Design and Testing of a Novel Electrical Stimulator Base on Wrist- Ankle Acupuncture and Transcutaneous Electrical Nerve Stimulation

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Abstract. This paper developed a novel electrical stimulator. This electrical stimulator, based on wrist-ankle acupuncture in traditional Chinese medicine and transcutaneous electrical nerve stimulation (TENS), aimed at reliving pains. The electrical stimulator has wide band voltage adjustment (0V-100V with 3.3V power supply) with voltage-mode electrical stimulation (ES) circuit. The novel topology of the circuit was implemented without operational amplifier (OPAM) and the transformer was used. A boost converter was applied in the circuit to produce treatment voltage, meanwhile an H-Bridge to produce the required biphasic pulses to effectively reduce the tolerance and polarization reaction. The low treatment voltage was used to make this circuit safer for users. The circuit tests were carried out and a pain model was established on healthy volunteers. The experiment suggested that the stimulator had good effect on pain relief and meanwhile increased the pain threshold.

Introduction

The incidence of pain in the world remains high and still rises rapidly. And the patient's demands for pain relief are pressing. The most frequently used for analgesic methods are analgesic drugs, traditional Chinese medicine acupuncture, TENS in clinical therapy [1].

Analgesic drugs cannot be used for long or large doses due to their certain dependence and side effects. Traditional Chinese medicine acupuncture and massage need professional TCM doctor’s operate especially acupuncture operation. Additionally, acupuncture was an invasive therapy which was not well accepted by most patients. TENS was introduced in the 70s of the last century as a method of pain management including chronic pain and malignancy related pain [2]. However, the TENS device was too large to carry easily, and the placement of the electrodes is technological required. The clinical trials of wrist-ankle acupuncture on human body proved that the pain to some extent was relieved or cured. Clinical practice showed that the combination of traditional Chinese acupuncture and TENS can achieve better analgesic effect.

Based on the analgesic mechanisms of wrist ankle acupuncture and TENS, a novel electrical stimulator in voltage-mode was developed in this study to relief pain.
System Requirement

**Pulses shape**—Monophasic or biphasic pulses as two types of pulses commonly used in ES device. Pulses should be symmetrical and there should be a delay used between each stimulation pulse. Therefore, biphasic pulses are preferred since they reduce and delay the fatigue of patient's tissue or muscle [3]. In Table 1, waveform A is monophasic pulses. This kind of simple stimulated pulse could cause electrode corrosion, therefore monophasic pulses were not considered as a priority in clinical applications. Waveform B is the biphasic symmetric pulses. This kind of treatment pulses can effectively reduce the tolerance and avoid polarization reaction [4]. In order to achieve the better treatment effect, Waveform C is the biphasic symmetric pulses with delay between each pulse. With this kind of pulses, the delay time can be allocated reasonably. Moreover, the absolute refractory period, the relative refractory period and subnormal period can be avoided [5]. Therefore, the effective stimulation pulse will work in the supernormal phase to not only to achieve the best treatment results but also reduce the peak of the stimulation voltage and energy consumption.

| Number | Waveforms | Threshold | Electrode Corrosion | Tissue damage |
|--------|-----------|-----------|---------------------|--------------|
| A      | \[\]      | \[\]      | \[\]               | \[\]         |
| B      | \[\]      | \[\]      | \[\]               | \[\]         |
| C      | \[\]      | \[\]      | \[\]               | \[\]         |

The more \[\] is, the better effect will be achieve.

**Pulse frequency**—Stimulation frequency of ES device can be a wide adjustment based on the purpose of the research or specific illness. Some studies indicated that the lowest threshold emerged at 0 Hz-100 Hz [6]. Stimulation with 50 Hz caused significant tremor. Simulation frequency with 100 Hz has the function of calming central nervous system and curing or relieving pain.

**Pulse width/duration**—Normally, different kind of pulse width were applied in ES devices. The typically used pulse width of ES device in the market varies from 100 us to 500 us [7]. Some studies showed that the threshold of ES is the reciprocal of the pulse width. Additionally, some studies indicated that even shorter pulse width can affect the recovery of muscle fibers [8].

**Voltage-mode stimulation or current-mode stimulation** [9]—The majority ES device in the market was current mode stimulator. The typical current-mode stimulation (CMS) would occupy most of the main chip area [10]. In the present paper, a voltage mode stimulation (VMS) was adopted. Specifically, it was more efficient to use a VMS in high-current stimulators (such as pacemakers and spinal cord stimulators) compared to CMS [11].

**Pulse amplitude/intensity**—The pulse amplitude to induce muscle contraction or action potential was different from each other due to the different stimulate site and impedance of different tissues [12]. For this voltage mode stimulator, the stimulation amplitude was adjusted from 0 V to 100 V with the resolution is 1 V.
System Structure

The system structure of this voltage mode ES was shown in Fig. 1. The device was powered by a supply voltage of 3.3 V (voltage regulator convert rechargeable lithium battery voltage of 4.7 V to 3.3 V) and controlled with voltage feedback. The boost convert was controlled by the pulse-width modulation (PWM) wave which was emitted by the main controller to boost 3.3 V supply voltage to the desired stimulation voltage up to a maximum voltage of 100 V. The required biphasic stimulation pulse was generated by the H-bridge which was controlled by the main controller. There were two channels in the system and each channel was controlled by different frequency and pulse width.

Two main components, i.e., the boost converter and the H-Bridge were controlled by an ultra-low-power microcontrollers, i.e., STM32L152RCT6. A wealth of resources in the microcontroller STM32L152RCT6 including a 32-bit timer, 6 general-purpose timers, 2 basic timers, etc. It was enough to produce the PWM waves to control the required circuit. Moreover, the microcontroller communicated with a smart phone through a Bluetooth module. Users set stimulation parameters (frequency, voltage and pulse width) on the smart phone and send parameters back to the microcontroller through Bluetooth module. With this microcontroller, users could control the amplitude, pulse width, and frequency easily.

Boost Converter

The boost converter is one of the core components of ES device. The TENS devices on the market used the traditional boost converter with a transformer. In this study, we used an axial leaded inductor to replace the transformer, which usually have a heavy volume and take too much space. The circuit schematic of the boost converter was shown in Fig. 2. In this boost converter, we did not use any OPAM and transformer, therefore it will not take too much space and light weight as make this circuit easier to apply to wearable devices. This novel boost converter can boost the supply voltage of 3.3 V to a wide adjustable voltage from 0 V to 100 V. However, the output of a boost converter is susceptible to load resistor, the output voltage will

Figure 1. System Structure for Voltage-Mode Stimulator.
have a great change as the load resistor change. In order to ensure the stability of the treatment voltage and take the variability of the impedance of human skin, a closed-loop voltage feedback is implemented.

The frequency of PWM1 wave was 32 kHz. In order to produce a high stimulation voltage up to 100 V, the transistor Q2 should be adopted carefully. Moreover, a common axial leaded inductor was used to keep the current steady. A capacitance of 10 uF was used as the output capacitance. Two resistors were placed in parallel with the output capacitance to develop a closed-loop circuit and make sure the boost converter could work in discontinuous conduction mode.

**H-BRIDGE**

H-bridge is the typical motor control circuit, with the on and off of the switching transistors, it can produce symmetrical biphasic stimulation pulse. *Fig.3* is the diagram of the H-bridge circuit.

The PWM1 wave and PWM2 wave had the same frequency and pulse width with phase difference of 180 degree to produce symmetrical biphasic pulses. In *Fig. 3*, the transistor Q2, Q3, Q5 conducted while the PWM2 was on high level and PWM3 was on low level. The H-bridge input voltage flowed through Q2, R5, Electrode2, Electrode1 and Q5 to the ground (Electrode2 was on high level, Electrode1 was on low level). On the contrary, the transistor Q4, Q7, Q9 conducted while PWM3 was on high level and PWM2 was on low level, the H-bridge Input voltage will flowed through Q1, R3, Electrode1, Electrode2 and Q6 to the ground.
(Electrode1 was on high level, Electrode2 was on low level) [4]. There were no biphasic pulses generated while PWM2 and PWM3 were in the same state.

Safety

Two important safety issues should be focus on in the novel ES device: high-voltage stimulation and safety precautions.

High-voltage stimulation- The skin impedance depends on the frequency, type of skin, circumstance of contact and so on. Skin impedance may be a nonlinear function of time and voltage. There are four types of skin: dry skin, skin with conductive paste, skin with cuts, and skin with cuts and conductive paste. For the maximum simulation frequency of 100 Hz in this ES device, the skin of humans was considered as dry skin or skin with conductive paste, therefore the impedance of skin within 100 Hz was more than 10 KΩ. In literature [12], the maximum safety DC current flow a person was 200 mA. In the boost circuit (Fig.2), the 1 MΩ resistor R1 was in series with another 20 KΩ resistor R2 to limit the output current to a safe state. The output current was no more than 0.098mA with 100V output voltage. Therefore, the circuit could be considered safe.

Safety and Precautions- There were still several precautions needed to take into consideration. The electrodes of this stimulation device should be placed on the wrists or ankles only, not across the chest. Additionally, the device should not be used on wet skin or skin with cuts. When this device was used to cure pain, the parameters should be slowly increased till the suitable stimulation parameter without pricking feeling was told by users. Moreover, patients implanted with electrical device, e.g. pacemaker or respirator, were prohibited from using this device [6].

Experimental Result

20 healthy subjects (22 to 25 years) were participated in the experiment to verify the effectiveness of this system on pain relief. Shanghai Pain Rating Scale [13] was used to assess the level of the pain. The specific processes were described as followed. Table 2 showed that the boost converter with voltage feedback reduced the output errors and improved the accuracy of the output voltage.

Table 2. The output of boost converter with and without voltage feedback.

| Expected Voltage (V) | Output(No Feedback) (V) | Error 1 (V) | Output(Feedback) (V) | Error 2 (V) |
|----------------------|--------------------------|-------------|----------------------|-------------|
| 10                   | 8.8                      | -1.2        | 9.9                  | -0.1        |
| 20                   | 18.4                     | -1.6        | 20.2                 | +0.2        |
| 30                   | 26.1                     | -3.9        | 29.8                 | -0.2        |
| 40                   | 44.2                     | +4.2        | 40.3                 | +0.3        |
| 50                   | 51.4                     | +3.4        | 50.2                 | +0.2        |
| 60                   | 57.6                     | -2.4        | 59.7                 | -0.3        |
| 70                   | 65.0                     | -5.0        | 69.8                 | -0.2        |
| 80                   | 73.8                     | -4.2        | 79.9                 | -0.1        |
| 90                   | 82.9                     | -7.1        | 90.1                 | +0.1        |
| 100                  | 92.2                     | -7.8        | 100.2                | +0.2        |

Experiment process—The subjects were asked to take a good rest prior to the testing to ensure their body without any pain or discomfort. The subjects were told the experiment steps in advance. Firstly, the subjects unfold the left hand fingers and put the whole hand into the 0℃
cold water for 3 minutes. Next, the level of pain was assessed and recorded according to the *Changhui Pain Rating Scale* for every 30 seconds. The subjects were able to draw their hand back when they cannot endure the pain. Then, the subjects took a rest in a quiet environment for 30 minutes. Later, the subjects were asked to use the ES system to cure pain for 10 minutes. According to the clinical experience of Chinese medicine wrist-ankle acupuncure, the electrodes of ES were placed on the sites which between radius and the ulna, i.e., the central of the carpal. After the placement of the electrodes, using the stimulation pulses with 2 Hz and 100 Hz to cure pain and alternating the frequency once for every 30 seconds. The amplitude of stimulation pulses was set at the maximum value that the subjects could endure without pricking generation. The total cure period is 10 minutes. The experiment was repeated four times and the results were averaged.

*Experiment results*—The experimental results were shown in *Fig.4*. It was suggested that the level of pain to some extent were reduced after curing by this analgesic system. The results still need more clinical trials to verify.

![Figure 4. Contrast of pain level before and after treatment.](image)

*Fig.5* showed the output waveform generated by this systems. The frequency, amplitude and pulse width of pulse set on the smart phone were 54 Hz, 60 V and 100 us respectively. From the oscilloscope, the parameters set on the smart phone were match with data on the oscilloscope.

![Figure 5. The output of the ES circuit.](image)

(a) Output of the ES circuit  
(b) Single Cycle of the ES Output

**Summary**

The circuit of *ES* device based on the theory of wrist-ankle acupuncture and *TENS* was designed in order to relieve pain. In this novel electrical voltage mode stimulation device, users were able to adjust the treatment voltage in a wide range from 0 V to 100 V. Moreover, there would be less power consumption compared to commercial electrical devices since no *OPAMP*
and transformer were used. The output voltage was accurate due to voltage feedback and closed-loop resistors implemented in this circuit. The circuit has been successfully tested to relieve pain by putting the electrodes on the certain place of ankle or wrist. Further clinical trials should be conducted at a large number of subjects.

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