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A Wearable Stimulation Bandage for Electrotherapy Studies in a Rat Ischemic Wound Model

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Abstract— **The clinical efficacy of electro-therapy in the treatment of chronic wounds is currently debated, and a in-vivo evaluation of stimulation parameters will provide the statistical evidence needed to direct clinical guidelines. A low-cost, wearable electrical stimulation bandage has been developed for use with an established rat ischemic wound model. The bandage consists of a user-programmable stimulator PCB and a plastic bandage with two hydrogel electrodes. The battery-powered bandage may be used for up to seven days between dressing changes, and the stimulator may be reused. The microcontroller-based stimulator uses a boost converter circuit to generate pulses up to 90V from a 3V coin cell battery. Consistent operation of the boost converter over the wide input and output voltage ranges is achieved using voltage feed-forward and soft-start techniques implemented in firmware. The bandages are laser-cut to shape, and electrical traces are applied using stencils and conductive nickel paint. Both the PCB and electrical traces are encapsulated to protect the animal. The device has been successfully demonstrated using the rat ischemic wound model for a period of seven days, and clinical experiments are ongoing.**

I. INTRODUCTION

CHRONIC wounds are a major clinical challenge for patients with diabetes, paraplegia, and other physical impairments. These wounds do not heal in a normal period of time, and clinical treatment is both difficult and costly [1]. The presence of endogenous electrical currents in chronic wounds [2] suggests that electro-therapy may be an effective method to increase the rate of healing. Several studies using electrical stimulation to treat chronic wounds have been conducted, but, an optimal stimulation pattern has not yet been identified [3] to provide evidence-based treatment guidelines for electrical wound stimulation.

In-vivo studies are necessary to quantitatively compare stimulation waveform parameters using tissue histology, immunohistochemistry, and other biological metrics. An animal model provides wounds in ischemic tissue with consistent size and etiology, and tissue samples may be harvested at the conclusion of the experiment. Rats are a practical species for testing a range of stimulation parameters in a statistically-significant sample size. However, they must be allowed to move freely within their cage during the 28-day experiment, so a stimulation device must be wearable and self-contained (e.g., no wire leads). The relatively small size of the animal requires a compact stimulation device to minimize physiological stress that would otherwise influence the outcome of the study. The stimulator should be as accurate as reasonable within the size and power constraints of the device to identify the best combination of waveform parameters. This paper presents a wearable stimulation bandage suitable for comparing waveform parameters in the treatment of chronic wounds in a small animal model.

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II. STUDY OVERVIEW

A previously-validated ischemic wound model in rats [4] has been adapted for electrotherapy studies using the device. As shown in Figure 1, an ischemic tissue flap is created along the back of the rat according to the wound model procedure. Two ischemic wounds are created using a biopsy punch in this slowly-healing region. Two more wounds are created in the healthy tissue adjacent to the ischemic wounds. These control wounds do not receive stimulation but are used to normalize the rate of healing between subjects.

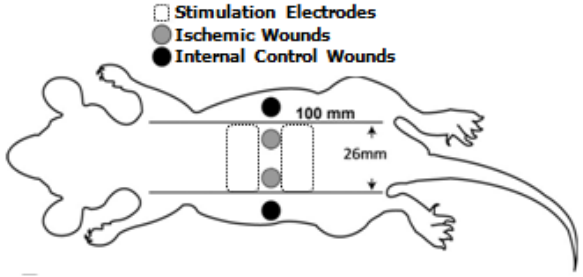


Fig 1. Rat ischemic wound model used to compare stimulation waveforms.

The ischemic wounds are stimulated via two 3 cm x 1 cm hydrogel electrodes located on the bottom of the device. The protective liner is removed from the gels, and then the device is applied to the back of the animal. In addition to providing stimulation, the bandage also serves as a dressing to keep the wounds clean and moist. The device is sutured in place, and then a secondary occlusive dressing is applied over the entire device. The rat is then placed in a fabric jacket to further protect the device and to keep the electrodes in position next to the ischemic wounds.

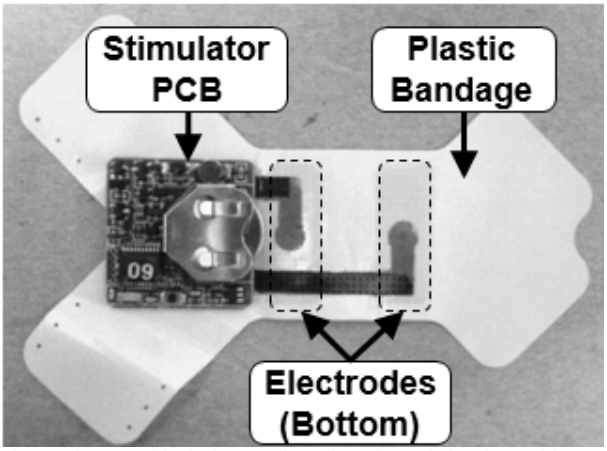


Fig 2. The wearable device consists of an electrode bandage with two gel electrodes and a battery-powered stimulator PCB.

The device and dressings are replaced weekly when the wounds are measured and photographed. Tissue oxygenation measurements of the flap and healthy tissue are also taken at this time. The used device is then replaced with a new one programmed with the same stimulation parameters. The ischemic wounds are stimulated for a total 28 days, then tissue samples are collected for laboratory analysis.

III. STIMULATOR DESIGN

The device consists of a battery-powered stimulator PCB mounted to a flexible plastic electrode bandage. The two components are manufactured separately, then assembled and sterilized prior to use.

A. Stimulator PCB

The stimulator PCB measures 2.5 cm square by 0.6 cm thick and weighs 14 grams. The microcontroller-based system shown in Figure 3 is powered by a replaceable 3V, 120mAh Lithium coin cell battery. All logic functions are implemented using an 8-bit microcontroller [5], and the stimulator control algorithm may be tuned in firmware. A small pushbutton activates the stimulator, and an LED indicates when current pulses are being discharged. A PC connects to the device using a serial port and is used to program the stimulation parameters and download measurements from memory. The PCB is protected from wound exudate and moisture by a conformal 20 µm coating of parylene applied after assembly and testing. The serial port pins are then covered with a header to prevent damage during use.

The first stage of the stimulator is a boost converter that steps up the battery voltage to charge a large tank capacitor up to a maximum of 90 V. The tank capacitor charge is adjusted to deliver the commanded peak current based on a measurement algorithm that provides an estimate of the skin resistance across the electrodes.

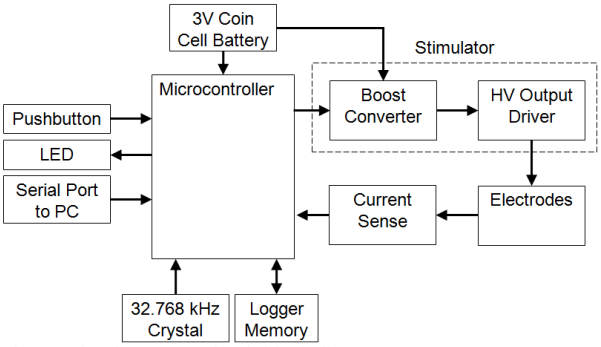


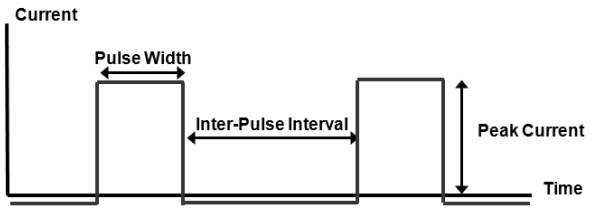
Fig 3. Stimulator PCB circuit block diagram.

The boost converter control loop is implemented in the microcontroller using the built-in hardware modules and firmware. The voltage of a coin cell battery decreases linearly as it discharges, so voltage feed-forward is used to maintain a consistent charging time for the tank capacitor. Lithium batteries also have limited peak current capacity, so a soft-start feature is implemented to limit the boost converter current and achieve reliable operation.

The output stage of the stimulator generates a biphasic current waveform based on timing parameters stored in the non-volatile memory of the microcontroller. The device may be programmed to deliver DC or AC stimulation. The stimulation waveform timing is carefully controlled in the firmware, and a crystal provides an accurate time base for the treatment duration. The range of each programmable stimulation parameter is given in Table 1.

TABLE I
PROGRAMMABLE STIMULATION PARAMETERS

Parameter	Range
Peak Current	0-18 mA[a] AC or DC coupled
Pulse Width	0-200 µs 1 µs resolution
Inter-Pulse Interval	40 ms – 80 ms 1 ms resolution
Stimulation Period	0-60 min/hr 1 min resolution
Treatment Duration	1-168 hrs 1 hr resolution



[a] The stimulator output voltage is limited to 90V. The range indicated assumes the skin resistance across the electrodes ranges between 5kΩ and 50kΩ.

Power consumption must be carefully managed to provide 7 days of stimulation using a small battery with limited capacity. The stimulator will consume static current when the tank capacitor is charged, so the circuit must be only activated just before discharging a pulse. Power

consumption is also reduced to below 1 mW by placing the microcontroller in sleep mode when the device is not actively stimulating.

B. Flexible Electrode Bandage

The electrode bandage substrate is cut to shape from a bio-compatible flexible plastic sheet using a CNC laser cutting tool. This approach has allowed the substrate shape to be iterated quickly based on clinical experience with the animal. The laser also drills holes for electrical vias and for suturing the bandage to the animal. The substrates are ultrasonically cleaned, then the surface is slightly roughened using an oxygen plasma treatment to improve bonding of the electrical traces.

Hydrogel electrodes are cut to shape, and a conductive tape backing is applied to uniformly distribute current across the gel. The prepared electrodes are attached to the bottom of the substrate using an alignment jig. The conductive tape fills the vias through the thin substrate to connect the electrodes to metal traces that will be created on the top side.

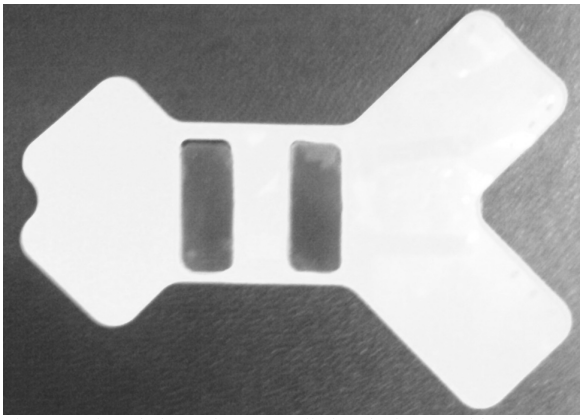


Fig 4. Hydrogel electrodes are applied to the bottom side of the substrate.

Electrical traces between the gels and the PCB are formed on the top side using conductive nickel paint using a technique previously demonstrated on a paper substrate [6]. The traces are sprayed onto the substrate using a stencil, and then dried in a warm oven. The traces are then covered with a protective layer of acrylic applied in a similar manner.

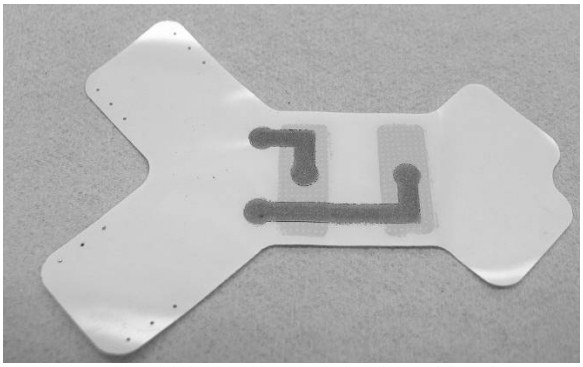


Fig 5. Top side of completed electrode bandage with nickel electrodes.

C. Device Assembly & Refurbishment

The stimulator PCB and electrode bandage are assembled into complete devices prior to sterilization and use. The stimulator is reusable, so it must be attached in a way that does not damage the parylene conformal coating on the PCB. Conductive tape strips measuring 5 mm wide connect the stimulator output to the electrode traces, and double-sided tape firmly attaches the PCB to the bandage. A fresh battery is installed, and then the completed devices are sterilized for 15 minutes per side under a germicidal UV lamp.

After delivering stimulation for seven days, the used device is removed from the animal. The soiled bandage is immediately removed and discarded, and then the PCB is topically disinfected using isopropyl alcohol wipes. The logger memory is downloaded to the PC, and then the depleted battery is disposed.

IV. RESULTS AND DISCUSSION

A. Stimulator Performance

The stimulator PCB performance has been measured using resistor loads within the normal skin impedance range of 5kΩ-50 kΩ. A typical stimulation current waveform is shown in Figure 6. The stimulator slews to over 90% of the peak pulse current within 10 μs and turns off nearly instantaneously. The high-voltage level shifters limit the minimum turn-on time, but they are designed to minimize power consumption from the tank capacitor.

The pulse amplitude drops over time as the tank capacitor discharges, and lower tissue impedance increases the rate of discharge. Using a larger output capacitor would improve output compliance at the cost of charging time and overall efficiency.

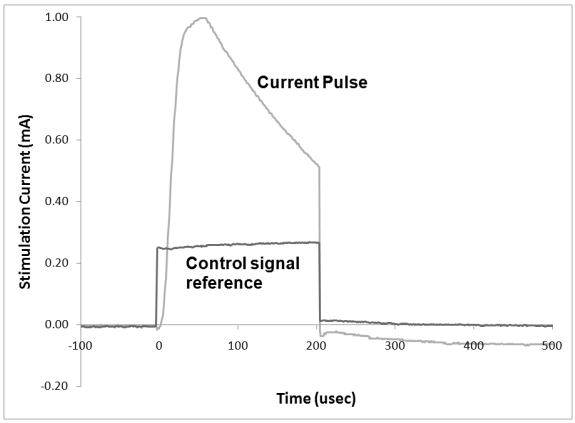


Fig 6. Typical current pulse waveform measured at the stimulator PCB terminals with 20 kΩ resistor load. The stimulator parameters are 200 µs pulse width, 1 mA peak amplitude, and 50 ms pulse interval.

B. In-Vivo Device Performance

The devices have been used to provide electrotherapy treatment to the ischemia rat wound model described. Initial versions of the device used only veterinary-grade adhesive to attach them to the animal and did not remain in place for the required length of time between dressing changes. When the bandage is sutured in place and protected with a fabric jacket, the electrodes remain in position to deliver stimulation adjacent to the wounds for the entire week-long period.

The used stimulator PCB remains operational after a week of use when programmed to deliver 2 mA stimulation pulses. The stimulators have been re-sterilized and reused an average of 8 times each with minimal damage, meeting the need for a cost-effective research tool to study electro-therapy in the treatment of chronic wounds.

V. CONCLUSION

A stimulation bandage suitable for unrestrained animals has been developed for use in a rat ischemic wound model. The device consists of a reusable stimulator PCB and a disposable electrode bandage. The device remains intact on the unrestrained animal for 7 days, and stimulation current pulses up to 2 mA and a 40 ms interval may be delivered continuously during that time. The efficacy of electro-therapy in the treatment of chronic wounds remains a long-term outcome of the study.

In a future version of the device, the stimulator circuits will be implemented in an integrated circuit to improve the boost converter efficiency and increase the stimulation current accuracy. Fewer PCB components will be needed, so the stimulator size will be reduced in this integrated version. The skin impedance measurement technique will also be improved to provide another source of data to observe the changes in tissue health over time.

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