SP6 PATCH IMPROVES ORGAN FUNCTION

Sherry Blake-Greenberg ND, MA, HMD, and Homer Nazeran PhD, C**PE**ng (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

Hypothalamus is a small area of the brain. It is the size of an almond, and is located immediately beneath the thalamus in the center of the brain. It is involved in control and automatic regulation of a large variety of physiological functions. Its main job is to maintain the balance and harmony in all of our bodily functions. In the acupuncture community, it is now suggested that acupuncture works by stimulating peripheral sensory nerves and their endings and causing an increase in cutaneous blood flow and microcirculation, as well as release of neurotransmitters, neuropeptides, and hormones. SP6 patches are non-transdermal patches that mildly stimulate Spleen 6 and Stomach 36 (Zusanli) acupuncture points. As stimulation of these acupuncture points have been indicated to have an effect on hypothalamic function, it is great of interest to investigate the effect of SP6 on physiology of some of the organs that are affected by hypothalamic regulation.

Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from ten volunteers [1 male and 9 females, 19-81 years of age, 157-219 lbs (~ 72 – 99.5 Kg) in weight, 4 ft, 11 inches (~150 cm) – 5 feet, 9 inches (~175 cm) in height] after giving informed consent. Cellular physiologic function in these subjects were evaluated in 10 organs (*pancreas, liver, intestines, left and right kidneys, thyroid, left and right adrenal glands, hypothalamus and pituitary gland*) while wearing the SP6 patch daily for a period of 1 week. Physiologic function (EIS) testing was performed at baseline while wearing no patches, 30 minutes after wearing the SP6 patch and then repeated after wearing the patch daily for 1 week. Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the SP6 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 SP6 patch worn daily for 1 week, 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 corresponding baseline data. The results showed a *highly significant ($p < 0.001$)* improvement in physiologic functional status of the *liver, pancreas, right and left kidney.* There was a *very significant* (*$p < 0.01$*) improvement in the functional status of *thyroid, intestines and hypothalamus*. There was a *significant* improvement ($p < 0.05$) in the functional status of the *left and right adrenal glands*. The *pituitary gland* did not show a significant improvement ($p = 0.19$). Average statistical power considering the effect size (% improvement in physiologic function, sample number, and level of significance) was at least 89% in the *pancreas, liver, intestines, left and right kidneys, thyroid, left and right adrenal glands, and the hypothalamus.*

In summary, the overall data in this study demonstrated that SP6 patches worn daily over a period of 1 week produced a *highly significant* improvement in physiologic functional status of the *liver, pancreas, right and left kidney*s with an average statistical power > 97% and a *very significant* improvement in the functional status of the *thyroid, intestines and hypothalamus* with an average power> 87% and a *significant* improvement in the *adrenal glands* with an average statistical power > 75%. Stated differently all organs, except the pituitary gland achieved *significant* cellular physiologic functional status improvement compared to baseline with a statistical power> 89%.

Keywords: ***SP6 patch, Spleen 6 and Stomach 36 (Zusanli) acupuncture points, Electro interstitial scan (EIS) system.***

INTRODUCTION

Hypothalamus is a small area of the brain, the size of an almond, located immediately beneath the thalamus in the center of the brain. It is known as the main ganglion and the control center of the autonomic nervous system and is often referred to as "brain of the brain". It is an integrating center for homeostatic functions that maintain the balance and harmony of our physiological processes and is an important link between the autonomic nervous system and the endocrine system. It is involved in the direct regulation of the internal environment (milieu) of the body. It is responsible for orchestrated coordination of many regulatory functions of different organs. Specifically it controls our body temperature, thirst and hunger, food intake, urine output, production and secretion of anterior pituitary hormones, uterine contractions, and milk ejections. As a major autonomic coordinating center it affects all smooth muscle, cardiac muscle, and exocrine glands. It is part of the motivational system of the central integrative systems of the brain, which provide the drive to satisfy our basic needs. It also plays a role in emotional and behavioral patterns [1].

In the acupuncture community, it is now suggested that acupuncture works by stimulating peripheral sensory nerves and their endings and causing an increase in cutaneous blood flow and microcirculation, as well as release of neurotransmitters, neuropeptides, and hormones [2]. Subhuti Dharmananda, Ph.D., Director, Institute for Traditional Medicine, Portland, Oregon in a review of a study on hormonal effects of electro-acupuncture stimulation at zusanli (Stomach 36) on the hypothalamus states that "needling zusanli in several animal models (rabbits, cows, and sheep) could increase plasma hormones, and that the adrenocortical hormones were being stimulated via the hypothalamus (which is encompassed by the brain). An effect of acupuncture on the higher brain center was suggested as a possible basis for the hypothalamic-adrenal response." [3-4].

In a study in normal subjects entitled "Activation of the hypothalamus characterizes the acupuncture stimulation at the analgesic point in human: a positron emission tomography study" performed by Hsieh et al., they used regional cerebral blood flow as the index of brain activity to address the *specificity* of brain activation pattern by acupuncture stimulation of short duration. They showed that stimulation at 2 Hz at a classical point of prominent analgesic efficacy (Li 4, Heku) and a near-by non-classical/non-analgesic point, respectively activated the *hypothalamus* with an extension to midbrain, the insula, the anterior cingulate cortex, and the cerebellum. The conclude that their "data suggested that the hypothalamus might characterize the central expression of acupuncture stimulation at the classical analgesic point and serve as one key element in mediating analgesic efficacy of acupuncture stimulation." [5].

SP6 patches are non-transdermal patches that mildly stimulate Spleen 6 and Stomach 36 (Zusanli) acupuncture points. As stimulation of these acupuncture points have been indicated to have an effect on hypothalamic function, it is great of interest to investigate the effect of SP6 on physiology of some of the organs that are affected by hypothalamic regulation.

This is the first study of its kind to investigate the effect of the SP6 patch on organ physiologic function. Bioelectrical impedance data indicative of cellular physiologic organ function (status), using an Electro Interstitial Scanning (EIS) system, were acquired from ten volunteers [1 male and 9 females, 19-81 years of age, 157-219 lbs (~ 72 – 99.5 Kg) in weight, 4 ft, 11 inches (~150 cm) – 5 feet, 9 inches (~175 cm) in height] after giving informed consent. Cellular physiologic functional status of different organs in these subjects were evaluated in 10 organs (pancreas, liver, intestines, left and right kidneys,

thyroid, left and right adrenal glands, hypothalamus and pituitary gland) while wearing the SP6 patch for a period of 1 week. Physiologic function (EIS) testing was performed at baseline while wearing no patches, 30 minutes after wearing the SP6 patch and then was repeated after wearing the patch daily for 1 week. Cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the SP6 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 SP6 patch worn daily for 1 week, significantly improves cellular physiologic functional status in different organs.*

The overall data in this study demonstrated that SP6 patches worn daily over a period of 1 week produced a *highly significant* improvement in physiologic functional status of the *liver, pancreas, right and left kidney*s with an average statistical power > 97% and a *very significant* improvement in the functional status of the *thyroid, intestines and hypothalamus* with an average power > 87% and a *significant* improvement in the adrenal glands with an average statistical power > 75%. Stated differently all organs, except the pituitary gland achieved *significant* cellular physiologic functional status improvement compared to baseline with a statistical power> 89%.

MATERIALS AND METHODS

For this investigation, the SP6 patch (LifeWave, La Jolla, California, USA) was used. The SP6 patch is described as a new method for stimulating the SP6 or Stomach 36 acupuncture points on the body with a combination of pressure and infrared energy. The LifeWave Sp6 patch is a non-transdermal patch that does not put any chemicals or drugs into the body. The LifeWave SP6 patch contains natural nontoxic crystals that absorb body heat to generate infrared signals that stimulate these acupuncture points.

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 pCO2, sympathetic system activity and microcirculation blood flow.” [7]. The EIS System uses chronoamperometry based on Cottrel’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 SP6 patch and participate in the study for a period of one week. 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 SP6 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. Ten volunteer subjects [1 male and 9 females, 19-81 years of age, 157-219 lbs (~ 72 – 99.5 Kg) in weight, 4 ft, 11 inches (~150 cm) – 5 feet, 9 inches (~175 cm) in height] participated in this pilot study. After giving informed consent, cellular physiologic function baseline data were acquired from all subjects at the beginning of the study period before the SP6 patch was worn, 30 minutes after wearing the patch and one week afterwards. 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 SP6 patch on Spleen 6 or Stomach 36 acupuncture points.

RESULTS

The Electro Interstitial Scan (EIS) System used in this investigation measured cellular physiologic function on a scale of -100 to -20 for under-function and +20 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 the male subject as examples. Table 3 shows the average cumulative readings and their standard deviations. Functional status changes from baseline to 30 minutes after wearing the SP6 patch is represented as Δ_1. Δ_2 stands for cellular physiologic changes in the organs after wearing the SP6 patch daily for 1 week. $\Delta_{T\text{-base}}$ represents the total EIS reading change with respect to baseline measurements. Table 3 shows the overall mean values and standard deviations for baseline and total change in physiologic function for each of the organs in all subjects (n =10).

Table 1. Typical Electro Interstitial Scan (cellular function physiologic status) data for a female subject (38 years old).

	ORGAN NAME									
	Pancreas	Liver	Thyroid	Intestine	Right Adrenal	Left Adrenal	Hypoth.	Pituitary	*Right Kidney*	*Left Kidney*
Baseline	-31	-41	-64	11	-66	-73	-46	-21	-1	9
After 30 min	-38	-44	-76	1	-89	-86	-55	-21	-4	0
After 1 Week	-9	-21	-14	-2	-16	-25	-17	-3	-12	-1
Δ_1	-7	-3	-12	-10	-23	-13	-9	0	-3	-9
Δ_2	22	20	50	-13	50	48	29	18	-11	-10
Δ_T	15	17	38	-23	27	35	20	18	-14	-19
$\Delta_{T\text{-base}}$	46	58	102	-34	93	108	66	39	-13	-28

Table 2. Typical Electro Interstitial Scan (cellular function physiologic status) data for the male subject (19 years old).

	ORGAN NAME									
	Pancreas	Liver	Thyroid	Intestine	Right Adrenal	Left Adrenal	Hypoth.	Pituitary	*Right Kidney*	*Left Kidney*
Baseline	-7	-15	-2	-5	-10	-10	0	-9	-8	-3
After 30 min	-31	13	-4	27	-15	-18	1	-6	0	14
After 1 Week	17	-16	-18	34	-22	-23	-19	0	23	35
Δ_1	-24	28	-2	32	-5	-8	1	3	8	17
Δ_2	24	-1	-16	39	-12	-13	-19	9	31	38
Δ_T	0	27	-18	71	-17	-21	-18	12	39	55
$\Delta_{T\text{-base}}$	7	42	-16	76	-7	-11	-18	21	47	58

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

	ORGAN NAME									
	Pancreas	Liver	Thyroid	Intestine	Right Adrenal	Left Adrenal	Hypoth.	Pituitary	*Right Kidney*	*Left Kidney*
Avg Baseline	-28.2	-32.9	-32.4	-16.9	-36.3	-36.8	-24.8	-4.9	-27.5	-22.3
Avg ΔTotal	35.2	51.3	29.2	24.5	17.1	13.1	18.7	3.9	33.7	38.8
Avg Std Baseline	13.1	15.3	25.5	13.9	29.1	24.6	16.6	6.1	18.7	18.1
Avg Std ΔTotal	24.4	31.3	58.2	37.5	59.6	60.2	35.0	19.5	19.2	34.7

DISCUSSION AND CONCLUSION

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 corresponding baseline data. The results showed a *highly significant ($p < 0.001$)* improvement in physiologic functional status of the *liver, pancreas, right and left kidney.* There was a *very significant* (*$p < 0.01$*) improvement in the functional status of *thyroid, intestines and hypothalamus*. There was a *significant* improvement ($p < 0.05$) in the functional status of the *left and right adrenal glands*. The *pituitary gland* did not show a significant improvement ($p = 0.19$). Average statistical power considering the effect size (% improvement in physiologic function, sample number, and level of significance) was at least 89% in the *pancreas, liver, intestines, left and right kidneys, thyroid, left and right adrenal glands, and the hypothalamus.*

In summary, the overall data in this study demonstrated that SP6 patches worn daily over a period of 1 week produced a *highly significant* improvement in physiologic functional status of the *liver, pancreas, right and left kidney*s with an average statistical power > **97%** and a *very significant* improvement in the functional status of the *thyroid, intestines and hypothalamus* with an average power > 87% and a *significant* improvement in the *adrenal glands* with an average statistical power > **75%.** Stated differently all organs, except the pituitary gland achieved *significant* cellular physiologic functional status improvement compared to baseline with a statistical power> **89%**. *Therefore, the hypothesis was accepted as true.*

REFERENCES

1. Sherwood L. *Fundamentals of Physiology: a human perspective*, 2nd ed., West Publishing, St Paul, 1995; pp. 98-99.

2. Cai W. *Acupuncture and the nervous system*, American Journal of Chinese Medicine, 1992; 20(3–4): pp. 331–337.

3. Dharmananda S. ***ZUSANLI (STOMACH-36).*** http://www.itmonline.org/arts/zusanli.htm. Retrieved on March 14, 2010.

4. Lin J H, et al. *Treatment of iatrogenic Cushing's Syndrome in dogs with electroacupuncture stimulation of Stomach 36*. American Journal of Chinese Medicine, 1991; 19(1): pp. 9–15.

5. Hsieh J C, Tu C H, Fang-Pey C, et al. *Activation of the hypothalamus characterizes the acupuncture stimulation at the analgesic point in human: a positron emission tomography study*. Neuroscience Letters, 2001; 307, pp. 105-108.