Freedom from electromagnetic interference between cardiac implantable electronic devices and the FMwand Ferromagnetic Surgical System

To the Editor:

The use of electrosurgical cutting tools has become almost ubiquitous in the modern operating room and medical procedure suite. These devices are intended to give physicians the ability to precisely dissect tissue (similar to a traditional scalpel) with the additional benefit of better bleeding control during and after procedures. One characteristic of many of the devices, particularly those utilizing monopolar energy delivery, is their transmission of electrical current through the patient as energy is delivered from the cutting instrument, through the patient’s tissue, to a grounding electrode.

At the same time, cardiac implantable electronic devices (CIEDs), including permanent pacemakers and implantable cardioverter defibrillators (ICDs), are implanted in an estimated 1.5 to 2 million individuals in the United States, and an estimated 4 to 6 million individuals worldwide (personal communication, St. Jude Medical, Inc., St. Paul MN, USA). These patients are characterized by a diverse set of clinical indications for cardiac rhythm device therapy and are implanted with a wide variety of devices produced by several different manufacturers. Of course, these patients will at times require surgical procedures.

As early as 1965, concerns were raised about the interaction between electro surgical devices and CIEDs [1]. Subsequent reports have clearly described the association of electrosurgical devices with both pacemaker and ICD malfunction [2]. Possible adverse events related to operative electrocautery in these patients include: damage to the pulse generator or leads, failure to deliver pacing and/or defibrillation when needed, inappropriate pacing or ICD shock delivery, temporary changes in pacing behavior, and electrical reset of the device to backup pacing modes.

Based on these concerns, in 2011 the ASA, in association with the Heart Rhythm Society (HRS), produced a consensus statement providing updated recommendations on the perioperative management of patients with CIEDs who are undergoing procedures involving electrosurgical devices [3]. An additional Expert Consensus Statement also was produced in the same year by HRS in collaboration with ASA, the American College of Cardiology, the American Heart Association, and the Society of Thoracic Surgeons [4]. Each statement provides extensively detailed references, explanations, and recommendations for the care of these patients, highlighting the complexity involved in the management of this highly diverse patient population.

The FMwand® ferromagnetic surgical system (Domain Surgical, Inc., Salt Lake City, UT, USA) is a novel electrosurgical cutting tool that received Food and Drug Administration 510(k) clearance in July of 2011, and has been in increasing use in clinical practice. The system consists of a power generator and the handheld FMwand, and is based on unique technology in which energy is used to excite a ferromagnetic coating at the tip of the FMwand, producing rapid heating. The system operates at 40.68 MHz, a frequency that is considerably higher than typical electrosurgical devices. In addition, the energy circuit is a closed loop, eliminating the need for a remote grounding electrode (Fig. 1). Thus, the system is able to simultaneously cut and coagulate soft tissue while minimizing collateral tissue damage, without
passing electrical current into the patient. This feature presumptively eliminates the potential for pacemaker/ICD damage or erroneous sensing due to conducted energy.

![Fig. 1 Simplified schematic of the FMwand electrosurgical device (Domain Surgical, Inc., Salt Lake City, UT, USA), demonstrating the electrical current path. The entire path is contained within the device itself, without the need for remote grounding.](image)

To test this hypothesis, we conducted a benchtop series of experiments in which a variety of CIED devices now in clinical use, including both pacemaker and ICD generators along with associated leads (St. Jude Medical, Inc., St. Paul, MN, USA) (Table 1), were implanted within a tissue phantom gel developed to mimic the electrical properties (both conductivity and permittivity) of muscle (Table 2). The choice of this model was made based on its use in several similar in-vitro studies in the medical literature [5-8]. Each CIED was configured and programmed in a fashion consistent with typical clinical use.

| Table 1 Pacemaker and implantable cardioverter defibrillator generators, lead models, and configurations |
| --- | --- | --- |
| Experimental container | Generator model no. | Lead models |
| A | CD2211-36Q | 2088/58, 7U2Q/52 |
| B | PM2212 | 1888T/46, 1888158 |
| C | PM2212 | 1788T/40, 1688T/46 |
| D | CD223 1-40 | 7120165, 1788T152 |
| E | 5386 | 2088152, 1688T/58 |
| F | CD2211-36Q | 7120Q165, 1888T158 |

All devices quoted above are manufactured by St. Jude Medical, Inc. St. Paul, MN, USA.

| Table 2 Phantom muscle model electroconductivity properties |
| --- | --- | --- |
| Actual muscle tissue (37°C) | Phantom muscle tissue (22°C) |
| Dielectric constant | Conductivity (S/m) | Dielectric constant | Conductivity (S/m) |
| 97 | 0.68 | 97.9 ± 38 | 0.70 ± 0.02 |


Once prepared, each experimental vessel was exposed to a series of standardized cuts into the phantom gel. The first applications were made with a control device selected to represent a commonly used electro surgical technology (Force2; Covidien Surgical Solutions Group, Boulder, CO, USA). Similar applications were then made with the FMwand device. A variety of different energies representing the typical clinical usage of each device were applied at a variety of distances and orientations from lead sensing tips and each CIED generator. Real-time CIED monitoring and recording was performed during each energy application using the St. Jude ICD/pacemaker programming platform with the programming and telemetry antenna placed beneath the container directly under the CIED generator.

Next, each CIED was extracted from the tissue phantom and placed in a saline bath of similar conductivity (0.68 S/m). Although the saline bath permittivity values are not as similar to muscle tissue as the phantom gel, the saline bath was used to allow for direct visual observation of the FMwand – lead interaction, thus allowing very close approximation. Under direct visualization, the FMwand was
activated at 60W and brought to within one mm of the tip of the leads and pulse generators. All orientations were tested as before, with dwell times up to 15 seconds; again, real-time CIED telemetry was performed and recorded.

The results were striking in that the control experiment utilizing monopolar electrocautery produced detected electromagnetic interference in 100% of energy applications in both the pacemaker and ICD setups. This finding was true at both low (5W) and high (35W) energy settings and with both "coagulate" and "cut" modes. The CIED devices usually appropriately recognized these signals as noise interference. At times, however, this interference resulted in detection of false ventricular fibrillation and delivered ICD shocks (Fig. 2). In contrast, the FMwand experiments produced detected electromagnetic interference in 0% of energy applications. This was true at even the highest power setting. In addition to the phantom gel tests, there was also no interference signal detected with the system immersed in saline, even with the FMwand held in immediate proximity (1-2 mm) to the lead sensing tip. There were no exceptions to these findings across any of the device configurations tested.

![Figure 2](image_url)

**Fig. 2** Application of mono polar electrosurgical energy at 5W in coagulation mode (Force2; Covidien Surgical Solutions Group, Boulder, CO, USA), showing electromagnetic interference on sensing circuit of the CIED. In this example, the interference leads to (A) inhibition of pacing followed by a pacing mode switch due to detected atrial fibrillation, (B) detection of ventricular fibrillation, and (C) delivery of a high-energy shock.
As of this writing, over 100 neurosurgical procedures have been performed with the FMwand. Anecdotal reports have reported no described interference with physiologic monitoring, including somatosensory-evoked potentials, motor-evoked potentials, intraoperative electroencephalograph, or specific cranial or peripheral nerve stimulation. In addition, more than 100 cardiac surgery procedures have been performed with no observed disturbance to electrocardiographic monitoring. Furthermore, no heart arrhythmias have been induced during dissection adjacent to the myocardium, as has been described with monopolar electrocautery [9].

In the few cases where a pacemaker has been in place, there has been no observed evidence of disruption, although in each case the pacemakers were managed per the guidelines referenced above. The present report presents the first controlled and systematic evaluation of the hypothesis that the FMwand does not cause electromagnetic interference with CIEDs.

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