Injury, Int. J. Care Injured 46 (2015) 2230–2238

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Clinical comparison of two different plating methods in minimally invasive plate osteosynthesis for clavicular midshaft fractures: A randomized controlled trial

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ARTICLE INFO

Article history:
Accepted 7 August 2015

Keywords:
Clavicular midshaft fracture
MIPO
Superior plating
Anteroinferior plating

ABSTRACT

Aim: The aim of this study was to compare the clinical and radiographic outcomes between two different plating methods (superior vs. anteroinferior) in minimally invasive plate osteosynthesis (MIPO) for acute displaced clavicular shaft fractures.

Materials and methods: A prospective, randomized controlled trial was performed in a single centre. Nineteen patients were treated with superior plating and 18 with anteroinferior plating using the MIPO technique. A 3.5-mm locking reconstruction plate was bent preoperatively and applied to either the anteroinferior or superior aspect of the clavicle through two separate incisions. The operating time, time to union, the proportional length difference, complications, and functional outcome of the shoulder joint were evaluated using the Constant score and the University of California Los Angeles (UCLA) score.

Results: There was no statistically significant difference in the Constant score and UCLA score. The mean time to union was 16.8 weeks for superior plating and 17.1 weeks for anteroinferior plating ($p = 0.866$). The average operation time was 77.2 min in superior plating and 79.4 min in anteroinferior plating ($p = 0.491$). One patient in the superior plating group showed plate failure. Despite no significant difference, one patient had nonunion in the superior plating group ($p > 0.999$).

Conclusions: From a clinical perspective, although MIPO with anteroinferior plating provides better outcomes especially in complications without statistically significant difference, both plating methods provided satisfactory clinical and radiographic outcomes.

Level of evidence: Level I, a single-centre, prospective, randomized controlled trial.

Introduction

Traditionally, most clavicular midshaft fractures have been treated by conservative methods with high union rates and good patient satisfaction levels [1–3]. However, recent studies have reported higher nonunion rates in displaced clavicular shaft fractures after nonoperative treatment than after operative treatment [4–6]. Although open reduction and internal fixation with a plate have been considered to be a gold-standard treatment method for clavicular midshaft fractures, this treatment modality also has several complications, which may be partly caused by extensive periosteal stripping of the fracture site, such as infection, nonunion, implant failure, and refracture after implant removal [7–9]. Because biologic fixation has been emphasized to ameliorate fracture healing, minimally invasive plate osteosynthesis (MIPO) has been applied to not only other long bone fractures but also clavicular shaft fractures, and good clinical and radiological results have been reported [10–12].

Although superior plating is the preferred and most frequently used method for clavicular midshaft fracture, some authors have reported good outcomes with anteroinferior plating for treating acute and nonunited clavicular shaft fractures [13,14]. Although several biomechanical studies and one clinical comparative study between the two plating methods have been reported [15], no clinical comparisons of the MIPO technique for clavicular shaft fractures have been performed. We speculated that the biomechanical properties and clinical outcomes of the MIPO for clavicular shaft fracture probably differ from those of open plating because MIPO makes use of a bridging plate that does not achieve complete reduction, but induces secondary bone healing.

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http://dx.doi.org/10.1016/j.injury.2015.08.018
0020–1383/

The aim of this study was to compare the clinical and radiographic outcomes between two different plating methods (superior vs. anteroinferior) in MIPO for treating acute displaced clavicular midshaft fractures. Our null hypothesis was that there were no differences in clinical and radiographic outcomes between two plating methods in different positions.

Materials and methods

Study design and ethical approval

This study was a single-centre, prospective, randomized controlled trial of patients with clavicular midshaft fractures, who were treated with the MIPO technique using either the superior or anteroinferior plating method. The Institutional Review Board of the National Medical Center (approval number H-1012/006-001) approved the study protocol from October 2010 to March 2013. Patients were prospectively reviewed as part of their care and enrolled in the follow-up study, and written informed consent was obtained from all participants. All patients who enrolled in this study were counselled on the benefits and risks of minimally invasive plate surgery.

During the study period, 55 patients with clavicular shaft fracture were recruited in our hospital. Ten patients did not meet the inclusion criteria or wished to be treated conservatively. Three patients refused to participate in the study after being counselled on the benefits and risks of minimally invasive plate surgery. Finally, 42 patients were enrolled in this study. Twenty-two patients were assigned to the superior plating method and 20 were randomized to undergo anteroinferior plating. Five patients were lost to follow-up (Fig. 1).

All clavicular shaft fractures were classified according to the AO/OTA classification system. The inclusion criteria for this study were an age of 18–70 years, unilateral clavicular fracture, previously uninjured clavicle, time to surgery within 3 weeks, displaced clavicular midshaft fracture (no cortical contact between the medial and distal fragment and/or >2-cm shortening), and medical fitness for undergoing surgery. The exclusion criteria were an associated scapular fracture (floating shoulder), associated neurovascular injury, open or impending fracture, pathological fracture, and patient ineligibility for follow-up.

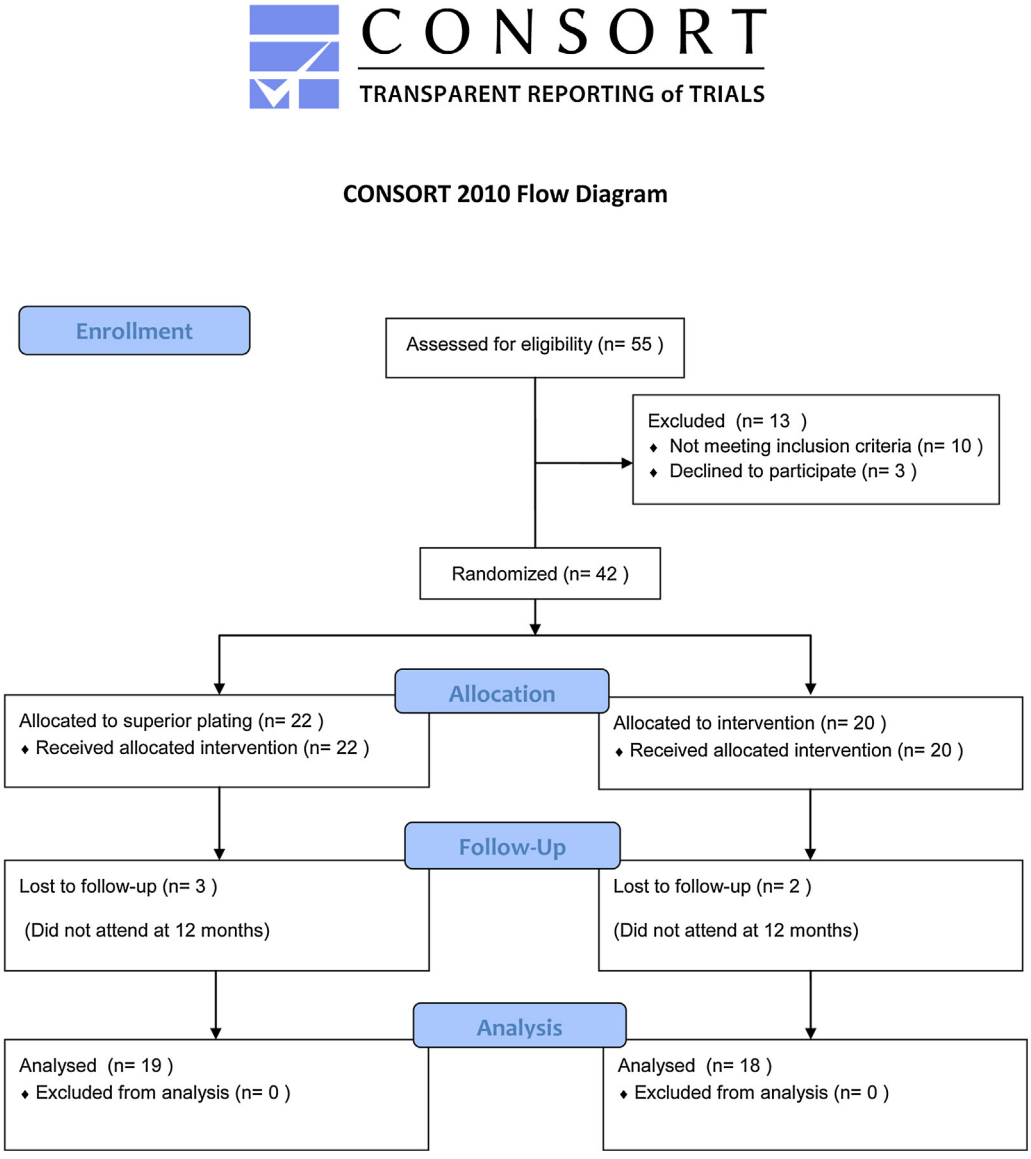

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart of the patient enrollment and analysis.