Neurosurgical implant safety in 7 T MRI: a scoping review

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Neurosurgical Implant Safety in 7 T MRI: A Scoping Review

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The use of 7 Tesla (T) magnetic resonance imaging (MRI) is expanding across neurosurgical and neurologic specialties. However, few neurosurgical-related implants have been tested for safety at 7 T, limiting its use in patients with cranial fixation, shunt placements, and other implants. Implant safety can be determined via the American Society for Testing Materials International (ASTM) guidelines. To assess the current state of neurosurgical implant safety at 7 T, a systematic search was performed using PubMed, MEDLINE, Web of Knowledge, and citation matching. Studies written in English that included at least one neurosurgical implant and at least one safety outcome were included. Data were extracted for implant studied, implant composition, deflection angle, torque, temperature change, and ASTM guidelines followed. PRISMA reporting guidelines for scoping reviews were followed. Overall, 18 studies consisting of 45 unique implants were included. Implants included cranial fixation devices, aneurysm clips, spinal rods, pedicle screws, ventriculoperitoneal (VP) shunts, deep brain stimulation devices, and electroencephalogram (EEG) caps and electrodes. Cranial fixation devices, deep brain stimulation devices, spinal rods, and pedicle screws are likely 7 T MRI compatible based on outcomes reported. Aneurysm clips and EEG devices had variable safety outcomes. The VP shunts studied lost functionality after 7 T MRI exposure. We identified several implants that are likely compatible with 7 T MRI. Given the growth in 7 T imaging and expansion of the technology, neurosurgical implants should be constructed with the aforementioned considerations. Caution must be taken with all implants, especially aneurysm clips, programmable VP shunts, and EEG recording devices. It is also noteworthy that several implant testing reports did not report following ASTM standards. This scoping review seeks to concisely summarize all neurosurgical-related implants that have been tested for safety in 7 T MRI.
Evidence Level: 2
Technical Efficacy: Stage 2

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The use of 7 Tesla (T) magnetic resonance imaging (MRI) of the brain has increased due to its ability to noninvasively characterize neoplasms[1] and differentiate cerebral microbleeds and vasculature.[2,3] Additionally, 7 T MRI offers an increased signal-to-noise ratio enabling greater spatial resolution, spectral resolution, and enhanced molecular data compared to 3 T scanners.[1] Ultra-high-field (UHF) MRI (7 T or greater) is becoming increasingly common in research and clinical settings.

UHF MRI use in patients with biomedical implants is limited by the lack of safety testing available for MRI strength beyond 1.5 or 3 T. Additionally, UHF imaging is approved for clinical usage by the Food and Drug Administration (FDA), but its use does not garner higher reimbursement rates by health insurance.[4,5] With increased static magnetic field strength, caution must be taken as implants not suitable for MRI can cause radiofrequency (RF) heating burns and projectile effects, and devices can become incapacitated due to the magnetic field.[6–8] Without this safety testing, many patients are denied 7 T MRI scans, reducing clinical and research discovery.[9] This is especially impactful for neurosurgery patients as implants are used extensively in neurosurgery, and patients undergoing neurosurgery are often target populations of 7 T imaging research. For example, patients

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undergoing a tumor resection and subsequent cranioplasty require fixation with plates, screws, and mesh. Additionally, programmable ventriculoperitoneal (VP) shunts are common in patients with chronic hydrocephalus, and spinal surgery frequently utilizes screws, rods, and other fixation devices.

Given the potential complications of imaging implants and past MRI-related injuries, there are guidelines for device labeling and parameters for RF heating, translational force, and torque.[6,10,11] American Society for Testing and Materials (ASTM) International and the American College of Radiology utilize the following labeling for implants: MR Safe identifies an object safe in any MRI setting, MR Unsafe identifies an object contraindicated in any MRI setting, and MR-conditional identifies an object that is only safe in certain MRI settings.[9,10] For example, many titanium aneurysm clips are labeled MR-conditional and safe only in 3 T or weaker fields; other clips are labeled MR-conditional, but only at 1.5 T fields[12] (mrisafety.com). Other common neurosurgical implants, such as burr hole covers, meshes for cranial plating, cranial screws, intracranial stents, intracranial pressure monitoring catheters, and intracranial electrodes, do not have documented safety testing at 7 T (mrisafety.com). Only implants labeled as MR Safe can be imaged at 7 T; this can include implants made of silicone, plastic, or other materials known to be safe in the MR environment.

Many neurosurgical implants have undergone some degree of safety testing at 7 T MRI. Safety testing of biomedical implants will reduce the number of contraindications for 7 T MRI expanding its use in neurosurgical patient populations. This systematic review seeks to concisely summarize neurosurgery-related implants tested at 7 T MRI, conformity with ASTM standards, and the results of safety testing. Our scoping review will further allow future manufacturers of medical devices to consider specific design constraints, such as materials and prior testing, to ensure devices are compatible with this emerging technology.

Materials and Methods

No IRB approval was necessary nor sought for this study. A systematic search was performed. PRISMA reporting guidelines for scoping reviews was followed. This review was not registered. A priori search protocol can be obtained upon request to the corresponding author. Searches were performed using PubMed, MEDLINE, and Web of Knowledge. We included all study designs, except reviews or meta-analyses. Databases were searched on July 14, 2022 and applicable articles written in English were included if published on or before July 14, 2022. Search terms included 7 T MRI, safety, radiofrequency heating, spinal implants, neurosurgical implants, VP shunts, aneurysm clips, and electrodes. Search terms were combined utilizing Boolean operators. While not implantable, electroencephalogram (EEG) caps and electrodes were included due to the potential use in functional MRI studies at 7 T. After removing duplicates, full-text articles were included if at least one neurosurgery-related implant was tested at 7 T MRI and at least one safety outcome (temperature change, torque, or deflection angle) was reported. We included human and phantom subjects testing. Each article was independently screened by two authors.

Data Collection

Data were collected independently by two authors and synthesized using a spreadsheet. Included devices were categorized by function (cranial fixation devices, aneurysm clips, spinal rods, pedicle screws, VP shunts, deep brain stimulation [DBS] devices, and EEG caps and electrodes) and neurosurgical procedure (cranioplasty, cerebrovascular, spinal, shunts, and functional).

Safety Outcomes

Safety outcomes studied were RF-induced temperature change,[13] torque,[14] and deflection angle.[15] The deflection angle served as a measure of translational force. The spatial magnetic field can pull ferromagnetic objects toward the isocenter of the MRI scanner causing injury to the patient or imaging staff.[9] When the deflection angle is 45°, the force of gravity is equal to the translation force of the magnet; if the deflection angle exceeds 45°, the magnet exerted more force on the object than gravity.[9] Thus, a deflection angle less than 45° is considered to have passed the magnetic force criterion.[6,9] The static magnetic field can create torque on an implant causing the implant to rapidly align itself with the static magnetic field potentially causing tissue damage.[9] The amount of ferromagnetic material within a device is related to translational and rotational forces; incorrect estimation of ferromagnetic content did lead to death in one case of a patient with an aneurysm clip.[10,16] Devices made of non-ferromagnetic materials do not cause force-related injuries.[10] Temperature change is also a safety consideration. Interaction between the oscillating electric field from the transmit coil and conductive tissue can increase the temperature of the patient globally and locally near the implant.[10,11] Several RF-induced heating injuries have been reported.[17] Temperature rises of less than 1 °C have been considered safe in humans,[18] and the ASTM International recommends users define their acceptance criteria.

Results

We identified 18 records that met our inclusion criteria (Fig. 1). The included studies are summarized in Table 1. In total, we studied 45 unique implants consisting of cranial fixation devices, aneurysm clips, spinal rods, pedicle screws, VP shunts, DBS devices, and EEG caps and electrodes (Tables 1 and 2). All studies reported deflection angle, torque, and/or temperature change, with temperature change most commonly reported. Seven studies (38.9%) were reported following at least one ASTM testing standard. Limited testing was performed in human models (Table 2).

Cranial Fixation Implants

Cranial fixation plates, burr hole covers, orbital plates, and mesh made of titanium or titanium alloy were tested in both phantoms and humans. Two studies reported following ASTM International standards. In studies reporting RF heating, all implants had a change in temperature less than

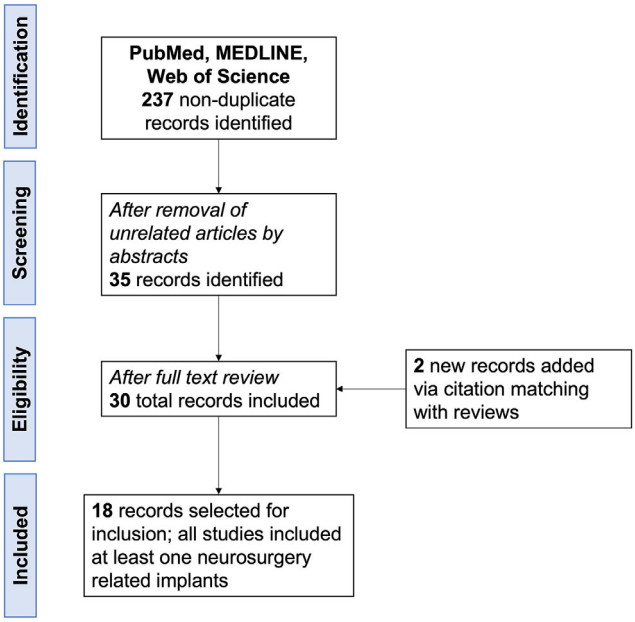

FIGURE 1: PRISMA diagram illustrating search strategy.

1 °C.[21,22] Two studies tested cranial fixation plates and screws in human models and found no adverse effects related to heating.[19,20] Chen et al imaged patients after craniotomy surgery and found that fully implanted cranial fixation plates and screws did not have adverse effects with 7 T MRI.[19] Deflection angle was also found to be acceptable, ≤7°, in all studies where reported.[9,21] Torque categorized as minimal by Feng et al where burr hole covers, orbital plates, and mini plates were tested using a qualitative test to evaluate an implant's potential rotation.[9]

Aneurysm Clips

All aneurysm clips were tested in phantom models and two studies reported following ASTM International standards. RF heating change exceeded 1 °C when a 45°-angled type, straight fenestrated type, and long straight type clips were imaged.[25] The greatest temperature increase was seen in the longest aneurysm clip (51.5 mm).[25] Additionally, when two aneurysm clips were scanned together in varying orientations, the temperature change exceeded 1 °C in some scenarios.[24] Noureddine et al imaged Mizuho aneurysm clips (No. 17-001-02, 17-001-92) considered MR-conditional up to 7 T and found only 17-001-02 to meet regulatory standards of remaining below 40 °C.[23] The Yasargil FE 863 K clip exhibited a very strong torque and a deflection angle >45°; however, the shorter aneurysm clip (Yasargil FT 790D) did meet safety standards for deflection angle, torque, and temperature.[18]

Spinal Rods and Pedicle Screws

Medtronic brand spinal rods of lengths ranging from 5 to 20 cm and made from titanium, titanium alloy, or cobalt-chrome were imaged. All rods had acceptable deflection angles (<45°) and temperature change (<1 °C).[26] At every length, cobalt-chrome rods had the greatest deflection angle, which increased as length increased.[26] Both screws[26,27] and the cross-linking bridge[26] also met safety standards for deflection angle and temperature. Both studies reported following ASTM International standards.

VP Shunts

A programmable VP shunt valve and assistant device were imaged and deemed incompatible with 7 T MRI due to permanent loss of the ability to program the valve.[7,8] Additionally, the assistant device was found to have unpredictable pressure changes when imaged adding to its unsuitability for 7 T MRI.[7] Current programmable VP shunts are likely unsuitable for ultra-high-field imaging. ASTM International compliance was not reported for either study.

Deep Brain Stimulation Devices

Implantable DBS leads and electrodes were imaged in two studies, and one study reported following ASTM International standards. All components had temperature increases <1 °C when tested in phantom models.[28,29] Ashok Kumar et al imaged carbon electrodes and reported a lower temperature increase of 0.1 °C compared to 0.9 °C when traditional platinum-iridium electrodes were used.[29]

Electroencephalogram

Several EEG configurations were tested using electrodes made of gold or silver/silver-chloride.[30–32] Angelone et al and Vasios et al reported large temperature changes with a maximum of 6.61 °C depending on probe location.[30,32] The greatest temperature increases were found at the EEG paste.[30,32] When the temperature probe was placed near the Fp1 electrode, temperature increases were much closer to 1 °C, and when the probe was placed centrally in the phantom head, temperature increases were <1 °C.[30,32] The "InkCap" design described by Vasios et al experienced reduced heating.[32] Additionally, the EEG design with low conductivity lead wires tested by Gregerson et al did not exceed 39 °C.[31] ASTM International compliance was not reported for any study.

Discussion

Ultra-high-field MRI of the brain and spine has several clinical applications, including neoplasm, neurodegenerative disease, epilepsy, and spinal cord perfusion mapping.[1,33–35] While the number of UHF MRI scanners is rapidly expanding in the United States and globally, 7 T scans may not be routinely performed, in part due to their similar level of reimbursement despite higher cost of equipment. A 7 T MRI is approved for clinical use by the FDA in extremities and the brain, but research must continue to demonstrate significantly

TABLE 1. Neurosurgery-Related Implants Studied in 7 T MRI

Record	Implant(s) Tested (Material)	Model Utilized	ASTM Guidelines Satisfied	Deflection Angle (deg)	Torque	Temperature Change (°C)
Cranial fixation devices						
Chen et al[19]	Biomet cranial fixation plates (titanium) Biomet 4 mm screws	Craniotomy patients	NR[a]	NR	NR	No adverse effects related to heating
Feng et al[9]	KLS Martin burr hole cover (titanium) GPC Medical Ltd orbital plate with bridge (titanium) GPC Medical Ltd mini plate with bridge (titanium)	Gel-saline phantom	ASTM F2052-06, F2213-06, F2182-11a	7 7 6	Moderate[b] None[b] None[b]	−0.07 NR NR
Kraff et al[20]	Biomet miniplates (titanium) Biomet 4 mm screws (titanium alloy)	Duke head model, healthy volunteer	NR	NR	NR	Insignificant
Rauschenberg et al[21]	CranioFix® implant system (titanium alloy)	Phantom	ASTM F2052-02, F2213-02, F2182-02a, F2119-01	<7	None[b]	0.8
Sammet et al[22]	MatrixNEURO burr hole cover (titanium) MatrixNEURO double-Y plate (titanium) MatrixNEURO strut plate (titanium) MatrixNEURO mastoid mesh (titanium)	Gel-saline phantom	Adapted	NR	NR	0.88 ± 0.02 0.79 ± 0.02 0.85 ± 0.02 0.66 ± 0.02
Aneurysm clips						
Dula et al[18]	Yasargil FE 863 K aneurysm clip (cobalt-chromium-nickel alloy) Yasargil FT 790D aneurysm clip (titanium alloy)	Gel-saline phantom	ASTM F2052, F2213-06, F2182-11a, F2119-07	49 7	Very strong[b] None[b]	0.6 0.8
Noureddine et al[23]	Mizuho aneurysm clips: No. 17–001-02 (titanium alloy) and No. 17–001-92 *Considered MR Conditional up to 7 T*	Ella and Duke head models	NR	NR	NR	Clip 02 did not exceed 39° in any scenario; clip 92 reached a maximum 40.83°
Noureddine et al[24]	Mizuho aneurysm clips: No. 17-001-02 (titanium alloy) and No. 17-001-92 *Considered MR Conditional up to 7 T*	Ella and Duke head models	NR	NR	NR	Regulatory limit temperature exceeded by <1° in some scenarios

TABLE 1. Continued

Record	Implant(s) Tested (Material)	Model Utilized	ASTM Guidelines Satisfied	Deflection Angle (deg)	Torque	Temperature Change (°C)
Tsutsui et al[25]	Aneurysm clip 17-001-22 No. 22 right-angled type Aneurysm clip 17-001-02 No. 2 short straight type Aneurysm clip 17-001-49 No. 49 45°-angled type Aneurysm clip 17-001-30 No. 30 straight fenestrated type Aneurysm clip 17-001-92 No. 92 long straight type	Gel-saline phantom	ASTM F2182-19e2	NR	NR	0.8 0.6 1.2 1.1 3.3 *Maximum temperature change listed*
Spinal rods and pedicle screws						
Tsukimura et al[26]	Spinal rod, diameter (d) = 5.5 mm, length (l) = 50 mm (titanium, titanium alloy, or cobalt-chrome) Spinal rod, d = 5.5 mm, l = 100 mm (titanium, titanium alloy, or cobalt-chrome) Spinal rod, d = 5.5 mm, l = 150 mm (titanium, titanium alloy, or cobalt-chrome) Spinal rod, d = 5.5 mm, l = 200 mm (titanium, titanium alloy, or cobalt-chrome) Screw, d = 6.5 mm, l = 58 mm (titanium alloy or cobalt-chrome) Cross-linking bridge, d = 8 mm, l = 52 mm (titanium alloy) *All Medtronic brand implants*	Gel-saline phantom	ASTM F2052-06, F2181-11a	5, 5.7, 17.8, respectively 5.8, 6.5, 19.2, respectively 6.2, 6.8, 20.3, respectively 6.2, 7.7, 21, respectively 10 6.7	NR	0.8, 0.7, 0.8, respectively 0.9, 0.8, 0.9, respectively 0.8, 0.9, 0.9, respectively 0.9, 0.7, 0.8, respectively 0.7 0.5
Van Speybroeck et al[27]	Medtronic pedicle screw (stainless steel, nonferromagnetic)	NR	ASTM F2052-15	5	NR	NR
Ventriculo-peritoneal (VP) shunts						
Mirzayan et al[7]	Programmable VP-shunt assistant device	NR	NR	Shunt assistant devices were incompatible due to pressure changes and loss of function with 7 T MRI		
Wrede et al[8]	Programmable VP-shunt valves	NR	NR	Shunt valves lost ability to be reprogrammed indicating their unsuitability for 7 T MRI		

TABLE 1. Continued

Record	Implant(s) Tested (Material)	Model Utilized	ASTM Guidelines Satisfied	Deflection Angle (deg)	Torque	Temperature Change (°C)
Deep brain stimulation devices						
Bhusal et al[28]	Medtronic lead 3387 (Pt-Ir) Medtronic lead 3389 (Pt-Ir) Fully implantable deep brain stimulation (DBS) system: Medtronic lead 3389 (Pt-Ir), extension 3708660, IPG Activa SC-37603	Phantom head	ASTM F2052-15	NR NR 36 for IPG	NR	0.58 ± 0.23 0.57 ± 0.3 0.52 ± 0.32
Kumar et al[29]	Electrodes with Medtronic lead 3389 (Pt-Ir) 2C carbon electrodes	Gelled mixture of agar, NaCl, $CuSO_4$	NR	NR	NR	0.9 0.1
Electroencephalogram (EEG)						
Angelone et al[30]	32 standard gold electrodes with copper leads 32 standard silver/silver-chloride electrodes with copper leads 32-electrode 4 T MRI-compatible EEG cap with carbon-fiber leads and silver/silver-chloride electrodes	Custom-made phantom head	NR	NR	NR	0.35 ± 0.04–6.61 ± 0.2[c] 0.56 ± 0.05–2.82 ± 0.06[c] 0.35 ± 0.05–1.71 ± 0.04[c]
Gregersen et al[31]	Transcranial electrical stimulation electrodes with silicone-rubber/copper leads insulated with glass-fiber braided sleeving	Duke phantom	NR	NR	NR	0.6 maximum
Vasios et al[32]	32-electrode EEG "InkCap" (silver/silver-chloride ink, silver/carbon ink, nylon) 32-electrode EEG "QuickCap" 32 standard gold electrodes	Phantom head, healthy volunteers	NR	NR	NR	0.15 ± 0.08–3.64 ± 0.04[c] 0.19 ± 0.05–6.6 ± 0.09[c] 0.35 ± 0.04–6.61 ± 0.2[c]

ASTM standards listed where reported.
[a]Not reported.
[b]Torque rated on a qualitative scale 0 (no torque) to 4 (very strong torque); 0, 1 (mild or low torque), and 2 (moderate torque) were considered acceptable. Quantitative measurements of torque were not reported.
[c]Depending on probe location; maximal temperature change observed in the EEG paste.

TABLE 2. Number of Implants Tested Per Neurosurgical Specialty/Procedure, Model(s) Tested In, and Safety Data Available

Neurosurgical Specialty or Procedure	Included Devices	Number of Tested Devices	Phantom Testing	Human Testing	Deflection Angle	Torque	Temperature Change
Cranioplasty	Cranial fixation plates, mesh, burr hole covers, 4 mm screws	10	✓	✓	✓	✓	✓
Cerebrovascular	Aneurysm clips	9	✓		✓	✓	✓
Spinal	Spinal rods, cross linking bridge, pedicle screws	15	✓		✓		✓
Shunts	VP shunt and valve	2	✓				
Functional	DBS electrodes and leads, EEG electrodes and leads	9	✓	✓	✓		✓

greater utility in comparison to lower field examination to increase reimbursements.[4] Current usage of 7 T MRI is also significantly limited in patients with biomedical implants such as aneurysm clips, burr hole covers, and pedicle screws. The timing of our review, therefore, is highly relevant, because in this early stage of technological adoption, and given the likely increased clinical usage, device manufacturing companies can leverage the appropriate materials, tools, testing protocols, and equipment to ensure devices are safe in the higher magnetic field.

MR-conditional status determinations are based on translational forces, rotational force or torque, and temperature changes in the subject and at the implant. If an implant experiences excessive force within the MR system, both patient and staff safety is at risk. Many implants have undergone some degree of safety testing in 7 T MRI, but the rigor of testing is variable. To ensure safety, clinicians, researchers, and device manufacturers can follow FDA-recognized consensus standards and testing specifications published by ASTM International, International Organization for Standardization, and International Electrotechnical Commission.[36] In this review of 18 studies, only seven (38.9%) reported following ASTM testing guidelines for any reported safety variable. There was also inconsistency in reporting of safety variables; for example, Dula et al reported deflection angle and torque for a titanium alloy aneurysm clip, while others provided only temperature for similar clips.[18,23,24] More comprehensive studies of each specific implant and standardization in reporting of safety testing are necessary for an implant to be deemed MR Safe or MR Conditional at 7 T and added to a database, such as mrisafety.com. Increasing availability of standardized safety data will help promote the utilization of 7 T MRI among patients with biomedical implants.

Across studies, implant size, shape, and material had substantial impacts on safety. We noted that cobalt-chrome and long-type aneurysm clips induced greater temperature change, and cobalt-chrome spinal rods had greater deflection angles than their titanium or titanium-alloy counterparts.[25,26] However, too few studies were available to recommend against certain types of aneurysm clips or metallic compositions. Additionally, it is difficult to provide generalized statements about implant material compatibility, thus each new implant should be individually evaluated.[37] The placement location of the temperature probe also changed safety outcomes. In EEG studies, probe placement in the EEG paste resulted in unsafe temperature increases, while placement near the electrode was more likely to be safe (<1 °C).[30,32]

Across medical specialties, biomedical implants are sparsely tested. Thelen et al evaluated several ear, nose, and throat surgical implants and identified several nonferromagnetic implants that were incompatible with 7 T.[37] Limited evaluation has been pursued in the field since 2006.

Similarly, despite interest in UHF imaging of the knee, orthopedic implants have undergone limited safety testing, with few safety outcomes published.[9,18] In all fields, it would likely behoove device manufacturers to investigate their devices for 7 T safety.

Overall, the following implants are reported to have passed the temperature and deflection angle standards: spinal rods ranging in length from 50 mm to 200 mm and made of titanium, titanium alloy, or cobalt-chrome; Yasargil FT 790D aneurysm clip, Mizuho 17-001-02 aneurysm clip, 17-001-22 right-angled type aneurysm clip, titanium cranial fixation plates, mesh, and screws; and Pt-Ir leads for DBS. However, most studies did not report torque, thus the risk for rotational force should be assessed before imaging. Additionally, few studies addressed the safety of multiple implants in proximity to each other. Noureddine et al found unsafe rises in temperature when two aneurysm clips were within a phantom.[24] Chen et al found no adverse reactions to heating when craniotomy patients underwent 7 T MRI.[19] Overall, caution is warranted when a patient has multiple implants, especially aneurysm clips.

Limitations

The review addresses implant safety but does not discuss artifacts or imaging quality when the implant is present. To be included, a study must have had reported deflection angle, torque, or temperature change. Many studies did not report all three variables limiting the information available for a given implant. Furthermore, studies utilized different models, including healthy human volunteers, neurosurgical patients, and phantoms of various compositions, and not all testing was adherent to ASTM guidelines. Importantly, this review summarizes implants tested to guide future testing and evidence for which implants may be safely imaged for research or clinical purposes.

Conclusions

This systematic review summarizes neurosurgery implants tested for 7 T MRI compatibility and identifies several implants that do not exceed temperature and deflection angle standards. For future testing, we recommend following ASTM guidelines and thoroughly reporting implant composition, deflection angle, torque, and temperature change.[13–15] Additionally, the functionality of devices following imaging, particularly programmable VP shunts, is also critical to evaluate. With increased evidence, more biomedical implants can be categorized as MR safe or MR-conditional for 7 T.

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