

Comments on MR Heating Tests of Critical Implants

MAGNETIC RESONANCE IMAGING (MRI)-related heating for certain implants may be excessive, causing substantial patient injury. The determination of implant heating is particularly challenging because of the numerous variables that must be considered in order to properly identify both MRI- and implant-related conditions that can impact the findings (1,2). Therefore, I applaud the recent commentary by Kainz (3), a member of the Food and Drug Administration (FDA), for presenting several of the confounding factors that complicate tests used to characterize implant heating.

Kainz's (3) guest editorial refers to possible issues associated with the *in vitro* assessment of MRI-related heating, with an emphasis on "MR critical implants." MR critical implants were defined as: "active implantable medical devices (AIMDs); semiactive implants, *i.e.*, implants powered from outside the body; and elongated metallic structures that are in the range of the critical length (defined later in the guest editorial) (3). Notably, there was no mention of devices that have "resonant conducting loops," which may likewise generate excessive heating in association with MRI (4). Examples include cervical fixation devices and external fixation systems.

As a member of the MRI community involved in the evaluation of implants since 1988 (5,6), I welcome the opportunity to respond to the content of this guest editorial insofar as our group and other investigators have extensive experience testing many of the so-called MR critical implants (7–23). In addition, we have been involved in the development of the methodology utilized to evaluate these devices (24). Importantly, findings from many studies have resulted in labeling approved by the U.S. Food and Drug Administration (FDA) to permit MRI procedures to be performed in patients with active, semiactive, and elongated devices, including cochlear implants, bone fusion stimulators, Foley catheters with temperature sensors, implantable infusion pumps, a deep brain stimulation system, spinal cord stimulators, a vagus nerve stimulator, a microstimulator (Bion), relatively long, orthopedic implants, and many others (7–23). As a result of this work, patients with "MR critical implants" throughout the world un-

dergo MRI procedures safely, as MR healthcare workers follow FDA-approved guidelines (or guidelines approved by other agencies), which usually state specific instructions for a given device with respect to MRI parameters and other instructions. These instructions often indicate a particular whole-body averaged specific absorption rate (WB-SAR) that should not be exceeded during the MRI examination.

For the aforementioned devices, the evaluation of MRI safety included an assessment of heating caused by MRI procedures. Interestingly, as the guest editorial indicates, "Most MR heating tests refer to [American Society for Testing and Materials International] ASTM Standard 2182-02a which is for passive implants only" (3). One of the reasons for this is that, currently, there is no standard for testing MR critical implants and, therefore, the ASTM standard used for passive implants has been modified to test active, semiactive, and elongated implants. In spite of this issue, the fact remains that the FDA approved MRI-related labeling for implants that utilized findings from heating tests suggested to be problematic. Notably, to date, there is no evidence that patient injuries have occurred in relation to the use of labeling approved by the FDA for these devices relative to the heating information. By comparison, there have been serious patient injuries related to not following specific instructions intended to prevent excessive implant heating (25–27).

CRITICAL IMPLANT LENGTH

Kainz (3) stated that the length and dimensions of the implant (*i.e.*, lead length, stent length, etc.) in relation to the wavelength of the MR radio frequency (RF) field inside the patient or phantom is a critical detail to consider when performing heating tests. Once "resonant" with the electromagnetic field, the implant heating could become dangerously high. However, regardless of an implant's resonant length, other unknown length-related factors might generate excessive heating. These comments were partially based on the yet unpublished results of the ASTM SAR Intercomparison in which an insulated 20-cm straight wire with 1-cm-long bare ends showed up to a 48°C temperature rise at 1.5-T, using a maximum WB-SAR of 2 W/kg. This important aspect of assessing MRI-related heating for implants has been recognized in the peer-reviewed literature (2,4,15,20–22,28–32).

Importantly, merely considering the length of an implant may be too simplistic insofar as other factors

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significantly influence MRI-related implant heating. For example, while the length and dimensions of insulated wires (such as those used for cardiac pacemakers and neurostimulation systems) may impact heating in a somewhat predictable manner (21,26,28–32), connecting a pacing lead to the pulse generator tends to *decrease* MRI-related heating at both 1.5 T/64 MHz and 3 T/128 MHz (32). In addition, Baker et al (28) described how the number of small concentric loops applied to a deep brain stimulation lead directly affected MRI-related heating. Fewer loops increased heating while additional loops decreased heating (28). In a study involving coiled wire forms commonly used for cardiac pacemakers and neurostimulation leads, Gray et al (33) reported how a simple design modification could substantially decrease MRI-related heating for a given lead length.

Finally, for metallic stents, the winding pattern and overall configuration of the wires used to make these implants greatly changes the amount of MRI-related heating that occurs. Notably, stent heating is not just a function of overall length. Obviously, we need a more complete understanding of how the dimensions and configurations of implants influence MRI-related heating.

MRI HEATING IN PHANTOMS

Kainz (3) points out that the field distribution of the ASTM head/torso block-phantom (24), as it is centered in the transmit RF coil, has a minimum electric field at its center and, thus, the heating of implants is expected to be minimum at the center of this phantom. This phenomenon has been observed in studies that examined different placement scenarios for implants that have a variety of possible implantation positions or configurations, such as neurostimulation leads, cardiac pacemaker leads, certain vascular stents, and external fixation devices (29–31). Surprisingly, the distribution of the electrical field is asymmetric and depends on the direction of the B1 field rotation (3). This asymmetry may explain the asymmetric heating reported for deep brain stimulation leads (28,34). Therefore, Kainz (3) contends, using an anatomic placement of an implant in the ASTM phantom will not create a “realistic or worst case” MRI heating test for the whole patient population.

While for certain implants that have multiple possible implantation sites, it is appropriate to identify the worst case location in the ASTM phantom in order to study MRI-related heating (and, in fact, this is what is done when characterizing heating for these implants), placing a device that is implanted *only* in the center or close to the midline of a patient (e.g., an abdominal aorta aneurysm stent graft) is also deemed appropriate. Hopefully, the revised version of the ASTM standard intended to address MRI-related implant heating for MR critical implants will consider this matter (although, as a member of ASTM Committee F04 on Medical and Surgical Materials Devices, Sub-Committee F04.15 on Material Test Methods, to my knowledge, a comprehensive discussion of this issue has not occurred).

The guest editorial indicates that, “Computer modeling, using anatomically correct models of the whole patient population, can be used to evaluate the local field distribution inside the patient for the specific implant location” (3). Regrettably, Kainz (3) did not provide references or standards to support or substantiate that such modeling is valid for implant heating associated with MRI procedures. The MRI community would benefit from seeing information in the peer-reviewed literature pertaining to this topic because of the importance it has on how we conduct investigations of implant heating and how this may ultimately influence patient safety.

“Worst-case” positioning for an implant is admittedly a complex interaction between an individual patient (or phantom) and a given MR scanner. Modeling proposed by Kainz (3) may not suffice to address this problem. Why don’t we follow the FDA’s precedent for other MR critical implants that is based on clearly stating the clinically relevant position or positions that should be used and determine MRI-related heating for the implant, accordingly? This has been the strategy for many of the aforementioned MR critical implants that have FDA-approved labeling for MRI. A substantial departure from this may lead to undue confusion and, in some cases, misunderstandings that could result in patient injuries.

SAR ISSUES

The use of MR system-reported WB-SAR is, indeed problematic with regard to MRI-related implant heating, as demonstrated by Baker et al (34,35). Kainz (3) stated that, “Preliminary results of the SAR Intercomparison Protocol (3) show that using this WB-SAR number for scaling the heating results of implants, as required by ASTM 2182, could underestimate the heating by as much as a factor of 7. To avoid errors in using the WB-SAR displayed on the MR scanner console when performing phantom testing for implants, the International Electrotechnical Committee (IEC), Sub-Committee 62B, Maintenance Team 40 is considering a proposal to display on the MR scanner console a more direct measurement of the RF electromagnetic field, [B1 root mean squared] B1rms, which can be used to evaluate implant heating.” To date, there is no evidence in the peer-reviewed literature that the use of B1rms is better than the MR system-reported WB-SAR value for implant heating. Therefore, the potential of using the B1rms as a solution to the problem of MR system-reported SAR values remains unknown. Additional information on the topic of B1rms vs. the MR system SAR would be very much appreciated.

Concerns exist regarding the amount of time required for the IEC to address this matter as well as the time it will take for MR system manufacturers to implement such a scheme. Furthermore, what will be done for all of the implants that already have FDA-approved labels that indicate a particular SAR value that needs to be followed to ensure safety? How do we manage patients with these implants as they are referred for MRI examinations? Finally, how does the FDA plan to employ B1rms values in existing or older MR systems and who

will absorb the cost of such an endeavor (e.g., the MR system manufacturers, MRI facilities, others)? These are critical questions that must be addressed.

TISSUE DAMAGE ASSESSMENT

Kainz (3) proposes that the “Cumulative Equivalent Minutes at 43°C” (CEM43) concept (36) could be used to assess possible tissue damage related to implant heating because the CEM43 is a “well established concept and values are available in the literature for most tissues.” In reviewing CEM43 (36), it was apparent that this is a complicated and somewhat confusing document. Of note is that the “*Quality of literature used for review*” section of the CEM43 article, states: “This evaluation is based on the peer-reviewed scientific literature. Much of the tissue sensitivity data came from therapeutic hyperthermia studies and, although some studies examined a broad range of time-temperature combinations, many were conducted only at time-temperature combinations severe enough to assure the desired effect (i.e., cell killing). Few of the studies were independently replicated, using identical methods. By using the CEM 43°C normalization, however, it may be possible to generally classify different tissues with respect to their thermal sensitivity. A stronger case could be made if some key studies were reproduced by independent laboratories. Most of the studies reviewed were not designed for meeting data needs of risk assessment and establishing levels below which no effects are seen.”

In consideration of the statements indicated above, there appears to be many unknowns that should cause us to be reluctant to embrace the use of CEM43 with regard to MRI implant heating. The implications of CEM43 for MRI-related heating of implants are currently unknown and may, in fact, be irrelevant.

Why Kainz (3) believes that CEM43 is an appropriate concept to apply to MRI-related heating of implants, especially since this is a departure from what has been used by the FDA previously is unspecified. Perhaps we can receive guidance from the FDA with regard to what temperature elevation is deemed potentially injurious for implanted devices and not further complicate an extremely complex issue. Therefore, what does the FDA consider an excessive temperature elevation for an implant in a patient undergoing an MRI examination?

HEATING TEST FOR BOTH 1.5-T AND 3-T SYSTEMS

The issue that implant heating may be significantly different when using different 1.5-T MR systems is an important detail presented in the Kainz (3) guest editorial. Significantly different implant heating for a deep brain stimulation lead in association with different 1.5-T scanners (notably from the same manufacturer) was first reported by Baker et al (35). Baker et al (34) and our group (30) provided further elucidation of this interesting topic in later studies. Many members of the MRI community may not be aware of this vital information and, to date, there is no apparent solution to this disconcerting matter. Suffice to say that MR system-reported SAR values appear to be overestimates or

“conservative” estimates intended to be an upper bound (3) and, thus, current FDA-approved labels for implants that rely on this information likely function with a margin of safety relative to MRI-related heating.

Another important point made by Kainz (3) is that implant heating studied at one particular field strength/frequency cannot be translated to an MR system operating at another field strength/frequency. For example, our group has presented preliminary findings for a cardiac pacemaker lead in which MRI-related heating was found to be significantly *lower* at 3 T/128 MHz compared to what was recorded at 1.5 T/64 MHz (32). We have observed similar results for implants that include a vagus nerve stimulation system, Foley catheters with temperature sensors, and external fixation devices.

While the guest editorial suggests that the observed differences between implant heating using different 1.5-T MR systems or comparing 1.5-T to 3-T may be due to “uncertainty factors” (including fluoroptic thermometry probe placement, implant location, scanning position, etc.) (3), when careful attention to experimental detail is implemented, and specific setup parameters are defined and utilized (e.g., taking into account the transmit RF coil, implant position, scan parameters, and other known variables that may effect heating), the resulting implant heating is consistent and repeatable. Therefore, experimental experience and background knowledge of the numerous aspects of MRI-related heating test procedures are necessary components of investigations intended to characterize implant safety.

THE FUTURE

The ASTM and other groups are now focused on understanding the issues presented by Kainz (3) and applying this knowledge to the development of guidelines that are intended to be used when investigating MRI-related heating for MR-critical implants. Unfortunately, the process involved with these endeavors may take two to three years to complete. In the meantime, with the continued desire to permit the diagnostic benefits of MRI to be afforded to patients with MR-critical implants, investigators must interact closely with knowledgeable members of the FDA to ensure that MRI-related heating studies are conducted properly. In conclusion, Kainz (3) should be congratulated for bringing the important aspects of MRI-related implant heating to the attention of the MRI community.

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