Safety and Complications Associated With MRI-Conditional External Fixators in Patients With Tibial Plateau Fractures: A Case Series

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Objectives: To address the safety of obtaining magnetic resonance imaging (MRI) in patients with temporary knee-spanning external fixators placed for tibial plateau fractures.

Design: Institutional Review Board–approved retrospective review.

Setting: Level 1 trauma center.

Patients/Participants: Records were reviewed on patients with knee-spanning external fixators applied during staged management of tibial plateau fractures from 2009 to 2015 and who also had an MRI performed.

Main Outcome Measurements: Complications associated with the MRI; secondary outcomes were pain scores, narcotic requirements, and fracture healing.

Results: A total of 56 patients with 57 fractures were included, and 55 scans (96.5%) were completed without complication. Two scans (3.5%) were stopped prematurely for patient-reported pain and subjective warmth of the external fixator. For all 57 studies, pain scores and narcotic usage were unchanged, and all fractures healed without complication.

Conclusions: Knee-spanning external fixator placement does not preclude MRI for patients with tibial plateau fractures. MRIs can be safely performed on patients with external fixators if patients are educated before imaging. Even in the small percentage of patients who experienced discomfort, there were no long-term complications.

Key Words: magnetic resonance imaging, external fixator, tibial plateau fractures, fracture healing

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

With the implementation of damage control orthopaedics, temporizing external fixators are used to provide fracture stability and maintain overall length and alignment. External fixators simultaneously stabilize the soft tissues and protect from further damage, allowing for soft tissue healing before definitive internal fixation.[1–4] Patients placed in external fixators often require magnetic resonance imaging (MRI) for spinal cord injury, intracranial pathology, or soft tissue injury to the musculoskeletal system.[5]

The safety of magnetic resonance (MR) scans in patients with implants is an important concern; the magnetic effect of an MRI depends on both the strength and the spatial gradient of the magnetic field (determined by the scanner), and the shape, mass, and magnetism of objects within the field (external fixators or other implants).[6] First-generation external fixators were made of highly magnetic materials, inhibiting the concurrent use of MRI due to torque, force, or heating of the device within the MR field.[7] As a result, many manufacturers introduced external fixator systems with low ferromagnetism that would be compatible with MRI scanners and were thus considered MRI-safe under the previous Food and Drug Administration (FDA) classification system.

In 2014, the International Electrotechnical Commission (IEC) and FDA developed a new labeling system to classify objects into 1 of 4 categories regarding safety for use during MRI scans.[8,9] "MRI-safe" devices are nonmetallic, nonconducting, and nonmagnetic; in laboratory testing, they present no additional risk to the patient, but may affect the quality of the diagnostic information. "MRI-compatible" devices meet all the criteria for MRI-safe; in addition, they do not affect the quality of diagnostic information and are not functionally affected by the MR environment. "MRI-conditional" items pose no hazards in an MRI environment that has been set up with predetermined specifications for parameters such as magnetic field strength, absorption rates, and artifact distortion; outside of those set zones, however, the object can cause hazards.[10] Finally, items labeled "MR-unsafe" are known to pose hazards in all MRI environments. Despite the designation that MRI-conditional devices can be operated safely using predetermined MR specifications,[6] radiology departments considered restricting the use of MRIs for patients with external fixators, for medical and legal reasons.

The purpose of this study, therefore, was to review any safety issues or complications in patients with tibial plateau

fractures who had an MRI performed with a knee-spanning external fixator in place.

PATIENTS AND METHODS

An Institutional Review Board–approved retrospective chart review was performed for patients treated for a tibial plateau fracture at a Midwest Level I trauma center from 2009 to 2015. Patients were initially identified by searching hospital billing records for CPT codes 27535 and 27536, indicating unicondylar and bicondylar tibial plateau fractures treated with open reduction and internal fixation. From this initial chart review, 396 tibial plateau fractures were identified. Patients who did not have an MRI were excluded, leaving 183 fractures. From this subset, patients who had an MRI with a knee-spanning external fixator in place were identified, leaving 57 tibial plateau fractures in 56 patients (1 patient had bilateral injuries; Fig. 1).

All MRIs were performed using the same 1.5-T scanner. Our institution regularly performs safety tests to ensure that there is no magnet-related damage resulting from these scans. MRI function is checked via daily phantom scans, and bimonthly preventative maintenance is performed on all machines to ensure patient safety and machine efficiency. There have been no functional issues since our institution began scanning metal external fixators.

MR images were obtained using the main (body) coil rather than surface coils, both to reduce risk of electrical conduction between the coil and the fixator and because the bulk of the fixator makes placement of a surface coil suboptimal. Both spin echo and short tau inversion recovery (STIR) sequences were used. Gradient echo images, which have a high degree of metal artifact, were avoided. Standard sequences used were coronal fast spin echo (FSE) T1 and STIR, oblique sagittal FSE proton density and T2 (aligned with the anterior cruciate ligament), and axial FSE proton density. Fat suppression was not used on spin echo sequences to avoid the associated increase in metal artifact.

Patient safety was also a priority throughout this study, and radiology technicians were taught to counsel patients before entering the MR scanner and alert the technician should they experience warmth at the pin sites. Screening for complications was performed as follows. First, radiology technician reports for each scan were reviewed to assess whether any complications were noted. It is our institutional protocol for all MRI technologists and radiologists to manually inspect skin for suspected burns at the time of any incident. Subsequent radiologist reports were also reviewed to determine if any complication was noted. Nursing and orthopaedic progress notes for 48 hours after the scan were examined to further identify any documented complications. Visual analog pain scores and narcotic usage were analyzed for the 48 hours before and after the MRI. Direct visualization of the patient's skin and pin sites were also performed daily during their hospital stay by nursing staff and orthopaedic surgery residents as per our institution's

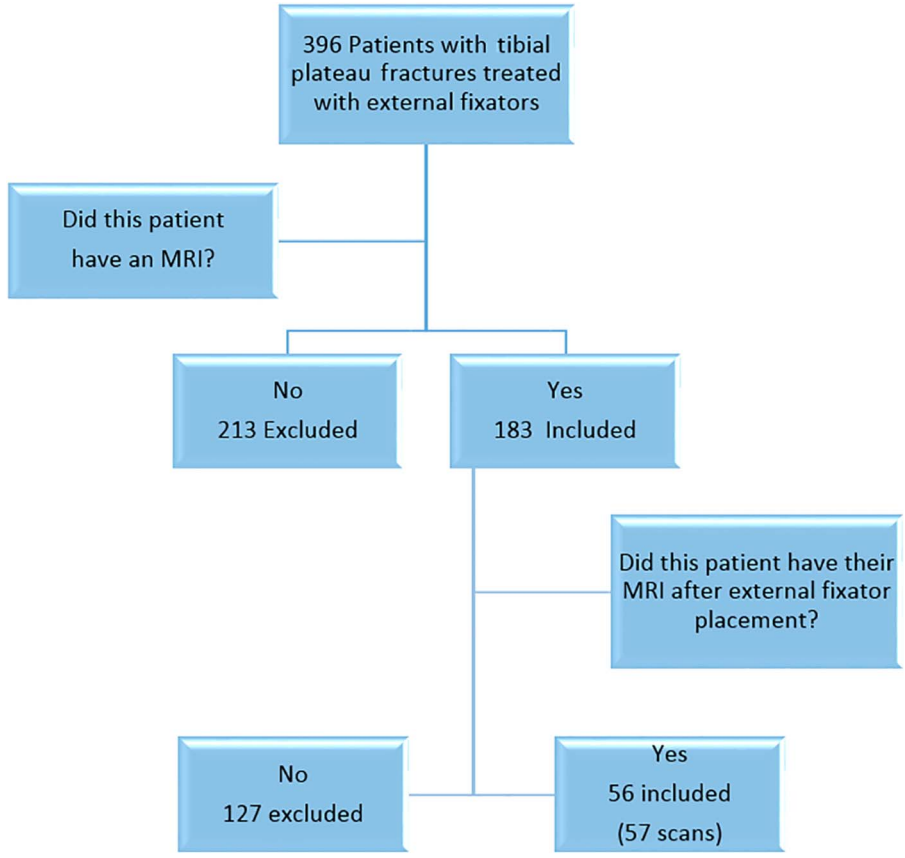

FIGURE 1. Flowchart showing the process for identifying patients for inclusion in the study. **Editor's Note:** A color image accompanies the online version of this article.

pin site care for external fixators protocol. Finally, patients were followed for up to 1 year postinjury to identify any long-term complications that might have resulted from the MRI. Finally, all morbidity and mortality logs for the duration of the study were analyzed for both the departments of orthopaedics and radiology to further capture patient complications. All adverse events in our radiology department are recorded in a centralized system, and this system was also reviewed against the patients included in our study.

RESULTS

Fifty-five of 57 scans (96.5%) were completed without complications noted in radiology technician reports, orthopaedic progress notes, or patient follow-up reports. Two patients experienced symptoms that led to early cessation of their scans. In both cases, scans were stopped immediately and no complications were noted. No surgeries were performed to revise the external fixator, and radiographs showed that there was no change in the position of the device. In both cases, the radiology technician reports noted that the sensation of pain was subjective, and no subjective change in external fixator temperature or placement was evident as noted by the technician. The first scan was stopped due to complaints of heat and pain, and the second scan was stopped because of pain and a sensation of the leg being pulled.

All 56 patients' charts were reviewed to compare the 48 hours before and after their MRI scan; no increases in self-reported pain scores or changes in narcotic use were noted, even in the 2 patients whose scans were truncated. No nursing or physician notes regarding patient wound care discussed the observation of any burns or worsening of the patient's soft tissue envelop after the MRI scans nor any complications surrounding their pin track sites. After 1 year of follow-up, all patients showed fracture healing, and there were no pin site infections and no return visits to the operating room as a result of complications.

DISCUSSION

This study shows that there were no lasting complications from MRI scans among 56 patients who had external fixators placed for tibial plateau fractures at our institution. Fifty-five (96.5%) of our patients safely underwent MRIs while in external fixators that were deemed MRI-conditional, and only 2 scans (3.5%) had to be stopped secondary to patient-reported symptoms. Of the 2 patients who experienced symptoms and had truncated scans, neither had sustained symptoms after cessation of their scans. Furthermore, there was no increase in narcotic medication use or visual analog pain scores relative to prescan levels. Finally, neither patient had long-term complications 1 year after the scan regarding fixation, fracture union, infection, or need for further surgery. From these results, we demonstrate that the use of a 1.5-T MRI in patients placed in an external fixator for tibial plateau fractures conferred little risk, and thus, we suggest that further research be performed to determine the safety of external fixation devices in MRI scanners. We recommend educating these patients before an MRI scan that the risk of symptoms is low, and they should alert the technician if symptoms develop. Radiology technicians should also be educated on the signs and symptoms of external fixation complications in MRI scanners. Furthermore, a multidisciplinary approach between radiologists, orthopaedic surgeons, and radiology technicians is required to ensure high levels of patient safety, correct MRI protocols, and accurate understanding of patient pathology so that the best possible care is provided to patients.

Several studies investigated the safety of low or nonferromagnetic external fixator components for use in MRI. Luechinger et al[11] tested nonferromagnetic clamps and frames for pelvis or knee-spanning external fixators in an MR environment. No torque effects were noted, and the rise in temperature was 0.7°C for a pelvic frame and 2.1°C for a diamond knee bridge in a 1.5-T scanner, and 0.9°C and 1.1°C, respectively, in a 3-T scanner. All these measurements were below the limits set by the IEC (60601-2-33), which considers a temperature increase of up to 3°C to be safe for extremities.[8] Davison et al[7] found that more than 10 commercially available constructs did not show a temperature increase of more than 2°C during a 30-minute MRI scan. Additionally, Lui et al[12] described technical considerations that can limit heat formation, such as placing pins bicortical, closer together, or at increased depth.

In April 2014, DePuy Synthes (Johnson & Johnson Company, Raynham, MA) reclassified its external fixators from MRI-safe to MRI-conditional. This change was initiated secondary to changes made in the American Society for Testing and Materials Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment guidebook and the FDA's new classification guidelines.[13] This new classification changed the considerations for use of MRI in patients with external fixators and caused conflicts between orthopaedic physicians and their radiology colleagues. Despite the designation that MRI-conditional devices can be operated safely using predetermined MR specifications,[6] radiology departments considered restricting the use of MRIs for patients with external fixators, for medical and legal reasons.

The concerns regarding simultaneous use of MRI and external fixators are primarily the creation of micromotion and induction of heat in the fixator components. However, excessive heating and the induction of electrical currents are MR safety issues that are typically associated with implants that have looped configurations, or that are electronically activated, such as neurostimulation systems and cardiac pacemakers. Neither of these considerations are pertinent to orthopaedic external fixator systems.[7,11]

We routinely obtain MRIs for preoperative planning in tibial plateau fractures, due to the incidence of soft tissue injury associated with these fractures.[14,15] Our imaging protocol for these injuries initially included radiographs and computed tomography (CT) scans for these injuries and progressed toward radiographs and MRI without the need for CT scans over the course of our study. This change in institutional protocol was related to the addition of new faculty attendings and improved image quality that improved boney anatomic visualization. Advanced imaging tended to

be obtained for patients with Schatzker IV, V, and VI tibial plateau fractures but was dependent on the operative surgeon's preference. A subset of patients who underwent MRI for these fractures had a knee-spanning external fixator in place. Given the perceived absence of complications among patients in external fixators who have undergone diagnostic MRIs at our institution, we reasoned that it was safe to continue acquiring scans, with close oversight for patient complaints. The noted cost differential of obtaining an MRI instead of a CT scan amounted to an estimated increase of $500 per scan.

At our institution, only the main (body) magnetic coil is used for imaging in the presence of external fixators. This is done for 2 reasons. First, the bulk of the fixator precludes use of the knee coil. Second, the radiofrequency generated by the MRI transmit coil can create electrical currents in conducting material, such as an external fixator, if the patient's skin or the fixator is in contact with the coil. If a surface coil is used, there must be insulating material between the coil and the patient's skin, but this may be insufficient to prevent electrical currents.

Imaging in the presence of metal must be adjusted to achieve optimal imaging quality.[16] Spin echo and STIR rather than gradient echo techniques are used for evaluation in the presence of metal fixators. This is primarily because metallic artifact is considerably more severe with gradient echo techniques. Increasing bandwidth and decreasing slice thickness will also reduce artifact.

Despite increased concerns regarding MRI safety and the reclassification of external fixation devices, studies in cadaveric models and in vivo analyses have demonstrated the value of MRI for assessing the extent of soft-tissue injury in orthopaedic patients.[7,17–21] MRI has also been shown to be particularly useful for identifying injuries in tibial plateau fractures.[14,15] Increases in external fixator temperature during MRI are within the IEC-recommended guidelines of 3°C,[7,11] and experts point out that current methods for evaluating the safety of medical devices in the MR environment are imperfect and that standards will continue to evolve.[22,23] Until there is contrary evidence regarding safety, the benefit of MRI scans for preoperative planning in periarticular knee injuries outweighs the small risk of temporary pain and warmth experienced by a small percentage of patients.

A limitation of our study is that the results are relevant to 1.5-T MRIs and cannot be extrapolated to newer 3-T MRI scanners. Also, because the study was retrospective, our results are dependent on the accuracy of documentation in the medical records. A prospective study would ensure more accurate and consistent documentation and could outline definitive criteria for when a scan should be truncated rather than leaving it up to the discretion of the radiology technician. Future studies investigating alternative external fixator locations, configurations, and manufacturers could expand these results and further support the safety of these devices for use with MRI. Finally, objective temperature monitors could be incorporated in the future to determine if any subclinical temperature fluctuations in the external fixator occur.

We find that these initial results provide sufficient evidence for continued use of MRI-conditional external fixator systems in 1.5-T scanners after proper patient education. This report specifically addressed the compatibility of the Synthes Large Trauma External Fixator System in 1.5-T MRI scanners, in patients with external fixators placed for tibial plateau fractures. Further monitoring of patients during scans will help bolster our understanding of the implications of using external fixators in MRI environments and help to reduce fears regarding complications and liability that might currently limit the ability to obtain MRI scans in these patients.

Although they have been reclassified as MRI-conditional, we did not find any significant short-term or long-term complications from use of the DePuy Synthes large external fixator as a knee-spanning external fixator in patients who had a 1.5-T MRI scan.

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