Clinical/Basic Science Research Article

OPEN

# Clinical implementation of MRI for evaluation of titanium press-fit osseointegration implants

LaYow C. Yu, BA[a], Tyler D. DeSena, BA[a], Alissa J. Burge, MD[b], S. Robert Rozbruch, MD[a], Taylor J. Reif, MD[a], Jason S. Hoellwarth, MD[a]

**Abstract**

**Objective:** This investigation of the safety of titanium transcutaneous osseointegrated nail (TiTON) implants in a magnetic resonance imaging (MRI) suite evaluated whether any adverse events occurred for patients (pain, heating sensation, implant loosening, and delay in care) or for the MRI machine (device damage).

**Design:** Retrospective chart review.

**Setting:** Academic medical center specializing in musculoskeletal health in Manhattan.

**Patients/Participants:** Patients who had osseointegration surgery underwent retrospective chart review and were also contacted inquiring whether they had subsequent MRI to any body part. Thirty-four patients had 51 total MRI scans: 24 of the osseointegrated limb and 27 of other anatomy.

**Intervention:** 1.5T or 3.0T MRI after TiTON implantation.

**Main Outcome Measurements:** Patients were asked if any adverse experiences such as pain, heating sensation, or implant loosening occurred. All original MRI and reports were sought to evaluate for evidence of adverse patient or machine events.

**Results:** No patients had any recognizable adverse event associated with MRI, including specifically pain, heating sensation, or implant loosening. No evidence of adverse machine interaction could be identified.

**Conclusions:** MRI is safe for patients with press-fit TiTON implants. To optimally ensure safety, osseointegrated patients seeking MRI should confirm with their implant company that no nontitanium components might be part of their total prosthesis construct and confirm they have no after-market modifications that may be ferromagnetic, such as screws or clamps.

**Keywords:** osseointegration, titanium, MRI, radiology, safety, implant, amputation, rehabilitation

## 1. Introduction

Nearly 2 million people in the United States are living with the loss of a limb. This number continues to increase annually and it is expected to double by 2050.[1] Titanium transcutaneous osseointegrated nail (TiTON) surgery, shown in Figure 1, is a surgical reconstruction technique for patients with limb amputation in which a metal implant is placed into the intramedullary canal, which passes through a permanent skin portal, and then connects to a normal terminal prosthetic limb.[2,3] Although there was a period when some surgeons used cobalt-chrome alloy implants, all currently marketed osseointegration implants are titanium alloys. TiTON often confers improved quality of life and mobility for amputees by eliminating the socket and thereby socket-related problems.[4]

Plain radiography is the most common imaging performed to routinely evaluate the implant-bone relationship. As with other implants,[5] patients with TiTON implants may need magnetic resonance imaging (MRI) for advanced visualization either of the local anatomy, such as evaluating for infection or neuroma, or of the distant anatomy, such as evaluating for brain injury. The presence of a metal object, particularly one that is transcutaneous and not yet familiar to the general medical community, may lead to uncertainty of the safety of MRI to the patient or machinery.[6,7] There are no publications available for the patient or health professional to refer to that describe the safety of MRI for TiTON implants. In general, the United States Food and Drug Administration (FDA) places medical devices into 3 categories: MR Safe, MR Conditional, and MR Unsafe. The implant evaluated in this study, the OPL (Osseointegrated Prosthetic Limb, Osseointegration International Pty Ltd, Sydney, Australia) is currently available by humanitarian device exemption and its MRI compatibility has not been categorized.

To address that knowledge gap, this study directly investigates the use of MRI for patients with 1 specific press-fit TiTON

*The authors declare that there are no disclosures or conflicts of interest relevant to the subject matter of this article. No funding was received for this work.*

*[a] Limb Lengthening and Complex Reconstruction Service, Osseointegration Limb Replacement Center, Hospital for Special Surgery, New York, NY, [b] Department of Radiology and Imaging, Hospital for Special Surgery, New York, NY.*

** Corresponding author. Address: Limb Lengthening and Complex Reconstruction Service, Osseointegration Limb Replacement Center, Hospital for Special Surgery, 519 E 72nd St, Suite 204, New York, NY 10021. E-mail address: yula@hss.edu (L. C. Yu).*



*OTAI (2025) e396*

*Received: 2 December 2024 / Received in final form: 13 February 2025 / Accepted: 27 February 2025*
*Published online 23 April 2025*

*http://dx.doi.org/10.1097/OI9.0000000000000396*

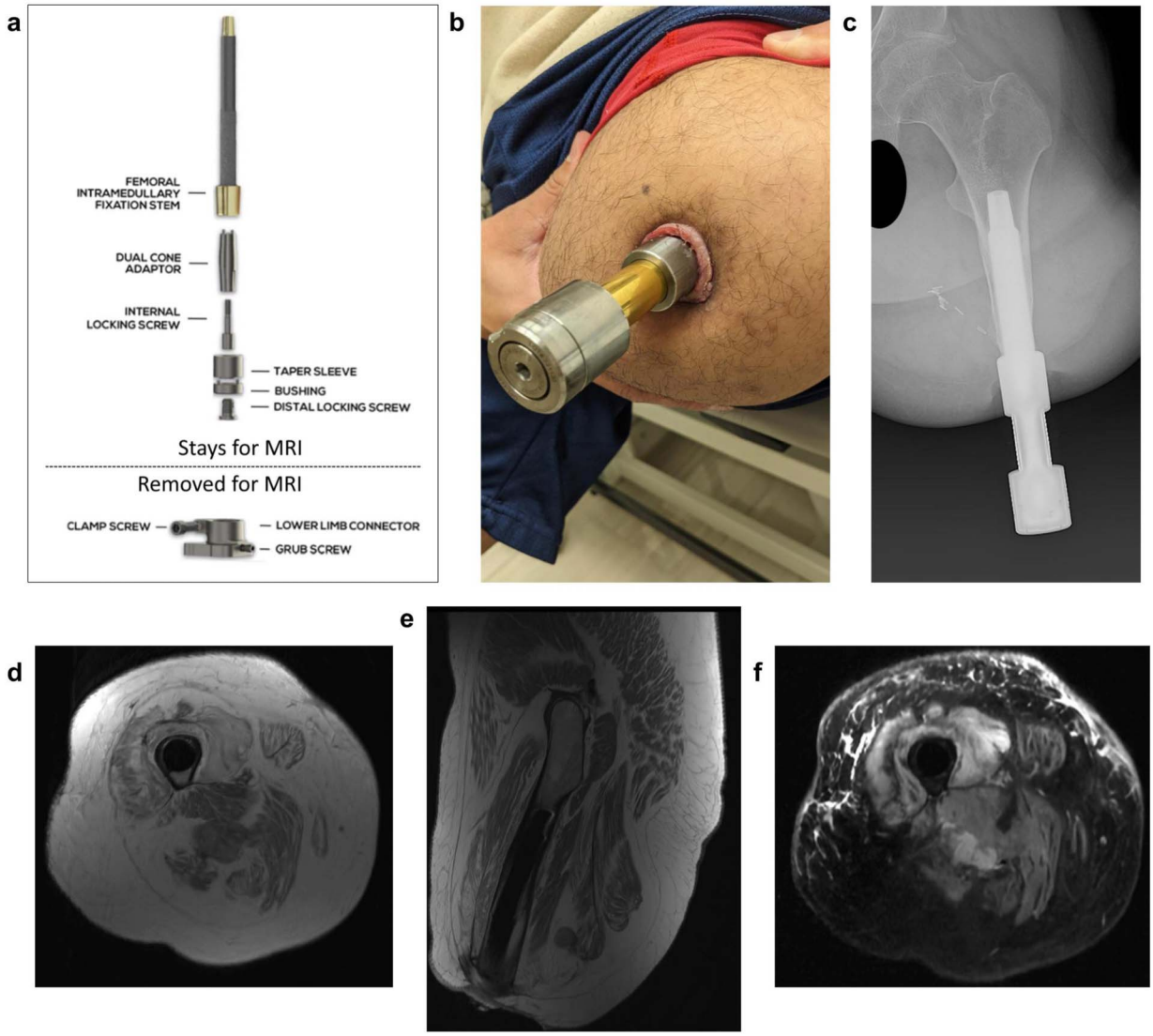


**Figure 1.** Osseointegration prosthetic limb (OPL) evaluated in this study. A, Exploded view with the components arranged at approximately the proximal-distal levels in which they would be once assembled and implanted in a patient who had undergone a femoral amputation. The figure identifies the upper components that remain connected to the implant (which is implanted into the patient) for the MRI, whereas the lower components are removed with the prosthetic leg as the patient is accustomed to doing for the MRI. Figure used with permission, modified for clarity, from Osseointegration Amputation Reconstruction, Reif TJ, Jacobs D, Fragomen AT, et al. Curr Phys Med Rehabil Rep 2022;10:61–70. B, Photograph showing a patient with transfemoral osseointegration, with the osseointegrated implant and attachment hardware on, but the prosthetic leg removed. Radiograph of the OPL implant in a patient who had undergone a femoral amputation. C, Anterior-posterior radiograph of the left femur with the osseointegration implant in the patient's femur and attachment hardware on the distal aspect of the implant, but the prosthetic leg removed. D, 1.5-Tesla axial T1 MRI proton density pulse sequence of the same patient; note the titanium implant (occupying the entirety of the femoral canal) is completely dark and the resolution of the local anatomy is good quality. E, Sagittal T1 MRI proton density pulse sequence of this patient shows again the dark outline of the implant within the femur and good resolution of adjacent anatomy. F, Axial T2 inversion recovery sequence again shows the implant within the canal to be dark and the local anatomy to be of good resolution. This patient's MRI was obtained to evaluate for potential osteomyelitis or other local infection, which was not identified. Intramuscular edema is noted, which is consistent with muscle atrophy in this specific patient who had a prolonged period of immobility.

implant. The primary aim was to evaluate the patient safety when MRI is obtained of the local osseointegrated limb and of distant anatomic sites. The secondary aim was to describe any situations of problems to the MRI machinery during or after imaging of these patients. The tertiary aim was to investigate the occurrence of delay in care related to safety concerns.

## 2. Methods

This research was approved by the IRB at Hospital for Special Surgery under IRB# 2023-0816. After obtaining institutional research board approval, the osseointegration patient cohort in the author's practice was contacted and retrospective chart review was performed. Written informed consent was obtained for all patients as part of their surgical paperwork before osseointegration.

### *2.1. Studied Patient Selection*

Patients were included if any MRI was performed after osseointegration, of any body location, for any reason. Patients were excluded if they did not have any MRI after osseointegration. This identified 34 patients with unilateral TiTON who had 51 MRI studies, the demographics of whom

are summarized in Table 1. All MRI scans were performed at 1.5T or 3T.

Table 1 presents the patient demographics, summarized with descriptive statistics. The average patient age was 52.0 ± 10.5 years (range 26–69). There were 19 (56%) men. 21 (62%) were femur amputees, 12 (35%) tibia, and 1 (3%) forearm. No patients had multiple implants. The average time between osseointegration and the first MRI was 14.5 ± 12.5 [0.9–43.3] months. Of the 51 MRI studies, 24 (48%) were performed of the specific limb segment.

### 2.2. Outcomes

The primary aim of this study was to identify any adverse patient experience. All original imaging outside institutions were obtained for primary interpretation and also all reports obtained to evaluate for documented issues. Along with report evaluation, patients were asked over phone call about the MRI experience whether an unexpected event occurred during or seemingly related to the MRI, specifically pain, heating sensation, or implant loosening within the 3 months after MRI.

The secondary aim was to describe any situations of problems to the MRI machinery during or after imaging of these patients. Patients were asked, and reports evaluated for any indication that studies were aborted because of issues with image acquisition or other machine or software problems.

Tertiary aims were to investigate the occurrence of delay in care related to safety concerns. Patients were asked whether when initially scheduling or upon presenting for an MRI they encountered any apparent delay in obtaining the MRI because of the imaging center's concern regarding them being an osseointegrated patient.

### 2.3. Analysis

Data were evaluated as simple data descriptions. Comparative statistical analysis was not performed.

**Table 1**

**Demographics.**

| Variable | Value |
|---|---|
| Age at surgery, mean ± SD [range], y | 52.0 ± 10.5 [26–69] |
| Months between osseointegration and first MRI | 14.5 ± 12.5 [0.9–43.3] |
| Sex | |
| Male | 19 (56%) |
| Female | 15 (44%) |
| Osseointegrated anatomy | |
| Femur | 21 (62%) |
| Tibia | 12 (35%) |
| Forearm | 1 (3%) |
| Imaged anatomy* | |
| Osseointegrated limb segment | 24 (47%) |
| Contralateral limb | 6 (12%) |
| Abdomen/pelvis | 4 (8%) |
| Thoracic/lumbar spine | 10 (20%) |
| Head/neck | 5 (9%) |
| Shoulder | 2 (4%) |
| Imaging location* | |
| Our institution | 23 (45%) |
| Other institution | 28 (55%) |

* Total number of studies (51) exceeds the number of patients because some patients were imaged more than once. The denominator for these percentages was 51 rather than the number of patients (34).

## 3. Results

The primary aim of this study was to identify any adverse patient experience related to having an MRI after TiTON surgery. Among the 34 patients with 51 total studies, no adverse patient experiences were identified. Specifically, no instances of pain, heating sensation, or implant loosening were reported by the patient or mentioned in the radiologist report.

The secondary aim was to describe any situations of problems to the MRI machinery during or after imaging of these patients. No instances were reported by the patient, documented in the imaging report, or apparent from evaluation of imaging.

The tertiary aim was to investigate the occurrence of delay in care related to safety concerns and also the impact of metal artifact interference. Patient charts were reviewed for evidence of MRI safety concerns, and patients were asked whether when initially scheduling or upon presenting for an MRI they encountered any apparent delay in obtaining the MRI because of the imaging center's concern regarding them being an osseointegrated patient. No situations of delays in MRI performance occurred. However, there were 2 instances documented in patient charts of both the provider and the patient expressing uncertainty about the safety compatibility of the TiTON implant with MRI. In the first instance, an emergency medicine provider at an outside hospital avoided ordering lumbar spine MRI because of the patient's TiTON implant. The second instance involved a patient contacting their care team before their scheduled MRI appointment to express concern about the safety of their TiTON implant.

## 4. Discussion

The purpose of this study was to investigate the safety of MRI regarding 1 specific press-fit TiTON implant. The most important finding was that there were no adverse events (such as pain or heating sensation) for any patient. A secondary aim of the study was to evaluate whether there was any adverse impact to the MRI machinery; also, no instances occurred. None of the patients reported experiencing delays when scheduling or undergoing MRI scans because of concern about metallic components in their TiTON implant, only 2 instances of uncertainty or unawareness about the safety of MRI with the TiTON implant (which were resolved before MRI scheduling). Given the primacy of this study regarding MRI for osseointegrated limbs, leading to limited direct literature comparison, the Discussion section will present the considerations, principles, and potential merits and concerns of MRI for patients with metallic implants.

Concerns regarding MRI in patients with metallic implants largely relate to safety and image quality. Concerns regarding image quality have been the subject of extensive research and technical development, with the utilization of modified routine sequences and specially developed advanced sequences such as multiacquisition variable-resonance image combination and slice encoding for metal artifact correction, allowing the acquisition of high-quality diagnostic MR images in patients with most large orthopaedic implants such as arthroplasties and osseointegration implants. Safety concerns remain regarding many types of implants, often with the safety being determined experientially or by consensus.[8] The underlying mechanism causing safety concerns typically relates primarily to the potential for heating of tissues related to specific absorption rate (SAR), a measure of the rate at which energy is absorbed per unit body mass when in the presence of a radiofrequency pulse during MRI. SAR values are

proportional to the square of the main magnetic field, the square of the flip angle, and the radiofrequency bandwidth, and therefore relative elevations in SAR may be observed when MR acquisition parameters are modified in an attempt to increase image quality; for example, a 2D fast spin echo sequence with a long echo train, large number of excitations, and wide radiofrequency bandwidth produces a relatively elevated SAR, which can result in gradual heating of the patient.[9] Attempted quantification of the degree of heating has largely been performed using phantoms; however, these are likely to overestimate the degree of actual heating because they fail to fully replicate the qualities of living tissue, in particular the presence of biologic perfusion, which is an effective method by which biological tissues may dissipate excess heat. Phantom studies have reported potential temperature increases between 1 and 9°C in the tissues adjacent to hip arthroplasties. In comparison, the curing of bone cement, which is commonly used during the placement of metal implants, has been shown to generate temperature increases between 48 and 90 degrees, with increases in adjacent bone of up to 3–17 degrees.[10,11] In addition, SAR values and estimated potential temperature elevation may not correlate directly with patient discomfort. Our institution routinely scans patients with large metallic implants such as arthroplasties, extensive spinal fixation, and osseointegration implants on a daily basis without reported patient discomfort and has been doing so for decades without incident.

Although a full discussion of MRI physics and the relationship to metal implants is beyond the scope of this article, the following principles are very informative and help understand the decision making early in this cohort's care. These articles[12–14] describe in further details what is summarized subsequently. MRI is possible because magnetic fields generate a different spin in body tissues based on the fat-versus-water relationship, which is detected by the machine and processed by the computer and software to the clinician to visualize. The metal inside a magnetic field experiences atomic-level and potentially gross forces as the metal becomes increasingly energized by the magnetic field. The magnitude of energization is an intrinsic property of the metal. Artifact occurs from situations such as gross physical position change (motion artifact) or difficulty of the detector and software to accurately process the fluctuations in magnetic field because of the frequency that resonates from substantially different materials (such as fat, bone, titanium, or steel). The visual artifact can be attenuated with less fluctuation of the field (less magnetic material, the subject being more stationary, or the subject being more central in the imaged field) and also with increasingly better software to execute correction algorithms. These physics principles can potentially manifest in clinically relevant patient adverse events should the forces acting upon an implant be strong enough to dislodge an implant or generate heat because of activation of the metal. Although the literature could not be identified which documented actual mechanical issues of orthopaedic implants subjected to MRI, there is documentation of cochlear implant loosening.[15] An ex vivo study of 39 implants including titanium, steel, cobalt, and other alloys evaluated at 7 T, only a single titanium implant had meaningful torque forces that moved the implant.[16] The same study identified that after 30 minutes of field application, the greatest temperature change was 0.41°C, clinically inconsequential. The authors conjecture that the implant of focus in this study is likely to be labeled as "MRI conditional" upon potential commercial market approval after an eventual formal trial.

MRI has value as a single imaging modality that can diagnose osteomyelitis,[17] cellulitis,[18] abscess,[19] implant loosening,[20] and neuroma.[21] These are all potential etiologies of pain that can present a diagnostic challenge for a patient with TiTON. Osseointegration is a relatively recent and low-volume procedure worldwide, with associated limited literature exploring the evaluation of adjunctive care situations, such as imaging modalities including MRI. This study's authors have explored using MRI for osseointegrated patients to differentiate potential diagnoses as listed above, and a conscious part of the use of MRI was whether it was safe for the patient. This was the specific motivation for the performance of this investigation. The authors expected MRI to be safe for TiTON implants based on the existing literature of MRI use for other metal orthopaedic implants. The use of MRI for arthroplasty is rather extensive and has been considered reliably safe for titanium implants using typical magnetic flux density since at least 1992,[22] to the extent that review articles focus much more on image interpretation than on the concern for patient adverse events.[12] The safety of implants that pass through the skin has been much less explored, with the first study likely published in 2017 evaluating MRI safety for external fixators.[23] Those authors reported that 38 patients with 44 external fixators, 13 within the MRI bore and the remaining outside the bore, no adverse events occurred. Based on those studies, the authors expected MRI of TiTON to be safe, which indeed was the primary finding of this study.

Additional questions of this study were the safety of MRI regarding the MRI machinery and the implant and the impact of this uncertainty on obtaining imaging. Implant manufacturers often do not explicitly state the safety of MRI with orthopaedic implants, perhaps to mitigate potential legal liability or development cost, and that lack of clarity increases the burden upon individual medical professionals who may have varying knowledge of the implant.[5] In this study cohort, it specifically led to a delay in imaging for 1 patient whose emergency doctor was unsure. Beyond the patient, MRI may affect the use of the implant. A study of titanium magnetically motorized intramedullary lengthening nails identified that 3-T fields impaired the nail's lengthening force by 60%–90%; interestingly, 1.5 T had no apparent effect.[24] While the TiTON componentry is not motorized, there are different components screwed or impacted together that potentially could respond differently based on a magnetic field. There are general protocols followed by most MRI technicians,[25] but given the limited awareness of osseointegration and the reality that some patients have had injury due to MRI with deep hardware present,[26] and the potential of legal action,[27] it is reasonable that as TiTON becomes more prevalent, such confusion may occur more frequently. It is hoped that this study provides evidence of the safety of MRI use not only for the patient but also for the implant and machine.

This study has several limitations to consider. Only 1 specific model type of press-fit osseointegration implant was studied (OPL). There are other osseointegration implants with fundamentally different designs; given that the current models are also made of titanium alloy, it is likely the MRI safety is similar, but the associated componentry may not be exclusively titanium, and there does exist a cobalt-chrome alloy osseointegration model, so this study's findings may not be fully applicable to other products. A major strength of the study is the number of patients and imaging episodes evaluated. A total of 34 patients with 51 studies, 24 of the osseointegrated limb and 27 of other anatomy, provides high confidence that any adverse patient or machine-related episode likely would have occurred if directly related to the

implant. It is also important that this is the first study to evaluate press-fit TiTON implants in the context of MRI and that it establishes the safety profile to the patient, to the implant, and to the MRI machine. It is hoped that 1 specific benefit of the study is to reduce potential delays in obtaining MRI related to safety concerns.

## 5. Conclusions

It is safe to perform MRI for patients who have press-fit osseointegration with TiTON implants. There is no recognized risk regarding patient safety or machinery safety. Further research of MRI and osseointegration is safe to perform and would be highly helpful to establish machine settings, imaging features, and the role for diagnosis in situations such as pain or concern for infection.

## References


1. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, et al. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil*. 2008;89:422–429.
2. Hoellwarth JS, Tetsworth K, Rozbruch SR, et al. Osseointegration for amputees: current implants, techniques, and future directions. *JBJS Rev*. 2020;8:e0043.
3. Hoellwarth JS, Tetsworth K, Akhtar MA, et al. The clinical history and basic science origins of transcutaneous osseointegration for amputees. *Adv Orthop*. 2022;2022:7960559.
4. Hebert JS, Rehani M, Stiegelmar R. Osseointegration for lower-limb amputation: a systematic review of clinical outcomes. *JBJS Rev*. 2017;5:e10.
5. Iwatsuki K, Yoneda H, Onishi T, et al. Compatibility of magnetic resonance imaging in patients with orthopedic implants: manufacturer questionnaires. *Nagoya J Med Sci*. 2020;82:79–84.
6. Hudson D, Jones AP. A 3-year review of MRI safety incidents within a UK independent sector provider of diagnostic services. *BJR Open*. 2019;1: 20180006.
7. Bhuva AN, Moralee R, Moon JC, et al. Making MRI available for patients with cardiac implantable electronic devices: growing need and barriers to change. *Eur Radiol*. 2020;30:1378–1384.
8. Jabehdar Maralani P, Schieda N, Hecht EM, et al. MRI safety and devices: an update and expert consensus. *J Magn Reson Imaging*. 2020;51:657–674.
9. Bernstein MA, King KF, Zhou XJ. *Handbook of MRI Pulse Sequences*. Cambridge, MA: Elsevier, Academic Press; 2004.
10. Reckling FW, Dillon WL. The bone-cement interface temperature during total joint replacement. *J Bone Joint Surg Am*. 1977;59:80–82.
11. Homsy C, Tullos H, Anderson M, et al. Some physiological aspects of prosthesis stabilization with acrylic polymer. *Clin Orthop Relat Res*. 1972;83:317–328.
12. Fritz J, Lurie B, Potter HG. MR imaging of knee arthroplasty implants. *Radiographics*. 2015;35:1483–1501.
13. Koch KM, Hargreaves BA, Pauly KB, et al. Magnetic resonance imaging near metal implants. *J Magn Reson Imaging*. 2010;32:773–787.
14. Koff MF, Burge AJ, Koch KM, et al. Imaging near orthopedic hardware. *J Magn Reson Imaging*. 2017;46:24–39.
15. Loth AG, Fischer K, Hey AK, et al. Magnetic resonance imaging in patients with hearing implants - follow-up on prevalence and complications. *Otol Neurotol*. 2021;42:1334–1341.
16. Feng DX, McCauley JP, Morgan-Curtis FK, et al. Evaluation of 39 medical implants at 7.0 T. *Br J Radiol*. 2015;88:20150633.
17. Kapoor A, Page S, Lavalley M, et al. Magnetic resonance imaging for diagnosing foot osteomyelitis: a meta-analysis. *Arch Intern Med*. 2007; 167:125–132.
18. Klein DA, Lee BH, Bezhani H, et al. The clinical utility of MRI in evaluating for osteomyelitis in patients presenting with uncomplicated cellulitis. *J Foot Ankle Surg*. 2020;59:323–329.
19. Weaver JS, Omar IM, Mar WA, et al. Magnetic resonance imaging of musculoskeletal infections. *Pol J Radiol*. 2022;87:e141–e162.
20. Koff MF, Burge AJ, Potter HG. Clinical magnetic resonance imaging of arthroplasty at 1.5 T. *J Orthop Res*. 2020;38:1455–1464.
21. Arnold DMJ, Wilkens SC, Coert JH, et al. Diagnostic criteria for symptomatic neuroma. *Ann Plast Surg*. 2019;82:420–427.
22. Ebraheim NA, Savolaine ER, Zeiss J, et al. Titanium hip implants for improved magnetic resonance and computed tomography examinations. *Clin Orthop Relat Res*. 1992;275:194–198.
23. Hayden BL, Theriault R, Bramlett K, et al. Magnetic resonance imaging of trauma patients treated with contemporary external fixation devices: a multicenter case series. *J Orthop Trauma*. 2017;31:e375–e380.
24. Gomez C, Nelson S, Speirs J, et al. Magnetic intramedullary lengthening nails and MRI compatibility. *J Pediatr Orthop*. 2018;38:e584–e587.
25. Ghadimi M, Sapra A. *Magnetic resonance imaging contraindications*. Treasure Island, FL: StatPearls Publishing; 2023.
26. Dempsey MF, Condon B. Thermal injuries associated with MRI. *Clin Radiol*. 2001;56:457–465.
27. Deveci C, Atilgan M, Demirçin S. The forensic aspect of thermal injuries during MRI: a case report with a review of literature. *Rom J Leg Med*. 2021;29:49–52.