Safety Evaluation of Large External Fixation Clamps and Frames in a Magnetic Resonance Environment

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Abstract: Large orthopedic external fixation clamps and related components were evaluated for force, torque, and heating response when subjected to the strong electromagnetic fields of magnetic-resonance (MR) imaging devices. Forces induced by a 3-Tesla (T) MR scanner were compiled for newly designed nonmagnetic clamps and older clamps that contained ferromagnetic components. Heating trials were performed in a 1.5 and in a 3 T MR scanner with two assembled external fixation frames. Forces of the newly designed clamps were more than a factor 2 lower as the gravitational force on the device whereas, magnetic forces on the older devices showed over 10 times the force induced by earth acceleration of gravity. No torque effects could be found for the newly designed clamps. Temperature measurements at the tips of Schanz screws in the 1.5 T MR scanner showed a rise of 0.7°C for a pelvic frame and of 2.1°C for a diamond knee bridge frame when normalized to a specific absorption rate (SAR) of 2 W/kg. The normalized temperature increases in the 3 T MR scanner were 0.9°C for the pelvic frame and 1.1°C for the knee bridge frame. Large external fixation frames assembled with the newly designed clamps (390 Series Clamps), carbon fiber reinforced rods, and implant quality 316L stainless steel Schanz screws met prevailing force and torque limits when tested in a 3-T field, and demonstrated temperature increase that met IEC-60601 guidelines for extremities. The influence of frame-induced eddy currents on the risk of peripheral nerve stimulation was not investigated. J Biomed Mater Res Part B: Appl Biomater 82B: 17–22, 2007

Keywords: fracture fixation; stainless steel; titanium (alloys); magnetic resonance; external fixation

INTRODUCTION

External fixation systems have been designed for management of fractures and lesions of the upper or lower extremities and pelvis. This fracture treatment concept may also be utilized to stabilize tibial osteotomies and to provide rigid support for knee or ankle joint arthrodeses. Open fractures, however, represent major trauma application for external fixators because of the ability to properly manage soft tissue damage. Infection and vascular complications can be minimized while providing adequate fracture stabilization.[1]

Magnetic resonance (MR) scans of patients with external fixation devices are not common but polytraumatized patients may be subjected to head, spinal, or other MR evaluations. Many of the metallic components of conventional external fixation devices are fabricated from feebly or highly magnetic materials.[2] Thus, MR scans of patients with external fixation devices cannot be performed because of the possibility that torque, force or heating may occur due to large magnetic coupling effects in the MR field.

Nonmagnetic external fixation metallic components were recently designed by a medical device manufacturer (Synthes (USA), Paoli, PA), and the components plus large frame assemblies were evaluated with respect to MR safety.

MATERIALS AND METHODS

External Fixation Clamps

Five new external fixation clamp components (Synthes (USA), Paoli, PA) were fabricated from nonmagnetic iron-base, cobalt base, and titanium base alloys that do not contain any secondary magnetic phases. Material information for the alloys used to fabricate the *390 series* clamps are shown in Table I. All clamps and components were marked with either a five-digit or a six-digit Synthes product number.

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TABLE I. Material Information for *Synthes External Fixation Devices – 390 Series Clamps*

Alloy	Implant Quality 316L Stainless Steel	Ti-6Al-4V	Elgiloy	MP35N
Type	Iron base	Titanium base	Cobalt base	Cobalt base
Specification	ASTM F 138	ASTM B 348	AMS 5876	AMS 5844
Microstructure	100% Austenite	$\alpha + \beta$	100% Austenite	100% Austenite
Magnetic classification	Nonmagnetic	Nonmagnetic	Nonmagnetic	Nonmagnetic
Magnetic attraction	Negligible	Negligible	Negligible	Negligible
Published magnetic permeability (μ)	1.00301	1.00005	1.0004	1.0009
Measured magnetic permeability (μ)	<1.01[a]	<1.01[a]	<1.01[a]	<1.01[a]
Supplier	Carpenter Technology	Perryman Co.	Elgiloy Limited Partnership	Carpenter Technology

[a] High sensitivity Lo-Mu permeability indicator measurement at Synthes Technical Center.

The clamps were identified as 6-position multipin clamp (390.002); rod attachment for multipin clamp (390.003); 4-position multipin clamp (390.004); large combination clamp (390.005); titanium tube-to-tube clamp (390.007); open adjustable clamp (390.008) and some examples are shown in Figure 1.

Additional external fixation components that were tested included carbon fiber reinforced epoxy (CFRE) rod (394.86); implant quality 316L stainless steel Schanz screw (294.55); and titanium Grade 4 Schanz screw (494.785).

Older clamps that contained feebly or moderately magnetic components were tested for comparison. Clamp identities were as follows: two adjustable clamps (393.64) (one made in Switzerland and a second one made in USA); open adjustable clamp (393.978); large combination clamp (393.647); universal clamp, 6-position (393.756).

MR Force, Acceleration, and Angular Displacement Measurements

MR testing was performed in a 3-Tesla (T) active shielded short bore whole body MR scanner (Intera 3 T Philips Medical Systems, Best, The Netherlands) according to ASTM F 2052.[3] From evaluations of force and torque effects on pacemakers it is known that the magnetic response in the 3 T system is about twice the response seen in a 1.5 T system from the same manufacturer.[4] In addition, an active shielded short bore magnet used in the present study provides higher force and torque effects than unshielded magnets of the same field strength.[5] The measurement methods are described in detail in different publications.[5–7] The mass of each component was weighed to the nearest 0.1 g and the mass values were rounded to the closest whole number. Deflection angle from the vertical was measured within $\pm 1^\circ$ for all components suspended with a thin string at the portal of the MR imaging unit. This location point represents the strongest field gradient along the z-axis through the isocenter. The coordinate system within the scanner consisted of the z-axis along the central axis of the cylindrical magnet and the x- and y-axis which were orthogonal to the z-axis in horizontal and vertical direction. The spatial change of the magnetic field at the place of measurement was 45 ± 5 mT/cm. The angular deflection (α) from the vertical direction was measured. The strength of the magnetic force vector was determined by the formula[6]:

$$F_M = F_G \tan \alpha = m_{clamp}\ g \tan \alpha$$

where m_{clamp}, mass of the clamp and g, acceleration of gravity. This formula is correct only if the magnetic force F_M is orthogonal to the gravitational force F_G. This is the case on the z-axis through the isocenter (central axis) due to the rotation symmetry of the superconducting magnet. Magnetic accelerations on the clamps can be calculated by dividing the magnetic force through the clamp mass.

A qualitative evaluation of torque effects was performed by turning the clamp and each of its parts at the isocenter of the magnet. The same rating as mentioned in the publication by Luechinger et al. was used.[7]

External Fixation Frames

Two different external fixation frames were constructed with newly designed nonmagnetic metallic clamps, CFRE rods, and implant quality 316L stainless steel Schanz screws. The frame assemblies evaluated in the present study were relatively large and contained a multitude of components to accentuate any possible radio frequency (RF)-induced heating effects. Figure 2 depicts the two external fixation frame assemblies that were evaluated in the MR heating study.

Figure 1. Examples of redesigned clamps evaluated in a 3-T active-shielded MR scanner. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

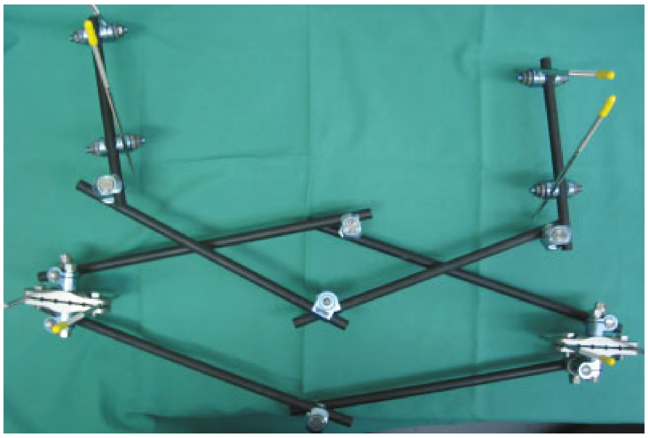

Figure 2. External fixation frames evaluated for MR heating. Upper frame, pelvic frame; lower frame, diamond knee-bridge frame. Plastic protective caps on tips were removed during measurements. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

The diamond knee bridge frame consisted of: two 6-position multipin clamps (390.002) + two rod attachments (390.003) + two large combination clamps (390.005) + four CFRE rods (394.86), 11.0 mm diameter and 350 mm long + four 316L stainless steel self-drilling Schanz screws (294.785), 5.0 mm diameter and 175 mm long.

The pelvic frame was assembled with two large combination clamps (390.005) + one titanium tube-to-tube clamp (390.007) + four open adjustable clamps (390.008) + two CFRE rods (394.83), 11.0 mm diameter and 200 mm long + two CFRE rods (394.85), 11.0 mm diameter and 300 mm long + four 316L stainless steel self-drilling Schanz screws (294.785), 5.0 mm diameter and 175 mm long.

Heating Measurements

The heating experiments followed the general guidelines established in ASTM F 2182[8] with slight modifications. Both frames were placed in a 80 × 25 cm^2 Plexiglas tank filled with 20 L of 0.45% saline solution. During a turbo-spin echo sequence (field of view, 400 mm; scan matrix, 256 × 205; echo time, 19 ms; repletion time, 300 ms; 8 slices; flip angle, 90°; turbo factor, 6; 32 number of signal averages, 1 or 2 dynamic, scan duration, 7–13 min; whole body specific absorption rate (SAR), 3.8 W/kg) the temperature changes were continuously measured by fiberoptic temperature probes (Luxtron, Santa Clara, CA). The accuracy of the fiberoptic thermometer was ±0.1°C with a temporal resolution of 0.25 s. The tips of the 316L stainless steel Schanz screws were placed in a round agar block doped with 0.45% salt. Two temperature sensors were placed next to the screw tips in the agar block and a third sensor was placed outside the agar block in the saline solution as a reference. The knee-bridge was placed about 15 cm in average out of the isocenter (in *x*-direction), because it is known that heating effects are higher at the border of the MR scanner.[9,10] The four screws were attached to the rods with clamps at locations normally used for large external fixation frames. The general arrangement for measuring the heating of the diamond knee-bridge frame is shown in Figure 3. The pelvic frame was placed in a nonphysiological orientation, along the *z*-axis instead of orthogonal placement due to tank size limitations. Placing the frame orthogonal and symmetrically to the *z*-axis reduced the heating effects due to the change in RF-field geometry.[10] The recorded temperature curves were averaged over 6 s and the difference between the highest and the lowest value was reported as the peak temperature increase.

RESULTS

Using the mass and the measured deflection angle, magnetic force and acceleration for the various components were calculated and summarized in Table II. The calculated maximum acceleration value obtained for the newer 390

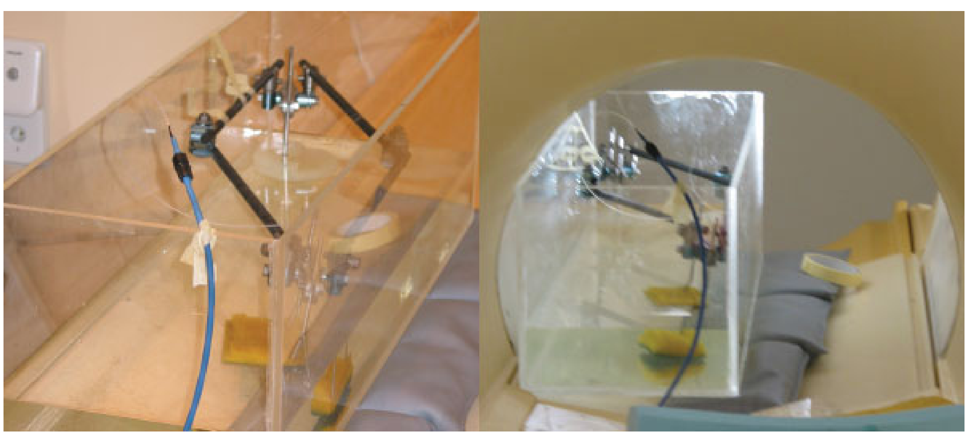

Figure 3. The diamond knee-bridge frame was placed in right–left direction asymmetrically in the scanner bore to induce maximum heating. The screws and temperature sensors were placed in a circular agar block to prevent convection. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

TABLE II. Forces Induced by the Main Magnetic Field of a 3 T MR Unit on Different Parts of External Fixation Frames[a]

Part	Nr.	Mass (g)	Force (N)	Accel. (N/kg)	Angle (°)
Redesigned clamps					
6-position multipin clamp	390.002	203	0.31	1.5	9
Rod attachment	390.003	79	0.27	3.4	19
4-position multipin clamp	390.004	165	0.33	2.0	12
Large combination clamp	390.005	49	0.04	0.9	5
Ti tube-to-tube clamp	390.007	49	0.02	0.3	2
Open adjustable clamp	390.008	39	0.01	0.3	2
CFRE rod	394.86	53	0.01	0.2	1
Stainless steel Schanz screw	294.55	23	0.06	2.6	15
Ti Schanz screw	494.785	14	0.004	0.3	2
Older clamps					
Adjustable clamp (Swiss)	393.64	50	>5.6	**>110**	**>85**
Adjustable clamp (USA)	393.64	50	0.53	**10.5**	**47**
Open adjustable clamp	393.978	64	>7.1	**>110**	**>85**
Large combination clamp	393.647	94	1.02	**10.9**	**48**
6-position universal clamp	393.756	275	1.82	6.6	34

[a] In the upper part the redesigned external fixation system. To visualize the improvement, the force effects on the same clamps from the older 393 series were added. Accelerations above 9.81 N/kg are not safe with respect to magnetic forces.[3] Such implants can be recognized with a simple hand magnet.

series clamps was about 35% of earth's gravitational acceleration of 9.81 N/kg, which is considered the safety limit for magnetic force induced by the high static magnetic field of the MR unit.[3] All of the older 393 series clamps, except for the 6-position universal clamp 393.756, exhibited acceleration values that exceeded the acceleration limit. Acceleration values of over 10 times the gravitational acceleration could be seen for two of the older clamps. The 393.64 adjustable clamp showed variable magnetic response depending on the manufacturing site. This was related to the specific type of stainless steel that used to fabricate the 393.64 clamp since the designs were identical.

No significant torque affects could be sensed when turning the newer 390 series clamps and the Schanz screws within the isocenter of the 3 T MR unit. The majority of the older 393 series clamps demonstrated very high torque effects, exceeding the safety limits.[11] The torque results were not quantified.

Temperature measurements in the 1.5 T scanner (scan duration, 13 min; SAR, 3.8 W/kg) showed highest temperature increases next to the screw tip of 4.1°C ± 0.2°C for the diamond knee-bridge frame and 2.1°C ± 0.2°C for the pelvic frame. In the 3 T scanner (scan duration 20 min, SAR 0.9 W/kg) temperature increases of 0.5°C ± 0.1°C for the diamond knee-bridge frame and 0.4°C ± 0.1°C for the pelvic frame could be measured. A plot of temperature *versus* MR scan time for the diamond knee-bridge frame at 1.5 T is shown in Figure 4. The temperature sensor placed at opposite position away from the frames showed a temperature increase of up to 0.5°C ± 0.1°C at 1.5 T (scan duration, 13 min; SAR, 3.8 W/kg) and up to 0.3°C ± 0.1°C at 3 T (scan duration, 20 min; SAR, 0.9 W/kg). Normaliz-

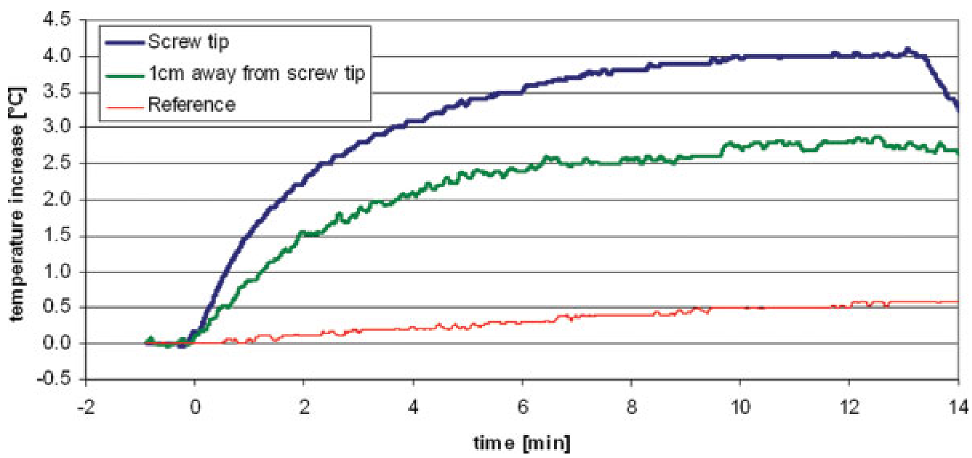

Figure 4. Time–temperature plot for the diamond knee-bridge frame in the 1.5 T MR scanner. Sensor 1 contacted one of the screw tips; Sensor 3 was placed 1 cm away from the screw; Sensor 2 was placed in a second agar block as a reference. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

ing the temperature to a SAR value of 2 W/kg, as recommended in ASTM F 2182,[8] reduced at 1.5 T the temperature rise to 2.1°C for the diamond knee-bridge frame and 0.7°C for the pelvic frame and increase the temperature for the measurements in the 3 T scanner to 1.1°C for the diamond knee-bridge frame and 0.9°C for the pelvic frame.

DISCUSSION

MR safe and MR conditional have been redefined in a recent editorial revision of ASTM F 2052-06e1.[3] The ASTM superscript epsilon (e) indicates an editorial change since the last revision or reapproval.

"MR safe: an item that poses no known hazards in all MR environments. MR Safe items include nonconducting, nonmagnetic items such as a plastic Petri dish."

"MR conditional—an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, d*b*/d*t* (time rate of change of the magnetic field), RF fields, and SAR. Additional conditions, including specific configurations of the item, may be required."

Acceleration values derived from force and mass measurements for the newly designed 390 series clamps and related external fixation devices in a 3 T MR environment were significantly less than earth's gravitational acceleration of 9.81 N/kg. The acceleration values were much smaller than the acceleration of gravity constant and there was negligible risk of magnetic attraction under the testing conditions reported in this study. Displacement angles for all components were within the maximum 45° angular displacement limit[2] established for medical devices. No torque effects could be observed qualitatively with any of the new clamps (part number starts with 390) and, therefore, no quantitative values have been measured according to ASTM F 2213 standardized method.[11]

The measurement of heating effects near implants induced by an RF field is not well established. Temperature measurements are very dependent on position, configuration, and type of phantom and type and positioning of temperature sensors used in the experiments. The standard test methods gave some guidelines for measurements; however, positioning and configuration of the frame are not described in detail, which may have a large influence on the results. The use of an agar block will lead to an overestimation of the heating effects compared to perfused tissue because perfusion in tissue provides additional cooling. For the normal operating mode of the body coil (SAR < 2 W/kg) the temperature increase was within the IEC 60601-2-33 limit of 3°C specified for extremities.[12] The external fixation frames typically are positioned outside of the body coil during the most common brain MR scanning. Limited or no heating is therefore expected when the diamond knee-bridge frame is outside the magnet during MR scans of the brain or thorax.[13] The pelvic frame showed reduced heating effects and it would even be lower if the frame was anatomically correct positioned. Since the whole body SAR was limited to 0.9 W/kg in the 3-T scanner to stay within the limits for local SAR, for the used system no additional limitations would be needed. However different SAR-model in future scanners but also scanners from other vendors may lead to increased heating, but even with an extrapolated whole body SAR of 4 W/kg (first level controlled operating mode), 3° would not be reached with the measured frames at 3 T. 3-T MR scanners have the well known disadvantage to send four times the RF-power into the body than a 1.5-T scanner for an identical MR sequence. However, this should not be used to argue that higher field strength will show higher heating around large implants, since on all MR scanners whole body SAR is limited to 4 W/kg (first level controlled operating mode). Therefore, the main difference will be the efficiency to concentrate the RF-field to the edges of the implant, which depends strongly on the different RF-field frequency. Because of antenna effects[14] peak heating will be seen at 3 T at a shorter length compared to 1.5 T.

The dimensions and position of the frame within the MR scanner has a major influence on the temperature increase. Placing the frame near the boarder of the bore, as done in evaluation should provide highest heating. Recent discussed effects of the RF-body coil of MR scanners from different manufacturer may have an additional influence on heating effects as shown by Baker et al.[15] In a worst-case situation the temperature rise near the tips of the Schanz screws may approach the IEC 60601-2-33 limit when the frames lay inside the body coil of a 1.5 T MR system. Therefore, the SAR level should be reduced below 2 W/kg under these circumstances to avoid any potential heating risk.

However, from the literature higher temperature increases without adverse effects have been reported. Bone necrosis resulting from thermal energy[16] has been reported with temperatures above 70°C, while tissue exposure to a temperature of 47°C for 1 min has been shown to cause bone resorption and eventual replacement.[17] Temperature excursions during medullary reaming procedures[18] indicated that tibial peak temperatures of 51.6°C were recorded during reaming. None of the 18 patients in the study experienced intraoperative or postoperative complications related to skin or bone thermal necrosis, and bone healing progressed in a normal manner. However, the short time/high temperature thermal excursions cited in the referenced studies may not be directly comparable to the lower temperature heating effects associated with MR scan times of 10–30 min.

In contrast to the paper of Davison et al.[2] we could see some heating effects. Because of the long well-conducting frames heating effects have to be expected. In the study from Davison et al., heating effects were not monitored during MR-scanning but shortly afterwards. The unknown position of the frame in the scanner and whether a water tank was used may be responsible for the differing results.

Additional eddy currents may be induced within the frame due to the low electrical resistance (−800 Ω) between any two screws. They can increase the possibility that peripheral nerve stimulation may occur. The influence of external fixation frames on the risk of peripheral nerve stimulation was not investigated in the present study.

CONCLUSION

Results indicated that all of the 390 series clamps, CFRE rods, and 316L stainless steel or titanium Schanz screws evaluated in the present study demonstrated no known hazards under the tested MR conditions. The force and torque effects have been tested in two clinical active shielded whole body MR system with field strengths of 1.5 T and 3 T. Magnetic field interactions for the 390 series clamps, CFRE rods, and 316L stainless steel or titanium Schanz screws were minor. Testing of assembled large external fixation frames indicated that RF heating within a 1.5 T or a 3 T MR unit was within the IEC 60601-2-33 temperature limits specified for extremities when normalized to a SAR of 2 W/kg (normal operating mode). The older external fixation clamps (393 series) containing ferromagnetic components should not be subjected to MR scans because of excessive force, acceleration, and angular displacement interactions within the MR environment.

Synthes (USA) provided the external fixation components and assembled frames that were evaluated in this study.

REFERENCES

1. Synthes (USA). The AO ASIF Large External Fixator Technique Guide. GP 1585. Paoli, PA: Synthes (USA); 2003.
2. Davison BL, Cantu RV, Woerkom SV. The magnetic attraction of lower extremity external fixators in an MRI suite. J Orthop Trauma 2004;18:24–27.
3. Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment. West Conshohocken, PA: ASTM; 2006. ASTM F 2052-06e1.
4. Luechinger R, Zeijlemaker V, Lamerichs R, Duru F, Candinas R, Boesiger P. Potential risk of magnetic resonance imaging at 3.0 Tesla on pacemakers. Pacing Clin Electrophysiol 2002; 25:546 (abstract).
5. Shellock FG, Tkach JA, Ruggieri PM, Masaryk TJ, Rasmussen PA. Aneurysm clips: Evaluation of magnetic field interactions and translational attraction by use of "long-bore" and "short-bore" 3.0-T MR imaging systems. AJNR Am J Neuroradiol 2003;24:463–471.
6. New PF, Rosen BR, Brady TJ, Buonanno FS, Kistler JP, Burt CT, Hinshaw WS, Newhouse HJ, Pohost GM, Taveras JM. Potential hazards and artifacts of ferromagnetic and nonferromagnetic surgical and dental materials and devices in nuclear magnetic resonance imaging. Radiology 1983;147:139–148.
7. Luechinger R, Duru F, Scheidegger MB, Boesiger P, Candinas R. Force and torque effects of a 1.5-Tesla MRI scanner on cardiac pacemakers and ICDs. Pacing Clin Electrophysiol 2001;24:199–205.
8. Standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging. West Conshohocken, PA: ASTM; 2002. ASTM F 2182.
9. Yeung CJ, Atalar E. A Green's function approach to local RF heating in interventional MRI. Med Phys 2001;28:826–832.
10. Luechinger R. Safety Aspects of Cardiac Pacemakers in Magnetic Resonance Imaging, Ph.D. Thesis. Switzerland: ETH Zurich; 2002. Available at http://e-collection.ethbib.ethz.ch/cgi-bin/show.pl?type=diss&nr=14655.
11. Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment. West Conshohocken, PA: ASTM; 2004. ASTM F 2213.
12. IEC. Medical Electrical Equipment, Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis; Geneva, Switzerland: International Electrotechnical Commission; 2002. IEC 60601-2-33.
13. Luechinger R, Zeijlemaker VA, Pedersen EM, Mortensen P, Falk E, Duru F, Candinas R, Boesiger P. In vivo heating of pacemaker leads during magnetic resonance imaging. Eur Heart J 2005;26:376–383.
14. Konings MK, Bartels LW, Smits HF, Bakker CJ. Heating around intravascular guidewires by resonating RF waves. J Magn Reson Imaging. 2000;12:79–85.
15. Baker KB, Tkach JA, Nyenhuis JA, Phillips M, Shellock FG, Gonzalez-Martinez J, Rezai AR. Evaluation of specific absorption rate as a dosimeter of MRI-related implant heating. J Magn Reson Imaging 2004;20:315–320.
16. Berman AT, Reid JS, Yanicko DR, Sih GC, Zimmerman MR. Thermally induced bone necrosis in rabbits. Relation to implant failure in humans. Clin Orthop 1984;284–292.
17. Eriksson AR, Albrektsson T. Temperature threshold levels for heat-induced bone tissue injury: A vital-microscopic study in the rabbit. J Prosthet Dent 1983;50:101–107.
18. Giannoudis PV, Snowden S, Matthews SJ, Smye SW, Smith RM. Temperature rise during reamed tibial nailing. Clin Orthop 2002;255–261.