X-15 Patch Improves Cellular Physiologic Functional Status of Liver, Kidneys, Pancreas, Intestines, Hypothalamus, Adrenal and Thyroid Glands

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ABSTRACT

Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from two cohort volunteers (A and B) after giving informed consent. Cohort A comprised of 10 subjects: 3 males and 7 females, 47-79 years of age, with a weight range: 123 -198 lb (~ 60 – 90 Kg) and a height range: 5', 1" - 5', 10" (~155 - 178 cm). Cohort B were 10 subjects: 6 males and 4 females, 30 - 67 years of age, weight range: 123 - 202 lbs (~ 60 – 92 Kg), and height range: 5', 1" – 6" (~155 – 183 cm). Cellular physiologic function in subjects were evaluated in 10 organs (pancreas, liver, left and right kidneys, intestine, left and right adrenal glands, hypothalamus, pituitary and thyroid glands) while wearing the X-15 patch for a period of 2 weeks. Physiologic function testing was repeated each week. Cohort A wore the X-15 patch for 12 hours/day (MWF), while Cohort B wore the X-15 patch for 12 hours/day for 5 days a week (M-F). Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the X-15 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 X-15 patch worn 12 hours/day, 5 days/week for 2 weeks significantly improves cellular physiologic functional status in all 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 A showed a *highly significant ($p < 0.001$)* improvement in physiologic functional status of *adrenals* and *hypothalamus*. No significant improvement in the physiological functional status of other organs was observed in Cohort A. Average statistical power considering the effect size (% improvement in physiologic function, sample number, and level of significance) was at least 88% in the 3 organs that responded to X-15 patch in Cohort A.

The results in Cohort B showed a *highly significant ($p < 0.001$)* improvement in physiologic functional status of *liver, hypothalamus, adrenal glands, and thyroid gland* with an average statistical power of at least 92% in these tests. There was a *very significant ($p <0.01$)* improvement in functional status of *intestines* with a statistical power of at least 63% and a significant *($p <0.05$)* improvement was observed in *kidneys* and *pancreas* with a statistical power of 62%. No significant improvement in cellular physiologic status was observed in *pituitary* gland in Cohort B.

In summary, the overall data in Cohort B in this study demonstrated that X-15 patches worn 12 hours for 5 days a week (M-F) over a period of 2 weeks produced a *highly significant* improvement in physiologic functional status of *liver, adrenals, hypothalamus* and *thyroid gland* with a *very significant* improvement in left *kidney* and *intestines* and *significant* improvement in *kidneys* and *pancreas*. Stated differently all organs except pituitary gland achieved *significant* cellular physiologic functional status improvement compared to baseline with an average statistical power of at least 80% and the hypothesis was accepted as true.

Keywords: ***X-15 patch, Cellular physiologic function measurements, Electro interstitial scan (EIS) system.***

INTRODUCTION

This is the first study of its kind carried out in February and March 2010, to investigate the effect of the X-15 patch on organ physiologic function. Bioelectrical impedance data indicative of cellular physiologic function, using an EIS system, were acquired from two cohort volunteers (A and B) after giving informed consent. Cohort A comprised of 10 subjects: 3 males and 7 females, 47-79 years of age, with a weight range of 123-198 lb (~ 60 – 90 Kg) and a height range of 5', 1" – 5', 10" (~155 - 178 cm). Cohort B were 10 subjects: 6 males and 4 females, 30 - 67 years of age, weight range: 123 - 202 lbs (~ 60 – 92 Kg), height range: 5', 1" – 6" (~155 – 183 cm). Cellular physiologic function in subjects were evaluated in 10 organs (pancreas, liver, left and right kidneys, intestine, left and right adrenal glands, hypothalamus and pituitary and thyroid glands) while wearing the X-15 patch for a period of 2 weeks. Physiologic function testing was repeated each week. Cohort A wore the X-15 patch for 12 hours/day 3 days a week, while Cohort B wore the X-15 patch for 12 hours/day for 5 days a week (on week days). Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the X-15 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 X-15 patch worn 12 hours/day, 5 days/week for 2 weeks significantly improves cellular physiologic functional status in all organs.*

The overall data in Cohort B in this study demonstrated that X-15 patches worn 12 hours, 5 days a week over a period of 2 weeks produced a *highly significant ($p < 0.001$)* improvement in physiologic functional status of *liver, adrenals, hypothalamus* and *thyroid gland* with a *very significant ($p < 0.01$)* improvement in *intestines* and *significant ($p < 0.05$)* improvement in *kidneys* and *pancreas*. Stated differently all organs except pituitary gland achieved *significant* cellular physiologic functional status improvement compared to baseline with an average statistical power of at least 80% and the hypothesis was accepted as true for all tested organs except the pituitary gland.

MATERIALS AND METHODS

For this investigation, the X-15 patch (LifeWave, La Jolla, California, USA) was used. The LifeWave X-15 patch is a non-transdermal patch that does not put any chemicals or drugs into the body. The LifeWave X-15 patch contains natural nontoxic crystals that absorb body heat to generate infrared signals that cause the body to improve cellular repair.

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^+-K^+ATPase pump activity, tissue pCO_2, sympathetic system activity and microcirculation blood flow." [1]. The EIS System uses chronoamperometry based on Cottrel's equation [2]. 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." [3].

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 X-15 patch and participate in the study for a period of two 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 X-15 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.

Subjects were randomly assigned to one of two treatment groups: Cohort A and Cohort B. Cohort A comprised of 10 subjects: 3 males and 7 females, 47-79 years of age, with a weight range: 123-198 lb (~ 60 – 90 Kg) and a height range of 5', 1" – 5', 10" (~155 - 178 cm). Cohort B were 10 subjects: 6 males and 4 females, 30 - 67 years of age, weight range: 123 - 202 lbs (~ 60 – 92 Kg), height range: 5', 1" – 6" (~155 – 183 cm). After giving informed consent, cellular physiologic function in subjects were evaluated in 10 organs (pancreas, liver, left and right kidneys, intestine, left and right adrenal glands, hypothalamus and pituitary and thyroid glands) while wearing the X-15 patch for a period of 2 weeks. Physiologic function testing was repeated each week. Cohort A wore the Xl5 patch for 3 days (MWF) on acupuncture point CV_{17}. Cohort B wore the X-15 patch 5 days per week (M-F) on alternate acupuncture points between CV_{17} and CV_6 for the duration of the study. Subjects were instructed to wear the X-15 patch for 12 hours per day and remove at night. Subjects were requested to consistently use the same patch application points for the duration of the study. Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the X-15 patch was worn. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control. Subjects were also requested to keep a daily log and were asked to turn them in to the study coordinator at the end of their study participation.

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 System readings (cellular function physiologic status) for a female subject from Cohort B, while Table 2 shows typical EIS System readings for a male subject from the same cohort, as examples. Functional status changes from week to week are noted as Δ_1, Δ_2 for the 2-

week period showing cellular physiologic changes in the organs. Δ_{avg} representes the average value of EIS readout changes for the 2-week period, and Δ_T stands for the average total physiologic status change after 2 weeks. $\Delta_{T\text{-base}}$ reflects the average cumulative change in physiologic function 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 B (n =10).

Table 1. Typical Electro Interstitial Scan (cellular function physiologic status) data for a female subject from Cohort B. Age: 39, Weight: 162 lb, Height: 5 ft, 5 inches.

Date	Pancreas	Liver	Kidneys	Intestines	Adrenals	Hypoth.	Pituitary	Thyroid
Baseline	-22	-23	-18	-27	-35	-21	0	-10
Week 1	15	-5	17	4	-21	0	22	5
Week 2	28	9	34	20	0	-26	1	13
Δ_1	37	18	35	31	14	21	22	15
Δ_2	50	32	52	47	35	-5	1	23
Δ_T	87	50	87	78	49	16	23	38
$\Delta_{T\text{-base}}$	109	73	105	105	84	37	23	48

Table 2. Typical Electro Interstitial Scan (cellular function physiologic status) data for a male subject from Cohort B. Age: 34, Weight: 170 lb, Height: 5 ft, 10 inches.

Date	Pancreas	Liver	Kidneys	Intestines	Adrenals	Hypoth.	Pituitary	Thyroid
Baseline	-15	-24	-19	-28	-35	-16	1	-6
Week 1	-11	-21	16	21	-21	-13	1	10
Week 2	-10	-14	-12	-21	-30	-17	1	3
Δ_1	4	3	35	49	14	3	0	16
Δ_2	5	10	7	7	5	-1	0	9
Δ_T	9	13	42	56	19	2	0	25
$\Delta_{T\text{-base}}$	24	37	61	84	54	18	-1	31

Table 3. Summary of statistics for EIS readings in 10 organs in Cohort B, n = 10.

Statistical Measures	Pancreas	Liver	Kidneys	Intestines	Adrenals	Hypoth.	Pituitary	Thyroid
Avg $_{\text{Baseline}}$	-2.0	-17.3	-2.2	-4.3	-22.4	-21.5	6.3	-16.1
Avg $_{\Delta\text{Total}}$	33.1	29.5	36.75	32.9	35.1	16.1	-16.3	41.3
Avg $_{\text{Std Baseline}}$	25.84	20.80	24.63	23.88	19.86	14.20	10.18	15.58
Avg $_{\text{Std }\Delta\text{Total}}$	42.44	17.63	43.30	33.32	30.00	26.60	24.92	40.18

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 A showed a *highly significant ($p < 0.001$)* improvement in physiologic functional status of *adrenal* glands and *hypothalamus*. No significant improvement in the physiological functional status of other organs was observed in this cohort. Average statistical power considering the effect size (% improvement in physiologic function, sample number, and level of significance) was at least 88% in *adrenal* glands and *hypothalamus* that responded to wearing these patches in Cohort A. As X-15 patches were worn only for 3 days/week (MWF) for 2 weeks, it seems reasonable to conclude that the majority of organs did not have adequate exposure to demonstrate significant change in their physiological functional status.

The results in Cohort B showed a *highly significant (p < 0.001)* improvement in physiologic functional status of *adrenals* and *thyroid glands, liver* and *hypothalamus* with an average statistical power of at least 92% in these tests. There was a *very significant (p <0.01)* improvement in functional status of *intestines* with a statistical power of at least 63% and a *significant (p <0.05)* improvement was observed in *pancreas* and *kidneys* with an average statistical power of 62%. No significant improvement in cellular physiologic status was observed in pituitary gland in Cohort B.

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

1. In Cohort A (n =10), the average statistical power was more than 88% for the organs showing a *highly significant (p < 0.001)* improvement in their cellular physiologic function.
2. In Cohort B (n = 10), the average statistical power was more than 92% for all organs (namely liver, adrenal glands, and thyroid gland) showing a *highly significant (p < 0.001)* improvement in their cellular physiologic functional status.
3. In Cohort B (n = 10), intestines showed a *very significant (p < 0.01)* improvement in cellular physiologic function with a statistical power of 63% and the kidneys showed a *significant* improvement ($p<0.05$) with a power of 61%. In this cohort the pituitary gland did show an improvement but did not reach significance.

In conclusion, the overall data in Cohort B in this study demonstrated that X-15 patches worn 12 hours for 5 days a week (M-F) over a period of 2 weeks produced a *highly significant* improvement in physiologic functional status of *liver, adrenals, hypothalamus* and *thyroid gland* with a *very significant* improvement in *intestines* and *significant* improvement in *pancreas and kidneys*. ***Stated differently all organs except the pituitary gland achieved significant cellular physiologic functional status improvement compared to baseline with an average statistical power of at least 80% and the hypothesis was accepted as true for all tested organs except the pituitary gland.***

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