



Review Article

Trends in the Development of Sham Acupuncture-Related Technologies Focused on Patents Applied for in South Korea

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ABSTRACT

Background: This study aimed to analyze the trends in Korean patents for sham acupuncture.

Methods: The electronic database of the Korea Intellectual Property Rights Information Service was searched for Korean patents for sham acupuncture from inception till September 2020. Patents, which were not related to sham acupuncture, were excluded. The applicant, application date, International Patent Classification, and technological content of sham acupuncture were analyzed.

Results: This study included eight patents. Application analysis identified the following sham acupuncture types: four (50%), two (25%), and two (25%) patents were for non-penetrating sham acupuncture, electronic sham acupuncture, and patch sham acupuncture, respectively. All patents aimed to use sham acupuncture as a control for rigorous double-blind clinical trials to verify the efficacy of real acupuncture treatment.

Conclusion: The present findings suggest that technological advances were focused on developing various types of sham acupuncture methods for double-blind studies. Further large-scale studies using rigorous designs are needed to investigate new sham acupuncture applications.

Keywords: Korean patent, patent, patent analysis, review, sham acupuncture

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Introduction

Acupuncture is among the most commonly used alternate-medical treatments worldwide. Sham acupuncture control-treatment is required to investigate the effects of acupuncture, since acupuncture can be used to treat myriad diseases [1].

Numerous clinical trials have evaluated the efficacy of acupuncture treatment and used the comparison with sham acupuncture reports to indicate whether acupuncture treatment was effective or not. Therefore, appropriate acupuncture control groups should be established to improve the quality of clinical trials [2,3].

In evidence-based medicine, the effect of a specific intervention can only be tested by randomized controlled trials (RCTs). For a successful RCT, it is important to establish a control that has no specific effect and allows blinding [4,5]. For sham acupuncture, the method of needling points other than traditional acupoints or needling acupoints that are unrelated to the therapeutic purpose being tested may be

used. However, these methods could still elicit physiological activity and are thus not appropriate placebo-control methods [6].

The difficulty in designing an appropriate control group is one of the biggest controversies faced by clinical trials on acupuncture. Consequently, sham acupuncture controls, including Streitberger's needle [7] and Park sham needle [8], have been developed and used in related clinical trials.

Non-invasive sham acupuncture needles have been developed with dull points so that they are unable to penetrate the skin; participants are unable to visually distinguish between sham and real acupuncture needles, thereby permitting blinding.

Patients should be blinded to the sham acupuncture and should be unable to distinguish the placebo from real acupuncture in an ideal sham acupuncture procedure. Moreover, a placebo that is intended for use as a control should not have physiological or biological effects. However, the currently available non-penetrating sham acuapunctures barely meet the above-mentioned prerequisites [9].

In the future, sham needles should appear more similar to real acupuncture needles or result in psychological effects, while minimizing their physiological effects on the human body. This would enable maintaining the blinding of participants or investigators over a long period during the clinical trial for them to be effective as ideal sham acupuncture controls.

The recent advances in science and medical technology can be elucidated by collecting and analyzing the relevant patent information, which is used to develop new technology and actively promote technological competitiveness [10]. Upon analyzing patent trends in sham acupuncture, we can utilize information on the current advances for the development of sham acupuncture-related technologies. Taking into consideration the overall patent trends can facilitate novelty and innovation of sham acupuncture techniques.

Therefore, this study aimed to seek and analyze information on the currently filed or granted Korean patents for sham acupuncture. We aimed to systematically analyze the current status, content, and technical features of sham acupuncture-related patents, and obtain basic data for developing new sham-acupuncture procedures in the future.

Materials and Methods

An electronic search for Korean sham acupuncture patents was conducted using the database of the Korea Intellectual Property Rights Information Service (KIPRIS). The KIPRIS provides a database of all domestic intellectual property-related information held by the Korean Intellectual Property Office. The following search terms were used as of September 15, 2020: “sham acupuncture” OR “placebo acupuncture” OR “blind acupuncture.”

The patents identified by the electronic search were screened. First, the title and abstract of each patent were reviewed to exclude irrelevant records. Subsequently, the full text of the records was reviewed if the summary was unclear and irrelevant records were excluded. Data were extracted from the selected patents based on a predetermined data extraction method.

The following parameters that pertained to the overall status of the patents for sham acupuncture were obtained: 1) the final status, application year, and applicant of each patent; 2) patent analysis according to the International Patent Classification (IPC); and 3) patent analysis according to specific technological features.

Results

1. Search results

A total of 23 patents were searched and 15 patents were excluded, since they were irrelevant to the research. Eleven of the 15 disqualified patents were not related to acupuncture as identified by the first selection and elimination process; furthermore, two patents were excluded during the second selection and exclusion process, in addition to the remaining two patents regarding pad for acupuncture. Finally, eight patents were included in the final analysis (Fig. 1).

2. Final status, application year, applicant of the patents

The final status of the sham-acupuncture patents was as follows: six were registered patents, one was a patent application, and one patent had expired; thus, the proportion of registered patents was the highest. One, one, and six patent applications were made in 2000, 2006, and after 2014, respectively; thus, there was trend of steady filing and granting of patents after 2014 (Table 1). The National Rehabilitation Center had the highest number of patent applications for sham acupuncture ($n = 3$), followed by the University-Industry Cooperation Group of Kyunghee University ($n = 2$), Korea Institute of Oriental Medicine ($n = 1$), and Hanada College ($n = 1$; Table 1 [11-18]).

2.1. Patent analysis according to the International Patent Classification

To analyze the sham acupuncture patents according to the IPC, 24 IPCs, including all the IPCs described in the eight

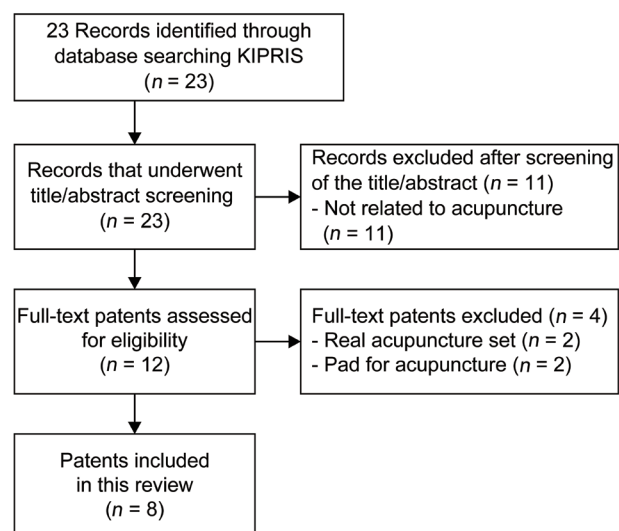


Fig. 1. Flow chart of the patent selection process.

Table 1. Status and Applicants of Patents.

Types of SA	Inventor	Applicant	Application (y)	Final status	Title
Non-penetrating SA	Takakura N [11]	Hanada College	2000	Registration	Safe needle, placebo needle, and needle set for double blind
Non-penetrating SA	Park KM, Lee JH, Lee SH [12]	University-Industry Cooperation Group of Kyung Hee University	2014	Registration	Sham acupuncture needle set
Non-penetrating SA	Lim SM, Lee EJ [13]	National Rehabilitation Center	2016	Registration	Non-penetrating acupuncture with piston and cylinder
Non-penetrating SA	Lee EJ [14]	University-Industry Cooperation Group of Kyung Hee University	2018	Application	Sham acupuncture needle set for double blind test
Electronic SA	Lim SM, Lee EJ [15]	National Rehabilitation Center	2015	Registration	Electronic sham acupuncture operating device, and method for operating electronic sham acupuncture
Electronic SA	Lim SM, Lee EJ [16]	National Rehabilitation Center	2017	Registration	Double-blind electric device
Patch-type SA	Kim SC, Choi SM [17]	Korean Institute of Oriental Medicine	2006	Extinction	Patch-type non-penetrating acupuncture for double blind test
Patch-type SA	Lim SM, Lee EJ [18]	National Rehabilitation Center	2016	Registration	Patch-type sham acupuncture with spring

SA, Sham-acupuncture.

selected patents, were analyzed. Sham acupuncture patents were most commonly classified as A61 (hygiene; medicine or veterinary medicine) under the IPC [$n = 22$ (91.6%)]. The sham acupuncture patents are usually further subclassified as A61H within the A61 category (physical treatment devices, e.g., devices that detect or stimulate the locations of vital body points; artificial respiration; massage; bathing devices for special treatments or specific body parts) [$n = 10$ (41.6%)], followed by A61B [diagnosis; surgery; personal identification; $n = 7$ (29.1%)]. Specifically, sham acupuncture patents were most commonly classified as A61H 39/08 [instruments for applying acupuncture to a body part; $n = 7$ (29.1%)], followed by A61B 5/00 [measurement for diagnosis; personal identification; $n = 4$ (16.6%); Fig. 2].

3. Patent analysis based on technological features

The eight selected sham acupuncture patents were classified into three categories on the basis of the specific type of technology used: non-penetrating sham acupuncture for double-blind studies [$n = 4$ (50%)], electronic sham acupuncture [$n = 2$ (25%)], and patch-type sham acupuncture [$n = 2$ (25%)].

The non-penetrating sham acupuncture technique for double-blind tests included safe needles, placebo needles,

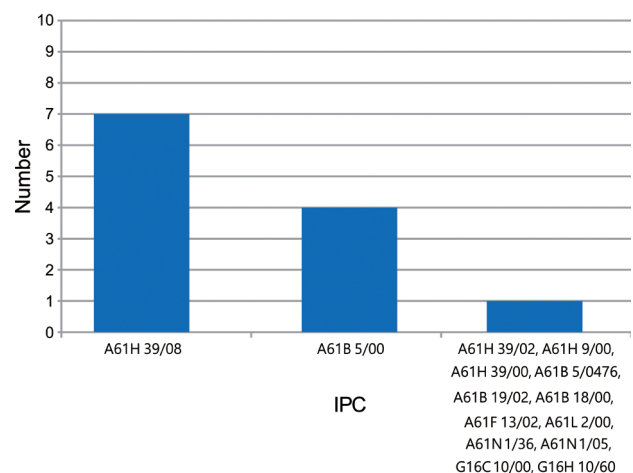


Fig. 2. Frequency analysis based on the International Patent Classification (IPC).

needle sets for double-blinding [11], sham acupuncture needle sets [12], non-penetrating needles with a piston and cylinder [13], and a sham acupuncture set for double-blinding [14]. The electronic sham acupuncture included an electronic sham acupuncture drive device [15] and electronic acupuncture for double-blinding [16]. Furthermore, the

patch-type sham acupuncture included a patch-type non-penetrating acupuncture needle for double-blinding [17] and patch-type sham acupuncture with a spring [18].

The safe needle, placebo needle, and needle set for double-blinding [11] are designed to rigorously determine the therapeutic effects of real or sham acupuncture treatment with blinding of both patients and practitioners; moreover, the needle insertion depth, needle thickness, and insertion site can be masked for both patients and practitioners.

The sham acupuncture needle set [12] involves the insertion of a fixed block into the inner space from the needle bottom, where the external structure of the acupuncture tube is minimized, to make patients and practitioners believe that they are receiving and providing real acupuncture treatment. Consequently, this improves the reliability of blind studies and improves the accuracy of results regarding acupuncture treatment.

The non-penetrating needle with a piston and cylinder [13] is used as a control in studies on the effects of acupuncture treatment, where it forms a vacuum pressure using the piston and cylinder to fix the needle on the affected site.

The sham acupuncture for double-blinding [14] is designed for forcible insertion and settling of the needle body into the needle groove of the filling block with elasticity similar to that of human skin, where the filling block is designed to hit the skin by the pressing force of the needle body, which is generated while inserting the body of the needle.

The electronic sham acupuncture drive device [15] can provide electrical stimulations that cause sensory stimulation similar to real acupuncture without sham insertion, thus, allowing accurate verification of whether the effects of electronic acupuncture treatment are placebo effects.

The double-blind electric acupuncture device [16] has both real and sham acupuncture needles on one electrode patch, which allows the electronic acupuncture device, instead of the practitioner, to randomly select the acupuncture type to be administered. This allows assessment of the therapeutic effect of acupuncture using a double-blind method and improves the reliability of the results.

The patch-type non-penetrating acupuncture device for double-blind studies [17] is designed to make it difficult to distinguish between sham and real acupuncture with respect to the appearance and pricking feeling, thus, rendering it suitable for double-blind studies.

The patch-type sham acupuncture with a spring [18] is designed to be used as a control in studies focusing on the therapeutic effects of acupuncture. The needle is inserted into the patch using the spring to induce stimulation during acupuncture; however, this device can prevent the needle from being inserted into the skin.

Discussion

This study aimed to collect and analyze information regarding sham acupuncture patents to identify the latest trends in related technology, as well as to provide basic data for the development of new technology. Therefore, this study systematically analyzed the current status, content, and technological features of currently filed and granted sham acupuncture patents. The patents covered in this study are patents applied for in South Korea and it does not mean the devices were developed in South Korea.

The Streitberger, Park and Takakura devices developed in Germany [19], USA [20], and Japan [21], respectively are the recently developed and studied non-penetrating sham acupuncture techniques. Among these three devices, only the Takakura device, invented by Takakura, had a patent in South Korea in 2000.

The placebo acupuncture technique was first introduced into acupuncture research by Konrad Streitberger [7], who published its effects in the *Lancet* in 1998. The Streitberger device consists of a needle handle, needle shaft, blunt needle head, plastic ring, and plaster. When holding the needle handle and pressing it onto the skin, the needle seems to be inserted into the skin as the needle shaft retracts into the needle handle and is attached to the skin by the plaster [19,22,23].

The Park device consists of a needle handle, guide tube, park tube, flange, and double-sided tape, which attaches to the skin. The Park device includes a guide tube and a flange with adhesive tape to hold the sham acupuncture in place, which serves a similar purpose to the plaster used in the Streitberger's sham needle [19,20]. For both the Streitberger's sham needle and Park sham acupuncture, practitioners delivering acupuncture know which needle type, real or sham, is applied. Accordingly, the application of these devices is limited to single-blind testing [22,23].

Similar to the needles in the Park and Streitberger devices, the needle tip in the Takakura device makes non-penetrating contact with the skin, but it can use both real and placebo needles, keeping both the patient and the acupuncturist blinded to needle types administered. In other words, when using a real needle, the sharp needle tip penetrates the skin, whereas, in the placebo device, when the needle is inserted into the lower stuffing, the patient has a sensation similar to skin pricking, while the acupuncturist has a sensation similar to tissue penetration. Therefore, both the patient and the acupuncturist cannot recognize the treatment conditions. However, the Takakura device has not yet been commercialized, unlike the Streitberger's sham needle and Park SA, and customized manufacturing is required [21-23]. There is a need to develop more sophisticated sham acupuncture techniques using more rigorous blinded studies on sham acupuncture to improve the quality of clinical trials using sham acupuncture

controls.

Sham acupuncture currently entails the use of a needle with a blunt tip that cannot directly penetrate the skin, which is indistinguishable from real acupuncture needles in appearance, thus, allowing for blinding of participants and/or practitioners. The development of sham acupuncture with similar psychological effects as real acupuncture, minimal physiological effects, and sustained blinding of both participants and practitioners even in long-term clinical trials could facilitate the creation of an ideal sham acupuncture control group.

The analysis of the technical features of the (included) patents indicated that technological advances are more focused on developing sham acupuncture for double-blinding. Moreover, this study observed a new development trend toward establishing appropriate control groups with respect to the technical aspects of various acupuncture intervention types, including non-penetrating sham acupuncture, electronic sham acupuncture, and patch-type sham acupuncture, for investigating the therapeutic effects of acupuncture. Therefore, the development of new sham acupuncture-related technologies in the future requires technological specialization and a research milieu that can guarantee the discovery of novel, protean, and original patents and solutions.

These significant findings provide information regarding technological differentiation, as well as the overall future development trends for new sham acupuncture in oriental medicine, which should be considered to ensure novelty and innovation of the relevant patents. Moreover, this study reported all the currently available patents, including registered patents, pending patent applications, and expired patents. Moreover, it attempted to provide extensive information regarding the types and technological features of various sham acupuncture devices.

This study has a limitation in that it did not include related patents in foreign countries, given the difficulty in accessing patent-related resources from other countries. Therefore, further studies are needed to identify more diverse technological trends in sham acupuncture devices by searching and analyzing foreign patents on sham acupuncture.

Conclusion

This study systematically reviewed and analyzed the current status, contents, and technological features of currently filed and granted sham acupuncture-related patents in South Korea. This study revealed that the technical advances in sham acupuncture are currently focused on technological development that allows double-blinding, on the basis of the analysis of the technical features of these sham acupuncture patents. Moreover,

this study observed a new developmental trend in the technical aspects of various acupuncture intervention types, including electronic sham acupuncture and patch sham acupuncture, as well as non-penetrating sham acupuncture. The development of new sham acupuncture techniques requires consideration of the technological differences and the overall trends to ensure novelty and innovation in these patents.

Author Contribution

Conceptualization, planning data acquisition and analysis, formal investigation, and writing - review and editing: SML.

The author has read and approved the final manuscript for submission.

Conflicts of Interest

The author has no competing interests to declare.

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Ethical Statement

This research did not involve any human or animal experiments.

Data Availability

All data generated or analyzed during this study are included in this published article.

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