How do we identify the worst-case device for RF heating during MRI?

Introduction

There are several safety concerns for patients with metallic implants who require MRI, including magnetic interactions (i.e., force and torque) as well as radiofrequency-induced heating. MED Institute helps medical device manufacturers evaluate their devices for safety in the MRI environment and performs physical MRI testing for magnetically induced displacement force, magnetically induced torque, MR image artifact, and RF-induced heating according to ASTM F2052, F2213, F2119 and F2182, respectively [1-4]. After the testing is complete, we provide the necessary information for MRI safety labeling and supporting scientific rationale that is reported in the instructions for use (IFU) of the device according to ASTM F2503 and the FDA Guidance on establishing safety and compatibility of passive implants in the magnetic resonance environment [5-6].

One example of a device that needs to be evaluated for MRI safety is a vertebral body replacement (VBR) device (**Figure 1**). VBRs are used to treat patients who have experienced severe spinal trauma or who have had a vertebra removed with a spinal tumor. VBR devices restore alignment and mechanical stability to the lumbar or thoracic regions of the spine and are often made of metallic materials, therefore it is important for patients with VBR devices to know if it is safe to undergo MRI scanning.

Figure 1. A representative images of commerical VBR devices are shown (from left to right, Ulrich Medical [7], Globus Medical [8], Stryker [9] and DePuy Synthes [10]).

Identifying the worst-case VBR device for magnetic force and torque is relatively straightforward since these magnetic interactions are mostly dependent upon material properties of the device, which are known. The more challenging task is the determination of the worst-case VBR device for RF-induced heating when there are multiple sizes, configurations, materials, orientations, MRI scanners, etc. Furthermore, it is necessary to know the location of maximum heating so temperature probes can be positioned for ASTM F2182 physical testing [4].

Since many VBR devices are height-adjusted to fit each patient, there are numerous possible lengths of the device. To determine the worst-case VBR device configuration for RF-induced heating, multiple physical tests can be conducted according to ASTM F2182. Alternatively, computer modeling and simulation (CM&S) can be used much more efficiently to identify the worst-case VBR device and reduce the cost and burden of physical testing.

Computer Modeling & Simulation

MED Institute has successfully used validated CM&S to identify the worst-case size, configuration, material, orientation and MRI scanner for a wide range of medical devices. A generic VBR device was created to show how CM&S is used to identify the worst-case device for RF-induced heating (**Figure 2**).

Figure 2. A representitive image of a CAD model for a generic VBR device (not commerically available).

One of the primary considerations of RF-induced heating is the resonant length effect. The resonant length effect is a phenomenon which describes the dependence of the magnitude of RF-induced heating on the geometry (i.e., the length) of the device and the operating RF frequency of MRI systems (e.g., 64 MHz at 1.5 T, 128 MHz at 3.0 T).

Worst-case VBR device length at 1.5 T and 3.0 T

CM&S identified the resonant length of the 14 mm diameter VBR device to be 170 mm at 1.5 T and 110 mm at 3.0 T, as shown at the top of **Figure 3**.

Worst-case VBR device diameter at 1.5 T and 3.0 T

CM&S identified the worst-case diameter of the VBR device to be 14 mm at 1.5 T and 3.0 T, as shown at the bottom of **Figure 3**.

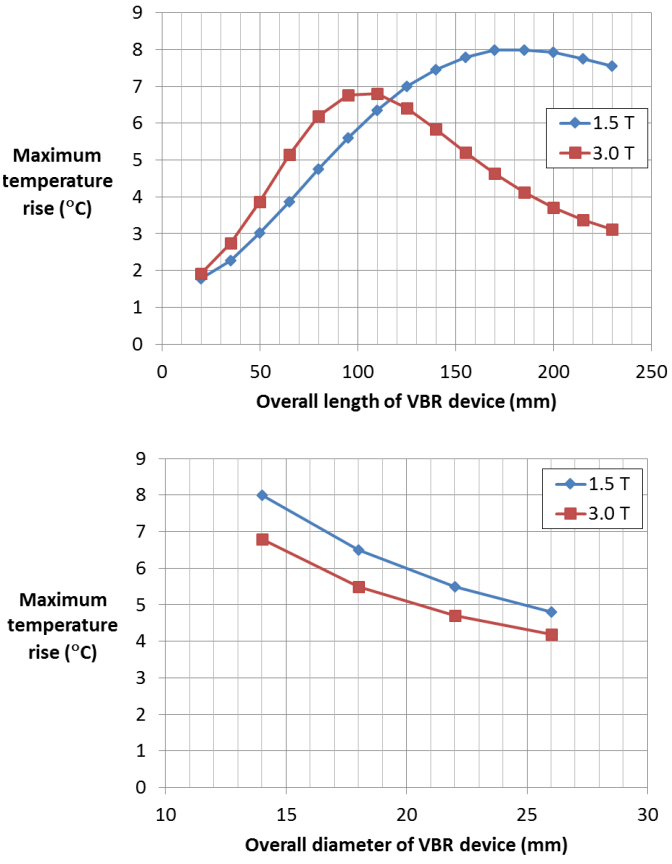

Figure 3. A plot of the maximum temperature rise versus the overall length of the 14 mm diameter VBR device (top) and overall diameter of the 170 mm long VBR device at 1.5 T and 110 mm long VBR device at 3.0 T (bottom). The maximum temperature rise from RF-induced heating at 1.5 T and 3.0 T is compared after 15 minutes at a whole phantom specific absorption rate (SAR) of 2 W/kg.

Overall worst-case VBR device for RF heating

Figure 4 presents the temperature contours of the worst-case generic VBR devices at 1.5 T (left) and at 3.0 T (right) after 15 minutes of RF-induced heating at a whole phantom SAR of 2 W/kg.

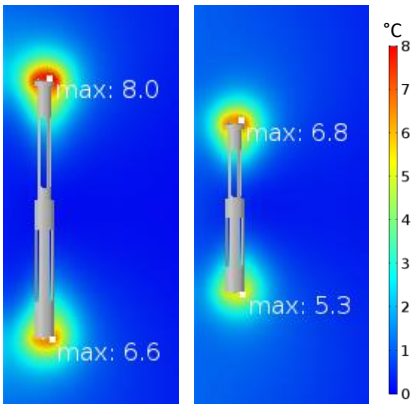

Figure 4. Temperature contours of the 14 mm diameter generic VBR device are shown for the 170 mm long device at 1.5 T (left) and the 110 mm long device at 3.0 T (right) after 15 minutes of RF heating at a whole phantom SAR of 2 W/kg.

Conclusions

The CM&S results show the overall worst-case is the 14 mm diameter 170 mm long generic VBR device at 1.5 T. The temperature contours in **Figure 4** show that the temperature probes should be placed at the proximal and distal ends of the VBR device during ASTM F2182 testing.

Our Services

At MED Institute, we have the tools and the experience to evaluate your medical device for MRI safety using simulation and testing. We will provide you with an easy-to-understand report that meets your global regulatory needs for MRI labeling. If you have questions about how we can help you achieve MR Conditional labeling for your device, please contact:

David Gross, PhD, PE
Manager, MRI Safety Evaluations
dgross@medinstitute.com
765.404.4692

References

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