided the Investigator with sufficient X 29 Patches for 11 subjects for 30 days. The Investigator was responsible for study articles and their distribution, while paying special attention to keep them at room temperature and protecting from light, heat and moisturizers. Any remaining X 29 Patches were disposed of at the end of the study or subjects were given the choice to continue to use them.

All subjects were assigned a subject ID and all records were coded with all subject identifiers removed before data sharing and communication between parties involved. An Excel spreadsheet with data was complied including the Subject ID, Demographics and all EIS readings at baseline, week 1, week 2, week 3, and week 4. All informed consent forms and data collection forms remained at the data collection site and the compiled data were sent to LifeWave. Study records acquired in this research and the link to the subject's ID will be kept in separate locked cabinets at the PI's research site for seven years.

Figure 1: The anatomical position of the CV7 acupuncture point located at the base of the back of the neck

Figure 2. The anatomical position of the CV4 acupuncture point located below the belly button

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 range is indicative of normal values for organ function.

Table 1 shows typical EIS readings (cellular function physiologic status) for a female subject, while Table 2 shows typical EIS recordings for a male subject as examples. Table 3 shows the acquired EIS data for all the subjects (n =10), while Table 4 shows the total cumulative changes in the EIS data with respect baseline for all the subjects (n = 10) over the study period. Table 5 the summary of the mean and standard deviation values for the total cumulative EIS readings compared to baseline as well as EIS readings at baseline in 12 organs for all subjects (n = 10). In these tables please note that the functional physiological status changes in different organs from Week 1 compared to baseline is designated as Δ_1 and changes from Week 2 to Week 1 is symbolized as Δ_2, from Week 3 to Week 2 is shown as Δ_3, and from Week 4 to Week 3 is represented as $\Delta_{T\text{-}B}$ represents the total change with respect to baseline. Avg (B) shows the mean value of the baseline EIS readings for all the subjects, while STD (B) represents the standard deviation of all the EIS readings acquired at baseline. Avg $(\Sigma\Delta - B)$ stands for the average of the cumulative changes of EIS values for all subjects (n = 10) compared to the baseline over the duration of the study, and STD $(\Sigma\Delta - B)$ represents the standard deviation of the cumulative changes of EIS readings for all subjects (n = 10) with respect to baseline readings over the duration of the study.

Table 1. Typical Electro Interstitial Scan (cellular function physiologic status) data for a female subject.
Age: 51, Weight: 134 lb, Height: 5 ft, 6 inches.

	ORGAN NAME											
Data Point	Left Adrenal	Right Adrenal	Left Kidney	Right Kidney	Liver	Pancreas	Intestine	Left Frontal Lobe	Right Frontal Lobe	Pituitary Gland	Hypo-thalamus	Thyroid Gland
Baseline	-35	-35	10	10	-25	-8	21	-51	-31	0	-31	-19
Week 1	-35	-35	-43	-97	-48	-65	-82	-54	-36	1	-47	-26
Week 2	-30	-30	-20	-95	-47	-54	-69	-61	-52	0	-50	-20
Week 3	-35	-35	-5	-1	-46	-20	-11	-55	-42	0	-52	-45
Week 4	-35	-35	-32	-96	-50	-57	-74	-48	-40	0	-43	-22
Δ_1	0	0	-53	-107	-23	-57	-103	-3	-5	1	-16	-7
Δ_2	5	5	23	2	1	11	13	-7	-16	-1	-3	6
$\Delta 3$	-5	-5	15	94	1	34	58	6	10	0	-2	-25
$\Delta 4$	0	0	-27	-95	-4	-37	-63	7	2	0	9	23
Δ_T	0	0	-42	-106	-25	-49	-95	3	-9	0	-12	-3
$\Delta_{T\text{-base}}$	35	35	-52	-116	0	-41	-116	54	22	0	19	16

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

Age: 46, Weight: 188 lb, Height: 5 ft, 10 inches.

	ORGAN NAME											
Data Point	Left Adrenal	Right Adrenal	Left Kidney	Right Kidney	Liver	Pancreas	Intestine	Left Frontal Lobe	Right Frontal Lobe	Pituitary Gland	Hypo-thalamus	Thyroid Gland
Baseline	-35	-35	-10	-8	-23	-19	-14	-37	-12	-1	-25	-15
Week 1	-25	-25	-28	-93	-45	-57	-74	-35	-21	-1	-29	-5
Week 2	-21	-21	-31	-96	-48	-61	-74	-11	15	-1	-21	-8
Week 3	-35	-35	-30	-31	-25	-35	-34	-3	13	0	-13	-18
Week 4	-35	-35	-22	-13	-26	-25	-28	-17	15	-1	-12	-12
Δ_1	10	10	-18	-85	-22	-38	-60	2	-9	0	-4	10
Δ_2	4	4	-3	-3	-3	-4	0	24	36	0	8	-3
$\Delta 3$	-14	-14	1	65	23	26	40	8	-2	1	8	-10
$\Delta 4$	0	0	8	18	-1	10	6	-14	2	-1	1	6
Δ_T	45	45	4	-72	4	-13	-32	19	-24	1	8	22
$\Delta_{T\text{-base}}$	80	80	14	-64	27	6	-18	56	-12	2	33	37

Table 3. EIS data at baseline for all subjects (n=10)

	ORGAN NAME											
Subject Number	Left Adrenal	Right Adrenal	Left Kidney	Right Kidney	Liver	Pancreas	Intestine	Left Frontal Lobe	Right Frontal Lobe	Pituitary Gland	Hypo-thalamus	Thyroid Gland
S1	-35	-35	10	10	-25	-8	21	-51	-31	0	-31	-19
S2	30	30	4	-91	-21	-30	-60	-17	-9	0	-11	19
S3	-25	-25	34	37	-21	21	31	-63	-68	-2	-48	-8
S4	-25	-25	-10	-94	-34	-42	-67	-56	-42	0	-40	-3
S5	-35	-35	-19	-21	-44	-29	-24	-19	-3	0	-39	-45
S6	30	30	27	32	32	45	19	-16	-2	1	6	10
S7	-35	-35	-10	-8	-23	-19	-14	-37	-12	-1	-25	-15
S8	-30	-30	25	29	21	24	38	-70	-64	1	-48	-6
S9	-21	-21	8	2	13	26	24	6	-14	0	-10	0
S10	-25	-25	-15	-12	-9	-8	-22	-31	-18	-1	-15	12

Table 4. The total cumulative changes in the EIS data with respect to baseline for all subjects (n=10) over 30 days.

	ORGAN NAME											
Subject Number	Left Adrenal	Right Adrenal	Left Kidney	Right Kidney	Liver	Pancreas	Intestine	Left Frontal Lobe	Right Frontal Lobe	Pituitary Gland	Hypo-thalamus	Thyroid Gland
S1	35	35	-52	-116	0	-41	-116	54	22	0	19	16
S2	-81	-81	-1	87	24	30	61	-18	-28	0	-4	-14
S3	15	15	-56	-62	15	-63	-54	60	81	3	50	-2
S4	50	50	44	215	92	121	176	85	68	1	70	16
S5	35	35	-12	-1	44	19	-2	32	40	0	57	58
S6	-60	-60	-19	-74	-28	-61	-4	-9	-25	-2	-24	3
S7	80	80	14	-64	27	6	-18	56	-12	2	33	37
S8	30	30	-31	-41	-54	-39	-51	76	70	-2	55	2
S9	17	17	-5	-2	-35	-31	-47	-10	47	0	16	-3
S10	15	15	9	1	-1	-4	16	37	48	2	17	-31

Table 5. Summary of the mean and standard deviation values for total cumulative EIS changes compared to baseline as well as EIS readings at baseline in 12 organs for all subjects (n = 10) over 30 days.

	ORGAN NAME											
Statistical Measure	Left Adrenal	Right Adrenal	Left Kidney	Right Kidney	Liver	Pancreas	Intestine	Left Frontal Lobe	Right Frontal Lobe	Pituitary Gland	Hypo-thalamus	Thyroid Gland
Avg (ΣΔT-B)	136	136	-109	-57	84	-63	-39	363	311	4	289	82
STD (ΣΔT-B)	48.6	48.6	30.4	95.4	42.3	55.1	79.1	37.0	40.2	1.64	29.6	25.2
Avg (B)	-17.1	-17.1	5.4	-11.6	-11.1	-2	-5.4	-35.4	-26.3	-0.2	-26.1	-5.5
STD (B)	25.3	25.3	18.8	46.8	25	29.1	37.7	24.3	24.2	0.9	18.2	18.3
p	<0.001	<0.001	<0.001	<0.01	<0.001	<0.01	0.122	<0.001	<0.001	<0.001	<0.001	<0.001
Significance	Highly	Highly	Highly	Very	Highly	Very	No	Highly	Highly	Highly	Highly	Highly

DISCUSSION AND CONCLUSION

This is the first study of its kind to investigate the effect of the ALAVIDA Anti-aging Patch on organ physiologic function. This open-label, single-site pilot investigation enrolled 10 volunteers (2 males and 8 females, 44-65 years of age, 126-188 lbs in weight, 4', 11" -6', 1" in height) by applying careful inclusion and exclusion criteria. Measurements were performed using an Electro Interstitial Scanning (EIS) system at baseline, week 1, week 2, week 3, and week 4 to monitor the ALAVIDA Anti-aging Patch effects on physiological functional status of 12 organs: left and right kidneys, left and right adrenal glands, left and right frontal lobes, pancreas, liver, intestines, hypothalamus, as well as pituitary and thyroid glands while wearing the patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period.

Statistical analyses were carried out comparing the *cumulative averages of the net changes* in cellular physiologic functional status of each organ at the end of the study period with respect to the corresponding baseline data. The results showed a *highly significant ($p < 0.001$)* improvement with a statistical power of at least 99% in physiologic functional status of the (right and left) frontal lobes and adrenal glands as well as liver, hypothalamus, pituitary gland and thyroid gland. There was a *very significant* ($p < 0.01$) improvement with an average statistical power of at least 90% in the functional status of (left and right) kidneys and pancreas. The intestines did not achieve statistical significance *($p < 0.05$)* over this period probably requiring more time for the ALAVIDA Patch to take effect in this organ.

In summary, the overall data in this study demonstrated that the wearing a new ALAVIDA Patch nightly for 5 consecutive nights a week with 2 nights off for a duration of 30 days produced a highly significant ($p<0.001$) improvement in the physiologic functional status of the frontal lobes, hypothalamus, adrenals, thyroid gland, pituitary

gland and liver with a statistical power of at least 99%. The frontal lobes exhibited the most remarkable effect size. The results also revealed a very significant improvement ($p<0.01$) with an average statistical power of at least 90% in the functional status of kidneys and pancreas. The intestines did not reach a significant ($p<0.05$) improvement in 10 subjects over a period of 30 days. With these findings we accept the hypothesis as true, that is: *wearing a new ALAVIDA Anti-aging Patch nightly for 5 consecutive nights a week with 2 nights off over a 30 day period significantly improves cellular physiologic functional status in different organs.*

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