



## Preparation, Preclinical Safety and Effectiveness Research of Body Insulated Acupuncture Needle



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The interdisciplinary research group formed by University of Science and Technology Beijing (USTB) and Xiyuan Hospital CACMS has been researching "Preparation of body insulated acupuncture needle" for many years. Based on the project support of Beijing Municipal Science & Technology Commission, we explored the therapeutic effect of body insulated acupuncture needles for electrotherapy. Now, we had successfully prepared the acupuncture needle and applied for the patent. Also, the needle has passed the test of biocompatibility, skin sensitization, intradermal test, cytotoxicity. Our research makes full use of modern nanotechnology, applies nanomaterials to the needle preparation, uses plasma vapor deposition technology, scanning electron microscope (SEM), transmission electron microscope (TEM), and other technical methods to characterize the needle body. We have prepared the acupuncture needle to meet the relevant standard of Chinese medical devices (Standard number: GB 2024-2016) to fulfill clinical application requirements. The study aims to acquire a product that can completely fulfill clinical application requirements and have industrial conditions to realize the independent research and development on the acupuncture needle product. The new acupuncture needles can realize quantitative control of the therapy process and targeted electroacupuncture treatment to acupoint at different needling points, such as superficial fascia, deep fascia, nerve trunk, and ganglion. While solving the poor safety issues caused by the high current intensity of electrotherapy and practicing the idea of precision medicine, "Sancai" Acupuncture Therapy of Academician Cheng Shennong could be better achieved. In the meantime, the difficulty of fundamental experiments like collecting physiological electrical signals of specific structures in animals can also be solved. The body-insulated acupuncture needle can be used to explore the impact of different kinds of stimulation and stimulation signals on the treatment and physiotherapy of illness. This application is a real inheritance and development of traditional Chinese medicine by modern medical methods.

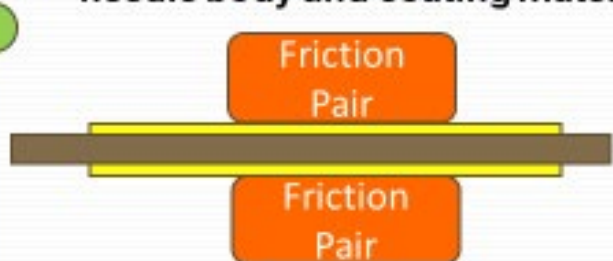
### 5.2 Key technology

Under conditions of large curvature, mechanical testing and evaluation



The needle cylinder has a large curvature and compressive stress. Compared with a flat surface, the problem of coating peel off under the condition of a large curvature should be considered.

Bonding performance test of needle body and coating material



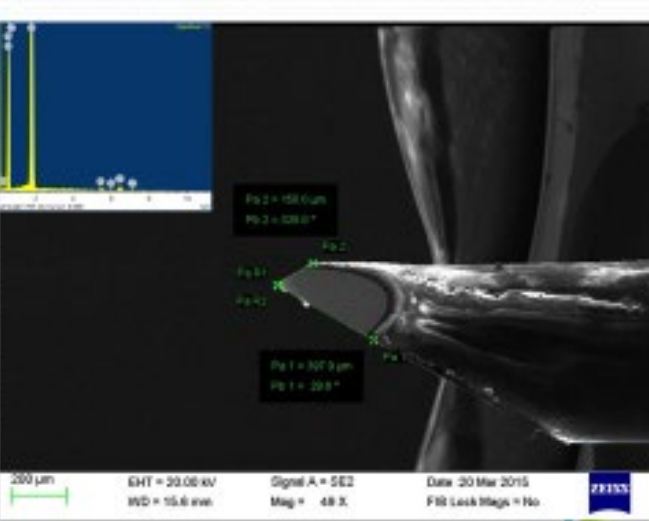
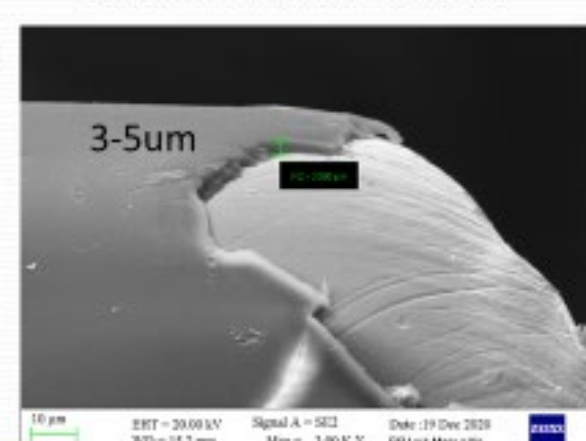
Bending & fatigue performance test



Torsion & fatigue performance test



Surface characterization



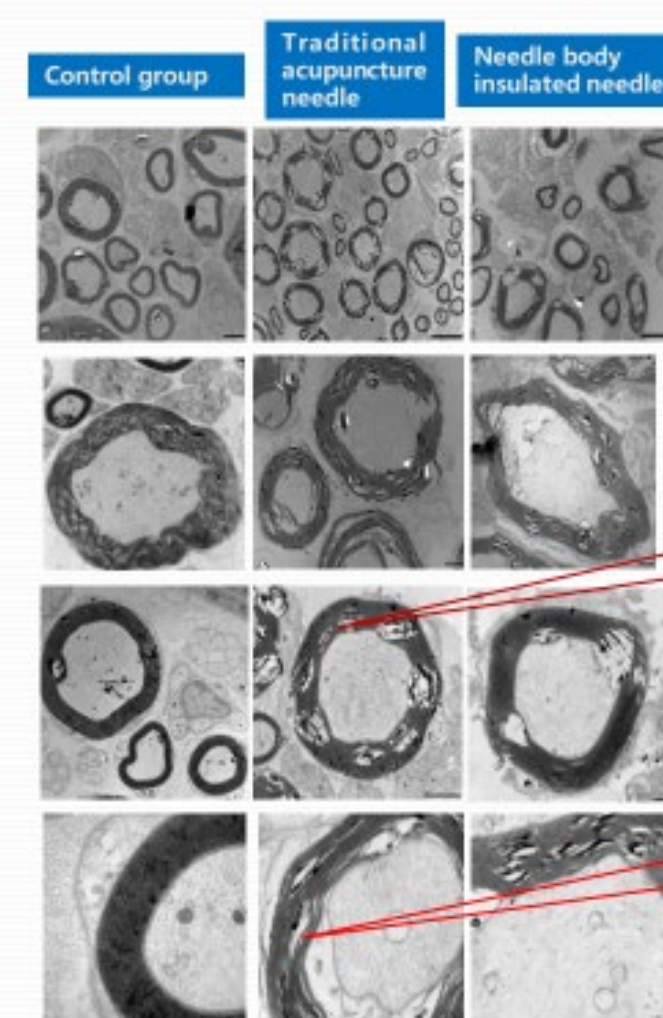
Comparison of the lowest current intensity that triggers the plantar curve reflex in rabbits:

Group	n	Weight (kg)	Stimulation intensity (mA)
Needle body insulated acupuncture needle	6	3.55 ± 0.32	0.29 ± 0.07**
Traditional acupuncture needle	6	3.53 ± 0.41	0.86 ± 0.08
Control group	6	3.58 ± 0.31	-

Tips: \*\*, Compared with traditional acupuncture needles,  $P < 0.01$ ,  $x(-) \pm s$ :  $-0.56 \pm 0.36$

Comparison of nerve damage between traditional acupuncture needles and needle-body insulated acupuncture needles after electrical stimulation of rabbit sciatic nerve:

Compared with traditional needles, the application of needle-insulated acupuncture needles in electroacupuncture can induce nerve effector reflexes under small currents, and cause slight nerve damage.



Nerve sheath injury

Mitochondrial disintegration

### 3.1 Apparatus application and effect—Inheritance and innovation

Shouzheng acupuncture academic idea



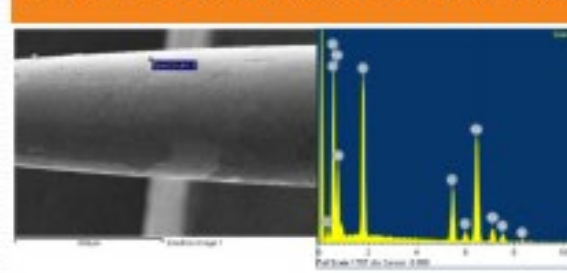
Acupuncture academician Cheng Xinnong: "Sancai" acupuncture: Stimulation at different depth will have different clinical effects to the same acupoint. The therapeutic effects are related to the precise stimulation at different depth of the acupoints.

Clinical application: rhinitis treatment



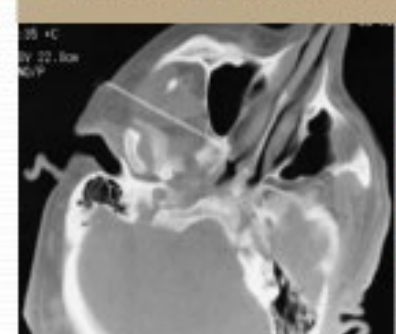
Directional needle tip discharge in the pterygopalatine fossa area stimulates nerves to regulate the function of nasal mucosa. Treatment: allergic rhinitis and paranasal sinusitis.

Innovation to achieve tool breakthroughs



Modern material technology: 0.30mm diameter acupuncture needles with 30 microns invisible insulating coating can achieve precise electrical stimulation of acupoints at different depths.

Clinical application: rhinitis acupuncture path



The needle-body insulated acupuncture needle tip 2mm area will accurately discharge to stimulate the pterygopalatine fossa area.

SEM image of needle insulation layer and EDS element analysis result

### 3.2 Apparatus application and effect—Innovation & innovation

Clinical Application: Overactive bladder



Zhong Liao (third sacral nerve) stimulation treats overactive bladder.

Clinical application: Acupuncture path



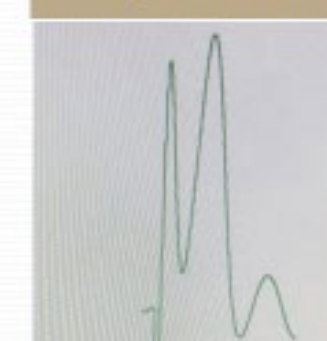
The 3mm area of the needle tip accurately discharges to stimulate the third sacral nerve.

Experimental Application: Collect hippocampal signal



Only the 1 mm needle tip is conductive, and it penetrates the hippocampus of the brain of the experimental mouse in a directed direction.

Experimental application: rat hippocampal signal



Needle body insulation acupuncture needle can realize specific electrical signal M wave in hippocampus.