

## A Possible Physiological Action Mechanism of Sham Acupuncture, and Proposal of New Sham Device for Clinical Research

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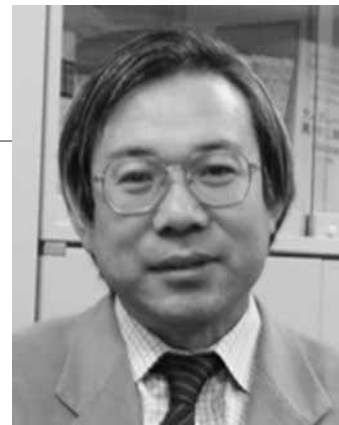
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Recent well-designed large scale RCTs of acupuncture and their meta-analysis have clearly demonstrated that, for some conditions, real acupuncture interventions are more effective than usual care, but no significant difference between real and sham acupuncture. These results tend to lead a conclusion that acupuncture has no specific effect and it has strong placebo and/or expectation effects.

In this brief review, we introduce several pieces of physiological evidence that sham acupuncture such as minimal acupuncture, Streitberger or Park sham needle used in recent clinical trials are not physiologically inert intervention. It should be noted that the polymodal receptors, which are assumed to be a candidates for acupuncture and moxibustion, could be activated by such sham interventions. Japanese acupuncture seems to be quite similar to sham interventions, so we need other types of inert sham/placebo intervention to clarify the specific effect of acupuncture.

Recently press tack needle (PTN, Seirin Japan) and its sham device have been developed. In the real version, a thin and short needle (0.2mm in diameter, 0.6mm in length) is attached vertically below the surface plastic plate (3.5mm in diameter), but the sham version has only a plate without needle. Using these devices, a RCT for pain relief of subjects in triathlon race was conducted. The primary outcome measure was pain in VAS after the race. Masking to two types of PTN was successfully performed, and real PTN produced significantly higher effects than sham PTN.

These results clearly indicate that clinical benefits of acupuncture have been well established, and sham acupuncture interventions also have their physiological effects. The specific effects of acupuncture should be demonstrated by further experimentations using newly developed real and sham PTN devices in near future.

**Keywords:** sham device, specific effect, placebo effect, polymodal receptor, press tack needle