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A True to Life Simulation of Electrosurgery

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***Abstract*—A laboratory simulation has been devised for use in developing and testing physiologic monitoring systems' performance in the presence of electrosurgical interference. This facilitated the development through iterative optimization of an EEG based parameter whose performance is improved during electrosurgery. The system was found to have an improvement of 94% in response to electrosurgery interference in the laboratory simulation. It was found to be improved 78% from all interference sources when tested clinically during actual surgery. This demonstrates the efficacy of the simulation.**

I. Introduction

THE monitoring of vital signs in the operating room environment presents many special challenges. The potential for artifact and interference is very high. Very small physiologic signals can be overwhelmed by ambient noise. Surface biopotential signals in particular are susceptible to interference from surgical tools and therapeutic equipment [1].

A. Electrosurgery

Electrosurgical equipment (ESU) has been in use since the 1920's [2]. Cutting and coagulation of tissue is obtained by passing current into the patient via an electrosurgical scalpel, or "pencil", and out through a dispersive return electrode. The current density is very high at the tip of the pencil, and low through the large area of the dispersive electrode. Heat generated at the pencil desiccates the tissue. Modern ESU generators operate at frequencies between 200kHz and 2MHz [3]. The carrier frequency may be duty cycle modulated at between 20kHz and 60kHz rates to coagulate or fulgurate tissue. ESU generators can deliver up to 300W of power into a 300Ω load. Open circuit voltages can be as high as 10kV peak-to-peak. Most modern ESU generators are isolated from earth ground. As a result the patient can have as much as half the open circuit voltage impressed on them via the return electrode when the pencil is not in contact [4].

D'Arsonval reported in 1891 that neuromuscular tissue would not be excited by electrical current at frequencies above 10kHz [5]. Yet muscular contraction has long been reported during ESU use [6]. This suggested that the high frequency current of the ESU was being demodulated to relatively low frequencies. Some have measured the spectrum resulting from ESU use and found substantial low frequency content [7], [8]. This was commonly attributed to the non-linear nature of sparking [6], [7]. However, Slager *et al.* demonstrated that sparking alone does not explain the phenomenon [9]. Using saline and porcine tissue they showed that the impedance of the ESU metal-electrode junction changed non-linearly during electrosurgery. They also show that this effect is nearly independent of the different ESU equipment that operates substantially according to the same principles.

B. Biopotential Monitoring

Electrocardiograph signals are in the range of millivolts. Electrosurgical interference can reduce the signal to noise ratio of the ECG signal to less than zero [1]. The focus on the development and validation of ECG systems has largely been on protecting them from damage due to excessive voltage at the electrode inputs. There are now harmonized standards for validating the performance of ECG systems that claim to have electrosurgical interference suppression (ESIS) [4]. The tests involve the use of an isolated battery powered R-wave simulator to drive the ECG system under test during electrosurgery. The electrodes in the system are modeled with resistors and capacitors. The ESU equipment is connected to the simulated electrodes via a metal plate and resistor divider network, intended to model the conditions found in the surgical environment. Operation of the ESU is accomplished by contacting the metal plate with the ESU pencil, then slowly withdrawing it to produce an arc. The particular performance requirement is that the heart rate must not change by more than +/- 10%.

Electroencephalography (EEG) signals range from tens or perhaps 100uV in an awake subject, and may be below 1uV in an anesthetically induced or comatose patient [10]. Recent advances in signal processing have made it possible to derive the level of consciousness of a subject undergoing anesthesia [11]. In one such system, the Bispectral Index (BIS), a number between 0 and 100 is computed, corresponding to the patient's level of consciousness. The technique for computing BIS involves sophisticated algorithms that analyze subtleties in the EEG signals using bispectral analysis [12]. It is therefore especially challenging to devise a system of electronic hardware and software that is able to accurately process the EEG during ESU use. Such a development lends itself to careful testing and iteration. This work is best done in the laboratory environment, where the effect of changes to the design can be evaluated quickly and efficiently.

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The method described in the ECG industry standard may be adapted for use in EEG testing. However this method would be limiting in several ways. The non-linear behavior at the site of action of the ESU as described by Slager would have an affect on the characteristics of the interference created during ESU. The electronic model of the simulation does not allow for differences in surgical procedures, site, and technique. These differences have an important impact on the interference created by ESU [9]. As a consequence the variety and blend of interferences due to differential and common mode voltages, as well as electromagnetic susceptibility are not tested. Finally, the variety of EEG states would not be represented, some of which may be more susceptible to interference than others.

The construction and use of a real-world surgical model in the laboratory is described. The performance of the EEG system that was developed in the laboratory is described. Finally, the performance of the system was tested in the clinical setting, in order to demonstrate that the laboratory test is a valid simulation of the surgical environment.

The intention of the simulation is to create conditions that are typical in surgery. These are used to develop and measure the performance of patient monitoring systems, and to compare two systems to determine the difference in performance in a statistically meaningful way. It is therefore not necessary to simulate all possible conditions, such as outlying worst case ones. In fact it is desirable not to, as this would make comparison more difficult.

II. Laboratory Methods

A. Clinical Observations

Measurements were made of the capacitance between a patient and earth ground while the patient was lying prone on a grounded operating room table. The capacitance was found to be 1500 pF +/- 500.

Observations of ESU use during surgery and interviews with surgeons were conducted to understand their techniques and the effect on the generation of ESU artifact. The information gathered was used to establish typical patterns of use as to ESU modes and power settings, ESU on and off times, and amount of arcing.

B. Simulation Construction

The simulation replicates the physical conditions as literally as is practical. The human form is re-created as to size and capacitance to earth ground. The physiologic waveform is injected in such a way that its propagation is much like it is in a human. Physiologic monitoring is similarly re-created. The surgery itself is re-created by actual dissection of animal flesh in a way that replicates the actions of a surgeon. Surgical techniques are replicated based on observations of actual surgeries.

A piece of aluminum foil was used to cover the outside bottom of a roughly torso-sized tub measuring 17 by 22 inches. The foil was connected to earth ground using two parallel lengths of 10AWG wire to simulate the body's capacitance to earth ground. The tub was filled with an isotonic 0.9% salt solution. Conductive electrode gel was chosen for its antibacterial properties and resistance to evaporation. A "head" was created by placing a smaller tub in the larger "torso" tub. Four holes were drilled through the bottom of the head, each about ½ inch diameter and 2 inches on center. These formed the "neck" of the patient, in order to limit the circulation of ESU current past the EEG electrodes. The head was filled with gel.

Two EEG sensors (BIS Quatro, and BIS Standard, Aspect Medical Systems, Inc.) were placed side-by-side on the gel in the head. These were connected to the system under test (XP Platform, Aspect Medical Systems, Inc.) and to the reference system for comparison (A-2000, Aspect Medical Systems, Inc.). Each system was connected to a personal computer for recording of the EEG signal and processed data.

An EEG playback device was developed to inject recorded EEG signals into the head. The device operates on battery power and is placed within the confines of the simulated head so as not to compromise the ground isolation of the simulation. The playback device was interfaced to the head via two Ag/AgCl electrodes placed on the gel between the two sensors. The amplitude of the EEG signal was adjusted to accurately re-create the amplitude of the EEG as it was recorded from the patient.

The ESU patient return electrode (E7507, Valleylab division of Tyco Healthcare Group) was placed in the torso section. This was connected to a commonly used ESU (Force 2, Valleylab division of Tyco Healthcare Group). A commonly used surgical pencil (E2350HS, Valleylab division of Tyco Healthcare Group) was employed. A smoke evacuator (Optimumm, Valleylab division of Tyco Healthcare Group) was attached to the surgical pencil to reduce the surgical plume.

A piece of chicken, skin on, was used for the surgical tissue. This was placed in the torso.

Fig. 1. ESU simulator with head, brain, and torso.

C. Laboratory Method

Three different EEG recordings of actual surgeries were utilized for the tests. Each recording was approximately 40 minutes in length, during which the patient was initially awake, then induced with anesthesia, operated on, then re-awakened. The three recordings were chosen to encompass the variety of EEG states that are encountered in the surgical population.

A total of nine "surgeries" were performed. Six different "surgeons" performed them in order to vary the technique.

Each surgeon was instructed to carefully dissect the skin off the chicken during the period of adequate anesthesia for each recording. They were instructed to adjust the ESU mode and power settings over the course of surgery as follows: cut mode 30 to 60 watts, coag mode 20 to 50 watts.

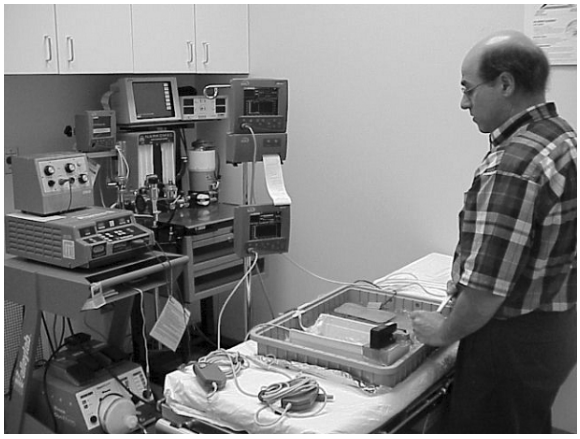

Fig. 2. ESU laboratory in use.

D. Validation

It was important to validate that the clinical measurement under test, BIS, was accurately processed during periods of electrosurgery. Measurements were taken from the simulator of each surgical recording without the use of ESU. The time trend results of these were compared to measurements made during ESU use. An example is depicted in Figure 3.

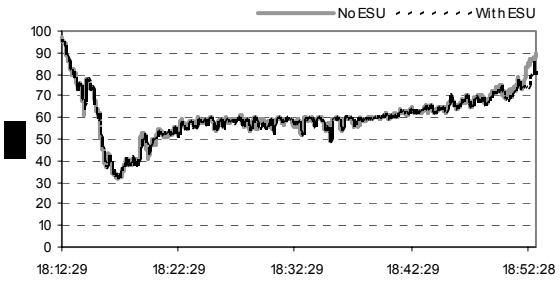

Fig. 3. BIS trend plot with and without the use of ESU, confirming that the BIS computation is unaffected by ESU use.

E. Analysis

Processed EEG recordings were analyzed. Results from all nine surgeries were aggregated. Comparisons were made between the system under test and the reference system using paired t testing. P value of <0.05 were considered significant.

The primary endpoint was the total percent of time that the BIS number was not available due to interference, referred to as "blanking". Blanking occurs when 85% of the previous 30 seconds of data contains artifact. The secondary endpoint was the signal quality index (SQI), which is the aggregate total percentage of EEG epochs that were artifact free and analyzable.

The XP platform included a detector to indicate precisely when the ESU is actuated. This was used to determine the percentage of epochs that were free of artifact during ESU use.

F. Results

Total ESU use time percentage was 49%.

Total blanking time percentage for the reference system was 19%. Total blanking time percentage for the XP platform was 1%, for an improvement of 94%. Overall SQI for the reference system was 43% versus 73% for the XP platform, yielding a 70% improvement.

Only 5% of the reference system's EEG epochs were free of artifact during ESU use, vs. 65% for the XP platform.

III. CLINICAL TRIALS

A. Methods

A clinical trial of actual surgeries was conducted at four centers in the United States [13], [14]. Each patient had a BIS Quatro sensor placed on his or her forehead, and was monitored with the BS XP platform. A laptop computer was used to record the processed data.

The reference system was not used in the trials, but was simulated as described herein. The reference system was simulated by first examining the ESU detector data of the XP platform. Each EEG epoch of the reference system during which ESU was actuated was considered to contain artifact, as had been demonstrated previously. Blanking time for the reference system was then computed off-line using the same algorithm the reference system uses.

B. Results

Following institutional review board approval and informed consent a total of 88 patients were enrolled. Surgical sites and procedures included facial, cardiac, spinal, breast, abdominal, and orthopedic of the arm, knee, and feet. Seven different models of ESU were used.

Processed EEG recordings were analyzed. ESU interference artifact was present in 82 of the recordings. Two of the recordings were excluded due to persistent non-

ESU artifact (electronic pacemaker). Results from each individual center were reported [13], [14]. In a separate analysis all surgeries were aggregated. A total of 190 hours of surgery were included in the analysis. Comparisons were made between the system under test and the reference system using paired t testing. P values of <0.05 were considered significant.

Total ESU use time percentage averaged 9.8% for all surgeries (standard deviation 6%). Total ESU use time percentage for the cardiac surgery center averaged 11.6%.

Total aggregate blanking time percentage due to all interference sources for the reference system was 2.3%. Total aggregate blanking time percentage due to all interference sources for the XP platform was 0.5%, for an overall reduction of 78%.

IV. Conclusion

A laboratory simulation of electrosurgery was developed that facilitated the efficient development of hardware and software for the improvement of a physiologic monitoring system in the presence of ESU artifact. Improvement of the resulting system was demonstrated in the laboratory when the improved system was subject to electrosurgical interference alone. Improvement was demonstrated in the clinical setting when the improved system was subject to all environmental interference, including ESU, thus demonstrating the efficacy of the laboratory simulation.

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