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Prosthetic Heart Valves and Annuloplasty Rings: Assessment of Magnetic Field Interactions, Heating, and Artifacts at 1.5 Tesla

Frank G. Shellock

University of Southern California, School of Medicine, Los Angeles, California

ABSTRACT

The purpose of this study was to determine the magnetic resonance (MR) safety aspects and artifacts for three different heart valve prostheses and two different annuloplasty rings that have not been evaluated previously in association with the 1.5-T MR environment. Ex vivo *testing was performed using previously described techniques for the evaluation of magnetic field interactions (deflection angle and torque), heating (gel-filled phantom and fluoroptic thermometry; 15 min of MR imaging at a whole body–averaged specific absorption rate of 1.2 W/kg), and artifacts (using T1-weighted, spin echo, and gradient echo pulse sequences). One heart valve prosthesis and one annuloplasty ring showed no magnetic field interactions. Two heart valve prostheses and one annuloplasty ring displayed relatively minor magnetic field interactions (i.e., deflection angle ≤ 6 degrees, torque, +1). Heating was ≤0.7°C for the five different implants. Artifacts varied depending on the amount and type of metal used to make the implants. For the three heart valve prostheses and two annuloplasty rings, the lack of substantial magnetic field interactions and relatively minor hearing indicated that MR procedures may be conducted safetly in patients with these implants using MR systems operating with static magnetic fields of 1.5 T or less. Notably, these findings essentially apply to 54 different heart valve prostheses and 37 different annuloplasty rings (i.e., based on the various models and sizes available for these implants).*

Key Words: *Artifacts; Implants; Heart valve prostheses; Heating; Magnetic resonance imaging, bioeffects; Magnetic resonance imaging, safety*

Address correspondence and reprint requests to Frank G. Shellock.

INTRODUCTION

The electromagnetic fields associated with the magnetic resonance (MR) environment may pose serious risks to patients with certain types of implants (1,2). In general, most injuries that occur in this setting are the direct result of magnetic field–induced movement or dislodgment of ferromagnetic objects (1,2). Excessive heating and the misinterpretation of an imaging artifact as an abnormality (1–14) may produce other implant-related hazards or problems. While the induction of an electrical current may also cause injury, this does not appear to be problematic for ''passive'' implants (i.e., implants that do not operate by means of electrical power) (1,2,13).

Maintaining a safe MR environment is a daily challenge for MR health care workers. The types of medical implants and devices that are encountered in patients continue to grow, especially with regard to those used for cardiovascular applications (e.g., stents, coils, filters, prosthetic heart valves, annuloplasty rings, etc.). Ex vivo testing must be conducted on implants and devices to ensure patient safety and to facilitate effective pre-MR procedure screening (1,2,8,11,15–19). Therefore, the goal of this investigation was to determine the MR safety aspects and artifacts for three different heart valve prostheses and two different annuloplasty rings that have not been evaluated previously in association with the 1.5-T MR environment. Because of the various models and sizes that exist for these implants, the test results essentially apply to 91 different implants: 54 heart valve prostheses and 37 annuloplasty rings. Of note is that to my knowledge, this is the first report of MR safety testing conducted on annuloplasty rings.

MATERIALS AND METHODS

Heart Valve Prostheses and Annuloplasty Rings

Five different implants were assessed for MR safety: three heart valve prostheses and two annuloplasty rings (Table 1). The devices that were evaluated are representative of the largest versions for these heart valve prostheses and annuloplasty rings (i.e., relative to the various models and sizes that are available; 54 heart valve prostheses and 37 annuloplasty rings) and thus contain the most ferromagnetic material across the available size range for each product. These implants were selected for assessment because these are commonly used implants and there is currently a lack of safety information with regard to the 1.5-T MR environment. Details for the implants (all from Edwards Lifesciences, Irvine, CA) that underwent testing are as follows:

1. The *Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis* (mitral, model 6900) is a trileaflet valve primarily comprised of bovine pericardium and Elgiloy. The frame (wireform) of the valve is covered with a woven polyester cloth and is designed to be compliant at the orifice and commissures. The compliance of the pericardial valve commissure reduces the closing loading shocks at the commissure tips and fee margin of the leaflet. The frame is made of Elgiloy. An Elgiloy band attached to a polyester film band surrounds the base of the wireform, providing structural support for the orifice. A suture ring covered with polytetrafluoroethelene (PTFE) cloth is attached to the wireform frame. The suture ring contains silicone rubber and nonwoven polyester.

2. The *Carpentier-Edwards Low Pressure Bioprosthesis* (porcine, mitral, model 6625-LP, size 35 mm) is comprised of a porcine aortic valve and Elgiloy. The frame is designed to be flexible at the orifice and at the commissures. The compliance of the stent's commissure supports is intended to reduce the loading shock at the valve commissures and free margins of the leaflets. The flexibility of the orifice is intended to reduce the loading shock at the base of the leaflet. The lightweight frame is made of Elgiloy. The metal frame is covered with porous, knitted, PTFE cloth to facilitate tissue ingrowth and encapsulation. The suture ring has a silicone rubber insert that is covered with a porous, seamless, PTFE cloth.

3. The *Edwards MIRA Mechanical Valve* (mitral, model 9600) is a low profile valve consisting of two curved hinged leaflets within an annular housing. The leaflets are constructed of pyrolytic carbon deposited on a radiopaque graphite substrate. The housing consists of a titanium alloy coated Carbofilm, a thin turbostatic carbon film with a high-density crystalline structure.

4. The *Carpentier-Edwards Physio Annuloplasty Ring* (mitral, model 4450) is constructed of Elgiloy bands separated by polyester strips and has a sewing ring margin that consists of a layer of silicone rubber covered with a woven polyester cloth. It is designed to conform to the configuration of a normal mitral annulus. It is kidney shaped with one long curved segment corresponding to the posterior leaflet annulus. The rectilinear portion corresponds to the anterior leaflet annulus. The design is intended to provide support after annuloplasty surgery. This annuloplasty ring maintains a fixed maximum annula dimension to prevent excessive distension of the natural valve annulus, while adapting to the dynamic mo-

Table 1

Heart Valve Prostheses and Annuloplasty Rings Tested for MR Safety at 1.5 T

Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis (mitral, model 6900, size 33 mm)
Primary materials(s): Elgiloy, bovine pericardium, silicone, polyester
Includes the following:
Mitral, model 6900; sizes 25 mm, 27 mm, 29 mm, 31 mm, 33mm
Aortic, model 2700; sizes 19 mm, 21 mm, 23 mm, 25 mm, 27 mm, 29 mm
Aortic, model 2800; sizes 19 mm, 21 mm, 23 mm, 25 mm, 27 mm, 29 mm
Aortic, model 2900; sizes 19 mm, 21 mm, 23 mm, 25 mm, 27 mm, 29 mm
Carpentier-Edwards Low Pressure Bioprosthesis (porcine, mitral, model 6625-LP, size 35 mm)
Primary material(s): Elgiloy, porcine tissue, silicone, PTFE cloth
Includes the following:
Mitral, model 6625-LP; sizes 27 mm, 29 mm, 31 mm, 33 mm, 35mm
Mitral, model 6625-ESR-LP Duraflex; sizes 27 mm, 29 mm, 31 mm, 33 mm, 35mm
Aortic, model 2625; sizes 19 mm, 21 mm, 23 mm, 25 mm, 27 mm, 29 mm, 31 mm
Edwards MIRA Mechanical Valve (mitral, model 9600, size 33 mm)
Primary material(s): graphite substrate with pyrolytic carbon coating, titanium alloy (Ti6a14V)
Includes the following:
Aortic, model 3600; sizes 19 mm, finesse; 21 mm, finesse; 21 mm; 23 mm; 25 mm; 27 mm; 29 mm; 31 mm
Mitral, model 9600; sizes 23 mm; 25 mm; 27 mm; 29 mm; 31 mm, 33 mm
Carpentier-Edwards Physiol Annuloplasty Ring (mitral, model 4450, size 40 mm)
Primary material(s): Elgiloy, silicone
Includes the following:
Mitral, model 4450; sizes 24 mm, 26 mm, 28 mm, 30 mm, 34 mm, 36 mm, 38 mm, 40 mm
Carpentier-Edwards Classic Annuloplasty Ring (mitral, model 4400, size 40 mm)
Primary material(s): titanium alloy, silicone
Includes the following:
Mitral, model 4400; sizes 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, 38 mm, 40 mm
Tricuspid, model 4500; sizes 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm
Mitral, model 4425 (with Duraflo*); sizes 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm
Tricuspid model 4525 (with Duraflo*); sizes 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm

* Duraflow coating is used as an anticoagulant and does not affect MR safety.

tion of the mitral annulus throughout the cardiac cycle. The indications for the use of this valve are for mitral (i.e., mitral valve models and sizes) and tricuspid (i.e., tricuspid valve models and sizes) valve repair.

5. The *Carpentier-Edwards Classic Annuloplasty Ring* (mitral, model 4400) is constructed of titanium alloy and has a sewing ring margin that consists of a layer of silicone rubber covered with a polyester knit fabric. It is designed to provide retention of the natural valve apparatus, remodeling of the annulus, retention of the normal valve orifice during systole, and prevention of secondary distension of the annulus (frequently the cause of recurrent incompetence after conventional valvuloplasties). The mitral ring model is kidney shaped with one long curved segment corresponding to the posterior leaflet annulus. The ring is open in the rectilinear portion, corresponding to the anterior leaflet.

Magnetic Field Interactions

An assessment of magnet field translation attraction was performed on each implant. This test was conducted using a standardized procedure indicated as the deflection angle test (3–8,18–20). The implant was suspended by a 30-cm-long piece of lightweight thread attached to the estimated center of the device. The thread was then connected to a sturdy plastic protractor so that the angle of deflection from the vertical could be measured. The accuracy of this measuring device is ± 0.5 degrees based on the ability to read the protractor in the MR system (4–8,18,19). The deflection angle test was conducted at the position in the shielded, 1.5-T MR system where the spatial gradient of the magnetic field was previously determined to be at a maximum (4 -8,18,19). This was done to assess the magnetic field translational attraction with

regard to an extreme condition, as previously described (4–8,18,19). The highest spatial gradient for the shielded 1.5-T MR system used for this evaluation is 450 G/cm and occurs at an off-axis position, 35-cm inside the bore of the magnet, according to the survey conducted on the magnetic field using a Gauss meter (4 -m8,18,19). Deflection angles were determined three times for each implant and averaged.

The next assessment of magnetic field interactions was conducted to qualitatively determine the presence of magnetic field–induced torque (6–8,10,19). Each implant was positioned in the center of the MR system, where the effect of torque from the 1.5-T static magnetic field is known to be the greatest (6–8, 10,19). The implant 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 the bore of the magnet during this test procedure to observe the effects of torque. This process was repeated to encompass a full 360-degree rotation of positions for each implant (6–8, 10,19). It should be noted that although a prior attempt to use a quantitative technique to evaluate rotational forces for heart valve prostheses has proved difficult (7), no such similar problem occurred with the use of this qualitative torque assessment for these implants.

The following qualitative scale of torque was applied to the results, as previously described (6–8,10,19): 0, no torque; +1, mild torque—the implant slightly changed orientation but did not align to the magnetic field; +2, moderate torque—the implant aligned gradually to the magnetic field; +3, strong torque—the implant showed rapid and forceful alignment to the magnetic field; and +4, very strong torque—the implant showed very rapid and very forceful alignment to the magnetic field.

Assessment of Heating

Each implant was assessed for heating during MR imaging performed using a high level of exposure to radiofrequency (RF) radiation. A 1.5-T/64-MHz MR System (General Electric Medical Systems, Milwaukee, WI) was used along with the body coil for this experiment. To use a relatively high exposure to RF power, the following imaging parameters were used: T1-weighted spin echo pulse sequence; total imaging time, 15 min; axial plane; repetition time, 135 msec; echo time, 25 msec; field of view, 48 cm; imaging matrix, 256 × 128; section thickness, 20 mm; number of section locations, 5; number of excitations, 54; number of echoes, 4; phasing direction, anterior to posterior; transmitter gain, 200. This pulse sequence produced a whole body–averaged specific absorption rate of 1.2 W/kg. This level of exposure to RF energy exceeds that typically used for MR imaging of patients and is similar to that used to examine heating for other implants in association with MR imaging (8,12,13,19).

The experiment was conducted with each implant positioned in a phantom filled with semisolid gel (8,12,13,19). A plastic phantom was used with the following dimensions: 22 cm deep, 54 cm long, and 30 cm wide (i.e., to approximate the size of the human thorax). This phantom was filled with a semisolid gel to provide a highly conductive medium to surround the implant for the heating experiment.

The semisolid gel was prepared to simulate human tissue. This was accomplished using a gelling agent (hydroxyetheyl-cellulose) in an aqueous solution (91.58% water) along with 0.12% NaCl to create a dielectric constant of approximately 80 and a conductivity of 0.8 S/m at 64 MHz (8,12,13,19). This is an acceptable dielectric constant and an acceptable conductivity for evaluation of MR-related heating of an implant (8,13,19). A plastic frame (i.e., with 5-mm holes spaced 5-mm apart) was used to position each implant within the phantom to simulate an in vivo position and orientation. Because there is no blood flow associated with this experimental setup, it simulates an extreme condition for MR-related heating of an implant.

An MR-compatible fluoroptic thermometry system (model 3100, Luxtron, Santa Clara, CA) was used to measure temperature before and during MR imaging (8,19). The thermometry probes were placed on the implants to record temperatures that would be representative and indicative of RF- induced heating (8,12,13,19), as follows:

1. Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis
   a. Probe 1, placed 0.5 mm from the edge of the ring
2. Carpentier-Edwards Low Pressure Bioprosthesis
   a. Probe 1, placed 0.5- mm from the edge of the ring
3. Edwards MIRA Mechanical Valve
   a. Probe 1, placed 0.5 mm from the edge of the ring
   b. Probe 2, placed 0.5 mm relative to one of the leaflets
4. Carpentier-Edwards Physio Annuloplasty Ring
   a. Probe 1, placed 0.5 mm from the edge of the ring

5. Carpentier-Edwards Classic Annuloplasty Ring
   a. Probe 1, placed 0.5 mm from the edge of the ring

Additionally, a fluoroptic thermometry probe was placed in the gel-filled phantom on the opposite side of the implant to record a reference temperature in the gel-filled phantom during the heating experiment (8,19).

The room and magnet bore temperatures were stable and recorded to be 20.4°C for the heating experiments. The MR system fan was not on during the testing procedures. Baseline temperatures were recorded for 5 min at 1-min intervals after which MR imaging was performed for 15 min with temperatures recorded at 20-sec intervals. The highest temperature changes are reported herein for the implants and the reference temperatures (8,19).

Evaluation of Artifacts

Artifacts associated with the implants were assessed by performing MR imaging with them placed in a gel-filled phantom (i.e., with T1 and T2 values similar to muscle) 8,19). A plastic phantom was used with the following dimensions: 22 cm deep, 54 cm long, and 30 cm wide. The implants were attached to a plastic frame to facilitate positioning within the phantom (8,19). MR imaging was performed using the 1.5-T MR system, a transmit-receive body coil, and the following imaging parameters:

1. T1-weighted spin echo pulse sequence; repetition time, 500 msec; echo time, 20 msec; matrix size, 256 × 256; section thickness, 5 mm; field of view, 30 cm; number of excitations, 2; bandwidth; 16 kHz.
2. Gradient echo (GRE) pulse sequence; repetition time, 100 msec; echo time, 15 msec; flip angle, 30 degrees; matrix size, 256 × 256; section thickness, 5 mm; field of view, 30 cm; number of excitations, 2; bandwidth, 16 kHz.

These pulse sequences have been used previously for artifact assessments and may be used in the clinical setting for MR imaging (8,19) (although it is acknowledge that this experimental procedures is not relevant to the use of cardiac MR procedures). In addition, the GRE pulse sequence is a partial flip angle technique that tends to have a great degree of artifact associated with it (i.e., relative to the use of spin echo pulse sequences) when MR imaging is performed on a metallic implant and thus represents a type of extreme condition (8,19).

The imaging planes were oriented to encompass the long axis and short axis of each implant. The frequency encoding direction was parallel to the plane of imaging. Artifacts that result from other positions of the imaging plane relative to the implant or with regard to the particular orientation of the implant to the main magnetic field of the MR system may be slightly more or less less to that observed under the experimental conditions used in this test for artifact assessment. Nevertheless, the MR imaging technique used to assess artifacts is comparable with that published in the peer-reviewed literature (6–8, 10, 19). For this reason, it was selected to assess the implants in this study because it is considered appropriate and facilitates comparison with previously evaluated metallic implants.

The artifact size was characterized using the software provided with the MR system to perform planimetry to determine the cross-sectional areas for the signal voids associated with the implants (8). All image display parameters (i.e., window and level settings, magnification,

Table 2

Summary of Test Results for Magnetic Field Interactions and Heating for Prosthetic Heart Valves and Annuloplasty Rings

Implant	Deflection Angle (degree)	Torque*	Heating (°C)†
Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	2	+1	+0.5
Carpentier-Edwards Low Pressure Bioprosthesis	0	0	+0.7
Edwards MIRA Mechanical Valve	2	+1	+0.5
Carpentier-Edwards Physio Annyloplasty Ring	6	+1	+0.6
Carpentier-Edwards Classic Annuloplasty Ring	0	0	+0.6

* The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild torque—the implant slightly changed orientation but did not align to the magnetic field; +2, moderate torque—the implant aligned gradually to the magnetic field; +3, strong torque—the implant showed rapid and forceful alignment to the magnetic field; +4, very strong torque—the implant showed very rapid and very forceful alignment to the magnetic field.

† Highest temperature change in degrees Celsius.

etc.) were carefully selected and used in a consistent manner to facilitate a valid assessment of artifact size.

RESULTS

A summary of the test results for magnetic field interactions and heating for the heart valve prostheses and annuloplasty rings is presented in Table 2. The deflection angles for these implants exposed to the 1.5-T MR system ranged from 0 to 6 degrees. The torque values ranged from 0 to +1. For the assessment of RF heating associated with MR imaging, the highest temperature changes recorded for the implants ranged from +0.5 to +0.7°C. The highest reference temperature changes ranged from +0.4 to +0.5°C.

A summary of the test results for the evaluation of artifacts is indicated in Table 3. In general, the artifacts for the implants appeared as localized signal voids, easily recognized on the MR images. Artifact size was dependent on the amount and type of metal used for the respectived implant. The GRE pulse sequence produced larger artifacts than the T1-weighted spin echo pulse sequence for the implants. Figure 1 shows MR images that display representative artifact findings for the implants using the T1-weighted spin echo and GRE pulse sequences.

DISCUSSION

Magnetic Field Interactions

The deflection angles measured for the implants evaluated in this study ranged from 0 to 6 degrees. According to the American Society for Testing and Materials, if a passive implant ''deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). 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'' (20). As such, from a magnetically induced displacement force consideration, these five different implants are safe for patients in an MR environment of 1.5 T or less.

The assessment of torque for the implants showed qualitative values ranging from 0 to +1 (i.e., mild torque). This, torque is not a substantial problem for these devices, especially when one considers the intended in vivo use of these implants. That is, the heart valve prostheses and annuloplasty rings evaluated in this study are typically fixed in position using multiple sutures. Furthermore, over time, tissue granulation and ingrowth serve to provide additional retentive counterforces to any minor torque that may be related to exposure to the 1.5-T MR environment.

Therefore, the rest results for magnetic field interactions indicate that there are no concerns with regard to movement or dislodgment for the heart valve prostheses and annuloplasty rings in association with MR systems operating with static magnetic fields of 1.5 T or less. These MR safety findings are compatible with data reported for passive implants made from materials similar to those used to make the implants that underwent testing in the present study (1–4, 6–8, 10, 15–19)

Heating

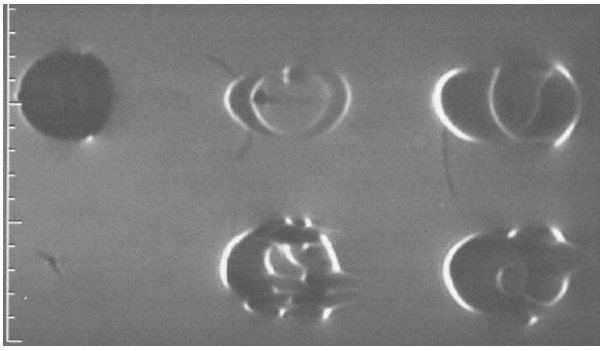
The results of the heating experiments for the heart valve prostheses and annuloplasty rings indicated minor temperature increases associated with MR imaging per-

Table 3

Summary of MRI Imaging Artifact Information for the Heart Valve Prostheses and Annuloplasty Rings (Cross-sectional Area, mm^2)

	Pulse Sequence and Orientation			
Implant	Parallel	Perpendicular	Parallel	Perpendicular
Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	2254	1248	3103	2085
Carpentier-Edwards Low Pressure Bioprosthesis	2308	1367	2594	1759
Edwards MIRA Mechanical Valve	1407	756	1824	991
Carpentier-Edwards Physio Annuloplasty Ring	2403	1118	3785	1517
Carpentier-Edwards Classic Annuloplasty Ring	1499	124	1968	236

SE, spin echo.



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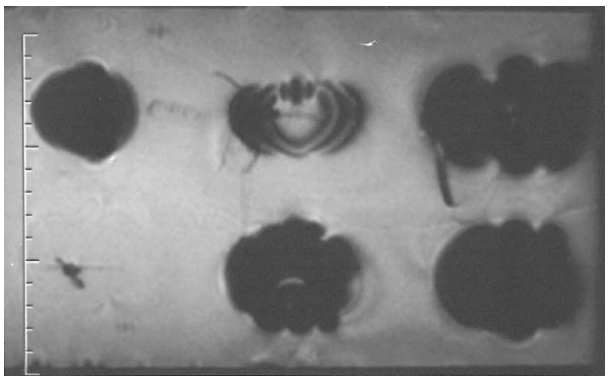

B

Figure 1. MR images showing artifacts for the heart valve prostheses and annuloplasty rings. (A) T1-weighted spin echo (TR/TE 500/20 msec) pulse sequence (imaging plane oriented through long axis of implants). Top row, left to right: Carpentier-Edwards Physio Annuloplasty Ring, Carpentier-Edwards Classic Annnuloplasty Ring, and Edwards MIRA Mechanical Valve. Bottom row, left to right: Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis and Carpentier-Edwards Low Pressure Bioprosthesis. (B) GRE (TR/TE 100/15 msec, flip angle 30 degrees) pulse sequence (imaging plane oriented through long axis of implants). Top row, left to right: Carpentier-Edwards Physiol Annuloplasty Ring, Carpentier-Edwards Classic Annuloplasty Ring, and Edwards MIEA Mechanical Valve. Bottom row, left to right: Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis and Carpentier-Edwards Low Pressure Bioprosthesis.

formed using a relatively high level of RF energy (i.e., whole body averaged specific absorption rate of 1.2 W/kg). In general, previous studies have indicated that temperature elevations measured for passive devices during MR imaging tend to be less than +1.0°C and therefore will not present hazards to patients (1,2,5–7,9,10,14). If a higher level of RF energy is used for MR imaging, additional investigation of implant heating may be warranted. However, the cooling effects of flowing blood (i.e., from convective heat less) will likely prevent excessive temperature rises from occurring for cardiovascular implants.

Artifacts

MR imaging artifacts for the heart valve prostheses and annuloplasty rings varied according to the size and type of materials used for the implants. This is primarily due to the magnetic susceptibility aspects of the respective materials, although the mass, shape, and distribution of these materials will also influence artifact size (21,22). Implants made from titanium and titanium alloy have been reported to produce smaller MR imaging than those made from Elgiloy (22). Obviously, artifacts are only problematic if the imaging area of interest is in the exact same position where the implant is located (which may be the case for cardiac MR examinations). The relative size of the artifact may be reduced for a metallic implant by proper selection of imaging parameters (e.g., such as use of a fast spin echo in comparison with a conventional spin echo pulse sequence, changing the phase and frequency encoding directions, etc.) and by other means.

CONCLUSIONS

For the three heart valve prostheses and two annuloplasty rings studied, the lack of substantial magnetic field interactions and relatively minor heating indicated that MR procedures may be conducted safely in patients with these implants using MR systems operating with static magnetic fields of 1.5 T or less. Accordingly, these implants should be considered ''MR safe'' according to the specific conditions used for testing. Notably, these findings essentially apply to 54 different heart valve prostheses and 37 different annuloplasty rings (i.e., based on the various models and sizes available for these implants).

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