



Clinical comparison between open plating and minimally invasive plate osteosynthesis for displaced proximal humeral fractures: A prospective randomized controlled trial



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ARTICLE INFO

Keywords:

Proximal humerus fracture
Open plating
Minimally invasive plate osteosynthesis

ABSTRACT

Background: Recently, minimally invasive plate osteosynthesis (MIPO) has been widely used for the treatment of proximal humeral fractures. However, there is concern about whether the MIPO in comminuted proximal humeral fractures is also comparable to open plating. The purpose of this study was to compare the clinical and radiographic outcomes of open plating and MIPO for acute displaced proximal humeral fractures.

Materials and methods: In this prospective, randomized controlled study, 107 patients who had an acute proximal humeral fracture were randomized to either the open plating or MIPO techniques. Forty-five patients treated with open plating and 45 with the MIPO technique who were followed up at least 1 year were evaluated. Shoulder functional assessment, operating time, several radiographic parameters, and complications were evaluated at final follow-up.

Results: The mean follow-up period was 15.0 months in the open plating and 14.3 months in the MIPO technique. There were no statistically significant differences in functional assessment scores and radiographic parameters between the two groups. High complications rates were found in 4-part fracture in both surgical methods. The average operation time in the MIPO group were significantly lower compared to the open plating group ($p < 0.05$).

Conclusion: This study showed MIPO in proximal humerus fractures had similar clinical and radiographic outcomes compared to the open plating. However, the MIPO technique in proximal humerus fracture provided significantly shorter operation time than the open plating.

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Introduction

Among various treatment methods for proximal humeral fractures, open reduction followed by internal fixation with a plate has become the commonly preferred surgical modality [1,2]. Open plating using the conventional deltopectoral approach has several benefits such as excellent wide view of the anterior aspect of the proximal humerus and ease in applying the plate decreased risk of neurovascular injury. However, open plating has a biological weakness due to inevitable soft tissue stripping and technical concerns from limited exposure of the lateral humeral aspect where the plate is positioned [3,4]. The minimally invasive plate osteosynthesis (MIPO), which is currently used for the treatment of

lower extremity fractures, has been developed as a potential solution to ameliorate the weak points of open plating in terms of soft tissue preservation in proximal humeral fractures [5–7]. Recently, MIPO has been widely used in treatment for proximal humeral fractures and demonstrated satisfactory clinical outcomes and fracture healing comparable to open plating [3,8].

Although the MIPO technique for proximal humeral fracture is considered an alternative surgical method, postoperative results have not always provided successful clinical and radiographic outcomes, especially with severely comminuted fractures. Because MIPO for proximal humeral fracture is achieved by an indirect reduction technique, there is some concern with regard to anatomical reduction when considering comminuted fracture such as 4-part fractures. For this reason, several authors suggested that conversion to open plating in complex humeral fracture should be considered when anatomical reduction is unlikely to be achieved with the MIPO technique [4,8]. However, the outcomes in

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complex proximal humeral fractures treated with open plating were also not always satisfactory in 4-part fractures [9–12].

The purpose of this study was to compare the clinical and radiographic outcomes of open plating to MIPO in acute displaced proximal humeral fractures. The hypothesis is that there are no differences in clinical and radiographic outcomes between the MIPO technique and conventional open plating.

Materials and methods

Patient selection

This study was a prospective, randomized controlled trial of patients with acute displaced proximal humeral fractures treated with either the open plating or MIPO techniques. Following approval by the Institutional Review Board, from August 2010 to May 2014, patients were prospectively reviewed as part of their care and enrolled into the follow up study. Written informed consent was obtained from all participants.

All proximal humeral fractures were classified according to the Neer classification. Inclusion criteria were patients who were skeletally mature, those with two-part surgical neck fractures, three and four-part proximal humeral fractures, unilateral proximal humeral fracture, previously uninjured humerus, time to surgery within 3 weeks, and 3 dimensional computed tomography (3D CT) evaluation. Exclusion criteria were as follows: isolated greater or lesser tuberosity fractures, injuries with more than 3 weeks between the injury and surgery, pathologic fractures, open fractures, combined dislocation or scapular fractures, neurovascular compromise from the initial trauma, and less than 1 year follow up.

Detailed past history for the patients, including pre-existing problems in the shoulder joint, smoking, alcohol, diabetic status, cardiovascular disease, and body mass index, were also evaluated.

Sample size calculation

The sample size was calculated based on the interim results of this study. The Constant score of the patients after bone union was considered the primary outcome. The Constant score was compared between patients treated with open plating and MIPO when data was obtained from the first 40 patients (20 patients with MIPO and 20 patients with open plating). An effect size of 0.6 was calculated based on a mean difference of 5 and a standard deviation of 3 observed in the interim results of 40 patients. The pilot study indicated that a sample size of 45 patients in each study group would provide a statistical power of 80% with Type I error set as 0.05 to detect significant differences in the Constant score. Assuming a 15% drop out rate, the final sample size was set at 52 patients for each group. All enrolled patients were allocated to either the open group (patients who underwent open reduction and internal fixation with a plate) or MIPO group (patients who underwent internal fixation with a plate using the MIPO technique), without stratification by demographic characteristics.

Method of randomization

The randomization was performed by permuted block randomization. The block length was 4, and randomization was performed by means of consecutive numbering. The randomization sequence was created using a web-based service with a 1:1 balanced allocation. After the patients were transferred to the

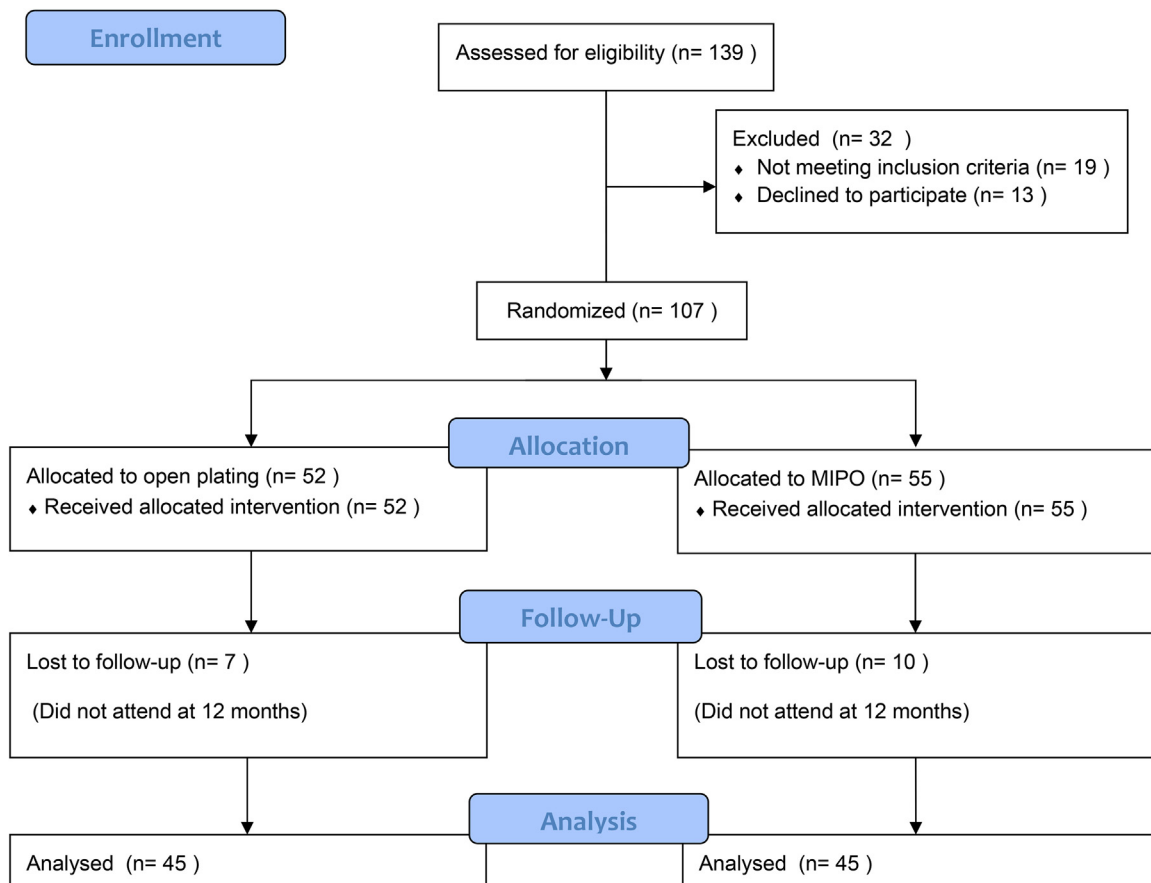


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart for patients enrollment and analysis.

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