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Bidirectional Communications in Wireless Microstimulators Based on Electronic Rectification of Epidermically Applied Currents

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Abstract— **Functional Electrical Stimulation (FES) has been used in order to restore muscle functions in patients suffering from neurological disorders. This therapeutic approach benefits from technological improvements that yield miniaturization. We previously have proposed and demonstrated an innovative electrical stimulation method in which wireless implants act as rectifiers of innocuous high frequency (HF) currents. These currents are conductively supplied to the tissues where the implants are located through external electrodes. Locally, the implants generate low frequency currents capable of stimulating excitable tissues. The method has the potential to enable unprecedented levels of miniaturization. The implant needs only two peripheral electrodes both for picking-up the HF current and for performing electrical stimulation. In addition, a tiny hybrid microcircuit, or a single integrated circuit, may integrate all the necessary electronic components. No bulky parts such as coils or batteries are required. We have demonstrated a number of circuit architectures for the implants with advanced capabilities such as digital addressability. In here, we demonstrate that the proposed method also allows bidirectional communications between the implants and the external system that powers and governs them, enabling proprioception-like sensing capabilities that may be crucial for closed-loop FES systems. We demonstrate a scheme based on amplitude modulation and Manchester encoding.**

I. Introduction

Functional Electrical Stimulation (FES) has been widely used in order to restore muscle functions of patients suffering from neurological disorders, such as spinal cord injury and stroke. Electric currents are applied at the vicinity of the motor nerves in order to stimulate the muscles. This is usually done through multiple electrodes that are connected to leads, which in turn are connected to a pulse generator. As this may imply highly-invasive complex surgical procedures and the risk of infections, it has been proposed the use of a distributed network of single channel wireless microstimulators governed by an external unit. This strategy ensures ease of implantation and minimal invasiveness, but implies the development of devices with minimal dimensions [1] that are capable of generating high enough current pulses for electrical stimulation. A number of wireless microstimulators have been developed according to that approach and all of them have either relied on inductive coupling or batteries as powering methods [2][3]. Yet, these microstimulators are still too large and stiff for their intended functionality, as a minimum coil diameter is needed to generate enough power for FES applications in the former method, and a battery *per se* takes up an important amount of volume in the latter one.

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We recently proposed and *in vivo* demonstrated an alternative electrical stimulation method [4] that avoids the use of coils and batteries inside the implants. The implant acts as a rectifier of innocuous high frequency (HF) current bursts that are conductively supplied to the tissues using external electrodes, accomplishing locally low frequency (LF) currents capable of stimulating excitable tissue. This method is schematically illustrated in Fig. 1. We numerically showed in [5] that the method can be put in practice avoiding unsought electrical stimulation and tissue overheating according to international standards.

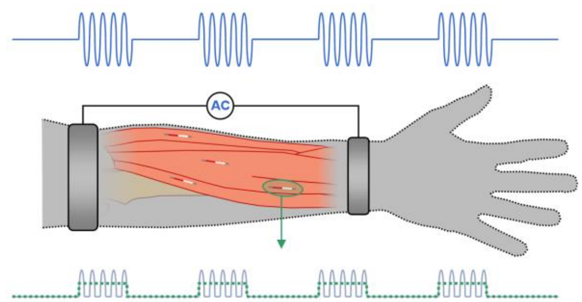

Figure 1. The electrical stimulation method proposes the use of implants as rectifiers of innocuous high frequency current bursts (> 1 MHz), which are conductively supplied to the tissues through external electrodes. Locally, the implants generate low frequency current densities that are capable of stimulating excitable tissue.

We conceive ultrathin elongated implant bodies (diameter < 300 μm) that can be easily deployed in tissues (e.g. by injection). These implants would contain ASICs with advanced capabilities such as current magnitude control, bidirectional communication and sensing, allowing the use of several implants that will form a complex network of addressable single channel wireless microstimulators for fine muscle recruitment, controlled by an autonomous portable external unit.

In [6] we demonstrated that an implant with a simple circuit consisting of a rectifier, a capacitor and a resistor is able to deliver charge-balanced low frequency currents capable of stimulating tissues. Furthermore, we have also demonstrated that current magnitude control and downlink

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communications are feasible: we *in vivo* demonstrated in [7] that addressable wireless stimulators based on the proposed method were able to receive commands and generate controlled current pulses capable of stimulating an anesthetized earthworm.

In addition to addressability and stimulation capabilities, it would be highly beneficial to include sensing features within the implants. There are a few cases of microstimulators that include sensors [8]. The Bionic Neuron (BION) has been an important development in this sense [9]. BIONs include sensing capabilities for biopotentials, pressure, temperature and angle/position [8]. These sensors can be used as the basis for an artificial proprioception system so that closed-loop FES systems can be developed. In addition, these sensors can be used to interpret commands from the patient. For instance, internal electromyogram signals can be sensed for detecting movement intention rather than employing an external joystick or a set of press buttons.

As it becomes obvious that an uplink to send sensing data from the implants to the external unit is a beneficial feature for the proposed method, here we present a proof-of-concept prototype of a bidirectional communication link. We propose the use of the implant architecture demonstrated in [7] and an uplink communications scheme appropriate for the electrical stimulation method.

II. Proof-of-Concept Prototype

A. Uplink Communications Scheme

As previously mentioned, we demonstrated in [7] the implementation of a downlink between an external system and the stimulators. We transmitted commands by means of amplitude-shift keying (ASK) using the Manchester code, at a rate of 20 kBd on the auxiliary 1 MHz sinusoidal current. That is, the delivered HF current to power up the stimulators also included addresses and commands to control the devices. In response to those commands, the stimulators generated 500 µs current pulses at a repetition rate of 20 Hz.

Fig. 2 illustrates the uplink communications scheme developed here. It relies on the implant's circuit architecture explained in depth in [7]. The external HF current generator is connected in series to a sensing resistor R_S, and to the external electrodes. The electrodes of the implants pick up the HF current to power up the electronics; the implant's control unit activate/deactivate the internal current sources. The activation of these current sources causes an amplitude modulation of the rectified HF current across the implants which can be detected across the external sensing resistor. Thereby ASK is performed for the uplink.

The frequency band for the ASK uplink must be low enough to differentiate itself from the high amplitude HF current and high enough to avoid unwanted electrostimulation generated by LF [10]. Depending on their frequency of activation F, the currents generated by the implants will electrically stimulate motor neurons ($F < 200$ Hz), or will generate an amplitude modulation for uplink that can be read in R_S (5 kHz $< F < 100$ kHz).

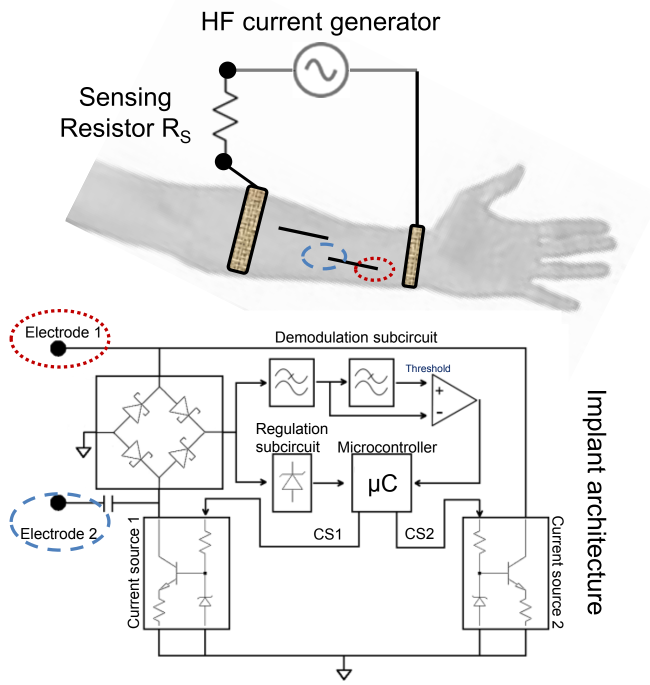

Figure 2. Proposed scheme for bidirectional communication. A sensing resistor is connected in series with a high frequency generator for detecting the current signals generated by the implants.

An additional constraint in the proposed bidirectional communication scheme are the electrochemical reactions that take place at the electrode-tissue interface, which can cause electrode corrosion and tissue damage [11]. These reactions are generally avoided using bipolar current pulses. The implant's architecture proposed in [7] uses two independent current sources that are able to apply charge-balanced current waveforms for stimulation. To perform uplink communications, we propose the use of biphasic symmetric current waveforms with a half-phase period HPT of less than 50 µs (i.e. data rates of more than 5 kBd) as shown in Fig. 3. In the prototype developed here (implemented on the implant hardware described in [7]) we programmed the implants for performing Manchester encoding for the uplink at rates ranging from 5 to 25 kBd.

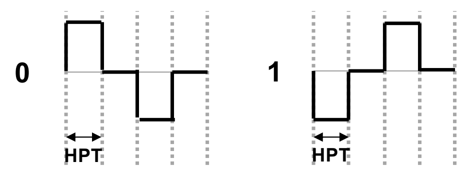

Figure 3. Schematic representation of bits '0' and '1'. The implant generates biphasic pulses that force zero net charge injection.

B. Receiver architecture

The external unit includes the HF current generator. This generator is connected in series with the sensing resistor R_S (Fig. 2) for obtaining a voltage drop proportional to the modulated signal. A receiver contained in the external unit (Fig. 4) is triggered in order to capture, demodulate and decode this signal.

The architecture of the receiver included in the external system uses a RC low-pass filter that attenuates the HF components of the voltage. This low-pass filtered signal is then captured by means of a data acquisition board and digitally high-pass filtered so that low frequencies interferences (e.g. power line) are attenuated. The signal is then processed in order to extract a window in which the positive and negative peaks of the biphasic pulses appear. The resulting signal will have 18 positive and negative peaks, 2 per transmitted bit (8 bits of information and a parity bit) which are similar to those shown in Fig. 3. The extracted window is processed using an algorithm that finds local minima and maxima, therefore detecting the peaks of the signal. A local peak is defined as a data sample that is smaller/larger than its two neighboring samples. The identified peaks are then translated into rising and falling edges of the Manchester code, and an algorithm decodes these edges into '1' or '0' bits. Finally, a parity bit detector compares the parity bit sent by the implant against the parity bit calculated using the read data stream, in order to check if the uplink was error-free.

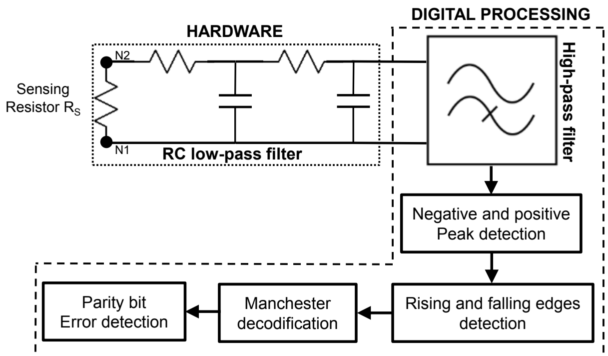

Figure 4. External receiver architecture. It consists of a hardware stage (RC low-pass filter) followed by a digital processing stage (high-pass filter, peak detector, Manchester decoder and parity bit error detector).

III. In Vitro Demonstration

An *in vitro* setup was developed in order to evaluate the capability of the system for performing bidirectional communications (Fig. 5). A prototype circuit of the implant was connected to a pair of electrodes which were inserted at a distance of 3 cm in a 2.5 cm diameter agar cylinder made from a 0.9% NaCl solution. The external system was connected to the agar cylinder using two aluminum band electrodes that were placed at a distance of 12 cm. The external system consisted of: 1- a computer that generated a modulating signal for downlink communication and which performed the software tasks depicted in Fig. 4 for the uplink communication; 2- a carrier generator and modulator, 3- a high voltage amplifier and 4- the sensing resistor previously described.

The sensing resistor R_S has a value of 100 Ω, low enough to avoid a high voltage drop, but high enough to allow the analog and digital processing of the uplink. The second order RC low-pass filter shown in Fig. 4 was implemented using two 10 kΩ resistors and two 330 pF capacitors (cutoff frequency of 48.2 kHz). The digital processing stage used a second order Butterworth high-pass filter with a cutoff frequency of 100 Hz.

The control unit inside the implant was configured to generate biphasic pulses (Fig. 3) with a HPT value that varied from 10 to 50 µs in 10 µs steps, corresponding to data rates from a 25 kBd to 5 kBd respectively.

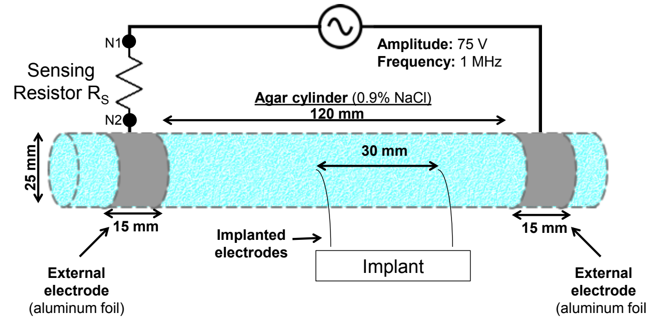

Figure 5. Setup for bidirectional communications demonstration.

Both the modulating signal generation (downlink communication) and the digital processing for demodulation and decoding (uplink communication) were implemented using a LabVIEW (National Instruments Corp.) virtual instrument running in a PC. It encoded a data stream of 8 bits and a parity bit, and sent this stream to the modulator using an ACQ board (NI-USB6216 by National Instruments Corp.). A 1 MHz carrier signal was generated and modulated by a function generator (AFG3022 by Tektronix, Inc.) and then amplified (WMA-300 by Falco Systems). The analog input of the ACQ board was used to acquire the filtered signal of the receiver for the uplink communication.

The demonstration trials consisted in using the virtual instrument to generate a byte, and sending it to the implant. Then, the implant demodulated and decoded the information, and checked for errors using the parity bit. If there were no communication errors, the implant sent the information back to the external system using the bipolar waveforms shown in Fig. 3, and this information was demodulated and decoded by the external receiver of Fig 4. Finally, the decoded byte was compared to the originally sent byte.

IV. Results

An example of an obtained filtered signal in the virtual instrument is shown in Fig. 6 (top). In this example, the control unit inside the implant was configured to transmit at a data rate of 6.25 kBd. Positive and negative peaks were detected using the local maxima and minima algorithm described in Section IIB. Fig. 6 (bottom) shows the demodulated bits that were obtained by the virtual instrument. As the algorithm knows the HPT value used as half-phase period (Fig. 3), the system was able to identify falling and rising edges, and so, was able to decode the data stream of '0's and '1's.

Fifteen trials per HPT value were performed in order to evaluate the dependency of the demodulation and decoding methods proposed for the external system with the data rate used for the uplink. As the data rate increased from 5 to 25 kBd, the byte error rate (ByER) increased from 0 to 33%. This limitation is caused by the implemented external receiver rather than by the emitter and it would be ameliorated by improving the triggering method of the receiver and the edge detection in the digital processing stage (e.g. using a cross correlation signal processing algorithm).

In short, the implant's current sources were able to modulate the 1 MHz current to generate an uplink. The obtained filtered signal had a high enough amplitude for processing purposes (≈ 50 mV), and the information was effectively sent to and echoed by the implant, demonstrating the bidirectional communication capabilities of the proposed system.

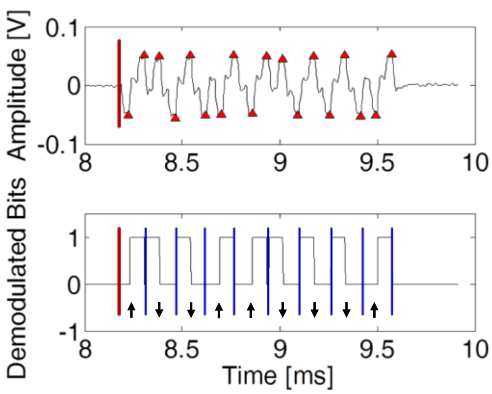

Figure 6. Rising and falling edge detection using the obtained filtered signal (data rate of 6.25 kBd). The edges are illustrated using up and down arrows, and correspond to the combination of local minima/maxima of the biphasic pulses generated by the implant.

V. Discussion

In the *in vitro* trial we presented here, we have demonstrated that it is possible to generate bidirectional communications for wireless microstimulators that are based on electronic rectification of epidermically applied currents. We have been able to send data from the external system to the implant (downlink), and then echo this data from the implant back to the external system (uplink) using transmission rates ranging from 5 to 25 kBd.

We anticipate that the proposed method will be able to provide much higher data rates than those obtained in here. In the presented proof-of-concept prototype, the uplink data rate was limited by the maximum sampling frequency of the DAQ board, the triggering method employed to capture the signal, the digital processing approach, and the speed of the control unit (i.e. microcontroller) used for the biphasic pulse generation.

The uplink communication method proposed in here may cause two phenomena that may be inconvenient in terms of safety: 1- tissue heating and 2- unwanted electrostimulation. Joule heating will occur because electric field bursts are generated in tissues by the implant during the data transmission. The duration of the burst depends on the data rate, while the number of bursts depends on the amount of bytes to transmit (in the presented case only one byte was transmitted). Therefore, tissue heating can be made negligible by limiting the half-phase period HPT used for the data transmission. The second phenomenon encourages further discussion: the proposed method uses the same waveforms to stimulate tissues and to transmit data and, therefore, unwanted electrostimulation could be expected to occur during transmission. However, it needs to be noted that the frequency used for stimulation is much lower than the frequency defined for data transfer. Hence, since the threshold to elicit electrical stimulation in excitable tissues increases with frequency [10], the use of a much higher frequency for uplink communication avoids surpassing the threshold for electrostimulation. In other words, unwanted stimulation will be prevented by increasing the data rate (therefore increasing the current threshold). An alternative uplink communications scheme would avoid this issue: to simultaneously activate both current sources so that load modulation is performed. In this case, the implant would not generate stimulation because no LF current would be injected into the tissues.

The proof-of-concept prototype presented here is a first step towards an electrical stimulation method that includes bidirectional communication. Thereby, sensing capabilities (e.g. biopotential or goniometry) could be added to the microstimulators, enabling the development of closed-loop FES systems.

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