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The use of 7 Tesla (T) magnetic resonance imaging (MRI) is expanding across medical specialties, particularly, clinical neurosciences and orthopedics. Investigational 7 T MRI has also been performed in cardiology. A limiting factor for expansion of the role of 7 T, irrespective of the body part being imaged, is the sparse testing of biomedical implant compatibility at field strengths >3 T. Implant compatibility can be tested following the American Society for Testing and Materials International guidelines. To assess the current state of cardiovascular implant safety at field strengths >3 T, a systematic search was performed using PubMed, Web of Science, and citation matching. Studies written in English that included at least 1 cardiovascular-related implant and at least 1 safety outcome (deflection angle, torque, or temperature change) were included. Data were extracted for the implant studied, implant composition, deflection angle, torque, and temperature change, and the American Society for Testing and Materials International standards were followed. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses reporting guidelines for scoping reviews were followed. A total of 9 studies were included. A total of 34 cardiovascular-related implants tested ex vivo at 7 T and 91 implants tested ex vivo at 4.7 T were included. The implants included vascular grafts and conduits, vascular access ports, peripheral and coronary stents, caval filters, and artificial valves. A total of 2 grafts, 1 vascular access port, 2 vena cava filters, and 5 stents were identified as incompatible with the 7 T MRI. All incompatible stents were 40 mm in length. Based on the safety outcomes reported, we identify several implants that may be compatible with >3 T MRI. This scoping review seeks to concisely summarize all the cardiovascular-related implants tested for ultrahigh field MRI compatibility to date. **(Am J Cardiol 2023;201:239−246)**

Magnetic resonance (MR) imaging (MRI) is a valuable tool to assess soft tissues, including the heart, because it provides a high resolution, a high tissue contrast, and the ability to obtain functional information.[1] Clinical MRI is largely limited to 1.5 and 3 Tesla (T). Systems with magnetic field strengths >3 T are called ultrahigh field (UHF). Substantial data have demonstrated that exposure to static magnetic fields up to 8 T is a nonsignificant risk to humans; thus, the Food and Drug Administration (FDA) has authorized the use of MRI up to 8 T in research settings and limited clinical scenarios.[2−5] The approved clinical uses of UHF MRI are for the brain and knee. Experimental applications for UHF MRI are emerging within cardiology, including enhanced visualization of the myocardial wall and valve cusp motion, noninvasive tissue characterization, and improved MR angiography.[6−10] A barrier to routine clinical use of UHF MRI across medical specialties is that biomedical implants, including cardiovascular-related implants, are insufficiently tested beyond 3 T. Thus, implants are a common contraindication to MRI at or higher than 3 T, limiting the population for research and patient utilization of UHF MRI.[6,11] Biomedical implants, such as prosthetic valves and intracoronary stents, can cause serious complications if the implant experiences excessive torque or temperature change in the MRI environment.[12,13] In an effort to avoid iatrogenic injuries, the FDA requires devices to be labeled as MR safe, MR unsafe, or MR conditional.[12,13] Implant MRI safety is logged in registries, such as *mrisafety.com*. Implants classified as MR safe do not contain metallic, magnetic, or electrically conductive materials, and implants classified as MR unsafe are dangerous in the MRI environment. MR conditional implants are safe only in specified MR settings. Many common cardiovascular-related implants are classified as MR conditional and lack documented safety testing (*mrisafety.com*). Standardized testing methods to determine implant safety are outlined by the American Society for Testing and Materials

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International (ASTM).[14] The types of safety concerns that require evaluation include magnetic forces, torques, and heating. Although heating can only occur in areas exposed to the radiofrequency or gradient magnetic fields, magnetic forces and torques can be experienced throughout the MRI scanner and its fringe field. Thus, it is important that the implants routinely used in all medical specialties undergo safety testing. In this review, we summarize the cardiovascular-related implants tested for safety at 4.7 and 7 T MRI. Although 4.7 T MRI is primarily used in preclinical research settings, the results were included because they may be relevant for future safety testing initiatives.

Methods

A systematic literature search was performed. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines for scoping reviews were followed. This review was not registered. An a priori search protocol can be obtained upon request to the corresponding author. The searches were performed using PubMed and Web of Science. We included all study designs, except reviews or meta-analyses. The databases were searched on October 2, 2022 and applicable articles written in English were included if published on or before October 2, 2022. The search terms included 7 T MRI, 4.7 T MRI, safety, radiofrequency heating, surgical implants, displacement, deflection angle, metal implant, stent, intravascular coil or filter, clamp, valve, pacemaker, implantable cardiac defibrillators (ICDs), and defibrillator. The search terms were combined using Boolean operators. After removing duplicates, the articles were included if at least 1 cardiovascular-related implant was tested at 4.7 or 7 T MRI and at least 1 safety outcome (temperature change, torque, or deflection angle) was reported. We included human participant and phantom assessments. Each article was independently screened by 2 authors.

The data were collected independently by 2 authors and combined. The included devices were categorized by their function and the MRI field strength and included grafts and conduits, vascular access ports, vascular stents, coronary artery stents, and caval filters.

The safety outcomes studied were radiofrequency-induced temperature change,[15] torque,[16] and deflection angle.[16] The explanations of each parameter have previously been summarized and are briefly described here.[17] Temperature change can cause injury and is recommended to be no more than 1°C.[13,18,19] The torque and deflection angle are measures of rotational and translational force, respectively.[12,13]

Results

We identified 9 records that met our inclusion criteria (Figure 1).[19–27] The included studies are listed in Tables 1 and 2. In total, we studied 125 unique implants consisting of grafts and conduits, vascular access ports, vascular stents, coronary artery stents, and caval filters (Tables 1 and 2). A total of 34 implants were tested at 7 T, and 91 implants were tested at 4.7 T. All implants were assessed in the phantom models.

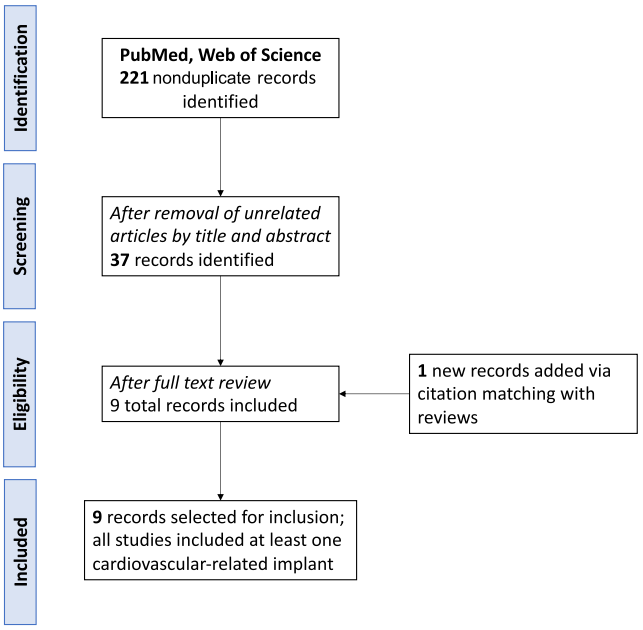

Figure 1. PRISMA diagram illustrating search strategy.

Vascular grafts and conduits: 6 grafts and 1 conduit were tested at 7 T, according to ASTM standards.[19,20] All grafts were of the same composition. A total of 2 grafts exceeded the safe deflection angle (<45°). Torque and unsafe increases in temperature were not observed in any grafts or conduits.

Vascular access ports: 2 vascular access ports were evaluated for deflection angle and torque at 7 T according to the ASTM standards.[19] The Celsite port (B. Braun, Bethlehem, PA), classified as MR conditional at 3 T, did not exceed the safety parameters. The Port-A-Cath system (SIMS Deltec, Saint Paul, MN), however, displayed significant translation force (deflection angle 90°) and significant torque and exceeded the safety parameters.

Vascular stents: 21 stents were tested at 7 T and 1 at 4.7 T, according to the ASTM standards.[19,21,23,24] No stent exceeded a safe deflection angle. Torque was only tested in 2 implants without adverse findings. A total of 4 stents exceeded the 1°C temperature increase. Ansems et al[23] evaluated 20 vascular stents of varying lengths and found that temperature increases peaked at stent lengths of 40 mm.

Caval filters: 3 vena cava filters were tested at 7 T for deflection angle and torque, according to the ASTM standards. The 2 VenaTech (B. Braun, Bethlehem, PA) filters are classified as MR conditional at 3 T (*mrisafety.com*). The filter composed of Conichrome (Cook Medical, Bloomington, IN) did not exceed the safety parameters; however, the filters composed of cobalt-chromium-nickel alloy exceeded the deflection angle parameters. A total of 2 filters did not exceed the deflection angle parameters at 4.7 T.

Coronary artery stents: a total of 3 stents were tested at 7 T.[19,20,22] A total of 2 stents did not exceed the safety parameters, but the stent composed of cobalt-chromium exhibited a 5.7-°C temperature change at its tip.

Prosthetic valves: D'Avenio et al[25] tested 3 prosthetic heart valves at 4.7 T and found that the force equivalent of

Table 1
Cardiovascular-related implants studied at 7T

Record	Implant(s) tested (manufacturer, material)	Model utilized	ASTM guidelines satisfied	Deflection angle (degrees)	Torque	Temperature change (°C)
Vascular Grafts and Conduits						
Feng et al., 2015[20]	Zenith Flex® AAA Endovascular Graft Bifurcated Main Body Graft G48409 (Cook Medical, Polyester fabric sewn to stainless steel)*	Implant suspended on string; saline gel phantom (used in heating experiments)	F2052-06 F2213-06 F2182-11a	90	–	–
	Zenith Flex® TAA Endovascular Graft with ProForm G53422 (Cook Medical, Polyester fabric sewn to stainless steel)			2	No torque†	–
	Zenith Flex® AAA Endovascular Graft Bifurcated Main Body Graft G48406 (Cook Medical, Polyester fabric sewn to stainless steel)			0	No torque†	0.14
	Zenith Flex® TAA Endovascular Graft with ProForm G53418 (Cook Medical, Polyester fabric sewn to stainless steel)*			90	–	–
	Zenith Flex® TAA Endovascular Graft with ProForm G53433 (Cook Medical, Polyester fabric sewn to stainless steel)			3	No torque†	–
	GORE PROPATEN® Vascular Graft (Cook Medical, Polyester fabric sewn to stainless steel)			1	No torque†	–
Dula et al., 2014[19]	corVCD conduit coupling device (corlife)	Implant suspended on string	F2052-06 F2213-06	7	No torque†	–
Vascular Access Ports						
Dula et al., 2014[19]	Celsite (B. Braun)	Implant suspended on string	F2052-06	1	No torque†	–
	Port-A-Cath (SIMS Deltec)*		F2213-06	70	Strong torque†	–
Vascular Stents						
Ansems et al., 2012‡,[23]	Abbott Vascular RX Acculink: 20 mm, 40 mm (2)	Implant suspended on string; phantom (used in heating experiments)	F2052-06 F2128-11	<33 for all implants tested	–	0.7, 0.4, 0.7, respectively
	Abbott Vascular Xact Carotid Stent: 20 mm, 40 mm (2)*					0.6, 1.2, 1.9, respectively
	BS Adapt™ Monorail™: 32 mm, 40 mm*					0.5, 1.3, respectively
	BS Carotid Wallstent Monorail 24 mm					0.4
	Cordis Precise: 20 mm (2), 40 mm (2)*					0, 0.5, 0.8, 1.6, respectively
	Ev3 Protege RX: 40 mm, 60 mm					0.7, 0.3, respectively
	EV3 Protege Everflex 100 mm					0.1
	Invatec Maris 80 mm					0.2
	Invatec Scuba 30 mm					0.4
Dula et al., 2014[19]	Luminexx (Bard Peripheral Vascular)	Implant suspended on string	F2052-06	6	No torque†	–
	Valeo biliary Y stent (Bard Peripheral Vascular)		F2213-06	6	No torque†	–

(*continued on next page*)

Table 1 (***Continued***)

Record	Implant(s) tested (manufacturer, material)	Model utilized	ASTM guidelines satisfied	Deflection angle (degrees)	Torque	Temperature change (˚C)
Van Speybroeck et al., 2021[21]	Iliac stent (Cordis, nitinol)	Implant suspended on string	F2052-15	5	–	–
Caval Filters						
Feng et al., 2015[20]	G2 Vena Cava Filter G21360 (Cook Medical, Conichrome)	Implant suspended on string	F2052-06 F2213-06	5	No torque†	–
Dula et al., 2014[19]	VenaTech LP vena cava filter (B. Braun, cobalt-chromium-nickel alloy)*	Implant suspended on string	F2052-06 F2213-06	49	Strong torque†	–
	VenaTech LGM vena cava filter (B. Braun, cobalt-chromium-nickel alloy)*			48	Strong torque†	–
Coronary Artery Stents						
Feng et al., 2015[20]	Filter inserted into stent (Cook Medical, stainless steel)	Implant suspended on string; phantom (used in heating experiments)	F2052-06 F2213-06 F2182-11a	5	No torque†	-0.16
Dula et al., 2014[19]	TMR coronary artery stent 4 × 28 mm (Biocore Biotechnologia)	Implant suspended on string	F2052-06 F2213-06	10	Moderate torque†	–
Winter et al., 2014[22]	PRO-Kinetic Energy Cobalt Chromium Coronary Stent System 4 × 40 mm (Biotronik)*	Saline gel phantom	F2182-11a	–	–	Maximum increase of 5.7 ˚C observed at stent tip

* Implant not compatible with 7T MRI based on one or more safety parameter.

† Torque was reported qualitatively where 0 – no torque, 1 – mild or low torque, 2 – moderate torque, 3 – strong torque, and 4 – severe torque. No torque to moderate torque was considered compatible.

‡ Two implants tested were not reported due to inconsistency in stent length reporting. Diameters of stents were not reported. (2) Denotes stents of the same length tested twice, likely due to differences in diameter.

Table 2
Cardiovascular-related implants studied at 4.7T

Record	Implant(s) tested (manufacturer, material)	Model utilized	ASTM guidelines satisfied	Deflection angle (degrees)	Torque	Temperature change (˚C)
Vascular Stents and Caval Filters						
Teitelbaum et al., 1988[24]	Amplatz vena cava filter (Cook Medical, MP32N alloy)	Implant suspended on string	F2052-06	0	–	–
	Cragg nitinol spiral filter			0		
	Maass helical vena cava filter (Medinvent, Mediloy surgical steel)			0		
	Mobin-Uddin vena cava/umbrella filter (American Edwards, Elgiloy and heparinized silicone)			0		
	Maass helical endovascular stent (Medinvent, Mediloy surgical steel)			0		
Prosthetic Valves						
D'Avenio et al., 2007[25]	Bileaflet prosthetic heart valve 27 mm (pyrolitic carbon)	Implant suspended on copper wire	–	–	$(2.3 \pm 0.2) \times 10^{-5}$ N•m	–
	Bileaflet prosthetic heart valve 29 mm				$(1.5 \pm 0.2) \times 10^{-6}$ N•m	
	Monoleaflet prosthetic heart valve 25 mm				$(1.12 \pm 0.2) \times 10^{-5}$ N•m	
Edwards, et al., 2002[27]	60 aortic or mitral mechanical, porcine, human tissue prosthetic valves	Implant suspended on string	F2052-00:1-5 F2213-02	0 to 7.5	12 valves exhibited no torque 15 valves exhibited rotation of 0˚ to <45˚* 8 valves exhibited rotation >45˚*	–
Edwards, et al., 2005[26]	23 mechanical or porcine prosthetic valves or annuloplasty rings	Implant suspended on string	F2052-00:1-5 F2213-02	0 to 22	17 valves/rings exhibited no torque 6 valves/rings exhibited rotation >45˚*	–

Eighty-three heart valves and annuloplasty rings have been previously tested at 4.7 T and summarized by Edwards et al., 2002[27] and 2005.[26] For brevity, the implants are not individually listed here.
* Implant interaction with the magnetic field was considered unlikely to cause adverse effects by the authors.

torque does not exceed the force of a beating heart. Edwards et al[26,27] tested 83 heart valves and annuloplasty rings at 4.7 T. The deflection angle ranged from 0° to 22°, and 29 of the valves/rings exhibited rotational forces. However, the rotational forces exerted on the valve by the MR environment were significantly less than those exerted by the beating of the human heart.

Discussion

Applications for UHF MRI are becoming increasingly common throughout medicine, especially for cardiovascular disease,[6] clinical neuroscience applications,[28,29] and orthopedics.[30] The availability of 7 T MRI has also increased, with over 80 7 T MR systems worldwide.[4] However, 7 T MR systems are not routinely used in clinical practice because their regulatory clearance was obtained only recently and because of cost and implant safety concerns. FDA-approved clinical uses of 7 T proton MRI include the brain and knee.[3] 7 T MRI carries a similar reimbursement rate as 1.5 or 3 T scans, despite a higher cost of equipment.[30] Biomedical implants also carry a significant risk in the MR environment. Implants not compatible with UHF MRI can dislodge,[31,32] permanently dysfunction,[33,34] and cause thermal injury.[35]

There has been limited safety testing of cardiovascular-related implants for magnetic field strengths higher than 3 T. In this review of 9 studies, we identified 34 implants tested at 7 T and 91 implants tested at 4.7 T. All but 1 study reported following at least 1 ASTM testing guideline. The deflection angle and torque were most commonly reported, with few studies reporting temperature change. Temperature change is a critical safety variable because severe injuries have occurred, and large temperature increases have been documented previously.[36] Based on the safety measures reported, no implant was identified as incompatible with 4.7 T MRI; however, 2 grafts, 1 vascular access port, 2 vena cava filters, and 5 stents were identified as incompatible with 7 T MRI. All stents that exceeded >1-°C temperature increase were 40 mm in length.[22,23] Stents 60 to 100 mm in length did not exhibit heating >1°C.[23] Previous studies found continual increases in heating as stent length increases (up to 180 mm) at 1.5 T, whereas peak heating occurred at a stent length of approximately 100 mm at 3 T.[37] The stent length at which peak heating occurs is expected to decrease as the field strength increases. The temperature differences noted here may also be attributed to the heterogeneity in material composition, stent indication, and vendor. The temperature change owing to the MRI environment may also differ in an in vivo model where blood is continually flowing through the stent.[35] Further studies investigating the temperature changes at 7 T MRI of cardiovascular-related implants are recommended.

A total of 3 implants, the Port-A-Cath and B. Braun vena cava filters, experienced strong torque, as revealed by a rapid and forceful alignment with the magnetic field. Implants with strong torque also displayed an unsafe deflection angle, further showing their incompatibility at 7 T. Several heart valves tested at 4.7 T also experienced torque; however, it was likely moderate because the valves were described as gradually aligning with the magnetic field, though a more forceful and rapid alignment may be seen at higher field strengths. All implants were suspended on a string and their alignment with the field were assessed. Clearly, the movement and stability of the implanted valve are likely different when sutured and incorporated into the tissue. As such, different behavior may be seen in vivo. Animal models will likely better represent an implant's response to MR exposure; however, precise measurements of an implant's torque and temperature change may be more difficult to obtain.

Limited reports of cardiovascular implants imaged in humans at 7 T have been published. Noureddine et al[38] imaged the brains of 2 patients, 1 with a femoral artery stent and the other with a Y-stent and coronary artery stent. No adverse outcomes or side effects were observed; however, the stents were composed of nonferromagnetic material and were located 15 cm or further from the exposure volume of the head coil. The German Ultrahigh Field Imaging national network has recommended that passive implants considered MR conditional at 3 T and not containing ferromagnetic materials may be safely imaged at 7 T if located a sufficient distance from the radiofrequency coil.[39] Under this recommendation, more implants may be safely imaged; however, the distance from the radiofrequency coil must be determined on an individual basis.

A major discrepancy between 4.7 T and 7 T testing was the lack of valve testing reported at 7 T. A total of 86 valves and annuloplasty rings were tested at 4.7 T, and the deflection angle and torque were reported within safe limits.[26,27] The valves tested were labeled as MR safe or MR conditional at 3 T. Given the high volume of valve replacements performed in the United States, it is recommended that the valves labeled MR conditional undergo safety testing at 7 T.[40] ICDs were also not tested at 4.7 T nor 7 T. Although some systems are labeled MR conditional at 1.5 or 3 T, many patients still have a "legacy" system, which are not labeled for safety and are thus contraindicated.[41] A large prospective study imaged various body regions of patients with legacy systems at 1.5 T and found that a power-on reset occurred in approximately 1 in 200 examinations.[41] A power-on reset can disrupt device function and necessitated a replacement of 1 device in the study. It is unknown if higher strength MR fields would increase the number of power-on resets or cause other side effects. Further study is recommended. In addition, MRI studies of increasingly common occlusive devices, such as those used for atrial septal devices, were noticeably absent from past studies altogether.

To be included, a study must have reported 1 or more safety variables. Many studies did not report all 3 safety variables, limiting the information available about an implant's behavior in the MR environment. As such, generalized statements for MR compatibility cannot be made. Studies were also performed in phantoms, as required by the ASTM guidelines; however, a different behavior may occur in in vivo models owing to the differences in fixation, blood flow, and tissue composition. Lastly, this study did not evaluate the image artifacts caused by implants. Artifacts have been observed for tested implants and may decrease the accuracy of imaging near the implant.[20]

The use of 7 T MRI for cardiovascular pathology is not routine; however, pilot studies have demonstrated its efficacy.[1,8,42,43] The assessment of global cardiac function and myocardial wall motion is improved owing to the greater contrast between blood and myocardium seen with UHF MRI.[6] Investigations of aortic flow parameters at 7 T have shown mixed results.[44,45] Tissue characterization and quantification of intramyocardial hemorrhage after myocardial infarction have also been studied.[46–48] Vascular applications of 7 T MRI have been primarily related to the brain and were previously summarized by Rutland et al.[29]

This review summarizes the cardiovascular-related implants tested for 4.7 T and 7 T compatibility. We identify several implants that did not exceed the tested safety parameters and may be compatible with field strengths >3 T. Importantly, not every implant was tested for translational force, rotational force, and temperature change. For future testing, we recommend following the ASTM guidelines and thoroughly reporting deflection angle, torque, and temperature change. ICDs, prosthetic valves, and occlusive devices are also recommended for UHF MR compatibility testing.

It should be noted that this was a scientific review, and there may be discrepancies between the safety information provided here and institutional policies and future safety recommendations. As such, all providers are strongly encouraged to review their local policies when selecting patients for 7 T MRI.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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