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JOURNAL OF CARDIOVASCULAR MAGNETIC RESONANCE®
Vol. 5, No. 2, pp. 387–397, 2003

SAFETY

Cardiac Pacemakers, ICDs, and Loop Recorder: Evaluation of Translational Attraction Using Conventional ("Long-Bore") and "Short-Bore" 1.5- and 3.0-Tesla MR Systems

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ABSTRACT

Purpose. To evaluate magnet-related translational attraction for cardiac pacemakers, ICDs, and an insertable loop recorder in association with exposure to "long-bore" and "short-bore" 1.5- and 3.0-Tesla MR systems. *Materials and methods*. Fourteen cardiac pacemakers, four ICDs, and one insertable loop recorder were evaluated for translational attraction using deflection angle tests performed at the points of the highest spatial gradients for long-bore and short-bore 1.5- and 3.0-Tesla MR systems according to ASTM guidelines. *Results*. Deflection angles ranged from 9–90° for the long-bore and from 11–90° for the short-bore 1.5-T MR system. Deflection angles ranged from 23–90° for the long-bore and from 34–90° for the short-bore 3.0-T MR system. Three of the cardiovascular implants exhibited deflection angles $\geq 45°$ (i.e., indicating that they are potentially unsafe for patients) on the long-bore and short-bore 1.5-T MR systems. Eight implants exhibited deflection angles $\geq 45°$ on the long-bore 3.0-T MR system, while 14 exhibited deflection angles $\geq 45°$ on the short-bore 3.0-T MR system. In general, deflection angles for these cardiovascular implants were significantly ($p < 0.01$) higher on 1.5- and 3.0-Tesla short-bore compared to the long-bore MR systems. *Conclusions*. Several of the cardiovascular implants that underwent evaluation may be problematic for patients undergoing MR procedures using 1.5- and 3.0-T MR systems because of risks associated with magnet-related movements. Obviously, additional MR safety issues must also be considered for these implants.

Key Words: Magnetic resonance imaging; Safety; Implants; Cardiac pacemakers; ICDs.

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DOI: 10.1081/JCMR-120019424
1097-6647 (Print); 1532-429X (Online)

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INTRODUCTION

Clinical magnetic resonance (MR) procedures used for imaging, angiography, spectroscopy, and functional assessment are important diagnostic tools with increasing medical applications. Unfortunately, patients with implanted cardiac pacemakers, cardioverter defibrillators (ICDs), and similar electronic devices (e.g., an insertable loop recorder used for continuous electrocardiographic monitoring and arrhythmia detection) are generally restricted from the MR environment because of a variety of safety concerns (Achenbach et al., 1997; Duru et al., 2001; Erlebacher et al., 1986; Fetter et al., 1984; Gimbel, 2001; Hayes et al., 1987; Holmes et al., 1986; Lauck et al., 1995; Pavlicek et al., 1983; Shellock, 2001a,b; Shellock, 2003; Sommer et al., 2000; Vahlhaus et al., 2001).

Cardiac pacemakers, ICDs, and other similar electronic devices present potential problems to patients undergoing MR procedures from several mechanisms including: (1) movement of the device (e.g., the pulse generator and/or leads) due to the magnetic field of the MR system; (2) MR-related heating of leads by the time-varying magnetic fields; (3) inhibition or modification of the function of the device by the electromagnetic fields used for MR procedures; and (4) inappropriate or rapid pacing due to the pulsed gradient magnetic fields and/or pulsed radiofrequency (RF) fields (i.e., electromagnetic interference with the lead acting as an antenna) (Achenbach et al., 1997; Duru et al., 2001; Erlebacher et al., 1986; Fetter et al., 1984; Gimbel, 2001; Hayes et al., 1987; Holmes et al., 1986; Lauck et al., 1995; Pavlicek et al., 1983; Shellock, 2001a,b; Shellock, 2003; Sommer et al., 2000; Vahlhaus et al., 2001). These problems may result in serious injuries or lethal consequences for patients, as well as device malfunctions or damage (Gimbel, 2001; Shellock, 2001a,b; Shellock, 2003). Despite the recommendation to prevent performance of MR procedures in patients with electronic implants, there have been attempts to implement various strategies to enable patients with these devices, including cardiac pacemakers, to undergo MR imaging safely (Duru et al., 2001; Gimbel, 2001; Gimbel et al., 1996; Shellock, 2001b; Shellock, 2003; Shellock et al., 1999; Sommer et al., 2000; Vahlhaus et al., 2001).

One particular effect of the MR environment on cardiac pacemakers, ICDs, and similar devices is the magnet-related mechanical force associated with the static magnetic field of the MR system (Duru et al., 2001; Gimbel et al., 1996; Luechinger et al., 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 1999; Sommer et al., 2000; Vahlhaus et al., 2001). For example, some parts of pacemakers and ICDs, such as batteries, reed-switches (pacemakers), or transformer core materials [ICDs], may contain ferromagnetic materials (Gimbel et al., 1996; Luechinger et al., 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 1999). Therefore, substantial magnetic field interactions could occur during exposure to the MR environment, causing these implants to be displaced, moved, or uncomfortable for patients (Gimbel et al., 1996; Luechinger et al., 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 1999). In consideration of this possible scenario, as an important part of the evaluation of MR safety for pacemakers and ICDs, testing for magnetic field interactions has been conducted using MR systems operating at field strengths ranging from 0.2-Tesla (i.e., the dedicated-extremity MR system) to 1.5-Tesla (Duru et al., 2001; Gimbel et al., 1996; Luechinger et al., 2001; Shellock et al., 1999; Sommer et al., 2000; Vahlhaus et al., 2001). These investigations reported that modern-day pacemakers pose no serious safety risk with respect to magnetic field interactions at 1.5-Tesla or less, while most ICDs may be problematic due to substantial magnetic field interactions at 1.5-Tesla (Duru et al., 2001; Gimbel et al., 1996; Luechinger et al., 2001; Shellock et al., 1999; Sommer et al., 2000; Vahlhaus et al., 2001).

The clinical use of 3.0-Tesla MR systems for brain, musculoskeletal, and body applications is increasing worldwide. In fact, cardiovascular applications are emerging for clinical procedures for 3.0-Tesla MR systems. Because previous investigations performed to determine MR safety for pacemakers and ICDs used MR systems with static magnetic fields of 1.5-Tesla or less (Duru et al., 2001; Gimbel et al., 1996; Luechinger et al., 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 1999; Sommer et al., 2000; Vahlhaus et al., 2001), it is crucial to perform ex vivo testing at 3.0-Tesla to characterize magnetic field-related safety for these implants, with full acknowledgment that there may be other MR safety issues present for these devices, as described above.

An important aspect of evaluating metallic implants for magnetic field interactions involves the determination of translational attraction (Edwards et al., 2000; Luechinger et al., 2001; Shellock, 2001a,b,c; Shellock, 2003; Shellock and Crues, 1988; Shellock and Shellock, 1998; Shellock et al., 1999; Shellock et al., 2003), Translational attraction is assessed for metallic implants using the standardized deflection angle test recommended by the American Society for Testing and Materials (ASTM) (ASTM, 2002; Shellock, 2003). According to ASTM guidelines, the deflection angle for an implant should be measured at the point of the "highest spatial gradient" for the specific MR system

used for testing (ASTM, 2002). Notably, the deflection angle test is commonly performed as an integral part of MR safety testing of implants and devices (Edwards et al., 2000; Shellock, 2001c; Shellock and Crues, 1988; Shellock and Shellock, 1998; Shellock et al., 2003).

Various types of magnets exist for commercially available 1.5- and 3.0-Tesla MR systems, including magnet configurations that are used for conventional "long-bore" scanners and newer "short-bore" systems. Because of physical differences in the position and magnitude of the highest spatial gradient for different magnets, measurements of deflection angles using long-bore vs. short-bore MR systems can produce substantially different results for a given implant (Shellock et al., 2003). Therefore, in order to obtain initial MR safety information for various cardiovascular implants, the purpose of this investigation was to determine translational attraction for cardiac pacemakers, ICDs, and a loop insertable recorder in association with exposure to long-bore and short-bore 1.5- and 3.0-Tesla MR systems. To our knowledge, this is the first investigation of these cardiovascular implants in association with 3.0-Tesla MR systems.

MATERIALS AND METHODS

Fourteen cardiac pacemakers, four ICDs, and one insertable loop recorder were evaluated in this investigation. Each implant was representative of the manufactured "finished" version and was not altered in any manner prior to testing. These implants were selected for this study because they represent various types of older and newer cardiovascular implants from a variety of different manufacturers. Tables 1 and 2 list specific information for the devices that underwent testing (i.e., name, type or model, and manufacturer). Notably, none of these cardiovascular implants have been tested previously for magnetic field interactions at both 1.5- and 3.0-Tesla.

Rationale for Testing on Long-Bore and Short-Bore 1.5- and 3.0-T MR Systems

According to the American Society for Testing and Materials (ASTM, 2002), translational attraction should be assessed for implants at the point of the highest spatial gradient for the MR system used for testing. This is done to evaluate the magnet-related mechanical force at an extreme or worst case position for a metallic object. As previously stated, there are various types of magnets used for 1.5- and 3.0-Tesla MR systems, including "long-bore" and "short-bore" scanners utilized for head-only and whole-body clinical applications. Since there are physical differences in the position and magnitude of the highest spatial gradient for a given magnet (based on a review of technical specifications provided by MR system manufacturers), measurements of deflection angles for metallic implants may be substantially different, as has been recently reported by Shellock et al. (2003). Therefore, in this study, long-bore and short-bore 1.5-T and 3.0-T MR systems were used to evaluate translational attraction for the cardiovascular implants in consideration of the fact that there may be significant differences in the highest spatial gradients for long-bore vs. short-bore MR systems, resulting in substantially different deflection angle measurements (Shellock et al., 2003).

1.5-Tesla MR Systems

The 1.5-Tesla MR systems used in this investigation were, as follows: *long-bore, 1.5-Tesla MR system*-magnet length, 200 cm (MAGNETOM Vision, Siemens Medical Solutions, Erlangen, Germany); and *short-bore, 1.5-Tesla MR system*-magnet length, 160 cm (MAGNETOM Symphony, Siemens Medical Solutions, Erlangen, Germany).

In consideration of the in situ position for cardiac pacemakers, ICDs, and the insertable loop recorder that underwent evaluation, the highest spatial gradients were determined for the long-bore and short-bore MR systems with respect to the centers of the MR tables and the isocenters of the MR systems, similar to Luechinger et al. (2001). For the long-bore, 1.5-Tesla MR system, the highest spatial gradient occurs 110 cm from isocenter. The highest magnetic spatial gradient at this position is 1.8 Tesla/meter. For the short-bore, 1.5-Tesla MR system, the highest spatial gradient occurs 85 cm from isocenter. The magnetic spatial gradient at this position is 2.5 Tesla/meter. Each position was determined for each 1.5-Tesla MR system using gauss line plots provided by the manufacturer, measurements, and visual inspection to identify the location where the spatial magnetic field gradient was the highest. The locations of the highest spatial gradients were marked using tape.

3.0-Tesla MR Systems

The 3.0-Tesla MR systems used in this investigation were, as follows: *long-bore, 3.0-Tesla MR system*-magnet length, 248 cm (head-only, MR system; General Electric

Table 1. Cardiac pacemakers, ICDs, and insertable loop recorder assessed for translational attraction using conventional ("long-bore") and "short-bore" 1.5-Tesla MR systems.[a]

Description	LB, deflection angle (°)	SB, deflection angle (°)
Cosmos Model 283-01 Pacemaker Intermedics, Inc. Freeport, TX	64[a]	66[a]
Cosmos II Model 283-03 Pacemaker Intermedics, Inc. Freeport, TX	16	21
Cosmos II Model 284-05 Pacemaker Intermedics, Inc. Freeport, TX	16	21
Delta TRS Type DDD Model 0937 Pacemaker Cardiac Pacemakers, Inc. St. Paul, MN	20	23
GEM DR 7271 Dual chamber implantable Cardioverter defibrillator Model serial number PIM603937R Medtronic, Inc. Minneapolis, MN	27	27
GEM II DR 7273 Dual chamber implantable Cardioverter defibrillator Model serial number PK306405H Medtronic, Inc. Minneapolis, MN	30	32
KAPPA DR403 Dual chamber rate responsive Pacemaker Model serial number PET400897H Medtronic, Inc. Minneapolis, MN	15	19
KAPPA DR706 Dual chamber rate responsive Pacemaker Model serial number PGW101799H Medtronic, Inc. Minneapolis, MN	23	23
MARQUIS DR 7274 Implantable cardioverter defibrillator Model serial number PKC600093S Medtronic, Inc. Minneapolis, MN	41	42
MICRO JEWEL II 7223CX Implantable cardioverter defibrillator Model serial number PFR219645H Medtronic, Inc. Minneapolis, MN	35	37
Nova Model 281-01 Pacemaker Intermedics, Inc. Freeport, TX	63[a]	90[a]
Nova II Model 281-05 Pacemaker Intermedics, Inc. Freeport, TX	11	14
Nova II Model 282-04 Pacemaker Intermedics, Inc. Freeport, TX	9	11
Quantum Model 253-19 Pacemaker Intermedics, Inc. Freeport, TX	30	32
Relay Model 294-03 Pacemaker Intermedics, Inc. Freeport, TX	15	17
Res-Q ACE Model 101-01 Pacemaker	90[a]	90[a]

(*continued*)

Table 1. Continued.

Description	LB, deflection angle (°)	SB, deflection angle (°)
Intermedics, Inc. Freeport, TX		
Reveal 9525 Insertable loop recorder Model serial number AAA008038M Medtronic, Inc. Minneapolis, MN	25	33
SIGMA SDR306 Dual chamber rate responsive Pacemaker Model serial number PJE101076H Medtronic, Inc. Minneapolis, MN	22	26
THERA VDD 8968I Dual chamber atrial sensing, Ventricular sensing/pacing pacemaker Model serial number PEC400621H Medtronic, Inc. Minneapolis, MN	16	19

LB, long-bore; SB, short-bore.

[a] Exceeds the ASTM safety guideline for deflection angle. The ASTM guideline for deflection angle testing of implants and devices in the MR environment states that, "if the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight)" (ASTM, 2002). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the earth's gravitational field (ASTM, 2002).

Medical Systems, Milwaukee, WI); *short-bore, 3.0-Tesla MR system*-magnet length, 125 cm, (head-only MR system; MAGNETOM Allegra 3-T Headscanner, Siemens Medical Solutions, Erlangen, Germany) (Shellock et al., 2003).

Again, in consideration of the in situ position for the cardiac pacemakers, ICDs, and the insertable loop recorder that underwent evaluation, the highest spatial gradients were determined for the long-bore and short-bore MR systems with respect to the centers of the MR tables and the isocenters of the MR systems (Shellock et al., 2003). For the long-bore, 3.0-Tesla MR system, the highest spatial gradient occurs 96 cm from isocenter. The highest magnetic spatial gradient at this position is 3.3 Tesla/meter. For the short-bore, 3.0-Tesla MR system, the highest spatial gradient occurs 78 cm from isocenter. The magnetic spatial gradient at this position is 5.25 Tesla/meter. Each position was determined for each 3.0-Tesla MR system using gauss line plots provided by the manufacturer, measurements, and visual inspection to identify the location where the spatial magnetic field gradient was the highest. The locations of the highest spatial gradients were marked using tape (Shellock et al., 2003).

Assessment of Translational Attraction

Translational attraction was assessed for the cardiac pacemakers, ICDs, and the loop recorder using a standardized procedure known as the deflection angle test, according to guidelines provided by the ASTM (ASTM, 2002). The device was attached to a special test fixture to measure deflection angles in the long-bore and short-bore 1.5- and 3.0-Tesla MR systems at the points of the highest spatial gradients (ASTM, 2002; Shellock et al., 2003). The test fixture consists of a sturdy structure capable of holding the test object in a proper position without movement of the test fixture. The test fixture has a plastic protractor (1° graduated markings) rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically. A plastic bubble level was permanently affixed to the top of the test fixture to ensure proper orientation in the MR system during the deflection angle measurements.

The test object was suspended from a thin, light-weight string (weight, less than 1% of the weight of the implant) that was attached at the 0° indicator position on the protractor. The length of the string was 20 cm, allowing the test object to be suspended from the test fixture and hang freely in space. Sources of forced air movement within the respective 1.5- and 3.0-Tesla MR system bores were shut off during the deflection angle measurements.

As previously-indicated, measurements of deflection angles for the cardiovascular implants were obtained at the positions in the 1.5- and 3.0-T MR systems that produced the greatest magnetically induced deflections relative to the center of the MR system tables and isocenters of the MR system (i.e., the points of the highest spatial gradients) (ASTM, 2002; Shellock et al., 2003).

Thus, the test fixture was placed at the point of the highest spatial gradient for each long-bore and short-bore 1.5 and 3.0-T MR system, respectively. Each test object was held on the test fixture so that the string was vertical

Table 2. Cardiac pacemakers, ICDs, and insertable loop recorder assessed for translational attraction using conventional ("long-bore") and "short-bore" 3.0-Tesla MR systems.[a]

Description	LB, deflection angle (°)	SB, deflection angle (°)
Cosmos Model 283-01 Pacemaker Intermedics, Inc. Freeport, TX	90[a]	90[a]
Cosmos II Model 283-03 Pacemaker Intermedics, Inc. Freeport, TX	33	42
Cosmos II Model 284-05 Pacemaker Intermedics, Inc. Freeport, TX	35	47[a]
Delta TRS Type DDD Model 0937 Pacemaker Cardiac pacemakers, Inc. St. Paul, MN	42	55[a]
GEM DR 7271 Dual chamber implantable Cardioverter defibrillator Model serial number PIM603937R Medtronic, Inc. Minneapolis, MN	44	90[a]
GEM II DR 7273 Dual chamber implantable Cardioverter defibrillator Model serial number PK306405H Medtronic, Inc. Minneapolis, MN	51[a]	90[a]
KAPPA DR403 Dual chamber rate responsive Pacemaker Model serial number PET400897H Medtronic, Inc. Minneapolis, MN	31	43
KAPPA DR706 Dual chamber rate responsive Pacemaker Model serial number PGW101799H Medtronic, Inc. Minneapolis, MN	41	51[a]
MARQUIS DR 7274 Implantable cardioverter defibrillator Model serial number PKC600093S Medtronic, Inc. Minneapolis, MN	64[a]	90[a]
MICRO JEWEL II 7223CX Implantable cardioverter defibrillator Model serial number PFR219645H Medtronic, Inc. Minneapolis, MN	56[a]	90[a]
Nova Model 281-01 Pacemaker Intermedics, Inc. Freeport, TX	90[a]	90[a]
Nova II Model 281-05 Pacemaker Intermedics, Inc. Freeport, TX	24	37
Nova II Model 282-04 Pacemaker Intermedics, Inc. Freeport, TX	23	34
Quantum Model 253-19 Pacemaker Intermedics, Inc. Freeport, TX	54[a]	90[a]
Relay Model 294-03 Pacemaker Intermedics, Inc. Freeport, TX	33	46
Res-Q ACE	90[a]	90[a]

(*continued*)

Table 2. Continued.

Description	LB, deflection angle (°)	SB, deflection angle (°)
Model 101-01 Pacemaker Intermedics, Inc. Freeport, TX		
Reveal 9525 Insertable loop recorder Model serial number AAA008038M Medtronic, Inc. Minneapolis, MN	47[a]	58[a]
SIGMA SDR306 Dual chamber rate responsive Pacemaker Model serial number PJE101076H Medtronic, Inc. Minneapolis, MN	42	53[a]
THERA VDD 8968I Dual chamber atrial sensing Ventricular sensing/ pacing pacemaker Model serial number PEC400621H Medtronic, Inc. Minneapolis, MN	31	44

LB, long-bore; SB, short-bore.

[a] Exceeds the ASTM safety guideline for deflection angle. The ASTM guideline for deflection angle testing of implants and devices in the MR environment states that, "if the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight)" (ASTM, 2002). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the earth's gravitational field (ASTM, 2002).

and then released. The deflection angle for each device from the vertical direction to the nearest 1° was measured three times and averaged (ASTM, 2002; Shellock et al., 2003).

Statistical Analysis

Deflection angles measurements obtained for the cardiovascular implants during exposure to the 1.5- and 3.0-Tesla long-bore MR systems were compared with those recorded during exposure to the short-bore MR systems, respectively, using a Wilcoxon Signed Rank Test (StatView, SAS Institute, Inc., Cary, NC).

RESULTS

The findings for the deflection angle measurements recorded for the cardiovascular implants are summarized in Tables 1 and 2. Deflection angles ranged from 9–90° for the long-bore and from 11–90° for the short-bore 1.5-T MR system. Deflection angles ranged from 23–90° for the long-bore and from 34–90° for the short-bore 3.0-T MR system.

It should be noted that the guideline from the American Society for Testing and Materials for deflection angle testing of implants and devices in the MR environment states that, "if the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight)" (ASTM, 2002). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field (American Society for Testing and Materials). Therefore, in general, the findings for the implants that underwent testing should be considered with respect to this recommendation.

Three (16%) of the cardiovascular implants, all cardiac pacemakers (Cosmos, Model 283-01 Pacemaker, Intermedics, Inc., Freeport, TX; Nova Model 281-01 Pacemaker, Intermedics, Inc., Freeport, TX; Res-Q ACE, Model 101-01 Pacemaker; Intermedics, Inc., Freeport, TX) exhibited deflection angles $\geq 45°$ on both long-bore and short-bore 1.5-T MR systems.

Eight (42%) implants displayed deflection angles $\geq 45°$ on the long-bore 3.0-T MR system (Cosmos, Model 283-01 Pacemaker, Intermedics, Inc., Freeport, TX; GEM II DR 7273, Dual Chamber Implantable, Cardioverter Defibrillator, Medtronic, Inc. Minneapolis, MN; MARQUIS DR 7274, Implantable Cardioverter Defibrillator, Medtronic, Inc., Minneapolis, MN; MICRO JEWEL II 7223CX, Implantable Cardioverter Defibrillator (ICD), Medtronic, Inc. Minneapolis, MN; Nova Model 281-01 Pacemaker, Intermedics, Inc., Freeport, TX; Quantum, Model 253-19 Pacemaker, Intermedics, Inc., Freeport, TX; Res-Q ACE, Model 101-01 Pacemaker; Intermedics, Inc., Freeport, TX; Reveal 9525, Insertable Loop Recorder, Medtronic, Inc. Minneapolis, MN) while 14 (74%; the eight above with the addition of the following six: Cosmos II, Model

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284-05 Pacemaker, Intermedics, Inc. Freeport, TX; Delta TRS, Type DDD, Model 0937 Pacemaker, Cardiac Pacemakers, Inc., St. Paul, MN; GEM DR 7271, Dual Chamber Implantable, Cardioverter Defibrillator, Medtronic, Inc., Minneapolis, MN; KAPPA DR706, Dual Chamber Rate Responsive Pacemaker, Medtronic, Inc., Minneapolis, MN; Relay, Model 294-03 Pacemaker, Intermedics, Inc., Freeport, TX; SIGMA SDR306, Dual Chamber Rate Responsive Pacemaker, Medtronic, Inc., Minneapolis, MN) exhibited deflection angles ≥ 45 degrees on the short-bore 3.0-T MR system.

In general, deflection angles measured for the cardiovascular implants were significantly ($p < 0.01$) higher on both the 1.5- and 3.0-Tesla short-bore MR systems compared with the long-bore MR systems.

DISCUSSION

Over the years, many different implants have been tested for MR safety, with an emphasis on characterizing magnetic field interactions (Edwards et al., 2000; Luechinger et al., 2001; Shellock, 2001a,b,c; Shellock, 2003; Shellock and Crues, 1988; Shellock and Shellock, 1998; Shellock et al., 1999; Shellock et al., 2003). This information has been summarized and is available in published forms and on-line at www.MRIsafety.com and www.IMRSER.org. Importantly, because prior testing of pacemakers and ICDs was conducted at 1.5-Tesla or lower and there are now commercially available 3.0-Tesla MR systems, it is now necessary to evaluate these implants for magnet-related effects associated with these more powerful MR systems. Thus, the present study provides new MR safety information related to translational attraction for cardiac pacemakers, ICDs, and an insertable loop recorder exposed to long-bore and short-bore 1.5- and 3.0-Tesla MR systems.

From a magnetic field consideration, translational attraction and/or torque may cause movement or dislodgment of a ferromagnetic implant resulting in injury or uncomfortable sensations experienced by the patient (Luechinger et al., 2001; Shellock, 2001a,b; Shellock, 2003). Translational attraction is proportional to the strength of the static magnetic field, the strength of the spatial gradient, the mass of the object, the shape of the object, and the magnetic susceptibility of the object (Luechinger et al., 2001; Schenck, 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 2003). The effects of translational attraction on external and implanted ferromagnetic objects are predominantly responsible for possible hazards in the immediate area around the MR system (Schenck, 2001; Shellock, 2001a,b; Shellock, 2003; Shellock et al., 2003), that is, as one moves in close proximity to the MR system and/or is moved into the MR system for an examination. The deflection angle test is commonly used to characterize magnetic field-related translational attraction for implants, materials, and devices (ASTM, 2002; Edwards et al., 2000; Shellock, 2001c; Shellock and Crues, 1988; Shellock and Shellock, 1998; Shellock et al., 2003).

The ASTM guideline for deflection angle testing of implants and devices in the MR environment states that, "if the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight)" (ASTM, 2002). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the earth's gravitational field (ASTM, 2002). Basically, findings from the deflection angle test permit implants and devices made from nonferromagnetic or weakly ferromagnetic materials that display deflection angles between 0° and 44° to be present in patients or individuals undergoing MR procedures without concerns for movement of dislodgment (Edwards et al., 2000; Shellock, 2001c; Shellock and Shellock, 1998; Shellock et al., 2003).

However, the "intended in vivo use" of the implant or device must also be taken into consideration (Erlebacher et al., 1986). For example, there may be substantial "retentive" or counter forces that are present provided by sutures or other means of fixation, tissue ingrowth, scarring, or granulation that serve to prevent the implant from presenting a substantial risk or hazard to the patient or individual in the MR environment (Erlebacher et al., 1986). Regarding the cardiovascular implants that underwent evaluation for magnetic field translational attraction in this study, this particular aspect of MR safety must be considered and warrants further study.

In a recent comprehensive study (Luechinger et al., 2001), investigated magnetic field interactions for 31 cardiac pacemakers and 13 ICDs in association with exposure to a 1.5-Tesla MR system (Gyroscan ACS NT, Philips Medical Systems, Best, The Netherlands). The investigators reported that newer cardiac pacemakers had relatively low magnetic force values compared to older devices. With regard to ICDs, with the exception of one newer model (GEM II, 7273 ICD, Medtronic, Minneapolis, MN), all ICDs showed relatively high magnetic field interactions (Luechinger et al., 2001). Luechinger et al. (2001) concluded that modern-day pacemakers present no safety risk with respect to magnetic field interactions at 1.5-Tesla, while ICDs may pose problems due to strong magnet-related mechanical forces.

Cardiac Pacemakers

Findings from the present study for cardiovascular implants tested at 1.5-Tesla generally supported the contention of Luechinger et al., (2001) insofar as all of the newer cardiac pacemakers displayed acceptable deflection angles ($\leq 45°$), while only older pacemakers exhibited deflection angles of $\geq 45°$. Additionally, similar to Luechinger et al. (2001), several of the older pacemakers that were tested exhibited deflection angles of $\leq 45°$. At 3.0-Tesla, only older cardiac pacemakers ($n = 3$) exceeded a deflection angle of $\geq 45°$ on the long-bore MR system. On the short-bore 3.0-Tesla MR system, an additional two older pacemakers as well as two newer pacemakers (KAPPA DR706 Dual Chamber Rate Responsive Pacemaker, Medtronic, Minneapolis, MN and Sigma SDR306, Dual Chamber Rate Responsive Pacemaker, Medtronic, Minneapolis, MN) exceeded a deflection angle of 45°. Thus, even new cardiac pacemakers may be problematic for patients undergoing MR procedures on a short-bore 3.0-Tesla MR system from a magnet-induced mechanical force consideration.

ICDs

Findings from this investigation for ICDs tested at 1.5-Tesla were different from those reported by Luechinger et al. (2001). That is, all four ICDs displayed deflection angles that were $\leq 45°$ on both the long-bore and short-bore 1.5-T MR systems. Thus, from a translational attraction consideration, certain ICDs exist that could conceivably be acceptable for patients in the 1.5-T MR environment, despite published findings to the contrary (Luechinger et al., 2001).

At 3.0-Tesla, three of the four ICDs exceeded a deflection angle of $\leq 45°$ on the long-bore MR system, with an additional one exceeding 45° on the short-bore MR system. Therefore, all of the newer ICDs may present magnet-related risks to patients undergoing MR procedures on the short-bore 3.0-Tesla MR system.

Insertable Loop Recorder

The Insertable Loop Recorder (Reveal, Medtronic, Minneapolis, MN) is a device that is implanted subcutaneously to continuously monitor the patient's heart rate and rhythm in order to capture and store ECG data associated with a fainting episode or similar condition. Data from the present study indicates that there should be no risk associated with movement or dislodgement of this cardiovascular implant in relation to exposure to long-bore and short-bore 1.5-Tesla MR systems (i.e., the deflection angles were 25° and 33°, respectively). By comparison, the deflection angles measured during exposure to long-bore and short-bore 3.0-Tesla MR systems (47° and 58°, respectively) suggest that there may be problems related to movement of this device.

Long-Bore vs. Short-Bore Deflection Angle Measurements

An important result of this investigation is the fact that there were significantly ($p < 0.01$) higher deflection angles measured for the cardiovascular implants associated with exposure to the short-bore vs. the long-bore 1.5- and 3.0-T MR systems. This finding has also been reported for aneurysm clips tested on short-bore and long-bore 3.0-Tesla MR systems (Shellock et al., 2003); however, there has been no prior work conducted on implants to compare long-bore and short-bore 1.5-T scanners (Shellock et al., 2003) Basically, the differences in deflection angle measurements are related to differences in the highest spatial gradients for long-bore vs. short-bore scanners (Shellock et al., 2003)

With regard to the long-bore and short-bore 1.5-Tesla findings, the number of cardiovascular implants that showed deflection angles below vs. above 45° was the same (i.e., 16 vs. three implants, respectively). However, with regard to the long-bore and short-bore 3.0 Tesla MR findings, there were certain cardiovascular implants that may be safe (i.e., based on the ASTM criteria for acceptable deflection angles) on a long-bore 3.0-T MR system that may be *unsafe* on a short-bore 3.0-T MR system. For example, eight cardiovascular implants had deflection angles that exceeded 45° on the long-bore, 3.0-Tesla MR system, while 14 cardiovascular implants exceeded deflection angles of 45° on the short-bore 3.0-Tesla MR system. Of note is that these results are specific to the MR scanners and bore designs used in this investigation or to those MR systems with comparable spatial magnetic gradients characteristics.

Possible Limitations

The findings of this study are limited to translational attraction measurements for the specific cardiac pacemakers, ICDs, and the insertable loop recorder that were exposed to long-bore and short-bore 1.5- and 3.0-Tesla MR systems. Obviously, there are other

previously-described factors that may impact MR safety for these cardiovascular implants (Achenbach et al., 1997; Duru et al., 2001; Erlebacher et al., 1986; Fetter et al., 1984; Gimbel, 2001; Hayes et al., 1987; Holmes et al., 1986; Lauck et al., 1995; Pavlicek et al., 1983; Shellock, 2001a,b; Shellock, 2003; Sommer et al., 2000; Vahlhaus et al., 2001). Therefore, regardless of the fact that magnetic field interactions may not present a risk for some of the cardiovascular implants that were tested, these additional potentially hazardous mechanisms should be considered carefully for pacemakers, ICDs, and similar implants.

CONCLUSIONS

Cardiac pacemakers, ICDs, and an insertable loop recorder were evaluated for translational attraction using deflection angle tests performed at the points of the highest spatial gradients for long-bore and short-bore 1.5- and 3.0-Tesla MR systems according to ASTM guidelines. In general, deflection angles for these cardiovascular implants were significantly ($p < 0.01$) higher on 1.5- and 3.0-Tesla short-bore compared to long-bore MR systems. Several of the cardiovascular implants that underwent evaluation may be problematic for patients undergoing MR procedures using 1.5- and 3.0-T MR systems because of possible risks associated with magnet-related movements. Additional potential MR safety hazards (e.g., MR-related heating of leads, inhibition or modification of the function of the device, electromagnetic interference) should be taken into consideration for all of the cardiovascular implants that underwent evaluation.

ACKNOWLEDGMENTS

Special thanks to Mr. Ron Kalin for providing pacemakers, ICDs, and the insertable loop recorder from Medtronic, MN. Also, we are grateful to Dr. Mark Cohen, Dr. Susan Bookheimer, and Dr. John Mazziotta at the UCLA Brain Mapping Division, Los Angeles, California for permitting use of the 3.0-Tesla MR system and, thus, facilitating the performance of this research project.

This investigation was supported by The Cleveland Clinic Foundation, Cleveland, Ohio and the Institute for Magnetic Resonance Safety, Education, and Research, Los Angeles, California (www.IMRSER.org).

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Received August 2, 2002
Accepted November 5, 2002