

External Orthopaedic Implants in the Magnetic Resonance Environment: Current Concepts and Controversies

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Abstract

MRI provides diagnostic three-dimensional imaging and remains extremely important in the diagnosis and management of spinal trauma as well as other acute traumatic injuries, including those of the extremities. The American Society for Testing and Materials has created standards against which all implantable medical devices are tested to ensure safety in an MR environment. Most implantable passive orthopaedic devices can undergo MRI without consequence to the patient. However, the American Society for Testing and Materials has recently updated its terminology resulting in confusion among providers and institutions. Primary safety concerns are radiofrequency-induced heating and magnetically induced torque or displacement. These safety concerns have emerged as a recent source of debate, particularly regarding the imaging of patients with external fixation and cervical immobilization devices in place. Surveys have shown a lack of consensus among radiologists regarding this issue. Having an institutional protocol in place for the imaging of these patients streamlines the diagnosis and early stabilization of certain polytraumatized patients. The purpose of this review is to summarize the pertinent literature as well as the current industry recommendations regarding the safety of commonly used external fixation, cervical immobilization, and traction devices in the MR environment.

The ability of MRI to render high-quality, three-dimensional images of soft-tissue structures gives treating surgeons valuable diagnostic and prognostic information for a wide range of traumatic injuries. Often this information directly impacts management decisions and guides operative intervention. For a polytraumatized patient to require spanning external fixation devices before MRI of the extremity or spine is not uncommon. Although external fixation

devices are frequently necessary to stabilize the patient's fracture before additional testing and diagnostic imaging, the very presence of the device raises safety concerns in an MR environment.

The need for MRI in patients stabilized with an external device is common, especially at trauma centers. Approximately 3.7% of patients undergoing a trauma evaluation have cervical spine injuries.¹ In many patients, MRI provides additional information beyond that obtained

with conventional radiographs or CT. With the addition of MR, management plans may be adjusted, particularly in patients who are obtunded or with neurologic deficit.² In addition to guiding surgical management, a preradiation MRI is recommended to prevent iatrogenic neurologic complication. This preradiation MRI is sometimes the case for cervical spine facet dislocations, although agreement is not universal.³⁻⁵ At other times, the placement of preoperative halo immobilization is recommended for unstable cervical injuries including occipitocervical dissociation or highly unstable cervical spine fractures, such as in the setting of ankylosing spondylitis.⁶ For patients with knee dislocations and multidirectional instability, urgent reduction and spanning external fixation is considered standard-of-care. These injuries are typically associated with multiligamentous knee injuries and benefit greatly from MRI evaluation.⁷ Compared with examination under anesthesia, MRI findings correlate more strongly with findings at the time of surgery^{8,9} and are sometimes necessary for adequate surgical planning.¹⁰ In addition to providing information to guide acute management, MRI is often used to determine the extent of diffuse axonal injury in severely traumatized patients and provide prognostic information on long-term outcome that may impact patient care decisions.^{11,12}

Patients with one or multiple external fixation devices in place frequently need an MRI after being resuscitated and stabilized. Still, the final decision to obtain the MRI requires an assessment of the diagnostic benefit of the examination relative to the potential for harm that may result from imaging with an external fixation device in place. This assessment of potential for harm is subjective and can be variable. Surveys have shown a general

lack of consensus among radiologists in regard to doing MRI scans on patients with external fixation devices in place.¹³ This lack of consensus has the potential to result in delayed patient care, refusal to do the study, or required removal of an implanted device before obtaining the study.

This review details guidelines governing implantable medical devices in the MR environment, manufacturer responsibilities, frequently used implantable external devices, and clinical studies relating to this issue.

MRI Safety Concerns

Safety concerns around placing implants in the MR environment fall into four main areas. First, is thermal injury resulting from heating of the implant? This thermal injury occurs through radiofrequency-induced antenna effects, electromagnetic induction, or current induction making thermal necrosis of the surrounding tissue a theoretical possibility. Magnetically induced torque and displacement gives rise to a second area of concern by causing materials to move or loosen in the MR environment, potentially resulting in patient injury. For MRI unsafe devices or retained shrapnel containing ferromagnetic materials, the static magnet field exerts a substantial attractive force and may cause devices external to the patient to become a projectile. Finally, the distortion of the static magnetic field and induced eddy currents resulting from implanted metallic devices can produce image artifact that limits diagnosis and may result in a non-diagnostic study.

To investigate the clinical relevance of these concerns, we conducted a systematic literature search of the PubMed, MEDLINE, and Cochrane databases using MeSH terms “magnetic resonance imaging,” “burns,” and “wounds and injuries” yielding

1,351 results. Titles and abstracts without mention of injuries sustained in the MR environment were discarded leaving 121 articles for more in-depth review. Of these 121 articles, 98 were discarded because they did not involve an external fixator, halo traction device, or skeletal traction. The remaining 23 articles were reviewed. Within these 23 publications, one report of a patient receiving scalp burns from a halo device while undergoing MRI is found.¹⁴ In this brief report, the patient underwent a 1.5 T cervical MRI wearing an unspecified titanium six-pin halo vest system. Notable, apparent third-degree burns (based on clinical photographs) were noted at the posterior two pin sites at the conclusion of the procedure, although details of injury severity and treatment are not documented in the report. This “stoic patient,” according to the authors, had felt notable pain during the MRI “but did not notify the technicians.” Based on our review, no reports of a patient being harmed in the MR environment with a pelvic or extremity external fixator are found. Numerous case reports of patients receiving burns in the MR environment from other devices are found.¹⁵⁻¹⁸ With the exception of the aforementioned halo report, these occurrences involved monitoring equipment such as pulse oximetry and electrocardiography leads.

Guidelines

The American Society for Testing and Materials (ASTM) provides standards, adopted by the FDA, against which all passive, implantable medical devices that may be placed into an MR environment are tested.¹⁹ Guidelines were originally released in 1997; however, the accepted terminology of “MR Safe” and “MR Compatible”

produced confusion among providers and failed to require the manufacturer to list specific MR parameters under which the device could be safely imaged. Therefore, in 2005 and 2014, the ASTM and FDA updated the terminology to improve clarity^{20,21} and to place the burden of testing and labeling implantable devices on the manufacturer. “MR Safe” now refers to devices made from materials that pose no known risks in any foreseeable MR environment. “MR Conditional” labeling is applied to an implant that can be safely placed in the MR environment with specific parameters determined by experimental data. Parameters include whole-body averaged specific absorption rate, which is an indirect measure of the amount of heating produced by the MRI examination, magnetic field strength, spatial gradient, coil restrictions, and location inside or outside the bore of the scanner. Expected heating of the implant, image artifact production, magnetically induced torque, and displacement under the listed conditions must also be reported.^{22–25} “MR Unsafe” refers to implants that cannot be safely placed in any MR environment under any condition.

Manufacturer Responsibilities

FDA policy dictates that manufacturers are responsible for the testing and labeling of their products in accordance with the updated ASTM terminology. Implants are tested under specific MR conditions; however, to test all conceivable fixator configurations is not possible. As a result, universally accepted MR conditions for external fixation devices are not found, and conditions vary based on manufacturer. Table 1 summarizes manufacturer recommendations for the most commonly used external fixation

devices on the market.^{26–32} More specific details regarding the MR parameter specifications for each device can be found in their respective product information documentation. To the best of our knowledge, no manufacturer recommendations for skeletal traction systems at this time are found, but these implants are traditionally made of implant quality metals and are believed to react similar to other implantable devices.

Clinical Studies

Despite manufacturer recommendations with specific parameters for safe imaging, a great deal of confusion regarding the use of these devices in the MR environment is found. This confusion may in part be due to the fact that it is impossible to test the infinite number of potential external fixator configurations for safety. Until recently, a lack of in vivo clinical studies investigating the safety of patients with external fixation devices in the MR environment was found. Perhaps, the greatest contributing factor is that, until the ASTM changed guidelines, most external fixator devices were used in the MR environment without issue or concern. Practitioners are therefore confused by the idea that these devices have somehow become dangerous in an MR environment despite no notable changes being made in either MR scanners or the devices themselves.

In a recent retrospective level IV study, Hayden et al³³ evaluated the safety of placing patients in the MR environment, both inside and outside the bore, with various external fixation devices in place. The patients in the study were trauma patients who had DePuy Synthes, Stryker Hoffmann two MRI, or Hoffman three large external fixators in place. These patients subse-

quently were imaged in either a 1.5 T or 3.0 T MRI. Thirty-eight patients with a total of 44 external fixators were included who had undergone an MRI. Anytime, an external fixator was exposed to the MR environment it was counted as an “Ex-Fix/MRI event.” The authors reported a total of 72 Ex-Fix/MRI events in their study. Fourteen of these events were with the external fixator located inside the bore of the MRI, and 58 were outside the bore. In all 38 patients (72 Ex-Fix/MRI events), no adverse events were reported, and the image quality was considered to be diagnostic. All three brands of external fixators were placed inside the bore without issue. In another study by Javidan et al,³⁴ 19 patients with spanning external fixators placed for knee dislocations underwent MRI. All fixators were located inside the bore with no adverse events being reported. These findings, along with previous experience, lead us to question the clinical relevance of manufacturer recommendation and the utility of ASTM guidelines for the management of external fixation devices labeled “MR Conditional.”

Ex Vivo Investigations

Ex vivo studies evaluating the safety of external fixation devices in the MR environment can be found scattered throughout the literature. Luechinger et al³⁵ evaluated DePuy Synthes Large External Fixators in diamond knee-spanning and pelvic configurations in 1.5 and 3.0 T static magnetic fields for magnetically induced torque and displacement as well as implant heating. The authors reported the forces experienced by the frames from the MRI were greater than two times lower than the forces on the devices from gravity. In other words, the force on the frames from the MRI would not

Table 1**Manufacturer Published Recommendations for the Most Commonly Used External Fixation and halo Devices in the United States**

Manufacturer	Designation	Magnetic Field Strength (Tesla)	Safe to Go Into Bore	Additional Recommendations/Information
External fixation				
DePuy Synthes Large and Medium	MR Conditional	1.5 or 3.0	No	Must remain 7 cm outside of bore
Zimmer XtraFix Large (11 mm)	MR Conditional	1.5 or 3.0	No recommendation given	Applies to glass fiber rods only
Zimmer XtraFix Small (6 mm)	MR Conditional	1.5 or 3.0	No	Applies to glass fiber rods only
Stryker Hoffman II	MR Unsafe	1.5 or 3.0	No	Unsafe in MRI under any conditions
Stryker Hoffman II MRI	MR conditional	1.5 or 3.0	Variable	—
Stryker Hoffman 3	MR Conditional	1.5 or 3.0	No	—
halo device				
Anjon Bremer halo System	MR Conditional	1.5 or 3.0	Yes	Testing before new ASTM regulations
PMT halo System	MR Conditional	1.5 of 3.0	Yes	Applies to titanium skull pins and carbon graphite open black ring
Resolve halo System	MR Conditional	1.5 of 3.1	Yes	Applies to glass-composite halo ring with ceramic-tipped skull pins (titanium-tipped pins are considered <i>MR unsafe</i>)

Conditions are based on published technique guides.^{26–32}

overcome the force of gravity and therefore would not result in clinically notable torque or displacement of the implants in either 1.5 or 3.0 T static magnetic fields. The maximum temperature rise reported for the 1.5 and 3.0 T magnetic fields was 2.1°C and 1.1°C, respectively. Davison et al³⁶ subjected 10 commonly used external fixators to multiple 1.5 T MRI scans at three separate locations: 30 cm outside

the bore, at the edge of the bore, and 30 cm inside the bore. In each instance, the frames were evaluated for magnetic attraction and implant heating. Of the 10 fixators tested, the Ilizarov with carbon fiber rings, Richards Hex-Fix, and DePuy Synthes Large Fixators did not show any notable magnetic attraction or temperature increases and were concluded to be safe for use in the MR environment. The remaining

fixators, which included the Stryker Hoffman II, Hoffman II Hybrid, and DePuy Synthes Hybrid (Hybrid = rings, transfixion wires, and half-pins), experienced >1 kg of magnetic attraction, but the clinical relevance of the remaining fixators is unclear. In a cadaveric study, Elsisy et al³⁷ tested the DePuy Synthes Large External Fixator and Stryker Hoffmann II MRI for image quality in a 3 T MRI scan.

The authors concluded that, although the presence of an external fixator increased artifact, all images were still of diagnostic quality. Diaz et al³⁸ in 2010 evaluated four external cervical fixation devices undergoing MRI at 3 T. Two of the tested devices, the Generation 80 and V1 halo fixators, produced notable increases in temperature up to 11.6°C with sparking evident during the scan. These devices were concluded to be unsafe in the MR environment. The Resolve Ring and Superstructure/Resolve Ring and the Jerome Vest/Jerome Superstructure, however, showed no notable heating or image artifact and were concluded to be safe at 3 T. This is no surprise as the former two halo devices are labeled MR Unsafe and the latter MR Conditional according to ASTM guidelines.

Skeletal traction is commonly applied to temporize many fractures before definitive fixation. Although no manufacturer recommendations currently exist, a recent cadaveric study by Mansour et al³⁹ is the first to evaluate the safety of such devices in the MR environment. The authors tested multiple implant quality stainless steel Steinmann pins of varying diameter in cadaveric distal femur specimens placed in a 1.5 T MRI suite. Using the ASTM guidelines for testing, all tested Steinmann pins could safely undergo MRI. In addition to this, the Bohler-style Steinmann pin tractor bow and Kirschner wire bow were also evaluated. The former was found to be “weakly ferromagnetic” and the latter to be unsafe due to its strong ferromagnetism. The authors concluded that implant quality stainless steel Steinmann pins can be left in place during MRI. The authors also suggest tractor bows could be imaged safely; however, they strongly recommend

these devices undergo individual safety evaluations at each institution before clinical use as the composition of nonimplantable devices can be variable. Similar to Gardner-Wells tongs, these devices may be made of various combinations of stainless steel, titanium, or carbon fiber depending on when they were manufactured. Risks need to be balanced against the risk of removing traction, especially in patients who have just undergone a cervical spine closed reduction.

Author’s Institutional Policy

The author’s institution is the tertiary referral center for adult and pediatric level I trauma. Currently, all MRI requests for patients with external fixation devices in place are reviewed on a case-by-case basis. The ordering physician and radiologist discuss the merits of the study as well as the rationale for obtaining it. If the external fixator or halo device is to be placed into the bore of the MRI, patients must be able to perceive and report increased temperatures or discomfort. Theoretical risks are explained to the patient, and the radiologist who protocols the scan obtains informed consent. Intubated and/or sedated patients, as well as those who are unable to verbalize discomfort, are not permitted to undergo MRI unless the conditions meet the exact specifications listed by the manufacturer. During the MRI, the patient is given the option to stop the study at any time. For patients with skeletal traction, the weights and traction bow are removed, but the traction pin is left in place. To date, after 1.5 years with the policy in place, no studies have needed to be stopped prematurely due to patient discomfort, and no adverse events have been recorded.

Summary

The use of MRI for patients in the acute trauma setting with external fixation devices in place remains controversial. Technological advances and expanded indications for MRI studies seem to have brought this issue into the spotlight at many centers across the country. The lack of consensus among providers likely stems from discrepancies between the “worst case scenario” manufacturer recommendations and the more clinically relevant ex vivo and retrospective studies. To date, very few clinical studies investigating the safety of external fixation devices in the MR environment are found. Such studies will likely be necessary in the future to give providers the evidence-based platform they need to use clinical discretion in lieu of manufacturer recommendations which, at present, appear to be overly cautious for fear of legal ramifications. Until that time, we encourage each institution to create protocols for the management of these patients in the MR environment.

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