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Technical considerations and early results of magnetic compressive intramedullary nailing for humeral shaft delayed unions and nonunions

Daniel J. Cognetti, MD^{a,*}, Abdullah Ghali, BS^b, Jose M. Gutierrez-Naranjo, MD^b, Jordan Handcox, MD^b, Ravi Karia, MD^b, Anil K. Dutta, MD^b

^aDepartment of Orthopaedic Surgery and Rehabilitation, San Antonio Military Medical Center, San Antonio, TX, USA

^bUT Health San Antonio, Department of Orthopaedics, San Antonio, TX, USA

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Background: Expandable magnetic rods and intramedullary nails are being used in a number of innovative ways, including limb length discrepancy and scoliosis correction. However, recently, the full complement of these devices has been further explored, with the utilization of their compressive capacity to improve fracture healing. The purpose of the present study was to report on early results of compressive magnetic intramedullary nailing for humeral shaft delayed unions and nonunions.

Methods: This retrospective case series was completed at a level 1 trauma center, with adult patients who underwent compressive intramedullary nailing from 2017 to 2021 for humeral shaft nonunion or delayed union. The primary indication for this procedure was nonunion in the setting of previous conventional fixation, but a subset of patients with atrophic nonunions and risk factors for recalcitrant nonunion were also included.

Results: Fourteen patients, with a mean age of 51 ± 17 years, underwent compressive magnetic intramedullary nailing. Nine patients had previously undergone surgery, 6 of which had undergone multiple prior procedures. Five others were initially treated nonoperatively and underwent surgery 4.1 ± 2.9 months out from injury. Ten patients went on to union at a mean of 2.9 ± 2.4 months. One patient experienced hardware failure with nail cut-out at 2 weeks, and one required revision surgery for a wound infection. Three other patients were lost to follow-up, one of which was deceased for reasons unrelated to surgery.

Conclusion: Compressive magnetic intramedullary nails are a viable solution for complex humeral shaft nonunions, particularly in the setting of previously well-fixed fractures and those at risk of recalcitrant nonunion. However, comparative and prospective studies looking at union rates and secondary procedures are needed to more clearly define their role in treatment and assure their safety, given recent concerns regarding osteolysis at the nail modular junction.

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Most fractures of the humeral shaft can be managed conservatively with a functional brace, but indications for operative management include open fracture, polytraumatized status, body habitus incompatible with brace wear, and distraction or severe malalignment. Progression to nonunion has been noted at rates between 10% and 32% for closed management and 8%–10% for surgical treatment.^{2,17,21,26} In these instances of nonunion, the most commonly recommended treatment is open reduction internal fixation (ORIF) with compression plating and bone grafting. However, there is less certainty to this treatment approach in the setting

of a previously well-fixed fracture or in those individuals with risk factors for recalcitrant nonunion.²⁷

Compressive intramedullary nails (IMNs), with magnetic actuators, represent a unique potential solution to this clinical dilemma. Originally, these IMNs were designed for limb length discrepancy, allowing for distraction osteogenesis without the burden of an external fixator, but after showing favorable clinical results in this regard,^{3,13} including humeral lengthening,¹⁰ this technology was further adapted and harnessed for fracture management. Instead of lengthening, the IMNs can be sequentially shortened, applying compression across a fracture site, a key component of bone healing.

Watson and Sanders,²⁵ along with Dang et al,⁵ have discussed the potential benefits of this technology in humeral shaft fractures, but given the relative novelty of magnetic compressive IMNs, the purpose of the present study was to report on the early results from their use in humeral shaft delayed unions and nonunions. It was

UT Health San Antonio, Office of Clinical Research, approved this study (HSC20190409E).

*Corresponding author: Daniel J. Cognetti, MD, Orthopedic Surgery, US Army Brooke Army Medical Center, 3551 Roger Brooke Drive San Antonio, TX 78234, USA.

E-mail address: cognettidj@gmail.com (D.J. Cognetti).

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hypothesized that sequential compression from magnetic IMNs would result in high rates of radiographic union.

Materials and methods

After approval by the institutional review board, a retrospective review was completed on all adult patients who underwent compressive intramedullary nailing (PRECICE UNYTE Humeral Nail; Nuvasive Specialized Orthopedics, San Diego, CA, USA) of humeral shaft delayed unions or nonunions by 2 senior, fellowship (R.K.: Trauma, A.K.D.: shoulder and elbow) trained orthopedic surgeons from 2017 to 2021. Delayed unions were defined by continued fracture mobility without radiographic evidence of fracture healing at 6 weeks after injury.⁶ Nonunions were defined by a nonhealed fracture clinically and radiographically 6 months after surgery or injury (in nonoperative cases). For operative management, hardware failure, loosening, and/or interval displacement served as evidence of fracture mobility.

Patient characteristics and surgical variables (age, gender, smoking status, vitamin D level, past medical history, mechanism of injury, open fracture, prior procedures, follow-up, time to radiographic union, complications, rotator cuff strength, pain, and shoulder range of motion) were collected and analyzed.

Technique

The PRECICE Nail System is a collection of magnetic IMNs that can apply adjustable, noninvasive distraction and/or compression to the femur, tibia, and humerus in cases of limb length discrepancy, fracture, nonunion, and osteotomy. PRECICE UNYTE Nails are a subsegment of this system, which are predistracted initially to allow for eventual compression across the bone. Compression can be applied by placing the programmable external remote controller over the extremity at the location of the magnet within the IMN. The external magnetic field imparts torque on the internal magnet, causing it and the gearbox to rotate, leading to shortening of the nail and compression (Fig. 1). Importantly, the distance the nail is predistracted defines the limit of available compression, and this is typically between 1 and 2 cm. Although our protocol for humeral nonunions most commonly called for 1 cm of compression, if more compression is desired, the nail can be further predistracted with upper limits between 2 and 8 cm based on nail length. Any additional distance of predistraction should also be added to the chosen nail's total length to avoid distal perforation or impingement proximally.

Patients are positioned either in the beach chair position with the head of bed elevated approximately 40 degrees or supine with the arm on a hand table and C-arm from the foot of the bed or contralateral side. First, an anterior-based incision is made about the nonunion site or along the prior incision with dissection carried down to the interval between brachialis and brachioradialis for identification of the radial nerve and neurolysis. A brachialis splitting technique is then used for removal of any prior implants, fracture site debridement, and grafting.

After the fracture is provisionally reduced, a 3–4 cm incision is made off the anterolateral border of the acromion, with dissection down to the supraspinatus tendon. The tendon is divided in line, with care to avoid disruption of the rotator cuff footprint. A starting point is obtained at the apex of the humeral head, just medial to the greater tuberosity, in line with the humeral shaft. After placing a guidepin, an entry reamer opens the canal, followed by a ball tip guide wire, measurement for nail length, reaming and placement of the nail under fluoroscopic visualization. Rotation is assessed by visualizing the flat profile of the greater tuberosity and aligning it with the transepicondylar axis.

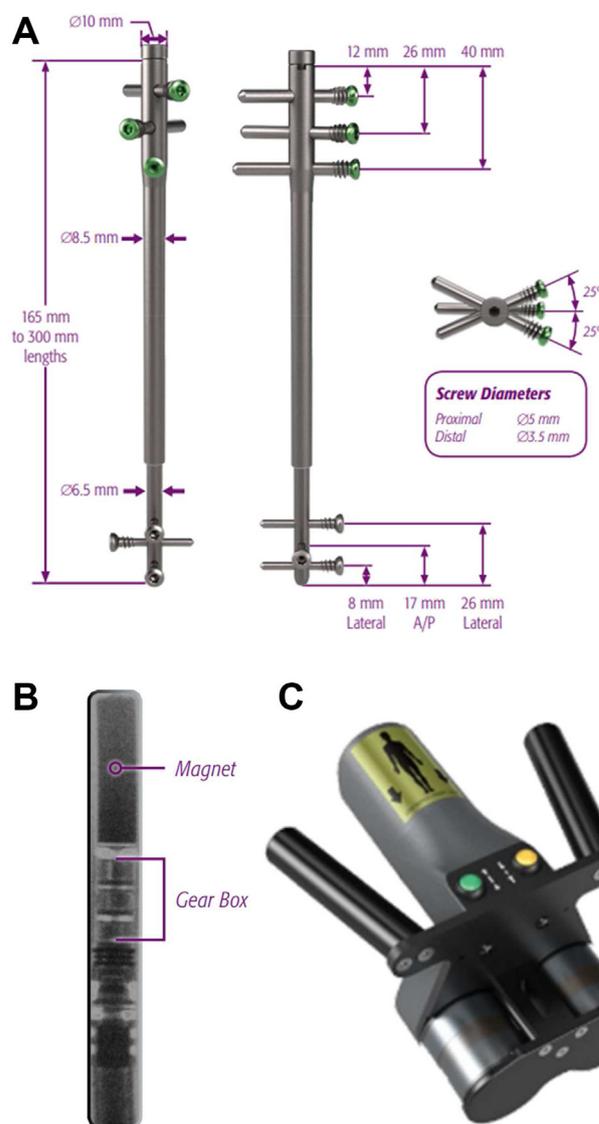


Figure 1 PRECICE Humeral Nail Diagram. (A) PRECICE Humeral Nail; straight, distally tapered design. (B) Radiograph of the PRECICE actuator with magnet, gear box, and threaded drive shaft. (C) External remote control, programmed to desired compression distance, and placed on the skin over the magnet after radiographic localization.

The nail is then placed with care to remove any fracture site gapping before locking the nail proximally and distally. After the nail is placed, bone graft or other biologic augments are applied, followed by the application of 2 mm of compression across the nail to ensure it is working and to further reduce any residual fracture gap. The external remote control is placed in a sterile bag to perform this step intraoperatively. Postoperative compression commences in clinic 2 weeks postoperatively, at 2-week intervals with 2 mm of compression at each visit, generally with maximum total compression of 1 cm. A pre-compression radiograph with a paperclip marker in clinic allows for accurate placement of the external remote over the nail's magnet. Completion of appropriate compression may be noted by a subtle bend of the distal interlocking screw.

Results

There were 14 consecutive patients who underwent compressive intramedullary nailing for a humeral shaft delayed union or nonunion from 2017 to 2021. The mean age was 51 ± 17 years, and

the mean postoperative follow-up after IMN was 8.9 ± 6.7 months (2 weeks to 22 months). There were 10 females and 4 males. Nine patients (64%) had undergone prior surgery, 6 (43%) of which had undergone multiple previous surgeries. All 9 were classified as nonunions. The 5 other patients were initially treated non-operatively in Sarmiento braces for a mean of 4.1 ± 2.9 months after the injury, before magnetic IMNs. Two of these patients were considered delayed unions, and 3 were considered nonunions. Further demographics can be found in Table I.

At our institution, the most applicable indication for a magnetic IMN was nonunion in the setting of a previously well-fixed fracture or nonunion (Fig. 2). However, this can be a subjective assessment, and in our experience, most nonunions occur in patients with previous nonoperative management or inadequate initial surgical management. Although the role of compressive magnetic intramedullary nailing is less clear in these patients, in the setting of multiple risk factors for recalcitrant nonunion, atrophic and long segmental delayed union and nonunions, magnetic IMNs were also given consideration (Fig. 3).

Nail length ranged from 195 to 285 mm. Various biologic adjuncts were used, including local autograft, cancellous allograft, bone morphogenetic protein 2, calcium sulfate, and tricalcium phosphate along with femoral strut allograft in 2 cases (Table II). Ten patients went on to radiographic union at a mean of 3.1 ± 2.2 months postoperatively, whereas one experienced hardware failure and nail cut-out 2 weeks postoperatively. Two other patients were lost to follow-up after their initial postoperative visit, and another patient passed away from reasons unrelated to the humerus 1 month postoperatively (Table II).

Two revision procedures were performed, one for hardware failure with revision to a distal humeral replacement and one for débridement and irrigation for an infection at the distal aspect of the incision. Three cases of osteolysis were noted at the modular junction of the IMN (where the smaller diameter distal segment telescopes inside the larger proximal segment), without clinical sequelae at final follow-up (Fig. 4).

Discussion

This study highlights early results and technical considerations for treating humeral delayed unions and nonunions with a compressive magnetic intramedullary nail. Outcomes from this series demonstrate overall acceptable union rates, but concern remains regarding osteolysis at the nail telescopic junction.

Table I
Demographic and injury characteristics.

Patient no.	Age	Gender	Comorbidities	Mechanism of injury	Open vs. closed fracture
1	69	F	HTN	MVC	Closed
2	21	M	Angelman's Syndrome	Fall from height	Closed
3	54	F	DM, CAD, CHF, HTN, RCC	Ground level fall	Closed
4	47	F	HTN, DM	MVC	Open
5	61	F	Hyperthyroidism, HTN,	Fall from height	Closed
6	66	M	Hypothyroidism, HTN, Cirrhosis	Fall from height	Closed
7	59	F	Osteoporosis, HTN, DM, HLD	Fall from height	Closed
8	59	F	Obesity	Fall from height	Closed
9	30	M	IV drug use	MVP; ground level fall	Closed
10	26	F	-	Fall from height	Closed
11	55	F	HTN, Severe Asthma	Fall from height	Closed
12	65	F	DM, HTN, HLD, CKD, COPD, BKA	Assault	Closed
13	32	M	Seizures	Fall from vehicle	Closed
14	72	F	Osteoporosis, RA	Ground level fall	Closed

M, male; F, female; HTN, hypertension; DM, diabetes mellitus; RA, rheumatoid arthritis; CAD, coronary artery disease; CHF, congestive heart failure; RCC, renal cell carcinoma; HLD, hyperlipidemia; CKD, chronic kidney disease; BKA, below knee amputation; ORIF, open reduction internal fixation; MVC, motor vehicle crash; MVP, motor vehicle vs. pedestrian.

Although ORIF with bone grafting is successful in approximately 75%-100% of primary humeral shaft nonunions, persistent nonunion after one or more surgeries and those with risk factors for recalcitrant nonunion represent significant clinical challenges.^{20,27} There have been a number of proposed treatments in these scenarios, including repeat ORIF and grafting, intramedullary nailing, cortical strut augmentation, and Ilizarov external fixation.^{1,11,16,19} However, none of these treatments has been unanimously effective, and each additional dissection and débridement leads to more devascularization, bone loss, and stress at the fracture site, given the longer time needed to achieve healing in a nonunion.

After ruling out (or treating) infection, surgeons treating nonunions must attempt to delineate contributors to the incomplete healing response. These causes can be simplified into 2 categories: problems of biology or stability. Biology includes host factors and healing potential, with relevant variables including injury characteristics, devascularized fracture fragments, tobacco use, endocrine abnormalities, and malnutrition. Poor biology and healing potential are best treated with medical optimization and biologic adjuncts, such as bone grafting or bone substitutes. Both components of treatment are well-accepted tenets of nonunion management and were routinely performed in this series.

After maximizing the biologic potential, the only remaining area of optimization is that of stability, addressing the biomechanical force profile across the fracture by improving reduction and/or fixation. In the setting of recalcitrant nonunions, surgeons must first determine if appropriate reduction and fixation were achieved initially. Obtaining operative reports and immediate postoperative imaging can be helpful, but even in the setting of hardware failure, a subjective determination can often be made as to the appropriateness of the initial surgery. Assessment should include plate characteristics, number of screws, callus formation, bone loss, and/or reduction, with 4.5 mm plates (or dual plates) and at least 3 screws proximal and distal to the fracture being conventionally preferred. If it is not felt the initial surgery was adequate, performing repeat ORIF and grafting, with better cortical apposition, alignment, and fixation, is reasonable. However, if adequate stabilization was obtained at the index operation, multiple prior procedures were performed, or there are multiple risk factors for recalcitrant nonunion, a more aggressive strategy may be warranted.

Although ORIF allows for compression to be applied across a fracture site, it can only be applied at the time of surgery, whereas magnetic IMNs allow for continued and enhanced compression over time. Although the theoretical benefits of reaming are

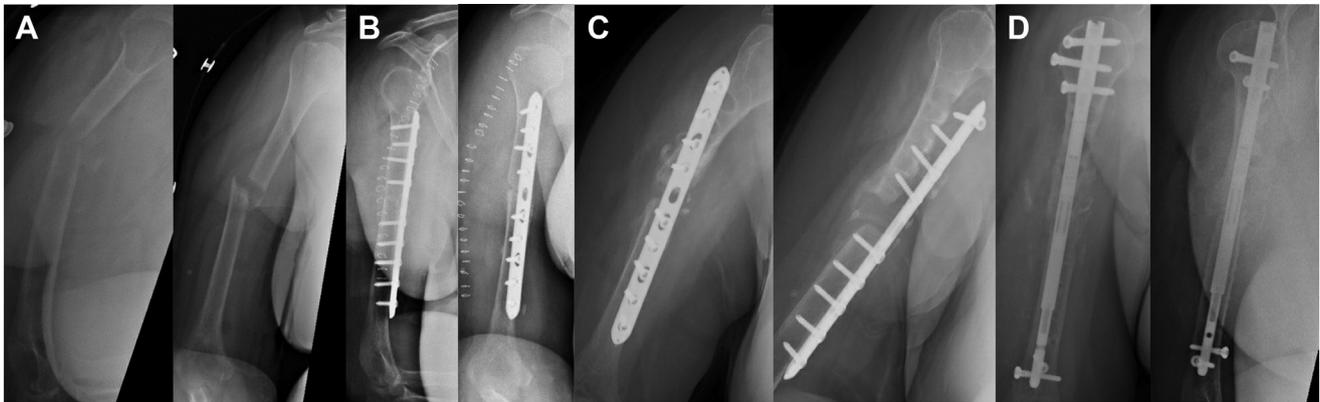


Figure 2 Radiographs of Humeral Nonunion Treatment Course. (A) Atrophic nonunion. (B) After open reduction internal fixation and grafting. (C) Failure of initial fixation. (D) Healing after magnetic intramedullary nail.

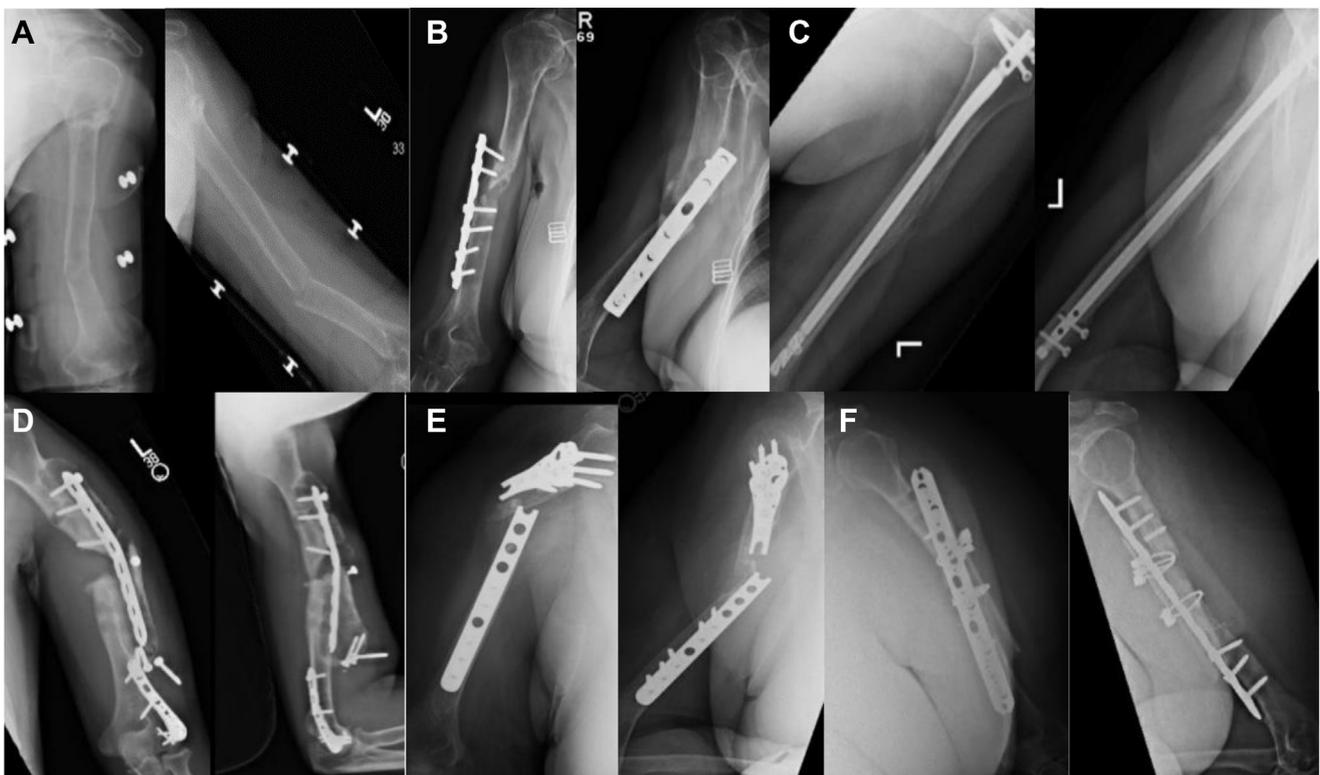


Figure 3 Radiographs of nonunions after nonoperative management, inadequate fixation and appropriate fixation: Radiographs demonstrate segmental nonunion of the proximal and distal humerus initially treated nonoperatively (A), inadequate proximal screw fixation of a humeral fracture (B) and constructs with varying degrees of appropriate fixation prior to magnetic IMN (A-F), including revision IMN with grafting (C), periprosthetic nonunion (D), failure of revision open reduction internal fixation (ORIF), and grafting (E) and failure of revision ORIF with strut allograft (F).

frequently discussed, the true benefit of this technique is that of compression, which can be sequentially increased, similar to Ilizarov external fixators, without the associated burden and complications.^{19,23,24} Magnetic IMNs may also be better equipped to treat segmental and severely comminuted nonunions compared with plates, which are most commonly placed with a bridging technique with limited ability for compression or would require extensive soft-tissue stripping. In addition, the central intramedullary position of the nail decreases its bending moment, compared with plate fixation, and IMNs have been shown to have a higher load to failure, for axial loads, compared with plate fixation.⁴

Another area of interest for surgeons treating nonunions (or fractures) with regard to how implant properties affect bone healing is that of reverse dynamization. Glatt et al described this technique for accelerating bone healing via the application of a low axial stiffness external fixator, to encourage robust callous formation. After callous formation is noted, the construct can be rigidly fixed, allowing for consolidation and mature bone formation.^{8,9} Clinical trials are pending, but early results in small and large animals suggest this technique may create paradigm shifts in our understanding of bone healing and may eventually be harnessed alongside magnetic IMNs as a solution for fracture and nonunion healing.

Table II
Patient treatment course and outcome.

Pt	Initial treatment	Initial treatment complications	Delayed/nonunion (D/N)	Classification	mIMN biologic augment	Smoking	Nail length (mm)	Union (Y/N)	Time to union (mo)	Complications
1	ORIF	Hardware failure	N	Atrophic	Allograft, calcium sulfate	N	240	Y	3.0	-
2	ORIF; Multiple I&Ds; ORIF	Osteomyelitis	N	Infected/Atrophic	Calcium sulfate	N	365	N	-	Hardware failure/nail cut-out
3	ORIF with allograft, calcium phosphate, calcium sulfate	Hardware failure	N	Atrophic	Allograft, BMP2, tricalcium phosphate	N	220	Y	2.4	-
4	I&D, ORIF	-	N	Atrophic	Autograft, allograft, tricalcium phosphate	Y	240	Deceased	-	-
5	ORIF; ORIF with allograft strut	Hardware failure; hardware failure	N	Atrophic	Femoral strut, calcium sulfate, tricalcium phosphate	N	275	Y	8.9	Osteolysis at modular junction
6	IMN; Multiple I&D and WVCs; I&D, HWR, Abx nail placement	Deep infection	N	Infected/atrophic	Calcium sulfate	N	250	Y	3.0	-
7	Non-op	-	N	Atrophic	None	N	225	Y	3.1	Osteolysis at modular junction
8	Non-op	-	D	Atrophic	None	N	260	Y	2.0	-
9	ORIF; multiple I&Ds and WVCs; I&D, HWR, Abx nail placement; I&D, Abx nail exchange	Osteomyelitis, hardware failure	N	Infected/atrophic	Allograft, calcium sulfate, tricalcium phosphate	Y	240	Y	2.0	-
10	Non-op	-	D	Atrophic/segmental	Calcium sulfate, tricalcium phosphate	Y	270	Y	1.6	I&D for infection
11	Non-op	-	N	Atrophic	None	Y	240	Y	1.2	-
12	Non-op	-	N	Atrophic	Femoral strut, allograft, calcium sulfate	Y	255	Lost to F/U	-	-
13	ORIF; I&D, Ex-fix, HWR; Ex-fix removal, Abx nail placement	Periprosthetic fracture; osteomyelitis, Ex-fix pin infections	N	Infected/atrophic	None	Y	285	Lost to F/U	-	-
14	ORIF with allograft; ORIF with bone marrow aspiration, allograft	Hardware failure	N	Atrophic	Allograft, calcium sulfate, tricalcium phosphate	N	195	Y	3.5	Osteolysis at modular junction

mIMN, magnetic intramedullary nail; ORIF, open reduction internal fixation; I&D, irrigation and debridement; WVC; wound vacuum change; HWR, hardware removal; Abx, antibiotic; BMP2, bone morphogenetic protein 2, F/U, follow-up.



Figure 4 Osteolysis at nail modular junction. The red arrow demonstrates osteolysis at the interlocking screw and nail modular junction.

The present study while able to serve its intended purpose is limited by its demographic heterogeneity, retrospective,

noncomparative design, and limited follow-up. Concerns regarding osteolysis at the modular junction of the nail have recently been reported,^{14,22} and despite limited follow-up in this study, osteolysis was noted in several cases. Based on previous reports, it appears the osteolysis may be the result of crevice corrosion because of differences in concentrations of electrolytes across the nail telescopic junction. Fretting corrosion, or micromotion at the same site, as well as pitting corrosion have also been implicated.^{7,12,15,18} However, further investigation regarding the incidence, consequence, and correction of this sequelae is needed.

Conclusion

Compressive magnetic intramedullary nails are a viable solution for complex humeral shaft nonunions, particularly in the setting of previously well-fixed fractures and those at risk of recalcitrant nonunion. However, comparative and prospective studies looking at union rates and secondary procedures are needed to define their role more clearly and assure their safety, given recent concerns regarding osteolysis at the nail modular junction.

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