Numerical Analysis of AIMD Lead Tolerances Using the Lead Electromagnetic Model

Mikhail Kozlov
Max Planck Institute for Human Cognitive and Brain Sciences
Leipzig, Germany
kozlov@cbs.mpg.de

W. Kainz
U.S. FDA, CDRH
Office of Science and Engineering Laboratories,
Silver Spring, MD, USA
wolfgang.kainz@fda.hhs.gov

***Abstract* — Influence of lead tolerances on the RF-induced power deposition (*P*) near a lead electrode was analyzed using the lead electromagnetic model and two sets of incident electric fields ($E_{\tan}$) with different profiles. Our results indicate that tolerance analysis shall be done for all lead lengths and clinically relevant $E_{\tan}$ because the sensitivity of *P* to a given variation of the lead properties can differ by an order of magnitude.**

Keywords— numerical simulation; electromagnetics; RF-safety

I. INTRODUCTION

The design steps of a lead for an active implantable medical device (AIMD) should include a tolerance analysis of the RF power deposition (*P*) for the lead geometry and the insulator relative electric permittivity ($\varepsilon_{r\_insulator}$). However, such an experimental analysis can be extremely time consuming and costly.

Clause 8 of ISO Technical Specification (TS) 10974:2018 [1] defines procedures for assessing the radio frequency (RF)-induced heating for patients with an AIMD undergoing magnetic resonance imaging (MRI). *P* around the AIMD lead electrode can be estimated using the lead electromagnetic model (LEM)

$$P = A \cdot \left| \int_0^L S(l) \cdot E_{\tan}(l) \cdot dl \right|^2 \qquad (1)$$

where: *A* are the calibration factor of the LEM, $S(l)$ is the transfer function (TF), $E_{\tan}(l)$ is the incident tangential electric field along the AIMD lead trajectory, and *L* is the lead length.

In this work, we focus on modelling the LEM for lead designs with two insulation thicknesses and two $\varepsilon_{r\_insulator}$ as well as evaluating *P* for two sets of $E_{\tan}(l)$.

II. METHODS

We investigated generic insulated leads (Fig. 1) with an insulation diameter of 1.46 mm, electrode length and diameter of 3 mm and 0.25 mm, respectively, titanium alloy straight wire of the length from 80 mm up to 600 mm in 10 mm steps. The lead design parameter matrix includes two wire diameters of 1 mm and 1.1 mm as well as two values of $\varepsilon_{r\_insulator}$: 2.7 and 5.5. They referred to as cases “1mm/2.7”, “1mm/5.5”, “1.1mm/2.7”, “1.1mm/5.5”.

The leads were positioned parallel to the Z axis in the middle of a box (600 mm × 400 mm × 2400 mm) surrounded by perfectly matched layer. The box was filled with a medium similar to nerve tissue: $\varepsilon_r = 44$ and electrical conductivity $\sigma = 0.354$ S/m. Numerical LEM evaluation at 128 MHz was done as in our previous study [2] using the reciprocity approach and 3D EM (ANSYS HFSS). Less than 3% variation of *P* and maximum of $|S(l)|$ over all spatial points between two consecutive adaptive runs with 30 % increase of mesh elements was defined as convergence criteria.

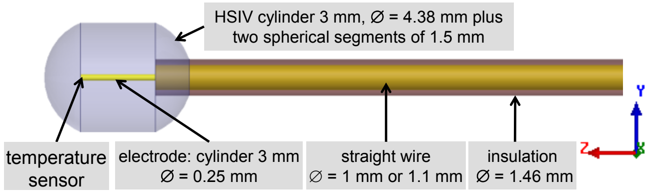
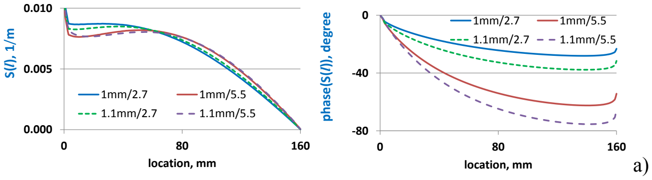


Fig. 1. Close-up view of lead geometry near lead electrodes with hot spot integration volume (HSIV).

The calibration factors (Table I) with R^2 close to 1 were obtained using a set of 120 $E_{\tan}(l)$ [2]. Using (1) *P* was calculated for two artificial sets of forty $E_{\tan}(l)$ generated for each lead length because without indicating a particular type of AIMD it is impossible to specify clinically relevant AIMD trajectories inside the human body and to obtain a set of clinically relevant $E_{\tan}(l)$. At each location $|S(l)|$ and phase $(S(l))$ ratios were calculated as a proportion of the maximum value to the minimum value over all investigated TFs. The *P* ratio was defined as a proportion of the maximum *P* values to the minimum *P* values over all studied cases.

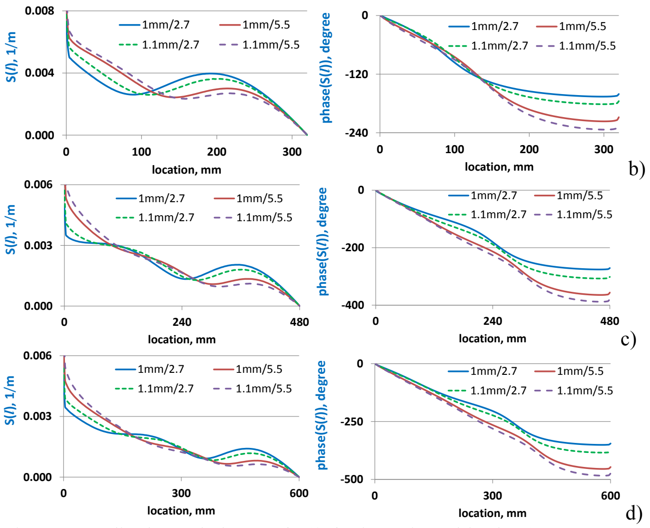
III. RESULTS AND DISCUSSION

The impact of the wire diameter and $\varepsilon_{r\_insulator}$ on the amplitude and phase of $S(l)$ was noticeable (Fig. 2, Table I and II). An increase of *L* changed the level of $\varepsilon_{r\_insulator}$ influence: it became smaller on the phase of $S(l)$ especially for location close to the electrode and it increased with the amplitude of $S(l)$ and *A*. For $L=\{80{:}480\}$ mm *L* increase resulted in a larger sensitivity of *A* to a variation of $\varepsilon_{r\_insulator}$. For $L=\{80{:}200\}$ mm the maximum of *P* ratios over all applied $E_{\tan}(l)$ was relative moderate, i.e., less than 1.2, despite large phase $S(l)$ discrepancy. The maximum value of the *P* ratio was observed for *L* of 480 mm.



a)

978-1-7281-0695-3/19/$31.00 ©2019 IEEE



b)

c)

d)

Fig. 2. Amplitudes and phases of $S(l)$ for investigated leads: a) L = 160 mm, b) L = 320 mm, c) L = 480 mm, d) L = 600 mm.

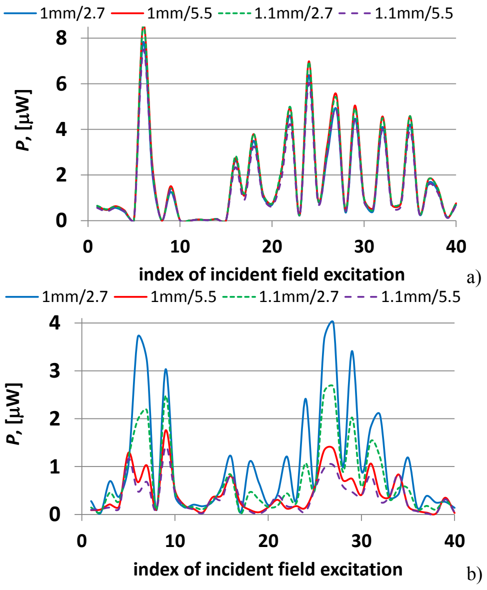
TABLE I. LEM CALIBRATION FACTOR A

L	***1mm/2.7***	***1mm/5.5***	***1.1mm/2.7***	***1.1mm/5.5***
160 mm	11.1	13.0	12.3	11.8
320 mm	27.4	19.1	23.3	16.7
480 mm	55.7	26.2	42.3	21.2
600 mm	49.3	28.6	42.4	22.5

TABLE II. MAXIMUM VALUES OF RATIOS

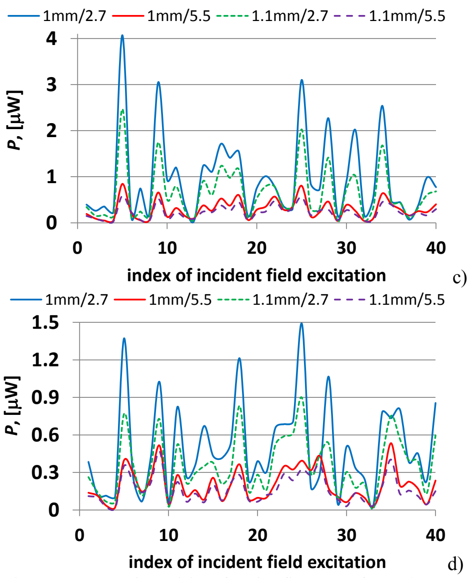
L	**max of |$S(l)$| ratios**	**max of phase($S(l)$) ratios**	**max of P ratios**
160 mm	1.36	2.80	1.15
320 mm	1.27	1.99	2.81
480 mm	2.01	1.97	6.91
600 mm	2.42	1.38	3.18

The ratio values P varied more than an order of magnitude for different $E_{tan}(l)$ and L (Fig. 3). For L > 220 mm maximum of P over all applied $E_{tan}(l)$ was observed for diverse $E_{tan}(l)$ for the studied lead cases.



a)

b)



c)

d)

Fig. 3. Power deposition for the first set of $E_{tan}(l)$. a) L = 160 mm, b) L = 320 mm, c) L = 480 mm, d) L = 600 mm.

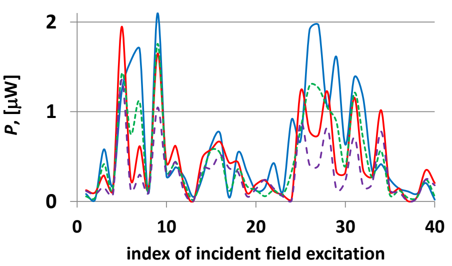


Fig. 4. Power deposition for the second set of $E_{tan}(l)$ and L= 320 mm.

P for lead length of 320 mm and second set of forty $E_{tan}(l)$ is presented in Fig.4. For this set the maximum of P ratio was 1.54, i.e., substantially less than for the first set of $E_{tan}(l)$.

IV. CONCLUSIONS

Our numerical case study assessing the variation of P on some lead tolerances, i.e., possible variation of the wire diameter and the insulator relative electric permittivity, resulted in the following conclusions: (*i*) it is impossible to estimate the variation of P for clinically relevant $E_{tan}(l)$ based only on known variation of the LEM $S(l)$ and A; (*ii*) a tolerance analysis shall be done for all possible lead lengths; (*iii*) it can be impossible to select a lead design that resulted in either the highest or the lowest P for any artificial set of $E_{tan}(l)$.

DISCLAIMER

The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or suggested endorsement of such products by the Department of Health and Human Services.

REFERENCES

[1] Technical specification ISO/TS 10974, “Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device”, 2018.

[2] M. Kozlov, W. Kainz, “Lead Electromagnetic Model to Evaluate RF-Induced Heating of a Coax Lead: A Numerical Case Study at 128 MHz”, *IEEE J. Electromagn., RF, Microw. Med. Biol.*, vol: 2(4), 2018, pp. 286-293.