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Comparison of clinical outcomes and complications in 2-part vs. 3- or 4-part proximal humerus fractures treated using an intramedullary nail designed to capture the tuberosities

B. Gage Griswold, MD*, Benjamin W. Sears, MD, Libby A. Mauter, MSPT, Mallory A. Boyd, MS, Armodios M. Hatzidakis, MD

Western Orthopaedics, Denver, CO, USA

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Background: Intramedullary nail fixation for proximal humerus fractures has been shown to provide satisfactory results. The quality of reduction correlates with clinical outcomes, the rate of complications, avascular necrosis, and postoperative loss of fixation. The purpose of this study was to evaluate the clinical outcomes and complications of 2-part proximal humerus fractures compared to 3- or 4-part proximal humerus fractures.

Methods: A single-center retrospective review was carried out of patients who underwent an intramedullary nail for a proximal humerus fracture by one of three surgeons between the years of 2009 and 2022, and who had a minimum of 12-months follow-up. Fracture pattern, American Shoulder and Elbow Surgeons score, Single Assessment Numeric Evaluation score, satisfaction, pain score, range of motion, and complications were recorded. The mechanism of injury (high energy vs. low energy), method of reduction (open vs. percutaneous), and evidence of radiographic healing were assessed. A P value of <.05 was considered to be statistically significant.

Results: The study included 78 patients (62 female, 16 male). The number of patients in each group (2-part, N = 32 vs. 3- or 4-part, N = 46), mean age (2-part, 64 vs. 3- or 4-part,61), follow-up (2-part, 42.5 months vs. 3- or 4-part, 34.5 months), injury type (2-part, 88% low energy vs. 3- or 4-part, 78% low energy), and method of reduction (2-part, 81% percutaneous vs. 3- or 4-part 72% percutaneous) were similar among the two groups. There was fracture union in all patients. All patients demonstrated satisfactory patient-reported outcome measures. However, 2-part fractures did have a significantly lower pain score, higher Single Assessment Numeric Evaluation score, and higher percentage of patients being satisfied or very satisfied when compared to 3- or 4-part fractures. The rate of subsequent procedures was 13% (n = 4) in 2-part fractures compared to 19% (n = 9) in 3- or 4-part fractures but was not statistically significant (P = .414). The overall rate of conversion to arthroplasty was 3.2% in 2-part fractures and 10.4% in 3- or 4-part fractures.

Conclusion: Multipart proximal humerus fractures remain difficult to treat. However, this study demonstrates an overall acceptable outcome with improvement in range of motion, patient-reported outcomes, and similar complication rates between 2-part and 3- or 4-part proximal humerus fractures treated with an intramedullary nail. However, the improvement in certain parameters is not as marked in 3- or 4-part fractures as 2-part fractures.

The treatment of proximal humerus fractures remains controversial. Conservative management, intramedullary nail (IMN) fixation, locking plate fixation, and shoulder arthroplasty are valid treatment options for proximal humerus fractures. Complication profiles often depend on the choice of treatment and intraoperative reduction achieved.[5,8] Complication rates in proximal humerus fractures treated with IMN vary depending on the fracture type, with the most common complication being postoperative loss of reduction due to intraoperative malreduction.[6]

IMN is an attractive treatment option due to preservation of fracture biology by maintaining the soft tissue envelope about the fracture. Humeral IMN fixation has undergone significant

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*Corresponding author: B. Gage Griswold, MD, Western Orthopaedics, 1830 Franklin St. #450, Denver, CO 80218, USA.

E-mail address: branumgriswold@gmail.com (B.G. Griswold).

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transformation since its introduction to clinical practice. First and second-generation IMN lacked an adequate locking mechanism for the proximal screws and had a curved proximal portion of the nail.[2] These generations were abandoned due to their high rate of screw back out and iatrogenic rotator cuff tears.[9] Third-generation IMN have been shown to have improved biomechanical qualities over the previous generations due to their proximal locking mechanism and their straight design, allowing for a more medial entry point which avoids damage to the hypovascular tendinous region of the rotator cuff.[4,5,10,11]

A prospective randomized controlled study by Zhu et al demonstrated that IMN is a successful option for treatment of 2-part proximal humerus fractures, with an acceptably low complication rate.[7] One may assume that fractures with increasing complexity and parts would be more difficult to treat, resulting in inferior patient reported outcomes and range of motion (ROM) with increased complications and rate of conversion to arthroplasty when compared to 2-part fractures. The purpose of this study was to evaluate the clinical outcomes and complications of 2-part fractures compared to 3- or 4-part fractures. With improved IMN techniques and technology the authors hypothesized that there would be a similar rate of union and a similar complication profile between the two groups.

Methods

Between April 2009 and February 2022, 106 patients with displaced proximal humeral fractures were managed by three surgeons with the same intramedullary locking nail designed to capture the tuberosities (Tornier Aequalis Intramedullary Nail; Stryker, Kalamazoo, MI, USA). Patients with displaced 2-, 3-, or 4-part proximal humerus fractures and were medically fit for surgical intervention were indicated for operative treatment. Contraindication for IMN fixation included: fracture fragments that were not amendable to being captured by the proximal interlocking screws due to their size, or significant osteopenia. A retrospective analysis of patients treated with IMN for acute proximal humerus fractures and with at least 12-month follow-up, was included. Twenty-seven patients were excluded due to inadequate follow-up. One patient with renal osteodystrophy required revision surgery which included IMN retention, addition of a proximal locking plate and allograft at five months after their index procedure. Given the revision occurred prior to 1 year, the patient was excluded from the final analysis of patient reported outcomes and ROM. However, the revision was accounted for in the complications and revision surgery analysis.

A cohort of 78 subjects was available for analysis and was separated into a 2-part fracture group and a 3- or 4-part fracture group based on Neer's original classification and[12] if intraoperatively the fracture fragments were mobile and required specific attention (ie, intentional reduction or targeted fixation through the nail) the fragment was considered a separate part. Demographic information, mechanism of injury (high energy vs. low energy), method of reduction (open vs. percutaneous), evidence of radiographic healing, and complications requiring surgery were recorded. Clinical outcomes at last available follow-up were assessed and included active range of motion (aROM), American Shoulder and Elbow Surgeons (ASES) score, Single Assessment Numeric Evaluation score, satisfaction, and pain (0-10 scale).

Continuous variables were summarized as mean, standard deviation, median and range. Categorical variables were summarized as counts and percentages. Differences between groups were evaluated using the Wilcoxson rank-sum test for continuous variables and the Chi-squared test or Fisher's exact test for categorical. A P-value of $<.05$ was considered statistically significant.

Surgical technique

The patients were placed in the beach chair position with the torso and head elevated to 40 degrees. The operative arm was maintained with the use of an arm positioner and held in neutral rotation throughout the entirety of the surgery. After sterile draping of the patient, the fracture was initially reduced utilizing a percutaneously placed Cobb elevator along the lateral margin of the fracture. The Cobb was placed under the head and used to lift the head out of malversion into a more anatomic neck shaft angle. For 3 or 4-part fractures with displaced tuberosity fragments, an open approach through a deltoid split or anterior deltoid sleeve approach was most commonly utilized to mobilize these fracture segments and reduce them to their anatomic position. The fracture segments were held with the Cobb or k-wires. After the reduction was completed and confirmed on imaging, the starting point for the intramedullary device was identified. This was most commonly located just anterior to the acromioclavicular joint. This correlates to the zenith of the humeral head on Grashey imaging and the midportion of the humeral on lateral imaging. After confirmation of the starting point, a guide wire was placed into the intramedullary canal. A starting reamer was utilized to open the articular surface and the device was placed over the guide wire into the intramedullary canal. The appropriate depth of the implant was confirmed with imaging and interlock screws were placed percutaneously utilizing an extramedullary guide. Patients with poor bone quality received injection of calcium phosphate allograft into the metaphysis; however, no supplementary fixation for the tuberosities were used. Patients were then placed in a sling and began passive motion under the direct care of a physical therapist starting between 2 and 4 weeks postoperatively. When callus was seen on imaging, active motion was initiated, typically at the 6-week mark. All weight bearing restrictions were lifted when complete union was achieved, typically at the 12-week mark.

Results

Seventy-eight patients met the study inclusion criteria. The 2-part group consisted of 25 females and 6 males, and the 3- or 4-part group included 37 females and 10 males. The mean age of the 2-part group was 63 years (range, 30-86 years), whereas in the 3- or 4-part group the average age was 61 years (range, 22-83 years). The mean follow-up for 2-part fractures was 42 months (range, 12-120 months) and 35 months (range, 12-123) for the 3- or 4-part group. Low energy injuries were the most prevalent cause of fracture occurring in 90% of the 2-part group and 77% of the 3- or 4-part group. A percutaneous approach was used in 84% of the subjects in the 2-part group and 70% of the 3- or 4-part group. There was no significant difference in the patients' demographics amongst the two groups. (Table I). There was evidence of fracture union in all patients, which was determined by postoperative radiographs that demonstrated callus formation and resolution of fracture lines, as well as clinically when the patient did not endorse pain at the fracture site.

Statistically significant ROM differences were found in forward flexion with 2-part fractures reaching 144° compared to 129° in the 3- or 4-part group ($P = .011$), abduction with 2-part fractures reaching an average of 149° compared to 126° in 3- or 4-part fractures ($P = .002$), and in internal rotation with 82% patients with 2-part fractures achieving internal rotation to T12 or higher while only 48% of the 3- or 4-part fractures achieved T12 or higher ($P = .048$). Average external rotation at the side was similar between groups (57° in 2-part vs 47° in 3- or 4-part fractures) and not statistically significant (Table II). There were statistically significant differences between groups in all patient-reported outcomes

Table I
Cohort demographics.

	2-Part, N = 31	3- Or 4-part, N = 47	*P* value*
Gender, n (%)			.8
F	25 (81%)	37 (79%)	
M	6 (19%)	10 (21%)	
Age at DOS			.6
Mean (SD)	63.8 (14.2)	60.8 (14.3)	
Median (range)	(66.0, 30.0-86.0)	(65.0, 22.0-83.0)	
Follow-up (mo)			.5
Mean (SD)	41.5 (29.5)	35.4 (27.2)	
Median (range)	(36.0, 12.0-120.0)	(25.0, 12.0-123.0)	
Prior surgery, n (%)			.6
N	29 (94%)	46 (98%)	
Y	2 (6%)	1 (2%)	
Injury type (energy), n (%)			.12
High	3 (10%)	11 (23%)	
Low	28 (90%)	36 (77%)	
Approach, n (%)			.2
Open	5 (16%)	14 (30%)	
Perc	26 (84%)	33 (70%)	

DOS, date of surgery; *SD*, standard deviation.
*Pearson's Chi-squared test; Wilcoxon rank sum test; Fisher's exact test.

Table II
Final active range of motion.

	2-Part, N = 31	3- Or 4-part, N = 47	*P* value*
Forward flexion			.011
Mean (SD)	144 (19)	129 (27)	
Median (range)	148 (90,170)	135 (60,170)	
Abduction			.002
Mean (SD)	149 (21)	126 (34)	
Median (range)	150 (90,180)	137 (40,170)	
External rotation			.036
Mean (SD)	57 (16)	47 (20)	
Median (range)	60 (20,88)	45 (0,85)	
Internal rotation, n (%)			.048
T7	12 (43%)	13 (33%)	
T12	11 (39%)	6 (15%)	
Lumbosacral	4 (14%)	12 (31%)	
Buttock	0 (0%)	4 (10%)	
Thigh	1 (4%)	4 (10%)	

SD, standard deviation.
*Wilcoxon rank sum test; Fisher's exact test.

measures except the ASES score, with the 2-part group demonstrating better outcomes scores when compared to the 3- or 4-part group: average Pain 1 compared to 3 ($P = .040$), average Single Assessment Numeric Evaluation 88% vs. 73% ($P = .029$) and satisfaction with 93% (n = 29) in the 2-part group reporting being satisfied/very satisfied compared to 71% (n = 33) in the 3- or 4-part group ($P = .041$) (Table III).

Complications requiring surgery included removal of hardware, conversion to arthroplasty, and subsequent arthroscopic procedures. The rate of subsequent procedures was 19% (n = 9) in 3- or 4-part fractures compared to 13% (n = 4) in 2-part fractures but not statistically significant ($P = .414$). There were four patients converted to arthroplasty in the 3- or 4-part fracture group; three were revised to an anatomical shoulder arthroplasty [diagnoses were avascular necrosis (AVN) (2), glenohumeral osteoarthritis (GHOA) (1)] and one was revised to reverse shoulder arthroplasty (RSA) due to AVN. Time to revision ranged from 23 to 61 months. One 2-part fracture was revised to RSA due to GHOA at 71 months; prior to this revision this patient underwent a rotator cuff repair with removal of the IMN (Table IV). Additionally, one patient (3-part fracture) with a history of renal disease required revision at 5 months postoperative. Therefore, the overall rate of conversion to arthroplasty was 3% in 2-part fractures and 10% in 3- or 4-part fractures.

Table III
Final patient reported outcomes.

	2-Part, N = 31	3- Or 4-part, N = 47	*P* value*
Pain (0-10)			.040
Mean (SD)	1 (2)	3 (3)	
Median (range)	0 (0,8)	1 (0,10)	
ASES			.029
Mean (SD)	87 (17)	73 (27)	
Median (range)	92 (20,100)	81 (7100)	
SANE			.004
Mean (SD)	88 (17)	73 (26)	
Median (range)	95 (20,100)	82 (0,100)	
Satisfaction, n (%)			.041
Very satisfied	23 (74%)	21 (45%)	
Satisfied	6 (19%)	12 (26%)	
Dissatisfied	1 (3.5%)	9 (19%)	
Very dissatisfied	1 (3.5%)	5 (11%)	

ASES, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numeric Evaluation; *SD*, standard deviation.
*Wilcoxon rank sum test; Fisher's exact test.

Discussion

This study demonstrates that IMN in the treatment of proximal humerus fractures provided results that were not significantly different in the rate of union and complication profile for 2-part and 3- or 4-part fracture. However, 2-part fractures did demonstrate better postoperative ROM, patient-reported outcomes and lower rate of conversion to arthroplasty.

There have been several studies evaluating the outcomes of 2-part fractures as well as 3- or 4-part fractures treated with IMN. To the authors' knowledge there has not been a direct comparison of these two groups in a study to evaluate outcomes and complications. A previous systematic review on the treatment of proximal humerus fractures with IMN evaluated 14 studies and 448 proximal humerus fractures and reported an overall reoperation rate of 15.8%. The reoperation rate for two-part and three-part fractures was 13.6 and 17.4%, respectively, with a reoperation rate of 63.2% for four-part fracture.[15] The current study found a reoperation rate of 19% for 3- or 4-part fractures and 13% in 2-part fractures, which is lower than described in this systematic review, especially in the more complex fracture types.

In a prospective study, Kloub et al evaluated the rate of revision procedure in 35 patients with 4-part fractures treated with intramedullary nailing (DePuy Synthes MultiLoc Humeral Nail; DePuy Synthes, Warsaw, IN, USA) with a mean follow-up of 25.8 months. The authors found a revision rate of 30%, with AVN being the most common cause (42%), followed by resorption of the greater tuberosity (25%) and loss of reduction (17%). Of these complications, 14% of patients were treated with either RSA or hemiarthroplasty. An additional 14% underwent removal of hardware.[7] The current study found a lower rate of AVN in 3- or 4-part fractures. However, patients with AVN after IMN do not preclude them from doing well with an anatomical shoulder arthroplasty if the tuberosities have healed anatomically (Fig. 1). Additionally, there were three patients in the 3-or 4-part fracture group who experienced symptomatic hardware with stiffness and underwent subsequent removal of hardware with lysis of adhesions. The average follow-up for this current study is one of the longest reported in the literature with the mean follow-up for the 2-part being 42 months and the 35 months for the 3- or 4-part fractures. With this longer duration of follow-up and larger patient cohort, still a lower revision rate and conversion to arthroplasty than Kloub et al.[7]

Table IV
Revision summary.

Gender	Age	Months to revision	Fracture type	Velocity of injury	Radiographic healing	Reason for revision	Revision surgery
F	60	71	2-part	Low	Yes	Stiffness, prominent hardward, GHOA	Surg 1: IMN removal, RCR; Surg 2: RSA (Dx: Stiffness, RC tear) Patient underwent IMN removal and open rotator cuff repair 16 months postoperative IMN. The patient had continued pain and limited function and was successfully treated with an RSA 59 months postoperative from IMN.
F	71	24	3-part	Low	Yes	Stiffness, AVN, GHOA	Surg 1: Arthroscopic débridement, LT screw removal Surg 2: aTSA (Dx: Stiffness, AVN, GHOA) Patient underwent a proximal interlock screw removal and arthroscopic débridement 9 months postoperative from IMN. The patient had continued pain and limited function and was successfully treated with a TSA 24 months postop from IMN.
F	68	24	3-part	Low	Malunion	AVN	Surg 1: Arthroscopic débridement; Surg 2: RSA (Dx: AVN) Patient underwent arthriscopic débridement 19 months postoperative IMN for continued pain and limited range of motion. The patient had continued pain and limited function and was successfully treated with an RSA 24 months postoperative from IMN.
F	66	61	3-part	Low	Yes	GHOA	TSA (Dx: GHOA)
F	58	23	4-part	Low	Yes	AVN	TSA(Dx: AVN)

AVN, avascular necrosis; *GHOA*, glenohumeral osteoarthritis; *IMN*, intramedullary nail; *RSA*, reverse shoulder arthroplasty; *TSA*, total shoulder arthroplasty; *RC*, rotator cuff; *RCR*, rotator cuff repair.

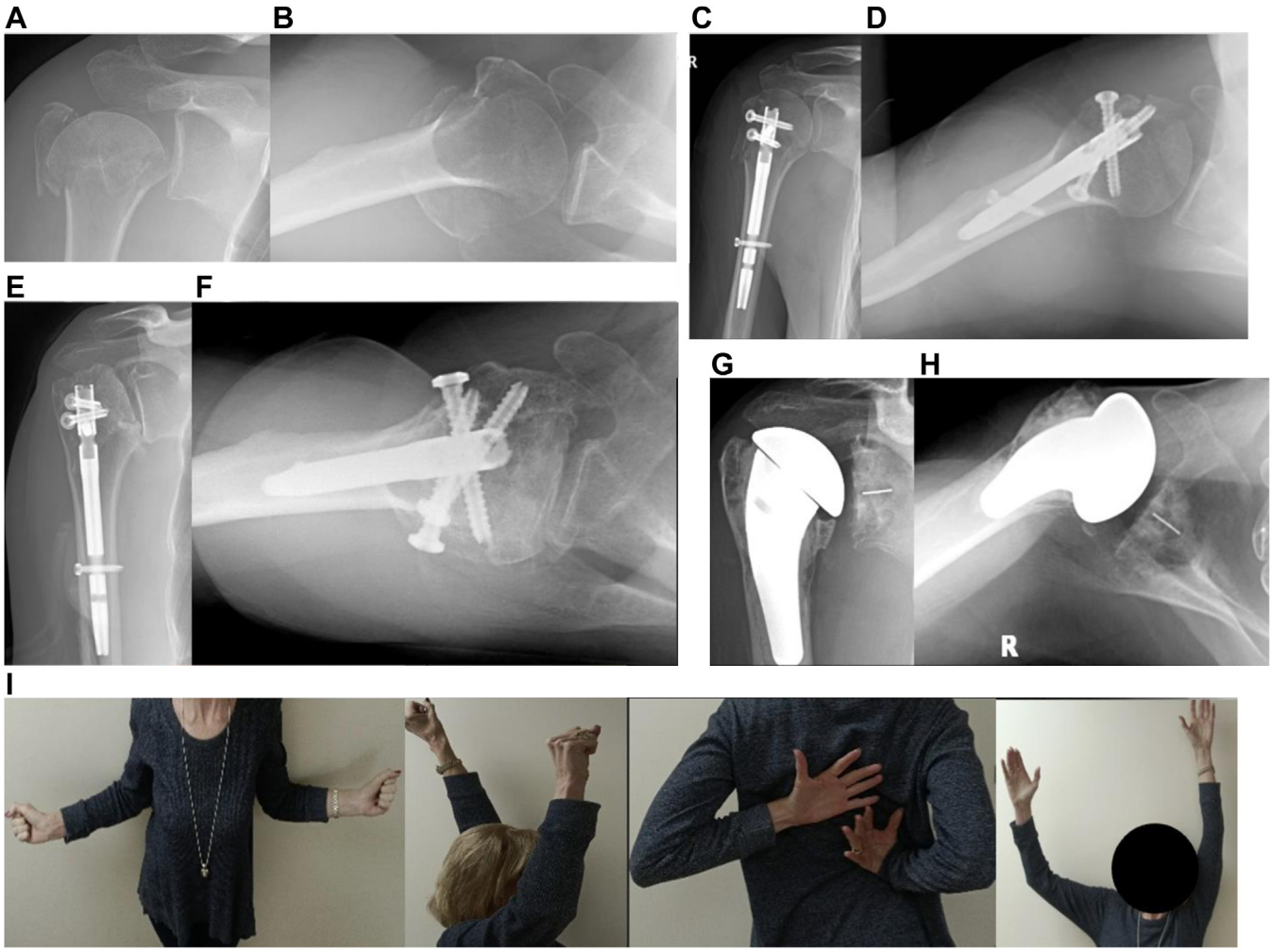

Figure 1 58-year-old-female with 4-part proximal humerus fracture (**A** and **B**). The patient was treated with IMN (**C** and **D**) and at 21-month follow up the patient developed AVN (**E** and **F**). The patient underwent removal of IMN and TSA (**G** and **H**) and at 8-years follow up the patient exhibits excellent ROM (**I**) and SANE score of 70% of a normal shoulder, and VAS pain score of 0. *IMN*, intramedullary nail; *ROM*, range of motion; *AVN*, avascular necrosis; *TSA*, total shoulder arthroplasty; *SANE*, Single Assessment Numeric Evaluation; *VAS*, visual analog scale; *TSA*, total shoulder arthroplasty.

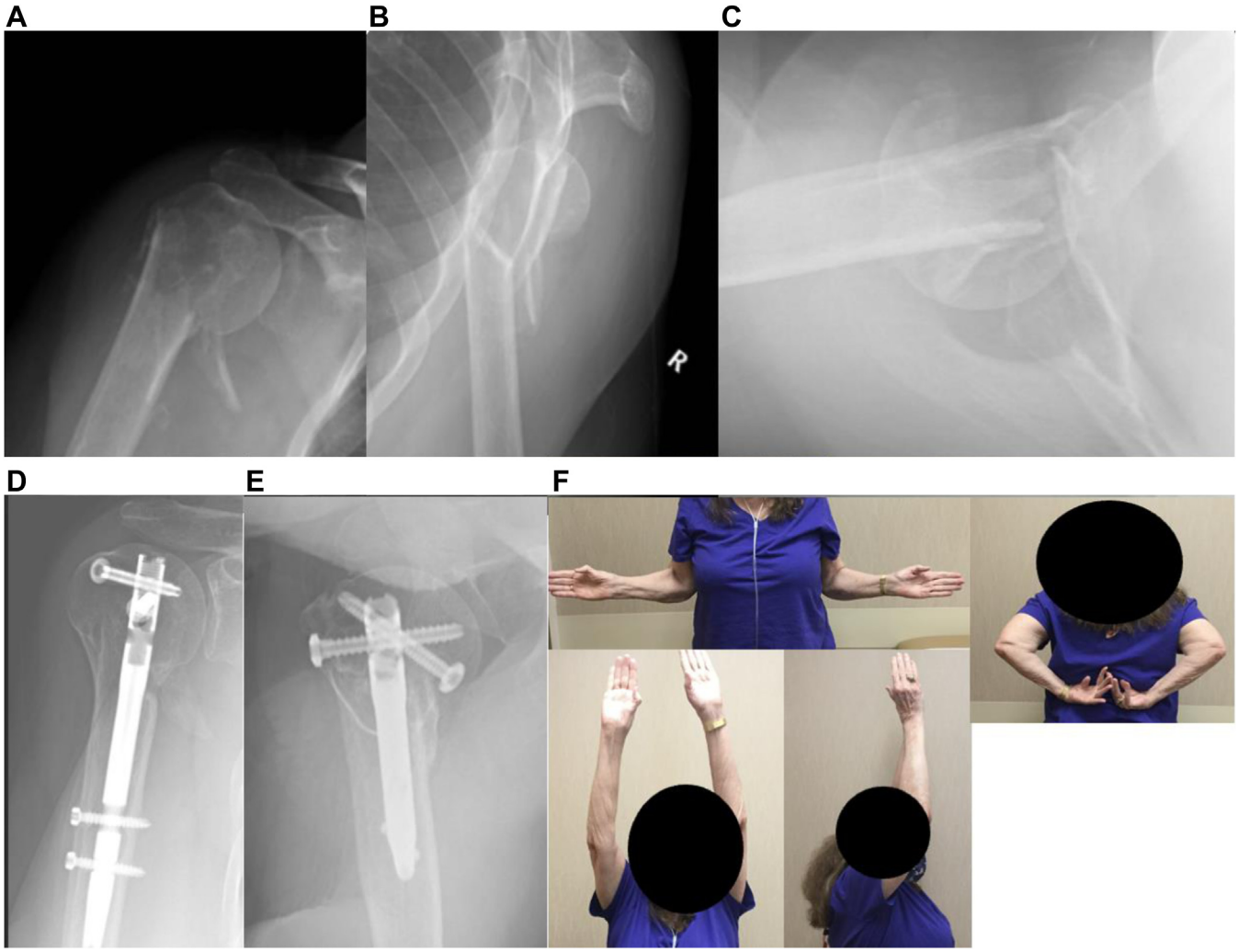

Figure 2 60- year-old female with 2-part proximal humerus fracture (**A**-**C**). At 8-year follow (**D** and **E**) patient exhibits excellent ROM (**F**) and a SANE score of 95% of a normal shoulder, ASES score 95, and VAS pain score of 0. *ROM*, range of motion; *SANE*, Single Assessment Numeric Evaluation; *ASES*, American Shoulder and Elbow Surgeons; *VAS*, visual analog scale.

Boileau et al, in a series of 41 two-part displaced surgical neck fractures, reported good clinical outcomes and low complication rates using a third-generation nail (Tornier Aequalis Intramedullary Nail; Stryker, Kalamazoo, MI, USA) and percutaneous approach. At the final follow-up, all fractures healed satisfactorily, with a mean forward elevation of 146°, and mean external rotation of 50°. They observed one partial AVN case and two (5%) cases of malunion due to malreduction at the time of the surgery with associated lateral entry point. There were no cases of screw loosening or intra-articular screw penetration. Two patients (5%) underwent revision surgery due to impingement and stiffness.[1] Hatzidakis et al evaluated 38 patients with 2-part displaced proximal humerus fractures that had least 12 months of follow-up and an average age of 65 year old. All but one healed with a neck-shaft angle of ≥125°. The patients also reported relatively high Constant scores and a mean forward flexion was 132° ± 22°.[4] The current study demonstrated similar ROM and patient satisfaction in the 2-part fractures with an average of 144° of forward flexion and external rotation to 57° (Fig. 2). However, aROM in the 3- or 4-part fractures was less than that seen in 2-part fractures with the difference in forward flexion and abduction being statistically significant.

Lopiz et al reviewed 32 proximal humerus fractures with a mean age of 82 years (80 years or older) treated with a third-generation IMN (DePuy Synthes MultiLoc, Humeral Nail; DePuy Synthes, Warsaw, IN, USA). The majority of fractures was 2-part (81%) and the remainder was 3-part (19%). The authors found that 15.6% of patients had less than 125° of forward flexion and the rate of revision was 18.8% (five due to subacromial impingement related to inadequate technique and one loss of reduction). In this elderly cohort of patients there were no cases of nonunion, AVN, or screw loosening.[10] The current study demonstrated similar final forward flexion with approximately 20% patients not achieving >125°. Our study found the rate of complications requiring surgery to be statistically similar between the two groups ($P = .414$). However, revision surgery and conversion to arthroplasty was higher in the 3- or 4-part fractures with 19% requiring additional surgery (3 removal of hardware and 3 conversions to arthroplasty) as opposed 13% of 2-part fractures requiring additional surgery (2 removal of hardware and 1 conversion to arthroplasty).

Another study by Kloub et al, demonstrated that the relative Constant score was associated with the quality of reduction. The authors reported that the score decreased from 88% when reduction was excellent, to 70% and 52% when fracture reduction was moderate or poor, respectively. The authors also found an association between the rate of AVN and reduction quality. The rate of AVN increased from 2% in those with anatomical reduction to 28%

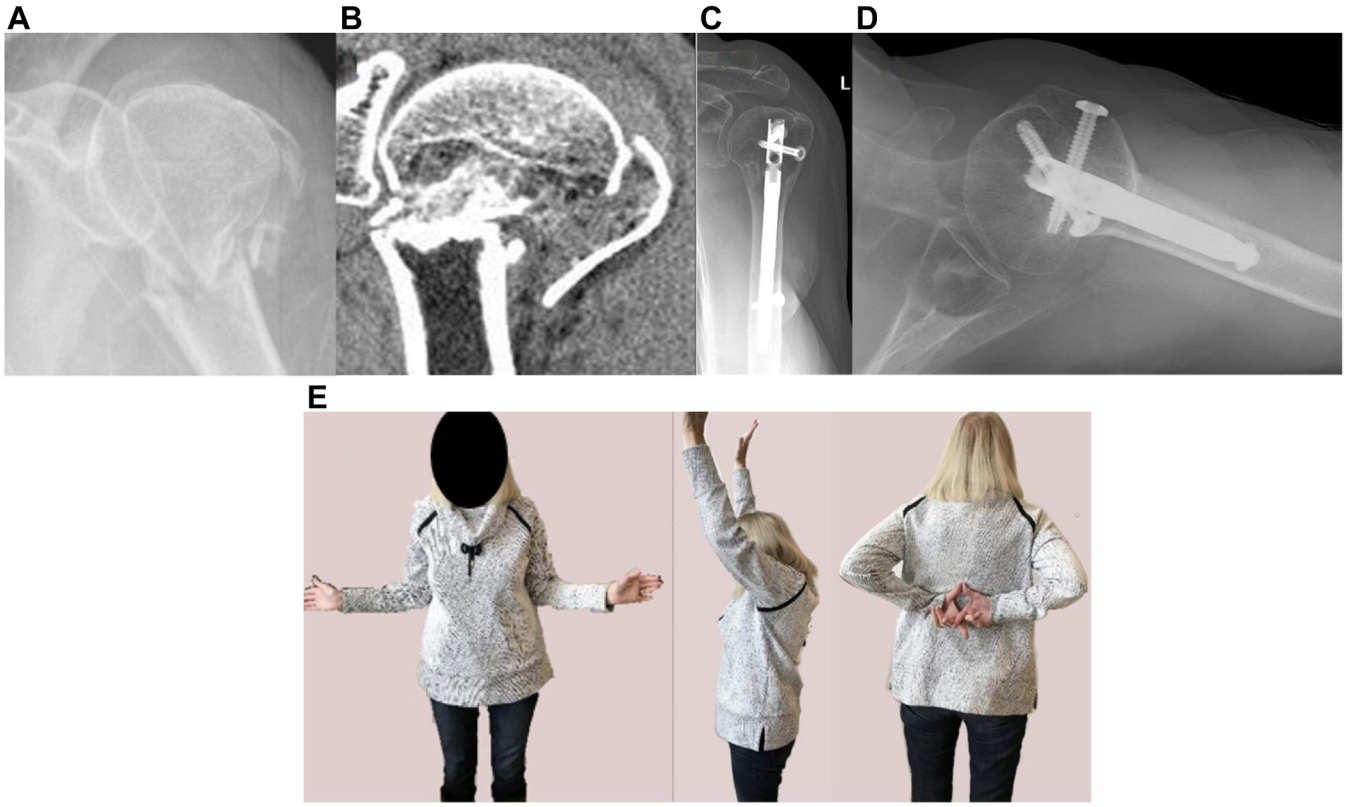

Figure 3 62-year-old-female with 3-part proximal humerus fracture (**A** and **B**). At 7-year follow (**C** and **D**) patient exhibits excellent ROM (**E**) and a SANE score of 95% of normal shoulder, ASES score 83, and VAS pain score of 2. *ROM*, range of motion; *SANE*, Single Assessment Numeric Evaluation; *ASES*, American Shoulder and Elbow Surgeons; *VAS*, visual analog scale.

and 60% in those with moderate- and poor-quality fracture reduction, respectively.[6] However, there is contradicting evidence that malreduction correlates with functional outcomes. Rotman et al in a study of 25 2-part displaced proximal humerus fracture treated with a third-generation nail (DePuy Synthes MultiLoc Humeral Nail; DePuy Synthes, Warsaw, IN, USA) observed that 24% of patients presented a postoperative decrease in neck-shaft angle of over 20°. However, functional outcomes were similar between patients with or without loss of fracture reduction.[13]

Correlation of the quality of reduction to patient-reported outcomes was not analyzed in this study, and there are no reports evaluating the minimal clinically important difference value for patient-reported outcomes in proximal humerus fractures.[14] It is the authors' opinion that tuberosity reduction is critical, and one should have a low threshold to reduce the fracture via an open exposure if necessary to ensure that tuberosities are well aligned (Fig. 3). In this study the rate of open reduction between groups was similar with 16% of 2-part fractures vs. 30% of 3-or 4-part fractures requiring open reduction.

Zhu et al conducted a randomized controlled trial on the treatment of 2-part fractures, comparing IMN vs. locking plate fixation, with a three-year follow-up. The authors found that the complication rate was significantly higher in the locking plate group compared to the IMN group, at 31% vs. 4%, respectively. The most frequent complication was screw penetration. Additionally, the IMN group demonstrated significantly lower ASES scores at one year postoperative. However, at three years postoperative, there was no difference.[16] In another randomized controlled study, Gracitelli evaluated 72 patients with 2-and 3-part proximal humerus fractures treated with IMN or a plate. The authors found a total of 38 complications, with 28 in the nail group and 10 in the plate group ($P = .001$). However, the authors of this study used an IMN with a proximal bend. It is the authors' belief that these older nails do not adequately capture the tuberosities, which could be a reason for worse outcomes.[3]

Limitations

There are several limitations to this study. The first is its retrospective nature, with only a minimum 1-year follow-up, along with a relatively high rate of patients being lost to follow-up. However, we do believe that the follow-up duration in this study is helpful in truly capturing the outcomes and complications that patients experience with IMN in the treatment of proximal humerus fractures. The learning curve associated with using the IMN for proximal humerus fracture management may have contributed to the outcomes in this study; additionally patients of 3 different surgeons with varied levels of surgical expertise utilizing this IMN were included in this cohort. Selection bias may have contributed to outcomes with the authors utilizing the IMN in patients that they believe would do well with internal fixation; however, it is not common practice for the authors to preform plate fixation or reverse arthroplasty for fracture. This follow-up duration might lend one to assume that patients were converted to arthroplasty as sequalae from the fracture. Given the length of follow-up, it is possible that some of these patients were converted to arthroplasty secondary to underlying primary GHOA. Further research is needed to delineate risk factors of patients needing to be converted to arthroplasty after IMN for the treatment of proximal humerus fractures. Another limitation of this study is that malunion or the

quality of reduction was not reported. However, reduction quality and how it correlates with outcomes and complications such as AVN has already been documented in the literature.[5,7]

Conclusion

Multipart proximal humerus fractures remain difficult to treat. This study demonstrates overall acceptable outcomes with improvement in aROM and patient-reported outcomes, as well as similar complication rates between 2-part and 3- or 4-part proximal humerus fractures treated with IMN. However, at final follow-up most clinical and patient-reported outcomes were significantly better in patients with 2-part fractures than in patients with 3- or 4-part fractures.

Disclaimers:

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