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Original Research Article

A COMPARATIVE STUDY OF OSTEOSYNTHESIS WITH INTRAMEDULLARY INTERLOCKING NAIL AND MINIMALLY INVASIVE PLATING FOR PROXIMAL AND MIDDLE THIRD HUMERAL SHAFT FRACTURES

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Abstract

Introduction: Options for the treatment of proximal and middle third fractures of the humerus include intramedullary interlocking nail (IMN) and minimally invasive plate osteosynthesis (MIPO). However, whether IMN provides better clinical outcomes than MIPO surgical technique still remains unclear. Hence this study is designed to compare clinical outcomes of the IMN with MIPO technique for the treatment of proximal and middle thirds of humeral shaft fractures.

Materials and Method: A retrospective cohort analysis of 45 proximal and middle third humeral shaft fractures treated surgically using IMN (n = 20) or MIPO (n = 25) from January 2019 to June 2022. Peri-operative and follow-up data (a minimum of 1 year) of the patients (aged from 20 to 60 years) were collected. Operation time, fracture union time, VAS scores, surgery-related complications, and implant removal rate were compared in this study. The functional outcomes were evaluated using the Rating Scale of American Shoulder and Elbow Surgeons' Form (ASES) and Mayo Elbow Performance Score System (MEPS).

Result: We observed much shorter operative time and also less blood loss in IMN group, and lower VAS scores in the IMN group after surgery at first and third months but not at the sixth month. Complication rate were relatively higher in the MIPO group when compared to the IMN group. No significant difference was observed between these two groups regarding ASES and MEPS scores. Three patients in the MIPO group suffered iatrogenic radial nerve injury and recovered after five to six months. No implant failures occurred in either group.

Conclusion: Intramedullary interlocking nail appeared to be superior to minimally invasive plate osteosynthesis in the treatment of proximal and middle third humeral shaft fractures due to shorter operative time and fracture union time, less early post-operative pain, and fewer complications. Therefore intramedullary interlocking nail could be considered as a better surgical option for the management of proximal and middle third humeral fractures, although it also depends on the surgeons' skills and learning curve. Hence in-depth prospective studies with large sample size are required to verify our conclusion.

Keywords: Humeral shaft fracture; Intramedullary interlocking nail(IMN); Minimally invasive plate osteosynthesis(MIPO); VAS scores; ASES; MEPS scores.

Introduction:

Humeral shaft fractures are one of the common injuries seen in orthopaedic practice[1]. They account for 20% of humeral fractures and approximately 3 to 5% of all fractures [2,3]. Surgical

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treatment allows an earlier return to work and Preinjury activities while preserving functionality and motion of nearby joints. Therefore over the last few decades there have been significant advances in the field of surgical management of humerus shaft fractures.
However proximal and middle third humeral shaft fractures typically are suitable for the treatment by both Minimally invasive plate osteosynthesis (MIPO) and Intramedullary nail (IMN), which are well-accepted, safe and effective biological fixations.

MIPO belongs to the plate-screw system and has emerged as a promising surgical technique which provides micro motions to stimulate osseous callus formation and allows plate fixation without disturbing the fracture site using a minimally invasive approach [4,5]. It stabilizes the fracture site and potently minimizes the risk of various surgical complications including nonunion, and infection. However improper manipulation, excessive traction and inappropriate placement of distal screws can cause iatrogenic radial nerve palsy and musculocutaneous nerve may be injured during the dissection of biceps and brachialis [6].

IMN has been used in treating humeral shaft fractures for years and has distinct advantages over traditional Open reduction internal fixation (ORIF). Advantages of IMN are characterized by its minimally invasive surgical approach and reduction assistance without disturbing the fracture site and thereby accelerating fracture healing. However impairment of shoulder movement might occur when the rotator cuff is accidentally damaged and shoulder impingement occurs. Repeated reaming might also cause debris accumulation around the rotator cuff which may result in chronic shoulder pain and disability [7].

Hence, there are both advantages and disadvantages of these two minimally invasive techniques. It is unclear whether one method is more effective than the other. Therefore, in our study, we aimed to compare IMN with MIPO in terms of the surgical effectiveness and potential risks of treating proximal- and middle-thirds of humeral shaft fractures.

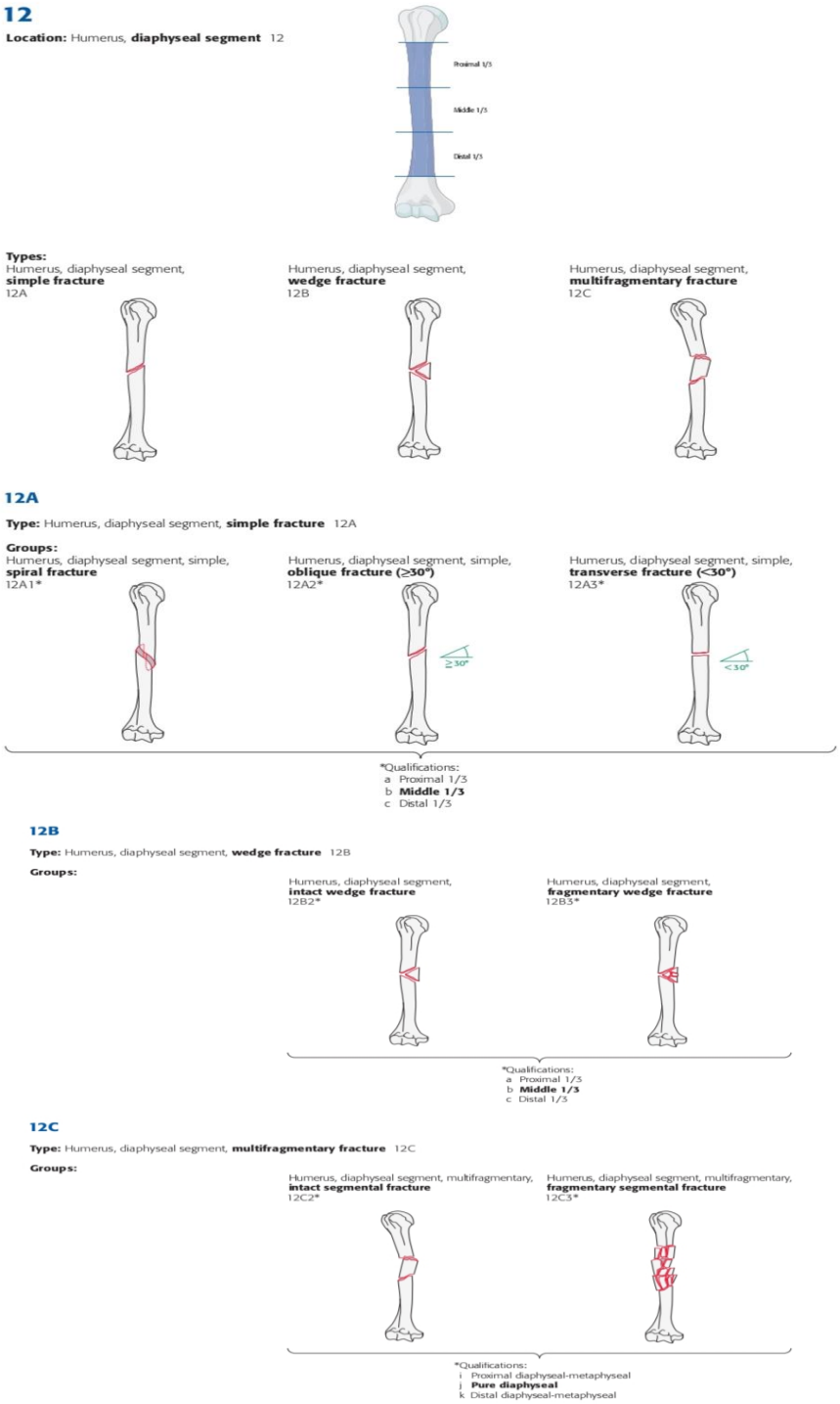
Patients and methods
A retrospective cohort analysis of 45 proximal and middle third humeral shaft fractures treated surgically using IMN (n = 20) or MIPO (n = 25) from January 2019 to June 2022 was done. All cases underwent surgical treatment by the same orthopaedic surgeon.

Inclusion criteria-
1) Unilateral closed unstable proximal and middle third humeral shaft fractures
2) Age- 20-60 years

Exclusion criteria-
1) Open fractures
2) Fractures extended to shoulder and elbow joints
3) Preoperative radial nerve injury
4) History of previous humeral fractures
5) Distal third humeral shaft fractures
6) Fractures older than three weeks
7) Pathological fractures were excluded.
Modified AO-OTA (2018) classification was used to classify the fractures. Type A-simple fractures, type B-wedge, while type C represented commuted fractures. All patients completed at least 1 year of follow up. Pertinent data on patient demographics, clinical assessments, pre-

operative X-ray, operative details, post-operative X-rays and complications were extracted and analyzed statistically.

Fractures were classified using modified AO/OTA classification(2018).



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Surgical technique

All surgeries were performed under brachial block and fluoroscopic guidance. Supine or beach chair position was used in the MIPO group to achieve supination with elbow flexed 70°. 5cms

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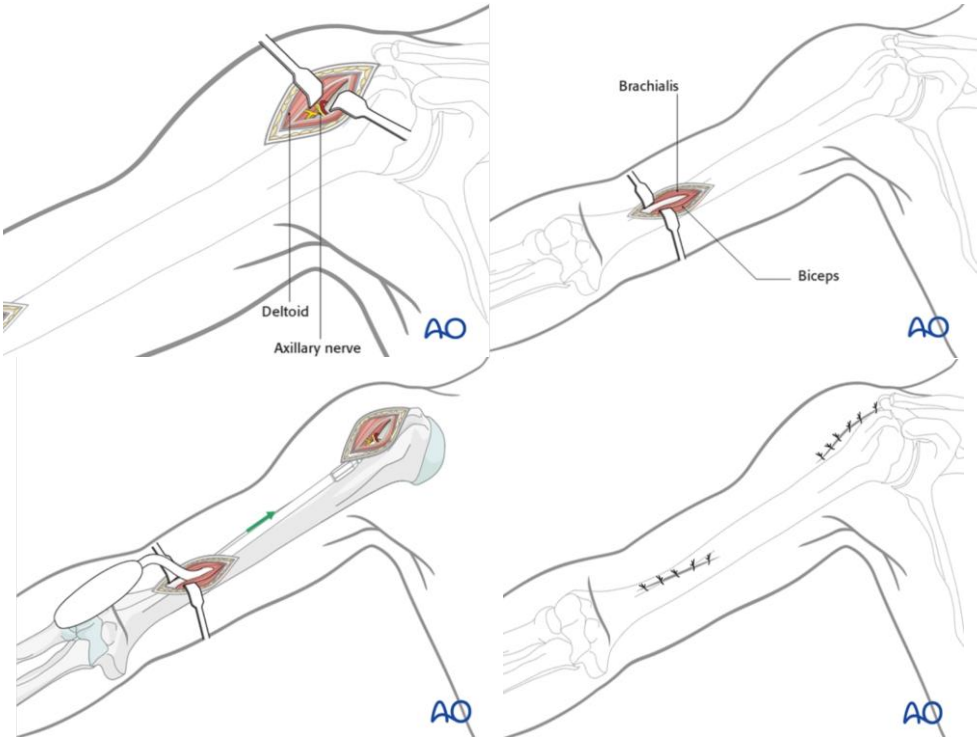
distal to the anterior part of the acromion an incision of 3cms between the proximal biceps and medial border of the deltoid was made and distally 3–4-cm incision extending to within 5 cm proximal to the flexion crease was made on the anterior surface of the arm. To minimize the risk of iatrogenic radial nerve injury, care was taken to pass the periosteal elevator anteriorly or anteromedially to avoid using lever retractors, and to use gentle traction and manipulation for reduction. No radial nerve was explored. A long PHILOS plate (depending on the fracture lenth) was gently inserted through the submuscular tunnel from the proximal or distal incision (based on the fracture location). Fractures were reduced by applying gentle traction and abduction manually. Reduction was checked under C-arm Xray image intensifier. Three bicortical screws were placed on the either side of the fracture to stabilize the reduction.



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In the IMN group, a 3-cm long longitudinal incision was made, beginning at the anterior tip of the acromion. The deltoid was split, separating its anterior and middle third fibres from the acromion to a point 3 cm distally. 1-cm incision was made on the supraspinatus tendon in line with its muscle fibre orientation, medial to the greater tuberosity. The medullary canal was opened with an awl. Under fluoroscopy guidance the entry point was made just 2 to 5 mm medial to the sulcus between the greater tuberosity and the articular margin. An humerus IM Nail was inserted after adequate measurements were made with fluoroscopy. After manual reduction and nail insertion, distal and proximal locking screws were inserted. The rotator cuff tendon and deltoid were carefully repaired. Long intramedullary nails were used in the study. The intramedullary nails were all distally locked to secure and stabilize the nail as to prevent rotation.

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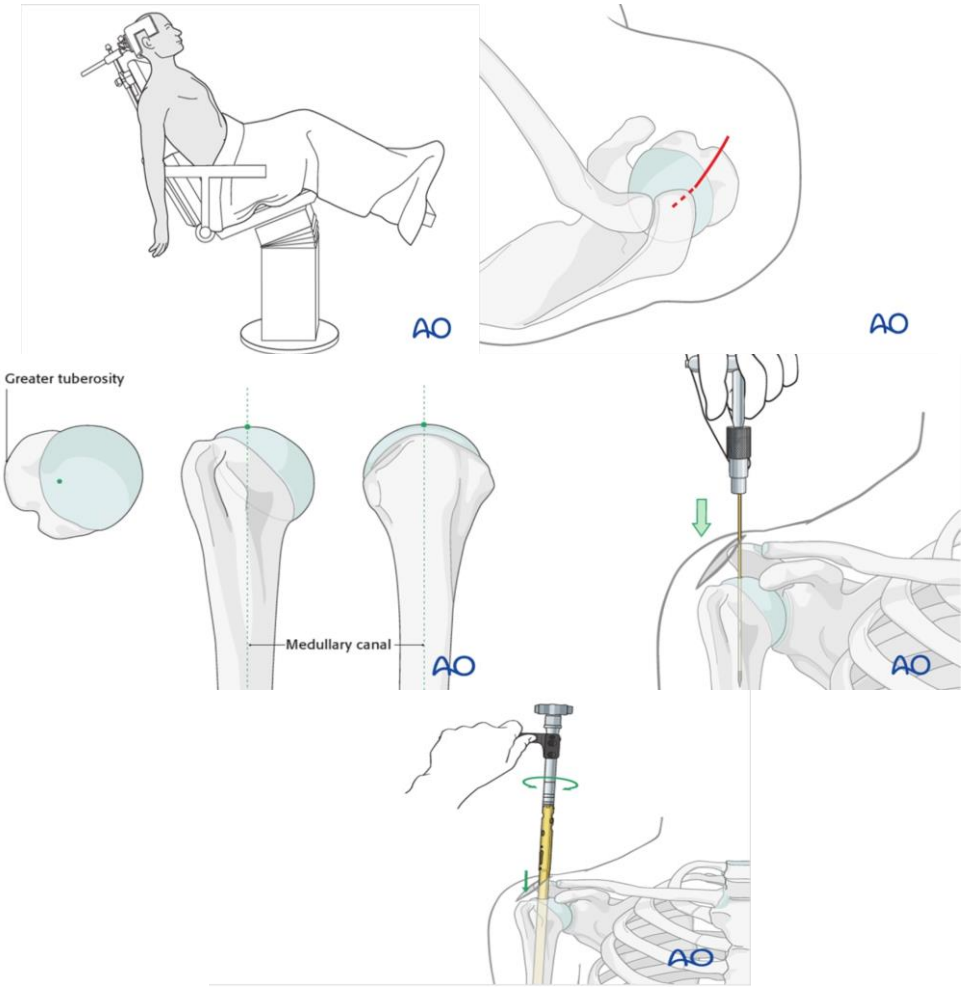

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Post-operative management

A loading dose of antibiotic was given intravenously every 12 hours for three days post-operatively. Post-operative rehabilitation management in both groups was same. Post-operative management included limb elevation until the swelling subsided. The arm was immobilized with arm pouch, and the patients were instructed to move the shoulders and elbows as early as three days after surgery. Suture removal was done at two weeks after surgery. Follow-ups were conducted each month, and plain radiographs were obtained every month until evidence of fracture healing was confirmed. Patients were allowed to report their discomforts or other complications during the follow-up. Postoperative follow-up lasted for 12 months.

Data collection and analysis

Intra-operative measurements included operation time, Intra-operative blood loss and fracture reduction. Fracture union was defined as the absence of pain at the fracture site and presence of bridging callus seen on the anteroposterior and lateral radiographic view of the humerus. Operative time was defined as the time from skin incision to skin closure. Non-union was defined as the absence of clinical and radiographic evidence of union for up to nine months.

Clinical outcome measurements included VAS (Visual Analog Scale) scores, Rating Scale of American Shoulder and Elbow Surgeons' Form (ASES), Mayo Elbow Performance Score System (MEPS), and complications.

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Table I Mayo Elbow Performance Score[7,9]

	No. of points*
Pain (45 points)	
None	45
Mild	30
Moderate	15
Severe	0
Range of motion (20 points)	
>100° flexion arc	20
50°-100° flexion arc	15
<50° flexion arc	5
Stability (10 points)	
Stable	10
Mild instability (<10° of varus-valgus laxity)	5
Gross instability (≥10° of varus-valgus laxity)	0
Daily function (25 points)	
Combing hair	5
Feeding oneself	5
Hygiene	5
Putting on shirt	5
Putting on shoes	5
Maximum possible (total)	100

* The outcome is rated as follows: excellent, 90 to 100 points; good, 75 to 89 points; fair, 60 to 74 points; or poor, less than 60 points.

Micheal C Cusick et al. J Hand Surg Am 2014.Jun

The American Shoulder and Elbow Surgeons standardized form for assessment of the shoulder.

Post-operative pain was evaluated using VAS in the first, third, and sixth months after surgery. Functional outcomes were assessed at the final follow-up, using Rating Scale of American Shoulder and Elbow Surgeons' Form (ASES) and Mayo Elbow Performance Score System (MEPS). Higher scores accessed by these two systems indicate better functional outcomes of the joints. The occurrence of radial nerve palsy, non-union, infection, varus deformity, and rotator cuff injury was recorded as complications in our studies.

Statistical analysis was conducted using the SPSS 21.0 software. Basic information including gender, fracture site, injury mechanism, fracture AO-OTA classification, and complications of the two groups was compared using a Pearson chi-square test. An independent sample t test was used to compare the result of patients' age, time from injury to operation, operation time, fracture union time, intraoperative blood loss, MEPS score and ASES score. The mean value of parametric variables was presented as mean ± SD. Statistical significance was determined as $p < 0.05$.

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SHOULDER ASSESSMENT FORM
AMERICAN SHOULDER AND ELBOW SURGEONS

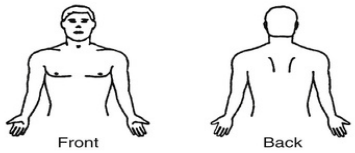
Examiner:

Name:	Date:
Age: Hand dominance: R L Ambi	Gender: M F
Diagnosis:	Initial Assessment? Y N
Procedure/data:	Follow-up: Y N

PATIENT SELF-EVALUATION

Are you having pain in your shoulder? (Circle the correct answer)	Y	N

Mark where your pain is



Do you have pain in your shoulder at night?	Y	N
Do you take pain medication (aspirin, Advil, Tylenol, etc.)?	Y	N
Do you take narcotic pain medication (codeine or stronger)?	Y	N
How many pills do you take each day (average)?	_____ pills	

How bad is your pain today (mark line)?

0 — No pain at all

10 — Pain as bad as it can be

Does your shoulder feel unstable (as if it is going to dislocate)?	Y	N

How unstable is your shoulder (mark line)?

0 — Very stable

10 — Very unstable

Circle the number in the box that indicates your ability to do the following activities: 0 = unable to do; 1 = very difficult to do; 2 = somewhat difficult; 3 = not difficult

Activity	Right Arm	Left Arm
1. Put on a coat	0 1 2 3	0 1 2 3
2. Sleep on your painful or affected side	0 1 2 3	0 1 2 3
3. Wash back/do up bra in back	0 1 2 3	0 1 2 3
4. Manage toileting	0 1 2 3	0 1 2 3
5. Comb hair	0 1 2 3	0 1 2 3
6. Reach a high shelf	0 1 2 3	0 1 2 3
7. Lift 10 lb above the shoulder	0 1 2 3	0 1 2 3
8. Throw a ball overhand	0 1 2 3	0 1 2 3
9. Do usual work–List:	0 1 2 3	0 1 2 3
10. Do usual sport–List:	0 1 2 3	0 1 2 3

Results

Demographic information

45 patients with proximal and middle third humeral shaft fractures were included in this study, 27 of whom were males and 18 were females. The age ranged from 20 to 60 years with a mean age of 38.9 years. Of all the patients, 25 were treated with MIPO and 20 were treated with antegrade interlocking nailing. All the patients in both the MIPO group and the IMN group completed the follow up, and all of them were followed up for at least one year. The IMN group comprised 14 males and 06 females, and the MIPO group comprised 13 males and 12 females. No significant difference was observed between the two groups in terms of age, gender, fracture types, and mechanism of injury. As for the fracture classification, type B accounted for the majority fractures in the IMN group and followed by type A and type C, which shared the same pattern with the MIPO group. With regard to the causes of the injury, most patients suffered from traffic accidents, 15 in the IMN group and 18 in the MIPO group; the second common cause is heavy object hits, 03 in the IMN group and 05 in the MIPO group. In short, **no significance of demographic information, including sex, mean age, fracture side, mechanism of injury, and AO-OTA classification was observed between these two groups**. (Table 1)

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Table 1: Demographic information

Result	MIPO group(n=25)	IMN group(n=20)	P
Gender no			0.58
Male	13	14	
Female	12	06	
Mean age	37.2 ± 9.3	39.3 ± 8.8	0.397
Fracture side			0.044
Left	09	13	
Right	16	07	
Mechanism of injury			0.683
Traffic accident	15	12	
Falling down	03	02	
Hit by heavy objects	04	02	
Others	03	04	
AO/OTA classification no			0.619
Type-A	08	05	
Type-B	12	12	
Type-C	05	03	

Intra-operative measurements

The time interval from injury to operation presented no significant difference between these two groups, with 3.5 ± 1.5 days in MIPO group and 3.2 ± 1.4 days in the IMN group (P= 0.228). Mean operative time in MIPO group was 102.8 ± 15.5 min and 92.9 ± 13.4 min in IMN group. Mean operative time was ten minutes shorter in the IMN group (P = 0.015). Meanwhile, less intra-operative blood loss was observed in the IMN group, 105.5 ± 9.5 ml in the MIPO group and 96.7 ± 11.7 ml in the IMN group (P= 0.003). However, when comparing fracture union time, these two groups showed no statistical significance, presented as 17.5 ± 4.5 weeks in MIPO group and 16.2 ± 3.5 weeks in IMN group (P = 0.215). In short, **the IMN group showed shorter operative time and less intra-operative blood loss in IMN group than in MIPO group, without significant difference on fracture union time.** (Table 2).

Table 2: Intra-operative measurements comparison

Result	MIPO group (n = 30)	IMN group (n = 25)	P
Time from injury to operation (days)	3.5 ± 1.5	3.2 ± 1.4	0.228
Fracture union time (weeks	17.6 ± 4.5	16.2 ± 3.6	0.215
Operative time (min)	102.8 ± 15.5	92.9 ± 13.4	0.015
Intra-operative blood loss (ml)	105.5 ± 9.5	96.7 ± 11.7	0.003

Clinical functional outcomes

Most patients in both groups were able to return to their previous jobs and normal life within six months post-operatively, except for one patient in the IMN group and 2 in the MIPO group because of non-union. No statistically significant difference was found in MEPS score (92.5 ± 5.2 vs. 91.2 ± 3.1, P = 0.288) and ASES score (88.4 ± 2.7 vs. 89.5 ± 3.5, p = 0.194) between these two groups. The VAS score was lower in the IMN group than MIPO group in the first month (5.5 ± 1.2 vs. 3.5 ± 1.3; P < 0.001) and the third month (2.6 ± 1.3 vs. 1.2 ± 1.1; p <

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0.001) but showed no significant difference at the sixth month (0.5 ± 0.7 vs. 0.2 ± 0.4; P = 0.170). Thus, we concluded that the VAS score of the first and the third month was lower in IMN group than that of the MIPO group. However, long-term (6th month) VAS score and functional outcomes (MEPS score and ASES score) were similar between these two groups(Table 3).

Table 3 Clinical outcome comparison

Result	MIPO group (n = 30)	IMN group (n = 25)	P
VAS score			
1 Month	5.5 ± 1.2	3.5 ± 1.3	< 0.001
3 Months	2.6 ± 1.3	1.2 ± 1.1	< 0.001
6 Months	0.5 ± 0.7	0.2 ± 0.4	0.063
MEPS score	92.5 ± 5.2	91.2 ± 3.1	0.288
ASES score	88.4 ± 2.7	89.5 ± 3.5	0.194
Complications			
Total number of patients with complications	7 (23.3%)	2 (8%)	0.126
Radial nerve palsy	3	0	0.104
Non-union	2	1	0.665
Infection	0	0	----------
Varus deformity	2	0	0.188
Rotator cuff injury	0	1	0.269

Complications

During the period of follow-up, No implant failures occurred in either group. One patient in the IMN group and two in the MIPO group failed to achieve union. Thus, the union rate was relatively higher in the IMN group (96.0%) than in the MIPO group (93.3%) without statistical difference. All non-union cases were managed by previous hardware replacement following with ORIF by screws and plate fixation, as well as bone grafting. No occurrence of iatrogenic nerve palsy was recorded in IMN group. Three cases of iatrogenic radial nerve palsy were found post-operatively in the MIPO group and all fully recovered within three months without surgical intervention. One patient in the IMN group had shoulder impingements and rotator cuff injury by physical examination, which was responsible for shoulder pain complaints of the patients. Two patients in the MIPO group suffered humeral varus deformity with varus angle of about 5°, which did not affect their daily life. Above all, **the overall complication rate was higher in the MIPO group (23.3%) than in the IMN group (8.0%)** (Table 3).

45-year-old man who suffered a right humeral shaft fracture (AO-OTA 12B2) by a motor vehicle accident.
Treated by MIPO technique

Follow-up xrays till 1year
Intra-op picture- showing 2 small incisions for MIPO technique.

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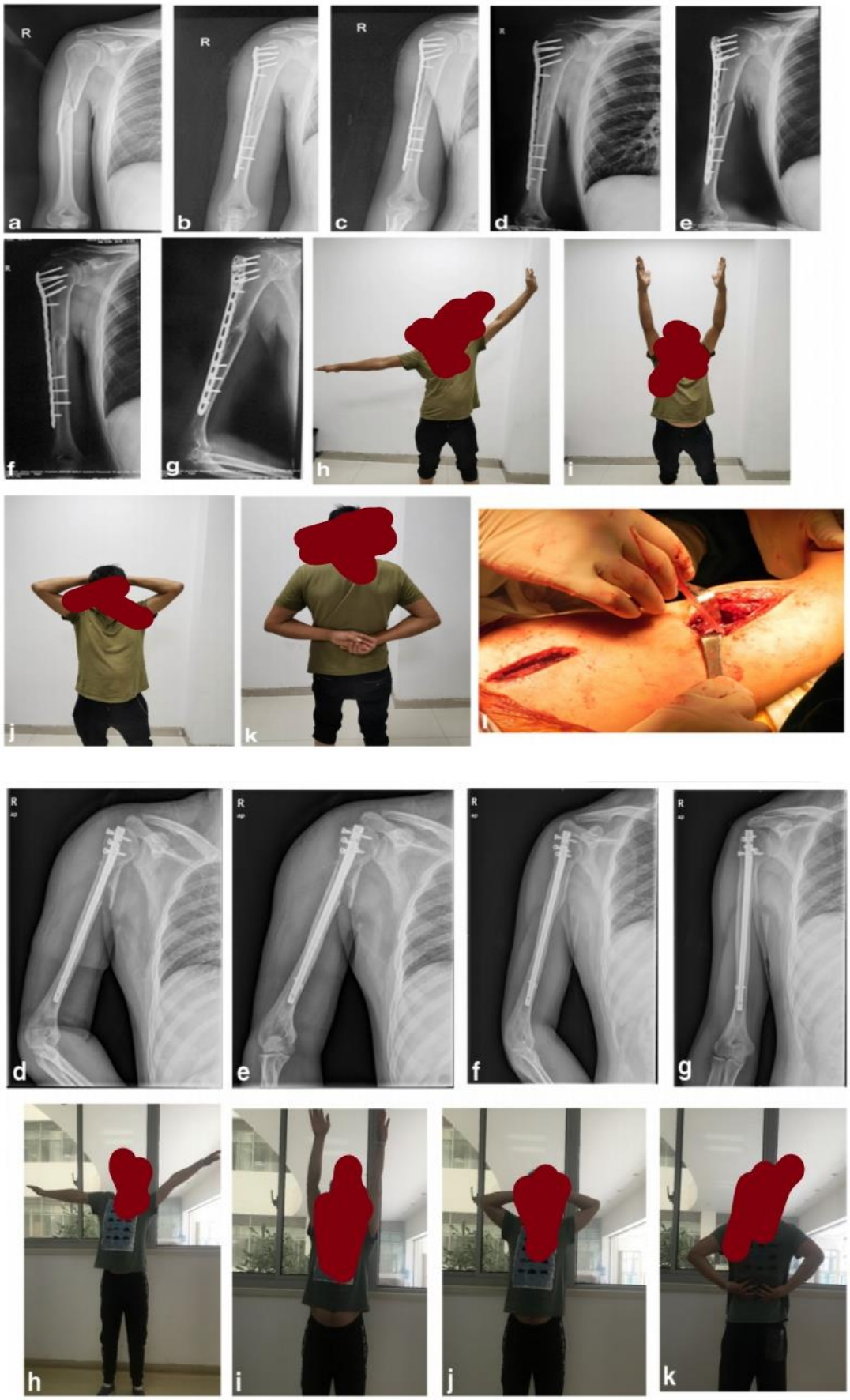

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31-yearold man who sustained a right humeral shaft fracture (AO-OTA 12B2) by a motor vehicle accident.
Treated by IMN
Follow-up X-rays till 1year
Clinical and functional outcome

Discussion

It has been long debated which one, MIPO or IMN, is the optimal technique to treat humeral shaft fractures, particularly for proximal- and middle-thirds of humeral shaft fractures. However, no consensus has been reached to date. We conducted this retrospective study to inspect their advantages and disadvantages. In terms of shoulder and elbow function and overall complication rates, IMN showed no significant difference with MIPO. **When it comes to surgical time, blood loss, and post-operative pain, IMN technique seemed to be superior to MIPO technique for humeral shaft fracture.**

ORIF is a widely accepted operative procedure for treating humeral shaft fractures [8]. However, it requires large incisions and needs to strip off soft tissues and periosteum from the bone, inevitably increasing the risk of non-union or delayed union, infection, and radial nerve damage. Nowadays, intramedullary nailing and minimally invasive plating osteosynthesis are biological fixations and emerging as good options for treating humeral shaft fractures. Previous studies showed that both IMN and MIPO could achieve similar decent clinical outcomes for mid-distal humeral shaft fractures [9]. As a result, **the purpose of this study was to compare MIPO with IMN in the treatment of proximal and middle third of humeral shaft fractures.**

The MIPO technique was developed to achieve adequate stability and to minimize the complications of open reduction internal fixation [10, 11].

MIPO surgical technique only requires two small incisions that will reduce the soft tissue iatrogenic injuries and subsequent infection and cosmetic problems. Anterior approach is adopted and the plate is inserted far away from the radial nerve as a result risk of iatrogenic neurovascular injury will be significantly minimized [4, 5, 12, 13]. Our study showed **no infection**

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and low non-union rates in both MIPO group mean and MIPO technique is a safe surgical procedure (Fig. 1)

Intramedullary nailing offers a variety of advantages. Minimal exposure helps to maximize soft tissue preservation[14]. IMN acts as a means to reduce the fracture and will increase the reliability of reduction and minimize the disturbance of soft tissue with fewer fluoroscopy and shorten the operating time, leading to less blood loss [15–18]. Hence operation time and blood loss in the IMN group were less than the MIPO group.

However, shoulder impingements may occur in some cases wherein the nail protrudes out more than 2 mm [21,22]. Impairment of shoulder function in IMN patients could be due to proximal nail migration, rotator cuff irritation, and adhesive capsulitis [23–25]. Standard approach must be adopted and the rotator cuff must be carefully sutured to avoid complications.

Kulkarni et al. suggested that IMN showed a comparably higher non-union rate than MIPO, while An et al. found all fractures united in both MIPO and IMN groups in their research [29, 30]. Our study showed no significant difference between the MIPO and IMN groups, with one case extra of non-union in the MIPO group, though. IMN has an advantage of gaining and maintaining good reduction. However, IMN may cause traction which will lead to non-union [7].

IMN makes it easier for reduction maintenance as a result of intramedullary fixation characteristic. That might be the reason for fewer cases of non-union and varus deformity in the IMN group in comparison to MIPO group.

Davis et al. reported a better outcome in MIPO as compared to IMN in a total of 30 patients in 2016 [33]. Our results showed that both the MIPO group and the IMN group had a good post-operative functional outcome. Furthermore, patients in the MIPO group are exposed to greater risks of postsurgical complications. The intramedullary interlocking nail was found to be advantageous when it comes operative time, union time, early post-operative pain, and complication rate.

Limitations of the study

1) Retrospective study design
2) Small sample size
3) Shorter follow-up

Hence randomized control trial (RCT)s are needed to determine whether one technique is superior to the other and to distinguish under what situations we should choose the MIPO or the IMN technique.

Conclusion

In conclusion, proximal and middle third humeral shaft fractures could be treated with both MIPO and IMN surgical techniques. MIPO and IMN both showed relatively good clinical outcomes of joints and low complication rates. However, IMN seemed to be safer with fewer complications, shorter operative time and intra-operative blood loss. Prospective studies are needed to determine whether these two techniques generate different clinical outcomes and whether one is superior to the other.

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