Original Research

Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3.0-Tesla MR System

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Purpose: To evaluate magnetic field interactions for 109 different biomedical implants and devices in association with exposure to a 3.0-Tesla magnetic resonance (MR) system.

Materials and Methods: A total of 109 implants and devices (aneurysm clips, 32; clips, fasteners, and staples, 10; coils and stents, 10; heart valve prostheses and annuloplasty rings, 12; orthopedic implants, five; suture materials, 13; vascular access ports and accessories, 13; miscellaneous implants and devices, 14) were tested for magnetic field interactions at 3.0-Tesla using previously-described, standardized techniques to assess magnetic field translational attraction and torque.

Results: The deflection angles and torque measurements ranged, respectively, from 0 to 16° and 0 to +2 for the aneurysm clips; 0 to 90° and 0 to +4 for the clips, fasteners, and staples; 0 to 47° and 0 to +4 for the coils and stents; 0 to 4° and 0 to +1 for the heart valve prostheses and annuloplasty rings; 0 to 12° and 0 to +2 for the orthopedic implants; 0 to 13° and 0 to +2 for the suture materials; 0 to 52° and 0 to +4 for the vascular access ports and accessories; and 0 to 28° and 0 to +3 for the miscellaneous implants and devices.

Conclusion: Of the 109 implants and devices assessed for magnetic field interactions at 3.0-Tesla, four (4%) are potentially unsafe based on deflection angle criteria. The implications of these results for patients undergoing MR procedures at 3.0-Tesla is discussed. Notably, these results are specific to the 3.0-Tesla MR system used for this evaluation.

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THE PRESENCE OF A metallic implant in a patient or individual in the magnetic resonance (MR) environment may create a hazardous situation primarily due to excessive magnetic field interactions (1–22). To date, over 1,100 implants and objects have been tested for this specific aspect of MR safety, and this information is readily available to MR users as a compiled, written list or on-line (19,20).

Presently, the clinical use of 3.0-Tesla (T) MR systems is increasing in the United States and abroad. There are important MR safety issues related to the use of these powerful MR systems, especially with regard to the management of patients and individuals with metallic implants. Notably, most previous ex vivo tests performed to determine MR safety for implants and devices used MR systems with static magnetic fields of 1.5-T or lower (1–15,18–20). This could be problematic for a patient or individual with a metallic implant or device. For example, it is possible that a metallic object that displayed "weakly" ferromagnetic qualities in association with a 1.5-T MR system may exhibit substantial magnetic field interactions in association with exposure to a 3.0-T MR system. Therefore, it is necessary to conduct ex vivo testing to identify potentially hazardous implants and devices before subjecting patients or individuals with these objects to the 3.0-T MR environment. This is especially crucial because most 3.0-T MR facilities currently do not perform MR procedures on patients with metallic objects (unpublished observations, March, 2002).

To date, with the exception of the assessment of a Guglielmi detachable coil (GDC) and various aneurysm clips (21,22), there has been no comprehensive evaluation of MR safety with regard to metallic implants and devices in association with MR systems operating at or above 3.0-T. Therefore, the purpose of this investigation was to perform an assessment of magnetic field interactions for more than 100 implants and devices exposed to a 3.0-T MR system. The results of this study have important MR safety implications for patients undergoing MR procedures at 3.0-T.

MATERIALS AND METHODS

Biomedical Implants and Devices

A total of 109 different implants and devices (aneurysm clips, 32; clips, fasteners, and staples, 10; coils and stents, 10; heart valve prostheses and annuloplasty

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rings, 12; orthopedic implants, five; sutures with needles removed, 13; vascular access ports and accessories, 13; miscellaneous implants and devices, 14) underwent evaluation in this study. Each implant and device was representative of the manufactured finished version of the object and not altered in any manner before testing. Tables 1–8 list specific information for these implants and devices (i.e., the name, material, and manufacturer). These implants and devices were selected for assessment because they represent a wide range of objects and materials that may be encountered in patients or individuals exposed to a 3.0-T MR environment.

3.0-T MR System

A shielded, 3.0-T MR system (General Electric Medical Systems, Milwaukee, WI) was used for this study. Because of inherent differences in magnets for various commercially available 3.0-T MR systems (e.g., conventional "long bore" head and body MR systems vs. "short bore" head-only MR systems), the results of this evaluation for magnetic field interactions for the implants and devices are highly specific to the use of this particular MR system.

Assessment of Magnetic Field Interactions

Translational Attraction

Translational attraction was assessed for each implant or device using the deflection angle method, according to the procedure described by New et al (1) and modified by the American Society for Testing and Materials (ASTM) (23). The implant or device was attached to a special test fixture to measure the deflection angle in the MR system (4,9,10,13–15). The test fixture consisted of a sturdy structure capable of holding the test object in a proper position without deflection of the test fixture, and contained a plastic protractor with 1° graduated markings, rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically. The test fixture had a plastic bubble level permanently affixed to the top to ensure proper orientation in the MR system during the test procedure.

The test object was suspended from a thin, lightweight string (weight, less than 1% of the weight of the implant or device) that was attached at the 0° indicator position on the protractor. The length of the string was 20 cm, which was long enough so that the test object could be suspended from the test fixture and hang freely in space. Sources of forced air movement within the MR system bore were shut off during the deflection angle measurements.

Measurements of deflection angles for the implants and devices were obtained at the position in the 3.0-T MR system that produced the greatest magnetically-induced deflection (4,9,10,13–15,23). This position was determined for the 3.0-T MR system using gauss line plots, measurements, and visual inspection to identify the location where the deflection angle was the greatest. The highest spatial gradient for the 3.0-T MR system occurs at a position that is 96 cm from the isocenter of the MR system. The magnetic spatial gradient at this position is 3.25 T/meter. This location was marked using tape to facilitate measurements of deflection angles for the implants and devices.

The test object was held on the test fixture so that the string was vertical and then released. The deflection angle for the test object from the vertical direction to the nearest 1° was measured three times and averaged.

Assessment of Torque

The next assessment of magnetic field interactions was conducted to qualitatively determine the presence of magnetic field-induced torque for the implants and devices (4,8–11,13–15,22,24). This procedure involved the use of a flat plastic device with a millimeter grid etched on the bottom. Each test object was placed on the device in an orientation that was perpendicular to the 3.0-T static magnetic field. This test apparatus was then positioned with the implant or device in the center of the MR system, where the effect of torque force from the 3.0-T static magnetic field is known to be the greatest. Each test object was directly observed for any type of possible movement with respect to alignment or rotation to the magnetic field. The observation process was facilitated by having the investigator inside of the bore of the magnet during the test procedure. The test apparatus with the test object was moved 45° relative to its previous position, and again observed for alignment or rotation. This process was repeated to encompass a full 360° rotation of positions for each implant or device (4,8–11,13–15,22,24). Measurements were obtained three times for each test object and averaged.

The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the test object showed very rapid and very forceful alignment to the magnetic field (4,8–11,13–15,22,24). Several peer-reviewed, scientific publications support the use of this methodology to qualitatively assess magnetic field-related torque for a metallic implant or device in association with an MR system (4,8–11,13–15,22,24).

RESULTS

The findings for magnetic field interactions for the implants and devices exposed to the 3.0-T MR system are summarized in Tables 1 to 8. In general, the deflection angle data correlated well with the torque data (i.e., the higher the deflection angle, the greater the torque value). For the aneurysm clips (N = 32, Table 1), the deflection angles and torque measurements ranged from 0 to 16° and 0 to +2, respectively. For the clips, fasteners, and staples (N = 10, Table 2), the deflection angles and torque measurements ranged from 0 to 90° and 0 to +4, respectively. For the coils and stents (N = 10, Table 3), the deflection angles and torque measurements ranged from 0 to 47° and 0 to +4, respectively. For the heart valve prostheses and annuloplasty rings (N = 12, Table 4), the deflection angles and torque measurements ranged from 0 to 4° and 0 to +1, respec-

Table 1
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Aneurysm Clips*

No.	Description	Deflection angle (°)	Torque
1	Perneczky Straight, 2 mm blade Material, stainless steel alloy Zeppelin Chirugishe Instrumente Pullach, Germany	8	+2
2	Perneczky Straight, 6 mm blade Material, stainless steel alloy Zeppelin Chirugishe Instrumente Pullach, Germany	12	+2
3	Perneczky Straight, 7 mm blade Material, stainless steel alloy Zeppelin Chirugishe Instrumente Pullach, Germany	12	+2
4	Spetzler Titanium Aneurysm Clip Model C-2200 Straight, 5 mm blade Material, C.P. titanium NMT Neurosciences Duluth, Georgia	0	0
5	Spetzler Pure Titanium Aneurysm Clip Model C-2212 Curved, 7 mm blade Material, C.P. titanium NMT Neurosciences Duluth, Georgia	0	0
6	Spetzler Titanium Aneurysm Clip Straight, 9 mm blade Material, C. P. titanium Elekta Instruments, Atlanta, GA	0	0
7	Spetzler Pure Titanium Aneurysm Clip Model C-2214 Curved, 11 mm blade Material, C.P. titanium NMT Neurosciences Duluth, Georgia	0	0
8	Spetzler Pure Titanium Aneurysm Clip Model C-2203 Straight, 11 mm blade Material, C.P. titanium NMT Neurosciences Duluth, Georgia	0	0
9	Spetzler Pure Titanium Aneurysm Clip Model C-2526 Straight, 11 mm blade Material, C. P. titanium NMT Neurosciences Duluth, Georgia	0	0
10	Spetzler Pure Titanium Aneurysm Clip Model C-2224 Straight, 11 mm/3.5 mm Fenestrated blade Material, C.P. titanium NMT Neurosciences Duluth, Georgia	0	0
11	Spetzler Titanium Aneurysm Clip Straight, 13 mm blade Material, C.P. titanium Elekta Instruments, Atlanta, GA	0	0
12	Sugita Fenestrated large Bent, 7.5 mm Material, elgiloy Mizuho America, Inc. Beverly, MA	5	+1
13	Sugita Fenestrated large Fujita blade deflected type aneurysm clip for permanent occlusion Angled, 10 mm serrated blade Material, elgiloy Mizuho America, Inc. Beverly, MA	8	+2
14	Sugita Large aneurysm clip for permanent occlusion Straight, 21 mm serrated blade Material, elgiloy Mizuho America, Inc. Beverly, MA	9	+2
15	Sugita Long aneurysm clip for permanent occlusion Straight, 19 mm nonserration blade Material, elgiloy Mizuho America, Inc. Beverly, MA	9	+2
16	Sugita Standard Bent, 8 mm blade Material, elgiloy Mizuho America, Inc. Beverly, MA	5	+1
17	Sugita Standard Curved, 6 mm blade Material, elgiloy Mizuho America, Inc. Beverly, MA	5	+1
18	Sugita Temporary mini Bent, 7 mm blade Material, elgiloy Mizuho America, Inc. Beverly, MA	3	+1
19	Sugita Temporary standard Straight, 7 mm blade Material, elgiloy Mizuho America, Inc. Beverly, MA	5	+1
20	Sugita Titanium Standard aneurysm clip for permanent occlusion 45 degree angled, 19 mm Serrated blade Material, titanium alloy Mizuho America, Inc. Beverly, MA	0	0
21	Yasargil Mini clip, titanium Model FT728T, Bayonet, 7 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0
22	Yasargil Standard aneurysm clip Model FE750, Straight, 9 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	6	+1
23	Yasargil Standard aneurysm clip Model FE780, Straight, 14 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	8	+2
24	Yasargil Standard aneurysm clip Model FE786 Curved, 15.3 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	6	+1

Table 1
(Continued)

No.	Description	Deflection Angle (°)	Torque
25	Yasargil Standard aneurysm clip Model FE790K Straight, 20 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	16	+2
26	Yasargil Standard aneurysm clip Model FE798 Bayonet, 20 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	6	+1
26	Yasargil Standard aneurysm clip Model FE798 Bayonet, 20 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	6	+1
27	Yasargil Standard aneurysm clip Model FE887, Angled, 7 mm blade Material, phynox Aesculap, Inc. Center Valley, PA	5	+1
28	Yasargil Standard aneurysm clip, titanium Model FT740T Straight, 7 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0
29	Yasargil Standard aneurysm clip titanium Model FT750T, Straight, 9 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0
30	Yasargil Standard aneurysm clip titanium Model FT758T Bayonet, 12 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0
31	Yasargil Standard aneurysm clip titanium Model FT760T Straight, 11 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0
32	Yasargil Standard aneurysm clip titanium Model FT790T Straight, 20 mm blade Material, titanium alloy Aesculap, Inc. Center Valley, PA	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

Table 2
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Clips, Fasteners, and Staples*

No.	Description	Deflection angle (°)	Torque
1	Endostaple Surgical fastener Material, MP35N MedSource Technologies Newton, MA	0	0
2	Endostaple Surgical fastener Material, nitinol MedSource Technologies Newton, MA	0	0
3	Fascia staple Material, 316L stainless steel United States Surgical North Haven, CT	0	0
4	GIA 4.8 staple Material, titanium United States Surgical North Haven, CT	0	0
5	MultApplier clip Material, titanium United States Surgical North Haven, CT	0	0
6	Royal staple Material, 316L stainless steel United States Surgical North Haven, CT	0	0
7	Ogden Suture Anchor Materials, titanium with titanium nitride coating United States Surgical North Haven, CT	0	0
8	Surgiclip spring Material, carbon steel United States Surgical North Haven, CT	90	+4
9	TA 90-4.8 directional staples Material, titanium United States Surgical North Haven, CT	0	0
10	Tacker helical fastener Material, titanium United States Surgical North Haven, CT	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

tively. For the orthopedic implants ($N = 5$, Table 5), the deflection angles and torque measurements ranged from 0 to 12° and 0 to +2, respectively. For the suture materials ($N = 13$, Table 6), the deflection angles and torque measurements ranged from 0 to 13° and 0 to +2, respectively. For the vascular access ports and accessories ($N = 13$, Table 7), the deflection angles and torque measurements ranged from 0 to 52° and 0 to +4, respectively. For the miscellaneous implants and de-

Table 3
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Coil and Stents*

No.	Description	Deflection angle (°)	Torque
1	BARD® LUMINEXX™ Biliary and Vascular Stent 12 × 120 mm Material, nitinol and tantalum C. R. Bard Angiomed GmbH & Co. Medizintechnik KG Karlsruhe, Germany	0	0
2	BARD CONFORMEXX Stent 12 × 120 mm Material, nitinol C. R. Bard Angiomed GmbH & Co. Medizintechnik KG Karlsruhe, Germany	0	0
3	BX Velocity Balloon-Expander Intracranial Intravascular Stent 4.0 mm × 8 mm Cordis Miami, FL	3	+1
4	EndoFit Endoluminal Stent Graft Aortomonoiliac (A), tapered Materials, 316L SS and nitinol ENDOMED, Inc. Phoenix, AZ 85044	33	+3
5	EndoFit Endoluminal Cuff (C) Stent Graft Suprarenal Materials, 316L SS and nitinol ENDOMED, Inc. Phoenix, AZ 85044	47	+4
6	EndoFit Endoluminal Stent Graft Extender (E) Materials, 316L SS and nitinol ENDOMED, Inc. Phoenix, AZ 85044	46	+4
7	GDC - 10 Description 4 × 4, coil Boston Scientific Corporation Watertown, MA	0	0
8	EndoFit Endoluminal Stent Graft Thoracic (T) Materials, 316L SS and nitinol ENDOMED, Inc. Phoenix, AZ 85044	29	+3
9	Percuflex Plus Stent Graft with Suprarenal Ureteral Stent 4.8 Fr. (1.6 mm × 220 mm) Microvasive Boston Scientific Corporation Watertown, MA	0	0
10	T40 × 22SC, Thoracic Stent Graft with Subclavian Materials, 316L SS and nitinol ENDOMED, Inc. Phoenix, AZ 85044	38	+3

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

vices ($N = 14$, Table 8), the deflection angles and torque measurements ranged from 0 to 28° and 0 to +3, respectively.

DISCUSSION

The MR environment may be unsafe for patients or individuals with certain biomedical implants or devices, primarily due to movement or dislodgment of objects made from ferromagnetic materials (1–22). While excessive heating and the induction of electrical currents may also present risks to patients with implants or devices, these MR safety problems are typically associated with implants that have elongated configurations and/or that are electronically-activated, or electrically conducting (e.g., neurostimulation systems, cardiac pacemakers, etc.) (4,5,9,10,15,17–20,24–30). Therefore, in consideration of the fact that it is important to characterize magnetic field interactions for implants and devices, and because of the lack of information for MR systems above 1.5-T, this investigation evaluated translational attraction and torque for 109 objects exposed to a 3.0-T MR system. To this investigator's knowledge, this study is the first to acquire such information for a comprehensive list of implants and devices relative to exposure to a 3.0-T MR system.

In the MR environment, magnetic-field related translational attraction and torque may cause hazards to patients and individuals with ferromagnetic implants or devices and is proportional to the strength of the static magnetic field, the spatial gradient, the mass of the object, the shape of the object, and the magnetic susceptibility of the object (1,2,4–15,22,23,32). Translational attraction is commonly determined for implants and devices using the deflection angle test (1,2,4–15,22,23). Torque rotates or aligns the object parallel to the magnetic field and is dependent on the strength of the magnetic field, the dimensions of the object (primarily the length), and the initial angulation of the object relative to the static magnetic field (1,22,32). Various techniques have been used to qualitatively or quantitatively determine magnetic field-related torque for implants, materials, and devices (1,4–15,27).

Recently, the ASTM issued a guideline for the measurement of induced displacement force that involves conducting the deflection angle test on a passive implant in the MR environment, indicating 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)" (23). 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. Accordingly, 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 in the MR environment (10,11,15,22,23). A test procedure and acceptable measurement value for torque imposed on implants and devices has not yet been defined by the ASTM. However, a torque value for an implant or device that is less than that produced by normal daily activi-

Table 4
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Heart Valve Prostheses and Annuloplasty Rings*

No.	Description	Deflection angle (°)	Torque
1	AnnuloFlo Mitral Annuloplasty Device Size 36 mm Model AR-736 Material, titanium Sulzer Carbomedics, Inc. Austin, TX	0	0
2	Carboseal Ascending Aortic Valve Conduit Size 33 mm Model AP-033 Material, nitinol Sulzer Carbomedics, Inc. Austin, TX	0	0
3	Carboseal Ascending Aortic Valve Conduit Size 33 mm Model AP-033 Material, titanium Sulzer Carbomedics, Inc. Austin, TX	0	0
4	Carpentier-Edwards Classic Annuloplasty Ring Mitral model 4400 Size 40 mm Edwards Lifesciences Irvine, CA	0	0
5	Carpentier-Edwards Low Pressure Bioprosthesis Porcine, mitral model 6625, Size 35 mm Heart valve Baxter Healthcare Corporation Santa Ana, CA	0	0
6	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Mitral model 6900 Size 33 mm Heart valve Edwards Lifesciences Irvine, CA	0	0
7	Carpentier-Edwards Physio Annuloplasty Ring Mitral model 4450 Size 40 mm Edwards Lifesciences Irvine, CA	4	+1
8	Edwards MIRA Mechanical Valve Mitral, model 9600 Size 27 mm Heart valve Edwards Lifesciences Irvine, CA	0	0
9	Reduced Aortic CPHV Carbomedics Prosthetic Heart Valve Size 29 mm Model R5-029 Material, nitinol Sulzer Carbomedics, Inc. Austin, TX	0	0
10	Reduced Aortic CPHV Carbomedics Prosthetic Heart Valve Size 29 mm Model R5-029 Material, titanium Sulzer Carbomedics, Inc. Austin, TX	0	0
11	Standard Mitral CPHV Carbomedics Prosthetic Heart Valve Size 29 mm Model R5-029 Material, nitinol Sulzer Carbomedics, Inc. Austin, TX	0	0
12	Standard Mitral CPHV Carbomedics Prosthetic Heart Valve Size 33 mm Model M7-033 Material, titanium Sulzer Carbomedics, Inc. Austin, TX	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

Table 5
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Orthopedic Implants*

No.	Description	Deflection angle (°)	Torque
1	Cobalt Chrome Staple Material, cobalt chrome (ASTM F75) Smith & Nephew, Inc. Orthopedic Division Memphis, TN	0	0
2	Compression Hip Screw Plate and Lag Screw (tested as assembly) Material, 316L stainless steel Smith & Nephew, Inc. Orthopedic Division Memphis, TN	12	+2
3	Hip Implant Material, austenitic stainless steel DePuy Inc. Warsaw, IN	11	+2
4	Oxidized Zirconium Knee Femoral Component Material, new alloy Smith & Nephew, Inc. Orthopedic Division Memphis, TN	0	0
5	Titanium Intramedullary Nail Material, titanium Alloy Smith & Nephew, Inc. Orthopedic Division Memphis, TN	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

ties (which might include rapidly accelerating vehicles or amusement park rides) is assumed to be safe (23). Obviously, in addition to the effects of translational attraction and torque, the "intended in vivo use" of the implant or device must be taken into consideration, as well as mechanisms that may provide retention of the object in situ (e.g., implants or devices held in place by sutures, granulation or ingrowth of tissue, or by other means).

Based on the findings for magnetic field interactions for the 109 implants and devices that were tested, four (4%) of these may be unsafe or present a risk to a patient or individual in the 3.0-T MR environment as a result of movement or dislodgment. These potentially problematic implants and devices are as follows: Surgiclip (United States Surgical, North Haven, CT), EndoFit Endoluminal Stent Graft (C) (ENDOMED, Inc., Phoenix, AZ), EndoFit Endoluminal Stent Graft (E) (ENDOMED, Inc., Phoenix, AZ), and the PORT-A-CATH Needle (Deltec, Inc., St. Paul, MN).

Findings for the aneurysm clips indicated that 15 of the 32 clips exhibited no magnetic field interactions, while the remaining clips showed minor or "weak" ferromagnetic qualities. Certain types of aneurysm clips (e.g., aneurysm clips made from martensitic stainless steels) are an absolute contraindication to the use of MR procedures because magnetically-induced forces can displace these clips and cause serious injury or death (1–3,7,11,12,18,19,22,33,34). By comparison, aneurysm clips classified as "nonferromagnetic" or "weakly ferromagnetic," including those made from phynox, elgiloy, austentitic stainless steels, titanium alloy, or commercially pure titanium, are safe for patients undergoing MR procedures at 1.5-T or less (1–3,7,11,12,18,19,33,34). Specific guidelines for the management of patients and individuals with aneurysm clips with regard to exposure to the MR environment have been previously published (11,18,19). Accordingly, it is not uncommon to use MR procedures in patients with nonferromagnetic or weakly ferromagnetic aneurysm clips. In fact, a recent study performed by Pride et al (34) reported that patients with nonferromagnetic cerebrovascular aneurysm clips who underwent MR imaging had no objective adverse outcome, confirming that MR imaging can be performed safely in patients with specific types of aneurysm clips.

To date, a variety of hemostatic vascular clips, fasteners, and staples that have been evaluated for magnetic field interactions did not display substantial ferromagnetism at static magnetic fields up to 1.5-T (1–3,9,18,19,35,36). In the present study, the Surgiclip spring made from carbon steel showed a deflection angle of 90° and a torque of +4. However, considering the "intended in vivo use" of this device, it may be possible that the closing force provides substantial counterforce that may prevent it from being moved or dislodged, but this remains to be determined by further experimental findings.

Many different types of intravascular and intracavitary coils and stents have been evaluated for safety with MR systems at 1.5-T or less (6,14,18,19,37–42). Additionally, a GDC tested at 3.0-T was reported to be safe for this environment (21). Several coils and stents demonstrated magnetic field interactions associated with MR systems. Fortunately, these devices typically become incorporated securely into the vessel or cavity

Table 6
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Sutures With Needles Removed*

No.	Description	Deflection angle (°)	Torque
1	Biosyn Needle removed Material, glycomer 631 United States Surgical North Haven, CT	0	0
2	Chromic gut Needle removed Material, gut United States Surgical North Haven, CT	0	0
3	Flexon, Needle removed Materials, stainless steel coated with FEP United States Surgical North Haven, CT	6	+1
4	Maxon Needle removed Material, polyglyconate United States Surgical North Haven, CT	0	0
5	Monosof Needle removed Materials, nylon, lead weight with latex bolster United States Surgical North Haven, CT	0	0
6	Novafil Needle removed Material, polybutester United States Surgical North Haven, CT	0	0
7	Plain gut Needle removed Material, gut United States Surgical North Haven, CT	0	0
8	Polysorb Needle removed Material, lactomer 9-1 United States Surgical North Haven, CT	0	0
9	SecureStrand Needle removed Material, UHMW polyethylene United States Surgical North Haven, CT	0	0
10	Sofsilk Needle removed Material, silk United States Surgical North Haven, CT	0	0
11	Steel Needle removed Material, 316L stainless steel United States Surgical North Haven, CT	13	+2
12	Surgilon Needle removed Material, braided nylon United States Surgical North Haven, CT	0	0
13	Surgipro Needle removed Material, polypropylene United States Surgical North Haven, CT	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

wall, primarily due to tissue ingrowth or granulation, within approximately 6 to 8 weeks after their introduction. Thus, it is unlikely that they would become moved or dislodged as a result of being attracted by static magnetic fields of MR systems up to 1.5-T (6,14,18,19,37–42). Furthermore, there has never been a report of such an incident. Importantly, for a coil or stent that exhibits no magnetic field interactions, it is unnecessary to wait any period after surgical placement to perform an MR procedure in the patient.

For the coils and stents evaluated at 3.0-T, two of the 10 implants displayed magnetic field interactions that exceeded the ASTM guideline (i.e., the deflection angles were slightly greater than 45°). However, it is possible that, similar to other coils and stents, tissue ingrowth may be sufficient to prevent these implants from posing a substantial risk to a patient or individual in the 3.0-T MR environment. Furthermore, certain stents have hooks or barbs to prevent migration after placement, which may also help to retain the implant in vivo. Thus, these issues warrant further study or analysis.

Various heart valve prostheses and annulopasty rings have been tested previously in association with MR systems (2,13,18,19,43–46). Of these, many displayed measurable yet relatively minor attraction to the static magnetic fields of the MR systems (2,10,18,19,43–46). Because the actual attractive forces exerted on these heart valves were deemed minimal compared to the force exerted by the beating heart (i.e., approximately 7.2 N) (43,44), MR procedures at 1.5-T or less are not considered to be hazardous for patients or individuals that have these devices (2,10,18,19,43–46). Furthermore, there has never been a report of an incident or injury related to the presence of a heart valve prosthesis or annuloplasty ring in an individual exposed to the MR environment.

In the present study, one implant (Carpentier-Edwards Physio Annuloplasty Ring, Mitral Model 4450, Edwards Lifesciences, Irvine, CA) out of the 12 heart valve prostheses and annuloplasty rings evaluated showed a very low deflection angle (4°) and torque (+1). Based on the ASTM criteria, this implant is considered safe, along with the others, from a magnetic field interaction viewpoint (i.e., deflection angle less than 45°) at 3.0-T.

Each of the five different orthopedic implants assessed for magnetic field interactions at 3.0-T are considered to be safe based on the findings for deflection angles, torque values, and the intended in vivo uses of these devices.

Most of the previously evaluated orthopedic implants and devices evaluated for ferromagnetism were reported to be nonferromagnetic or weakly ferromagnetic and, thus, safe for patients undergoing MR procedures at 1.5-T or less (1–3,18,19,47–49). Only the Perfix interference screw (Instrument Makar, Okemos, MI) used for reconstruction of the anterior cruciate ligament has been found to be highly ferromagnetic (90° deflection angle at 1.5-T) (50). However, because this interference screw is firmly imbedded in bone for its specific application, it is held in place with sufficient retentive forces to prevent movement or dislodgment. Patients with the Perfix interference screw have safely undergone MR procedures using systems operating at 1.5-T (50). This clearly illustrates the importance of careful consider-

Table 7
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Vascular Access Ports and Devices*

No.	Description	Deflection angle (°)	Torque
1	Millenium Medical Huber Plus Safety Infusion Set Manufacturer: Unknown	8	+1
2	Non-Coring (Huber) Needle Materials, unknown Medi-tech Boston Scientific Corp. Watertown, MA	24	+3
3	R-Port Premier Vascular Access Port Materials, silicone, plastic Medi-tech Boston Scientific Corp. Watertown, MA	0	0
4	P.A.S. Port Elite with PolyFlow Polyurethane Catheter Vascular Access Systems Division Deltec, Inc. St. Paul, MN	0	0
5	PORT-A-CATH GRIPPER Needle Vascular Access Systems Division Deltec, Inc. St. Paul, MN	4	+1
6	PORT-A-CATH II Dual-Lumen Low Profile with PolyFlow Polyurethane Catheter Vascular Access Systems Division Deltec, Inc. St. Paul, MN	0	0
7	PORT-A-CATH II Dual-Lumen with Silicone Catheter Vascular Access Systems Division Deltec, Inc. St. Paul, MN	0	0
8	PORT-A-CATH II Single-Lumen Low Profile with PolyFlow Polyurethane Catheter Vascular Access Systems Division Deltec, Inc. St. Paul, MN	0	0
9	PORT-A-CATH II Single-Lumen with PolyFlow Polyurethane Catheter Vascular Access Systems Division Deltec, Inc. St. Paul, MN	0	0
10	PORT-A-CATH Needle Vascular Access Systems Division Deltec, Inc. St. Paul, MN	52	+4
11	Vaxess Vascular access port 19 gauge × 1/2″, 90° hub Materials, plastic, polyurethane Medi-tech Boston Scientific Corp. Watertown, MA	0	0
12	Vaxess Titanium mini-port Vascular access port Materials, titanium, silicone Medi-tech Boston Scientific Corp. Watertown, MA	0	0
13	Vaxess Vascular access port Materials, titanium, polyurethane Medi-tech Boston Scientific Corp. Watertown, MA	0	0

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

ation of the intended in vivo use of an implant or device over and above the safety guidelines provided by the ASTM.

Various sutures with needles removed were selected for inclusion in this study because they have not been previously evaluated in association with the MR environment, and there is confusion regarding the implications of these materials for patients undergoing MR procedures. Eleven of the sutures displayed no magnetic field interactions, while two (Flexon suture and Steel suture, United States Surgical, North Haven, CT) showed minor deflection angles and torque. For these two sutures, the in situ application of these materials is likely to provide sufficient counter-forces to prevent

Table 8
Biomedical Implants and Devices Assessed for Magnetic Field Interactions With a 3.0-Tesla MR System: Miscellaneous Implants and Devices*

No.	Description	Deflection angle (°)	Torque
1	Bipolar Coagulation Forceps for use in intraoperative magnetic resonance imaging (MRI) systems Aesculap AG & CO.KG Tuttlingen, Germany	0	0
2	Blood Collection Set Material, stainless steel United States Surgical North Haven, CT	11	+2
3	Bone Fusion Stimulator Model SpF-100 Electro-Biology, Inc. Parsippany, NJ	28	+3
4	CranioFix Burr hole clamp FF100T, 11 mm Material, titanium Aesculap, Inc. Center Valley, PA	0	0
5	CranioFix Burr hole clamp FF101T, 16 mm Material, titanium Aesculap, Inc. Center Valley, PA	0	0
6	CranioFix Burr hole clamp FF0997, 20 mm Material, titanium Aesculap, Inc. Center Valley, PA	0	0
7	Epidural Catheter with Connector Material, 604V stainless steel ARROW International Walpole, MA 02081	8	+1
8	Essure Micro Insert Materials, 316L stainless steel, platinum, iridium, nitinol, silver solder Dacron Polyester Conceptus San Carlos, CA	3	+1
9	Implantable Infusion Pump Model 3000-16 Material, titanium ARROW International Walpole, MA	0	0
10	Implantable Infusion Pump Model 3000-30 Material, titanium ARROW International Walpole, MA	0	0
11	Implantable Infusion Pump Model 3000-50 Material, titanium ARROW International Walpole, MA	0	0
12	Intraspinal Catheter with Connector Material, titanium ARROW International Walpole, MA	0	0
13	MR-Brain Spatula with Silicone Model FF408K Aesculap AG & CO.KG Tuttlingen, Germany	0	0
14	Spiegelberg System Bolt Material, stainless steel 1.4441 Aesculap, Inc. Center Valley, PA	5	+1

*Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the test object slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the test object aligned gradually to the magnetic field; +3, strong torque, the test object showed rapid alignment to the magnetic field; +4, very strong torque, the test object showed very rapid alignment to the magnetic field. Material information provided for the implants and devices, if known.

movement or dislodgment. Therefore, in consideration of the ASTM criteria and the intended in vivo use of these materials, all of the sutures with the needles removed are regarded to be safe at 3.0-T.

Vascular access ports and accessories have been evaluated at 1.5 T (5,18,19,51). Some of these devices were attracted to the static magnetic fields of the MR systems used for testing, but the forces were considered

to be minor relative to the in vivo application of these implants (5,51).

In this study, the vascular access ports assessed for magnetic field interactions at 3.0-T did not exhibit any magnetic field interactions and, therefore, will not move or dislodge in this MR environment. For the accessories, the infusion set and needles showed measurable ferromagnetism, with the PORT-A-CATH Needle (Deltec, Inc., St. Paul, MN) exceeding the ASTM guideline. However, during the actual use of each accessory, it is unlikely that it will present a problem in the 3.0-T MR environment, considering that the simple application of a small amount of adhesive tape effectively counterbalances the relatively minor ferromagnetism that was determined for each device (unpublished observations).

Fourteen different miscellaneous implants and devices underwent magnetic field interaction testing at 3.0-T, including surgical instruments, a blood collection set, an implantable bone fusion stimulator, burr hole fixation clamps, an epidural catheter, a permanent contraceptive device, and implantable infusion pumps. Of these, five exhibited determinable ferromagnetic qualities (Blood Collection Set, United States Surgical, North Haven, CT; Bone Fusion Stimulator, Model SpF-100, Electro-Biology, Inc., Parsippany, NJ; Epidural Catheter with Connector, ARROW International, Walpole, MA; Essure, Conceptus, San Carlos; Spiegelberg System Bolt, Aesculap, Inc., Center Valley, PA), but the deflection angles were at levels that passed the ASTM criteria for MR safety (23). Qualitative torque measurements for these devices were relatively low, with the exception of the +3 value for the bone fusion stimulator.

With regard to torque for the bone fusion stimulator, a previous investigation quantified this magnetic field interaction at 4.7 T (then scaled to 1.5 T) (27). The findings indicated that there is a wide margin of safety for this device in situ for a number of reasons. First, the bone fusion stimulator is typically placed subcutaneously in the region of the spine, which corresponds to the horizontal patient orientation relative to a high-field strength MR system. In this position for the device, the torque was measured to be zero. The maximum torque for the bone fusion stimulator was observed when the stimulator was in a vertical orientation, perpendicular to the static magnetic field of a high-field-strength MR system. Because the long axis of the patient's body is always parallel to the static magnetic field of a 1.5-T or higher MR system during a MR procedure, this implant would not be perpendicular to the magnetic field nor subjected to the maximum torque. Obviously, this may not be the case when the patient sits on the scanner table; however, the strength of the spatial gradient of the MR system under this condition is considerably lower (again, note that the maximum spatial gradient occurs inside the magnet bore for high-field-strength MR systems). However, even under a worst-case scenario, magnetically-induced torque is unlikely to cause a problem for a patient in consideration of the counterforce created by the subcutaneous tissue (including granulated tissue that is formed as a result of encapsulation of the implant) that surrounds the bone fusion stimulator.

In summary, 109 implants and devices were assessed for magnetic field interactions at 3.0-T. Of these, four (4%) were found to possess magnetic qualities that may cause them to be unsafe based on ASTM criteria (23). However, further consideration must be given to the intended in vivo use of these specific implants or devices. Notably, these results are specific to the 3.0-T MR system used for this evaluation.

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