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Electromagnetic interference in intraoperative monitoring of motor evoked potentials and a wireless solution☆

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ABSTRACT

Intraoperative neurophysiological monitoring (IONM) is utilized to minimize neurological morbidity during spine surgery. Transcranial motor evoked potentials (TcMEPs) are principal IONM signals in which the motor cortex of the subject is stimulated with electrical pulses and the evoked potentials are recorded from the muscles of interest. Currently available monitoring systems require the connection of 40–60 lengthy lead wires to the patient. These wires contribute to a crowded and cluttered surgical environment, and limit the maneuverability of the surgical team. In this work, it was demonstrated that the cumbersome wired system is vulnerable to electromagnetic interference (EMI) produced by operating room (OR) equipment. It was hypothesized that eliminating the lengthy recording wires can remove the EMI induced in the IONM signals. Hence, a wireless system to acquire TcMEPs was developed and validated through bench-top and animal experiments. Side-by-side TcMEPs acquisition from the wired and wireless systems in animal experiments under controlled conditions (absence of EMI from OR equipment) showed comparable magnitudes and waveforms, thus demonstrating the fidelity in the signal acquisition of the wireless solution. The robustness of the wireless system to minimize EMI was compared with a wired-system under identical conditions. Unlike the wired-system, the wireless system was not influenced by the electromagnetic waves from the C-Arm X-ray machine and temperature management system in the OR.

1. Introduction

Intraoperative neurophysiological monitoring (IONM) is commonly used in a number of surgical procedures including neurological, orthopedic, and vascular surgeries to assure safety of the brain, spinal cord, and peripheral nerves during surgery [1,2]. IONM relies on various electro-biological signals such as transcranial motor-evoked potentials (TcMEPs), in which the patient's motor cortex is transcranially stimulated with electrical pulses and the evoked responses are recorded from limb muscles [3–5]. The stimulation-recording sequences are applied after each of the critical surgical procedures, such as spinal column instrumentation. If the evoked potentials disappear or show any significant deviation from baseline measurements, the surgeons are immediately alerted of possible neurological compromise and corrective actions can be implemented to prevent a permanent neurological deficit [2,6]. Despite the critical role of IONM, and in particular TcMEP, currently available systems to acquire such signals suffer from various limitations, and more importantly, are vulnerable to electromagnetic interference (EMI).

A typical IONM session requires up to 40–60 lead wires, typically 1.5–2.5 m in length, for stimulating and acquiring signals during spine surgery. There are three major concerns with the current wired systems. First, significant time is required to set up such a large number of electrodes, thereby increasing the duration of anesthesia, with possible deleterious effects for the patient [7]. Second, the numerous lengthy lead wires limit the maneuverability of the surgeons and staff during the operation, and contribute to a crowded surgical area. Finally, EMI caused by monitoring and supporting equipment surrounding the operating table in the OR, affects the signal integrity of the evoked potentials. Depending on the proximity of the lead wires to the equipment in the OR, the EMI can potentially affect

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the evoked potentials in ways ranging from low interference to high [8,9]. However, the effects of EMI on the IONM signals by the contributing equipment in the OR have not been characterized. Although EM shielded wires and high common-mode rejection ratio techniques have been employed to reduce EMI, neither of these techniques can eliminate the interference effectively [10], as any part of the long wire may behave as an antenna, thereby coupling surrounding EM waves into the wire. Furthermore, the disposable EM shielded wires are costly. Therefore, it was hypothesized that substituting the long lead connection wires with wireless communication technology can solve the interference problem in a more cost effective manner.

Various wireless systems have been established in the medical field [11–13]. To date, the only wireless system for acquiring TcMEPs was developed by our group [14]. However, this system was only capable of acquiring from a single channel at a time, a disadvantage compared to the wired system, and it utilized an analog transmitter that may potentially be affected by EMI. Thus, there is a need for a multichannel wireless system that is robust to EMI.

2. Methods

The effects of EMI were measured in two separate events. During the first event, the common OR equipment that may play a significant role on EMI were identified when a commercially available wired recording system (Cascade Elite, Cadwell laboratories Inc.) was used for signal acquisition. A multichannel wireless system for acquiring TcMEPs was developed and validated in bench-top and animal experiments. Throughout the second event in the OR, both the Cascade Elite system (referred to as the wired system) and the developed wireless system were examined in identical experiments to compare the EMI effects on both systems. Testing methods for investigating the EMI effects were designed based on the American National Standards Institute recommendation (ANSI C63.18), which describes systematic methods for EM immunity of medical devices by radio frequency transmitters [15,16]. The EMI effects were documented during both events for further analysis.

2.1. Development of the wireless system for TcMEP acquisition

The wireless system consists of a front-end transmitter connected to the electrodes on the patient, and a back-end receiver connected to a computer through a custom-made graphical user interface (GUI). The front-end module includes an analog board featuring four input channels that conditions the raw signals obtained from the subject, an analog to digital converter (ADC) that digitizes the signals, an 8051 microcontroller manages the clock and timing of the signal acquisition and transmission, and a 2.4 GHz transceiver transmits the signals to the back-end. NRF24Le1 (Nordic Semiconductor) provided the ADC, microcontroller and the transceiver on a single system-on-chip. On the analog board, signals first pass through a high-pass (3 Hz) passive filter to an instrumentation amplifier (INA333, Texas Instruments (TI)) with a gain of 20 dB. The amplified signals then pass through an active band-pass filter (100–1000 Hz) and are amplified with a gain of 34 dB. A precision operational amplifier (OPA 4330, TI) was used for the second stage amplification. More details about the topology of the analog board circuitry can be found in [13]. The conditioned signals are then streamed into an eight-bit ADC and sampled at 6.2 KHz per channel. The microcontroller loads the discrete signals from the ADC into payloads with a size of 32 bytes.

The back-end module receives the payloads and transmits them subsequently to a computer through a universal asynchronous receiver/transmitter. A GUI, developed in LabVIEW (National Instrument), receives the data, displays all four channels simultaneously, and stores data for off-line analysis. The stimulator module from the wired system (Cascade Elite) was used to evoke motor responses. Fig. 1 depicts the block diagram of the wireless system, the animal experimental setup and the fabricated module.

2.2. Validation of the wireless system in bench-top and animal experiments

To examine the frequency response of the wireless system in the bench-top setting, sinusoidal waveforms with an amplitude of 100 μV and at frequencies ranging from 10 to 3000 Hz were generated (Agilent 33120A) and fed to the wireless system. The measured waveforms by the wireless system were stored and compared to the input signals off-line.

For *in vivo* validation of the wireless system, an adult female Long Evans rat (310 g) was used. The animal was anesthetized with sodium pentobarbital (50 mg/kg, i.p.). Stimulating electrodes were placed subdermally over the motor cortex and four recording electrodes were placed in the deltoid and gluteal muscles of both right and left limbs of the animal. Reference electrodes were located in the paws (only one is shown in Fig. 1) and a ground electrode was inserted in the ventral thigh. Subdermal needle electrodes (Viasys Healthcare) were utilized for both stimulation and recording. The electrodes measure 12 mm in length and 0.4 mm (27 G) in diameter, and are made of stainless steel. All procedures were performed in accordance with the University of Texas at Arlington Institutional Animal Care and Use Committee.

The stimulator module from the wired system was used to evoke motor responses by applying a train of three stimulation pulses (6 V amplitude, 50 μs duration, and 2 ms inter-stimulus interval) over the primary motor cortex. The evoked potentials were simultaneously obtained from the four limb electrodes. For each electrode, signals were equally split between the wired and the wireless systems for comparison. In the wired system, TcMEPs were recorded at a rate of 21,500 Hz per channel and bandpass-filtered (100−1000 Hz). The wired system triggered the stimulation trains and labeled the trigger signals on the records. The TcMEPs from both systems were observed in real time, and were stored for off-line analysis.

2.3. Evaluation of the EMI effects on the wired and wireless systems in Bench tests

2.3.1. Identification of the significant EMI sources in the OR using a commercially-available wired system

A signal generator (33120A, Agilent) was placed on the operating table and was used to produce sinusoidal waves with various amplitudes and frequencies to simulate the IONM signals (referred to as pseudo-IONM signals). These signals were transferred via a 2 m long shielded lead wire to the wired system. The shielding of a 10-cm piece of the transferring wire was removed and the proximity of this piece to multiple machines was varied from 0 cm to the distance where the noise was negligible. The minimum noise effect was defined as 30% deviation from the peak-to-peak amplitude of the produced signal. The tested equipment included a C-Arm X-ray machine (OEC 9800), a temperature management unit (Bair Hugger Model 750), overhead surgical lights (Stryker, Visum LED II), and an electrosurgical unit (Conmed, Sabre 2400).

2.3.2. Evaluation and comparison of EMI effects on both wired and wireless systems following the ANSI C63.18 standards

After the major interference sources were identified, systematic experiments were conducted to characterize the noise effects. Similar to the previous section, the shielding of a 10-cm piece of the transferring lead wire was removed and it was exposed to the EMI sources (Fig. 2). This piece was later replaced with the front-end of the wireless system and identical procedures were repeated to document the EMI effects on the wireless module. Sinusoidal signals with various amplitude and frequencies were streamed into the lead wire and the