Technical Note

Assessment of Magnetic Field (4.7 T) Induced Forces on Prosthetic Heart Valves and Annuloplasty Rings

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Purpose: To assess the magnetic field interactions on 11 heart valve prostheses and 12 annuloplasty rings subjected to a 4.7 T MR system.

Materials and Methods: Ex vivo testing was performed to evaluate translational and rotational forces using previously described techniques.

Results: Seventeen out of 23 prostheses showed zero interaction with the magnetic field. Translational forces with deflection angles of 2–20° were demonstrated in six prostheses. Only two heart valves and two annuloplasty rings demonstrated rotational forces. The Carpentier Edwards (CE) Physio Ring, which contains Elgiloy, demonstrated deflection angles three times greater than those previously measured at 1.5 T. Furthermore, there was a direct relationship between increasing prosthesis size and increasing translational force. All heart valve prostheses attracted to the magnetic field were slightly paramagnetic/weakly ferromagnetic.

Conclusion: Twenty-three heart valve prostheses evaluated for MRI are considered safe in static fields up to 4.7 T based on current safety criteria. However, the CE Physio Ring appeared to develop an increasing magnetism upon re-entry into the MR system. We conclude that prostheses made from Elgiloy may not be acceptable for patients in an MR environment of ≥4.7 T. Further investigations are required to confirm the safety of Elgiloy.

Key Words: heart valves; annuloplasty rings; magnetic resonance imaging; MRI safety; Elgiloy
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THE LIST OF BIOMEDICAL implants and devices continues to increase rapidly. In the United Kingdom, for example, over 30 new heart valve prostheses have been introduced in the last 2 years alone (UK Heart Valve Registry, unpublished data). Although there is considerable evidence confirming the safety of many biomedical implants exposed to magnetic resonance imaging (MRI) at low field strengths (1,2), concerns are now being raised about exposing implant patients to increasingly higher-field-strength MRI systems (3–5). Despite the need to assess whether biomedical implants can be safely exposed to high-field-strength MRI systems, relatively few implants have been evaluated at field strengths greater than 1.5 T (6–9). This study adds to data we previously published (6) and expands our knowledge about the list of biomedical implants that are considered safe to undergo MRI. We assessed magnetic field-induced forces on 11 different heart valve prostheses and 12 annuloplasty rings. In response to initial results for the Carpentier Edwards (CE) Physio Ring, we assessed a further 10 samples of the same make of annuloplasty ring at 4.7 T and 1.5 T regarding their time-dependent ferromagnetic properties.

MATERIALS AND METHODS

Heart Valve Prostheses

Twenty-three heart valve prostheses (11 heart valves and 12 annuloplasty rings) were evaluated in this study for magnetic field-induced interactions associated with a 4.7 T MR system. All of the prostheses were obtained directly from the manufacturers, had not been opened prior to this study, and had remained in their sterile packaging. Each model of prosthesis chosen had been implanted in the UK and was registered on the UK Heart Valve Registry database (10) (UK Heart Valve Registry, unpublished data). With the exception of the Carpentier Edwards Rigid Ring, the CE Physio Ring, and the Carbomedics Annuloflo Ring, which were previously tested (9,11), to our knowledge none of the other implants in this study had been evaluated at high-field strengths for MRI safety. In response to the results of the CE Physio Ring, a further 10 samples of this particular implant were evaluated (five within the 4.7 T system and five within the 1.5 T system).

Full details regarding the heart valve implants are shown in Table 1.

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Table 1
List of Heart Valves and Annuloplasty Rings Evaluated for Safety at 4.7 T

No.[a]	Valve/annuloplasty name	Valve/ring type	Site	Model	Diameter (mm)	Cage and occluder	Sewing ring/graft
1	Aspire	Porcine bioprosthesis	Mitral	M55	27	Porcine xenograft with dacron tubing	PTFE
2	Elan	Porcine bioprosthesis	Aortic	AV33/P	22	Porcine xenograft	Porcine pericardium
3	Elan Valve Graft	Porcine bioprosthesis with valve graft	Aortic	RE80/P	23	Porcine xenograft	Porcine pericardium
4	CarbonArt	Mechanical bileaflet valve graft	Aortic	AVP27/30	27	Pyrolitic carbon deposited on graphite substrate (tungsten), Ti614V (titanium, aluminium + vanadium alloy) Carbofilm™ coated (thin pyrolitic carbon)	Polyacetal resin sleeve, PTFE and PET. Carbofilm™ coated, Graft is Carbofilm™ coated PET double velour woven fabric, ultra pure collagen impregnation
5	Contegra	Pericardial bioprothesis	Pulmonary	200	18	Bovine pericardium (composite), cloth covered polypropylene rings	Bovine jugular vein
6	Freedom	Pericardial bioprosthesis	Aortic	PF	25	Bovine pericardium coated with Carbofilm™	–
7	Freestyle	Porcine bioprosthesis	Aortic	995MS	27	Porcine xenograft	Polyester
8	MØre	Pericardial bioprosthesis	Aortic	PN	19	Bovine pericardium, polyacetal resin	PET fabric coated with Carbofilm™
9	Regent	Mechanical bileaflet	Aortic	AGN-751	17	Pyrolitic carbon with 10% tungsten, MP35N (cobalt-nickel alloy)	Double velour knitted polyester fibre
10	St Jude Mechanical Valve Graft	Mechanical bileaflet with root	Aortic	CAVG	25	Pyrolitic carbon, Meadox®, Hemashield®, woven double Velour graft	Double velour polyester material
11	Toronto Root	Porcine bioprosthesis	Aortic	Root	27	Porcine treated with BiLinx™ AC	Polyester
12	AnnuloFlex	Ring	Mitral	AF800	32	–	Titanium with Biolite® carbon
13	Carpentier Edwards Rigid/ Classic	Ring	Mitral	4425	32	–	Titanium alloy with silicone rubber covered with polyester knit fabric and coated with Duraflo II
14	Carpentier Edwards Rigid/ Classic	Ring	Tricuspid	4525S	30	–	Titanium alloy with silicone rubber covered with polyester knit fabric and coated with Duraflo II
15	Carpentier Edwards Physio	Ring	Mitral	4475	32	–	Elgiloy with polyester film strips, silicone rubber covered with woven polyester cloth and coated with Duraflo II
16	Colvin	Ring	Mitral	638B	32	–	MP35-N
17	Cosgrove	Ring	Atrioventricular	4625	34	–	Silicone rubber impregnated with barium sulphate with a silicone band covered with polyester velour cloth and coated with Duraflo II
18	Duran	Ring	Mitral	H608	27	–	Dacron with radiopaque core of silicone elastomer with barium sulphate
19	Duran	Band	Tricuspid	H610	29	–	Dacron with radiopaque core of silicone elastomer with barium sulphate
20	Mitral Repair System	Ring	Mitral	MRS	38	–	Knitted PTFE with barium-impregnated silicone marker
21	Tailor	Ring	Mitral	TARN	25	–	Double velour polyester
22	Seguin	Ring	Mitral	SARP	30	–	Polyethylene with knitted polyester cuff
23	Sovering	Ring	Mitral	SB-M	34	–	Carbofilm™, silicone/PET fabric impregnated with barium sulphate

[a]Valve manufacturer (valve numbers): Edwards Lifesciences Ltd, UK (13–15, 17); Koehler Chemie, UK (1–3, 20); Medtronic Ltd, UK (5, 7, 16, 18, 19); St Jude Medical Ltd, UK (9–11, 21, 22); Sorin Biomedica Cardio S.p.A. Italy (4, 6, 8, 12, 23).

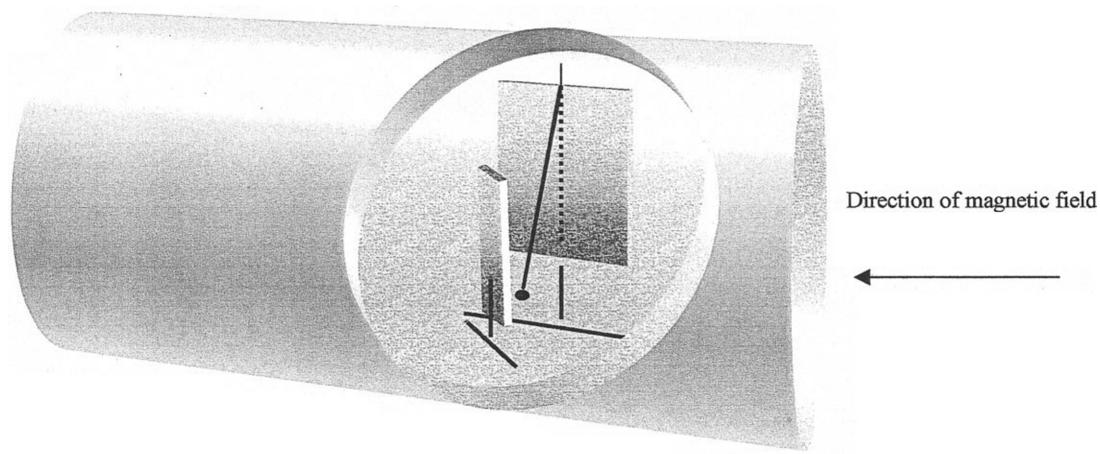

Figure 1. Diagram of the MR system and device used to measure translational and rotational forces on prosthetic heart valves (side aspect).

Assessment of Magnetic Field Interactions

An assessment of magnetically induced field interactions (i.e., translational and rotational forces) was performed on each prosthesis. A 4.7 T superconducting passively shielded MR system (Magnex, Oxford, UK) and nonferromagnetic test rig (Fig. 1) were used to assess all of the heart valve prostheses. Evaluation of the additional 10 CE Physio Rings was conducted using the same test rig (Fig. 1) and a 1.5 T actively shielded MR system (Philips Intera, Best, The Netherlands) as well as the 4.7 T Magnex MR system. Translation force (i.e., the deflection angle) was assessed using a standardized procedure (6,9,12). Each implant was attached to a piece of lightweight thread (0.3 m long) and suspended from the center of the test rig (Fig. 1). A mirror positioned at an angle of 45° to the protractor allowed the angle of deflection to be read and recorded accurately to within ±0.2°. Measurement of the translational force was conducted at the point at which the maximum gradient in the static magnetic field (4.7 T MR system) was previously determined (i.e., 5 T m^{-1} at 1.0 m from the magnet's isocenter) (6). Each implant was returned to the vertical twice, and two investigators confirmed the angle of deflection for both measurements. In the second part of the study, and with the same techniques used to assess translational force, 10 samples of the CE Physio annuloplasty ring (model 4450) were separated into two groups (five samples each) for assessment at 4.7 T or 1.5 T,[1] respectively. Each group included rings from different batches. Each annuloplasty ring was returned to the vertical three times, and two investigators confirmed the angle of deflection for each reading.

The magnetically induced deflection force exerted on each implant is given by:

$$F_m = m\ g \tan \alpha$$

where F_m is the magnetically induced deflection force due to the magnetic field spatial gradient, m is the mass of the implant, g is the acceleration due to gravity (9.81 m/s^{-2}), and α is the angle of deflection from the vertical. The sense of deflection is dependent upon whether the prosthesis is diamagnetic (negative χ) or paramagnetic (positive χ). The magnetically induced forces were then compared with the mechanical forces of a naturally beating heart to assess the potential risk of dislodgement and/or movement of the valve in vivo when in a 1.5 T or 4.7 T environment. In addition, magnetic acceleration was calculated for each prosthesis and compared with the gravitational acceleration. The magnetic acceleration is given by:

$$a_M = g \tan \alpha$$

Further assessment of the magnetic field interactions was conducted to determine magnetic field-induced torque. Although we are aware of the American Society for Testing and Materials (ASTM) test procedure for measuring torque (13), in this study we used the same test rig, procedure, and three-point qualitative scale of measurement employed in our previous study (6). This method was adopted so that we could relate the findings from both studies, assess any increases in magnetic forces between the 1.5 T and 4.7 T MR systems, and determine whether they were comparable. Each implant was oriented at 90° (parallel) and 180° (perpendicular) to the long axis of the bore in order to observe any rotation or alignment to the magnetic field (Fig. 2). Two observations were taken for each position. A three-point qualitative scale of measurement, as previously described (8), was then applied to the results as follows: 0 = zero torque; +1 = alignment or rotation of >0° to 45° from the starting position; and +2 = alignment or rotation of >45° to 90° from the starting position.

RESULTS

Table 2 presents the test results for magnetic field interactions on 23 heart valve prostheses evaluated at 4.7

[1]The 1.5 T actively shielded MR system (Philips Intera, Best, The Netherlands) had a clear bore of 0.5 m and a gradient field of 2.5 T m^{-1} occurring 1.0 m from the magnet's isocenter.

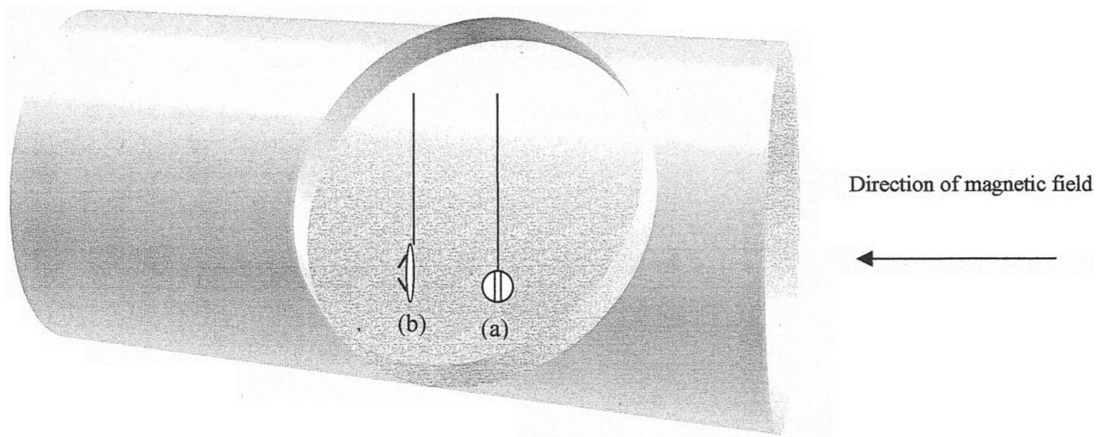

Figure 2. Diagram showing the orientation of the heart valve prostheses for measurement of the rotational forces in an MR system. The valve annulus is parallel to the magnetic field (a). The valve annulus is perpendicular to the magnetic field (b).

T. Overall, the deflection angles ranged from 0° to 22°. Seventeen out of 23 prostheses showed zero interaction with the magnetic field in terms of both translational and rotational forces. The remaining six prostheses (prostheses 9, 10, and 13–16) demonstrated some measure of interaction. Only two valves (valves 9 and 10), both of which were mechanical, demonstrated an interaction with the magnetic field deflecting by 2° and displaying a +2 measurement on our measurement scale for rotational force when oriented perpendicular to the magnetic field. Four annuloplasty rings (rings 13–16) demonstrated translational forces, but only two rings (rings 15 and 16) showed rotational force. All prostheses attracted to the magnetic field were slightly paramagnetic/weakly ferromagnetic, and all demonstrated a magnetic acceleration less than that due to gravity.

The CE Physio Ring initially deflected by 2° (Table 2). However, when the implant was placed into the MR system a second time so that any rotational forces could be measured, it reacted to a strong translational force that pulled it toward the center of the magnet. As a result of this reaction, the annuloplasty ring was twice returned to a distance of 1.0 m from the center of the MR system and the resultant angles of deflection were measured. The resultant deflection angles measured were 15° and 20° respectively. Rotational forces were also measured for both parallel and perpendicular orientations. In each instance, rotational forces were recorded only when the annuloplasty ring was perpendicular to the magnetic field.

Further testing of different samples of the CE Physio Ring revealed that without exception, all samples of the ring interacted with the magnetic field (Table 3). The five rings subjected to the 1.5 T MR system deflected by an angle of 2° with each exposure to the MR system and demonstrated a rotational force of +2 on the three-point qualitative scale when oriented perpendicular to the magnetic field. The results of the remaining five rings tested at 4.7 T showed deflection angles of 17–20°, suggesting a threefold increase in magnetically induced forces compared to 1.5 T. Furthermore, the angles of deflection recorded at 4.7 T increased with increasing implant size (Table 3).

DISCUSSION

In this study of 23 heart valve prostheses and annuloplasty rings, the translational force on the implant gave rise to deflections ranging from 0° to 20°. Rotational forces acting on the implant were apparent in only four cases and only when the implant was placed perpendicular to the magnetic field. In all four instances, the demonstrated rotational forces measured +2 on our qualitative scale of measurement (i.e., aligned/rotated between 45° and 90°). Of the six implants that reacted to the magnetic field, two were mechanical heart valves and four were annuloplasty rings. In all cases, although the implants were made from alloys recommended for use in biomedical implants, including Elgiloy (14,15), the implants interacted with the magnetic field. Thus, although these materials are intrinsically nonmagnetic, significant magnetic properties can be induced by cold-working the alloy. This may explain the apparent developing ferromagnetism of the CE Physio Ring (model 4475) at 4.7 T. However, when additional samples of this particular make and model of annuloplasty ring were tested at 1.5 T and 4.7 T, these initial results were not repeated.

A comparison of the results between tests performed at 1.5 T and 4.7 T shows variable results. Taking into account the prostheses' susceptibility and the fact that the gradient of magnetic field variation in the 4.7 T magnet is twice that in the 1.5 T magnet, one would expect the magnetic forces to be in the ratio of 6.3 to 1. An inspection of Table 3 shows that this is indeed correct when one compares annuloplasty rings 2–5 with 8–10. However, rings 6 and 7 had a lower magnetic moment by a factor of 2, which is consistent with having half the amount of magnetic material (by weight). The only result that is not consistent is the measurement of ring 1. However, we hypothesize that because the ring is light and the measurement was taken at the lower field strength, the lower deflection results in a larger experimental error.

Tables 2 and 3 show that all of the heart valve implants fall well within currently defined safety limits (16), and that the resultant magnetic forces exerted on

Table 2
Magnetic Forces Acting on Heart Valves and Annuloplasty Rings at 4.7 T

No.	Valve/ring	Site	Diameter (mm)	Deflection (degrees)	Torque (parallel)[a,b]	Torque (perpendicular)[b,c]	Weight (g)	Magnetic force (N)	Magnetic acceleration (m/s^{-2})	Mechanical forces of beating heart (N)
Heart valves										
1	Aspire	Mitral	27	0	0	0	4.94	0	0	6.9–10.7
2	Elan	Aortic	22	0	0	0	3.49	0	0	3.5–4.3
3	Elan valve graft	Aortic	23	0	0	0	6.23	0	0	3.9–4.7
4	CarbonArt	Aortic	27	0	0	0	11.67	0	0	5.3–6.5
5	Contegra	Pulmonary	18	0	0	0	3.94	0	0	0.7–1.0
6	Freedom	Aortic	25	0	0	0	2.59	0	0	4.6–5.6
7	Freestyle	Aortic	27	0	0	0	8.31	0	0	5.3–6.5
8	Møre	Aortic	19	0	0	0	2.25	0	0	2.6–3.2
9	Regent	Aortic	17	2	0	+2	1.23	1.9×10^{-4}	0.3	2.1–2.6
10	St Jude Mechanical Valve Graft	Aortic	25	2	0	+2	5.55	2.1×10^{-3}	0.3	4.6–5.6
11	Toronto Root	Aortic	27	0	0	0	8.93	0	0	5.3–6.5
Annuloplasty rings/bands										
12	AnnuloFlex	Mitral	32	0	0	0	0.98	0	0	9.6–15.0
13	Carpentier Edwards Classic/ Rigid	Mitral	32	2	0	0	1.72	5.9×10^{-4}	0.3	9.6–15.0
14	Carpentier Edwards Classic/ Rigid	Tricuspid	30	2	0	0	1.68	5.7×10^{-4}	0.3	1.9–2.8
15	Carpentier Edwards Physio (a)	Mitral	32	2	0	+2	1.91	6.5×10^{-4}	0.3	9.6–15.0
15	Carpentier Edwards Physio (b)	Mitral	32	15	0	+2	1.91	5.0×10^{-3}	2.6	9.6–15.0
15	Carpentier Edwards Physio (c)	Mitral	32	20	0	+2	1.91	6.8×10^{-3}	3.7	9.6–15.0
16	Colvin-Galloway	Mitral	32	5	0	+2	0.58	5.0×10^{-3}	0.9	9.6–15.0
17	Cosgrove	Atrioventricular[d]	34	0	0	0	0.95	0	0	10.9–16.9[e] 2.4–3.6[f]
18	Duran (ring)	Mitral	27	0	0	0	0.45	0	0	6.9–10.7
19	Duran (band)	Mitral	29	0	0	0	0.38	0	0	7.9–12.3
20	Mitral Repair System	Mitral	38	0	0	0	0.91	0	0	13.6–21.1
21	Tailor	Mitral	25	0	0	0	0.80	0	0	5.9–9.1
22	Seguin	Mitral	30	0	0	0	1.11	0	0	8.5–13.2
23	Sovering	Mitral	34	0	0	0	0.74	0	0	10.9–16.9

[a]Parallel to the magnetic field.
[b]Scale of measurement: 0, zero torque; +1 = alignment or rotation of >0° to 45° from starting point; +2 = alignment or rotation of >45° to 90° from starting point.
[c]Perpendicular to the magnetic field.
[d]Atrioventricular - the implant can be used in either the mitral or tricuspid sites.
[e]The force in Newtons for the mitral site.
[f]The force in Newtons for the tricuspid site.

each heart valve prosthesis were significantly smaller than the mechanical forces exerted by the beating heart and gravity (6). Although six prostheses demonstrated an interaction with magnetic rotational forces, it is not anticipated that these will pose a hazard or risk to the patient because each prosthesis is held in place by multiple sutures that become endothelialized after 6–8 weeks. Research suggests that the forces required to cause sutures securing a heart valve in place to pull out of the surrounding annulus tissue are at least two to three times greater than the mechanical forces associated with the beating heart (UK Heart Valve Registry unpublished data), which in turn are significantly greater than the magnetically induced forces associated with exposure in a 4.7 T MRI system (6).

The potential hazards caused by the Lenz effect were not considered in this study. However, studies undertaken thus far (17,18) have theorized that the Lenz effect will pose a hazard to the patient because as he/she is moved through the static magnetic field, the

Table 3
Magnetic Forces Acting on 10 Samples of the Carpentier Edwards Physio Annuloplasty Ring at 1.5 T and 4.7 T*

No.	Site	Model	Diameter (mm)	Serial no.	Translation forces, deflection (degrees) readings			Rotational forces: Torque (parallel)[a,b] readings			Rotational forces: Torque (perpendicular)[c] readings			Weight (g)	Magnetic Force (N)	Magnetic acceleration (m/s^{-2})	Force beating heart (N)
					1	2	3	1	2	3	1	2	3				
Philips Intera (Best) 1.5 T MR System																	
1	Mitral	4450	26	368028	2	2	2	0	0	0	+2	+2	+2	0.90	3.1×10^{-3}	0.34	6.4–9.9
2	Mitral	4450	38	348274	2	2	2	0	0	0	+2	+2	+2	1.87	6.4×10^{-4}	0.34	13.6–21.1
3	Mitral	4450	38	348275	2	2	2	0	0	0	+2	+2	+2	1.87	6.4×10^{-4}	0.34	13.6–21.1
4	Mitral	4450	40	352652	2	2	2	0	0	0	+2	+2	+2	2.00	6.8×10^{-4}	0.34	15.0–23.4
5	Mitral	4450	40	354663	2	2	2	0	0	0	+2	+2	+2	2.00	6.8×10^{-4}	0.34	15.0–23.4
Magnex (Oxford) 4.7 T MR System																	
6	Mitral	4450	26	368026	17	17	17	0	0	0	+2	+2	+2	0.90	30.0×10^{-4}	3.0	6.4–9.9
7	Mitral	4450	26	368027	17	17	17	0	0	0	+2	+2	+2	0.90	30.0×10^{-4}	3.0	6.4–9.9
8	Mitral	4450	38	348276	19	19	19	0	0	0	+2	+2	+2	1.87	63.1×10^{-4}	3.4	13.6–21.1
9	Mitral	4450	40	352645	20	20	20	0	0	0	+2	+2	+2	2.00	71.3×10^{-4}	3.6	15.0–23.4
10	Mitral	4450	40	352649	20	20	20	0	0	0	+2	+2	+2	2.00	71.3×10^{-4}	3.6	15.0–23.4

*The original Carpentier Edwards Physio ring was also re-tested. The translation forces recorded were: (i) 25°, (ii) 27° and (iii) 29°. Rotational forces displayed were 0 when the ring was placed parallel to the magnetic field and +2 when the ring was placed perpendicular to the magnetic field.
[a]Parallel to the magnetic field.
[b]Scale of measurement: 0 = zero torque; +1 = alignment or rotation of >0° to 45° from the starting point; +2 = alignment or rotation of >45° to 90° from the starting point.
[c]Perpendicular to the magnetic field.

moving parts of the heart valve prosthesis (i.e., the occluder (leaflets, disc, or ball)) create their own magnetic field that acts against the original magnetic field. While we acknowledge that such hazards may occur, we focused our evaluation on the magnetic field-induced forces that act on the static parts of the heart valve (i.e., the sewing ring and casings), rather than on the valve flap.

CONCLUSIONS

In conclusion, the 11 heart valve prostheses and 12 annuloplasty rings evaluated for MR safety at 4.7 T all fall within current safety parameters (deflection angles ≤45°) and are therefore considered compatible with the safe use of MR systems with static fields up to 4.7 T. However, the CE Physio Ring, which contains Elgiloy, appears to have a significantly smaller margin of safety at 4.7 T compared to the other implants. These findings are supported by other authors who evaluated the reaction of aneurysm clips made from Elgiloy and exposed ex vivo to strengths ≥3.0 T, and noted significant interactions with the magnetic field (7,9,19). Furthermore, we noted that this particular annuloplasty ring appeared to develop an increasing magnetism upon reentry into the MR system. We conclude that prostheses made from Elgiloy may, depending on their size and mass, pose a risk for patients within a static field of ≥4.7 T. We recommend that implants made from Elgiloy be used with caution until the safety of this alloy can be confirmed.

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