A Portable and Wireless Transcutaneous Electrical Nerve Stimulation System to Generate a Pressure Sensation on the Foot

Seong Ho Yeon[1], Bharathi Saravanabhavan[2], Anthony De Filippo[2], Hangue Park[1], and Stephen P. DeWeerth[1, 2]

1. School of Electrical and Computer Engineering, Georgia Institute of Technology, GA

2. Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology, GA

Abstract

The development of a diabetic peripheral neuropathy (DPN) ultimately leads to amputation due to the abnormal pressure distribution caused by loss of sensation. This paper presents a portable and wireless transcutaneous electrical nerve stimulation (TENS) system to generate pressure sensation on the foot for diabetic neuropathy patients in order to self-adjust the abnormal pressure distribution and prevent complications of diabetic peripheral neuropathy such as foot ulcer and amputation.

The system consists of the stimulator, surface electrodes mounted at the ankle level, targeting the specified nerves, and pressure sensors that extend down into the heel metatarsal joints. The portable and programmable stimulator is capable of stimulating up to 25 V with 3.7 V portable Li-polymer battery with selected stimulation parameters. The goal would then be using the spatial distribution of the pressure, the location of the pressure as person walks, would stimulate the corresponding nerve to produce a perceivable response. The proposed device from our studies provides a portable, non-invasive method of applying stimulation to bring the pressure sensation on the foot back to diabetic neuropathic patients.

Problem & New Solution

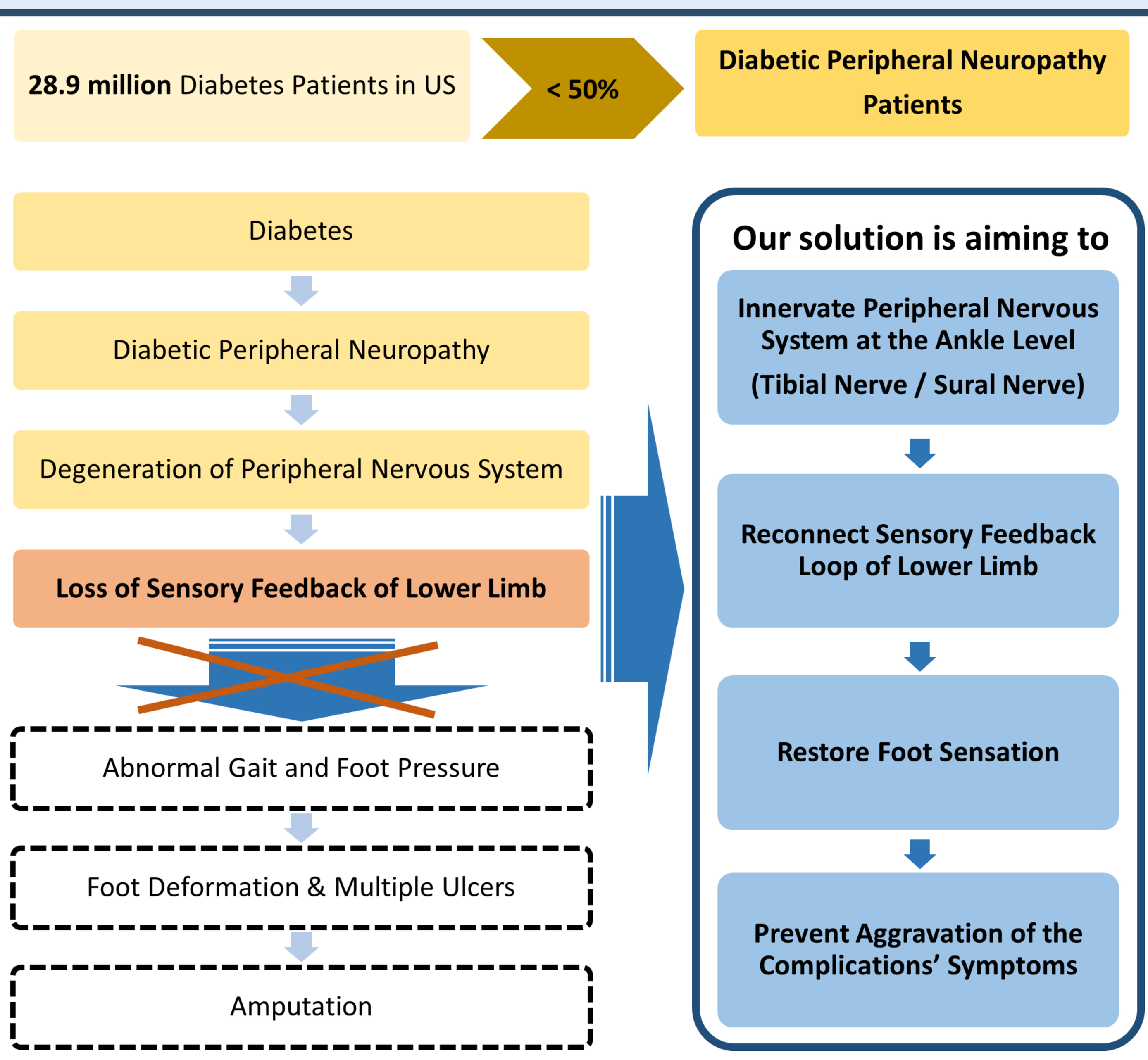

Fig. 1. Aggravation process of the complications of diabetic peripheral neuropathy (DPN) and our solution to overcome the complications using electrical stimulation.

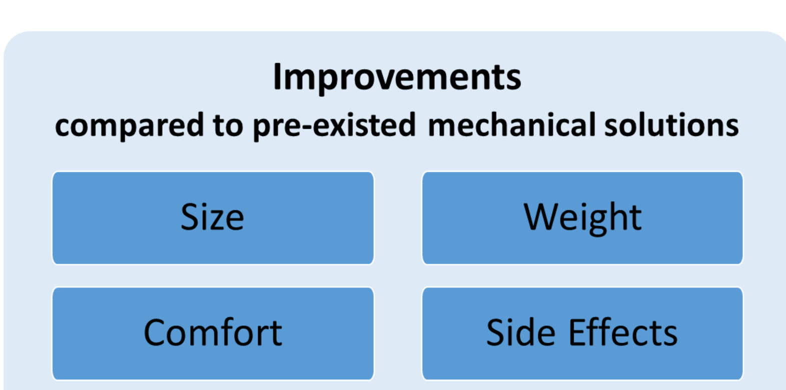

Fig. 2. Improvements of the proposed system compared to pre-existed mechanical solutions of the problem.

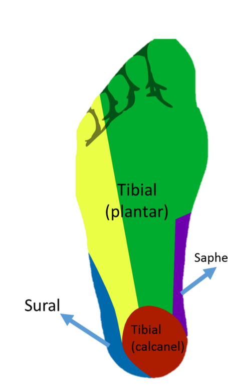

Fig. 3. The different points of innervation of the tibial, sural, and plantar nerves of the foot.

Proposed System Architecture

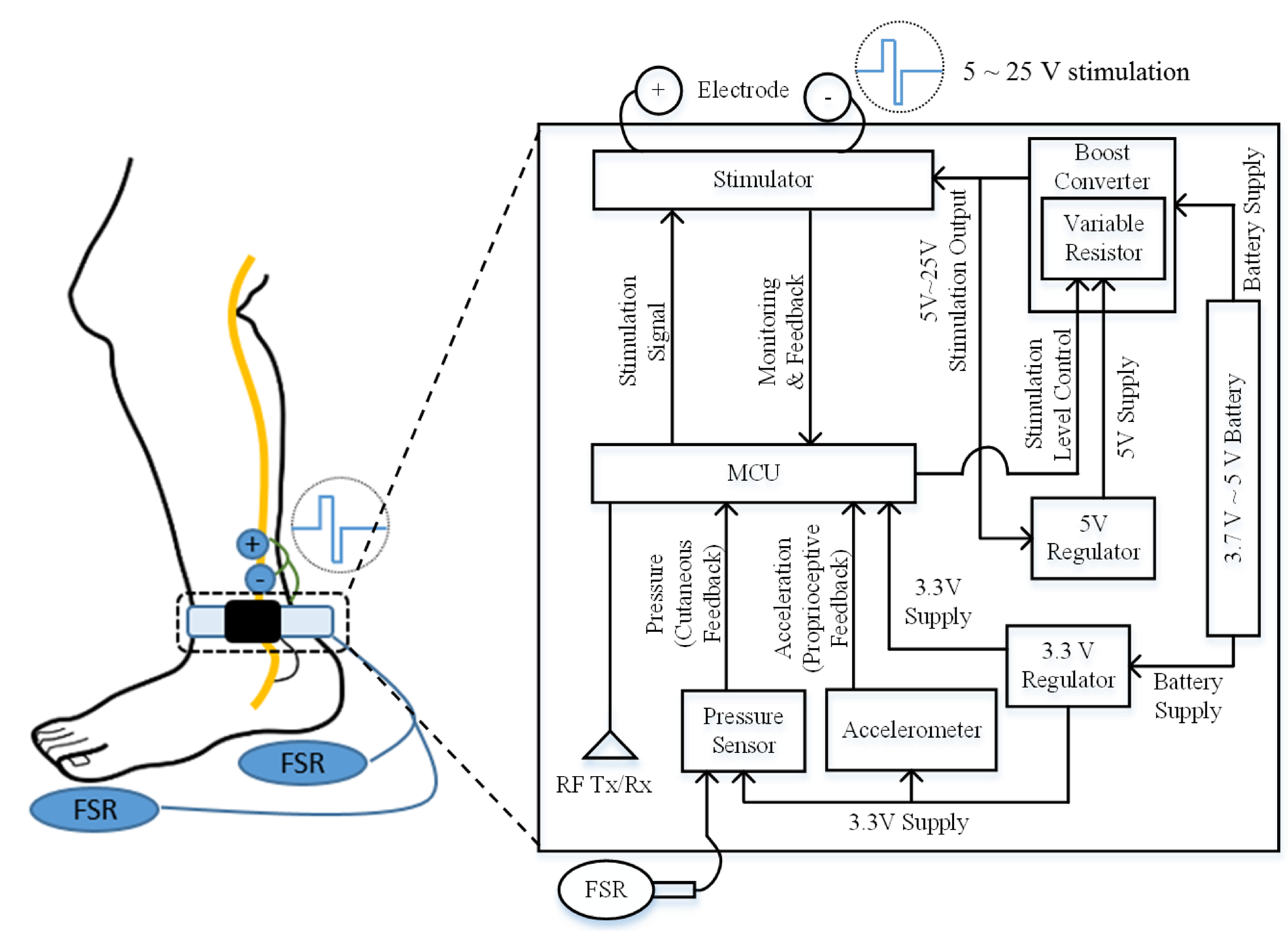

Fig. 4. Overall proposed System Architecture. The proposed system is controlled by MCU with 2.4 GHz RF-communication capability. The system has two force force-sensitive-resistors. These sensors mimic functionality of cutaneous feedback of a human body in order to test and build optimal stimulation scheme to generate natural pressure sensation. The system is designed to generate an electrical stimulus up to ±25 V by 3.7 V Li-ion portable battery with integrated DC-DC boost converter.

Table 1. Stimulator Specifications

Feature	Specification
Type	Biphasic
Current Range (mA)	0.5 ~ 10
Pulse width (us)	50 ~ 300
Pulse frequency (Hz)	10 ~ 200
Modulation frequency (Hz)	0 ~ 5

Table 1. Stimulation specifications of the stimulator. In order to generate the proper pressure sensation, stimulator parameters in Table 1 are being tested currently.

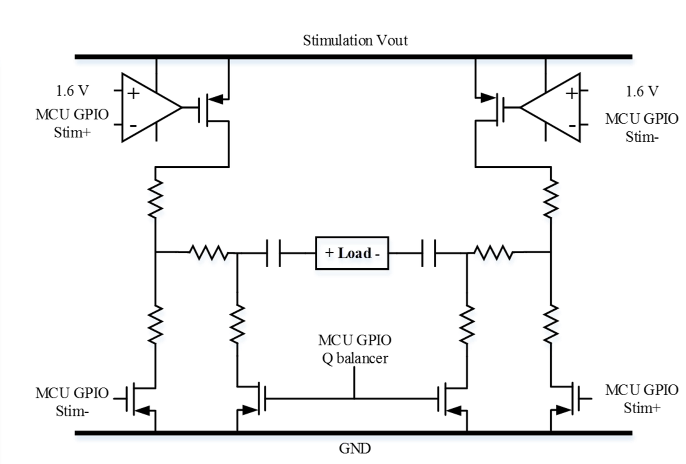

Fig. 5. Core Stimulation block structure. The stimulator core is controlled by 3.3 V GPIO signal of the MCU.

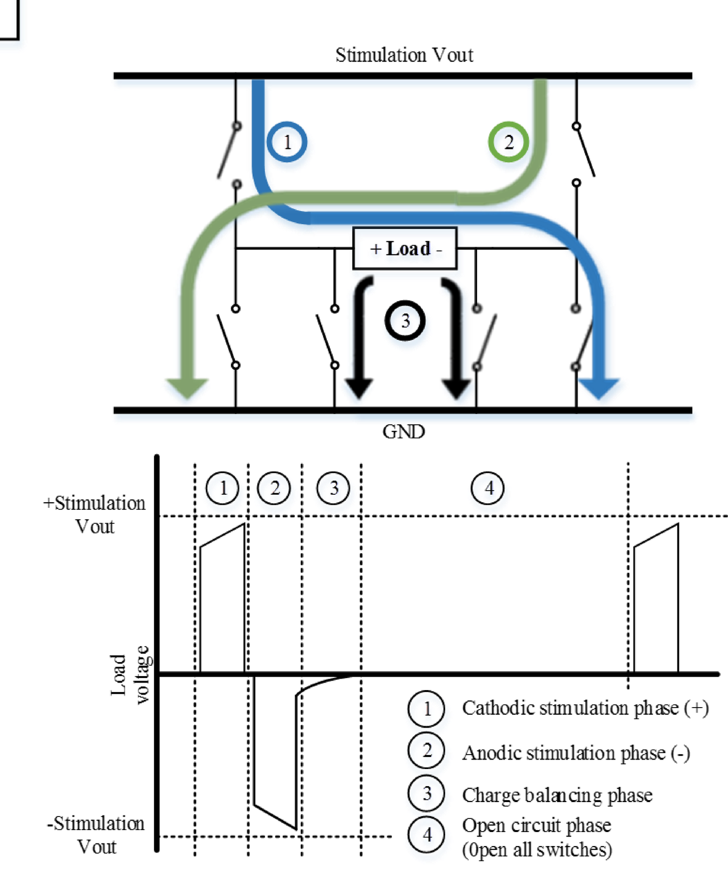

Fig. 6. Stimulation operation cycle consists of four phases. MCU enables precise control of the output voltage and period.

Implemented Prototype

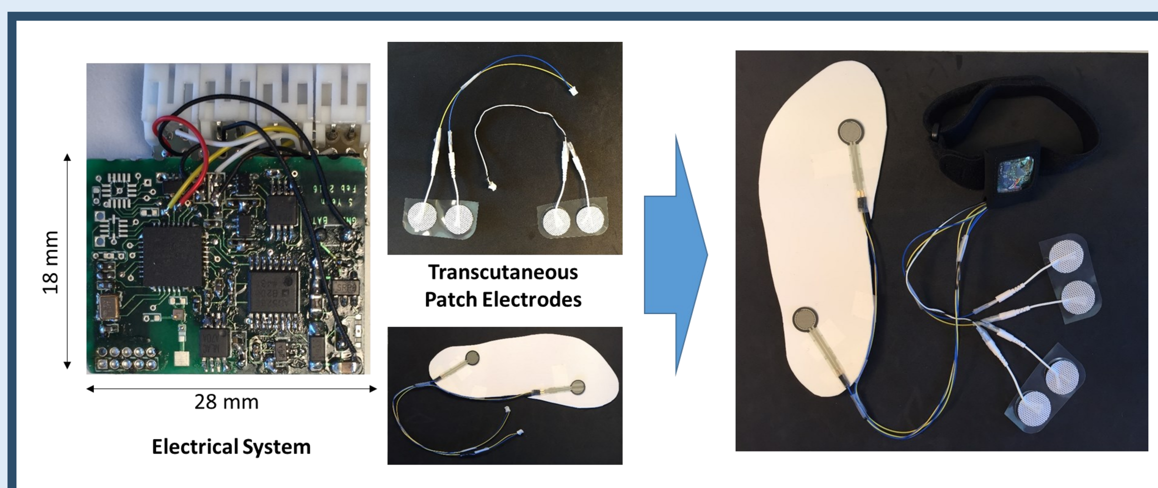

Fig. 7. The proposed system is currently implemented on the 28mm x 18 mm PCB. The system consists of a wearable shoe insole, electrical system with ankle strap, and two sets of transcutaneous electrodes. The system is powered by a 3.7 V rechargeable Li-polymer battery and is capable of stimulating up to 25 V with various stimulation parameters as shown in the table 1. Also, the electrical system has wireless capability and can be controlled with ordinary electronic devices such as a smartphone.

Fig. 8. The appearance and usage of the operation of the system. The electrodes are attached on the location right over the tibial and sural nerves at an ankle, with an array of pressure sensors located on the shoe insole. The system converts the spatial pressure distribution on the foot to an electrical signal to stimulate the tibial and sural nerves through electrodes;

Conclusion & Future Plan

We proposed a new solution to prevent complications caused by peripheral diabetic neuropathy using transcutaneous electrical stimulation. The device is capable of stimulating up to ±25 V powered by Li-Ion 3.7 V portable battery and programmable with various stimulation parameters such as amplitude, frequency, and pulse width. The parameters can be updated wirelessly from the outside.

The system is expected to improve the limit of existing solutions in aspects of comfortability and compactness. The system would allow DPN patients to protect their dignity by hiding their disease to other people. As a societal benefit, we believe that this would eventually offer DPN patients a new degree of freedom in the aspect of their social life.

With the expectation that our system would replicate the missing pressure sensation on the foot and recover the sensorimotor feedback loop of people with DPN, we will perform clinical tests to human subjects. At the same time, the next version of the system will have a higher wireless compatibility with Bluetooth Low Energy and a high-resolution pressure sensor.

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