Shoulder function after surgical treatment of displaced fractures of the humeral shaft: a randomized trial comparing antegrade intramedullary nailing with minimally invasive plate osteosynthesis

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\textbf{Background:} Minimally invasive plate osteosynthesis for humeral shaft fractures has been described recently, but there are no randomized studies comparing the clinical results for shoulder function between this technique and locking intramedullary nailing.

\textbf{Methods:} A prospective randomized study was performed. Forty-one humeral shaft fractures (40 patients) were randomized to be treated with a minimally invasive plate (n = 21) or a locking intramedullary nail (n = 19). Clinical and radiographic outcome assessments were conducted at 1 year postoperatively. Shoulder function was the primary outcome, as measured by the University of California, Los Angeles Shoulder Scale. Elbow function was measured by the Broberg-Morrey score, and fracture consolidation and complications were the main secondary outcomes.

\textbf{Results:} At 1 year postoperatively, no significant difference was found with regard to shoulder function according to the University of California, Los Angeles scale between the minimally invasive plate and locking intramedullary nail (31.4 points vs 31.2 points, $P = .98$). There was also no difference in elbow function (94.8 points vs 94.1 points, $P = .96$). Complications were similar between the groups, without significant differences regarding infection ($P > .99$), symptomatic shoulder stiffness ($P = .488$), and neurapraxia of the lateral cutaneous nerve of the forearm ($P = .475$). Fracture union was achieved in all but 1 patient (2.4\%) in the intramedullary nail group within 1 year after the surgical procedure.

\textbf{Conclusion:} There is no significant difference in shoulder function between antegrade intramedullary nailing and minimally invasive plate osteosynthesis for the treatment of displaced humeral shaft fractures, despite the limited power of our study.

This study was approved by the local institutional review board (No. 590/03, CAPesq [Comissão de Ética para Análise de Projetos de Pesquisa do Hospital das Clínicas da Universidade de São Paulo]).

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Humeral shaft fractures are the least common humeral fractures, with an annual incidence rate ranging from 14.5 to 20 per 100,000 persons and an increasing incidence with age. In the United States, approximately 66,000 fractures occur annually. Most fractures are amenable to conservative treatment because a certain amount of malalignment is well tolerated by patients. Klenerman found that deformities, including those with less than 20° of angulation in the sagittal plane, varus of less than 30°, or humeral shortening up to 3 cm, are generally considered acceptable and compatible with good function. Surgical treatment is indicated for displaced fractures above those limits, for polytrauma patients, bilateral or open fractures. There are currently 3 main operative techniques for definitively treating displaced humeral shaft fractures: open reduction with plate osteosynthesis (ORPO), intramedullary nailing (IMN), and the more recently described minimally invasive plate osteosynthesis (MIPO). The use of the relative stability principle in diaphyseal fractures with minimally invasive techniques has gained interest for its potential advantage in causing fewer soft tissue complications. Despite the fact that the infection and nonunion rates do not differ for IMN and ORPO, there are other potential benefits of using minimally invasive techniques for humeral fractures: there is less need for bone grafts, there is a smaller incidence of radial nerve lesions, and there are less demanding techniques for complex or comminuted fractures. However, IMN has been shown to cause more complications than ORPO, with a higher risk of shoulder pain and reoperation. The MIPO technique for humeral fractures has recently been described and was developed to allow the theoretical benefits of less soft tissue disruption without the complications of IMN. The objective of this study is to compare postoperative shoulder function between 2 minimally invasive surgical techniques for treating displaced humeral shaft fractures: antegrade IMN and MIPO.

Materials and methods

Study design

We conducted a parallel randomized study at a single orthopaedic trauma hospital. The inclusion criteria were skeletally mature patients who agreed to participate in the study, displaced-shaft humeral fractures (≥20° of anterior angulation, varus ≥30°, or shortening >3 cm), and bilateral fractures or open fractures classified as I to IIIa. Patients with fractures that occurred less than 30 days earlier were included. The following exclusion criteria were applied: nondisplaced fracture, fracture with displacement suitable for conservative treatment, open physes, vascular or nerve injury of the ipsilateral arm, previous humeral fracture, neurologic disease, psychiatric disorder, noncompliance with postoperative rehabilitation protocol (nonattendance of the sessions of physiotherapy at the hospital), pregnancy, open fracture classified as IIIb or IIIc, humeral shaft associated with proximal or distal articular fracture, and Holstein and Lewis pattern of humeral fracture.

Interventions

Thirty-four procedures were performed by the senior surgeon, and 7 procedures were performed by other trauma surgeons at the same hospital. Patients in both groups were positioned supine with 20° of inclination and a small cushion placed under the medial scapular area. General anesthesia and a brachial plexus nerve block were administered.

For the patients in the antegrade nailing 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 thirds from the acromion to a point 3 cm distally. A 1-cm incision was made on the supraspinatus tendon in line with its muscle fiber orientation, medial to the greater tuberosity. The medullary canal was opened with an awl. Under image control, the entry point was made just 2 to 5 mm medial to the sulcus between the greater tuberosity and the articular margin. An unreamed Solid Humerus Nail (UHN; Synthes, Oberdorf, Switzerland) was inserted after adequate measurements were made with fluoroscopy. After manual reduction and nail insertion, distal and proximal locking screws were inserted. An end cap was screwed on, and the rotator cuff tendon and deltoid were carefully repaired.

For the patients in the MIPO group, the technique was performed according to the description of Livani and Belanger. A stainless steel narrow 4.5-mm dynamic compression plate with a minimum of 12 holes (Synthes) was used. A longer plate was used when necessary, according to the fracture pattern. The proximal incision measured between 5 and 10 cm and was made at the distal portion of the deltopectoral approach. The distal incision was made between the biceps muscle and the brachial muscle. After the lateral antebrachial cutaneous nerve was identified, the brachialis muscle underwent longitudinal splitting in its lateral-third portion for a 3- to 5-cm extension to expose the anterior humerus. The fracture was reduced with fluoroscopy by applying traction and abduction of the shoulder to correct the angular deformities. The plate was inserted from the proximal to the distal direction, and the most distal screw was the first to be drilled. Plates were fixed with 3 proximal and 3 distal cortical screws in all cases.
The postoperative rehabilitation protocol was the same for both groups. A sling protected the affected extremity for 4 weeks postoperatively. Passive range-of-motion exercises, supervised by a physical therapist, were initiated on the first postoperative day. Active and active-assisted exercises began after 2 weeks. Strengthening exercises were started after initial signs of callus formation, usually between 6 and 8 weeks after surgery.

Outcomes

Shoulder function at 1 year after surgery, as measured by the University of California, Los Angeles (UCLA) Shoulder Scale, was defined as the primary outcome. Secondary outcomes included consolidation, elbow function as measured by the Broberg-Morrey score, operative time, fluoroscopy use, and complications (ie, infection, loss of reduction, neurologic lesion, or complications related to hardware). Clinical outcomes were evaluated at 1 year postoperatively. Consolidation was evaluated at 3, 6, 8, and 16 weeks and 6 and 12 months postoperatively. Consolidation was defined by the presence of callus bridging on at least 3 of the 4 cortices.

Sample size

There are no previous studies comparing MIPO with IMN. We assumed that shoulder function would be worse with IMN, according to the results of previous studies. We considered that a difference of 6 points in the UCLA score between the 2 groups was the minimal clinically important difference. We considered a 6.4 SD, based on the calculation of UCLA scale results from Bain et al. A 2-sided test with a confidence of 95% and a power of 80% required 18 patients in each group. Anticipating a 10% loss at follow-up, we determined that the estimated necessary sample was 20 patients per group.

Randomization

Patients were allocated to groups by a simple randomization strategy with a tool available at http://www.random.org/coins/. After the participant was anesthetized, the randomization was performed by an assistant who did not participate in the surgical procedure.

Blinding

A physiotherapist who was blinded to the patient allocation and was not involved with the patient rehabilitation conducted the clinical evaluation and application of postoperative scores. Patients used a long sleeve, and the outcome assessor was instructed to avoid questions related to patient treatment. Individuals responsible for the statistical analysis were blinded to the patient identification and group allocation. Patients were not actively informed of the performed surgical procedures.

Statistical analysis

Continuous variables were reported as the mean ± 1 SD. Between-group differences in continuous data were analyzed with the Student t test. For non-normal data, the median and interquartile ranges were reported, and a Mann-Whitney U test was used to perform the analysis. P < .05 was considered statistically significant. An intention-to-treat analysis was performed, and missing data were analyzed by the last observation–carried-forward method.

Results

Participant flow

Between June 2003 and December 2007, 132 patients with humeral shaft fractures were treated at our hospital and were evaluated for eligibility for this study (Fig. 1). Ninety-two patients did not meet the inclusion criteria, and no patient refused to participate in the trial. Forty patients (41 fractures) who met the inclusion criteria and agreed to participate were included in the study. One patient who underwent locking-nail treatment was excluded because of noncompliance with the postoperative rehabilitation protocol.

Baseline data

The mean patient age was 44.8 years (95% confidence interval [CI], 36.98-52.55 years; SD, 17.1 years) in the MIPO group compared with 38.4 years (95% CI, 28.55-46.71 years; SD, 19.1 years) in the IMN group. The right arm was affected in 22 patients (55%). The mean time elapsed between the fracture and the surgical treatment was 8 days, varying from 1 to 30 days in both groups. Fifteen patients had associated lesions. Three patients had open fractures (2 in the MIPO group and 1 in the IMN group). Other baseline characteristics are summarized in Table I. The fracture classification is summarized in Table II. A matched-pair analysis was performed in these 2 groups to ensure that the patients had similar demographic characteristics. No difference was detected between the 2 groups with regard to age, sex, trauma mechanism, AO classification, associated lesions, and ipsilateral superior limb fracture. The dominant limb was affected in 76.2% of the cases in the MIPO group and in 57.9% of those in the IMN group (P = .028).

Outcomes

Primary outcome

After 1 year of follow-up, the patients in the MIPO group showed no difference in total UCLA score compared with the IMN group (P = .98, Mann-Whitney U test). The mean UCLA score was 31.4 points (95% CI, 29.01-33.84 points; SD, 5.3 points) for the MIPO group and 31.2 points (95% CI, 28.49-33.83 points; SD, 5.5 points) for the IMN group. The results are summarized in Table III. The UCLA score domains showed no difference for pain (P = .95), shoulder function (P = .84), active flexion (P = .92), and shoulder flexion strength (P > .99). The UCLA scores showed good to excellent results in 85% of the patients in the MIPO group and 80% of those in the IMN group.
Secondary outcomes

**Elbow function**

At 1 year of follow-up, the mean Broberg-Morrey score was 94.8 points (95% CI, 88.62-98.53 points; SD, 9.7 points) for the MIPO group and 94.1 points (95% CI, 88.83-99.28 points; SD, 10.8 points) for the IMN group. There were no differences in the total Broberg-Morrey score ($P = .96$, Mann-Whitney $U$ test).

There were no differences between the IMN and MIPO groups for the Broberg-Morrey score domains of elbow pain ($P > .99$), stability ($P > .99$), range of motion ($P > .99$), and strength ($P = .92$). On the subjective evaluation, 2 patients (1 each in the MIPO and IMN groups) considered themselves unsatisfied with the treatment. The results are summarized in Table III. In the MIPO group, 85.7% of the patients reported good to excellent results; in the IMN group, the value was 90.5%.

**Operative time and fluoroscopy use**

There was no difference between the 2 groups for the total surgical time, but a statistically significant difference was shown in the fluoroscopy time spent during surgery, with a mean of 81.1 seconds for the MIPO group and 143.1 seconds for the IMN group ($P = .005$).

**Radiographic outcomes**

The fractures healed in 39 of 40 patients (Figs. 2 and 3), with a mean of 7.2 weeks for clinical union. Nonunion of 1 fracture occurred in the IMN group. There were no malunions. There were no significant differences between the groups with regard to nonunion ($P = .475$).

**Complications**

In 1 patient in the MIPO group, a deep wound infection developed and required debridement, and a patient in the...
IMN group presented with a superficial infection that was treated with an intravenous antibiotic that resolved the infection. Symptomatic shoulder stiffness developed in 2 patients in the MIPO group, and they were treated clinically and with physical therapy. The distal screw was oversized in 1 patient in the IMN group, but this problem did not disturb the triceps and elbow extension. Neurapraxia of the forearm cutaneous lateral nerve was observed in 1 patient in the IMN group, but it healed spontaneously after 3 days. An extensive hematoma developed in 1 patient in the MIPO group; the patient underwent drainage of the hematoma and revision of the hemostasis less than 3 hours after the fracture fixation. Complications were similar between the groups, with no significant difference for infection \((P > .99)\), symptomatic shoulder stiffness \((P = .488)\), and neurapraxia \((P = .475)\).

### Discussion

No previous prospective randomized studies have compared MIPO and IMN for humeral shaft fractures. This study can be considered the first randomized trial to compare 2 relative stability techniques for fractures of the humeral shaft. The results showed no difference in shoulder function and pain between MIPO and IMN. The groups achieved good to excellent results in 85% and 80% of the cases, respectively. The shoulder function, pain, and strength measured by the UCLA score were also not different. Although IMN is related to shoulder pain,8,22 our study showed no difference and no complications related to shoulder function with IMN. The IMN entry point was performed by an open approach, and the supraspinatus tendon was medially opened, preserving its insertion at the greater tuberosity. The postoperative rehabilitation protocol of both groups was also the same, avoiding prolonged restriction of shoulder range of motion, even in the IMN group. The good results related to the shoulder function in the IMN group could be explained by this standard approach. Unexpectedly, 2 cases presented with symptomatic stiff shoulders in the MIPO group. One patient had an infection during the early postoperative period and achieved a poor UCLA score (16 points) at the final follow-up. The other patient achieved a good final UCLA score (29 points) at final follow-up.

A criticism of MIPO is related to the risk of loss of elbow motion caused by scar formation at the brachial muscle. In a retrospective analysis of 35 patients, Concha et al10 showed that active elbow range of motion averaged 114° (range, 60°-135°). However, their study included 15 patients with an open fracture and 6 patients with preoperative radial nerve palsy. Our study did not include patients with preoperative radial nerve injuries, and we included only 3 cases of open fractures. Moreover, immediate postoperative rehabilitation was available for all patients in our study, allowing excellent results for elbow function and range of motion for both groups, with a mean Broberg-Morrey score of 94.8 points for MIPO and 94.1 points for IMN.

Nonunion is a common complication associated with ORPO for diaphyseal humeral fractures.30,32 Although previous randomized trials comparing ORPO and IMN for humeral shaft fractures have not shown that IMN decreased the incidence of this complication,8,15 there are several technical difficulties associated with ORPO for comminuted fractures. With IMN, the reduction and alignment of comminuted fractures are also technical challenges. We believe that MIPO is an easier technique, particularly for these fractures, and aligning these fractures is also easier with the assistance of an anterior plate.23 We did not observe a significant reduction in operative time but found that a shorter amount of time was spent performing fluoroscopy with MIPO.

We had 21 cases (12 in the MIPO group) with a type A fracture and 11 cases (7 in the MIPO group) with a type B fracture. Our study had 8 patients with a type C fracture, which is the best indication for the MIPO technique.23 Although it is not possible to draw conclusions from a small subgroup analysis, patients with type A, B, or C fractures did not show any difference in consolidation in the MIPO group because we had no cases of nonunion in this group. Only 1 patient in the IMN group had a nonunion. This patient had a transverse fracture, and a 2-mm gap remained after the surgical procedure. Although the patient had a poor clinical result, with a UCLA score of 16 points, she did not agree to undergo another surgical procedure to treat the nonunion and the IMN remained, without any further complication.

Previous studies comparing IMN with ORPO showed a mean 4.3% incidence of infection from pooled data from 4 clinical trials, and a systematic review did not show any difference in the infection rates.22 In our study, 2 patients, 1

### Table II AO classification of fractures

<table>
<thead>
<tr>
<th>AO classification</th>
<th>MIPO group</th>
<th>IMN group</th>
<th>P value</th>
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<tbody>
<tr>
<td>A</td>
<td>n</td>
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<td>7</td>
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<tr>
<td>C</td>
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\* \(P > .05\).

### Table III Clinical outcomes

<table>
<thead>
<tr>
<th>Clinical outcome</th>
<th>MIPO group</th>
<th>IMN group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA score</td>
<td>31.4 ± 5.3</td>
<td>31.2 ± 5.5</td>
<td>.98</td>
</tr>
<tr>
<td>Broberg-Morrey</td>
<td>94.8 ± 9.7</td>
<td>94.1 ± 10.8</td>
<td>.96</td>
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\(P = \text{value}\)
in each group, had infections, which indicated a 5% incidence of infection. There are several other factors related to infection rates, and finding a difference between similar minimally invasive techniques would most likely require a large sample size with patients with similar ages, comorbidities, and associated lesions.

Regarding the radial nerve injury in MIPO, Livani et al.\textsuperscript{24} showed that the distance from the radial nerve to the plate ranged from 1.6 to 19.6 mm in patients with midshaft fractures and was even closer (1.0-8.1 mm) in distal-third fractures. In our study, no patient had a radial nerve injury related to the surgical fixation of humeral fractures. The incidence of radial nerve injury from the MIPO technique is small. In a retrospective comparative study between MIPO and conventional open reduction, An et al.\textsuperscript{1} showed an incidence of radial nerve injury of 31.3% (5 cases) in the open reduction group versus a 0% incidence in the MIPO group. Other series also reported no radial nerve injuries.
nerve injuries. Pospula and Abu Noor and Ji et al reported radial nerve injury in 1 case each (incidences of 8% and 4%, respectively). We agree with Livani et al and believe that radial nerve injury can be prevented with MIPO using a standard approach: avoiding distal retractors, using gentle soft tissue handling, using anterior plate positioning, using a semiflexed elbow, and introducing the plate from the distal to proximal direction in more distal fractures and from the proximal to distal direction in midshaft fractures. Although the distal locking screw for IMN was inserted through a small incision, 1 patient had neurapraxia of the lateral cutaneous nerve of the forearm in our study. No patients in the MIPO group had this complication.

Using broad inclusion criteria, our study aimed to have adequate external validity, in which humeral fractures may have associated lesions. Associated lesions were present in 15 patients (7 IMN and 8 MIPO patients), and the mean UCLA score in this group was 29.3 points (range, 14-35 points). Five patients had an ipsilateral fracture, with a mean UCLA score of 31.4 points (range, 22-35 points). Two patients had poor results (UCLA score <20 points), and both had associated lesions. In our study, the distribution of associated lesions was similar between the 2 groups and did not seem to affect the comparison of the groups.

Our study had some limitations. The patients were not actively informed of the surgical procedure performed, and the outcome evaluation was performed by a blinded physiotherapist who was trained to avoid questions relating to patient treatment. However, in our institution, patients have free access to routine radiographs obtained, and they are usually used for workers’ compensation issues. Therefore, we believe that it is not possible to assume that the patients were blinded to the treatment they received. Another limitation is that the number of patients involved was small. A post hoc power analysis was performed and showed limited power, which is a potential indication of a false-negative result (type II error). Although we cannot state that both techniques are not different regarding shoulder function, our results showed that the MIPO technique is a safe and effective new technique, and these results might be used in future systematic reviews.

The main strength of our study is the originality. We believed that a control group with the same stability principle could be used to evaluate the effectiveness of the MIPO technique regarding shoulder function with less bias than an open reduction–internal fixation control group. We did not have a nonoperative control group because the inclusion criteria for the study involved only displaced-shaft humeral fractures.

We believe that the MIPO procedure has several other advantages that were not measured by this clinical trial. It is a safe technique with relatively easy reduction and alignment when compared with the other available techniques, and it involves less radiation exposure for the surgeon. Although costs were not directly evaluated by our study, the cost is decreased with dynamic compression plates compared with intramedullary nails.

Future randomized trials should be performed with larger sample sizes and longer follow-up periods to further evaluate the effectiveness of MIPO for displaced-shaft humeral fractures.

**Conclusion**

There is no significant difference in shoulder function between antegrade IMN and MIPO for the treatment of displaced humeral shaft fractures, despite the limited power of our study.

**Disclaimer**

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