MR Safety of Implants: How to Separate the Good from the Bad & the Ugly

Oliver Kraff, PhD

oliver.kraff@uni-due.de

Erwin L. Hahn Institute for MRI, University Duisburg-Essen, Essen, Germany

Since its introduction into clinical settings in the mid-1980s, magnetic resonance imaging has become an indispensable imaging modality for extensive clinical evaluation, diagnosis, and treatment control. Although MR examinations are generally considered safe with no known long-term effects when appropriate precautions are in place, imaging may be restricted or even denied to patients known to have implanted medical devices (IMDs). On the other hand, the aging population has led to increasing numbers of people with chronic conditions and also implants, which can either be passive IMDs (no powered electronic components present) or active IMDs (with powered electronic components).

The interactions between an IMD and the different fields of the MR system, which are the main static magnetic field, the gradient magnetic field operating in the kHz range, and the radiofrequency (RF) field, can pose various risks for the patient. Based on the information provided by vendors of the IMD as well as databases (http://www.mrisafety.com/, http://www.magresource.com/) or scientific publications, MR users have to judge if such a patient may be exposed to the MR system or not. In this regard, users have to separate the good (no risks expected) from the bad (e.g., risk-benefit analysis for medically indicated MR examination suggests imaging with high precautions) and the ugly (absolute contraindication). However, the categorization of an IMD or device in general with good, bad or ugly can also be seen with respect to the safety testing procedure rather than with the outcome of such an assessment. Some devices may need a lot of testing and even redesign, which can easily accumulate to several years of development until the device may be used within the MR environment; an example are pacemaker systems.

In 1997, the U.S. Food and Drug Administration requested that the American Society for Testing and Materials, now known as ASTM International, develop suitable test methods and guidance to address safety issues for IMDs and other devices in the MR environment. In addition, a joint working group between the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC) has published a new technical specification (TS) on testing active implants in 2012. The latter extends the test methods to various interactions of the MR system with active IMDs in particular, such as gradient-induced heating and vibration, and also addresses numerical simulations to assess RF heating in more detail, which are not included in the ASTM standards. However, methods described in the TS may also be more suitable for large passive IMDs than the methods described in the ASTM standards. An overview of the hazards, interactions with the MR system and recommended test methods is provided in Table 1. Ultimately, test methods and results

should be summarized according to standards ASTM F2503-13 and IEC 62570:2014, which then leads to labeling of the device as MR safe, MR conditional, or MR unsafe.

Potential hazard	Interactions between MR system and device	Test method
Force	B_0-induced displacement force	ASTM F2052-06
Torque	B_0-induced torque	ASTM F2213-06
Heat	RF-field-induced tissue heating	ASTM F2182-11a ISO TS 10974:2012
	Gradient-field-induced device heating	ISO TS 10974:2012
Vibration	Gradient-field-induced device vibration	ISO TS 10974:2012
Extrinsic electric potential	Gradient-field-induced lead voltage	ISO TS 10974:2012
Rectification	RF-field-induced rectified lead voltage	ISO TS 10974:2012
Malfunction	B_0-/RF-/Gradient-induced device malfunction	ISO TS 10974:2012
Image quality	Metal-induced image artifacts. Influences from eddy currents, RF noise, or other interferences to MR system components.	ASTM F2119-07 Defined by MR system manufacturer

Table 1: *Overview of potential hazards to the patient as a result from interactions between different fields of the MR system and (implanted) medical devices, and corresponding test methods.*

Please note that due to the enormous variability of implants and devices as well as MR systems (e.g. open vs. solenoid magnets, low vs. high field strength, single vs. multi-channel parallel transmission), standards should not be understood as written in stone mentioning all the details needed to perform a safety assessment for a given implant and exposure scenario. They are more guidelines that should always be critically questioned and, if needed, adapted accordingly. In particular at ultra-high field strengths (7 Tesla and above), implant safety is an emerging topic within the scientific community, as test methods need to be adapted to take the more complex coupling of the electromagnetic field with the human body and the implant at shorter wavelength as well as polarization effects into account.

In this presentation, an overview of the test methods will be given that help to separate the good (implanted) medical devices from the bad and the ugly ones. This may be of interest to those who design implants and devices, but also to those who have to perform screening interviews and interpret safety information from vendors, databases or other publications. In this regard, typical pitfalls will also be discussed.