

Magnetic Intramedullary Lengthening Nails and MRI Compatibility

Charles Gomez, MD,* Scott Nelson, MD,* Joshua Speirs, MD,† and Samuel Barnes, PhD‡

Background: Magnetic intramedullary nails (IMNs) are fully implantable lengthening devices that became available in the United States in 2011 for the correction of limb length discrepancies. This device represents a major advancement in the field of limb lengthening surgery as it is typically tolerated better than external fixation. Unlike traditional IMNs, surgeons recommend routine removal following limb lengthening. One such reason involves patient safety as it pertains to magnetic resonance imaging (MRI). Theoretical concerns with MRI exposure include implant migration, implant heating, and involuntary elongation of the lengthening mechanism. Our study seeks to investigate the effects of MRI on intramedullary magnetic lengthening nails.

Methods: Twenty-five intramedullary magnetic nails were studied. One nail was placed within the magnetic field to measure maximum magnetic force. Nails were then scanned using standard knee MRI protocols, 12 in 3 T and 12 in 1.5 T MRI scanners. The following parameters were measured: (1) distraction of the implants after MRI exposure, (2) temperature before and after MRI, and (3) internal distraction force before and after MRI.

Results: Maximum magnetic force was found to be 2 lbs. There was no involuntary distraction of the implants after MRI. Temperature increase of 3.3°C was found in the femoral nails and 3.6°C in the tibial nails that were exposed to 3 T MRI. This increase did not reach or exceed physiological temperature of 37°C. Distraction force was reduced by 61.7% in the femoral nails and 89.6% in the tibial nails after subjected to 3 T MRI. There was no reduction in distraction force after exposure to 1.5 T MRI.

Conclusions: Recommendations for routine removal of magnetic IMNs for safety concerns should be reconsidered. Exposure to 3 T MRI should be avoided in patients who are still undergoing lengthening or with plans for future lengthening with magnetic IMNs.

Clinical Relevance: To assess patient safety and implant function after magnetic IMNs have been exposed to MRI.

Key Words: magnetic intramedullary lengthening nails, MRI compatibility, IMNs and MRI

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The Precice intramedullary nail (Nuvasive Specialized Orthopaedics Inc.) is a fully implantable magnetic lengthening device which became available in the United States in 2011. This device represents a major advancement in the field of limb lengthening surgery as it is typically tolerated better than external fixation due to less soft tissue damage, lower infection rates, and improved joint motion.^{1,2} The nail is composed of a titanium alloy (Ti-6Al-4v) and contains a rare earth magnet and a series of planetary gears that are sealed from contact with body fluids and bone. The mechanical gear shaft rotates 210 times for each millimeter of distraction. This is actuated by a motor driven external remote control (ERC) which noninvasively lengthens the Precice implant using magnetic forces (Fig. 1). This lengthening process is performed by the patient or a family member by placing the ERC over a specific location on the affected extremity. This painless process is typically prescribed to lengthen a fraction of a millimeter several times per day. Because of its reliability, rate control, the ability to reverse, and the variety of sizing options, the Precice nail offers significant advantages over previous intramedullary lengthening devices and has become a popular means of limb lengthening.

Unlike other intramedullary nails (IMNs) commonly used for trauma, many surgeons recommend routine removal of this device upon completion of limb lengthening. One of the major reasons for implant removal is the presumed incompatibility with magnetic resonance imaging (MRI). Warnings exist about magnetically activated implants potentially causing serious harm or death in or around MRI, and instructions for use state that Precice magnetic IMNs are unsafe within the MR environment.³ Theoretical concerns include implant migration, implant heating, and involuntary elongation of the lengthening mechanism. Magnetic spinal growing rods (MAGEC Nuvasive Specialized Orthopaedics Inc.) are similar implants for which the effects of MRI have been studied.^{4,5} The MAGEC implants have recently been granted Food and Drug Administration (FDA) clearance for use with MRI under certain conditions.⁶ Our study seeks to investigate the effects of MRI on the Precice intramedullary nail. This knowledge is important for medical decision making in patients with Precice

From the Departments of *Orthopedics; and †Radiology, Loma Linda University, Loma Linda, CA.

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Reprints: Charles Gomez, MD, Department of Orthopedic Surgery, Loma Linda University, 11406 Loma Linda Drive, Suite 224, Loma Linda, CA 92354. E-mail: cdgomez@llu.edu.

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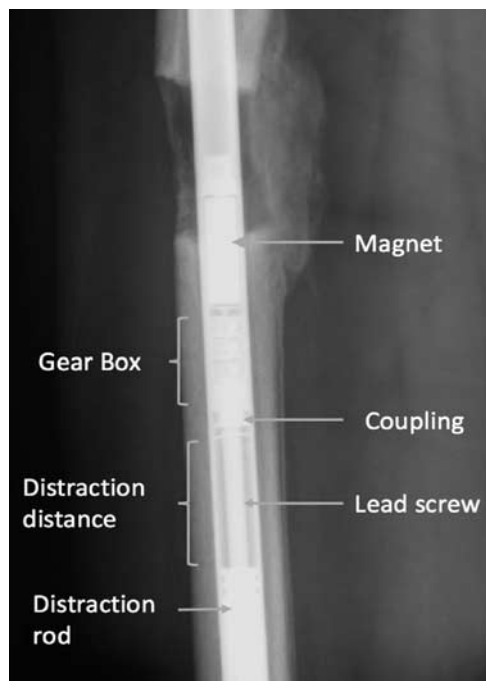


FIGURE 1. Internal components of the Precice intramedullary nail.

nails that need to have an MRI and should clarify the indications for routine removal of this implant.

METHODS

A total of 25 nails were studied. A single 10.7 mm diameter femoral Precice nail was used for the sole purpose of quantifying magnetic forces acting upon the rod in and around the 3 T MRI scanner. The remaining 24 implants were not used for this part of the study in order to preserve their magnets.

Twelve femoral and 12 tibial Precice IMNs were investigated by subjecting them to a standard MRI examination at a static magnetic field strength of 1.5 or 3.0 T. Six femoral nails and 6 tibial nails were subjected to lower extremity protocols in the 3 T MRI scanner. The MRI scans were repeated with separate IMNs in the 1.5 T MRI scanner. Three nail diameters were studied in each subgroup: two 12.5 mm, two 10.7 mm, and two 8.5 mm. These IMNs were placed into osteotomized tibial and femoral Sawbone models. Standard surgical technique was used to implant the nails. Two distal and 2 proximal interlocks were placed using the insertion jig and fluoroscopic guidance to simulate typical constructs. A window was cut into the Sawbone constructs to obtain temperature measurements around the internal magnet and adjacent parts of the nail (Fig. 2). The nontelelescoping ends of these constructs were then attached to an MRI compatible wooden platform leaving the telescoping end free to lengthen should any forces activate the distraction mechanism. This platform was surrounded with water bottles and then transferred onto the MRI table simulating

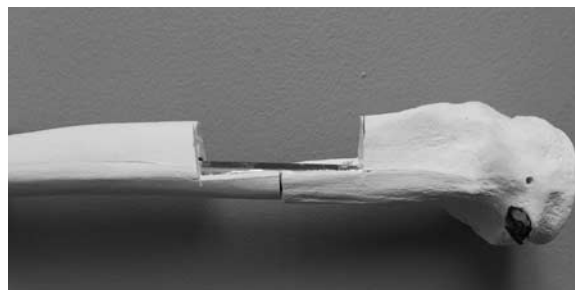


FIGURE 2. Osteotomized construct with windowing to allow for temperature measurements.

the typical transfer time and position of an actual patient. Water bottles were placed around the implants to provide a dielectric load on the MRI coils similar to a patient being scanned, this ensures the radiofrequency (RF) transmission, and amount of heating will be comparable with scanning a patient with an implant.

MRI scanning was performed on 12 nails (6 femoral and 6 tibial) in a 3.0 T Siemens Trio scanner, on the remaining 12 nails (6 femoral and 6 tibial) in a 1.5 T Siemens Sonata scanner. A standard lower extremity musculoskeletal protocol was run for 30 minutes. This consisted of a short-tau inversion recovery sequence, turbo spin echo T1-weighted sequence, and 3 planes of a proton density weighted turbo spin echo sequence, after this the short-tau inversion recovery sequence was repeated until 30 minutes was reached. Enough slices were added to all sequences so that the FDA first level maximum allowed specific absorption rate (SAR) of 4 W/kg was achieved and maintained for the entire 30-minute examination. SAR is defined as the RF power that is absorbed per unit of mass of an object. SAR was maximized to induce the worst-case scenario heating of the implants.

Implants were oriented within the MRI scanner in 1 of 2 ways. Half of the nails were positioned to simulate lower extremity MRIs, which were placed feet first within the MRI scanner. The remaining nails were placed in a head first position, to simulate patient positioning for a standard brain MRI. These positions were chosen to assess potential differences due to implant orientation, as the 2 vary by 180°.

The following parameters were studied:

- (1) *Maximal forces acting upon the nail within the MR environment:* a 10.7 mm diameter femoral nail was placed in a variety of positions in and around the MRI scanner to determine the location and magnitude of the strongest possible magnetic force acting upon the implant. These displacement forces were measured by using a hanging scale attached to the implant after the implant was allowed to freely be influenced by the magnetic force within the MR environment.
- (2) *Distraction of the implants after MRI exposure:* the amount of distraction for each nail was measured before implantation in the Sawbones models and then it was again measured after MRI exposure when the implants were removed.
- (3) *Temperature before and immediately after exposure to MRI.* Temperature was measured at the outer casing

of the nails located adjacent to the internal magnet and recorded both before and after the exposure. Temperatures were measured using an infrared thermometer placed 2 cm from the nail.

- (4) *Internal distraction force before and after exposure to MRI.* Internal distraction force refers to the amount of longitudinal distraction force that is generated by the lengthening mechanism while being activated by the ERC. Before MRI exposure, these nails were tested in the Nuvasive laboratory for distraction force using the ERC at a standard distance from the implant. Serial numbers and the force of distraction for each of these implants was recorded. After the MRI sequence was performed these nails were explanted from the Sawbones models and sent back to the Nuvasive laboratory for distraction force testing using the same protocol.

RESULTS

The maximal magnetic force acting on an average sized femoral nail (10.7 mm diameter) was 2 lbs. Maximum force measured was obtained at the entry to the MRI bore.

There was no measurable distraction at the telescoping segments of the implants after being subjected to 3 T or 1.5 T MRI scanning sequences. Total length remained the same after MRI in all nails studied.

The force generated by each of the implants after 3 T MRI while being distracted with the use of the ERC was significantly decreased for all of the implants. The tibial implants were affected to a much greater degree than the femoral implants.

- Before MRI the femoral nails had an average internal distraction force of 294 lbs (1307.8 N). After MRI, the average was 112.5 lbs. (500.4 N), which is 38.3% of the original.
- Before MRI the tibial nails had an average internal distraction force of 300 lbs. (1334.5 N). After MRI, the average was 31.2 lbs. (138.8 N), which is 10.4% of the original.

The force generated by each of the implants after 1.5 T MRI with the use of the ERC was not significantly diminished. However, one tibial nail tested showed a large increase in force post-MRI and was excluded in our calculation.

- Before MRI the femoral nails had an average internal distraction force of 274.5 lbs (1221 N). After MRI, the average was 272.7 lbs. (1213 N).
- Before MRI the tibial nails had an average internal distraction force of 389.7 lbs. (1744.6 N). After MRI, the average was 389.2 lbs. (1731.3 N).

The average temperature of the femoral implants increased by 3.3°C and that of the tibial implants increased by 3.6°C after being subjected to 3 T MRI. The final temperature approximated ambient temperature in the MRI.

- Average temperature of femoral implants before MRI was 17.6°C and after MRI, 20.9°C ($\Delta = 3.3^\circ$).
- Average temperature of tibial implants before MRI was 17.3°C and after MRI, 20.9°C ($\Delta = 3.6^\circ$).
- Average temperature within the MRI bore was 21.1°C.

There was no increase in temperature noted in the femoral or tibial implants after being subjected to 1.5 T MRI. The final temperature approximated ambient temperature in the MRI.

- Average temperature of femoral implants before MRI was 23.3°C and after MRI, 22.8°C ($\Delta = 0.5^\circ$).
- Average temperature of tibial implants before MRI was 22.8°C and after MRI, 22.6°C ($\Delta = 0.2^\circ$).
- Average temperature within the MRI bore was 23.3°C.

Internal distraction force of the IMNs was not affected by their orientation within the MRI scanner.

DISCUSSION

Intramedullary lengthening nails have been approved by the FDA for use in the correction of limb length discrepancies, and have been found to provide predictable results, decrease pain, hasten recovery, and offer a high level of safety.^{7,8} To our knowledge this is the first study to investigate MRI compatibility and patient safety concerns with use of magnetic intramedullary lengthening nails.

The results of our study demonstrated a maximum magnetic force of 2 lbs. at the front of the 3 T MRI scanner, given the weight ranges of a lower extremity and secure intramedullary fixation this magnetic force is not considered to be clinically relevant.

There was no involuntary distraction of the lengthening mechanism when subjected to 1.5 or 3.0 T static magnetic field or the changing gradient magnetic fields from standard MRI lower extremity protocols. This suggests that no soft tissue or neurovascular injury is likely to occur due to rapid elongation of the implant, even if performed after recent lengthening procedure.

Heat generation of metallic orthopaedic implants can be produced by the RF fields generated inside the MRI and lead to thermal injury of adjacent soft tissues.^{9,10} Furthermore, there is concern that subjecting the magnetic material found within lengthening nails may increase this heat generation. We found that there was no increase in temperature after exposure to MRI scanning at 1.5 T, and a 3.6°C increase in the tibial nails exposed to 3 T MRI. This increase was not considered to be clinically relevant and was likely caused by the nails reaching equilibrium with the ambient room temperature. The final temperature did not rise above physiological body temperature of 37°C. As described by Goldstein et al¹¹ there is little risk for thermal injury at temperatures $\leq 43^\circ\text{C}$, even after prolonged exposure. These findings are consistent with what was demonstrated by Poon et al⁴ in 2016 when studying cadaveric tissue adjacent to magnetic-controlled spinal growing rods after exposure to MRI. They found no structural or heat related damage to the soft tissue in contact with the metallic rods when observed histologically.

Our data also suggests that there is no risk for thermal soft tissue injury.

Although magnetic force and temperature changes were not found to be clinically relevant, there was significant deactivation of the implants after exposure to 3 T MRI. In the femoral nails, there was a 61.7% reduction in distraction force, and in the tibial nail group there was a reduction of 89.6%. This is most likely due to the demagnetization of the rare earth magnet that operates the lengthening mechanism. This demagnetization is thought to be due to the static magnetic field and therefore will occur when the rod/patient enters or is very close to the 3 T magnetic field, even in the absence of the changing magnetic gradients or RF fields generated during imaging. Demagnetization is greater in the tibial nail subset, likely due to the smaller size of the magnet within the IMN. The tibial nails were designed with a smaller magnet than femoral nails to avoid breaking the drive-shaft when the ERC is applied closer to the implant due to the more subcutaneous location of the tibia. It is important to note that the force needed for distraction osteogenesis varies depending on patient size and soft tissue envelope and these reductions in force may or may not render the nail useless. Within the 1.5 T subset of nails, there was no decrease in distraction force, which may be due to a threshold phenomenon above which significant demagnetization occurs.

Nail demagnetization may be an indication for nail removal and exchange if further lengthening is desired. It has, however, been recommended by some orthopaedic surgeons that nail removal is required 1-2 years post-operatively due to the presence of the rare earth magnet. Although sealed from bone and body fluids there is a theoretical concern that leakage could lead to systemic exposure within the patient. Rare earth elements are a group of metals that can be found in multiple mineral types and are present in devices used every day, from computer hard drives and optics, to wind turbines and hybrid vehicles.¹² When compared with the biological effects of heavy metals such as lead, cobalt, and chromium, there is limited knowledge with exposures to rare earth elements. There have been reported pulmonary complications in industrial workers, and anemia in individuals that have been exposed to industrial waste.^{12,13} While these comparisons are not equivalent to the use of intramedullary lengthening nails, further research may provide insight into the safety of rare earth magnets especially as it pertains to their interactions within strong magnetic fields.

Limitations of this study include the fact that the IMNs were not partially distracted before the MR exposure precluding their ability to compress should the forces have acted upon it in such a manner. However, there was no distraction of the nails independent of the direction which they were oriented in the scanner and thus it is unlikely that these implants could have involuntarily shortened. Another limitation is that the results of our study do not constitute an FDA approval. This study merely suggests that MRI can be safely performed in patients with these implants and must be interpreted in that

context. We have at least one patient who required advanced imaging of the shoulder that had 2 retained magnetic IMNs. There were no adverse complications as a result of MRI, and we know of several similar cases that have taken place uneventfully throughout the country.

CONCLUSIONS

In spite of instructions that state the Precice intramedullary nail is unsafe in the MR environment, this study shows no evidence of safety concerns as they pertain to heating, elongation, and migration forces acting upon this implant in 1.5 and 3.0 T environments. Recommendations for routine implant removal motivated by safety concerns for MRI should be reconsidered. For patients with these implants who need to have an MRI, risks and benefits of the imaging can now more clearly be evaluated. Interestingly, there is a significant decrease in the internal distracting force after exposure to the 3 T magnet, and no decrease in distracting force after exposure to the 1.5 T magnet. Given this data, 3 T MRI should be avoided when possible in patients who are still undergoing lengthening or have plans for future lengthening with the device.

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