An Electrical Stimulation based Therapeutic Wearable for Pressure Ulcer Prevention

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***Abstract*— This paper presents, for the first time, the design and implementation of a wirelessly controlled therapeutic wearable for the prevention of pressure ulcers. As a replacement to conventional methods of patient repositioning and air mattresses, the system delivers electrical stimulation (ES) to the pressured points in the gluteal muscles. The wearable includes an embedded electrical stimulation device along with flexible, skin adhesive electrodes. The electrotherapy parameters can be adjusted by the user via a user-friendly smartphone application connected wirelessly to the garment. Track of user's therapy history is stored on cloud, for analysis and physicians feedback. Optimized for muscle contraction and pressure ulcer prevention, the presented wearable can potentially help bed-ridden patients effortlessly and autonomously.**

I. Introduction

Pressure ulcers (PU), also called bedsores or decubitus ulcers, are wounds that develop when skin undergoes constant pressure for prolonged time. Due to the bony prominence, the common sites for PU include heels, shoulder blades, elbow and coccyx/sacrum (gluteal) with the latter being the most common one (Fig. 1) [1].

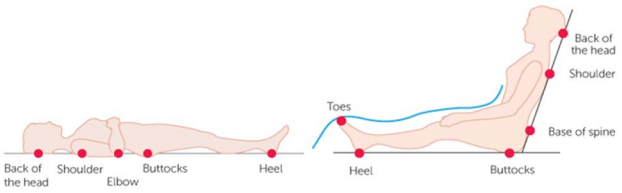

Fig. 1. Pressure points on body [2]

Every year almost 2.5 million people develop pressure ulcers and 60,000 deaths are caused directly by them [3]. Although all bed-ridden and wheel-chaired people are prone to develop pressure ulcers but the elderly are most vulnerable. More than three-quarter Spinal Cord Injury (SCI) patients develop pressure ulcer at some point in their life [4]. In 90% of the cases, patients receiving principle treatment for some other medical condition, develop pressure ulcers as a secondary condition [5]. As a result, they often go unnoticed until the wound becomes fully developed. At such a point, the ulcers not only become painful and difficult to treat but also cause hindrance in the treatment of patient's primary problem.

In US alone, the treatment cost of pressure ulcers is a staggering $11.6 billion, therefore prevention is considered a far more economical option. However, traditional methods for ulcer prevention involving frequent body repositioning, use of rich nutrition and air mattresses are either very expensive or less effective [6]. The most practiced method of body-repositioning not only involves high cost of nursing but also makes the individual dependent on a care taker.

This paper, to the best of author's knowledge, proposes for the first time, a system that delivers electrical stimulation to the gluteal muscles through a clip-on device and electrodes. Therapy parameters are adjusted through a smartphone app and therapy history is recorded on the cloud to be used for optimizing therapy patterns for future patients.

II. Working Principle and Electronic Design

Electrical stimulation (ES) is an established technique applied in different clinical settings. It is widely used in pain-relief, wound healing and muscle re-education [7]- [8]. Studies have also shown ES can be used as an effective tool to prevent pressure ulcers as it can help induce muscle contractions similar to natural ones [9]. Furthermore, it increases the oxygenation levels, regulate blood flow and intercept the development of pressure ulcers [10].

As highlighted in Fig. 2, this paper presents the design of the electrostimulation device for which the basic requirement is the generation of High Voltage Pulsed Current (HVPC) with specific voltage levels, frequency, pulse width and inter-pulse duration. Furthermore, the polarity of these current pulses is an important parameter and can be chosen either as mono-phasic or bi-phasic as represented in Fig.3. The latter type does not allow charges to accumulate in the muscles and is thus chosen in this work [11]. Other parameters of the waveform, their significance and suggested ranges are enlisted in Table 1.

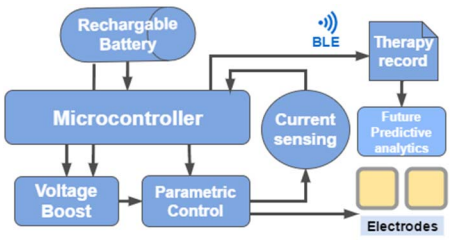

Fig. 2 . Block diagram of proposed solution

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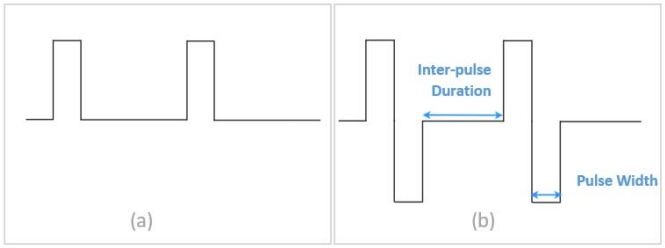

Fig. 3. (a) Monophasic and (b) Biphasic current waveforms

TABLE I. STIMULATION PARAMETERS

Stimulation Parameters		
Parameter	***Significance***	***Range***
Frequency	Speed of muscle contraction	15Hz – 50Hz
Pulse-width	Relaxation time between successive contractions	5% – 35% Duty cycle
Inter-pulse duration	Rest duration for muscle	30% - 90% Duty cycle
Intensity	Strength of muscle contraction	15Vpp – 50Vpp

The proposed design has two basic parts: hardware including ES device, wearable and flexible electrodes, and software including a smartphone application and a cloud server.

A. Hardware

Fig. 4 shows the schematic of developed ES device which consists of a step-up voltage converter, a digital potentiometer, a battery charge controller, an H-bridge circuit and a current sensor. All circuit components are surface-mount type and integrated in a miniaturized double sided PCB.

The ES device incorporates a step-up converter circuit to convert 3.7V input from a 1300mAH Li-ion rechargeable battery to a maximum of 25V utilizing which a 15Vpk-pk to 50Vpk-pk voltage range is achieved. The microcontroller, being the brain of the device, controls the frequency, pulse width and intensity of waveforms to be delivered to the skin. Output waveform is a rectangular, charge balanced, bi-phasic wave with an inter-pulse duration. The microcontroller also controls the start/stop of the stimulation and its duration. It has an onboard BLE chip which allows communication with the smartphone app. To adjust the stimulation intensity, a digital potentiometer is included in a specially designed resistive network, that when controlled through the microcontroller in turn controls the output voltage of the boost converter. Fig.5 shows the different values of resistance w.r.t to the numeric values in the micro-controller.

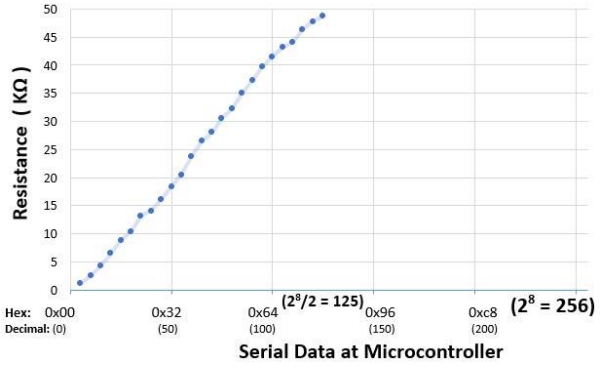

Fig. 5: Digital potentiometer resistance control

The constant DC voltage from the boost converter is converted to a bi-phasic rectangular waveform with specific inter-pulse duration using an H-bridge circuit. The H-bridge is controlled by the microcontroller to adjust the waveform frequency and pulse-width as required. As per established methods, stimulation of 10 seconds followed by a rest period of 10 minutes (i.e. 60 sec/hour) is sufficient to prevent

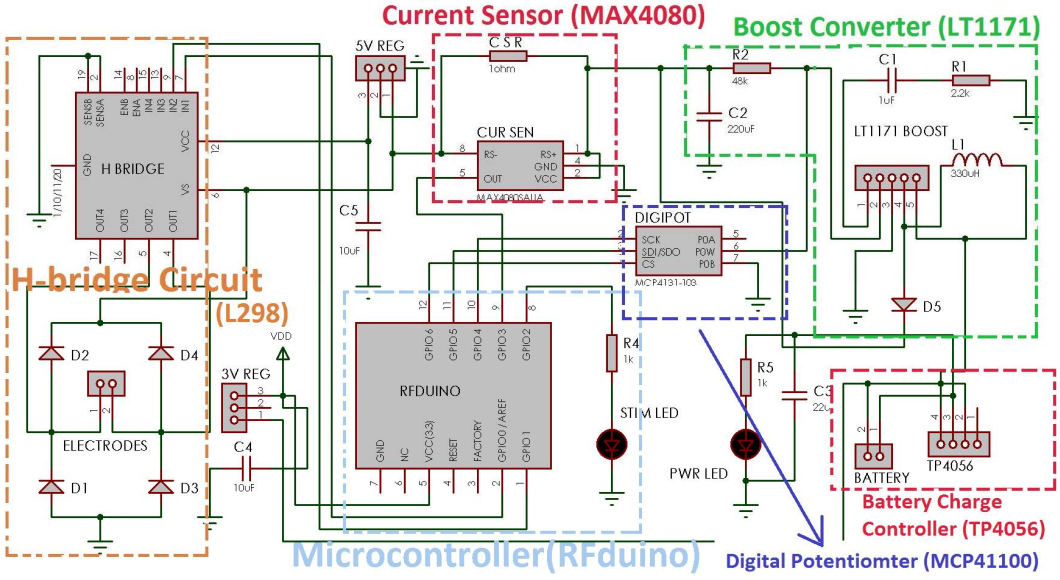

Fig. 4. Schematic of ES device

pressure ulcers [12]. The current consumption of the circuit is 830mA, however due to the pulsed operation, a battery life of 93 hours (>3 days) continuous operation is obtained with a 1300mAh rechargeable Li-ion battery. A smart charge controller is employed to prevent over-charge and over-temperature conditions of the Li-ion battery. To ensure safety from current over-flow, a current sensor is employed as feedback to monitor the stimulation intensity in real-time. In case of an over-current, stimulation automatically stops. In addition, a physical button is also present in the device to manually halt stimulation if needed.

The garment is made of a co-polymer, synthetic fiber called spandex. It is well known as a durable fabric and its elastic nature ensures direct contact with the skin. Furthermore, no loose ends or peeled corners are left behind during the electrode pocket stitching which improves the usability of the garment.

B. Software

The smartphone application empowers the user to adjust different stimulation parameters, i.e. pulse frequency, pulse width and stimulation intensity as required or suggested by the therapist. The application offers, basic and advanced modes of accessibility (Fig.6). The former includes three standard therapy plans with low, medium and high intensity whereas the advanced mode gives user control of all parameters to customize the therapy to his/her skin type and comfort.

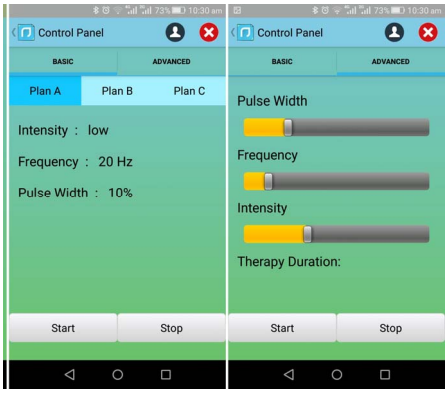

Fig. 6. Application layout

For every user, a patient profile is created on server and therapy history is recorded every time by the application and synced with the server. Having access to the data in tabular and graphical format, a physician can simultaneously monitor multiple patients undergoing stimulation therapy in a wide range of clinical settings. The therapy data displayed on server includes date, time, intensity, frequency, pulse-width and time duration of the stimulation. The data so collected can also be used for detailed insight and potential clinical studies. These web-based features of the proposed solution provide the doctors and nursing staff at a medical setting with a unique facility of remotely monitoring their patients.

Fig. 7. Example therapy time data of one patient on server

III. TESTING AND MEASUREMENT

To demonstrate the proposed solution, a stretchable pair of shorts is tailored with flexible, self-adhesive electrodes embedded at the back and the ES device packaged in a small plastic casing is clipped at the front (Fig.8).

Fig. 8. Backside and frontside of the ES device embedded in the wearable shorts

In order to validate the operation of the ES device, Electromyography (EMG) based testing was used to quantify the induced muscle contraction at two different hospitals. Since the muscle movement is due to an external stimulus, a special type of electromyography called needle EMG was used in which a needle is inserted in the muscle under stimulus.

Initial testing, performed at Armed Forces Institute of Rehabilitation Medicine (AFIRM), Rawalpindi, Pakistan was done on right lower-arm of the subject. Muscles were stimulated using the ES device and flexible pair of electrodes. Needle, inserted into the muscle under stimulus, picked up the potential generated by the contraction and relaxation of the muscles and displayed it on the screen. As shown in Figure 9, a flat graph was observed when no stimulation was applied while fluctuating peaks and physical movement of the fingers was observed when the ES device was turned ON. This indicated successful muscle contraction and relaxation within acceptable levels suitable for pressure ulcer prevention.

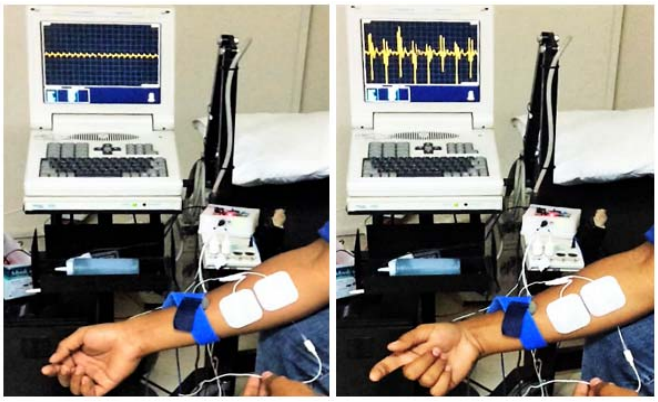

Fig. 9. Muscle activity due to (a) No stimulation (b) Stimulation applied by the ES device

Second phase of testing was done at the Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan. Muscles in upper-arm (biceps brachii) were stimulated and arm-flex was observed. Fig.10 displays the results of the EMG testing validating that the device was able to stimulate minimum of 3 motor points through adequate muscle contraction.

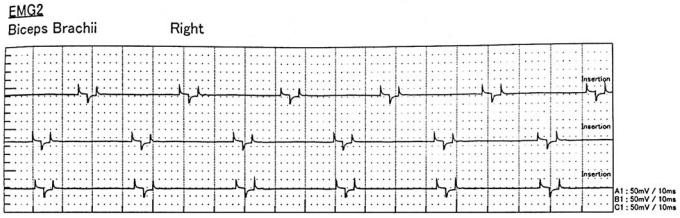

Fig. 10. EMG results at upper arm (biceps brachii) of subject

IV. Conclusion

A compact, rechargeable electrical stimulation device with wireless capability along with an electrode embedded wearable garment is presented as a system for pressure ulcer prevention. EMG testing of the device validates the intended operation. Therapy history stored on cloud facilitates the nursing staff and can potentially help medical practitioners analyze and conduct research on pressure ulcers.

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