Practical considerations in experimental evaluations of RF-induced heating of leaded implants

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Abstract

This study illustrates some considerations to accommodate the non-ideality of experimental conditions needed in the Tier 3 assessment of RF-induced heating of leaded implants. The method, based on Tier 3 safety assessment during MRI exposure of ISO/TS 10974, is currently used for the rapid modeling of RF-implant interactions. We summarize the theoretical accuracy of Tier 3 method and the practical considerations for its actual implementation.

1 Introduction

The Tier 4 method requires the direct modeling of electromagnetic field (EMF) interactions of the implant under clinical MRI conditions, which can be achieved by computational electromagnetic (CEM) modeling of the implant integrated within the human body under MRI-based RF exposure. Tier 4 remains the only method whereby RF-implant interactions within a complex anatomy are not compromised by any simplifying assumptions. Although the Tier 4 method is intuitively simple, it is computationally demanding—especially for leaded implants. The spatial resolution of the numerical model is usually dictated by the smallest geometry within the computational domain. For the case of RF-implant interactions during MRI exposure, submillimeter resolution is often required to resolve the geometrical features of the implant. Such fine resolution, when also extends to the RF-coil and the patient anatomy, would render the size of the whole computational domain exceedingly large.

Tier 3 method of [1] is designed to alleviate the computational burden inherent in Tier 4 evaluation. Simplifying assumptions regarding RF-implant interactions inside the complex anatomy are introduced to enable the separation of this computationally large problem. Tier 3 method comprises a separate evaluation of (a) RF-induced heating characteristics of the implant and (b) RF exposure of patients undergoing MRI; which are combined to provide an estimate of the local power deposition in tissues by the implant. Implementation of the Tier 3 method were demonstrated in several studies [2–4]. The evaluation of (a) is often conducted experimentally, while the evaluation of (b) is accomplished through CEM. Therefore, in vitro experiments are an intrinsic part of Tier 3 evaluation and here, we summarize some of the difficulties encountered in experimental evaluation methods during practical implementation of (a) and their practical mitigation strategies.

2 Experimental characterization of implant RF-induced heating

Piece-wise excitation (πX) is a Tier 3-compliant method that can be used to characterize RF-induced heating of medical implants. The characterization is based on the technique proposed in [2] where a transfer function, henceforth referred to as the πX model, h(l), is defined as the relationship between the locally induced electric field around an electrode pole and excitation along length l of the implant. Figure 1 depicts a schematic of the method.

![Figure 1. Schematic of the piece-wise excitation method. \( \hat{\mathbf{i}} \) is the unit tangential vector to the implant at length l.](image)

The tangential component of the local incident electric field, \( E_{\text{tan}} \), is coupled with the implant at length l and the induced electric field around a region of high-heating (e.g., in the vicinity of stimulating electrodes) at point \( \mathbf{r} \), \( E_{\text{ind}}(\mathbf{r}) \), is evaluated. Therefore, the total induced power of the tip electrode \( P_{\text{tip}} \), attributed to \( E_{\text{tan}} \) coupling along the entire implant of length L can be estimated from the relation:

\[
P_{\text{tip}} = W_0 \left( \sum_{j=1}^{N_t} h(l_j)E_{\text{tan}}(l_j)\Delta_j \right) \left( \sum_{j=1}^{N_t} h(l_j)E_{\text{tan}}(l_j)\Delta_j \right)^* 
\]

(1)

where \( W_0 \) is the \( P_{\text{tip}} \) of an implant for \( E_{\text{tan}} = 1 \) V/m.

The most evident simplifying assumption in the derivation of a Tier 3 model is that the complex tissue composition is approximated with a tissue-simulating medium (TSM). In practice, Tier 3 model is often derived from in vitro experiments with the implant submerged in a TSM-filled test phantom. We shall demonstrate our considerations during the design of the experimental system using two generic implants. The generic implants are 400-mm and 800-mm long insulated wires comprising a 1.5-mm diameter conductor.
with a 0.5-mm thick insulation layer. The insulation is removed at one termination, leaving a 10-mm long exposed conductive tip. To derive the \( \pi X \) model, each generic implant is placed in a homogeneous TSM-filled phantom and local excitation traverses along the length of the leaded implant, similar to the schematic of Figure 1. In this study, the dielectric properties of the TSM is similar to those specified in [1] \( (\varepsilon_r = 78 \text{ and } \sigma = 0.47 \text{ S/m}) \). We shall demonstrate the evaluation at 64 MHz \( (1.5T \text{ MRI}) \). Figure 2 illustrates our experimental system \( (\pi X \text{ system}) \), designed to derive a Tier 3 model of RF-induced implant heating.

The TSM has an attenuation constant of \( \alpha = 0.082 \text{ Np/cm} \) \( (\alpha = 0.72 \text{ dB/cm}) \). Our first prototype of the \( \pi X \) system comprised a 20L homogeneous TSM-filled phantom and the implant is placed 6 cm away from all boundaries; we anticipated that with such extreme loss of the TSM, the finite boundaries would insignificantly affect the \( \pi X \) models derived with the experimental system. However, we found that the \( \pi X \) models notably deviate from the numerical solution, derived from full-wave CEM simulations assuming implant immersion in an unbounded medium. The simulations are performed with SEMCAD X (SPEAG, Zurich), a platform based on the finite difference time-domain method [5]. It will be shown that this oversight substantially affects the prediction of the power deposition of the implants, calculated by the \( \pi X \) models. The \( \pi X \) system was revised to include a 70L homogeneous TSM-filled phantom with the distance between the implant and all boundaries of 12 cm. In Figure 3, we compare the \( \pi X \) models derived from full-wave CEM simulations, the experimental system with 20L phantom, and the experimental system with 70L phantom. It is clearly shown that the \( \pi X \) models derived from the revised experimental setup converge to the numerical solutions.

For each implant, the induced power deposition at the conductive tip of the implants from approximately 40 different exposures are computed from direct modeling of the implant-RF interactions via full-wave CEM simulations. The power deposition of the two implants and are compared with the values predicted by the \( \pi X \) models, numerically derived from CEM and the \( \pi X \) models, experimentally derived from the two revisions (20L and 70L TSM-filled phantoms) of the \( \pi X \) system. Same RF exposure conditions as those considered in the direct implant-RF modeling, are used for the \( \pi X \) predictions. The considered exposure conditions are shown in Figure 4. Figure 5 illustrates the power deposition of each generic implant under different RF exposures, obtained from (a) direct modeling of implant-RF interactions via full-wave CEM simulations; (b) Equation (1) with the numerically-derived \( \pi X \) model; (c) Equation (1) with the \( \pi X \) model experimentally-derived in 20L phantom; and (d) Equation (1) with the \( \pi X \) model experimentally-derived in 70L phantom. For the short implant \( (400 \text{ mm}) \), the estimated \( P_{\text{emp}} \) obtained with both experimental systems are within 1 dB of those obtained from direct CEM modeling and numerically-derived \( \pi X \) model; whereas for the long implant sample \( (800 \text{ mm}) \), the estimated \( P_{\text{emp}} \) obtained with the experimental system with 20L phantom is signif-

**Figure 2.** The experimental system for deriving \( \pi X \) models of implant RF-induced local power deposition. (a) The \( \pi X \) system. (b) Close-up of the local excitation source and the exposed 10-mm conductive tip of the 800-mm implant.

**Figure 3.** The \( \pi X \) models of the 400- and 800-mm implants, derived from numerical simulations with unbounded medium (black solid), the experimental system with 20L phantom (blue dotted), and the experimental system with 70L phantom (orange dotted).
3 Experimental radiated testing of implant RF-induced heating

Experimental radiated immunity test is also an integral part of RF-induced heating evaluation. For example, it is needed for the validation of an implant model. Radiated immunity test generally comprises a TSM-filled test phantom where the implant is submerged and an RF exposure source. For leaded implants, the RF-induced heating is dominated by the coupling of the implant with the tangential component of the electric fields along its length, $E_{\text{tan}}(l)$. Therefore, different exposure conditions can be carefully designed by adjusting the implant routing paths within the phantom. Several examples are provided in [1].

Despite what the provisional guidelines may suggest, the experimental uncertainty of the exposure design must still be carefully investigated before its experimental implementation. Here, we demonstrate the design of a phase-reversal exposure condition which is commonly used in the radiated test of leaded implants. Figure 6 illustrates two example experimental setups to achieve phase-reversal RF-exposure to the implant. The leaded implants are bent at the phase-reversal position and the different segments of the implants are separated by a finite distance.

In practice, this separation distance is limited to a small value to accommodate the finite size of the experimental phantoms. Depending on the electrical properties of the implants, the presence of the adjacent lead segment may have appreciable effects on $P_{\text{me}}$. We investigated this affect using full-wave CEM simulations of two 400-mm insulated

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**Figure 4.** Phase distribution along the length of the implants of the exposures used in the calculation of power depositions from the $\pi X$ models. $|E_{\text{tan}}(l)|$ is always unity. (a) Phase-reversal exposure. (b) Linear-phase exposure.

**Figure 5.** The power deposition of each generic implant per unit $|E_{\text{tan}}(l)|$ obtained from the direct implant-RF modeling (‘o’ markers), the numerically-derived $\pi X$ model (black solid), the experimentally-derived model in 20L phantom (blue dotted), and the experimentally-derived model in 70L phantom (orange dotted).

**Figure 6.** Two examples of radiated test experimental setup providing a phase-reversal incident condition to the implant. The implant routing paths are shown as red solid lines. The phase distribution of $E_{\text{tan}}(l)$ of the phase-reversal incident conditions are illustrated in Figure 4(a).
wires positioned parallel to each other with a separation distance, \(d\), and are immersed in unbounded medium (\(\varepsilon_r = 78\) and \(\sigma = 0.47\) S/m). The implants are impinged with TEM waves with the electric fields polarized along the long axes of the leaded implants and the propagation vector perpendicular to the common plane of the implants’ axes. Figure 7 illustrates \(P_{\text{tr}}\) as a function of the separation distance, \(d\). The results indicated that the scattering from the adjacent segment of a leaded-implant caused by a phase-reversal experimental configuration may significantly affect \(P_{\text{tr}}\) when \(d < 10\) cm.

4 Summary

We have demonstrated that the experimental assessment of RF-induced heating of implant must be conducted under carefully designed test setup. Examples of two types of experimental evaluations were provided. First, we showed that the \(\pi X\) models obtained with an unoptimized experimental system (20L phantom) lead to a significantly different prediction of the RF-induced heating of implants and the power deposition was estimated to be significantly less than the direct implant-RF CEM simulations and the numerically-derived \(\pi X\) model for the 800-mm implant. Whereas, the estimated power deposition evaluated from the \(\pi X\) model obtained with the optimized experimental system (70L phantom) has excellent agreement with those obtained from numerical solutions. Second, we demonstrated that radiated test configurations provided by provisional guidelines may not be suitable for all implants and their practical performance must be investigated prior to their implementation.

It is essential that the accuracy of the experimental methods and instrumentation themselves be assessed prior to their application to evaluate implant RF-induced heating performances. Admittedly, some inherent experimental uncertainties cannot be avoided, which is why optimizing the in vitro experiments is necessary to minimize the experimental uncertainty and to dismiss any potential false assumptions.

References


