Clarification of MR interactions in practice for implants and devices used in MRI - Rules of thumb (OR when to expect less MR interaction)

Susanne Matthey[1], RT(R)(MR), Janice M. Gardner[2,3], RT(R)(MR), Gregor Schaefers, Dipl.-Ing. (FH)[1]

[1]MR:comp GmbH, Geisenkirchen, Germany, info@mrcomp.com, www.mrcomp.com;

[2]NORTHEAST WISCONSIN MRI, www.newmri.com, [3]MagResource LLC, Green Bay, WI, USA, www.magresource.com/ www.magrecource.eu

Background

MR interactions, which have been identified in the past years of standardization and guidance documents ([1],[2]), show that there is a certain complexity in order to clarify hazards exhibited, if a device or item enters into the MR environment. The complexity of clarification is simpler with interactions caused by the static magnetic field (B_0 [T]; 0 Hz frequency), but it increases significantly with the increasing number of different parameters describing the switched gradient magnetic field (dB/dt [T/s]; kHz frequency) and the electromagnetic radio frequency (RF) field (B_1 [µT]; MHz frequency).

For MR users it is, therefore, difficult to assess whether it is safe or conditionally safe to scan patients with medical devices. It is especially difficult to assess multi-parameter dependent interactions if the MR user in charge does not have a professional background in physics or electromagnetics.

Teaching Point

In all MR systems Instruction For Use (IFU) using implants, instruments and other devices made of (metallic) magnetic material or electrically conductive materials (not part of the MR system or accepted MR accessories) is basically contraindicated, e.g. implants and other devices inside or at patients and MR users during MRI. For daily routine and maintaining a high-performance workflow, however, clarification of MR safety and compatibility is mandatory in a reliable and timely manner. The first choice for professionally performing the clarification of implants and other devices for use in the MR environment is reading the MR labeling provided by the medical device (e.g. implant) manufacturer. This MR labeling defined as "MR Safe" or "MR Conditional" according to ASTM F2503 is accepted in the 3rd edition of IEC 60601-2-33:2010 [3] to overcome the contraindication for MR scanning of implants and devices. However, with this MR labeling still certain difficulties remain as not all labeling is complete and comprehensive according to the up-to-date technical status of ASTM F2503 and the FDA guidance "Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment". Also, there is an ongoing improvement of these documents, so that MR labeling information will become more detailed and comprehensive in future. In addition, there will be modifications of the MR user interface at the MR system, providing additional information and settings to assess whether safe MR scanning is possible. Note also, that from acceptability standpoint only MR systems Instructions For Use upgraded to the 3rd edition of IEC 60601-2-33:2010 include the mentioned option for overcoming the contraindication. In cases of doubt, this should be clarified together with the MR system manufacturer.

In order to provide the MR user with additional information about dimensions and directions of possible interactions with MR, a rule of thumb system is provided here to assist basically if clarifying (risk assessment) issues using MR labeling information. This system of rules cannot replace the official MR labeling provided by a device manufacturer. It should only be used as background in addition to the original MR labeling information. Using the rule of thumb system given below without referring to existing MR labeling would constitute an off-label use of the MR system.

The following MR interactions are discussed:

1. a) Displacement force, magnetically-induced (static)
   b) Force, magnetically-induced (dynamic)
2. a) Torque, magnetically-induced (static)
   b) Torque, magnetically-induced (dynamic)
3. a) Voltages, gradient-induced
   b) Voltages, radio frequency-(RF)-induced
4. a) Heating, gradient-induced
   b) Heating, RF-induced
5. Vibration, gradient-induced, in relation with static field
6. Malfunction, static field, gradient and RF-induced
7. Artifacts, device related; susceptibility, RF-induced, plastics containing protons

Typical ferromagnetic materials are iron (steel), cobalt and nickel. These materials can be found as alloys in several implants and medical equipment. Not all have to be strong magnetic, e.g. Nitinol (nickel-titanium alloy). Whenever details about ferromagnetic materials can be identified, it is urgently needed to get more information and be very careful.

1. a) Displacement force (static)

Displacement force (static) is expected to be lower, if

- materials are
  - non-magnetic (e.g. wood, glass, ceramic, plastics (e.g. often listed with medical devices: glass fiber, silicone, polyether ether ketone (PEEK), polytetrafluoroethylene (PTFE: e.g. Teflon), high-molecular-weight (HMW) polyethylene (PE), polyurethane (PUR, PU), polypropylene (PP), polysulfone, polyester: polyethylene terephthalate (PET: e.g. Dacron), pyrolitic carbon, Polyoxymethylene (POM: e.g. Delrin), etc.),
  - low magnetic quality (titanium, Nitinol, platinum, tantalum, niobium, etc.) and
  - low ferromagnetic quality (high-alloy surgical steel, 316L, CrCoMo, Inconel, MP35N, Elgiloy, Phynox, etc.)

  Note: the range of ferromagnetism is large!
- MR magnets have
  - smaller static magnetic field B_0 (magnetic saturation) e.g. 1.5 T instead of 3 T
  - smaller static field gradients ∇B_0 of the fringe field, e.g. 8 T/m (800 Gauss/cm) instead of 15 T/m (1500 G/cm)

2. a) Torque (static) is expected to be lower, if

- materials are less magnetic (see 1. a))
- MR magnets have smaller static magnetic fields B_0 (see 1. a))
- geometric dimensions of the device are smaller, e.g. 1 cm instead of 10 cm
- devices are softer and more flexible, e.g. electrodes versus bone plates

1. b) Force (dynamic), and
2. b) Torque (dynamic) is expected to be lower, if

- the conductivity of the device's material is lower, e.g. plastics versus metals, but also amongst metals: e.g. titanium versus aluminum
- the effective area of induction is smaller, e.g. stent, clip versus hip joint e.g. needle versus surgical holding arm
- the speed of the movement is slower, e.g. slow patient table movement, walking in the static field versus fast handling of instruments or aluminum gas cylinders
- the magnitude of the static magnetic field is lower, e.g. 1.5 T instead of 3 T. The same applies to associated fringe fields

Dynamic forces and torques are possible for electrically conductive devices and structures, which are translated in the magnetic field.

3. a) Voltages, gradient-induced, which can lead to
4. a) Heating, gradient-induced, and
5. Vibration, gradient-induced in counteraction with the static magnetic field B_0

Switched gradient field interactions are most likely decreased, if

- electrically conductive devices (see RF paragraph)
  - are (if possible) kept out of the high dB/dt exposure area, e.g. the bore entrance and boundaries of the magnet bore, or if inside,
  - are short and have a small cross section
- dB/dt related sequence parameters, e.g.
  - gradient modes are adjusted to low output, ("whisper gradients")
  - the field of view (FoV) (in mm) is enlarged with constant or a lower matrix resolution (in pixel)

3. b) Voltage, RF-induced, which can lead to
4. b) Heating, RF induced

Radio frequency (RF) induced interactions are a complex and multi-parameter dependent issue. RF pulses have frequencies in the range of MHz and contribute substantially to heating power. Voltages induced lead to stimulation, activation of electronic circuits or malfunctions, either radiated or interactively rectified and induced into electronic circuits

RF interactions are most likely decreased, if

- electrically conductive devices (materials: e.g. aluminum, gold, carbon fiber, titanium, tantalum, platinum, tungsten, Nitinol, CrCoMo, stainless steel and alloys (316L, MP35N, L-605, Elgiloy), phynox, etc.)
  - are (if possible) kept out of the RF transmit coil, or if inside,
  - are oriented orthogonal to the electric (E)-field, e.g. for homogenous imaging area: orthogonally oriented to B_0 (parallel to E-field)

    Note: inhomogeneity of the E-field is likely close to the transmit coil and inside anatomical structures
  - are short relative to the half RF wavelength within the tissue
- SAR related sequence parameters, e.g.
  - TR is increased
  - Flip angles are decreased
  - B_1 and SAR modes are adjusted to low output
  - Number of RF pulses (Echo train length) is decreased
  - Distance of echo pulses (Echo spacing) is increased

6. Malfunction of the device within the MR environment is dependent on individual characteristics

Decreased interactions are most likely, if

- mechanical functions do use non- or low-magnetic components, e.g. springs, levers, metal spheres in valves
- electrically conductive devices
  - are kept out of the high dB/dt and RF exposure area
  - are short (relative to the half RF wavelength) and have a small cross section
  - are passive or non-electronic devices
  - do not use pressure sensors (interaction with acoustic noise likely)

7. Image artifacts generated by the presence of a device are dependent on a number of parameters. MR imaging of anatomy away from a device may still be possible even without image artifacts.

Placing low-magnetic (dia- or paramagnetic) or magnetic (ferromagnetic) materials in MRI, even if small ones only are used, those are distorting the homogeneity of the magnetic field and the cause of susceptibility artifacts.

Artifacts are most likely decreased, if

- the strength of the static magnetic field B_0 is lower e.g. 1.5 T instead of 3 T
- materials are
  - non- or low-magnetic; have a low magnetic susceptibility close to body tissue, e.g. gold instead of titanium instead of stainless steel (see 1.)
  - plastic materials are free from protons (possible generation of proton signal and backfolding into the MR image as signal spot) e.g. PEEK instead of PVC
- low-magnetic components are aligned with their long axis parallel to B_0 instead of orthogonal
- pulse sequences are chosen with low-artifact parameter:
  - spin echo based sequences instead of gradient echo based sequences
  - a short time of echo (TE)
  - a low flip angle or low strength of B_1
- electrically conductive devices (which will negatively influence the MR imaging conditions near the device, if the device contains conductive elements)
  - are kept out of the high dB/dt and RF exposure area
  - have a small cross section and are short (relative to the half RF wavelength)
  - have a low conductivity of the device's material, e.g. plastics versus metals, but also amongst metals: e.g. titanium versus gold

Summary

A compact rule of thumb system is shown, which should support the MR user basically, if clarifying and interpreting issues on MR conditional parameters using MR labeling information in clinical routine. The official MR labeling is important and necessary to consider provided by a (medical) device manufacturer or by an MR labeling database listing valid MR implant information, e.g. MagResource, The List, etc. Please note, that using the rule of thumb system given above without referring to the individual MR labeling or without considering the individual MR system Instruction For Use (e.g. older MR systems with IFU not upgraded to 3rd edition of IEC 60601-2-33:2010) would constitute an off-label use of the MR system.

References

1. Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2008
2. ASTM F2503-08, "Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment", 2008
3. IEC 60601-2-33:2010, "Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis", 3rd edition, 2010

Acknowledgement: We thank Dr. Harald Kugel (Clinical Radiology, University of Munster, Germany), Dr. Hans Engels (MR Safety Consultant, MR:comp, Netherlands) and Dr. Martin Muehlenweg (Radiology, University Clinic Halle, Germany) as well as Prof. Dr. Andreas Melzer (IMSaT, Dundee, UK and Chair of the German DGBMT Technical Committee 'MR Technique in Medicine' for commenting and reviewing this work.