

Study Report #1: Nazeran H, Blake-Greenberg S, Haltiwanger E. *Mild Stimulation of Stomach 36 Acupuncture Point by Organic Nanoscale SP6 Patch Improves Cellular Physiologic Functional Status of Different Organs.* Published in *International Journal of Genuine Traditional Medicine* (Vol 2, Issue 1, Feb 2012).

Safety issues:

- No adverse events reported in this study.

Patch instructions and study procedures:

- SP6 patches are non-transdermal patches that mildly stimulate Stomach 36 (ST 36) acupuncture points. As stimulation of these acupuncture points has 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 overweight volunteers [1 male and 9 female) who used the LifeWave SP6 patch in an open-label study.
- The hypothesis was: The SP6 patch worn 12 hours/day on the Stomach 36 acupuncture point for 1 week, significantly improves cellular physiologic functional status of the kidneys, intestine, liver, pancreas, adrenals, thyroid, hypothalamus, and pituitary as measured by EIS.
- 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.
- All subjects served as their own control.

Efficacy of patches in this study:

- 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 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, except the pituitary gland achieved significant cellular physiologic functional status improvement compared to baseline with a statistical power >89%.

Assessment: *In summary, the overall data in this study demonstrated that SP6 patch worn on the ST 36 acupressure point 12 hours daily over a period of 1 week produced a highly significant improvement in 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, the hypothesis that wearing LifeWave SP6 patch on ST 36 improves cellular physiologic functional status was accepted as true.

Study Report #2: Nazeran H, Kan K, Schlenger D. A Dual Site Investigation to Evaluate the Effectiveness of the SP6 Complete 4-Week Program on Weight and Waist Size Reduction.

Safety issues:

- The following adverse events were reported during the study:
 - Dizziness₂
 - Rash; skin irritation₄
 - Constipation₃
 - Trouble sleeping₃
 - Bloating₃
 - Relapse of bipolar disorder₂
 - Headache₂
 - Type II diabetic reported the juice spiked her blood sugar level₁
- Of the above reported reactions, three subjects removed themselves from the study

The Investigators concluded that

₁ was due to the Juice;

₂ was rapid detoxification effect from the overall system;

₃ were due to introduction of meat into diet during the study;

₄ was from the patch adhesive;

Patch instructions and study procedures:

NOTE: *The LifeWave SP6 Complete system was sold in the U.S. from November 2009 until August 2011. The system included the SP6 patches, which are still sold worldwide, in addition to a Meal Replacement powder, two daily Detox (herbal) tablets, and a Maqui (antioxidant) Revitalizing Juice.*

- Dr. Kan's research at Study Site 1 included 45 subjects (6 male, 39 females) with an age range: 18-69 years.
- The study was carried out over a period of 4 weeks using two protocols: one with initial 2 days of fasting and the other without fasting (non-fasting).
- Twenty three subjects (3 males, 20 females) followed the advanced protocol with fasting and twenty one subjects (3 males, 18 females) followed the advanced protocol without fasting.
- Acupoints used:
 - A. Stomach 36 (ST 36)
 - B. Spleen 6 (SP 6)
 - C. Kidney 3 (KI 3)
- Weight loss and waist loss data from 44 participants who completed this study were analyzed.
- Dr. Schlenger's research at Study Site 2 included 24 subjects (3 male, 21 female) with an age range of 62-69 years.
- The study was carried out over a period of 4 weeks and used the same points in the advanced protocol without fasting (non-fasting).
- Weight loss data from 20 subjects (2 male, 18 female) and waist loss data from 16 participants (2 male, 14 females) who completed the study were analyzed.

Efficacy of patches in this study:

- Study Site 1: The Fasting group data is shown in **Table 1** and the data from the Non-Fasting group is shown in **Table 2**.
- Study Site 2: The Non-Fasting group data is shown in **Table 3**.

Table 1: Data for Advanced SP6 Complete Protocol with 2 Day Initial Fasting (Study Site 1)

Subject Number	Pre Weight(lb)	Post Weight (lb)	Change in Weight (lb)	Pre Waist (in)	Post Waist (in)	Change in Waist (in)	Gender
1	129	126	-3	32	31.75	-0.25	F
2	206	195	-11	41	40.5	-0.5	M
3	159	150	-9	37.50	35.75	-1.75	F
4	203	190	-13	38	34.75	-3.25	F
5	148.5	148.5	0	35	35	0	F
6	173	167	-6	32.50	28.50	-4	F
7	182	175	-7	40	38	-2	M
8	195.5	192.6	-2.9	40	40	0	F
9	154	151	-3	32.50	30.50	-2	F
10	138	137	-1	30.50	30	-0.5	F
11	137	132	-5	35	33.75	-1.25	F
12	238	238	0	42	40	-2	F
13	161	153	-8	35.50	33	-2.5	F
14	172	166	-6	38.50	35	-3.5	F
15	234	227	-7	44.5	42.12	-2.38	M
16	187.5	173.5	-14	41	39	-2	F
17	256	249.5	-6.5	56	55.50	-0.5	F
18	152.5	150	-2.5	34	33	-1	F
19	192	188	-4	37	36.25	-0.75	F
20	155	152.9	-2.1	34.50	32.50	-2	F
21	168	154	-14	42	39	-3	F
22	177	168	-9	46	41	-5	F
23	161	152.6	-8.4	35.50	33.25	-2.25	F

Table 2: Data for Advanced SP6 Complete Protocol Without Fasting (STUDY SITE 1)

Subject Number	Pre Weight (lb)	Post Weight (lb)	Changes in Weight (lb)	Pre Waist (in)	Post Waist (in)	Changes in Waist (in)	Gender
1	236	231	-5	41.5	40	-1.5	F
2	180	176	-4	38	36.75	-2.25	M
3	159	153	-6	37.5	37	-0.5	F
4	228	225	-3	47	46.5	-0.5	F
5	142	140	-2	32	31	-1	F
6	180.5	173	-7.5	35.5	35	-0.5	F
7	268.5	261	-7.5	47.75	46	-1.75	M
8	183	179	-4	35.5	35	-0.5	F
9	149	151.5	+2.5	33	30	-3	F
10	150	147	-3	27	27	0	F
11	171	165	-6	35.75	32.5	-3.25	F
12	234	225	-9	43.5	37	-6.5	F
13	183	178	-5	39	37	-2	F
14	167.5	169	+1.5	42.5	41	-1.5	F
15	136	131	-5	33.5	32.75	-0.75	M

16	225	211	-14	43	40	-3	F
17	168.2	164	-4.2	34.5	31.5	-3	F
18	163	163	0	40	39	-1	F
19	305	296.5	-8.5	--	--	--	F
20	234	229	-5	44	42.5	-1.5	F
21	150	147	-3	35	34	-1	F

Table 3: Data for Advanced SP6 Complete Protocol Without Fasting (STUDY SITE 2)

Subject Number	Pre Weight (lb)	Post Weight (lb)	Change in Weight (lb)	Pre Waist (in)	Post Waist (in)	Changes in Waist (in)	Gender
1	150.5	152.5	+2	30.5	31	+0.5	F
2	161	155	-6	34	32	-2	F
3	180	165	-15	--	--	--	F
4	150	146	-4	38	36	-2	F
5	152	150	-2	33	32.5	-0.5	F
6	135	130	-5	33	31	-2	F
7	221	217	-4	38	36	-2	F
8	133.4	125.8	-7.6	34	32	-2	F
9	150	148	-2	29	29	0	F
10	142	134	-8	33	30	-3	F
11	168	165	-3	--	--	--	F
12	162	162	0	36	36	0	F
13	182	178	-4	39	37	-2	F
14	153	143	-10	39	34	5	F
15	280	255	-25	--	--	--	F
16	150	150	0	35	34.5	-0.5	F
17	171	173	+2	41	39.5	-1.5	F
18	198	190.5	-7.5	39	38.5	-0.5	M
19	141	137	-4	31.5	30.5	-1	F
20	162	158	-4	38.5	36	-2.5	M

- In the results for Study Site 1, the participants undertaking the advanced SP6 complete weight loss program fasting and without fasting (non-fasting) responded positively to this program and on average they shed off approximately 5.5 lbs (3%) of their original body weight and a reduction of 1.78 inches (4.64%) of their original waist sizes after 4 weeks.
- On average there was a higher percentage response to waist loss compared to weight loss in the total population at Study Site 1.
- In the results for Study Site 2, the participants undertaking the advanced SP6 complete weight loss program without fasting (non-fasting) responded positively to this program and on average they shed off 5.35 lbs (3.2%) of their original body weights and showed an average reduction of 1.53 inches (4.32%) of their original waist sizes after 4 weeks.
- On average there was also a higher percentage response to waist loss compared to weight loss in the population at Study Site 2.
- These results are in general agreement with the outcomes for the non-fasting group at study Site 1 tabulated in **Table 4** below, which showed an average weight loss of 4.92 lbs (2.57%) and a waist loss of 1.71 inches (4.46%). However, there were larger variations in percentage of weight and waist reduction at Study Site 2 compared to Study Site 1 and some subjects even experienced some weight gain. These complications were attributed to a number of issues and

were mainly due to carrying out the weight loss program during the festive season and the holidays.

Table 4: Succinct summary of SP6 weight and waist reductions at Study Sites 1 and 2

SP6 Protocol	Study Site	Average Weight Loss (lbs)	% of Average Weight Loss	Average Waist Loss (inches)	% of Average Waist Loss
With and Without Fasting	1	5.5	3.0	1.78	4.64
With Fasting	1	6.2	3.5	1.83	4.78
Without Fasting	1	4.92	2.57	1.71	4.46
Without Fasting	2	5.35	3.2	1.53	4.32

Assessment: *The summary of results indicates that there is general agreement between study outcomes at both independent sites. On average the SP6 Complete 4 week program produced positive outcomes at both study sites with approximately 5 lbs of weight loss and a waist size reduction of more than 1.5 inches. There was a 20% improvement in weight loss efficacy due to initial 2 day fasting compared to the non-fasting option. There was a 6.5% improvement in waist loss efficacy due to initial 2 day fasting compared to non-fasting option.*

Statistical analysis results of data acquired at both Sites 1 and 2 for the waist reduction data reveals that no statistical significance was achieved for the SP6 waist size reduction program during the 4 weeks. Further analysis of the data acquired in this preliminary investigation revealed that to achieve statistical significance in weight and waist size reduction a weight or waist size loss of about 10 percent (effect size) in a study population with comparable sample sizes with and without fasting may produce desirable outcomes.

This objective could be achieved by a number of different approaches in protocol design in future studies. For example the strength of acupuncture stimulation of SP6 appetite control patch could be increased or the duration of undertaking the program could be increased to more than 8 weeks or a larger population should undertake the weight loss program.

Study Report #3: Gruenwald, I. 4-Week Weight/ Waist Loss Study Using SP6 Complete: Basic Protocol.

Safety issues:

- Two reported cases of headaches and thirst and five subjects reported constipation. Subjects who reported the reactions chose to complete the study and the event resolved.

Patch instructions and study procedures:

- Twenty subjects participated in this single-site, open label study in evaluating the effectiveness of the system in weight reduction and decreasing waist circumference after four weeks of use.
- All subjects used the same protocol which did not include the two-day fast option.
- Average age of subjects was 47.7 and 14 females and 6 males participated.
- One person dropped out because he couldn't tolerate the taste of the meal replacement shake.
- Acupoints: The SP6 Patch was rotated between Stomach 36 and Kidney 3.

Efficacy of the system in this study:

- Overall, use of the SP6 Complete in 20 subjects showed a significant effect on both waist and weight loss during a period of 4 weeks (see **Table 5** and **Table 6**).
- If success is defined as an average decrease of 3-3.5 Kg in weight and 3-6 cm in waist circumference, we can easily say that the sp6 complete is effective for these results in 75% of the cases.
- Best result of weight loss over four weeks (13 Kg.) was achieved by females.
- Best result of waist loss over four weeks (20 cm.) was achieved by females.
- Significance of differences in average results are difficult to interpret due to low male participant numbers.
- Four subjects did not experience any change in weight nor waist, on dropped out (hence the 75% success rate).

Table 5: Overall Waist Loss Data

	Initial waist	End waist	Average waist loss	Best result of waist loss
Min (cm)	89	86	5.2	20
Max (cm)	138	138		
Average (cm)	109.2	104		

Table 6: Overall Weight Loss Data

	Initial weight	End weight	Average weight loss	Best result of weight loss
Min (Kg)	59	58	3.3	13
Max (Kg)	113	107		
Average (Kg)	85.4	82.1		