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

Seong Ho Yeon, *Student Member, IEEE*, Bharathimurugan Saravanabhavan, Anthony De Filippo, Hangue Park, *Student Member, IEEE*, and Stephen P. DeWeerth, *Senior Member, IEEE*

***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 foot pressure sensation for diabetic neuropathy patients in order to recover the abnormal pressure distribution and prevent complications of diabetic peripheral neuropathy such as amputation.**

I. Introduction

Nearly 30 million people in the United States experience various stages of diabetes in its progression. Diabetic peripheral neuropathy (DPN) is one the most common issues for the diabetic patients, which appears in nearly 50% of patients within 10 to 15 years [1]. The development of the DPN leads to the degeneration of the peripheral nerves within the lower limbs [2]. This ultimately cause peripheral nervous system to be damaged, which can lead to the abnormal gait associated with the foot pressure [1]. The local peak plantar pressure is significantly higher in subjects with DPN compared to those having normal plantar sensation [1]. Therefore, these abnormal changes in plantar pressure during gait can cause foot deformations and foot ulcers, and finally result in amputation [1], [2].

The goal of this study is to recover normal pressure sensation on the plantar surface of the DPN patients, using a low-cost, portable, and wireless system with transcutaneous electrical nerve stimulation (TENS). The TENS will be applied to either a distal-tibial or a sural nerve to re-connect sensory feedback loop of the peripheral nervous system and prevent complications of DPN.

II. Proposed System

The system consists of its main printed circuit board (PCB) with transcutaneous patch electrodes mounted at the ankle level, which target either a distal-tibial or a sural nerve as shown in Fig. 1. CC2510 microprocessor (Texas Instrument, TX) is used to control the system. It also has 2.4 GHz RF-communication capability for a parameter update. The system has two force sensors implemented with force-sensitive-resistors. These sensors are chosen to mimic the functionality of a cutaneous feedback of a human body. With these pressure sensors, the system stimulates either a distal-tibial or a sural nerves at specific phase of the gait cycle to mimic the natural pressure sensation caused by the gait. The system is programmable with various stimulation parameters such as pulse width, pulse frequency, modulation frequency, and stimulation voltage. The stimulator is designed to generate a biphasic stimulus up to 25 V peak-to-peak amplitude. The system prototype has been implemented on the 21×18 mm^2 PCB with a 3.7 V rechargeable Li-ion battery.

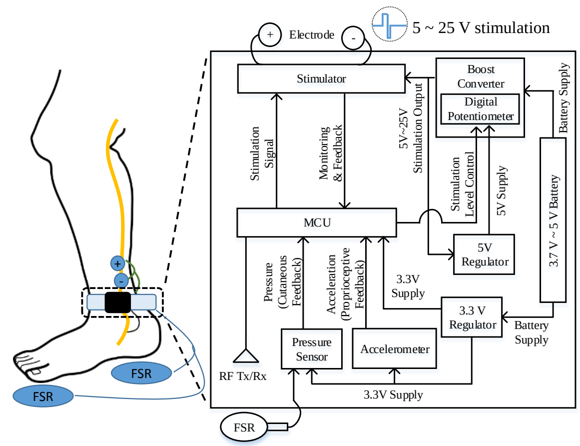

Figure. 1. The conceptual figure of the proposed stimulation system and the architecture of the stimulator

Table I. Stimulation Parameters

Parameter	Value
Stimulation Voltage	5 ~ 25 V
Pulse Width	50 ~ 250 μs
Pulse Frequency	10 ~ 200 Hz
Modulation Frequency	0 ~ 5 Hz

In order to generate a proper pressure sensation of the foot, stimulation parameters shown in Table I will be tested. Our short-term goal is to test different stimulation parameters to map them with pressure sensation on different areas of a foot. We will also perform clinical tests to human subjects. We expect our system will restore the foot sensation for DPN patients to prevent foot deformation, ulcer, and amputation.

Seong Ho Yeon and Hangue Park are with the School of Electrical and Computer Engineering, Georgia Institute of Technology, GA 30332 USA, (email:shyeon568@gatech.edu)

Bharathimurugan Saravanabhavan, Anthony De Filippo, and Stephen P. DeWeerth are with the Wallace. H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology, GA 30332, USA

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