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www.jcimjournal.com/jim

www.elsevier.com/locate/issn/20954964

Available also online at www.sciencedirect.com.

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• Letter to the Editor

The difference of Park and Streitberger single-blind needles from Takakura double-blind needle

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Keywords: acupuncture; single blind; double blind; sham treatment

Citation: Takakura N, Takayama M, Yajima H. The difference of Park and Streitberger single-blind needles from Takakura double-blind needle. *J Integr Med.* 2015; 13(4): 212–214.

In a recent study aimed at validating the Park sham needle for use as a double-blind control intervention, To and Alexander concluded that the practitioner who was performing acupuncture recognized the type of needle^[1]. This paper may lead the reader to misunderstand the design and purpose of placebo/sham acupuncture needles^[2–6], which have been developed in recent decades for the purpose of acupuncture research.

First, the Streitberger placebo needle (Asiamed Inc., United Kingdom)^[2,3] and the Park sham needle (Dong Bang Acupuncture Inc., Korea)^[4,5] are single-blind needles; that is, they are aimed at blinding the patient and not the practitioner. In contrast, the Takakura needle^[6] is designed to blind both the patient and the practitioner (a double-blind needle). The design differences between these three acupuncture placebo/sham needles that blind exclusively the patient or both patient and practitioner need to be clarified. The authors tested whether the Park sham needle could blind both practitioner and patient and found that it could not blind the practitioner^[1]. In the Discussion, the authors claim, “The Park sham needles cannot serve as a double-blind intervention tool for experienced acupuncturists, which are in contrast to the results of Takakura and Yajima who found that they were able to mask both practitioner and patient from the type of needle being used.”^[1] This statement gives the reader the impression that the Park sham needle is intended to be a

double-blind needle, which it is not.

Second, in the Introduction, the authors state, “All the placebo acupuncture needles are designed with the principle of a placebo needle that slides within the needle handle.”^[1] This is true for the Streitberger placebo needle and the Park sham needle but not for the Takakura needle. The principle of retreating the body of the former two needles is to blind the patient but not the practitioner. In contrast, with the Takakura needle, the body of the placebo needle is just long enough to allow its blunt tip to press against the skin when a stopper comes into play, and the body of the matched real needle is longer than the guide tube by an amount equal to the depth of insertion (Figure 1). This stopper prevents the needle handle from advancing further when the sharp tip of the real needle or the blunt tip of the placebo needle reaches a specified position, so that the amount of pressure to the skin with the blunt tip of the needle cannot be controlled by the practitioner. On the other hand, with the Streitberger placebo needle and the Park sham needle, after sliding the needle within the needle handle, the pressure of the blunt tip to the skin can be controlled by the practitioner. Therefore, the design of the Streitberger placebo and the Park sham needles is not intended to blind the practitioner. These differences are critical for single (patient)-blind and double (practitioner and patient)-blind needles.

Furthermore, in order to blind the practitioner, both the

[http://dx.doi.org/10.1016/S2095-4964\(15\)60189-3](http://dx.doi.org/10.1016/S2095-4964(15)60189-3)

Received April 19, 2015; accepted May 21, 2015.

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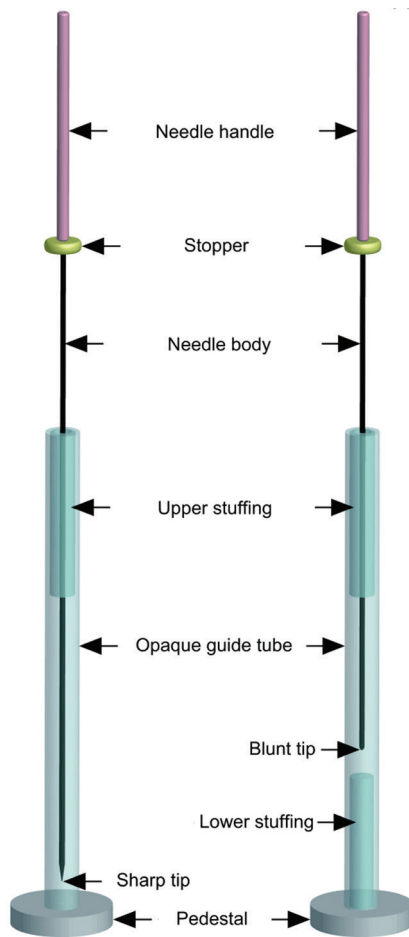


Figure 1 Real needle (left) and placebo needle (right) which presses against the skin with the blunt tip for double blinding^[6]

Takakura’s placebo and real needles are comprised of an opaque guide tube with stuffing in the upper portion to give resistance to the needle body during its passage through the guide tube. The stuffing is an indispensable component for blinding the practitioner. The guide tube of the placebo needle also has stuffing in the lower portion to give the practitioner a sensation similar to that of skin puncture and tissue penetration. This stuffing is an indispensable component for blinding the practitioner. Such a mechanism is not part of single-blind needles; thus, the design of the Takakura needle is clearly different from that of the Streitberger and Park needles, with the exception that all the placebo needles press the skin with its blunt tip. Structurally, the above-mentioned design of the Takakura needle makes it possible to design another no-touch placebo needle, where the needle tip does not reach the skin. This design element would help to settle the controversy over whether placebo needles, the tips of which press against but cannot penetrate the skin, are true placebos^[7-9].

Third, in the Introduction, the authors also state, “It remains unclear whether the needles can be used as a double-blind intervention.”^[1] The appearance of the Takakura placebo needle is identical to that of the matched real needle before, during and after removal. In addition, for the practitioner, the feel of the Takakura placebo needle is also indistinguishable from the matched real needle by virtue of the stuffing, which offsets the feeling of skin penetration through the needle handle (Figure 1).

Lastly, in the Introduction, the authors state, “Some problems with each of these studies leave open the question of the needles’ validity as tools for a double-blind control.”^[1] This is incorrect^[10]. In the first validation study of the Takakura needle, the practitioner-masking effect of the placebo needle and the matched real needle was statistically evaluated. Of 40 needles (23 placebo and 17 real needles) applied by each of 10 experienced acupuncturists, 43% were identified correctly, 42% were identified incorrectly, and 16% were unidentified^[6]. In the subsequent validation study for patient masking, of the 114 placebo and 114 real needles, subjects (patients) incorrectly guessed half of the placebo needles as penetrating and more than 30% of real needles as placebo^[11]. Further, whether the answers were correct or not, almost all the placebo and real needles were guessed without full confidence by either the practitioner or the patients^[7-9]. Even if a small number of practitioners or patients guessed the nature of placebo or real needles with full confidence, their answers were not always correct^[7-9]. These results indicate that the Takakura needle had the potential to blind both practitioner and patient. As shown above, the design of the Park and the Streitberger single-blind needles is not intended for practitioner masking like the Takakura double-blind needle.

Declarations of any conflicts of interest

NT and the Educational Foundation of Hanada Gakuen possess a U.S. patent 6575992B1, a Canadian patent CA 2339223, a Korean patent 0478177, a Taiwan patent 150135, a Chinese patent ZL00800894.9 (Title: Safe needle, placebo needle, and needle set for double blind) and two Japanese patents 4061397 (Title: Placebo needle, and needle set for double blinding) and 4315353 (Title: Safe needle) on the needles described in this manuscript. NT is a salaried employee of the Educational Foundation of Hanada Gakuen.

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Author response:

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Thank you for giving us the opportunity to respond to such a clear letter.

As the authors suggest, this study^[1] aimed to assess whether the Park sham needle and its device could be used effectively as a double-blind placebo control, within a clinical setting. We did not validate the Streitberger or Takakura and Yajima needles. We are happy to make it clear that the Takakura needle has been designed to be used as double-blind placebo needle^[2].

Just to clarify, the Park sham needle was validated as a single blind needle in acute stroke patients^[3]. We have extended this work by validating the needle in a population with a musculoskeletal disorder without the presence of changes in sensation.

In the discussion, we highlight factors that must be considered when using the Park sham needle and device. We also took the opportunity to discuss the other needles

that have shown potential for double blinding within a research setting, using healthy volunteers and one acupuncture point. We are sorry if this left the reader confused. We are unable to assess if the Takakura and Yajima needle would produce the same results in our clinical setting.

In summary, our study found that the Park sham needle and device could not be used as a double-blind acupuncture needle in a clinical setting with patients with shoulder impingement syndrome. If the same study was to be repeated with the Streitberger or Takakura and Yajima needles, the results may be different.

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