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Chapter 7

New Development in Sham Acupuncture Needle

Sungchul Kim

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/55113

1. Introduction

Since the inception of clinical research into acupuncture, the dilemma of how to create an appropriate placebo for acupuncture research has hindered the progress. There has been no good method of managing all confounding variables, particularly the implementation of double-blind method into experiments.

Due to the lack of an appropriate placebo, the general scientific society has questioned studies on the effects of acupuncture. The double-blind, placebo-controlled clinical trial is said to be the gold standard for showing that a treatment has a specific effect over placebo. But acupuncture treatments undoubtedly involve placebo effects. In order to support the study of acupuncture's effects and to give more credibility to acupuncture studies in the era of the EBM(Evidence Based Medicine), a thoroughly tested double-blind placebo for acupuncture needs to be developed.

2. The need for developing a successful sham acupuncture

Experimental studies of acupuncture have been actively conducted to discover new evidence for acupuncture treatment. To facilitate acupuncture research, the Standards for Reporting Interventions in Clinical Trials for Acupuncture (STRICTA) were published in 2010 as a revision of the 2002 version[1]. Blind study designs are the most important method for diminishing the placebo effect and bias. Due to the lack of an appropriate placebo method, few studies have been conducted in compliance with the standard guidelines for placebo-controlled clinical trials. So far by having appropriate placebo models, research on medical drugs has been advancing strongly while the research on the effects of acupuncture have remained using either single-blind or without any blinding in the study at all. A sham acupuncture needs to

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be developed for the purpose of double-blind, placebo control research. Acupuncture treatment holds a unique position in the medical research community in that most believe that it cannot be administered in a way both acupuncturist and patient do not know whether the patient is receiving real or sham treatment.

The patient receiving the placebo treatment should believe that they are receiving the real treatment, which entails giving the treatment without actually performing any sort of legitimate operation but still being impossible to distinguish from real treatment.

3. Previous studies in Sham acupuncture

Presently there are several sham acupuncture needles that have been invented. Some methods used the Placebo which is pricking[2-3] and superficially stabbing without manipulation at inappropriate acupoints which is not traditional acupuncture point located in the meridian[4]. However, these minimal acupunctures are inadequate Placebos because they can have physiological effects such as DNIC (Diffuse Noxious Inhibitory Controls) on the patient[5-6].

Sham TENS[7-8], sham tablets[9] and un-operative laser acupuncture[10] have been used as control groups, however their effects cannot be appropriately identified as truly having a placebo effect[11] as the participants were comparing their treatment to the real acupuncture group afterwards and finding differences which will cause non-placebo psychological effects. Several other placebo methods include: simply poke the subject with the fingernail[12], without breaking the skin;. stimulating with the acupuncture pipe[13] on the skin and lightly pricking with a real needles on the superficial skin[14];using placebo acupuncture needle with flat tip and only let the acupuncture needle enter to the plastic stopple at the edge of the acupuncture pipe[15] and not puncture the skin but only pressed it[16].

In addition, Streitberger and Kleinhenz, Park et al. developed sham acupuncture devices.

Streitberg's method was designed to use a blunted needle inserted into a prop to give the appearance that acupuncture was being administered through the skin when it was not[17]. By using this method as a placebo in an experiment on the clinical treatment of rotator cuff tendonitis in sportsmen, the results acquired favored real acupuncture over sham acupuncture[18] (Figure 1).

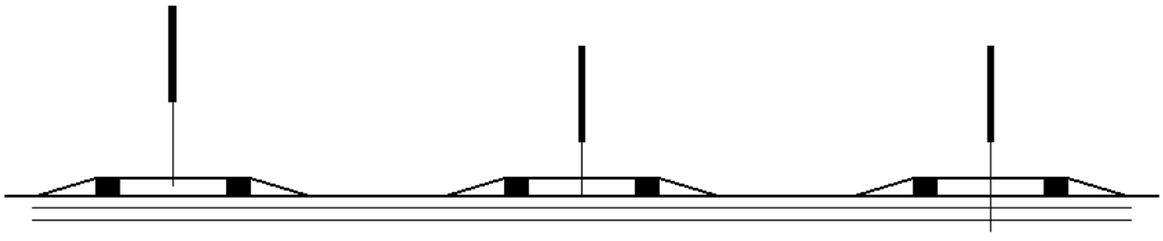


Figure 1. Streitberger and Kleinhenz sham and real needle

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Park's sham needle[19] was invented independently from Streitberger and Kleinhenz. The apparatus consists of a blunted needle, the shaft of which telescopes into the handle when tapped, so that, while the needle appears to have been inserted, it does not actually pierce the skin. And this consists of an oversize guide tube with a silicon flange at one end which adheres to the skin with double-sided tape. This needle diameter is 0.35mm and its length is 70mm including handle. Real needling can be performed to a depth of up to 15mm. In the published validation study, 22% of volunteers could feel a dull sensation with the sham needle, compared to 57% with a real needle. This needle has not been correctly validated in terms of *deqi* (specific needling sensation) (Figure 2).

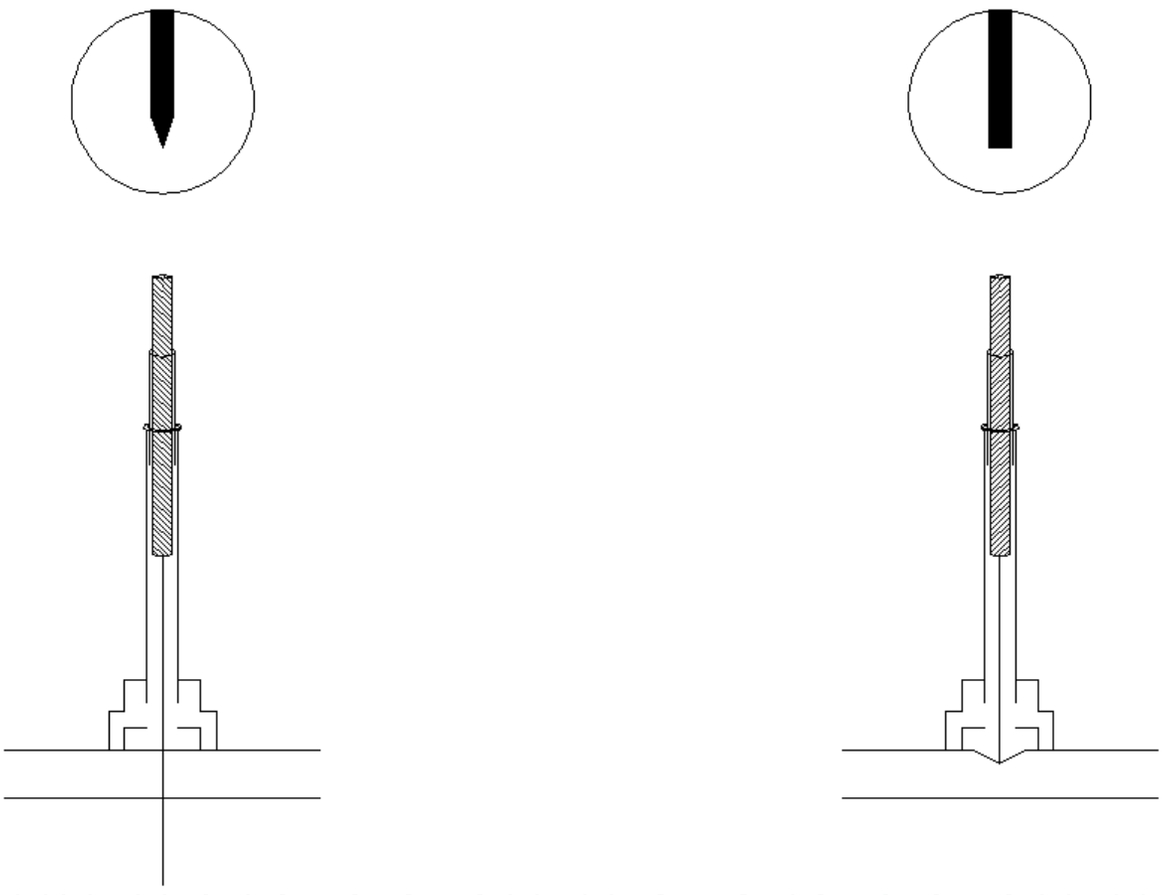


Figure 2. Park's real and sham needle

Miyazaki et al.[20] conducted a double-blind clinical trial to compare a press needle to a placebo lacking the needle element. Because of the characteristics of these devices, the ability to blind subjects was limited and double-blind studies are difficult to administer. Therefore, few studies have been conducted in compliance with the standard guidelines for placebo-controlled clinical trials to address this problem. Fregni et al.[21] claimed that an important challenge in using a placebo is the development of a sham device that has a similar appearance and induces a feeling similar to that induced by the real device.

Despite all of this difficulties, Kim[22] came to believe that one could create a type of sham acupuncture needle that would be identical to a real acupuncture needle in structure, color, and form but not break the skin because its edge, while appearing virtually identical to the real needle, is in fact blunt.

4. What is Kim's Sham needle?

Kim's sham acupuncture needles was invented as an intradermal T-shaped needle (thickness 0.2 mm, length 1.5 mm, diameter 2 mm).

The sham needles use the exact same manufacturing machines as the real type T. The structure, color, and shape of the sham needle (pre-produced by Dongbang Acupuncture Company, South Korea) were the same as that of the real needle with the exception of the blunt tip. This blunt tip makes it impossible to insert the needle into the skin, and the tactile sensation is similar to that of the real T-shaped intradermal needle. The patch consists of 3 layers, with the first and second film layer securing the needle to the patch and the third layer possessing the adhesive that attaches the needle to the patient's skin. The needle is still 1.5mm long and is secured to the patch to make vertical 90° contact with a skin (Figure 3 and Figure 4).

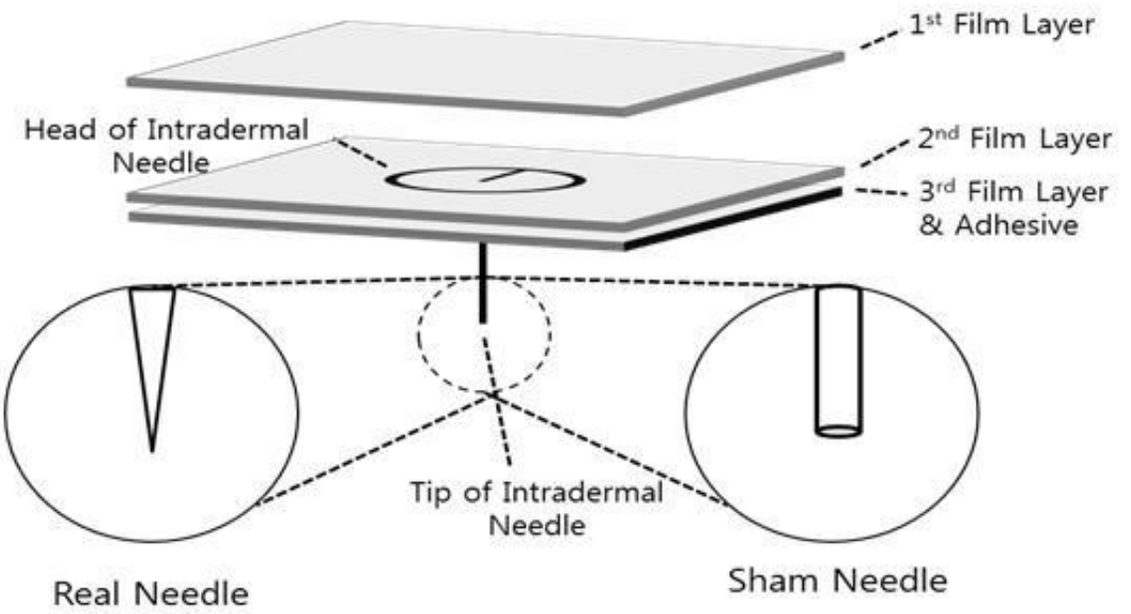


Figure 3. Differences between real needle and sham needle shape - The structure, color, and shape of the sham needle were the same as that of the real needle with the exception of the blunt tip.

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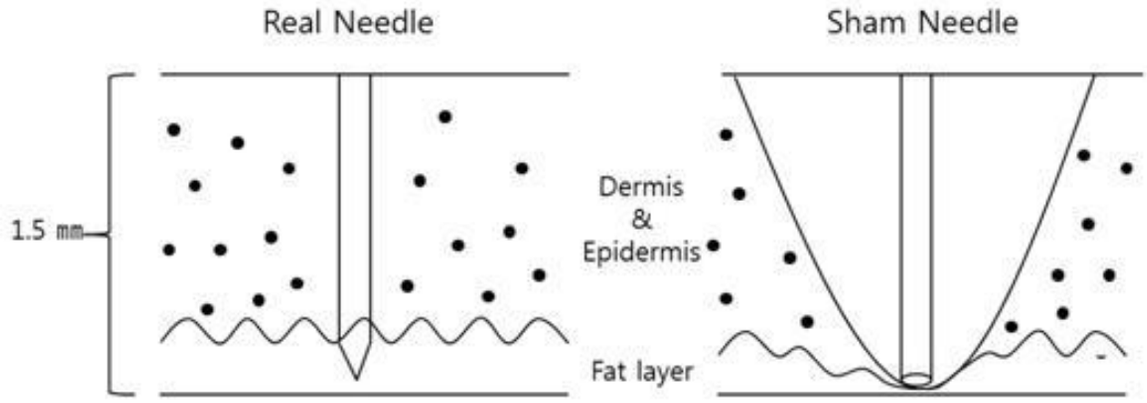


Figure 4. Difference between real needle and sham needle stimulation – While the real needle tip is inserted into the epidermis invasively, the sham needles tip simply presses the skin surface non-invasively.

In the packaging process, damage can occur to the tip of the intradermal needle, so suitable holder's development can overcome this problem. This holder was made using a transparent material to see whether or not the needle tips were damaged (Figure 5 and Figure 6).

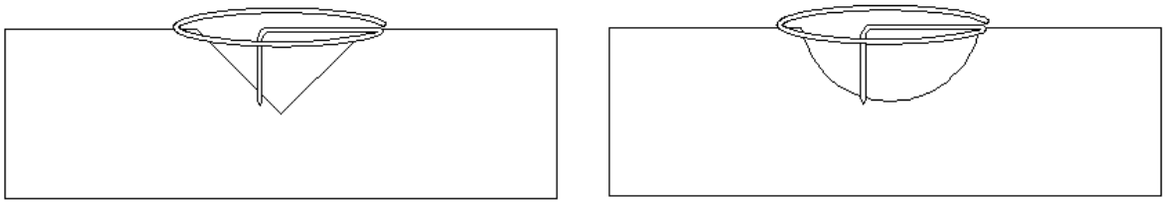


Figure 5. Ineffective sham acupuncture needle holders designs

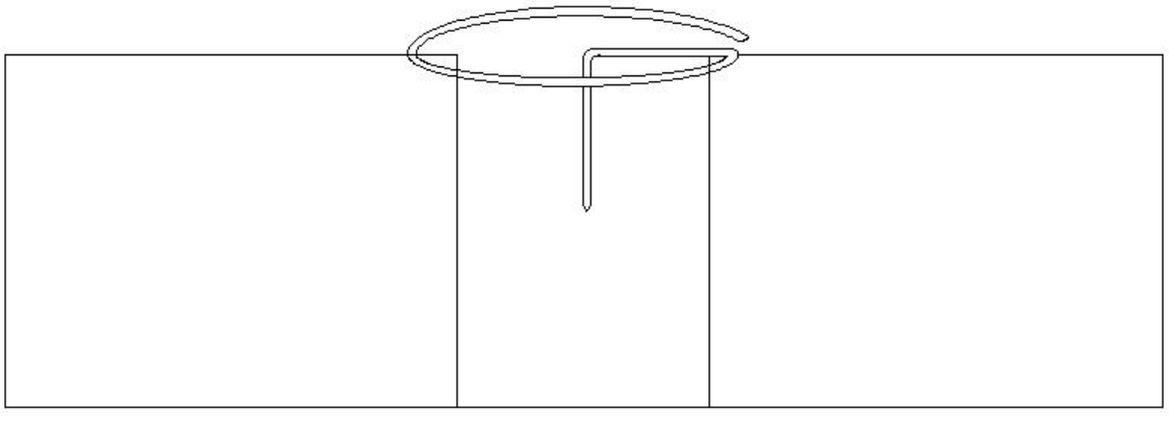


Figure 6. Manufactured Kim's sham acupuncture needle holder design

In the 2003 edition of Lee's paper[23], the placebo needles were manufactured type T needles that Lee cut down to 1mm with scissors. This method however caused problems with irregu-

larly shaped needles, some of which that may have actually punctured the skin like a real needle. Kim's sham acupuncture avoids this by using standardized mechanical manufacturing methods that create needles with the same length as real needles and that have edges that will not puncture the skin. In 2004, Menjo tried to test the possibility of a double blind for a sham 0.6mm dermal acupuncture needle at the 1st J-K Workshop meeting in Chiba, Japan. This acupuncture needle is shorter than the mean depth (1.5mm) of the adult dermis. It is very difficult to really prove the effects of acupuncture because the same real needle can't successfully stimulate the skin. Kim's sham acupuncture avoids this problem by using 1.5mm long needles. These experiments were also not successfully implemented in a double-blind manner. Kim's sham acupuncture has the result of using an iron needle to perform subcutaneous stimulation and maintained acupuncture fixed to the skin with a form evolved from classical slight acupuncture to modern short acupuncture. Generally, during normal acupuncture, the acupoint is selected for its corresponding internal organ or for being a tender point, Posterior Referred Point, Limb Referred Point, or Ear Point chosen by meridian theory. The adaptation range is largely applied to chronic internal organ diseases and chronic multiple pains. Kim's sham acupuncture gains several advantages from imitating endermic acupuncture. The simplicity of the puncturing method, the length of treatment (needles remain in for 2 to 3 days), and the uniformity of hand techniques results in standardization of the procedures. This makes Kim's sham acupuncture ideal for the research of endermic acupuncture's effect on pain.

5. Validation study of Kim's Sham needle

In order to investigate the possibility of sham acupuncture's application, we examined how well subjects who are accustomed to acupuncture treatment could distinguish between real acupuncture and sham acupuncture.

5.1. Determination of real from sham acupuncture by apperance or sensation

Prior to participating in the study, a consent form "Will you please participate in research comparing the appearance and feeling between real acupuncture and sham acupuncture." was obtained from the subjects. The selection criteria were similar with receiving acupuncture treatment. The study targeted 537 people who agreed to participate in the study. Amongst the those 537 people targeted, 120 of them were acupuncturists, 417 of them were from the general public, of which 150 were Korean and 57 were non-Korean.

Group A consisted of 60 Koreans drawn from the public, 40 acupuncturists and the 57 Non-Koreans drawn. These participants were trying to distinguish the real or sham acupuncture needles and all subjects were randomly selected and allocated to the trials by computer (Table 1). Prior to participating in the study, subjects were given a consent form "Will you please participate in research comparing the appearance and feeling between real acupuncture and sham acupuncture." Subjects had been selected for being familiar with receiving acupuncture treatment such as hospital patients, acupuncture assistants and acupuncturists working at the hospital of Korean medicine at Won Kwang University in South Korea and U.S. citizens.

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Group B consisted of 60 Koreans drawn from the public, 40 acupuncturists and the 57 Non-Koreans from the public. In this study participants received real or sham acupuncture treatment in the LI4 acupoint and were then asked to distinguish whether the treatment was real or sham (Table 1).

Group C consisted of the remaining 30 Koreans drawn from the public, 40 acupuncturists and the 57 Non-Koreans drawn from the public. In this study participants were shown real and sham acupuncture using the double-blind method in their left and right hands in varying orders as well as being given acupuncture in the LI4 acupoint. After receiving treatment in both hands, the subjects were asked to identify which hand received the real acupuncture. Whether the needle was placed on the right or the left was randomized to eliminate potential bias. Those who could not distinguish between the two needles after treatment were recorded as "wrong answers" (Table 1).

(C-1) left -real- right - real

(C-2) left -sham- right - sham

(C-3) left-real-right-sham

(C-4) left-sham-right-real

Subjects		***Public (120 Korean)***		***Acupuncturists(40)***		***Public(57Non-Korean)***	
Methods		**Correct**	**Incorrect**	**Correct**	**Incorrect**	**Correct**	**Incorrect**
A	From appearnce	N=67(56%)	N=53(44%)	N=18(45%)	N=22(55%)	N=31(54.4%)	N=26(45.6%)
		P=.201		P=.527		P=.508	
B	From sensation	N=68(57%)	N=52(43%)	N=22(55%)	N=18(45%)	N=27(47.4%)	N=30(52.6%)
		P=.144		P=.527		P=.691	
C	From appearnace and sensation	N=59(49%)	N=61(51%)	N=14(35%)	N=26(65%)	N=16(28.1%)	N=41(71.9%)
		P=.855		P=.058		P=.001**	

Table 1. Results from the public and acupuncturists in correctly distinguishing real and sham acupuncture treatment. The analysis of the statistics were done with a chi-square test which produced a statistically significant result at the p<0.05 * and p<0.01**level.

Regardless of whether the subject is an acupuncturist or a regular acupuncture patient; the order in which real and sham acupuncture are performed; or the exposure to the needle's appearance, the subjects ability to discriminate real endermic (intradermal) acupuncture from Kim's sham acupuncture was between 28.1% and 57%.

Examining the results of this experiment, the acupuncturists were unable to distinguish between real and sham acupuncture treatment by either appearance or sensation. It also may be inferred that the general public cannot distinguish by sensation whether it was real or sham acupuncture treatment and that this may indicate that Kim's sham acupuncture could be applied to other double-blind acupuncture clinical studies.

5.2. Validation study of Kim's Sham needle by measuring facial temperature[24]

Physiological stimulation of Kim's sham needle is different from that of a real needle. This study tested the feasibility of using Kim's sham needle in a double-blind clinical trial on the efficacy of acupuncture to reverse smoking-induced decreases in facial temperature.

This was conducted in N-of-1 randomized controlled trial with a double-blinded evaluation process, and the results were based using a statistical analysis. N-of 1 trials can be used in medical practice to determine the optimum treatment for an individual patient.

Seven healthy male smokers who met the following inclusion criteria were enrolled in this clinical trial.

The inclusion criteria was as follows : (1) a submission of the written informed consent, (2) a lack of exercise within the previous 24 hours, (3) a lack of intake of tobacco, alcohol, green tea and coffee within eight hours and (4) more than one hour elapsing after a meal before participating.

The exclusion criteria were as follows: (1) subjects with cardiovascular diseases,including hypertension, arrhythmia, and ischemic heart disease, (2) those with endocrine diseases, including diabetes mellitus and thyroid diseases, (3) those with kidney diseases, including chronic renal failure, (4) those with a past history of surgery for diseases, such as gastric cancer, (5) those with febrile diseases, such as epileptic seizure, and (6) other cases (e.g., dysautonomia, cancer or alcoholism).

	A	B	C	D	E	F	G
1	Sham	Verum	Verum	Sham	Sham	Sham	Sham
	Verum	Sham	Sham	Verum	Verum	Verum	Verum
2	Verum	Sham	Verum	Verum	Verum	Sham	Verum
	Sham	Verum	Sham	Sham	Sham	Verum	Sham
3	Verum	Verum	Sham	Sham	Sham	Verum	Sham
	Sham	Sham	Verum	Verum	Verum	Sham	Verum
4	Sham	Sham	Verum	Sham	Verum	Sham	Sham
	Verum	Verum	Sham	Verum	Sham	Verum	Verum
5	Sham	Verum	Sham	Verum	Sham	Verum	Verum
	Verum	Sham	Verum	Sham	Verum	Sham	Sham
6	Verum	Sham	Verum	Sham	Verum	Sham	Sham
	Sham	Verum	Sham	Verum	Sham	Verum	Verum

Table 2. Allocation of stimulation

The subjects were randomized and one set of needles was chosen randomly for use in one session of the trial(Table 2). The set was composed of two types of needles: a real needle and a sham needle. The experimental sequence of the needle types was set randomly by a third

party. Both the physicians and subjects were blinded using a masking test. One session was composed of two stimulations separated by a two hour washout period.

Following traditional Korean medicine literature, 'Saam Five Element Acupuncture', HT8 and KI2 acupoint on both sides were selected to stimulate the blood circulation. All the operations were performed by the acupuncturist according to the WHO(World Health Organization) criterion[25]for standard acupuncture point locations (Figure 7).

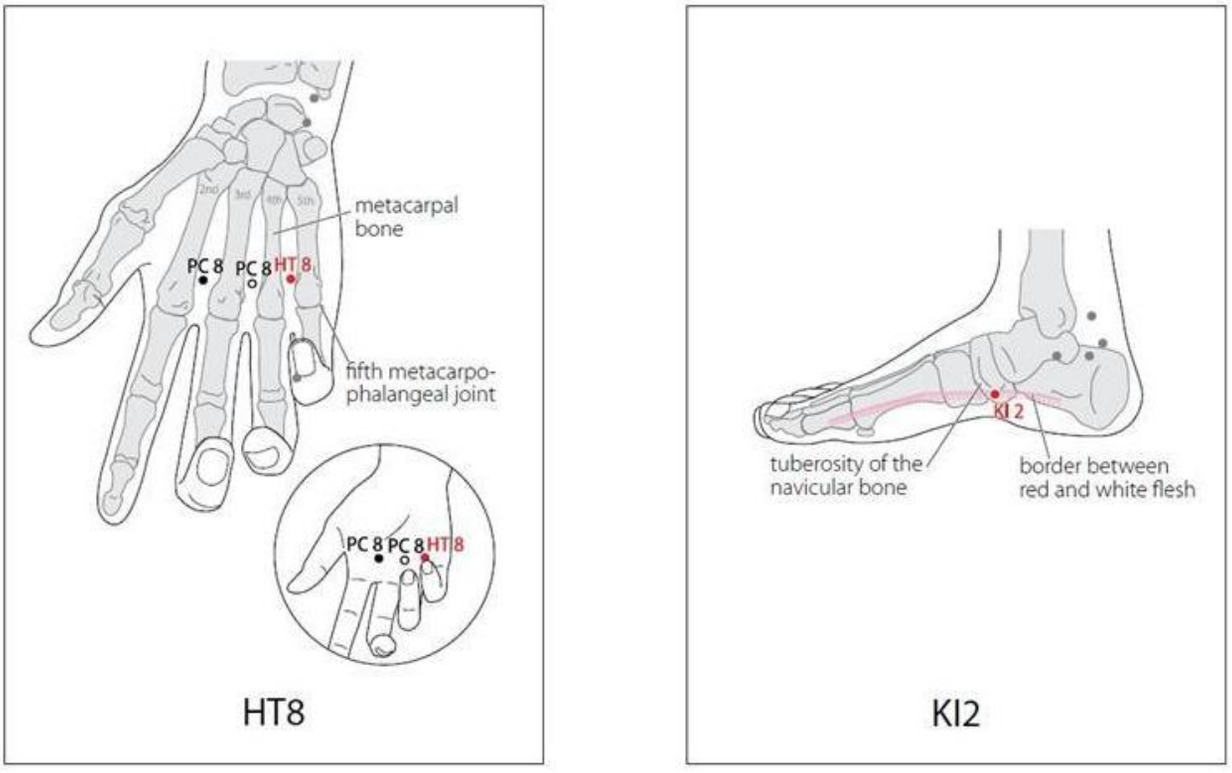


Figure 7. Location of selected acupuncture points for tonification of heart fire – HT8 is used to generate warmth by tonification of the heart fire and KI2 is used to generate warmth by tonification of the kidney fire. The selection of acupuncture points located were based on the publication of WHO standard acupuncture point locations.

The experimental procedures were as follows:

i. Following a thirty minutes stabilization period, the subjects were encouraged to smoke 1 cigarete during 3minutes (DunHill Light, Korea).

ii. After five minutes (once smoking was finished), with the use of DITI(digital infrared thermographic imaging, Dorex, DTI-16UTI, U.S.A.) photography, the facial temperature was photographed.

iii. Either an invasive needle or noninvasive needle was randomly applied to the subjects.

iv. After retaining a needle for fifteen minutes, DITI photographs were taken again.

v. Following a two hour rest period, the subjects were encouraged to smoke 1 cigarete during 3minutes.

vi. After five minutes (once smoking had finished), DITI photographs were taken again.

vii. Subjects were received the remaining needles.

viii. After retaining a needle for fifteen minutes, DITI photographs were taken again.

The above procedure was considered one pair. 1 pair of procedure was carried out six days with each subject (Figure 8.).

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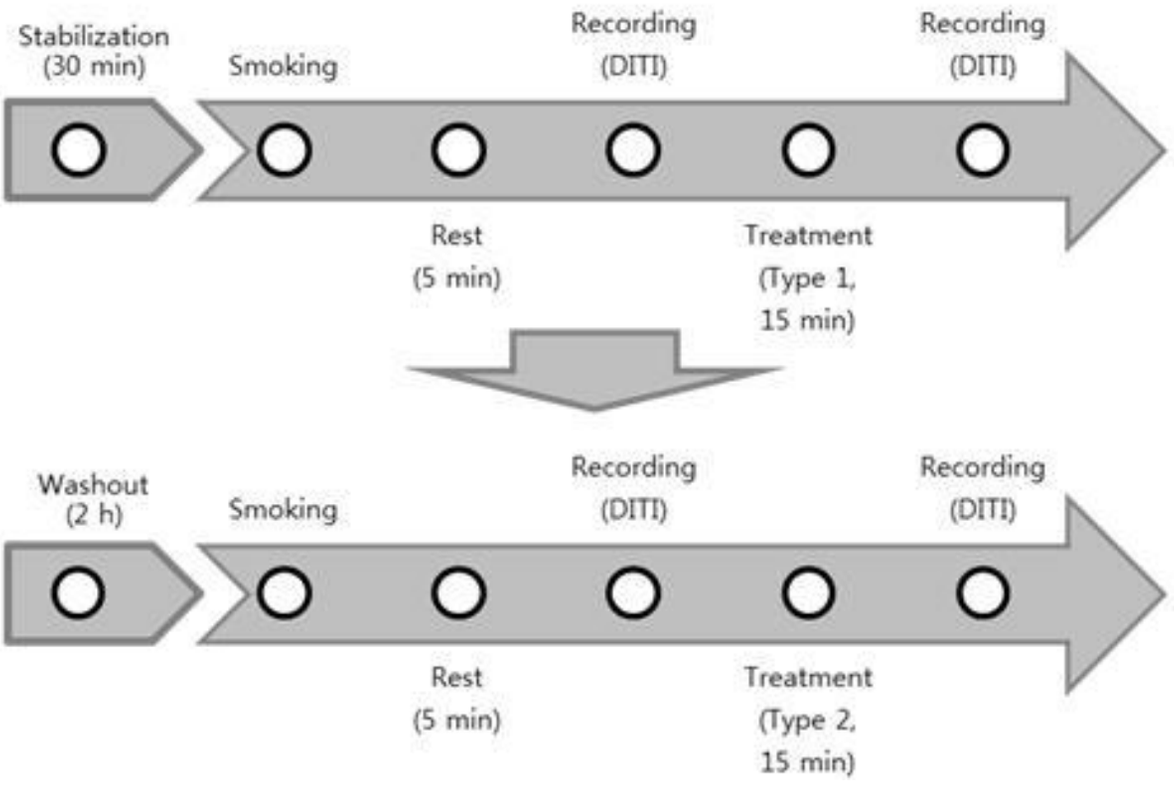


Figure 8. Flow of participants through the trial - The top panel represents the first treatment (either sham or real) that the subject underwent. This was followed by a 2 hr. washout period followed by the alternate treatment (either real or sham), as shown in the bottom panel.

DITI (digital infrared thermographic imaging, Dorex, DTI-16UTI, U.S.A.) was used to measure facial temperature, it is a method of measuring body temperature the apparatus for which is

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installed in a photographic laboratory (DITI studio). The mean temperature was measured by drawing a circle with a diameter that extended from a 1 cm above the median point between the eyebrows to 1 cm below the midpoint of the philtrum midline.

In subjects who were treated with a sham needle following smoking, DITI showed a marked decrease in facial temperature (Figure 9). In subjects who were treated with a real needle following smoking, however, DITI showed a marked increase in the facial temperature (Figure 10).

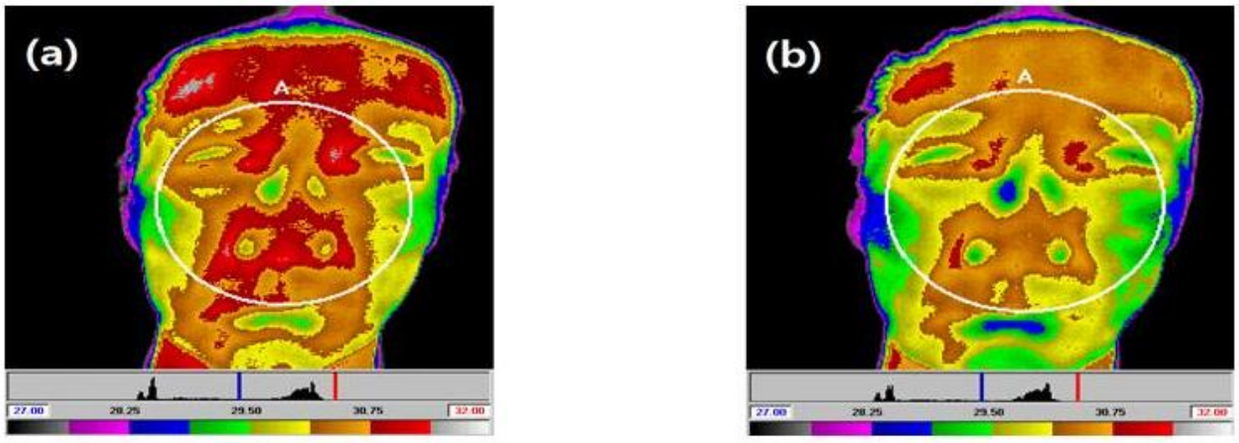


Figure 9. Facial temperature before and after treatment with a sham needle - The changes in facial temperature after smoking (a) and after being treated by sham needle (b). After treatment with sham needle, the average facial temperature shows an overall decrease. On the color bar below the photos, lower temperatures are located on the left.

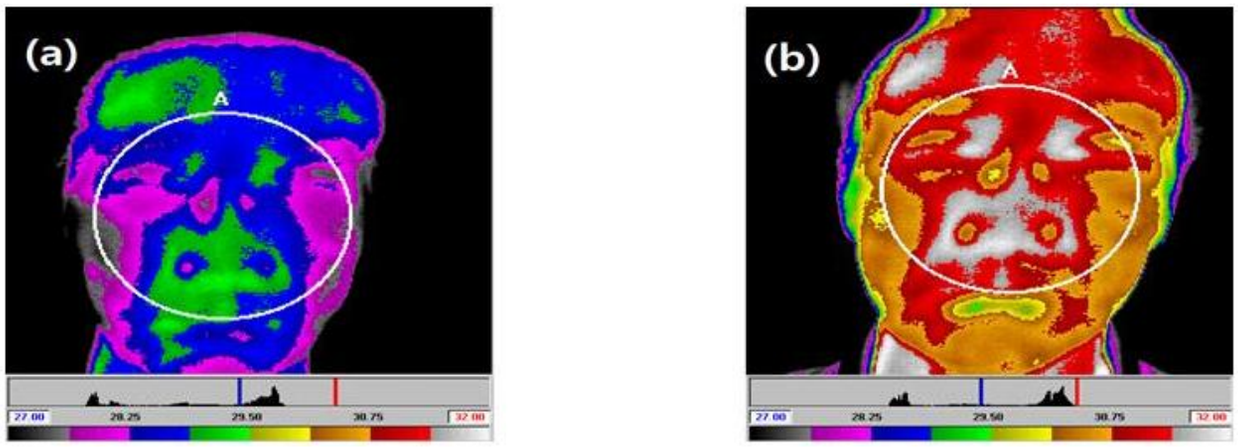


Figure 10. Facial temperature before and after treatment with a real needle -The changes in facial temperature after smoking (a) and after being treated by real needle (b). After treatment with a real needle, the average facial temperature shows an overall increase. On the color bar below the photos, higher temperatures are located on the right.

Considering the mean values of the differences in facial temperature, all subjects demonstrated decreased facial temperatures after treatment with sham needles, while 5 of the 7

subjects showed increased facial temperatures after treatment with real needles. Where as for 6 of the 7 subjects, a paired-sample T-test showed a significant difference ($p < 0.05$) in the facial temperature between the treatments with real and sham needles (Table 3 and Figure 11).

Subject	Needle	After smoking(°C)	After needling(°C)	Temperature difference(°C)	* P value < 0.05 ** P value < 0.01 (paired t-test)
A	Real	30.01±0.99	30.89±1.03	0.87±1.60	0.0270*
	Sham	30.71±0.96	29.89±1.20	-0.81±0.35	
B	Real	31.72±0.62	31.78±0.53	0.06±0.20	0.0072**
	Sham	32.04±1.32	31.65±1.41	-0.38±0.33	
C	Real	32.05±0.94	32.01±0.72	-0.03±0.26	0.0138*
	Sham	31.66±0.42	31.23±0.33	-0.43±0.26	
D	Real	31.16±0.92	31.50±0.73	0.20±0.39	0.0164*
	Sham	31.57±0.71	30.90±1.01	-0.67±0.92	
E	Real	31.86±1.10	32.17±1.01	0.31±0.32	0.0688
	Sham	32.49±0.65	32.20±0.37	-0.28±0.67	
F	Real	32.60±0.76	32.36±0.68	-0.24±0.21	0.0450*
	Sham	33.24±0.79	32.42±0.74	-0.81±0.39	
G	Real	32.32±1.03	32.67±0.78	0.34±0.34	0.0431*
	Sham	32.97±0.51	32.47±0.45	-0.50±0.57	

Table 3. Temperature changes after smoking and treatment with real or sham needle.

In conclusion, an N-of-1 trial was performed to validate Kim's sham by measuring facial temperature. Real needle treatment after smoking caused a significant increase in the facial temperature in 6 of 7 subjects compared to Kim's sham needle. This result indicates that Kim's sham needle has a different physical effect on skin temperature. After acupuncture treatment

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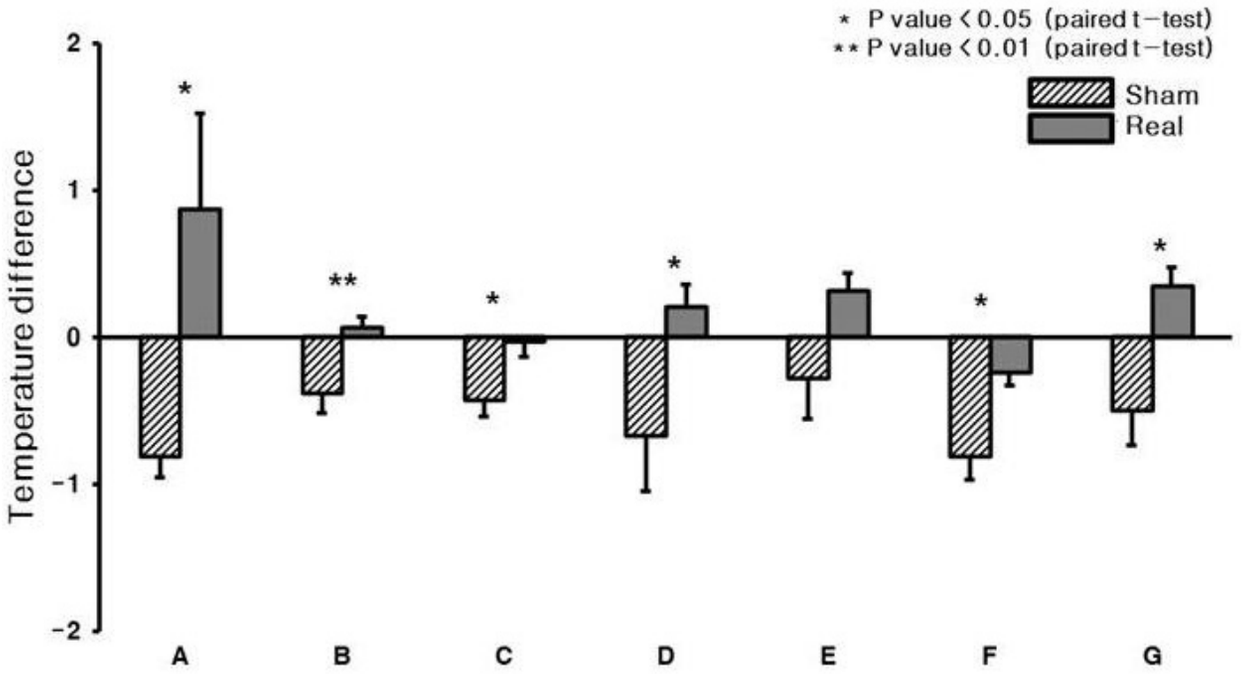


Figure 11. Temperature change before and after treatment with real or sham needle: Seven male smokers (A–G) were treated with either a sham needle or a real needle 5 mins after smoking and their facial temperature was monitored by DITI. The results show that treatment with a sham needle resulted in an overall decrease in facial temperature, while treatment with a real needle resulted in an overall significant increase in facial temperature in 6 subjects. Values on the graph represent the mean (SD) of 6 independent treatments with 2 hr intervals.. **For six out of the seven subjects,a paired sample T-test showed a significant difference ($p<0.05$) in facial temperature between treatments with verum and sham needle.**

with the sham needle, facial temperature decreased in all subjects. However, in real needle group, facial temperature increased in five subjects and decrease in two subjects. An analysis of seven subjects was performed using a paired T-test, and the results showed that all subjects but one had a significant difference in facial temperature. These results indicate that the real needle was more effective than the sham needle in raising the temperature, which was initially lowered because of smoking. However, Kim's sham needle was a realistic enough simulation to raise peripheral skin temperature.The results showed that real and sham acupuncture were significantly different in six of seven subjects. Further studies using this sham needle might provide more evidence and improve the scientific quality of clinical trials on acupuncture.

6. Conclusion

In conclusion the study on Real versus Sham needle the results show that the acupuncturists, Koreans and Non-Koreans were all unable to distinguish between Real and Sham needles. Also in the study for validation the effectiveness of the real needle, the results

showed that the real needle caused a significant increase in the facial temperature of smokers, compared with the Sham needle. Indicatory that the Sham needle has a different physical effect on the skin. As these studies were carried out as a double blind trial. The results would infer that Kim's Sham needle could be applied to the double blind study of acupuncture. Further research regarding acupuncture and non-acupuncture point treatments with real and sham needles may help garner sufficient scientific evidence to validate Kim's sham needle and increase scientific precision and accuracy in clinical trials on acupuncture.

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Acknowledgements

The author wishes to thank Dr. Sanghun Lee for help in obtaining good information on Kim's sham needle holder design and also thanks Dr. Sunmi Choi at the Korea Institute of Oriental Medicine and Sungha Kim at the Wonkwang ALS clinical center in South Korea.

Author details

Sungchul Kim[1,2,3*]

Address all correspondence to: kscndl@hanmail.net

1 Wonkwang University in Iksan, South Korea

2 Wonkwang University Oriental Medicine Hospital in Gwangju, South Korea

3 Won ALS Clinical Center, South Korea

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