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Development of a Uni-acupoint Transcutaneous Electric Nerve Stimulation Device for Electroacupuncture-like Neuromodulation

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Abstract— **Transcutaneous electric nerve stimulation (TENS) targeting at certain acupoints can be deemed as variation of electroacupuncture (EA) with the key advantage of non-invasiveness. However, existing operations of TENS usually involve placing at least two electrodes separately to form the electric circuit. To disentangle the concurrent stimulation of multiple sites and investigate the necessity of acupoint specificity on the basis of the traditional acupuncture theory, we developed a uni-acupoint TENS device aiming at performing non-invasive EA-like neuromodulation. It consists of a concentric anode-cathode arrangement with a maximal outer diameter of 32 mm integrated with a stimulating current generator. Once applied, it delivers square wave pulse trains with adjustable parameters (pulse form, intensity, frequency and width), and only a tiny area enclosing the selected acupoint would be electrically activated with no other acupoint of meridian affected. A simulated driving experiment was also carried out to verify the device's efficacy when conducting stimulation solely at the acupoint Neiguan (PC 6) to withstand driver fatigue. The results suggest that the device facilitates the application of effective EA-like stimulation with its most unique advantages of acupoint specificity and non-invasiveness.**

I. Introduction

Electroacupuncture (EA) is based on the conventional acupuncture theory and praxis dating back thousands of years and has been growing in popularity over the past several decades [1]. There is now much evidence demonstrating its favorable performance in alleviating, curing and rehabilitating disorders and diseases (somatic, visceral and neuropathic pain; arthritis and other motor impairments; obesity; nausea and vomiting; mental depression and distress and other psychological problems) [1-6].

Narrowly defined, EA is delivering electric stimulation via needles inserted through the skin into selected acupuncture points as a practical modality for percutaneous electric nerve stimulation (PENS) [7]. However, there are other operating modes, such as transcutaneous and subcutaneous electric nerve stimulation (TENS and SENS) related to acupoint location that can be analyzed as EA's variations owing to their very similar, if not identical, therapeutic effects and underlying mechanisms (TENS involves providing superficial stimulation via electrodes placed on the skin, while SENS mainly represents implanting electrodes deep into the tissue) [2-8]. When applied in electrotherapies, the devices for all three modalities have advantages over conventional acupuncture needles related to the ability to objectively and quantifiably set the stimulation frequency and intensity to easily achieve better controllability and repeatability. In addition, TENS devices also have the advantages of non-invasiveness, minimal adverse effects and less dependence upon professional operations in practice or research. Nonetheless, extant TENS units commonly have to place at least two electrodes separately to form the current loop. Therefore, paired acupoints together with meridians between are activated concurrently, which complicates the acupoint specificity and is also inconvenient for use. Only a few studies have considered this problem and introduce prototypical SENS devices stimulating a single acupoint, with animal tests verifying their equal analgesic effects for acute pain compared with bi-acupoint stimulation [8, 9].

This study presents the development of a uni-acupoint TENS unit, which fulfilled the favored characteristics of acupoint specificity and non-invasiveness, as well as adjustable parameters for customization. Its validation as an effective EA-like neuromodulation approach was also conducted using a human fatigue model during simulated driving circumstances.

II. Uni-acupoint Transcutaneous Electric Nerve Stimulation Device

A. Design

In our pioneering work, Niu used a uni-acupoint disc electrode as a countermeasure against muscle atrophy in microgravity [10]. Nevertheless, the standalone signal generator providing the requisite stimulating current is not very convenient and restricts practical applications. Hence, in this study, we integrated the electrodes with the signal generator to get a more portable stimulator for ease of use.

Fig. 1 shows the entity of the stimulator. The device had a ring electrode (with a 32 mm outer diameter and a 22 mm inner diameter) and a central electrode (with a 10 mm diameter) to form the electric circuit. Thus, once placed on the skin, only a tiny area around the single selected acupoint received the transcutaneous stimulation with no other acupoint or meridian affected. An integrated current source powered by a rechargeable lithium battery output a bidirectional electric flow, which was time symmetric to avoid potential harm to the

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human tissues induced by non-zero accumulated electric charge. The current parameters were adjusted and displayed via input buttons and an OLED screen. A low battery warning sign flashed on the screen when the supply voltage was lower than 4.2 V. The stimulator was Φ40 mm×18 mm in size and 21 g in weight (without the wrist strap). For acupoints located on extremities, a strap was a feasible accessory for fastening the device (e.g. Neiguan selected in the lower panel of Fig.1, which locates on the inner part of the forearm, proximal to the palmar wrist crease). The stimulator's block diagram is shown in Fig. 2.

Fig. 3 illustrates the detailed schematic of the output circuit which produced the bidirectional symmetric pulse current. The micro-control unit transmitted data words to the D/A converter to regulate the NPN transistors' base voltage and thereby control the current flowing out of the collectors into the transformer's primary winding. The analog switch changed the direction of the stimulating current by selecting the working transistor (A or B in Fig. 3) according to the time sequence set by the microcontroller. The ballast resistor (R in Fig. 3) in serious with the transistors and the transformer with a turns ratio of 1:10 both helped improve the control accuracy. Fig. 4 gives an example of a sequence chart of a bidirectional symmetric square wave.

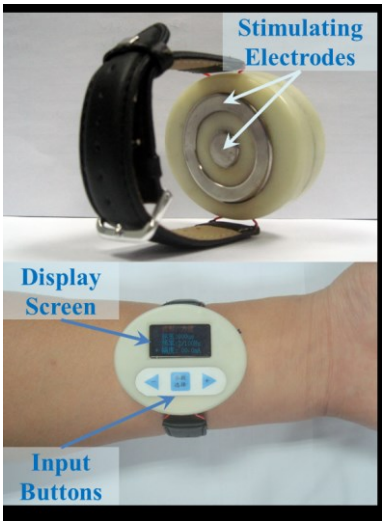

Figure 1. The uni-acupoint TENS device

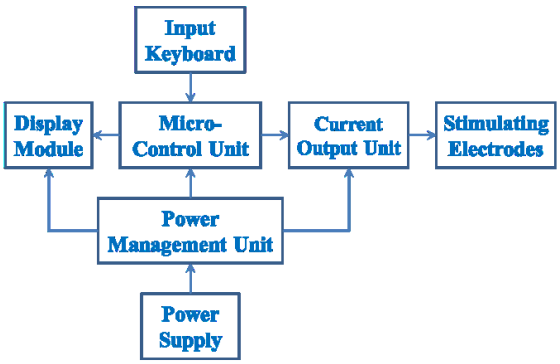

Figure 2. Block diagram of the stimulator

B. Specifications

The pulse pattern, intensity, frequency, and width of the stimulating current are possible determinants of electrotherapeutics performance discussed by an extensive literature [11, 12]. Hence, their controllability was favored for customized application. Table I lists their specifications. The required accuracy and stability were achieved when tested with a stimulating current of 3 mA and load resistors of 0.1, 0.5, 1, 2 and 3 kΩ, respectively. Fig. 5 presents a snapshot of the actual wave form generated by the stimulator.

III. Applying the Stimulator Against Driver Fatigue

To verify the availability of the uni-acupoint TENS device described above, we further conducted a simulated driving experiment and the device was used to activate the acupoint Neiguan (PC 6) for counteracting driver fatigue. With its unique ability of fulfilling the acupoint specificity criterion, we also examined the effects of administrating stimulation at true (Neiguan) and sham (a non-acupoint) points.

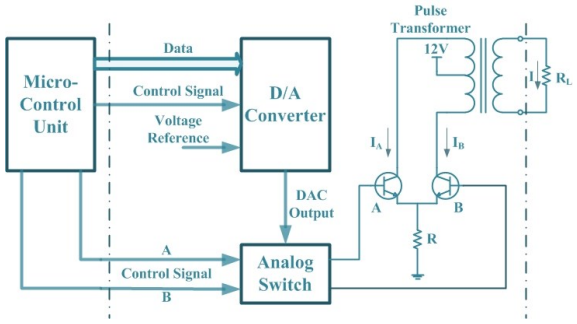

Figure 3. Schematic of the output circuit

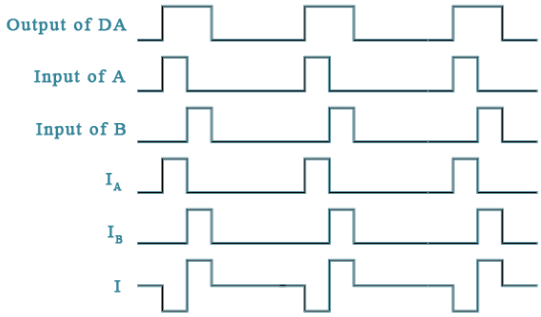

Figure 4. Generation of a bidirectional symmetric square wave

TABLE I. Stimulating Current Parameters

Parameter	Range	Accuracy & Stability
Pattern	Continuous or sparse-dense mixed square wave pulse train altering every 3 s	±2%
Intensity	0~20 mA in 1 mA steps	
Frequency	0~150 Hz in 10 Hz steps or altering between 2 and 100 Hz	
Width	0~600 μs in 50 μs steps	

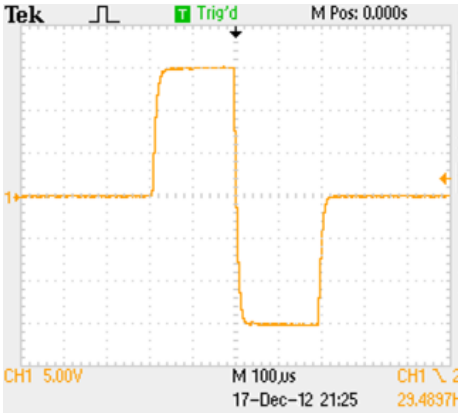

Figure 5. Sample of a bidirectional symmetric square wave

A. Subjects

36 male undergraduates or postgraduates aged between 20 and 26 (Mean = 23.7, S.D. = 1.3) were recruited for the research. The subjects all had a driver's license with car driving experience for a minimum of 0.5 years, good general health, a well-balanced sleep-wake schedule, no anamnesis for neuropathies or psychoses and no previous experience with acupuncture or acupuncture-like therapies. They were instructed to maintain a regular sleep-wake schedule during the course of the study and to consume no alcohol or caffeine for 24 h before the tests. All were made aware that they could withdraw from the experimental session at any time and then gave their written informed consent.

B. Driving simulator

A fix-based vehicle outfitted with normal manipulation components (a steering wheel, an accelerator, a brake, etc.) and a signal detection system was built for the driving simulations. A 2-lane city road scene was projected on a circular screen, providing the driver a panoramic view from his seat. The route had few curved sections and low traffic volume; hence, appeared monotonous and hypnotic to the driver.

C. Fatigue assessment method

The subjective perception of fatigue was evaluated using the self-rating Stanford Sleepiness Scale (SSS), which consists of 7-point Likert-typed items ranging from "feeling active and vital; alert; wide awake" (Score = 1) to "almost in reverie; sleep onset soon; lost struggle to remain awake" (Score = 7) (2, 33). The subjects selected the descriptor that best represented their feeling of fatigue before and after the tests.

D. Experimental procedures

The subjects were assigned randomly to four groups: 1) tactile sensory control with a self-adhesive disc electrode attached to the target acupoint Neiguan but without any electric stimulation, 2) non-acupoint stimulation with a disc electrode at a site on the inner part of the forearm evading Neiguan and any other acupoint or meridian, 3) Neiguan acupoint stimulation with a disc electrode and 4) Neiguan acupoint stimulation by wearing the uni-acupoint TENS device around the forearm (shown in the lower panel of Fig. 1). The self-adhesive disc electrodes used for group 1, 2 and 3, described in an early study [10], were powered by a standalone programmable pulse generator and could deliver identical uni-acupoint stimulation with the devices for group 4. Each group was tested at similar periods in the day to minimize the circadian effects.

Participants were required to fill in the first SSS questionnaire when they arrived at the experiment site to record their current state of fatigue. The self-adhesive stimulating electrode or the wearable electric stimulator was then applied according to their groups. They were given 5 min for a test drive, during which they familiarized themselves with the operation, while their sensory threshold, safety threshold and pain tolerance when electrically stimulated were recorded. Once all these preparations were completed, the subjects completed a second SSS questionnaire followed by simulated driving for 90 min. They were asked to maintain approximately 70 km/h along the straight sections of the road and a somewhat slower speed along the curved sections. No speeding or lane changing was permitted. Members of groups 2, 3 and 4 were given electric stimulation based on their sensory threshold and safety threshold using the following strategy: For the first 40 min when the feeling of fatigue was probably absent or at its early stage, stimulating currents of 2~5 mA (less than 50% of the individual's safety threshold) were applied. As time went on and the fatigue was expected to progress, the amplitude was increased by 1 mA every 10 min but no more than the individual's safety threshold (11~18 mA). The current alternated every 3 s between two forms of square wave pulse trains with a frequency of 2 Hz and a pulse width of 600 μs and a frequency of 100 Hz and a pulse width of 200 μs [13].

Once the 90 min formal driving task was finished, participants then filled out a third SSS questionnaire and narrated their subjective perceptions during driving.

E. Results

The progression of the subjective feeling of fatigue was characterized by analyzing the SSS responses using SPSS version 19.0. The statistical level of significance was set at 0.05.

The changes in these scores (shown as Mean ± S.E.) are shown in Fig. 6. Kruskal-Wallis tests of the "arrival" and "pretest" phase data showed that the scores had no significant differences among groups ($P = 0.881$ for "arrival" data and $P = 0.127$ for "pretest" data). Wilcoxon tests for each group also showed no significant differences between these two phases ($P \geqslant 0.157$). The "post test" scores, however, differed greatly ($P = 0.001$) among groups. A post hoc stepwise stepdown multiple comparison suggested that group 2 had a similar change in the subjective scale as the control group, showing a large increase in the SSS score compared with the "pretest" one, while group 3 and 4 were very different, both remaining stable at a relatively low level. Detailed statistics are shown in Table II.

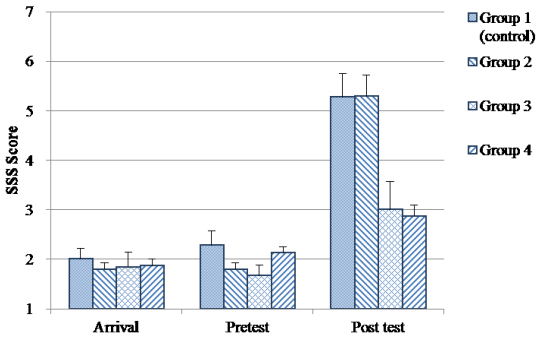

Figure 6. SSS scores

TABLE II. STIMULATING CURRENT PARAMETERS

Group	1	2	3	4
N (Raw Data)	10	10	8	8
N (Valid Data) [a]	7	10	6	8
Mean Rank (Post test) [b]	22.07	21.95	9.67	8.00
z (Post test; with control) [b, c]	-	-0.100	-2.411	-3.212
P (Post test; with control) [b, c]	-	0.920	0.016	0.001
z (Pretest – Post test) [d]	-3.180	-3.918	-1.844	-2.450
P (Pretest – Post test) [d]	0.001	< 0.001	0.065	0.041

a) 5 subjects eliminated due to early withdrawal from the experiment or violation of traffic regulations, b) Test for the "post test" phase, c) Matched-pairs test with the control group, and d) Matched-pairs test between the "pretest" and "post test" phases

IV. CONCLUSION

This study presents the development of a uni-acupoint TENS device aiming to perform EA-like neuromodulation with adequate fulfillment of the traditional acupoint specificity criteria. Its effectiveness was then verified by using it during prolonged simulated driving to electrically stimulate the acupoint Neiguan, which is conventionally believed to have an inhibitory action on fatigue. The outperformance of stimulating Neiguan with this device over delivering no stimulation or stimulation at a non-acupoint site not only demonstrates its efficacy per se but also, incidentally, provides supporting facts for the significance of targeting acupoints. Thus, with its favorable characters of acupoint specificity, non-invasiveness, portability, controllability, repeatability, few side effects and little interruption or distraction from the current activity, the stimulator provides a unique and promising approach for experimental research and clinical practice related to realization and application of EA-like neuromodulation.

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REFERENCES

[1] Ulett GA, Han SP, Han JS, "Electroacupuncture: mechanisms and clinical application", *BIOL PSYCHIAT*, vol. 44, pp. 129-138, 1998.

[2] Borup L, Wurlitzer W, Hedegaard M, Kesmodel US, Hvidman L, "Acupuncture as pain relief during delivery: a randomized controlled trial", *BIRTH-ISS PERINAT C*, vol. 36, pp. 5-12, 2009.

[3] Schliessbach J, van der Klift E, Arendt-Nielsen L, Curatolo M, Streitberger K, "The effect of brief electrical and manual acupuncture stimulation on mechanical experimental pain", *PAIN MED*, vol. 12, pp. 268-275, 2011.

[4] Ng MML, Leung MCP, Poon DMY, "The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation", *J ALTERN COMPLEM MED*, vol. 9, pp. 641-649, 2003.

[5] Ghoname ESA, Craig WF, White PF, Ahmed HE, Hamza MA, Henderson BN et al, "Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study", *JAMA-J AM MED ASSOC*. vol. 281, pp. 818-823, 1999.

[6] Mischoulon D, Brill CD, Ameral VE, Fava M, Yeung AS, "A pilot study of acupuncture monotherapy in patients with major depressive disorder", *J AFFECT DISORDERS*, vol. 141, pp. 469-473, 2012.

[7] Han JS. Acupuncture: neuropeptide release produced by electrical stimulation of different frequencies. *TRENDS NEUROSCI*, vol. 26, pp. 17-22, 2003.

[8] Niu CS, Hao HW, Lu J, Li LM, Han ZR, Tu Y. A novel uni-acupoint electroacupuncture stimulation method for pain relief. *EVID BASED COMPLEMENT ALTERNAT MED*, pp. 1-6, 2011.

[9] Liu XY, Hao HW, Niu CS, Li LM, Lu J, Tu Y. Study of implantable uni-acupoint electroacupuncture system, 2010.

[10] Niu CS, Hu CH, Hao HQ, Li LM, Wu MS. Programmable transcutaneous neuromuscular electrical stimulation system design. *AVIAT SPACE ENVIRON MED*, vol. 22, pp. 211-215. 2009.

[11] Shimoji K, Takahashi N, Nishio Y, Koyanagi Mika, Aida S. Pain relief by transcutaneous electric nerve stimulation with bidirectional modulated sine waves in patients with chronic back pain: a randomized, double-blind, sham-controlled study. *NEUROMODULATION*, vol.10, pp. 42-51, 2007.

[12] Wang BG, Tang J, White PF, Naruse R, Sloninsky A, Kariger R et al. Effect of the intensity of transcutaneous acupoint electrical stimulation on the postoperative analgesic requirement. *ANESTH ANALG*, vol. 85, pp. 406-413, 1997.

[13] Dong J, Li LM, Hao HW, Chen ZY. EEG Study on Transcutaneous Electrical Acupoint Stimulation as a Fatigue Countermeasure. *SPACE MED ENG* vol. 20: 447-450, 2007.