Eberhard-Karls-Universität
UKT
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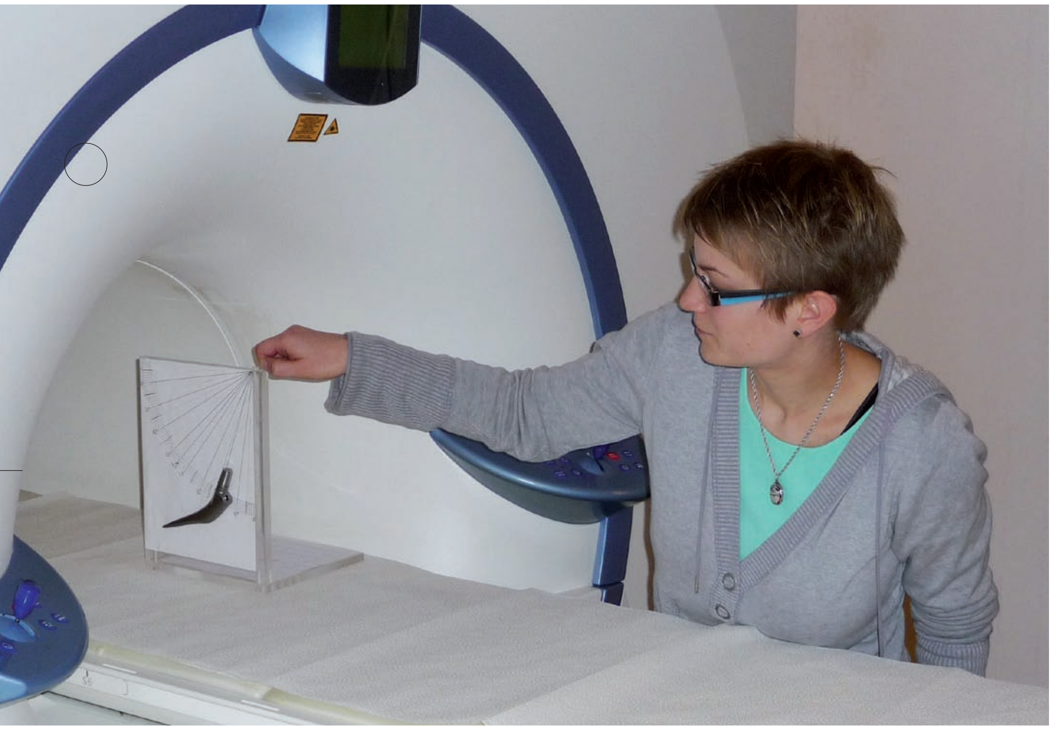
Diagnostic and Interventional Radiology

EXPERIMENTAL RADIOLOGY

MR-Compatibility: Testing of Medical Implants and Instruments and Manufacturer Support



Introduction

More and more patients which would benefit from an examination by magnetic resonance imaging (MRI) have implants. Examinations are only feasible if the implants together with the special physical environment in an MR device do not put the patient at risk of injury." Forces created by the magnetic field and heating arising from the application of radio frequency (RF) must not exceed given limits.

The same goes for instruments used during MR-guided interventions. There is an increasing tendency to use MR instead of X-ray techniques, as this avoids any exposure to ionising radiation for both the patient and the treating doctor.

We offer our expertise to manufacturers of medical products in order to assist in the development of MR-compatible devices as well as to test manufacturer's final products according to valid standards. Several MR scanners of different field strengths are available at our institute along with MR-compatible temperature measurement devices. The described field of activity was established in 2000 and a large variety of products has since been examined here.

Physical Background and Test Procedures

MR safety testing requires measurements according to four American standards (ASTM) related to deflection force, torque, RF-heating and image artifacts.

The tests for deflection force and torque are done in a straightforward way by measuring the forces acting on the devices in the fringe field and the homogenous magnetic field region of the scanner. The tests for RF heating and image artifacts are more sophisticated. Depiction of implants or microsurgical instruments in MR images depends in a complex way on numerous different parameters. Magnetic susceptibility of the material and its electrical conductivity are very important features. The orientation angle with respect to the static field also plays an important role. Solid materials with a magnetic susceptibility close to that of human tissue ($\chi \sim 10^{-5}$) have a negligible influence on the static field and are depicted as a geometry corresponding signal void. Objects made of typical implant materials (stainless steel, nitinol or phynox) show much higher susceptibility values. Depending on the imaging technique, artefacts can be enlarged by more than 10-fold the original size of the device.

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Key Results

If a device does not put the patient at risk at any field strength, it can be labelled "MR-safe"; if this is only the case for a restricted class of scanners they must be labelled "MR-conditional". The third label is "MR-unsafe" for devices which must not come in contact with MR-scanners.

A large number of implants and interventional instruments have already been examined:

- a large variety of stents for almost every application
- aneurysm clips of different sizes and materials
- vertebral column implants
- artificial hips
- invasive blood pressure devices
- hydrocephalus valves
- biopsy needles
- forceps.

Testing Protocols

Testing for displacement force is carried out according to ASTM F2052-06e1. The specimen is suspended on a filament. Maximal elongation of the pendulum in the fringe field of the scanner must not exceed 45°. Testing for magnetically induced torque is carried out according to ASTM F2213 – 06. The specimen must be mounted on a special magnetic field-compatible torque-weighing mechanism. The whole arrangement is brought into the homogenous field region of the scanner.

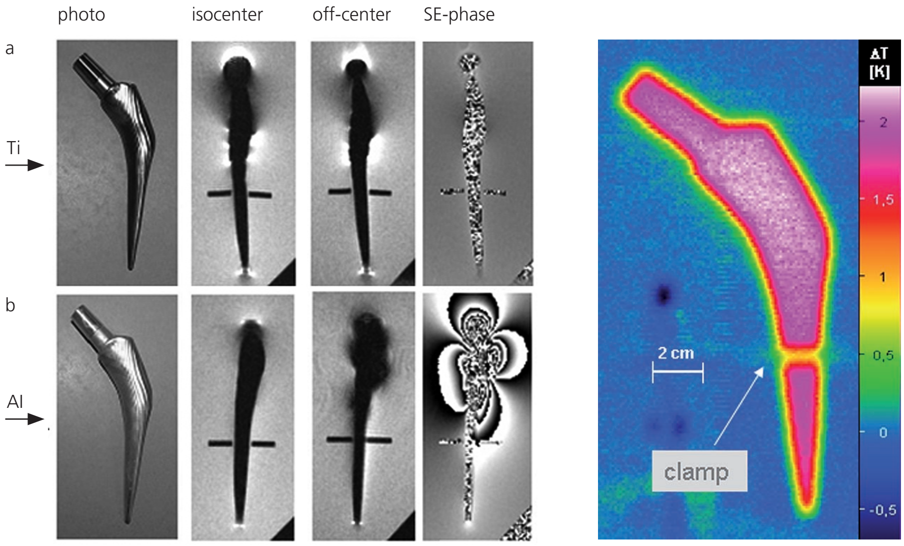
Testing for radio frequency-induced heating is described in ASTM F2182 – 09. This is usually the most elaborate test, since the specimen must be embedded in gelatin of specific electrical and thermal conductivity with MR-compatible temperature sensors placed at positions where heating seems probable. A scan protocol with high RF power must be applied.

The procedure for the testing of image artefacts is given in ASTM F2119 – 07. Special scan protocols are described and the size of the resulting artefacts must be documented.

Besides these official documents, the "MR Hazard Summary" (VA National Center for Patient Safety) also contains essential information.

Case study

Artificial hips are a typical and frequent implant nowadays. Apart from the mechanical properties we examined whether titanium could be replaced by aluminum in the sense of improved MR compatibility. The magnetic susceptibility of aluminum would appear to suggest that this is possible. However, our investigations showed that gradient switching induced image artifacts and heating discard this material as a candidate for artificial hips – due to its high electrical conductivity.



Comparison of MR image artifacts caused by a titanium artificial hip (Ti) and an aluminum replica (Al): Aluminum causes less susceptibility distortion at isocenter, but for off-center positioning its higher electrical conductivity together with gradient switching results in dephasing artifacts even in spin-echo imaging (SE-phase) and in heating (infrared image at right).

Publications

Graf H, Steidle G, Schick F. Heating of metallic implants and instruments induced by gradient switching in a 1.5Tesla whole-body unit. J Magn Reson Imaging 2007; 26: 1328 - 1333

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Klemm T, Duda S, Machann J, Seekamp-Rahn K, Schnieder L, Claussen CD, Schick F. MR imaging in the presence of vascular stents: A systematic assessment of artifacts for various stent orientations, sequence types, and field strengths. J Magn Reson Imaging 2000; 12: 606-615