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Assessment of MRI Issues at 7 T

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We are writing in regard to the article “Assessment of MRI Issues at 7 T for 28 Implants and Other Objects” [1] recently published in the *AJR*. The authors concluded that some of the implants tested may be safe at 7 T. However, we do not agree that sufficient evidence has been provided to establish safety, and we are concerned that such a statement may mislead patients and health care providers. Therefore, we offer our comments with the hope to further clarify the methodology and conclusions of the study.

MRI safety information is specific to the device make, model, and sometimes serial number. It is not possible to unambiguously identify a device by name or appearance; thus, the information presented in Table 1 of the article is insufficient to positively identify a device. Therefore, the results of the study are only applicable to the specific devices tested; they cannot be further generalized because small differences in physical characteristics can result in large differences in safety. The device manufacturer is the only accurate source of information about MRI compatibility for a particular device.

The rationale for selecting the position of the devices within the phantom was not clear, nor was the rationale for selecting the worst-case location of the fluoro-optic probes near the implants. The transmit architecture of the MRI system was also not specified. Additionally, the authors reported that testing was performed at “100% of allowed SAR [specific absorption rate]” without defining the actual power delivered (e.g., background heating was not reported).

Radiofrequency-induced heating is strongly dependent on geometric and electrical characteristics of the coil, phantom, and implant as well as orientation and location of the implant [2]. Additionally, fluoro-optic probes are limited to measurement within a small volume and are prone to significant errors related to the probe position [3]. The information provided by the authors does not clearly identify these variables and does not allow confirming that testing was performed under radiofrequency “worst-case” conditions.

The authors state that translational attraction is proportional to the static magnetic field strength. Although this statement is true for saturated ferromagnetic materials, for

paramagnetic materials the translational attractive force is proportional to the force product (i.e., the product of the magnitudes of the static magnetic field spatial gradient and the static magnetic field strength). Because most metallic implants are paramagnetic, it is the force product, not the magnitude of the static magnetic field, that needs to be considered for determining the mechanical safety in a given MRI environment. The authors measured the spatial gradient of the static magnetic field, but this may be insufficient to show safety.

Additionally, the x and y coordinates of the location of displacement force testing are unclear (i.e., were measurements made at the point of the highest patient-accessible spatial gradient or along the z -axis as a function of distance from the magnet isocenter?). We look forward to receiving further clarification from the authors about the issues raised.

References

1. Dula AN, Virostko J, Shellock FG. Assessment of MRI issues at 7 T for 28 implants and other objects. *AJR*. 2014; 202:401–405. [PubMed: 24450683]
2. Chou CK, Bassen H, Osepchuk J, et al. Radio frequency electromagnetic exposure: tutorial review on experimental dosimetry. *Bioelectromagnetics*. 1996; 17:195–208. [PubMed: 8809359]
3. Mattei E, Triventi M, Calcagnini G, et al. Temperature and SAR measurement errors in the evaluation of metallic linear structures heating during MRI using fluoroptic probes. *Phys Med Biol*. 2007; 52:1633–1646. [PubMed: 17327653]