Third Place: MRI safety of external fixation devices: a review of the literature

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ABSTRACT

Orthopaedic trauma patients often require temporary stabilization prior to definitive treatment following the principles of damage control orthopaedics (DCO). DCO includes the use of temporary or supplemental implants including pelvic external fixators, large external fixators, small external fixators, ring external fixators, skeletal traction, cervical traction, and cervical halo fixation. Once provisional stabilization has been obtained, and the patient is optimized medically, further testing can be performed prior to definitive stabilization. Since MRI may be required before definitive fixation, it is necessary to understand MRI safety in patients with external fixation devices.

Key Words
external fixation, magnetic resonance imaging, Trauma

INTRODUCTION

Orthopaedic trauma patients often require temporary stabilization prior to definitive treatment, sometimes in an urgent fashion. The principle of damage control orthopaedics (DCO) emphasizes the provisional stabilization of orthopaedic injuries to optimize patient physiology and avoid second hit injuries associated with early total care. DCO includes the use of temporary or supplemental implants, including pelvic external fixators, large external fixators, small external fixators, ring external fixators, skeletal traction, cervical traction, and cervical halo fixation. Once provisional stabilization has been obtained and the patient is optimized medically, further testing can be performed prior to definitive stabilization. MRI may be needed for evaluation, decision making, and prognosis of specific injuries before definitive fixation. Therefore, it is imperative to understand the MRI safety of DCO implants including external fixation devices.[1]

MRI has become an important part of the diagnostic algorithm for many orthopaedic trauma injuries including acute spinal cord trauma and occult femoral neck fractures.[2–4] Other injuries in which MRI may be indicated in orthopaedic trauma include knee dislocations and tibial plateau fractures to assess soft-tissue injuries.[5–8] Importantly, ligamentous injuries about a major joint may occur in association with a fracture requiring MRI compatibility of the method of fracture stabilization.[9] Open fractures, polytrauma patients, and high-energy injuries will often receive provisional stabilization prior to MRI. As the indications for MRI expand in orthopaedic trauma, paramount importance must remain on patient safety and the MRI compatibility of DCO implants.

MRI utilizes superconducting magnets and radiofrequency coils to manipulate protons and create detailed images. Because MRI utilizes powerful magnets, there are safety concerns regarding the use of metal implants in and around the scanner. Patients are routinely screened for metal implants including mesh, stents, foreign bodies, jewelry, cardiac pacemaker/defibrillators, deep brain stimulators and more.

MRI safety concerns include dislodgment or deformation of metal implants, heating of metal implants due to dissipation of electrical currents, and peripheral nerve stimulation caused by induced eddy currents within metal implants. As MRI imaging has increased, attention to MRI safety also has increased. The majority of metal implants come with MRI safety cards for patients to carry to inform physicians of their implants' MRI compatibility. Industry has rapidly adapted to the need for MRI compatible devices.

STANDARDS OF MRI SAFETY

In 1997 the American Society for Testing and Materials (ASTM International) recognized the need for standardized testing of MRI safety. In 2000 the first set of MR safety standardized tests were published and have since been revised to include evaluation of MR artifacts, radiofrequency-induced heating, measurement of induced translation and torque. The current ASTM MRI Standards include three categories with regards to safety: MR Safe, MR Conditional, and MR Unsafe, with corresponding markings (Table 1).

Testing of MRI safety for specific devices includes the measurement of displacement force, torque, radiofrequency (RF) heating, and image artifact. To measure displacement force, the implant of concern is suspended from a thin string and moved to the position in the magnetic field that produces the greatest displacement from the vertical axis. If the angular deflection from vertical is less than 45 degrees, the horizontal displacement force is less than the weight of the implant and deemed MR safe. If the translational force is no greater than

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TABLE 1. ASTM MRI safety standards

Category	Description	International icon
MR safe	An item which poses no known hazards in all MR environments	
MR conditional	An item which demonstrates no known hazards in a specified MR environment with specified conditions of use. Requires defined MR field strength, spatial gradient, time, RF fields, and specific absorption rate.	
MR unsafe	Item that is known to pose hazards in all MR environments	

RF, radiofrequency.

the implants' weight it should not cause forces in excess of gravity-induced stress.

Torque is produced across magnetized implants as they try to align in the long axis of the magnetic field, like a compass needle. To test the torque produced during MRI scanning, the implant is placed on a torsional spring in the center of the MRI scanner. The implant and spring are rotated through 360 degrees of motion in three orthogonal planes, and the maximal torques are recorded. If the largest torque produced is less than the product of the implants' longest dimension multiplied by its weight, then it is considered MR safe.

RF heating occurs as eddy currents are induced in the body. The specific absorption rate (SAR) is a measure of the rate at which RF energy is absorbed and is a measure of RF heating. SAR varies by imaging sequence and is a function of frequency, type, and number of RF pulses and their duration, repetition, and the type of transmission coil used. To test RF heating, the implant is placed in or on a gel phantom that simulates the electrical and thermal properties of the body. The phantom is then exposed to MR sequences with a minimum of 1 W/kg averaged over the volume of the phantom for at least 15 min. Temperature probes are used to record the points of maximal temperature change. There is no specific temperature change that is considered safe. Per the ASTM testing protocol, "The conditions and results of the testing should be included in the device labeling so that the attending physician can make the decision of whether to allow the patient with the implant to undergo an MRI procedure."[10]

Image artifact does not necessarily affect the MRI safety of a specific implant; however, it is important to consider before ordering an expensive imaging modality that could potentially be distorted.[10,11]

SPECIFIC IMPLANTS AND DEVICES

External Fixators

External fixators are a staple of orthopaedic surgical practice. Their use in orthopaedic trauma is ubiquitous. They are often applied as a means temporary fixation prior to obtaining necessary preoperative testing including MRI. Most large external fixation frames are constructed with large metal half-pins and clamps. The metal content of the external fixator clamps has historically been a source of angst between orthopaedic surgeons and radiologists regarding MRI safety.

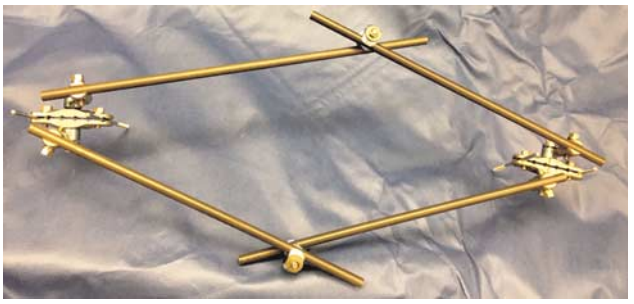

FIGURE 1. A diamond-shaped Synthes large external fixator with four stainless steel Schanz pins, four graphite rods, two combination clamps, two six position multi clamps, and two rod attachments similar to the construct studied by Luechinger *et al.*[13]

Industry has addressed the need for MRI safe external fixators and orthopaedic implants. Despite the rapid advancements in MRI safe and compatible external fixators, there are still no FDA-approved MRI safe external fixators. Despite studies showing MRI safety, the FDA has not approved any external fixator as MR safe to date, only MR conditional.[12–15]

The MRI safety of external fixators, including large and small external fixation, pelvic external fixation, and ringed external fixation all have been previously studied. In 2006 Kumar *et al.*[12] demonstrated that large external fixation clamps showed significant attraction at 1.0 Tesla (T) and recommended against the use of large external fixation clamps in the MRI suite. However, industry rapidly evolved to address MRI safety, and in the same year, Luechinger *et al.*[13] tested the newer Synthes (Paoli, PA) 390 series large external fixation clamps versus the older 393 series. All of the newer 390 series components showed MRI attraction less than the weight of the device, no torque, and negligible temperature change. All Synthes 390 series components were tested including the clamps, rods, and 316L stainless steel and titanium Schanz screws. Additionally, the standard diamond-shaped large external-fixation configuration (Figure 1) for knees and the large pelvic external fixation (Figure 2) were tested with both a 1.5 T and 3 T MR. Scans were done for 7–13 min with a whole body SAR of 3.8 W/kg. RF heating was deemed within safety limits when the MRI was used in normal operating mode.[13]

Davison *et al.*[14] tested 10 different external fixators in 2006 with a 1.5 T MRI scanner. All frames were tested for 30 min at three different positions: 30 cm outside the MRI bore, at the bore entrance, and 30 cm inside the bore. Only three of the 10 passed all safety standards at all three positions. The Ilizarov ringed external fixator with carbon fiber rings, Synthes large external fixation, and the Richards Hex-Fix (Smith and Nephew Richards, Memphis, TN) each showed no component with magnetic attraction greater than 1 kg or temperature change greater than 2 degrees at 1.5 T. In their study, the few implants that did not pass MRI safety standards could be predicted with the use of a handheld magnet. If the device showed ferromagnetism strong enough

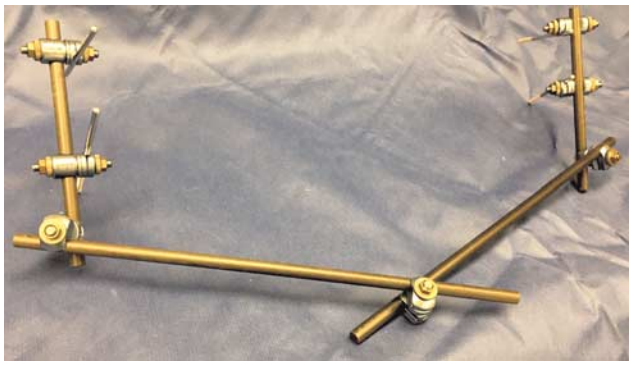

FIGURE 2. A pelvic frame with four adjustable clamps, two carbon fiber reinforced epoxy, four 316L stainless steel Schanz pins, two large combination clamps, and one tube-to-tube clamp.

to attract a 1-in long U-shaped handheld magnet, they predictably showed significant attraction at 1.5 T. Of note, the Hoffman II Hybrid (Stryker, Kalamazoo, MI) and the Ilizarov stainless steel fixator generated more than 10 kg of force, which was concerning for patient safety.[14]

In 2015 Elsissy *et al*.[15] tested two large external fixators for image artifact in a cadaveric knee model. There were no safety concerns with utilization of the Synthes and Stryker external fixation directly in the MR scanner. While there was a reduction in the signal to noise ratio suggesting image artifact from the external fixator, this did not affect the ability of three musculoskeletal radiologists to identify six key anatomic structures in the knee. They concluded that despite the noise artifact, it was still possible to obtain diagnostic quality images safely with an external fixator in place.[15]

Despite evidence from independent studies demonstrating MRI safety of external fixators, the industry leaders still only have external fixators with MR conditional status. Each company lists the conditions that were maintained for safe testing. These conditions vary considerably between companies (Table 2). A summary of the key parameters of each implant's conditional status are as follows: The Stryker (Kalamazoo, MI) Hoffman 3 is safe, but only with vectran-coated carbon rods and for certain configurations. The Smith and Nephew (Austin, TX) Jet-X is safe when the center of the fixator frame is at least 30 cm from the center of the bore magnet. The Synthes large external fixator is safe only when the entire fixator is outside of the MRI bore. The Zimmer (Warsaw, IN) Xtrafix large 11-mm system is safe but only with glass fiber rods. The company-approved conditions are very different than the conditions tested in independent studies which conclude that their implants are safe directly in the MR field. The reasoning for this discrepancy is unclear.

Hayden *et al*.[16] just published the first clinical retrospective case series of patients receiving MRI around external fixators. In their series, MRI was utilized both inside and outside of the MRI bore. External fixators utilized in this series included the Synthes large external fixation, Synthes small external fixator, Stryker Hoffman II MRI series, and Stryker Hoffman 3 external fixator. There were no reported adverse events in 38 patients with 44 external fixators.[16]

CERVICAL TRACTION, HALO TRACTION, WELLS TONGS

Cervical tongs and halo traction may be utilized for emergent reduction of facet dislocations or provisional stabilization of complex vertebral fractures. Often MRI will be necessary to elucidate the ligamentous extent of injury associated with complex spine fractures. Cervical spine injuries may have concomitant traumatic brain injuries or thoracic trauma requiring intubation and sedation. To avoid harm in these potentially obtunded or sedated patients, it is imperative to understand the MR safety of these cervical spine implants.[17,18]

Shellock[19] tested multiple cervical spine implants including halo rings, halo vest, skull pins, and Trippi-Wells tongs (Ace Orthopedic Manufacturing, Los Angeles, CA; Figure 3) and showed no attraction at 1.5 T and largest temperature change of 1.1°C. These tests were performed on live subjects and showed image artifact within acceptable tolerances. The subjects did report the sensation of heating when the magnetization transfer contrast (MTC) MR sequence was performed; however, no temperature change was recorded.[19] This sequence is utilized for brain magnetic resonance angiography, which is less likely to be utilized in the trauma setting.

In 2010 Diaz *et al*.[20] tested four different nonferromagnetic halo devices at 3T in a gel skull model. They showed significant temperature rise in the Generation 80 (Jerome Industries, Elizabeth, NJ) and V1 Halo System (Ossur Americas, Aliso Viejo, CA) and even observed spark formation for the Generation 80 device. However, the 2 Resolve Ring-based Halos (Ossur Americas, Aliso Viejo, CA) showed little or no heating. Hua *et al*.[21] also tested halo devices for MR safety and image distortion. The tested devices were deemed MR safe. There was significant image distortion that was improved by adjusting the phase encoding direction parallel to the halo.[20]

SKELETAL TRACTION PINS AND BOWS

Skeletal traction is ubiquitous in DCO. Patients often are placed in skeletal traction to improve alignment, provide provisional stabilization, and assist with patient comfort. It is often placed at bedside upon patient arrival in the emergency department before obtaining advanced imaging including CT or MRI. The Steinmann pins and Kirschner wires are made of implant-grade metal and for temporary skeletal traction are typically nonthreaded. The Kirschner bow and traction bow are not held to the same rigors of implant material quality testing and are subject to more variability.[22]

In 2009 Mansour *et al*.[22] tested the available forms of skeletal traction including Kirschner wire and bow and Steinmann pin and traction bow. All devices were tested in accordance with ASTM guidelines and then tested in a cadaver model. Their evaluation showed that both Kirschner wires and Steinmann pins were safe at 1.5 T with no displacement and no temperature change. The Kirschner bow is highly ferromagnetic and showed significant attraction and recommended it be removed before MRI (Figure 4). The implant quality stainless steel Steinmann traction bow showed weak ferromagnetism but appeared MR safe

TABLE 2. Large external fixator vendor MRI safetey information

Ex-fix	MRI status	Summary	1.5 T-temperature increases	3 T-temperature increases	1.5 T-static magnetic field conditions	3 T-static magnetic field conditions	Conditions not tested	Spacial gradient magnetic field	Maximum MR system reported	Website
Stryker Hoffman 3	MRI Conditional	Vectran coated Carbon Rods ONLY, Safe for most configurations, some configurations not tested with a 3T	1°C to 2.8°C	2.8°C to 7.6°C	None Reported	For Femur Frame, Pelvic frame with independent iliac crest pin, and distal tibia shaft frame, out of body coil is recommended with frame more than 25 cm away from body coil centre	3 T-Tibia single rod frame with Multiplanar Delta Coupling 3 T-Knee Spanning Z-frame	90 mT/cm or less	1.5 T: 0.5 W/kg at a whole body average SAR for MR imaging time of 15 min 3 T: 1W/kg at a whole body average SAR for MR imaging time of 15 min	https://www.strykermeded.com/media/1600/hoffmann-3.pdf
Smith and Nephew Jet-X	MRI Conditional	Patients may be safely scanned in the MRI chamber when the center of the JET-X Bar fixator frame is positioned at least 30 cm from the isocenter/longitudinal center of the bore of the magnet	< 19°C	< 5.7°C	Center of the JET-X bar fixator frame at least 30 cm from the isocenter of the bore	No restriction for the position of the JET-X Bar fixator frame	Not Described	720-Gauss/cm or less	Whole body specific absorption rate (SAR) of 2 W/kg (normal operating mode only)	https://www.smith-nephew.com/global/assets/pdf/temp/external_fixation_(english)_81056329_c_2010-04_(copy-1).pdf
Synthes Large Ex-fix	MRI Conditional	Fixator meets safety standards BUT ONLY when ENTIRE fixator construct is outside the MRI bore	Wrist frame <2°C, pelvic frame <1°C	Wrist frame <2°C, pelvic frame <1°C	When the fixator frame is positioned outside the MRI bore at Normal Operator or in First Level Control Mode	When the fixator frame is positioned outside the MRI bore at Normal Operator or in First Level Control Mode	Specialty Coils: knee or head coils have not been evaluated for RF heating and may result in higher localized heating	720-Gauss/cm or less	Whole body averaged SAR of 2 W/kg for the normal operating mode and 4 W/kg for the first level controlled mode for 15 min of scanning	http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Technique%20Guides/SUTGModularKneeBrdgJ3315I.pdf
Zimmer XtraFix Large 11 mm System	MRI Conditional	Safe with Normal Operating Mode only with Glass fiber Rods only (other rods have too much heating)	< 8°C	< 8°C	None Reported	None Reported	Frames using carbon fiber bars	1500-Gauss/cm or less	Whole body specific absorption rate (SAR) of 2 W/kg	http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/surgical-techniques/trauma/zimmer-xtrafix-external-fixation-system-large-small-surgical-technique.pdf

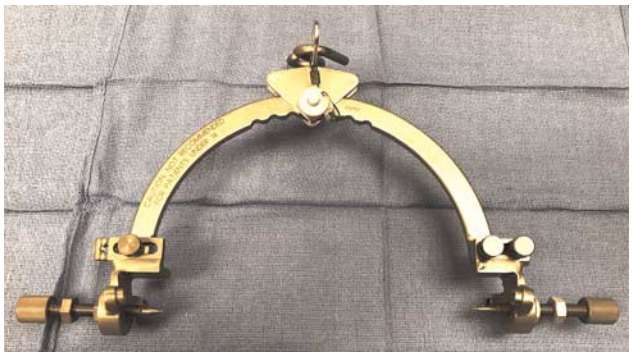

FIGURE 3. Trippi-Wells tongs.

(Figure 4). The Steinmann traction bow is not an implant, therefore its composition is not held to implant standards and there may be variability between traction bows. Implant quality stainless steel 316L, which is nonferromagnetic is typically composed of 62.5% iron, 17.6% chromium, 14.5% nickel, and 2.8% molybdenum. The authors recommended that each Steinmann traction bow be tested with the handheld magnet test prior to use in the MR scanner. There was no evidence of an induced conduction loop with retention of the Steinmann traction bow. The recommendation was made to develop MR safe weights so that traction can remain in place during MRI.[22]

Evidence suggests that all Steinmann pins and Kirschner wires are MR safe. All Kirschner bows should be removed prior to MR imaging. Steinmann traction bows may be MR conditional but require prior testing of individual bows.

DISCUSSION

External fixation devices are often placed before definitive imaging can be obtained, including MRI. A review of the available literature shows previous concerns regarding MR safety have been resolved with the evolution of industry implants. While no implant has gained MR safe status, most modern implants are MR conditional. In reality, there is little to no concern for MR safety of many popular implants, with evidence to support their safety; however, the FDA has not deemed any device MR Safe.

If any debate remains regarding the MR safety of a specific implant, the industry developer should have published MR compatibility standards. These standards typically specify the MRI settings, amount of time, and the location of the external fixator in relation to the center of the MRI bore that has been determined to be safe or MRI conditional. If these compatibility standards are not available, the handheld magnet test may predict MR compatibility.[22,23] It is ultimately the responsibility of the surgeon and the radiologist to collaborate to ensure patient safety. Additionally, the patient should be educated as to the possibility of heating of the implant. The patient should have the ability to communicate to the MRI technician during the entire scan. If the patient is obtunded or unable to communicate, adherence to the strict protocols is even more imperative. To avoid miscommunication, it may be advantageous to develop a protocol between the radiology and orthopaedic departments. The temporizing implant could be chosen based on which implant and MRI conditions both departments consider safe based on current literature and industry-specific data.

If at the time of provisional fixation, the surgeon is suspicious that an MRI may be indicated, it is imperative that they choose implants that will be MRI safe and provide the least image artifact. Radiology imaging protocols have been developed to minimize implant-induced artifact. While the specifics of these MRI protocols are outside of the scope of this paper, it is critical to discuss particular cases with the radiologist to optimize MR scans. The spatial arrangement of the magnetic field, pulse sequence, patient positioning, and coil placement can all be modified to produce an optimal study with external fixation devices in place.

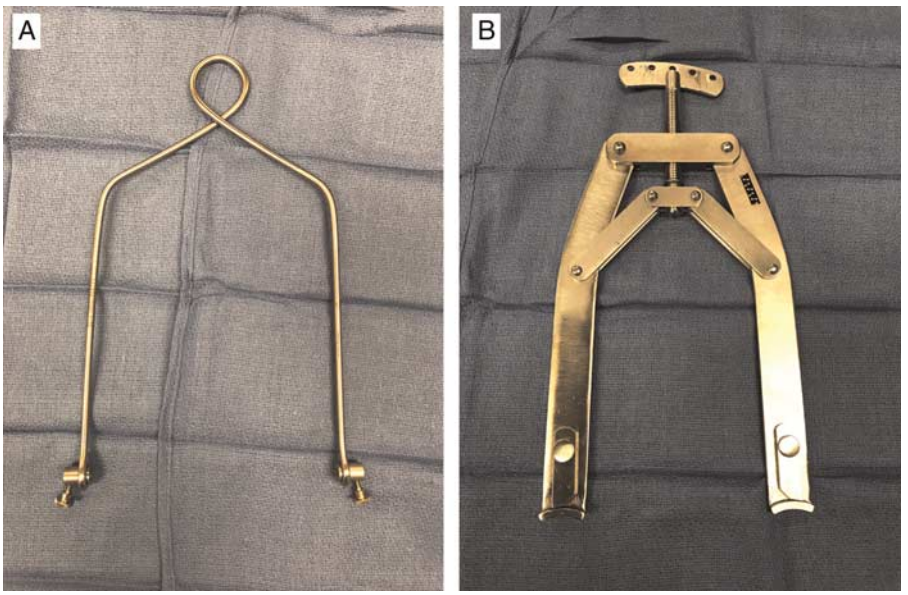

FIGURE 4. (A) Steinmann bow. (B) Stainless steel Kirschner bow.

CONCLUSION

Most implants utilized for provisional stabilization of skeletal injuries in DCO can safely remain in place during MR imaging with no consequence of attraction, torque, heat, induced current, or image artifact. Despite clinical series that elucidate the MRI safety of external fixation devices, industry recommendations lag behind. The handheld magnet test can reproducibly predict MR safety of implants. There is tremendous variability in available implants, and it is the surgeon's responsibility to know the MR compatibility of selected implants. Discussion should occur between radiologists and orthopaedists before imaging over implants to optimize the study and ensure patient safety.

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