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Mild stimulation of stomach 36 acupuncture point by organic nanoscale SP6 patch improves cellular physiologic functional status of different organs

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ABSTRACT

Acupuncture works by stimulating peripheral sensory nerves and their endings causing an increase in cutaneous blood flow and microcirculation, as well as release of neurotransmitters, neuropeptides, and hormones. SP6 Patch is a nanoscale nontransdermal device that mildly stimulates Stomach 36 (zusanli) and other acupuncture points. As stimulation of these points has been indicated to have an effect on hypothalamic function, it is of great research interest to investigate the effect of SP6 Patch on the physiology of organs that are affected by hypothalamic regulation. Bioelectrical tissue impedance data indicative of cellular physiologic organ function, using an Electro Interstitial Scan (EIS) system, were acquired from hypothalamus, pancreas, liver, intestines, kidneys, thyroid and adrenal glands in 10 (1 male, 9 females) volunteers while wearing the SP6 Patch daily for 1 week. EIS testing was performed at baseline with no patch, 30 min after wearing the patch, and after wearing the patch 12 h/day for 1 week. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control. The hypothesis was: The SP6 Patch worn 12 h/day on the Stomach 36 acupuncture point for 1 week, may significantly improve cellular physiologic functional status of different organs measured by EIS. All tested organs achieved significant improvement in their functional physiologic status after wearing the SP6 Pach 12 h/day for 1 week compared to baseline with an overall average statistical power > 89%. Based upon these results the hypothesis was accepted as true.

Keywords acupuncture points, stomach 36 (zusanli), electro interstitial scan, SP6 Patch

INTRODUCTION

Traditional medical theory or Traditional Chinese Medicine (TCM), including herbal medicine and acupuncture, constitutes an integral part of complementary and alternative medicine (CAM). CAM plays an essential role in integrative medicine (IM). TCM was formed more than 2 millennia ago and has been developing ever since. It recognizes the integrity of the human body as a seamlessly interconnected network of different self-controlled systems and the dynamic balance between these systems. Physiology (functioning of the body) is explained in terms mechanisms of system discrimination**,** and pathology (dysfunction) in terms mechanisms of dynamic changes in these systems with therapy as enhancing body's resistance to diseases and prevention by improving the interconnections among these self-controlled systems. It is characterized as holistic and emphasizes the integrity of the human body and its close relationship with natural and social environment (Lu et al., 1991).

Acupuncture, one of the key components of TCM, has been practiced in China, Korea, Japan and other Asian countries for thousands of years. It became better known in USA in 1971 when James Reston, a New York Times reporter, reported how doctors in China used acupuncture to help alleviate his pain after surgery. In 1997, a report from the Consensus Development Conference on Acupuncture supported by the National Institutes of Health (NIH) stated that acupuncture is being practiced by thousands of mainstream and complimentary medical practitioners in USA for pain relief or prevention of a variety of health conditions (NCCAM1, 2012).

In a comprehensive survey of the use of Complementary and Alternative Medicine in USA, performed by NIH in 2007, it was indicated that an estimated 3.1 million American adults and 150,000 children used acupuncture in 2006. It was also shown that between 2002 and 2007, the utilization of acupuncture among adults increased by approximately 1 million. According to this data, it could be stated that currently, medical traditions from Asian countries are now widely used in American practice of acupuncture (NCCAM2, 2012).

As stimulation of specific acupuncture points has been indicated to have an effect on hypothalamic function, it is of great research interest to investigate the effect of a new way of stimulating acupuncture points and explore how this approach may influence the physiology of organs that are affected by hypothalamic regulation. The 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 maintains the balance and harmony of physiological processes, and links the autonomic nervous system and the endocrine system to directly regulate the internal environment (milieu) of the body. It controls body temperature, thirst and hunger, food intake, urine

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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, and plays a role in emotional and behavioral patterns (Sherwood, 1995).

Acupuncture works by stimulating peripheral sensory nerves and their endings and causing an increase in cutaneous blood flow and microcirculation, as well as in the release of neurotransmitters, neuropeptides, and hormones (Cai, 1992). In a recent review of a study on the effects of electro-acupuncture stimulation of Stomach 36 (zusanli) on hypothalamus (Institute for Traditional Medicine, Oregon, USA) it is stated that: "needling zusanli in several animal models (rabbits, cows, and sheep) increased plasma hormones, and 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" (Lin et al., 1991).

In a study of 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., (2001) the authors 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 nearby non-classical/non-analgesic point respectively activated the hypothalamus with an extension to midbrain, the insula, the anterior cingulate cortex, and the cerebellum. They concluded 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." (Hsieh et al., 2001).

In addition to the established use of needle acupuncture, there have been a variety of ways to achieve acupuncture point stimulation to trigger flow of Qi in specific conductive pathways known as meridians that include electrical stimulation, deep pressure, heat (infrared light), cold, laser light, etc. There are a large number of studies in the literature describing these methods, and their therapeutic use and value in comparison with needle acupuncture.

In an infrared radiation (IR) study in China, Shen et al. used a highly sensitive infrared spectrum detection device to show that direct moxibustion with a traditional moxa stick burning over acupuncture points produced a potent therapeutic effect by thermal action occurring at a peak of 3.5 μm on the IR spectrum (Shen et al., 2006).

Litscher et al., in an Austrian study, described laser needle acupuncture as a new method to optically stimulate acupuncture points and assessed its use and value based on 511 measurements performed on 129-female, and 120-male' healthy volunteers. They summarized the results of a number of randomized, double-blind, controlled, crossover studies to show that the methods of laser Doppler flowmetery, functional multidirectional transcranial Doppler sonography, functional magnetic resonance imaging, and near infrared spectroscopy are able to objectify and quantify peripheral and cerebral effects of laser needle acupuncture. In their study, they provided scientific proof of the differences between needle acupuncture and laser needle acupuncture, with a continuous multichannel method of painless acupuncture, and concluded that laser acupuncture could induce specific reproducible changes in the brain, similar to the effects produced by manual needle acupuncture, as expressed by shifts in different parameters such as cerebral blood flow velocity (Litscher et al, 2004).

In another investigation, Litscher and Wang developed a miniaturized 48-channel skin impedance measurement system for needle acupuncture studies. Using their device they showed that "skin impedance in the immediate vicinity of the acupoint was lowered reproducibly following needle stimulation and also violet laser stimulation" (Litscher and Wang, 2010).

In a series of review articles, Litscher performed a comprehensive bioengineering assessment of acupuncture as a popular complimentary method to medical treatment and highlighted the milestones of acupuncture research within a 30-year period. In these reviews, Litscher carefully described a variety of advanced and well-established methodologies that have been used to prove and validate the quantifiable effects of acupuncture stimulation in the *brain* in a non-invasive and reproducible fashion in real time (Litscher 2006a; Litscher 2006b; Litscher 2006c; Litscher 2006d; Litscher 2006e; Litscher 2007a; Litscher 2007b).

In a Japanese animal study, Komori et al. demonstrated that acupuncture stimulation and phototherapy (both near IR lamp irradiation and near IR laser) produced an analgesic effect and improved the microcirculation in peripheral circulation in a quantitative and objective manner. They confirmed that these forms of acupuncture point stimulation increased the diameter and blood flow velocity of peripheral arterioles (Komori et al., 2009).

Organic nanotechnology is a novel means to mildly and continuously stimulate acupuncture points. The preliminary effectiveness of this technology has been shown in a number of studies (Nazeran and Greenberg, 2010a; Nazeran and Greenberg 2010b; Budzynski et al., 2008; Nazeran, 2007). It is also stated that: organic nanotechnology is used to balance the body's Qi in the form of electromagnetic frequencies (EMF) transported by the acupuncture meridians in the same way that metal needles, qigong energy needles, moxibustion, etc. modulate frequencies (Personal communication with Dennis Lobestein, PhD).

The SP6 Patch is a nanoscale nontransdermal organic device that mildly stimulates Stomach 36 (ST36) and other acupuncture points such as Spleen 6. As stimulation of the ST36 acupuncture point has been shown to have an effect on hypothalamic function, it is of great research interest for this study to investigate the effect of SP6 Patch on physiology of some of the organs that are affected by hypothalamic regulation.

This is the first pilot study of its kind to investigate the effect of the SP6 Patch on organ physiologic function. Bioelectrical tissue impedance data, indicative of cellular physiologic organ function (status), were measured using an Electro Interstitial Scanning (EIS) system.

MATERIALS AND METHODS

The cellular physiologic functional status of different organs in the volunteer subjects were evaluated by making electro-interstitial tissue conductivity measurements in the hypothalamus, pancreas, liver, intestines, kidneys, thyroid and adrenal glands, while wearing the SP6 Patch on the left ST36 acupuncture point 12 h/day for a period of 1 week (As this was a pilot investigation in a small number of subjects to show proof of the concept of effectiveness of the SP6 Patch in stimulating the ST36 acupuncture point, and as the intention was to preserve consistency in patch application in all subjects, we only focused on one acupuncture point: left ST36, even though the manufacturer recommends application of the patch to either ST36 or SP6 acupuncture points. As there was only

one male participant in the study we did not perform a comparison between genders.) Physiologic function testing was performed at baseline while wearing no patches, 30 min after wearing the SP6 Patch and then after wearing the patch 12 h daily for 1 week. 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, when worn 12 h/day on the Stomach 36 acupuncture point for 1 week, significantly improves cellular physiologic functional status of different organs measured by EIS.

The SP6 Patch

The SP6 Patch is a member of organic nanoscale nontransdermal patches described by its manufacturer (LifeWave Inc, San Diego, CA) as a new method to mildly stimulate acupuncture points in the body. This technology employs localized absorption of infrared radiation (IR) produced by the body. These patches both trap and absorb infrared radiation. In addition, they are composed of nontoxic materials that reflect back specific wavelengths of infrared radiation. These patches are designed to deliver infrared wavelengths to enhance the electrical conductivity of the tissue. They work by reflecting IR energy back into the body and they do not generate energy. The materials in the patches act like frequency specific mirrors or reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broadband reflectors. Placing a patch on the skin will allow the materials to passively absorb wide-band energy and reemit narrow-band energy back into the body. Infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy from the body and then reemit the energy across a wide energy band. The difference between these patches and infrared products is that they only mirror back a very narrow band of frequencies. In this context these patches are not significantly different in mechanism of action from infrared wraps, socks, bandages, blankets, etc.

Subjects

This study was carried out in May 2009. The International Institutional Review Board (IRB) approved the study protocol. For this investigation, the SP6 Patch (LifeWave Inc, San Diego, California, USA) was used. Electro Interstitial Scanning (EIS) data were acquired from ten volunteers [1 male and 9 females, 19-81 years of age, 157 - 219 lbs (~ 72 - 99 Kg) in weight, 4 ft, 11 inches (~150 cm) - 5 feet, 9 inches (~175 cm) in height] after giving informed consent. The data were then used to create a digital database.

Inclusion criteria for participation in this study were healthy individuals who were willing to wear the SP6 Patch and participate in the study for a period of one week and keep well hydrated. 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 in Los Angeles and may or may not have been previous patients of Health Integration Therapy. After participants gave 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 min after wearing the patch and then one week after wearing the patch 12 h daily. Subjects were instructed to keep well hydrated (by drinking at least 2 liters, approximately 8 large glasses of water daily) during the study period. All subjects served as their own control. The subjects were instructed to place the SP6 Patch on the left Stomach 36 acupressure point. Fig. 1 shows the position of the Stomach 36 acupressure point with a patch.

Fig.1. Stomach 36 acupoint.

Measurement of cellular functional status

An Electro Interstitial Scan system (LD Technology, Florida, USA), a programmable electro medical device, was deployed to acquire bioelectrical impedance measurements indicative of cellular physiologic functional status in the organs listed above. The EIS system is a French device, classified as a Biofeedback Class 2 device in the United States (FDA product Code: HCC). Recently the FDA has approved a number of Alternating Current (AC) bioelectric impedance (BIM) devices for use in cardiology and oncology (Bard et al., 2001; Van De Water et al., 2003; Gritchley 1998; Cotter et al., 2006; U.S. Dept. 2009; Morimoto et al., 1990). Before electro-interstitial measurements were made on subjects, four operational tests were carried out automatically by the device: power supply test, channel test, volume and conductivity measurement and correspondence tests, as well as cable and precision control tests. Electrodes and electrode application sites were prepared following the manufacturer's instructions.

Under software control, the hardware delivers a sequence of three 1.28 V pulses: 22 ac pulses, 1 s each, at 50 KHz (at 0.6 mA, energy/pulse = 0.77 mJ); 22 dc pulses, 1 s each (at 0.6 mA, energy/pulse = 0.77 mJ); and another set of 22 dc pulses, 3 s in duration for each pulse (at 0.6 mA, energy/pulse = 0.77 mJ) to 6 electrodes. These electrodes (2 disposable Ag/AgCl applied to the forehead, 2 reusable polished stainless steel hand electrodes, and 2 reusable polished stainless steel foot electrodes) form 22 different electrode pair (sensing) configurations and measure the intensity of interstitial fluid conductivity (by applying Maxwell's equation) from which on-screen 3-D models of the human body organs are generated. The measurements are scaled on a scale of -100 to + 100 (LD Technology, Florida, USA). Because Direct Current (DC) electricity only passes through the interstitial fluid (16% of the body's total water), the EIS device could measure the composition of interstitial fluid as well as other biochemical parameters in the detection of ionic abnormalities. As the measurements provided by the EIS are internally calibrated and highly reproducible (based upon frequent observations at the clinic using this system), with small between-test variability, in the interest of the clinic's time, only one measurement was performed on each subject and repeated measurements were not made, so as to provide an average readout at each test point.

The cellular physiological effects in different organs after 1 week of wearing the SP6 Patch on the ST36 acupressure point 12 h daily were compared to baseline data before wearing the patch by using the paired t-test. A p value < 0.05 was accepted as statistically significant. Sample size (n), level of significance (a or p), effect size (mean value of EIS reading after wearing the patch - mean baseline value) and statistical power were interrelated by the following formula:

$$F[Z_a + |m\text{-}m_0| \text{ Sqrt } (n)/s] = \text{Statistical Power } (1)$$

Here Z_a is the Z score related to the area under the normal distribution curve (F) at the desired level of significance, $|m-m_0|$ is effect size, s is the standard deviation, and n is the sample size. Sqrt is the square root.

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-range was indicative of normal values for organ function.

Table 1 shows typical EIS system readings for a female subject, while Table 2 shows typical EIS system readings for a male subject as examples. Table 3 shows the average cumulative readings and their standard deviations. Functional status changes from baseline to 30 min after wearing the SP6 Patch are represented as D_1. D_2 stands for cellular physiologic changes in the organs after wearing the SP6 Patch 12 h daily for 1 week. $D_{T\text{-base}}$ represents the total EIS reading changes 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). Data were collected while applying the SP6 Patch on the left Stomach 36 acupressure point.

DISCUSSION

Statistical analyses using the paired t-test 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. A p value < 0.05 was accepted as statistically significant. The results showed a highly significant ($p < 0.001$) improvement in physiologic functional status of the *liver, pancreas, and kidneys*. There was a very significant ($p < 0.01$) improvement in the functional status of the thyroid, intestines, and hypothalamus. There was a significant improvement ($p < 0.05$) in the functional status of the adrenal glands. Average statistical power considering the effect size (% improvement in physiologic function, sample number, and level of significance) was at least 89% in the hypothalamus, pancreas, liver, intestines, kidneys, and thyroid and adrenal glands.

In conclusion, the overall data in this study demonstrated that the SP6 Patch worn on the ST36 acupressure point 12 h daily over a period of 1 week produced a highly significant improvement in the physiologic functional status of the liver, pancreas, kidneys 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 achieved significant cellular physiologic functional status improvement compared to baseline with an overall average statistical power > 89%. Therefore this pilot investigation shows that the SP6 Patch, when worn 12 h/day on the Stomach 36 acupuncture point for 1 week, may significantly improve cellular physiologic functional status of different organs measured by EIS.

Limitations and recommendations

This study was a pilot investigation to prove the concept of whether mild and continuous stimulation of ST36 by using an organic nanoscale patch as an alternative approach to needle or laser light stimulation could produce significant changes in

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
D_1	-7	-3	-12	-10	-23	-13	-9	0	-3	-9
D_2	22	20	50	-13	50	48	29	18	-11	-10
D_T	15	17	38	-23	27	35	20	18	-14	-19
$D_{T\text{-base}}$	46	58	102	-34	93	108	66	39	-13	-28

Table 2. Typical Electro Interstitial Scan (cellular function physiologic status) data for a 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
D_1	-24	28	-2	32	-5	-8	1	3	8	17
D_2	24	-1	-16	39	-12	-13	-19	9	31	38
D_T	0	27	-18	71	-17	-21	-18	12	39	55
$D_{T\text{-base}}$	7	42	-16	76	-7	-11	-18	21	47	58

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

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

organ functions mediated by hypothalamic response as reported in a number of animal model and human studies. Study limitations were sample size (n = 10), limited male participation, lack of a control group, and placebo-controlled measurements. Future research should focus on a larger gender-balanced, representative randomized sample with a placebo-controlled trial using experimental design.

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CONFLICT OF INTEREST

The authors do not have any conflict of interest in the present study.

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