Mini-Symposia Title:

Current Trends in Bioelectronic Systems to Interface with the Human Nervous System

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Jeonghee Kim at Texas A&M University

Mini-Symposia Speaker Name & Affiliation 6:

Theme:

- ○ 01. Biomedical Signal Processing
- ○ 02. Biomedical Imaging and Image Processing
- ○ 03. Micro/ Nano-bioengineering; Cellular/ Tissue Engineering &
- ○ 04. Computational Systems & Synthetic Biology; Multiscale modeling
- ○ 05. Cardiovascular and Respiratory Systems Engineering
- ◉ 06. Neural and Rehabilitation Engineering
- ○ 07. Biomedical Sensors and Wearable Systems
- ○ 08. Biorobotics and Biomechanics
- ○ 09. Therapeutic & Diagnostic Systems and Technologies
- ○ 10. Biomedical & Health Informatics
- ○ 11. Biomedical Engineering Education and Society
- ○ 12. Translational Engineering for Healthcare Innovation and Commercialization

Mini-Symposia Synopsis— Max 2000 Characters

The nervous system is highly adaptive, which enables human rehabilitation or augmentation by the repetition of the sensorimotor loop operation. However, the direction of the neural adaptation is not always optimal. The adaptation often makes detrimental change to the human body and results in undesirable secondary conditions. Also, the adaptation for the augmentation is not always effective and often results in degradation of the function rather than augmentation. Therefore, it is important to guide the neural adaptation in the proper direction for the desired human rehabilitation or augmentation. Electrical systems have a huge potential to guide the adaptation by interfacing with the nervous system. Neural signals can be recorded to interpret the neural code and can be modulated with different modalities (electrically, optically, ultrasonically, to name a few) to intervene with the sensorimotor operation. Electrical systems can also monitor the changes in environments as well as the human body, and in turn provide proper intervention to the nervous system.
The neural intervention for the desired changes can be achieved only when all components of the electrical system work in harmony with the nervous system. Although design and selection of each electrical component is important, the system-level design of the electrical system is more critical, which can be learned from the examples that currently operate well with the human nervous system. In this mini-symposium, we will introduce our current applications on neuro-electronics system interfacing with the human nervous system and guiding its adaptation.
One associate professor at New York Institute of Technology and four assistant professors at Texas A&M University, The Pennsylvania State University, and Korea University will present their recent works on bioelectronic systems that interface with the nervous system

Plantar Cutaneous Augmentation using Transcutaneous Stimulation Improves Balance in Challenging Environment

Hangue Park and Jacob Azbell, Department of Electrical and Computer Engineering, Texas A&M University

Abstract— **Peripheral neuropathy of the lower legs is a serious nervous system disorder that increases the risk of falls, mainly due to decreased sensation on the plantar surface of the feet. The objective of this study is to test our hypothesis that tactile augmentation on the plantar surface is more efficient than indirect compensatory sensory feedback in improving postural regulation when plantar cutaneous feedback is reduced. In our experiments, ten healthy human subjects stood on a lateral balance board and maintained their balance for as long as possible until the balance board contacted the ground for a fixed number of trials. The average balance time of the subjects was increased by plantar cutaneous augmentation, and further increased by the cognitive load. This result suggests that plantar cutaneous augmentation can be a promising way to improve postural regulation, particularly for individuals with compromised tactile feedback on the foot sole.**

I. INTRODUCTION

Peripheral neuropathy is common among individuals with diabetes; about 50% of them develop the condition within 10-15 years. Peripheral neuropathy with reduced plantar cutaneous feedback increases the risk of slips, trips, and falls. To mitigate these risks, several sensory augmentation approaches have been proposed. However, most of these methods provide sensory cues via visual, audio, or vibrotactile feedback rather than addressing the original plantar sensory deficiency. The efficacy of such methods can be limited by the cognitive load involved in processing these sensory cues, because cognitive capability varies upon the situation and cognitive load increases response time and fatigue.

The objective of this study is to test our hypothesis that tactile augmentation, by stimulating the sensory nerves innervated onto the foot sole, is effective in improving lateral balance for individuals with reduced plantar cutaneous feedback, even at cognitively-demanding situation. Tactile feedback from the foot sole (*i.e.,* plantar cutaneous feedback) plays an important role in postural regulation, especially at challenging environment [1], and therefore electrical nerve stimulation can boost postural balance in an individual with compromised plantar cutaneous feedback.

*Research supported by the The Institute for Rehabilitation and Research (TIRR) foundation.

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II. METHODS

According to the procedure described in the protocol approved by the Institutional Review Board of Texas A&M University, ten healthy human subjects with no history of neurological disorders participated in the experiments in this study. The subject group consisted of seven males and three females. All subjects were over the age of 18, and the average age of subject group was 24.8 years. Subjects repetitively stood on a lateral balance board, which is challenging even for healthy individuals, and maintained balance for as long as possible. Subjects were instructed to close their eyes during the tests to increase dependency on plantar cutaneous feedback for balancing. A layer of foam was placed on top of the balance board to replicate the reduced plantar cutaneous feedback of peripheral neuropathy. For tactile augmentation on the foot sole, low-intensity electrical stimulation was transcutaneously applied on the calcaneal nerve. To test the effect of cognitive load, subjects was asked to continuously count backwards from a random two-digit number by 7.

III. RESULTS

Experimental data shows that plantar cutaneous augmentation increase balance time, which is the duration subjects remained balanced on the balance board [2]. With cognitive load, plantar cutaneous augmentation further increases the balance time. That is, cognitive involvement decreases the effectiveness of the plantar cutaneous augmentation. This result suggests that the plantar cutaneous feedback is intrinsically engaged in the human balance system during the balancing on the balance board.

IV. DISCUSSION & CONCLUSION

This result opens up room for more studies on this phenomenon in order to clearly define the best method of treating poor balance due to peripheral neuropathy, both in an assistive manner and a rehabilitative approach.

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A Wireless ASIC for Microscopic Ultrasound Neuromodulation

Mehdi Kiani, The Pennsylvania State University

***Abstract*— Previously, we have proposed microscopic ultrasound stimulation (µUS), as a minimally invasive neuromodulation tool which can provide sub-millimeter spatial resolution. This paper presents an ASIC with wireless power and data transmission capabilities to provide required control signals to efficiently drive an ultrasound transducer with sufficient power for successful ultrasound neuromodulation.**

I. Introduction

Neuromodulation can be used as a therapeutic strategy for treating neurological and psychiatric diseases and also as a study tool to investigate brain circuitry function. Currently, there are different invasive and non-invasive neuromodulation modalities. However, either they provide large spatial coverage noninvasively while yielding a poor spatial resolution (e.g. transcranial magnetic stimulation) or they provide sub-millimeter (mm) resolution while yielding a limited coverage with extremely invasive parenchymal implantation (e.g. deep brain stimulation).

To mitigate this tradeoff, recently we have proposed microscopic ultrasound stimulation (µUS) concept in which either an array of ultrasound transducers or several mm-sized transducers are placed under the skull on the brain surface to locally deliver acoustic pressure to the target brain tissue [1]. Therefore, undesired large attenuation and diffraction caused by the skull in conventional transcranial focused ultrasound stimulation (tFUS) can be eliminated in the µUS. For successful neural stimulation in both µUS and tFUS, the acoustic pressure at the target should be higher than a threshold. The transducer electrical-to-mechanical efficiency and input electrical power provided for the transducer are the main factors that determine the generated acoustic pressure by the transducer as discussed in [1]. In this paper, we focus on the design of an ASIC that can provide different stimulation patterns and can efficiently drive the transducer with sufficient power for successful ultrasound stimulation.

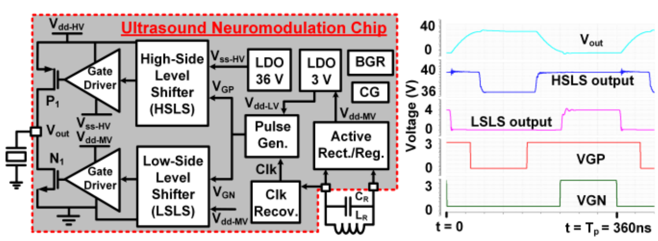
II. Methods

Fig. 1a shows the block diagram of our first prototype ultrasound neuromodulation ASIC which was designed in a 0.25-µm HV BCD CMOS process. To achieve the threshold acoustic pressure for successful neuromodulation, it is required to excite the transducer with a high voltage. Thus, the ASIC circuit blocks need different supply voltages, depending on their tasks and the fabrication process constraints. The ASIC is equipped with a power management unit (PMU) based on an inductive full-wave active rectifier-regulator topology to achieve short-range wireless power and data transfer. The PMU provides a supply voltage $V_{dd\text{-}MV} = 4$ V to power low-power blocks. The clock recovery block generates the reference clock signal (*Clk*) from the inductive link power carrier. Then, a signal generator block creates control switching signals (V_{GN} and V_{GP}). Moreover, there is a low-dropout regulator (LDO) that generates supply voltage for the signal generator block ($V_{dd\text{-}LV} = 3$ V).

Within the high-power circuits, first V_{GP} and V_{GN} signals are shifted to [$V_{ss\text{-}HV} = 36$ V, $V_{dd\text{-}HV} = 40$ V] and [0, $V_{dd\text{-}MV}$] levels via high-side and low-side level shifters (HSLS and LSLS in Fig. 1b), respectively. Note that the maximum gate-source voltage in this process for power transistors is 5 V. Then, the gate drivers apply switching signals to the power transistors (P_1 and N_1) to excite the transducer. Providing sufficient power with high efficiency was the main goal in the design of this ASIC. Thus, we have employed a class DE diver with nonoverlapping switching signals to reduce switching losses and achieve the maximum efficiency [2].

III. Results

Fig. 1b shows the simulation results of the neuromodulation chip operating at the frequency (f_p) of 2.78 MHz ($T_p=1/f_p=$ 360 ns). It can be seen that unlike conventional ultrasound inverter-based drivers, the switching signals (V_{GP} and V_{GN}) are not overlapped. The pulse width of the V_{GP} and V_{GN} are determined to achieve zero voltage switching (ZVS) and zero derivative switching (ZDS) for the voltage cross transducer (V_{out}) [2]. Simulation results show that the ASIC is able to provide high output power of 3.7 W with high efficiency of 87% thanks to the proper switching strategy. It is notable that the transducer impedance can considerably affect the output voltage (V_{out}). Thus, switching signals should be updated for a given transducer impedance.



(a) (b)

Fig. 1. a) Simplified block diagram of the ASIC, and b) simulation results of the proposed neuromodulation ASIC.

*This work was supported by the NIH under Grant 1R21EY029424.

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Energy-Efficient Wireless Neural Stimulation Systems for Implantable Devices

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Abstract— **Neural stimulating implantable medical devices (IMDs) have been widely used to treat neurological diseases. Recent IMDs demand higher performance for sophisticated therapies, while consuming higher power to handle more functions. Inductive power transmission across the skin is a viable solution to power up an IMD, while it demands high power efficiencies at every power delivery stage for safe and effective stimulation. This paper reviews various wireless neural stimulating systems and their power management techniques to maximize the IMD stimulation efficiency.**

I. INTRODUCTION

Implantable medical devices (IMDs) with stimulating functions have proven to be effective therapies to alleviate neurological diseases or substitute sensory modalities lost due to disease or injury [1]. These implantable stimulators are capable of injecting a designated amount of charge into the surrounding tissue by providing a precise amount of output current or output voltage between two or more electrodes for a predefined period. high power efficiency is paramount in reducing the risk of tissue damage from overheating as well as extending the range of a wireless power transmission link and external battery life. Therefore, the stimulation IMDs need to adopt efficient stimulating schemes and power management techniques to further improve stimulation efficiency.

II. METHODS

Voltage-controlled stimulation (VCS) enables power-efficient stimulation. However, balancing the stimulation charge is quite complicated in VCS because the electrode impedance can vary over time and position. On the other hand, current-controlled stimulation (CCS) has been widely used because of its precise charge control and safe operation by using current sources. However, the CCS system suffers from low power efficiency because of the dropout voltage across its current sources.

Recently, a wireless SCS system was proposed [2], which has inductive capacitor charging and charge-based stimulation capabilities for energy-efficient stimulation. Fig. 1 shows the conceptual block diagram of the inductive power flow from the external energy source to the tissue in the SCS systems as well as the resulting stimulus waveform. The streamlined inductively powered SCS efficiently charges the storage capacitors directly from the inductive link and delivers the quantized stored charge to the electrode/tissue, modeled by a series RC, improving stimulator efficiency. In addition, the SCS system can generate a decaying exponential stimulus by dumping the capacitor charge in the tissue without wasting additional power. This decaying exponential stimulus can be equally, if not more, effective in activating a larger target tissue area, compared to the conventional rectangular stimuli, while consuming the same amount of energy, thus improving both stimulus efficacy and safety.

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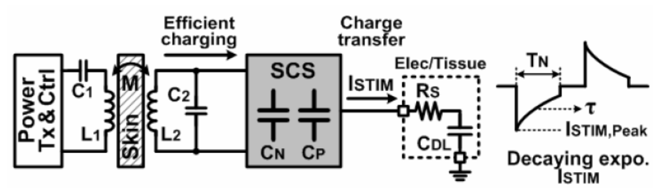

Fig. 1. Conceptual block diagram of the wireless switched-capacitor stimulating (SCS) system [2].

III. RESULTS

Multiple *In vivo* animal experiments with the SCS system were conducted. The stimulation pulses were applied to the posterior limb in the brain of an anesthetized cat, and the responses (EMG) were recorded from the arm muscle. The SCS system evoked sufficient EMG responses from arm muscle, while achieving higher power efficiency up to 80% compared to conventional systems with 40~60% efficiencies.

IV. DISCUSSION & CONCLUSION

Wireless neural stimulating systems require high stimulation power efficiency to perform effective therapies through multiple sites, without raising surrounding tissue temperature, and to operate with their limited available wireless power. Various circuit and system-level techniques can be utilized in stimulating IMDs to efficiently generate stimulus pulses from the wireless power and precisely deliver them to the tissue.

ACKNOWLEDGMENT

This work was supported by National R&D Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science & ICT (NRF-2017R1C1B5017989).

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System and Methodology to Map and Modulate the Gut Activity

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Abstract— **We are presenting a brief overview of the systems that we have developed to study the gastrointestinal (GI) bioelectrical activity, termed slow waves, and electrically modulate the GI to relieve functional disorders. The systems often consist of a front-end implantable unit (IU), a wearable unit (WU), and a back-end stationary unit (SU) connected to a computer. A graphical user interface (GUI) was designed to process and display the recorded data in real-time and store them for off-line analysis. The systems are equipped with a WU-IU wireless power transfer link, which makes them appropriate for long-term studies.**

I. Introduction

Stomach motility is regulated by an underlying electrophysiological activity termed slow waves (SWs) [1]. Analysis of SW activity —especially in high-resolution (HR)— has become a powerful tool in assessing the functional disorders of the GI tract such as gastroparesis and functional dyspepsia. However, most of systems currently available for HR mapping are wired and can be used while subjects going under abdominal surgery. Implantable wireless systems have been proposed as an alternative.

Electrical pulses directly applied to the GI have been used as a promising treatment. Long pulses (in the range of hundreds of milliseconds) applied at low-frequency (close to natural frequency of the organ) can modulate the SWs, and short pulses (in the range of hundreds of microseconds) applied at 5-100 Hz can improve nausea [2]. Due to the high energy consumption of the long pulses, there is no implantable system available for this modality.

II. Methods

The IU of the systems often consists of single- or multi-channel(s) recording, single- or multi-channel(s) stimulation, and power management circuits. The recording circuit is designed based on an analog conditioning circuitry to acquire the slow waves and deliver the amplified and filtered signals to a 12-/14-bit analog-to-digital converter. Afterward, a microcontroller takes the samples and by making RF data packets, transmits them to the WU/SU through a MICS/ISM band transceiver link. At the computer, data are received in real time and presented in GUI.

The stimulating circuit is capable of delivering electrical pulses with amplitudes of up to ±12 mA to a 1 kΩ load. The circuit can generate programmable bipolar, monopolar and unbalanced current pulses with the amplitude resolution of 0.73 μA and time-widths from 60 μs to 60 s. The stimulation parameters can be instructed by the user via the GUI. Furthermore, the power management circuit is added to the IU to receive, rectify and recharge a local battery through the power transmitted (Tx) inductively by the WU. The voltage of the IU's battery is measured consistently, and the amount of Tx power is regulated accordingly.

*Research supported by National Institutes of Health (#U18EB021789).

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III. Results

Three different systems were developed and validated. A 64-channel recording system with integrated array of 8×8 electrode spaced 4 mm apart, was used to map the SWs of the greater curvature, ~5cm proximal to duodenum, in a porcine [3]. The IU can be communicated through both RFID link with the WU, and through a 2.4 GHz link with the SU. The IU only consumes ~6 mW while in RFID communication, and recharges its 105 mAh battery with minimum rate of 60 mV/hr. This system is designed to be implantable through an endoscopic procedure. Another system with 3 recording and one stimulation channels was developed and validated in porcine. The system can deliver electrical pulses with both short and long pulses, and it was capable to module the stomach activity [2]. Finally, a single channel recording/stimulating system was developed for small animals and was validated in rats [4]. While the SW activity recorded from the stomach of the rat was in the range of approximately 5 cpm, pulses delivered to the rat's stomach every 15s, reduced the activity to 4 cpm.

IV. Discussion & Conclusion

The 64-channel system provides a powerful tool to study the stomach activity in fast and fed states. The second and third systems demonstrate the simultaneous recording and stimulation, with capability to modulate the SWs.

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Peripheral-Nerve Electrical Stimulation for Upper-Limb Tremor Modulation using a Wearable Wrist Device

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***Abstract*— For patients with treatment-resistant tremor, we have developed an effective, easy-to-use, non-invasive treatment method by providing a sensor feedback (i.e., peripheral nerve stimulation) that modulated the sensory pathway to suppress unwanted reparative oscillatory movements that interfere with daily activities. As a pilot study, we evaluated the efficacy of the stimulation and explored the proper range of the stimulation parameters (e.g., amplitude, frequency, duty cycle, phase, stimulation sites, and time spacing between the pulse trains). The dominant frequency and maximum amplitude of the tremor was significantly changed by the stimulation. This preliminary study lays the foundation for future studies in larger patient populations to evaluate the efficacy of this stimulation method with a closed-loop algorithm for parameter optimization to maximize tremor reduction.**

I. INTRODUCTION

Tremor is an abnormal oscillatory movement observed in patients with essential tremor (ET), Parkinson's disease (PD), and other neurological disorders. Kinetic tremors (i.e., ET), which particularly affect movements that require a high degree of dexterity and precision, can severely disrupt the activities of patients in daily life. Several studies applied cutaneous/peripheral nerve stimulation to the hand or the wrist to suppress tremor movement [1-3], but they did not study fully integrated systems as a wearable device, nor did they apply real-time parameter update. Thus, we have developed an easy-to-use, non-invasive, wearable tremor modulation system that uses peripheral nerve stimulation and real-time parameter updates and quantitatively evaluated the feasibility of the system for future implementation.

II. METHODS

The wrist device consists of a three-axis motion sensor (LSM303D, STMicroelectronics), a microcontroller (CC2510, Texas Instrument), a wireless transceiver (2.4 GHz radio frequency), stimulator circuitry (constant voltage mode), a rechargeable 3.7 V lithium ion battery, and a pair of surface electrodes (1" round TENS Unit Electrodes, Syrtenty). All custom-designed electronics ($18x28mm^2$) were enclosed in a wrist band, and the bi-phasic stimulation can be increased up to ± 25 V. The motion-sensor data were wirelessly conveyed to the computer, in which off-board signal processing determines the stimulation parameters, and the updates stimulation parameters in real time.

Data were collected from two participants (one 19-year-old male and one 20-year-old female) both of whom had kinetic tremor in both arms. This study was approved by the Institutional Review Board of the Georgia Institute of Technology. To evaluate the effects of the stimulation on the peripheral nerves, we placed the electrodes one at a time on the radial (R) and ulnar (U) nerves of the dorsal hand and on the upper limb skin independently. We changed four parameters—amplitude, frequency, duty cycle, and stimulation site—while observing kinetic tremor when the subjects relayed a small object from one cup to another using a spoon. We analyzed the dominant frequency and the maximum amplitude in the frequency domain. The root mean square (RMS) of the three-axis accelerometer data was high-pass filtered (HPF) (a cutoff frequency of 3 Hz) and used for frequency analysis.

III. RESULTS

Before the stimulation, the averaged dominant frequency of the tremor movement for the two participants (9.13 Hz), significantly changed by stimulation. The maximum amplitude of the tremor movement in the frequency domain (6.27 mg) also significantly changed by the stimulation. The effects of frequency and amplitude changes by stimulation did not differ significantly according to the site of stimulation.

IV. DISCUSSION & CONCLUSION

From this preliminary study, we observed that peripheral nerve stimulation significantly affected the dominant frequency and tremor amplitude. In future studies, we aim to pursue real-time parameter optimization to maximize the effects of stimulation, and to minimize "nerve fatigue" by electrical stimulation.

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