WORST-CASE ANALYSIS OF RF-INDUCED HEATING DURING MRI SCANNING IN A GENERIC MULTI-COMPONENT ORTHOPEDIC MEDICAL IMPLANT APPLYING THE DESIGN OF EXPERIMENT METHOD (DOE)

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Purpose

Magnetic resonance imaging (MRI) is a safe technique to obtain images of inner body in a non-invasive way. However, when the patient being imaged has a metallic implant, some prior tests need to be performed in order to guarantee the MR safety of the process. Calculation of spatial induced electric field (E-field) in medical implants during MRI imaging become complex as the behavior of electromagnetic fields in free space including an electrically conductive object is hard to predict if the object is nonuniform in shape. This problem is even increased for multi-component objects (like most of the medical implants). In this study, a generic hip implant has been designed and characterized in order to study the effect of each part's variation on RF heating of commercial hip implants for different body sizes. The model includes 6 parts, which leads to huge number of configurations assuming each part's dimension could vary in several levels. The goal is finding the worst and the safest configuration in terms of RF heating. However any other configuration could be predicted by studying the effect of each variable in the design of the generic model.

Method

Previous studies have shown a direct relation of specific absorption rate (SAR) and temperature rise, for the case when the environment of the implant is rather homogenous in terms of heating capacity as shown for a straight wire in [1]. SAR is proportional to the square of the E-Field, and to the conductivity of the medium where the E-Field is present. Therefore, for the case of an implant immersed in a medium with constant conductivity, RF-induced heating and temperature elevation can be estimated from the obtained values of SAR. A generic multi-component hip implant has been designed in a way that a large number of configurations are possible. The hip designed for this study includes 6 parts: main stem, body, screw (all with variable length and diameter), ball (with variable diameter), liner and cup (both with variable thickness). In this study, the mentioned multi-component hip implant has been immersed in a tissue simulating liquid (TSL) with similar electric properties than the real tissue of the human body. The set-up has been exposed to a 64 MHz medical implant RF test lab system (MITS 1.5, Zurich Med Tech) creating a worst-case RF electromagnetic environment equivalently produced by a 1.5 Tesla MRI scanner.. In addition, numerical simulations have been performed, using a 3D electromagnetic simulation software (SEMCAD X v.14.8, SPEAG). The method used in this study begins with the selection of the design parameters and their levels. By performing the numerical simulations on specific configurations given by the Design of Experiment (DoE), we are able to generate enough data to start analyzing and predicting the aimed best and worst values for the variables using the underlying Taguchi method.

Setup

Maximum heating is expected, if the main axis of the implant is parallel to the spatial distribution of the local E-field vector. In other words, the surface of the implant conductive material is orthogonal to the H-field. In the proposed multi-component implant, a total of nine parameters are assigned as variables. Three different values have been chosen for each variable, stem length 150, 170 and 200 mm, stem diameter 13, 15 and 18 mm, body length 30, 50 and 70 mm, body diameter 10, 15 and 20 mm, ball diameter 30, 35 and 40 mm, liner thickness 10, 15 and 20 mm, cup thickness 2.5, 3.5 and 4.5 mm, screw length 30, 35 and 40 mm and screw diameter 3.5, 4.5 and 5.5 mm. The total number of configurations that could be assembled using these variables is more than 19k configurations (3^9=19683). Given the combination of 9 control factors in 3 different levels, the type of design has been selected to be L-27 of the Taguchi method based on DoE. Mixed level factors are avoided to simplify the design. All chosen sizes are based on real hip implants. The SAR for the all 27 proposed configurations of the hip implant is simulated numerically. All simulations include the designed CAD model of the generic hip implant (with the given dimensions of each element for each case), a body phantom (following the ASTM recommendations [2]) filled with saline gel (simulating the body tissue with a permittivity of 81 and a conductivity of 0.46 S/m), and the RF coil with its surrounding shield. The hip model is placed in the middle of the phantom, with its main axis oriented in the z-direction (main axis of the coil and phantom), and 2 cm away from the phantom wall in order to maximize the z-component of E-field. The field enhancement effect at sharp edges is mitigated by flattening all edges in the designed model of the implant. The Taguchi quality characteristics of this study is based on the signal-to-noise ratio (SNR) according to "the larger the better" for SAR as the main goal is finding the worst configuration in terms of RF heating.

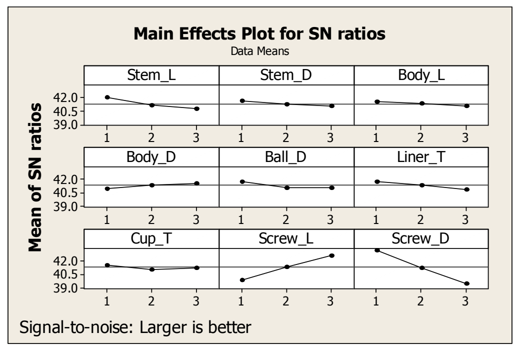

Fig.1 SNR of maximum induced SAR

Results

As a result of the numerical simulations, the SAR value generated in the surroundings of the hip implant due to the RF fields inside the phantom is obtained. The effect of changing the variable parameters of the implant on the maximum induced SAR is shown in Fig. 1. Almost all variables show a linear behavior on SAR, but the most significant effect is – obviously – seen on the stem and screw size. From the parameters shown in Fig. 1, we can predict the parametric combination to obtain the optimum goal (max. SAR). By comparing the control factor effects on the device performance, we have selected the combination of control factors that exhibits the highest value. The optimum (worst) combination for SAR is first level for stem length, stem diameter and screw diameter with third level of screw length (which is not along the simulated configurations) whereas the effect of other variable parameters like body, ball, liner and cup are neglected. In the same way, the most MR friendly combination of implant could be configured by selecting the dimension which generates lowest SAR and using the SNR according to "the smaller the better", which should be used when the goal is to minimize heating effects. This process covers a high range of the product matrix and enables us predicting the SAR for configurations, which are neither simulated nor measured. This inference has been validated in two steps: 1) evaluating the SAR of the predicted worst-case configuration, 2) measuring the temperature rise of the predicted worst-case configuration and the worst-case along the simulated configurations. The same procedure could be implemented finding the safest combination. Fig. 2 shows the CAD model of the designed generic medical implant, the simulation results of the worst-case configuration, the measurement setup in the RF test lab system and the ASTM phantom simulating the human body. The predicted SAR of the predicted worst-case configuration is 196.4 W/kg (estimated by the Taguchi method). The full-wave simulation of the same configuration yields 204.2 W/Kg, which is in good agreement with the predicted values. Finally, both worst combinations (derived by the numerical simulation and estimated by the Taguchi method) have been fabricated and the temperature rise in both cases has been measured. In the first configuration 3.1 K temperature rise has been registered (simulated SAR of 170.9 W/kg average on 0.1 g) in comparison with 3.3 K for the predicted worst-case (simulated SAR of 204.2 W/kg average on 0.1 g).

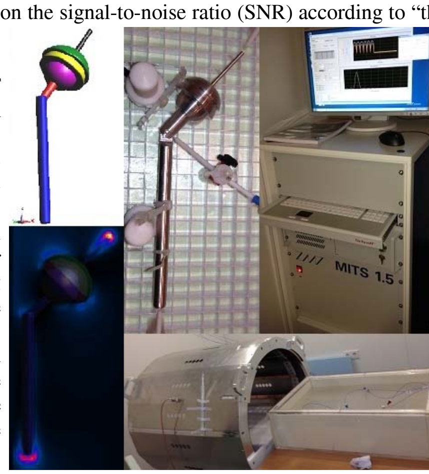

Fig.2 Measurement setup, generic model, simulation results

Conclusions

A novel solution is proposed here for predicting the EM behavior of multi-component medical implants in terms of RF-induced heating during MRI scanning. By using the Taguchi method, we were able to predict the effect of variable changes individually and find the worst and safest configurations as well as any arbitrary combination of parts. In the specific designed hip model, it was found that the screw length and thickness have the highest influence on SAR and the stem length is the second most important factor on the temperature rise. Hence, carrying out a Taguchi optimization prior to fabrication provides a very fast, easy to handle and reliable measure for estimating the effect of implant form factors (namely: implant designs) on any desired output characteristics.

References

1. Sung-Min Park, Journal of Magnetic Resonance Imaging, vol. 26, no. 5, pp. 1278-1285, 2007. 2. ASTM F2182-11a; 2011, www.astm.org