ORIGINAL RESEARCH

Magnetically Driven Intramedullary Limb Lengthening in Patients with Pre-existing Implanted Programmable Devices: A Case Series

Christopher A Iobst[1], Danielle N Hatfield[2], Stephen D Forro[3], Stephen M Quinnan[4]

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Abstract

Aim: The aim of the study is to demonstrate the safety and efficacy of the use of magnetically controlled intramedullary nails in patient with programmable implantable devices.

Background: Magnetically driven intramedullary limb lengthening devices have revolutionised the field of limb reconstruction. Because the system is powered by strong magnets, there are warnings to avoid the use of the device in patients with implanted programmable devices, such as cardiac pacemakers.

Materials and methods: Four patients with three different types of programmable implanted devices presented to two centres for limb lengthening and limb reconstruction. Each patient had a limb length discrepancy and desired correction using an intramedullary lengthening device. After thorough counselling about the potential risks and benefits of the procedure as well as discussions with each patient's medical team, the decision to proceed with surgery was made.

Results: All four patients underwent osteoplasty with insertion of a magnetically driven intramedullary lengthening nail. Goal length was achieved with successful consolidation and subsequent nail removal in all patients. There were no malfunctions of the implantable devices during the distraction phase in any of the patients.

Conclusion: With proper precautions, intramedullary lengthening can be performed safely and successfully using a magnetically driven nail in patients with previously implanted programmable devices.

Clinical significance: This initial experience suggests use of magnetically controlled intramedullary nails in patient with programmable implantable devices can be undertaken safely within constraints of precautions.

Key words: Intramedullary limb lengthening, Limb length discrepancy, Pacemaker.

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Introduction

Programmable implants are widely used in healthcare and can provide life-saving functions. Cardiac pacemakers are perhaps the most well-recognised programmable implant, with estimates of 700,000 devices being implanted worldwide per year.[1] Other programmable implants such as gastric pacers and ventriculoperitoneal shunts utilise similar technology to perform their role. Each of these programmable devices has warnings from the manufacturer about the risk of malfunction if placed in an electromagnetic field. Patients with these implantable devices may encounter many sources of an electromagnetic field during their daily activities, such as cellular phones and portable headphones but, fortunately, there are rarely any dangerous consequences.

In healthcare, however, potential interaction with stronger electromagnetic fields is more common and must be anticipated to prevent the device malfunctioning. For example, if a patient with a cardiac pacemaker needs to have a magnetic resonance imaging (MRI) study performed, the device may need to have the pacing mode changed temporarily to prevent damage. During surgery on a patient with a programmable implant, a bi-polar electrocautery system rather than a unipolar system should be used to prevent electromagnetic interference (EMI).

Limb lengthening using an intramedullary lengthening nail has become increasingly popular over the last 10 years.[2] Intramedullary lengthening offers multiple advantages to the patient over traditional lengthening using an external fixator. The patients are more comfortable, maintain their range of motion better, and avoid the problem of pin site infections related to the external fixator.[2] One of the most commonly used intramedullary lengthening nails, the PRECICE® nail (NuVasive®, San Diego, CA) was FDA approved

[1,2]Department of Orthopaedic Surgery, Nationwide Children's Hospital, Columbus, Ohio, United States

[3]Department of Orthopaedic Surgery, Nova University College of Osteopathic Medicine, United States

[4]Paley Orthopedic & Spine Institute, St. Mary's Medical Center, Palm Beach, Florida, United States

Corresponding Author: Christopher A Iobst, Department of Orthopaedic Surgery, Nationwide Children's Hospital, Columbus, Ohio, United States, Phone: +1 6147223390, e-mail: christopher.iobst@nationwidechildrens.org

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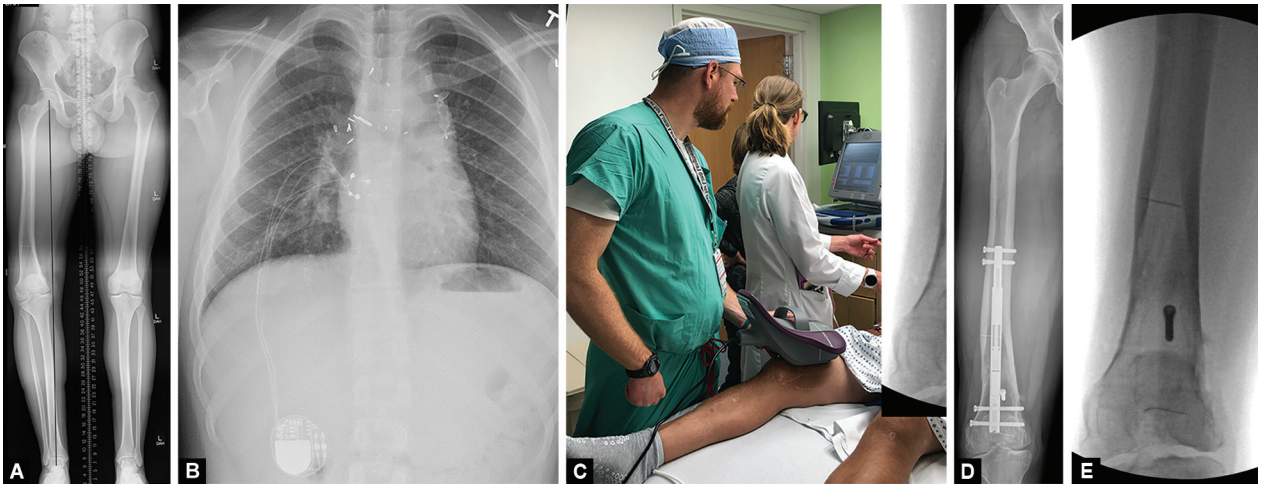


Figs 1A to E: (A) Pre-operative standing radiograph demonstrating varus deformity of the right lower extremity and leg length discrepancy of approximately 2.5 cm; (B) Radiograph demonstrating location of cardiac pacemaker at about the level of the third lumbar vertebra on the right side of the abdomen; (C) Photograph in the pre-operative holding area demonstrating the cardiology team assessing the function of the pacemaker while the ERC was being used at the anticipated magnet location in the right distal femur; (D) Post-operative radiograph demonstrating consolidation of the regenerate bone after lengthening and deformity correction with the magnetically driven intramedullary lengthening nail; (E) Post-operative image after nail removal demonstrating full consolidation of regenerate bone

in 2012. It uses communication between two rotating magnets in a hand-held device, the external remote controller (ERC), and a rotating magnet housed within the nail to power the distraction. To communicate through the intervening soft tissue envelope, strong rare earth magnets consisting of neodymium iron boron are used. As a strong magnetic field forms when the ERC is operated, there are warning labels posted on the ERC to remind users from operating the device near any patients with implanted medical devices. The patient information and instructions provided with the device states: "DO NOT USE the PRECICE System if you have a pacemaker or other active electronic implant such as an implanted infusion pump or implantable cardiac defibrillator. The magnets in the PRECICE System could interact with these implants or cause them to move in ways that could harm you". The potential implications of pacemaker dysfunction secondary to the strong magnetic fields created during ERC lengthening sessions include heart arrhythmias that may be fatal, as described in the cardiology literature.[3,4] Consequently, pacemakers are currently considered a relative contraindication to the use of the ERC.

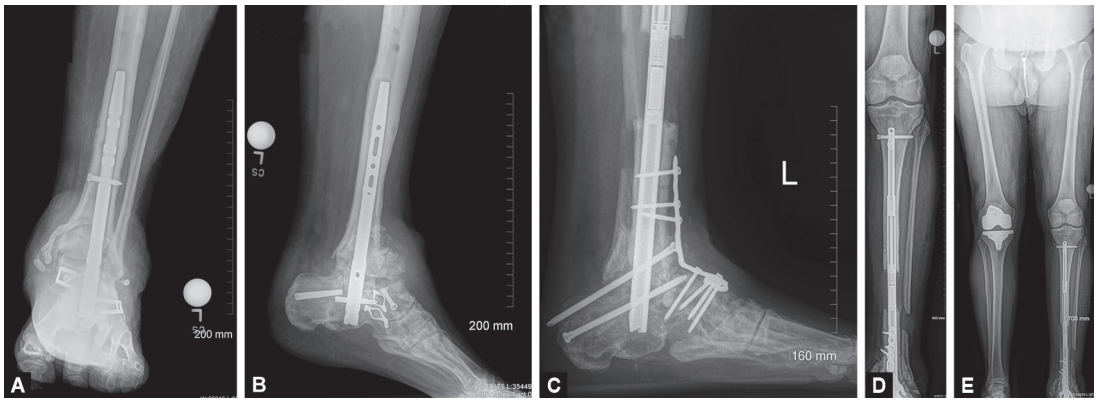
Although not common, some patients may present to the orthopaedic surgeon for the treatment of a leg length discrepancy who have had implanted magnetic field-sensitive programmable devices. In the discussion over management options for limb lengthening, many patients are aware of the advantages of intramedullary lengthening nails and often inquire about their availability. After open disclosure of the warnings on using such a device in patients with programmable implants, the surgeon and the patient must decide whether the risk of interfering with the function of the implantable device outweighs the advantages of using an intramedullary lengthening nail. Based on the information from two recent publications, and with informed consent from the patients, joint decisions were made on undertaking a correction of the limb length discrepancy using a PRECICE® nail in four patients who had, between them, three different types of programmable implants.[5,6] This case series will describe our experience with each patient and their device.

Case 1: Cardiac Pacemaker

A 20-year-old male patient presented to our centre for an evaluation of his right knee deformity and leg length discrepancy. At the age of 7 years, he had sustained a Salter-Harris IV fracture of his medial distal femur and developed a medial distal physeal growth arrest subsequently. A physeal bar excision was performed at the age of 9 years. At the time of presentation to our clinic, he had an approximately 2.5 cm leg length discrepancy, a varus deformity with a mechanical lateral distal femoral angle of 112° (Fig. 1A). A discussion was undertaken to perform an acute correction of the varus deformity combined with gradual lengthening. The family was interested in using an intramedullary lengthening nail rather than lengthening over a nail with an external fixator.

His past medical history indicated he was born with a double inlet left ventricle, transposition of great arteries, and sub-valvar pulmonary atresia. He underwent a staged repair; ultimately having a fenestrated Fontan with fenestration closure. Owing to the presence of a nodal rhythm and bradycardia, he had a Medtronic ADDR01 Adapta Pacemaker (Medtronic, Minneapolis, MN) implanted at the age of 4 years. This is an example of a "physiologic" pacemaker. It waits for the patient's natural heartbeat before delivering the pacing impulse to avoid unnecessary pacing. According to the device's listed precautions regarding wireless communication devices, such as demagnetisers, it recommends keeping the cardiac device at least 30 cm (12 inches) away from these sources. Using information from imaging studies, the radiographic location of his pacemaker (at the level of lumbar vertebra 3 and the expected location of his PRECICE nail magnet in the distal right femur were expected to have an intervening distance of approximately 63 cm (25 inches; Fig. 1B). The instruction was for the family to only approach the distal femur with the ERC from below his knee (i.e., from distal to proximal) so that the ERC was never near his abdominal region.

Before scheduling the surgery, the patient was evaluated by cardiology specialists and his pacemaker assessed. The opinion provided was that it was safe to attempt to proceed with his case



Figs 2A to E: (A and B) Pre-operative weight-bearing anteroposterior (AP) and lateral radiographs of patient's non-united ankle fusion demonstrating collapse and shortening; (C) Postoperative lateral radiograph showing compressed arthrodesis site with PRECICE nail with anterior plate spanning the junction with the head of the talus and anterior calcaneus in addition to the osteotomy with lengthening; (D) Postoperative AP radiograph after lengthening of 5.6 cm, demonstrating excellent regenerate formation as well as healing fusion site; (E) Postoperative standing bone length radiographs demonstrating equal leg lengths

but that he would require a pacemaker device interrogation prior to and following his procedure. On the morning of surgery, he was met in the pre-operative holding area by both the cardiology and the orthopaedic surgery teams. The ERC was placed over the distal femur at the expected location of his PRECICE nail magnet while the cardiologist simultaneously tested the function of the pacemaker (Fig. 1C). When the ERC was turned on, there was no evidence of interference with the function of the pacemaker. Based on this evidence, all parties (cardiology, orthopaedic surgery, patient, and family) agreed to proceed with the proposed surgery. Under cardiac anaesthesia, a fixator-assisted distal femoral osteotomy was performed with insertion of a 12.5 mm diameter by 190 mm length retrograde femoral PRECICE nail. The nail was tested intra-operatively by performing an acute lengthening of 1 mm. The nail appeared to function appropriately and the anaesthesia team did not report any disturbance to his cardiac function during this 7-minute test. Following surgery, a post-operative pacemaker device interrogation was performed by cardiology and the device found to function normally. From an orthopaedic surgery standpoint, the patient was comfortable and had passed his physical therapy requirements allowing a discharge home on post-operative day number one.

He was seen for his initial post-operative visit on day 6. The family was given instructions on how to operate the ERC device and reminded to avoid placing the machine near his abdomen. A single 0.25 mm lengthening was performed in the office without incident. He began his distraction at home the following day with a prescription of 0.25 mm three times per day for a total of 0.75 mm lengthening per day. He was seen in the office on a weekly basis to monitor his progress until his goal lengthening (2.4 cm) was achieved at 5 weeks. He did not experience any issues with his pacemaker during the 5-week distraction phase. Follow-up visit with cardiology at the end of distraction found no concerns with his cardiac function or pacemaker.

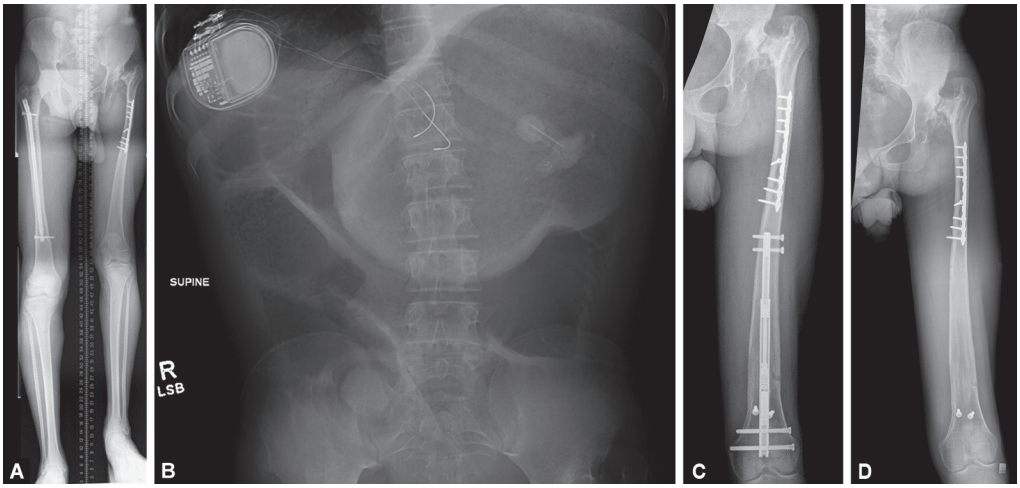
The patient was instructed to limit weight-bearing to touch-down only after surgery but gradually advanced his weight-bearing status; this was based on monthly radiographs during the consolidation phase. He was cleared for full weight-bearing at 4 months after surgery (Fig. 1D). Routine implant removal was performed at 14 months after insertion without incident (Fig. 1E). He has made a full recovery and no longer requires care from our centre.

Case 2: Cardiac Pacemaker

A 72-year-old man presented to our institute for evaluation of chronic osteomyelitis in a failed tibiocalcaneal arthrodesis following a failed total ankle replacement (Figs 2A and B). He initially had a total ankle replacement performed for osteoarthritis 8 years prior, and the implant was removed 6 years later after becoming infected. Several unsuccessful attempts at fusion were performed leaving osteomyelitis incorporating a femoral head allograft that was acting as a large nidus of infection.

At the time of presentation, severe pain that prevented walking, redness and the laboratory findings were consistent with deep infection. He was dependent on crutches and a wheelchair for mobility. He was also aware of a limb length inequality that was about 2 cm. Treatment of the ongoing deep bone infection would require removal of the femoral head allograft and surrounding devitalised bone resulting in an additional 3 cm of length loss. The option of a staged debridement and spacer placement, then followed by arthrodesis and lengthening with a circular fixator versus using a PRECICE nail compression/distraction technique including non-union compression and lengthening distraction at a distal tibial osteotomy, were discussed. The patient already had experience with external fixation and was eager to avoid this if possible.

The patient's medical history included atrial flutter for which he had a Biotronic Edora 8 DR-T Implantable Cardiac Pacemaker (Biotronik Inc., Lake Oswego, OR) inserted 3 years prior. Like case 1, the manufacturer lists precautions to EMI and advises discussing potential risks of electromagnetic fields on the pacemaker. However, there is no more specific guidance on recommended distances to maintain between the pacemaker and other electromagnetic field-generating devices. Based on the radiographic level of the pacemaker at the level of the heart on imaging studies, the distance to the magnet in the nail would be very large at greater than 100 cm. The patient evaluated by his cardiologist and the surgical plan with respect to the location of the ERC and nail magnet discussed with the manufacturer of the pacemaker; both felt that given the distance from the device there should not be an issue with using



Figs 3A to D: (A) Pre-operative standing radiograph demonstrating approximately 7 cm leg length discrepancy; (B) Abdominal radiograph demonstrating the location of the gastric pacer on the right side at about the level of thoracic vertebra eleven; (C) Post-operative radiograph demonstrating consolidation of the regenerate bone after 5 cm lengthening; (D) Post-operative radiograph after nail removal demonstrating full consolidation of the regenerate bone

the PRECICE nail. Nevertheless, given our lack of experience with using magnetic nails in the presence of a pacemaker, it was planned to have a representative from the pacemaker company at the procedure to monitor the device throughout the surgery.

The first stage went as planned and the patient was treated with a full course of culture-specific antibiotics for 6 weeks before proceeding with the second stage. At the second-stage procedure, a 12.5-mm diameter by 335-mm length trochanteric entry antegrade femoral PRECICE nail was used. The nail was inserted in a retrograde manner from calcaneus to tibia. Prior to placement of the nail, the spacer was removed and the arthrodesis site was prepared. An osteotomy was performed in the distal meta-diaphysis for gradual lengthening. At the time of nail placement, the nail had been pre-distracted 3.5 cm to allow for compression at the osteotomy site as well as the ankle and subtalar arthrodesis sites. The PRECICE nail was locked proximally and distally with pegs and a Fast Distractor Max was used to shorten the nail and thereby compress the osteotomy and two arthrodesis sites acutely (Fig. 2C). We performed the final 2 mm of compression with an ERC4 to test the clinical scenario for when lengthening at home was to be performed. After this compression, a second locking bolt distally that crossed the fusion sites and an anterior T plate to stabilise the junction of the anterior tibia with the neck of the remaining head and neck of the talus were then added. The company representative monitored the pacemaker throughout and reported no changes were observed at any time including when using the Fast Distractor Max and the ERC4. The patient was admitted postoperatively and discharged home on day 2. During his stay, there were no orthopaedic or cardiac incidents. A postoperative pacemaker interrogation of the pacemaker performed several weeks after the operation confirmed a normally functioning pacemaker.

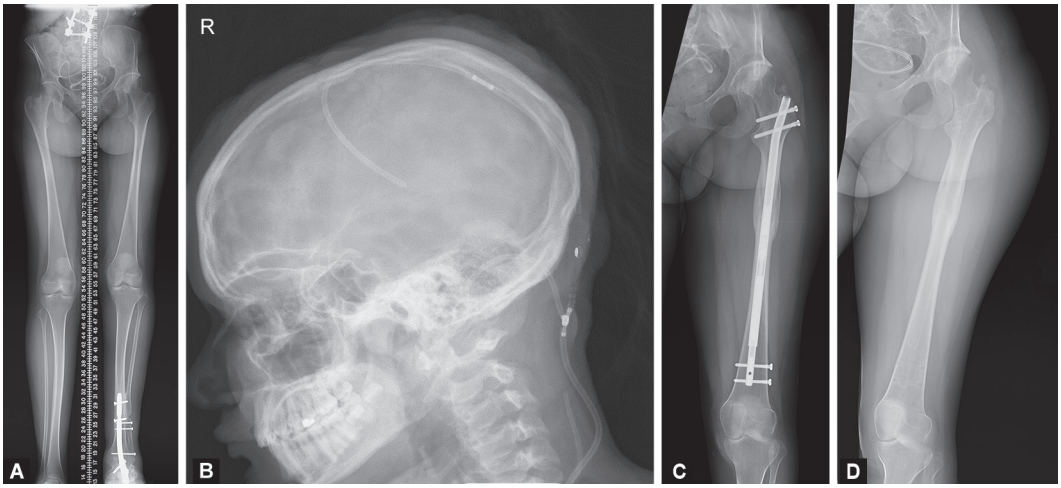
At the initial post-operative visit on post-operative day 21, which is our normal latency period for an osteotomy in this location, the patient was instructed on the operation of ERC including precautions to bring the device onto the leg from distally toward the foot and to keep the device away from the pacemaker site in the chest. Distraction began the day after his postop visit, at a rate of 0.15 mm/four times per day for a total of 0.60 mm lengthening per day. He was seen on a bi-weekly basis in the office until cessation of lengthening at 12 weeks post-operatively, at which time 5.6 cm of lengthening was confirmed on XR (Fig. 2D), and leg lengths were determined to be equal on bone length films (Fig. 2E). During lengthening the patient did not experience any issues related to cardiac pacemaker.

The patient was initially instructed to be non-weight-bearing after surgery but has since been advanced to 50% weight bearing based on monthly radiographs. He is currently doing well and in the consolidation phase. The plan for removal of the PRECICE nail is at approximately 18 months after the operation. Although in this case the nail is relatively far from the pacemaker, it demonstrates that even with the largest size nail, an ERC4P device with the largest magnets, and use of a Fast Distractor Max—that would be considered the worst-case scenario in terms of strong magnetic fields locally—no issues were encountered.

Case 3: Gastric Pacer

An 18-year-old male patient presented to our centre for evaluation of his leg length discrepancy. He had orthopaedic surgery for a left septic hip as a young child (exact age unknown) which left him with a 7-cm discrepancy at skeletal maturity (Fig. 3A). He also had a previous history of a left diaphyseal femur fracture fixed with a plate that was now incorporated into the bone. He was unhappy with using a 5-cm shoe lift and had difficulty performing activities of daily living due to the large leg length discrepancy. He desired femoral lengthening but did not have an external fixator.

He had also a diagnosis of chronic intestinal pseudo-obstruction requiring gastrostomy and ileostomy as an infant. He was total parenteral nutrition (TPN) dependent until 2012. He was gradually weaned off TPN and a Medtronic Enterra II gastric neurostimulator generator NHX703084H (Medtronic, Minneapolis, MN) was placed in 2013. Gastric electrical stimulation from the gastric pacer system helps control the chronic nausea and vomiting associated with gastroparesis by stimulating the smooth muscles of the lower stomach. Internal leads from the neurostimulator deliver mild, controlled electrical pulses to the antrum portion of the stomach muscle wall. According to the product manual, EMI from a bone growth stimulator is classified as a precaution but not



Figs 4A to D: (A) Pre-operative standing radiograph demonstrating a leg length discrepancy of approximately 2.5 cm on the left; (B) Lateral head and neck radiograph demonstrating the location of the programmable valve attached to the ventriculoperitoneal shunt; (C) Post-operative radiograph demonstrating consolidation of the regenerate bone after lengthening; (D) Post-operative radiograph after nail removal demonstrating full consolidation of the regenerate bone

a contraindication to use. The manual states that the bone growth stimulator coils are unlikely to affect the gastric pacer function if they are kept 45 cm away from the neurostimulation system. Based on preoperative radiographs the most inferior portion of the gastric pacer was positioned at the level of thoracic vertebra number 11 (Fig. 3B). The distance between the gastric pacer and the anticipated position of the magnet in the retrograde femoral nail was 66 cm. After a discussion with the patient's gastroenterology team and the patient, it was agreed to proceed to lengthen his left femur using a retrograde femoral intramedullary lengthening nail. The family was educated to only approach the distal femur with the ERC from below his knee (i.e., from distal to proximal) so that the ERC would not get near the abdominal region.

On the morning of surgery, the gastroenterology team turned the pacer off. A 10.7 mm diameter by 190 mm length retrograde femoral PRECICE nail was inserted into the left femur. An acute lengthening of 1 mm was performed intra-operatively to test the nail function. His pacer was turned back on when the patient arrived on the inpatient floor. He was discharged home the following day without any orthopaedic or gastroenterology issues during his overnight stay.

The initial post-operative visit was on post-operative day seven. The family was instructed how to operate the ERC device and reminded to avoid placing the machine near his abdomen. A single 0.25 mm lengthening was performed in the office without incident. Distraction began at home the following day with a prescription of 0.25 mm four times per day for a total of 1.0 mm lengthening per day. He was seen in the office on a weekly basis to monitor his progress until target lengthening (5 cm) was achieved at 7 weeks. He did not experience any issues with his pacemaker during the 7-week distraction phase. An assessment of the pacer performed by the gastroenterology at the end of the distraction phase reported no pacer dysfunction.

The patient was limited to touch-down weight-bearing after surgery initially but advanced his weight-bearing status gradually based on monthly radiographs during the consolidation phase. Full weight-bearing was permitted at 4 months after surgery (Fig. 3C). At 14 months after insertion, the retrograde femoral PRECICE nail was removed without incident (Fig. 3D). He has made a full recovery and no longer requires care from our centre.

Case 4: Ventriculoperitoneal Shunt

A 19-year-old female patient presented to our centre for evaluation of her leg length discrepancy. She was wearing a lift under her left shoe but wanted a more permanent solution. She had previously had a spinal fusion due to a tethered spinal cord. While able to ambulate independently, her residual neurologic loss resulted in the development of a Charcot ankle and subtalar joint. She underwent a pan-talar fusion of her left ankle one year prior to presentation at our centre. Standing radiographs demonstrated a 2.5-cm leg length discrepancy with a neutral mechanical axis (Fig. 4A).

She was diagnosed with Dandy–Walker syndrome as an infant and had a ventriculoperitoneal shunt placed. The shunt was revised multiple times over her childhood with the most recent version being a left ventriculoperitoneal shunt connected to Medtronic Strata II valve (Medtronic, Minneapolis, MN; Fig. 4B). As per guidelines provided with this product, all devices with magnets were to be kept a minimum of 5 cm away from the site where the valve was implanted. The radiographic location of the valve from imaging studies suggested an approximate distance of 53 cm between the valve and the anticipated location of the nail magnet. After discussion with the patient's neurosurgery team, the patient and the patient's family, it was agreed to proceed to lengthen her left femur using an antegrade femoral intramedullary lengthening nail. The family was instructed to approach the femur with the ERC from below her knee (i.e., from distal to proximal) so that the ERC would not get near her head.

On the day of surgery, a 10.7-mm diameter by 335 mm length trochanteric entry antegrade femoral PRECICE nail was inserted. An acute lengthening of 1 mm was performed in the operating room to test the nail function. Post-surgery, the patient was admitted overnight without further orthopaedic or neurosurgical incident. She had her shunt setting confirmed by the neurosurgery team prior to discharge on post-operative day 1.

The initial post-operative visit was on post-operative day 5. The family was instructed on how to operate the ERC device and reminded to avoid placing the machine near her head. A single 0.25 mm lengthening was performed in the office without incident. Distraction began at home the following day with a prescription of 0.25 mm three times per day for a total of 0.75 mm lengthening per day. Progress monitoring at the office on a weekly basis occurred until target lengthening (2.5 cm) was achieved at 5 weeks. She did not experience any headaches, seizures, or issues with her ventriculoperitoneal shunt during the 5-week distraction phase.

Instructions were for touch-down weight-bearing initially after surgery but advanced gradually based on monthly radiographs during the consolidation phase. Full weight-bearing was permitted 4 months after surgery (Fig. 4C). At 15 months after insertion, the antegrade femoral PRECICE nail was removed without incident (Fig. 4D). She has made a full recovery and no longer requires care from our centre.

Discussion

Currently there are no published clinical studies demonstrating whether or how to use a magnetically driven intramedullary lengthening nail in patients with pre-existing implanted programmable devices. Although it is rare to see patients with implanted programmable devices in a limb reconstruction clinic, these two centres had these four patients present within a year.

Concerns over the possibility of causing damage to the implanted devices with the ERC magnets were allayed by two recent publications. Gomez et al. tested the compatibility of magnetic lengthening nails and MRI.[6] Prior to this study, there was substantial concern about allowing a patient with an indwelling PRECICE nail to enter the magnetic field of the MRI. Implant migration, implant heating, and involuntary elongation of the lengthening mechanism were several of the possible undesirable outcomes caused by placing a PRECICE nail in an MRI environment. However, after testing 24 nails in Sawbones models, they found no involuntary distraction of the implants after MRI and no clinically relevant increase in implant temperature. Although distraction force was decreased in the nails, especially after being subjected to 3 Tesla MRI, the researchers concluded that the recommendation for routine removal of the PRECICE nail for safety concerns related to MRI should be reconsidered.

Tan et al. looked specifically at the interaction between a magnetically controlled growing rod and pacemakers.[5] Although this was an *in vitro* study, the authors' study design tried to recreate physiologic conditions. They found that the magnetic field of the ERC only interferes with pacemaker function when the ERC is employed <16 cm away from the pacemaker. Based on this information and the substantially larger anticipated distances between the implantable devices and the PRECICE nail magnet, we were reassured to proceed with attempting lengthening in these patients.

This case series describes the steps taken to narrow the likelihood of an unwanted outcome:

- For each implanted device in the patient, research into company literature about the specific device characteristics and sensitivity to extraneous magnetic fields was done;
- There were multi-disciplinary discussions between orthopaedic surgeons and the other relevant medical specialties and the family;
- Arrangements were made to test the function of the implanted device before and after exposure to strong magnetic fields, albeit at distances greater than the minimum recommended;
- The patient and their family were given explicit instructions on how the ERC was to be used to ensure it was not brought near to the implanted programmable device in the patient.

With these criteria met, we have found that use of magnetically controlled intramedullary nails in these patients with programmable implantable devices was safe. Larger lengthenings (with more prolonged use of the ERC) or repeated lengthenings in the same patient group remain untested. There were no complications even with the use of the largest size nails, the most current ERC (ERC4P), or a Fast Distractor Max, all of which represent the worst-case scenario in terms of magnetic fields generated from the intramedullary lengthening nail in the lower extremity.

There are several clinical tips to share if a greater margin of safety is desired, for example, use of such nails in the upper extremity. To keep the distance between the nail magnet and the implantable device as far apart as possible, use of a retrograde rather than antegrade femoral nail should be considered. Each iteration of the ERC has had a stronger magnet to improve communication through the patient's soft tissue envelope. Using the weakest version of the ERC magnet that still allows the nail to function will minimise the size of the magnetic field. Similarly, using a smaller diameter PRECICE nail will involve a smaller magnet. Importantly, always educate the patient and the patient's family to keep the ERC away from the patient's torso or head. The ERC should be brought to the nail magnet location in the direction from the toes (caudal to cranial) to the nail and not the reverse (cranial to caudal).

Clinical Significance

This case series provides the first evidence that when appropriate precautions and planning are undertaken, limb reconstruction can be successfully performed in patients with an implanted programmable device by using a magnetically driven intramedullary lengthening nail.

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