TISSUE HEATING DUE TO ENDOCARDIAL LEADS DURING MRI SCANS

Numerical Models and Experimental Validation

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Keywords: Endocardial Leads, Magnetic Resonance Imaging, Heating, Numerical Models.

Abstract: Magnetic Resonance Imaging (MRI) tissue heating due to implanted leads represents a major concern for the safety of patients bearing metallic devices. In this work temperature measurements were performed to validate the typical solutions adapted as endocardial lead models, that are a thin bare metal wire and an insulated one. Both experimental and numerical analysis was performed in the frequency range between 10kHz and 128MHz (frequencies of the gradient and RF fields of MRI systems). We found that the bare wire is not a reliable model to study the RF heating locally induced at the lead tip. At low frequencies (<1MHz), the PM lead can be properly modelled as an insulated thin metal wire, providing that the actual resistivity of the lead is also modelled. As frequency increases, such a model becomes less accurate and different solutions must be adopted.

1 INTRODUCTION

In the last years the number of patients with implantable devices, such as pacemakers (PM), cardioverter/defibrillators (ICD), deep brain stimulators (DBS) has notably increased. These patients are today considered strongly contraindicated to undergo magnetic resonance imaging (MRI) examinations. This is mainly due to the hazards that the radiofrequency (RF) field and the gradient field may represent for the implanted patient. The energy of the MRI field can couple into conductive leads, like that used for implantable devices, in two major ways: 1) the conductive lead acts as an antenna capable of receiving and supporting the field, and this mechanism can create the resonant waves (Pisa et al, 2008); 2) the implant acts as an electrical 'short circuit' to the electrical potentials induced within the body by the RF field (Konings et al, 2000). Each of these effects may create at the lead-tissue interface high electrical current density which, combined with the high electrical resistance of most of the biological tissues, can cause local resistive heating. This power deposition in tissues, that results in an increased local absorption rate (SAR) and consequently in temperature growing, is potentially harmful to the patient; an excessive temperature growth may bring living tissues to necrosis and to death. In addition, the induced currents that flow from the implant into the body may cause unwanted stimulation of excitable tissues, such as muscles or nerves. In this field, in-vivo studies are difficult to carry out for practical and ethical reasons, whereas computational techniques represent a favourable choice for testing the safety of implantable devices within an MRI environment. However, numerical studies often implies some simplifications of the actual physical model that is studied, which may affect the validity and generality of the results. For this reason, numerical studies always need to be firmly anchored in reality and have to be validated by experimental measurements. The aim of this paper is the validation, through experimental measurements of the induced heating, of the model of an endocardial lead. The analysis was performed in the RF range between 10kHz and 500kHz (frequencies of the MRI gradient fields), between 32MHz and

Mattei E., Calcagnini G., Triventi M., Censi F., Bartolini P., Piacentini V. and Pisa S..
TISSUE HEATING DUE TO ENDOCARDIAL LEADS DURING MRI SCANS - Numerical Models and Experimental Validation.
DOI: 10.5220/0003163503780381
In *Proceedings of the International Conference on Biomedical Electronics and Devices* (BIODEVICES-2011), pages 378-381
ISBN: 978-989-8425-37-9

128MHz (frequencies of the MRI RF fields). The most commonly used lead models, as thin bare metal wire or thin insulated metal wire, are first considered. In addition, since in clinical practice endocardial leads may not always have a negligible resistive impedance, a new model that takes into account a finite electrical conductivity of the lead is proposed.

2 METHODS AND MATERIALS

The RF behaviour of an endocardial lead was first validated in terms of induced heating at the tip versus the two typical models used to represents leads in numerical studies: a thin bare metal wire and an thin insulated metal wire. The same structure has been considered both numerically and experimentally. This provided us with a direct mean for validating the results of the numerical analysis, thus reducing the number of variables typically involved in other validation procedures. Due to the wide frequency range covered by the analysis (10kHz-128MHz), two experimental set-ups were designed and then reproduced as numerical models: a low-frequency (LF) set-up and a high-frequency (HF) set-up.

2.1 Experimental Setups

2.1.1 LF setup (10kHz, 100kHz, 500kHz)

The lead was placed inside a 20cm x 14cm x 30cm PVC box filled with gelled saline material (HEC 2%, NaCl 0.16%) that mimics the electrical and the thermal properties of human tissues at the considered frequency. The measured conductivity for the gel was 0.2 S/m. A density of 1006 kg/m^3, a thermal conductivity equal to 0.2 W/(m·K) and a specific heat of 4178 J/(kg·K) have been provided by the HEC manufacturer.

The current was injected directly into the lead by applying a voltage gap between one end of the lead and a metallic electrode placed on a wall of the PVC box. The temperature increase caused by the current at the lead tip-gel interface was measured by using a fluoroptic® thermometer (Luxtron model 3100) with SMM probes placed in transversal contact with the lead tip (Mattei et al, 2007). These plastic fiber probes (1mm diameter) have an accuracy of 0.1°C and operated at 8 samples per second. Temperature measurements were performed at the tip of a PM unipolar lead (*Hepta 2*, Sorin Biomedica) and at the tip of the two simplified lead models: a 20-cm long thin bare metal wire (radius=1 mm) and the same wire but with an insulation sheath. A constant current of 40 mA rms was injected in the leads at the different frequencies of interest (10kHz, 100kHz, 500kHz), for a period of 300s. The amplitude of the current as well as the voltage at the gap between the lead and the electrode on the box was measured in real-time during the experiments.

2.1.2 HF setup (32 MHz, 64MHz, 128MHz)

For the higher frequencies we designed an experimental set-up that allowed us to measure the RF current all along the lead. The three leads were placed inside a PVC tube (radius=2cm; height=30cm) filled with the same gel previously described, but with a conductivity of 0.6 S/m. The RF signal, was applied between the lead and an electrode placed on one end of the PVC tube, at the frequency of 32MHz, 64MHz, 128MHz. The current flowing inside the lead and the gel was measured by using a clamp current probe (*BCP512*, A.H. System, CA). This set-up allows to test the lead in a condition similar to the implant, but since the current probe is not submersible, we were forced to measure the total current crossing a section containing the lead and the surrounding gel. The temperature increase was measured with the amplitude of the RF signal set to have always the same current value of 40mA rms at the lead tip. In addition, we measured the current amplitude in seven positions along the tube (at 0cm, 5cm, 10cm, 15cm, 20cm, 25cm - lead tip, 30cm), so to have an estimation of the current amplitude distribution at the frequencies of 1MHz, 32MHz, 64MHz, 128MHz. Finally, temperature *VS* current curves were calculated for the PM lead and the two simplified models, in order to relate the temperature increase measured at the led tip to the amount of current flowing into the tissue.

2.2 Numerical Models

2.2.1 LF setup (10kHz, 100kHz, 500kHz)

Numerical simulations have been performed using a commercial software, CST studio 2008, based on the Finite Integral Technique. The experimental set-ups were faithfully reproduced in the numerical environment: the bare wire was modelled as a metal thin conductor (radius=1mm), while the insulated wire was modelled as the same wire with a rubber insulation (thickness=1mm). In order to define a new model that could better reproduce the behaviour of an actual endocardial lead, we measured the electrical parameters of the PM lead with an LCR meter and we found an impedance of about 50 Ohm. This impedance is likely to be localized at the lead tip, that is generally made of conductive ceramic materials. For this reason, the insulated wire was modified by adding at its end a cylindrical tip with radius and height both of 1mm and with electric conductivity σ=6.37 S/m. It results in a resistance of about 50 Ohm. The same voltage measured in the experimental tests was applied in the model, to ensure the comparability between experimental and numerical data.

2.2.2 HF set-up (32MHz, 64MHz, 128MHz)

As for the LF measurements, also the HF experimental set-up was faithfully reproduced in the CST environment. In this case, the excitation was applied in terms of current injected into the leads. The amplitude of the current was chosen to match the experimental value measured at one end of the lead when the current at the tip was 40 mA rms.

3 RESULTS

Both in experimental and simulated measurements, the bare wire showed temperature increases at its tip comparable with the resolution of the Luxtron thermometer (0.1°C). The temperature increments obtained from experimental and simulated data are reported in Figure 1, both for LF and HF. For each frequency, two couples of bars are reported: the first one compares the heating at the tip of the insulated wire, (experimental versus numerical); the second one compares the temperature increase measured at the tip of the PM lead (experimental) to that of the 50 Ohm-tip insulated wire (numerical). Figure 2 shows the current distributions measured along the PVC tube used for HF experiments. Up to 32MHz, no significant changes in the current amplitude were observed from the beginning of the tube to its end. At higher frequency, a downward trend is noticed, so that the current at the tip is much smaller than the one applied at the other end of the lead. At 128 MHz, the minimum for the current amplitude was observed at 25 cm from the tube end (position of the lead tip), afterwards the current start increasing. The same behaviour was observed both for the PM lead and the insulated wire, even if the decrease in current amplitude as frequency increases was more evident for the former than the latter. In Figure 3 the current *VS* temperature curves are reported. The current amplitude reported on the X-axis is measured at the lead tip. As expected from the relation between SAR and E field, a quadratic trend was found (R^2>0.95).

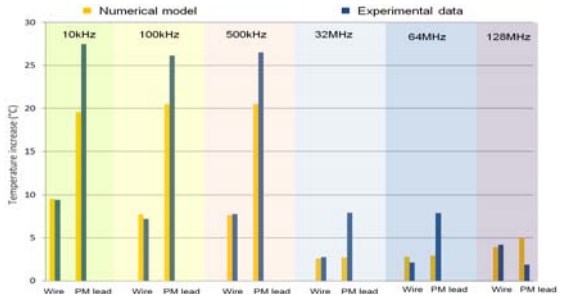

Figure 1: Comparison between experimental an numerical temperature increases measured at the tip of the insulated metal wire and of the PM lead. The numerical model of the PM lead refers to the 50Ohms insulated wire.

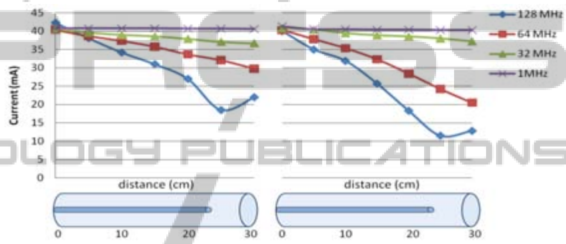

Figure 2: Current amplitude distribution along the PCV tube used for HF temperature measurements. Left panel: insulated metal wire. Right panel: PM lead.

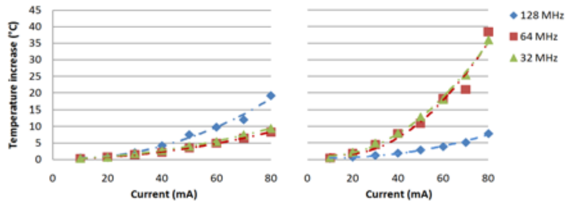

Figure 3: Current VS Temperature curves for the insulated metal wire (left panel) and the PM lead (right panel). Current values were measured inside the PVC tube, at the section corresponding to the lead tip.

4 DISCUSSION

The bare wire represents the simplest way to model an endocardial lead. However, our data show that it cannot be considered a reliable solution to investigate the RF induced heating in human tissues. The absence of an insulation sheath produces a more uniform power deposition along the wire, so that the local heating at the lead tip becomes not significant.
A thin metal wire insulated by a rubber sheath is the typical solution adopted both in experimental and numerical studies dealing with RF induced heating

on implanted leads (Bassen et al, 2007). We compared this model with an actual PM lead. First of all, we compared the temperature increase measured at the tip of an insulated metal wire with its equivalent numerical model: very good agreement between simulated and experimental results was found, for all the frequencies of interest (10kHz-128MHz). In the LF range, temperature increases measured at the tip of the PM lead are much higher than for the insulated wire (more than three times higher), for the same excitation conditions. Numerical simulations show that an improvement of the lead model can be achieved considering the actual resistivity of the lead: when modelling a wire with a finite-conductivity tip, the gap from the real PM lead becomes significantly lower (<28% respect to the experimental value). The lead impedance is a characteristic that can sensibly vary from lead to lead, mainly depending on the properties of the tip material, When it is made of ceramic components (such us pyrolitic carbon), the resistivity is close to 50 Ohm, whereas, in case of metallic materials, it goes down to few Ohm or even less. In any case the lead manufacturers should indicate the value of the impedance in the technical notes of their products; thus, it should be an easy element to take into account. At higher frequencies (32MHz, 64MHz, 128MHz), marked differences between the PM lead and its numerical model are observed, even when modelling the finite-conductivity tip wire. In particular, at 128MHz, the temperature increase at the PM lead tip, which up to 64MHz is always higher than the insulated wire, becomes lower. It suggests that at higher frequencies other mechanisms play an important role in the heat generation process, that the simple model of an insulated wire cannot take into account. To better understand this aspect, we measured the current peak distribution along the lead. The higher is the frequency, the closer is the length of the lead to the theoretical resonance value inside the gel. At 128MHz the theoretical resonance length is about 23cm for a dipole inside a dielectric mean with a permittivity of about 25. In such conditions, a kind of resonant wave can be supposed inside the lead. A resonance phenomenon in various kinds of linear structures (e.g. catheters used in interventional radiology) has been hypothesized also by other groups (Nitz et al, 2001). Heating induced by the same current measured at the section of the tip shows opposite trend with increasing frequency in the insulated wire and in the PM lead. This is a further confirmation that, at high frequencies, the simplified model of the insulated wire moves far from the actual behaviour of the PM lead. Thus, in order to obtain reliable results new and more realistic models must be developed. For example, as already proposed by some groups (Helfer et al, 2006, Neufeld et al, 2009), a model able to reproduce the actual inductance of the lead may represent a substantial improvement of the analysis.

5 CONCLUSIONS

Our study reveals that at frequency below 1 MHz, the RF–induced heating on endocardial leads can be properly evaluated by modelling the lead as an insulated wire. It is however necessary to take into account the resistivity of the lead, in particular the resistivity of the tip. At higher frequencies this model becomes less reliable and new solutions which consider also other aspects, such as the lead inductance, must be adopted.

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