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Comparative evaluation of 2.0 mm locking plate system vs 2.0 mm non-locking plate system for mandibular angle fracture fixation: a prospective randomized study

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Abstract. – OBJECTIVE: This prospective randomized study evaluated the efficacy of a 2.0 mm locking plate/screw system compared with a 2.0-mm nonlocking plate/screw system in fixation of 60 isolated non-comminuted mandibular angle fractures.

PATIENTS AND METHODS: Sixty patients were randomly assigned to receive a 2.0 mm locking plate (group A, n = 30) or 2.0 mm non-locking plate (group B, n = 30). All patients were followed up to 6 months postoperatively and evaluated for complications, occlusal stability and overall results of fixation.

RESULTS: Five complications occurred in the locking group and fourteen in the non-locking group with complication rates equalling 17% and 47% respectively. When comparing the overall results according to plates used, the χ^2 test showed a statistically significant difference between the locking and non-locking plates ($p < 0.01$). Fewer patients required IMF in group A.

CONCLUSIONS: Mandibular angle fractures treated with 2.0 mm locking plates show greater stability and were associated with fewer complications than with 2.0 mm non-locking plates.

Key Words:
Mandibular angle fractures, Locking plate system, Non-locking plate system, Erich arch bar fixation, Intermaxillary fixation, Occlusal derangment.

Introduction

Single non-compression monocortical miniplate fixation based on the principles advocated by Champy et al[1] and Michelet et al[2] has been known to be an accepted and reliable method for internal fixation of mandibular angle fractures. The stability of conventional bone plating systems utilizing these principles is achieved when the head of the screw compresses the fixation plate to the bone as the screw is tightened. Over time, the cortex of bone adjacent to the plate resorbs[3]. If the plate is not contoured precisely and is not in intimate contact with the bone or if the host is compromised (medically or nutritionally), the result will be unstable fixation[3]. To overcome this shortcoming, a screw that locks not only to the bone, but to the bone plate has been developed. The result is a locking plate system which in effect acts as a mini-internal fixator. Since the plate locks to the screw rather than gaining its rigidity by being compressed against the bone, it also avoids the cortical necrosis which is sometimes seen under a plate that is compressed against the bone[4]. A critical theoretical advantage of locking screws is the decreased potential of screw loosening that can promote infection[4].

The purpose of this study was to compare efficacy of single 2.0 mm locking miniplate/screws with 2.0 mm standard miniplates/screws in treating isolated unilateral non-comminuted mandibular angle fractures.

Patients and Methods

An internal review board (IRB) approved the study. All patients signed written informed consent. Sixty patients with isolated unilateral mandibular angle fractures were included in this study. Thirty patients in each group were randomly assigned to be treated with open reduction and internal fixation using a single 2.0 mm locking miniplate (Orthomax Ltd, Baroda, Gujarat,

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India) and four 8 mm length screws (group A) or 2,0 mm non-locking miniplate (Orthomax Ltd, Baroda, Gujarat, India) and 8 mm length screws (group B). The period of study was from January 2008 to September 2012. Inclusion criteria were patients aged between 18 to 60 years, non-comminuted mandibular angle fracture, no concomitant mandible or midface fracture, no post traumatic neurosensory deficit, a dentition complete enough to apply stable Erich arch bars and a non-infected fracture site. All cases were evaluated clinically and radiographically using orthopantomographs. The degree of fracture displacement was determined on a panoramic radiograph by assessment of the alignment of the mandibular canal. Whenever alignment of the mandibular canal was maintained across the fracture line, it was considered a non-displaced fracture. Fractures in which malalignment of the canal was less than 50% of the height of the canal were considered minimally displaced. Fractures in which misalignment was greater than 50% but less than the entire height of the canal were considered moderately displaced. Fractures in which misalignment was greater than the height of the canal were considered to be severely displaced. All patients received intravenous antibiotics and chlorhexidine mouth rinses from the time of admission until discharge. Oral antibiotics were prescribed for a week upon discharge. In all patients, fractures were reduced with upper and lower Erich arch bar fixation as a means for temporary intraoperative intermaxillary fixation. The surgical technique used to apply both plating systems was the same, except that a locking drill guide was used with the locking plates. All patients were treated under general anesthesia with nasotracheal intubation by a single operator along Champy's ideal line of osteosynthesis on the superior border of the mandibular angle. The fractures were treated ranging from 1 to 3 days with a mean of 1.6 days from the time of injury. Post operatively, neurosensory changes, occlusal discrepancies, need for intermaxillary fixation (IMF) and its duration, screw loosening/plate fracture, infection at the fracture site and need for removal of the plates and screws were analyzed. Neurosensory deficits were recorded using pin prick and two point discrimination. Post operative orthopantomographs were analyzed by an independent investigator not involved in the surgical treatment of cases, to analyze anatomic fracture reduction. All arch bars were removed four weeks postoperatively. Patients were advised to take liquid diet for two days and thereafter on a soft diet for two weeks. Postoperative clinical checks were made on the 1st, 3rd and 7th postoperative days and at 1, 2, 3 and six months.

Statistical Analysis

Results were statistically evaluated with the Chi square test (χ^2) test. $p < 0.05$ was considered statistically significant.

Results

Sixty patients who met the inclusion criteria for the study were included. Group A (n=30, locking plate group) included 17 male and 13 females, group B (n=30, non-locking plate group) included 18 male and 12 females. Average age was 35.4 (18-56 years) in group A and 37.3 (19-60 years) in group B. Group A included 19 right and 11 left angle fractures while group B included 17 right and 13 left angle fractures. Group A included five displaced, 12 minimally displaced, seven moderately displaced and six severely displaced fractures while group B included eight displaced, nine minimally displaced, eight moderately displaced and five severely displaced fractures. The lower third molar tooth was involved in the fracture line in 20 and 18 cases in group A and group B respectively. None of the lower third molars were removed in either group.

Postoperatively, two patients in group A presented mild occlusal derangement which was treated using rubber guiding elastics secured to Erich arch bars for a week. Both of these patients had severely displaced fractures. In group B, five patients had mild occlusal derangement (two with moderate fracture displacement and three with severe fracture displacement) and three patients (severe fracture displacement) had gross occlusal derangement. Guiding elastics were utilized for one week in the mild occlusal derangement patients and intermaxillary fixation was performed for two weeks followed by guiding elastics if necessary for one week in patients with gross occlusal derangement. After four weeks all the patients had a functional occlusion. There was a statistically significant difference between group A and B with respect to occlusal stability and need for IMF ($p = 0.008$).

Anatomic reduction (as assessed by panoramic radiographs) was observed to have a significant difference between group A and B, with contingency coefficient value of 0.463 and $p = 0.004$.

Temporary paresthesia was noted to be present in two and one patient postoperatively in group A and B respectively. There was no statistically significant difference between the two groups (p = 0.137). All cases demonstrated a complete neurosensory recovery between 3-6 weeks after surgery. In group B, soft tissue infection was noted in two patients, which was managed conservatively with oral antibiotics and rinses. Two patients in group B presented with screw loosening and one with a plate infection that required plate removal after three months. There were no cases of plate fracture in either group. In group A, one patient developed soft tissue infection which was managed with oral antibiotics and mouth rinses. None of the patients had non-union or osteomyelitis. There was no statistically significant difference in infection and plate removal rates between group A and B (p = 0.097 and 0.272 respectively).

The overall complication rate in group A was 17% (5/30) and in group B was 47% (14/30). There was a statistically significant difference between the two groups ($p < 0.01$).

Discussion

The goal of rigid internal fixation of the fractured mandibular angle is to eliminate the need for IMF, to achieve accurate anatomic reduction of the fracture segments, reduce the risk of postoperative displacement of the fractured segments while allowing an immediate return to function[5]. Research continues to focus on the number, size, shape, and biomechanics of plate/screw systems to improve surgical outcomes.

In this study, the locking plates for fracture fixation at the mandibular angle showed better stability after fixation when compared to the non-locking plates. This was evident from the number of cases that developed occlusal derangement and required an addition period of IMF post fixation (2 in group A [7%] vs eight in group B [27%]). These findings were particularly true in the most displaced fractures which demanded greater rigidity of fixation. Similar findings were reported by Singh et al[6] in their study comparing locking to non-locking miniplates in surgical treatment of mandibular fractures. These findings may be because conventional miniplates demand accurate adaptation to the underlying bone to prevent alterations in the alignment of fractured segments and changes in occlusal relationship[7]. The locking plate/screw system is designed to allow the screw to lock into the plate by a second thread under the screw head, thereby, acting as an internal fixator by locking the screw into the plate[7]. The result of this locking mechanism is that it becomes unnecessary to adapt the plate to the underlying bone making plate adaptation easier leading to lesser alterations in alignment of fracture segments and changes in occlusal relationship upon screw tightening[7].

Sauerbier et al[8] reported a 6% rate of postoperative malocclusion followed the use of locking miniplates for fixation of mandibular fractures. Yazdani et al[9] reported prevalence of 48% malocclusion after surgical fixation of mandibular angle fractures in 45 patients using a single non-locking miniplate. In our study, occlusal disturbances were noted in 7% cases in the locking plate group and 27% cases in the non-locking plate group. These findings were particularly true in cases of severe fracture displacement, indicating that the greater rigidity provided by locking plate/screws was a definitive advantage.

Anatomic reduction of fracture segments, as assessed by orthopantomographs, was significantly superior to the locking plate group (p = 0.004). This may be a result of the different fixation method. When using conventional miniplates, it is essential to contour the plate precisely to the bone surface. Otherwise, incongruence between the bone surface and plate will be transferred to the mobile bone fragments while tightening of screws resulting in more extended gaps and torsion leading to primary loss of reduction. If the locking plate is fixed with locking screws, reduction remains nearly unchanged[7].

Two patients in group B were observed to have screw loosening while none was observed in group A. This may be a result of the fact that in conventional miniplate system fixation is provided by the screw thread inserted into the bone, creating a friction lock between the plate and the bone which is essential to achieve stability after the reduction. Torsional forces between the bony fragments may lead to a loss of this friction lock and result in reduced primary stability. Cordey et al[10] state that the friction between the screw head and plate is the main weak point of the entire fixation. In the 2.0 locking system, the thread on the screw head locks into the congruent thread of the plate, transforming the screws and plate into a

unit, creating a rigid splint with higher mechanical stability. This corresponds to the principle of an external fixator[7].

Paresthesia was noted in 2 patients (7%) in group A and 1 (3%) patients in group B. This may a result of the need for greater tissue retraction in group A to accommodate the drill guide and subsequent placement of perpendicular screws.

Soft tissue infection was observed in two patients in group B and one patient in group A, with no statistically significant difference between them. Plate infection was noted in one patient in group B. Studies[11] have reported that the main reason for infection associated with rigid fixation is the failure to achieve stability even after placement of plates and screws.

Rebeiro et al[12] showed superior results when assessing resistance to displacement of the locking system when compared with conventional miniplates in a study on simulated angle fractures in polyurethane mandibles. Haug et al[13] showed superior results of a locking system when compared with conventional plates in a study on polyurethane mandibles as only the degree of the plate adaptation affected the nonlocking system. Poon and Verco[14] showed on sheep models that locking plates/screws demonstrated superior fracture union at eight weeks than conventional miniplates.

Locking plates/screws do not need a friction lock between the plate and bone for stability, thereby transmitted reduced pressure on the underlying bone than conventional miniplates. Less disturbance of perfusion of the underlying bone with decreased bone necrosis is the result, which might lead to increased bone healing and regeneration[7].

Cost issues also need to be considered when evaluating the utility of locking versus non-locking hardware. Locking plate/screw system is likely to cost between 1.5 to 2 times that of the non-locking system[15]. However, it is likely that the cost differential would be completely offset and justified considering the additional treatment costs incurred in treating the complications with a single non-locking plate seen in group B.

Conclusions

The current study demonstrated that use of 2.0 mm locking miniplate/screw system resulted in a lower occurrence of complications and provided better stability of fracture fixation in isolated mandibular angle fractures when compared with the non-locking miniplate/screw system. A single 2.0 mm locking miniplate placed along the superior border of the mandibular angle provided highly effective fixation for mandibular angle fractures without the need for postoperative IMF.

Conflict of Interest

The Authors declare that there are no conflicts of interest.

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