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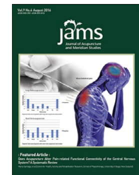

Research Article

The Biocompatibility of Nanoporous Acupuncture Needles

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Abstract
We investigate the biocompatibility of a new class of acupuncture needles that possess a hierarchical nano/microscale porous surface topology, referred to as porous acupuncture needles (PANs). The PANs are synthesized via a facile electrochemical anodization technique by which a surface area approximately 20 times greater than a conventional acupuncture needle, of the same diameter, is obtained. PAN biocompatibility is evaluated using a variety of standard tests, with results indicating that the PANs can safely be used within therapeutic practice.

1. Introduction

The efficacy and safety of acupuncture treatment are of ongoing interest [1–5]. White [6] summarized the range of significant adverse effects of acupuncture treatment and frequency of adverse events associated with acupuncture practice; it was concluded that the risk associated with acupuncture therapy is very low, about 0.05% per 10,000 treatments or 0.55 per 10,000 individual patients [6]. Yamashita et al [7] listed adverse events after acupuncture treatment; they found that there were vanishingly few cases where fatalities and injuries were reported because of infections and needle breakage. Reports by Adams et al and Park et al indicate few minor risks associated with acupuncture treatment of children [8] and pregnant women [9], respectively. Overall, these studies have concluded

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that risks associated with acupuncture can be minimized when correctly applied by trained acupuncturists and that unsupervised treatments should be avoided.

Recently, we reported porous acupuncture needles (PANs) with a surface topology of hierarchical micro/nano-scale conical pores possessing surface areas approximately 20 times greater than those of conventional smooth-surface needles of the same diameter [10]. In monitoring the electrophysiological and behavioral responses from *in vivo* stimulation of Shenmen (HT7) points in Wistar rats, we found the PANs to be more effective than conventional acupuncture needles in controlling electrophysiological and behavioral responses [10]. Herein, we investigate the mechanical and biological safety of the PANs through hemolytic, Guinea pig maximization, intracutaneous (intradermal) reactivity, and pyrogenic tests. In the biological tests, each result showed a significant difference from the positive control samples, whereas no difference was observed compared with the negative control samples. The results of this study suggest that the PANs are safe for therapeutic use, with all tests satisfying Korean government standards (MFDS) [11].

2. Materials and methods

(a) Preparation of PANs

Conventional SS304 acupuncture needles (6.0 cm length and 250 μm diameter) [12] were purchased from Dong Bang Acupuncture Inc., Republic of Korea, and used for fabrication of the PANs. Before anodization, the acupuncture needles were sequentially cleaned with acetone, ethanol, and finally rinsed with deionized (DI) water. Anodization of the stainless steel needles was performed using a two-electrode cell, see Fig. 1, with the acupuncture needle serving as the working electrode and carbon paper, 5.0 × 1.0 cm × 0.042 cm, purchased from Carbon and Fuel Cell, Republic of Korea, as the counter electrode. Anodization was performed for a duration of 1 hours at 30 V, using an electrolyte comprised of 0.3 weight percent (wt %) NH_4F (98%, American Chemical Society reagent; Alfa Aesar), and 2.0 volume percent (vol %) DI water in ethylene glycol (EG, extra pure; Daejung, Republic of Korea) [13]. After anodization, the acupuncture needles were rinsed with copious amounts of DI water and then dried in a flowing stream of nitrogen.

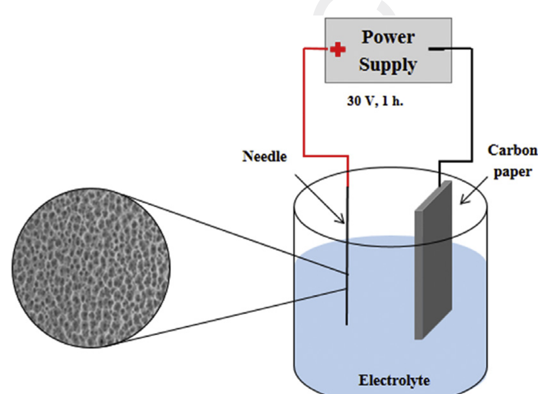

Figure 1 Schematic illustration showing PAN synthesis by electrochemical anodization of a conventional acupuncture needle.
PAN = porous acupuncture needle.

Two different PANs were studied, each fabricated from SS304 type needles of different diameter: PAN A1 with a nominal diameter of 144 μm and PAN A2 with a nominal diameter of 250 μm. Because both needles are of essentially identical composition, see Table S1 and Table S2, biocompatibility and cytotoxicity tests were only conducted on PAN A2.

(b) Animal and sample preparation for biocompatibility tests

For each test, only healthy animals were selected. Needle elasticity [14,15] was measured using an elastic test machine (DYC&T, DYC-10A) in accordance with the MFDS guideline [11]. Pullout tests were performed using a biomechanics tester (E1000; TestResource) by applying 3N and 5N force to PAN A1 and A2 in the direction of the needle axis. To assess the biocompatibility of the PANs, cytotoxicity tests were performed in accordance with the ISO 10993:2009 MFDS standard [11]. The test procedure is as follows:

The test article PAN A2 was prepared aseptically. Based on the ratio of 25ea:250 ml, the test articles were covered with 0.9% sodium chloride (SC) solution in DI water. After 1 hour, a single preparation was extracted and agitated at 37 ± 2°C. The reagent control was prepared equally using 0.9% SC solution in DI water. High-density polyethylene was used as the negative control. Based on the United States Pharmacopeial Convention ratio of 2g:20 ml, a single 2 g portion of the control material was covered with 20 ml of single strength minimum essential medium (1x MEM). A single preparation was extracted and agitated at 37°C for 24 hours. Zinc diethyldithiocarbamate (reagent grade) polyurethane film was used as the positive control. Based on the United States Pharmacopeial Convention ratio of 2g:20 ml, a single 2 g portion of the control material was covered with 20 ml of 1x MEM and extracted and agitated at 37°C for 24 hours.

(c) Animal preparation

L-929, mouse fibroblast cells, (ATCC CCL, NCTC Clone 929, of strain L) were propagated and maintained in open wells containing 1x MEM supplemented with 10% fetal bovine serum and 1% antibiotics (penicillin-streptomycin) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10-cm^3 wells were seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain confluent monolayers of cells before use. Triplicate culture wells were selected which contained a confluent cell monolayer. The growth medium contained in triplicate cultures was replaced with 2 ml of the test extract. Similarly, triplicate cultures were replaced with 2 ml of the reagent, negative, and control. The wells were incubated at 37°C in 5% CO_2 for 48 hours (CO_2 incubator, model: VS-9160C). After incubation, the cultures were examined microscopically at 100× to evaluate cellular characteristics

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