Regarding the Value Reported for the Term "Spatial Gradient Magnetic Field" and How This Information Is Applied to Labeling of Medical Implants and Devices

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Differences in interpretations of testing and reporting criteria, techniques, and perhaps even concerns about manufacturer legal liability have created a contemporary environment in which questions and confusion abound in the MRI industry. Of particular concern regarding the management of patients with implants and devices in the MRI environment are the disparities in the ways that the spatial gradient magnetic field information is presented.

The intensity of the static magnetic field around an MR system varies with respect to the distance from the scanner. This so-called "fringe field" of the MR system creates a "spatial gradient magnetic field." By definition, the spatial gradient magnetic field is a magnetic field that varies in intensity over distance. The spatial gradient magnetic field should not be confused with the time-varying gradient magnetic fields produced by the gradient coils that are used during the imaging process for spatial encoding of the MRI signals.

The spatial gradient of the magnetic field produces an attractive displacement (or translational) force on ferromagnetic objects placed into the static magnetic field of the MR system [1–4]. Importantly, the MRI-specific labeling that is used for medical implants and devices typically provides information for the "highest spatial gradient magnetic field" at which the medical device was tested and that is the what the device manufacturer indicates in the labeling as the maximum field strength allowed for the object's exposure, to ensure the safety of the patient relative to the device's translational attraction [1–6]. The assessment of translational attraction (or displacement force) is just one aspect of implant testing that is performed when evaluating a medical device [1–5].

In most cases, the Food and Drug Administration (FDA) accepts the determination of translational attraction for a medical device that is conducted according to the procedure described by the American Society for Testing and Materials (ASTM) International Designation F 2052–06e1, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the MR Environment." Using this technique, a test apparatus with a protractor (also called the fixture) is placed in an MR system with a horizontal magnetic field at the point of the highest accessible spatial gradient magnetic field [6]. In general, the highest spatial gradient magnetic field used to assess translational attraction for a medical device is located off-axis, at a side wall, and near the opening of the bore of the scanner [1, 3]. Alternatively, the medical device is assessed for translational attraction at the point where the highest deflection angle occurs in association with the particular MR system used for the assessment. The angular deflection of the device from the vertical is measured and the translational attraction is calculated [6].

Notably, the placement of the test fixture (apparatus with the protractor) in the MR system is at a position where it can be used properly (i.e., securely positioned) for the test procedure. This is almost always a worst-case position of greatest attractive force that the patient with the device will pass through when entering the bore of the MR system for an examination.

For example, Figure 1 shows the measurement of translational attraction using the deflection angle test as it was applied to evaluate an endoscope adapter. Note the positioning of the test fixture (the apparatus with the protractor). It was placed off-axis near the mouth of the bore of the scanner at the point of the highest accessible spatial gradient magnetic field (i.e., 720 gauss/cm for the 3-T MR system used for this test). The deflection angle was 36° for the endoscope adapter.

With regard to the translational attraction measurement for a medical device, if the deflection angle is less than 45° and the magnetic force is in the horizontal direction, the deflection force is less than the gravitational force associated with the device's weight and it is assumed that any risk imposed by the application of the magnetically induced deflection force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field [4, 6]. However, even if a device exceeds 45° of deflection, it may still be acceptable for a patient undergoing an MRI examination if sufficient counterforces are present (e.g., from sutures, scarring, tissue ingrowth, etc.) that prevent it from being moved or dislodged [3].

There is confusion about the term "spatial gradient magnetic field" (or "highest spatial gradient" or "magnetic spatial gradient") and how this parameter is reported for a given MR system relative to this term's use in the labeling of a medical device. Note: The term "spatial gradient magnetic field" may also be misunderstood because some MRI professionals see the term "gradient" and presume that it refers to the time-varying or gradient magnetic fields (dB/dt) used for spatial location in association with MRI [2]. The term "spatial gradient magnetic field" refers to the rate at which the static magnetic field strength changes over space or distance per unit of length. This parameter is indicated as dB/dx, using the units of T/m or gauss/cm.

According to the example shown in Figure 1, the highest accessible spatial gradient magnetic field of 720 gauss/cm was determined using highly involved methodology for the 3-T MR system used for the test procedure. Researchers and MRI professionals, however, must typically rely on the magnitude and location of the spatial gradient magnetic field provided by the MR system manufacturer. To test the device in this example, the apparatus with the protractor was placed at that position (720 gauss/cm) to measure the deflection angle. This information (i.e., the value for the highest spatial gradient magnetic field) is reported in the labeling for the device. Thus, the MRI-specific labeling would then state that the acceptable static magnetic field information for this endoscope adapter is, as follows [2]: 3-T or less; highest spatial gradient magnetic field, 720 gauss/cm or less.

Notably, to date, the FDA has approved MRI-specific labeling for more than 3,000 medical devices according to the previously described process, especially with regard to how the displacement force is determined (i.e., by following the procedure described in the ASTM document [6]) and with respect to how the findings are presented in the labeling (i.e., reporting the value for the highest spatial gradient magnetic field that was used for the determination of the deflection angle for the medical device, which was based on where the apparatus with the protractor was positioned). Furthermore, the ASTM document [6] that addresses the measurement of translational attraction for a medical device clearly calls for reporting "10.1.7….the magnitude of the spatial gradient of the magnetic field at the test location." That is why this particular spatial gradient magnetic field value has been used in the FDA-approved MRI labeling for thousands of medical devices. Of note is that the reported results describe the MR system variables under which the implant or device was tested and do not necessarily represent the safety threshold for translational forces.

Recently, MR system manufacturers have provided data to MRI professionals pertaining to the spatial gradient magnetic field values for a given scanner, including information for the highest spatial gradient magnetic field. Presumably, this was done in an effort to help address the case when a patient presents with a medical device that has labeling stating the highest spatial gradient magnetic field value permitted for that implant and that parameter is unknown for a specific MR system. The format, values, locations for measurement, and presentation of these reported MR system values have varied and even conflicted between and within the MR system vendors that have provided these data.

Considerable confusion has inadvertently arisen as a result of these recently reported spatial gradient magnetic field values. The reason for this misunderstanding is simple: The location, and therefore the values, of the highest spatial gradient magnetic field measured and reported by the MR system manufacturers is sometimes not the same as that which is used for the location at which the implant or device displacement force testing was performed. To elaborate, the location of measurement of the highest spatial gradient magnetic field that is used when evaluating the displacement force for a medical implant or device (i.e., the place in the MR system where the apparatus with the protractor is positioned, which is generally off-axis near the opening of the bore of the scanner) is not necessarily the same as the location where the MR system manufacturer measures the scanner's highest spatial gradient magnetic field.

The MR system manufacturer may have performed the measurement with the covers or shroud removed from the MR system or without the patient table present. This permits access to stronger static magnetic fields and spatial gradient magnetic fields and thus can result in a greater measured value for the highest spatial gradient magnetic field as reported by the manufacturer. This region, and therefore the measured value, however, is not one that can be reached by a patient with an implant and thus it does not represent a reasonable assessment of risk exposure for that situation.

Figure 2 illustrates this situation by showing the typical location of the accessible highest spatial gradient magnetic field that is used for placement of the apparatus with

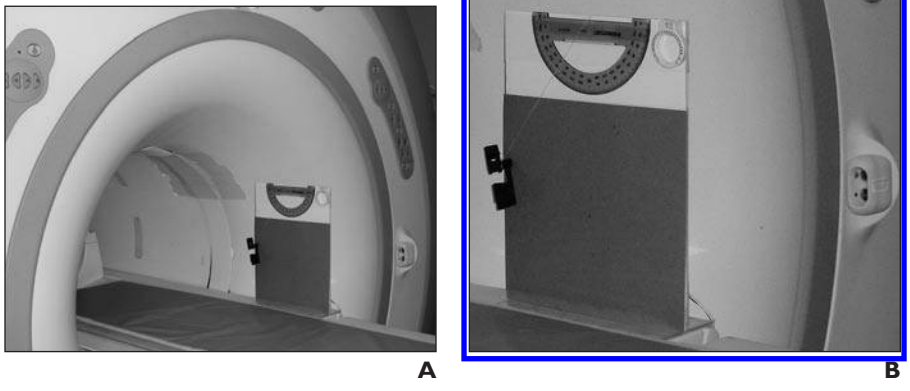

Fig. 1—Deflection angle measurement.
A and **B**, Photographs of standard view (**A**) and close-up view (**B**) show deflection angle of 36° was measured for this endoscope adapter. Positioning of apparatus with protractor was off-axis, near mouth of bore of scanner at accessible point of highest spatial gradient magnetic field (720 gauss/cm) for 3-T MR system that was used for determination of translational attraction.

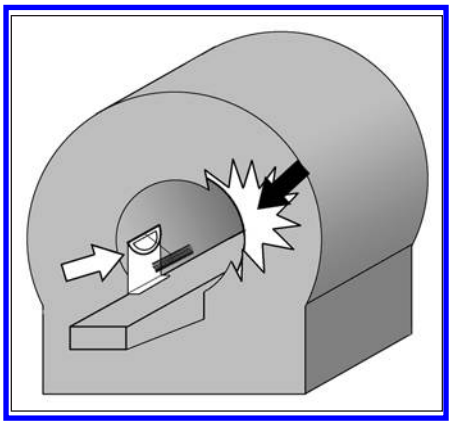

Fig. 2—Drawing shows position for test apparatus. White arrow shows position for test apparatus with protractor used to measure deflection angle for medical implant or device according to ASTM F 2052 [6]. Thus, deflection angle is measured at point of highest spatial gradient magnetic field within patient-accessible volume, and this particular value is provided in test report and presented in MRI labeling for device. This value for highest spatial gradient magnetic field has relevance for patient with medical device insofar as he or she may pass through this area when entering MR system. By comparison, highest spatial gradient magnetic field value reported by MR system manufacturer for given scanner may be made much closer to magnet (*black arrow*) of MR system. Therefore, value is higher than that reported by implant tester performing deflection angle test. Note that position shown by black arrow is not accessible to implant tester nor is it suitable place to position test apparatus with protractor. Furthermore, it is not accessible to patient. Therefore, value for highest spatial gradient at that position does not have relevance for patient with medical device.

the protractor when performing the deflection angle test on a medical implant or device in an MR system. Thus, the deflection angle is measured at the point of the highest spatial gradient magnetic field (i.e., relative to where the test fixture was placed), and this particular value is provided in the test report and presented in the MRI labeling for the device. Importantly, this value for the accessible highest spatial gradient magnetic field has relevance for the patient with the medical device insofar as he or she passes through this area when entering the MR system for the MRI procedure.

By comparison, the highest scanner spatial magnetic gradient value reported by an MR system manufacturer may be measured much closer to the magnet (Fig. 2) of the MR system (and, therefore, the value is higher than the one reported by an implant tester measuring the deflection angle), typically because the covers or shroud was removed from the scanner and the patient table was not present. This particular position of the highest spatial gradient magnetic field for the scanner is not accessible to the implant tester, but far more important, it is not accessible to a patient with an implant. Thus, even if a higher spatial gradient magnetic field value could be measured at some other location, if that region is not accessible to a patient with an implant, that location (or the spatial gradient magnetic field value reported thereof) is not of clinical concern.

We recognize that the values reported for the regions not normally accessible to patients may have significance or relevance for MR system manufacturers and their manufacturing and service employees. Nevertheless, from the point of view of clinical patient care, these patient-inaccessible regions and the spatial gradient magnetic field values reported for them are of no particular benefit. Indeed, reporting these values seems to have resulted in confusion. Furthermore, making decisions regarding the patients with implants or devices on the basis of these higher spatial gradient magnetic field values measured in patient-inaccessible regions might inadvertently lead to canceling requested and needed clinical MRI examinations for patients with devices tested and cleared to the patient-accessible region's translational forces—but not to those higher values reported at patient-inaccessible regions.

To illustrate the issues related to this disparity, the 3-T MR system shown in Figure 1 has a maximum spatial gradient magnetic field value of 720 gauss/cm at the patient-accessible volume, which is the location at which testing is performed to assess translational attraction for an implant or device. The MR system manufacturer reports the scanner's maximum spatial gradient magnetic field (measured behind the covers outside of the patient-accessible volume) for that same MR system as 910 gauss/cm. Clinical personnel responsible for assessing the labeling that states the MR conditional aspects of an implant or device rated as acceptable to a value of 720 gauss/cm when their MR system is identified as having a maximum value nearly 200 gauss/cm higher, may refuse to scan the patient with the implant on that MR system, which, ironically, is equivalent to the scanner used to show safety relative to translational attraction for the implant.

Although the value for the highest spatial gradient magnetic field that the MR system manufacturer reports for a given scanner does not have direct relevance to a patient with a medical device, if the MR system manufacturer provides measurements that are obtained in radial increments from that position, these values may be useful for managing patients with medical implants and devices if the position used to perform the deflection angle test on the device was known.

In consideration of the discrepancy between the MR system manufacturer's reported value for the highest spatial gradient magnetic field for a given scanner and the highest accessible spatial magnetic gradient value used for medical device testing that has led to confusion and frustration when MRI professionals must consider how to manage patients presented with MRI labeling information, we strongly recommend that standardization is necessary. Notably, it would be helpful and appropriate for all MR system manufacturers to report the greatest static magnetic field strength as well as the highest spatial gradient magnetic field values in regions that are readily accessible by patients and health care professionals working around an intact (i.e., with the covers or shroud not removed) MR system.

To accomplish such a task, the FDA needs to understand the nature of the present problems related to the MRI-specific labeling for implants and devices, develop an appropriate strategy to address this matter, and implement a solution in a timely manner.

Clinical Implications

For today, a recognition that the spatial gradient magnetic field values provided by the MR system manufacturers may differ (i.e., typically the values are higher) from those at which the implant might have undergone testing for translational attraction is the first step toward understanding the important issues presented in this article. Hopefully, this information will enable an appropriate determination of the risk–benefit ratio for the management of patients with implants.

If the deflection angle information for the implant can be obtained from the device manufacturer and the deflection angle value was somewhat trivial (e.g., 15° or lower) for the specific MR system to be used for the examination, it would be reasonable to expect

that a minor variation in the highest spatial gradient magnetic field value reported by the MR system manufacturer (i.e., compared with that reported in the labeling for the device) would not produce a clinically significant difference in the safety outcome. Of course, an entirely different conclusion might be reached if the translational attraction testing documented a significant deflection angle for the implant.

Conclusions

There are two different positions where the highest spatial gradient magnetic field may be measured and reported. One is the highest patient accessible spatial gradient magnetic field, which pertains to that used for the deflection angle test for a medical implant or device and through which a patient with an implant or device may pass. The other, the scanner's highest spatial gradient magnetic field as reported in the specifications for the magnet of a given scanner, reports the region of greatest dB/dx regardless of its accessibility to patients or health care providers. The values measured by the MR system manufacturers are inherently higher than those reported and used in the labeling of medical devices, are of dubious clinical value, and should be replaced or at the very least supplemented with the greatest dB/dx values reachable or accessible by patients and health care professionals.

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