Study of Efficacy and the Comparison Between 2.0 mm Locking Plating System and 2.0 mm Standard Plating System in Mandibular Fractures

B. Pavan Kumar · K. A. Jeevan Kumar ·
V. Venkatesh · A. P. Mohan · K. Ramesh ·
K. Mallikarjun

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Abstract

Purpose The purpose of this study was to evaluate the efficacy and comparison between 2.0 mm locking plate system and 2.0 mm Champy's titanium mini plating system in mandible fractures.

Materials and Methods A total of 20 patients with mandibular fractures were selected and divided into two groups A and B on randomized basis. Group A was treated with open reduction internal fixation using 2.0 mm locking plates and group B with 2.0 mm Champy's titanium miniplates. All patients were followed up for 12 weeks postoperatively.

Results Results of the study show less screw loosening, less precision in plate adaptation and less alteration of the osseous or occlusal relationship upon screw tightening in group A. Chi square test was applied to compare the results between the two groups. Statistical analysis did not show significant difference of incidence of malocclusion between the two groups (p value = 0.606). Statistical analysis using un-paired t test showed significant difference of working time between the two groups (p value = 0.00296). When comparing the overall complication rates according to plates used, the χ^2 test showed no statistically significant difference between the locking and nonlocking plates ($p > 0.05$).

Conclusion It is observed in our study that the locking plate/screw system offers significant advantages over the conventional plating system. The precise adaptation required for using conventional plates is not needed when this locking plate/screw system is used. Locking plate/screw system provides better stability than the conventional plate/screw system.

Keywords Locking plate and screw system · Champy's mini plates · Mandibular fractures · Open reduction internal fixation (ORIF)

Introduction

Treatment modalities over the years have evolved from the use of bandages, first mentioned by Hippocrates to semi rigid fixation used by Michelet et al. and Champy et al. [1–8]. Many of the innovations in the management and treatment of maxillofacial trauma began during the World War II era. In the decades that followed, the treatment of mandibular fractures evolved from closed reduction with or without maxillomandibular fixation to various forms of semi rigid internal fixation. The advent of rigid internal fixation improved the treatment outcomes of the maxillofacial trauma patient, allowing maxillofacial surgeons to restore form and function sooner, and with more stable and predictable results [9].

However, a disadvantage of traditional semi rigid internal fixation is that the plate must be bent to perfectly adapt to the underlying bone to achieve the desired results. Studies continue to cite high complication rates using these traditional methods [10–13]. Other studies report favorable results with the 2.0 mm titanium miniplate system [14]. According to Arbeitsgemeinschaft für Osteosynthesefragen (AO)/Association for the Study of Internal Fixation (ASIF) principles, the main objective

B. P. Kumar (✉) · K. A. J. Kumar · V. Venkatesh ·
A. P. Mohan · K. Ramesh · K. Mallikarjun
Oral and Maxillofacial Surgery, Kamineni Institute of Dental
Sciences, Sreepuram, Narketpally,
Nalgonda (Dist.) 508254, Andhra Pradesh, India
e-mail: pavankumarbatchu@yahoo.co.in

K. A. J. Kumar
e-mail: jeevan1983@yahoo.com

of open reduction and rigid internal fixation in the management of mandibular fractures is to achieve undisturbed healing and immediate restoration of form and function without the adjunctive use of maxillomandibular fixation (MMF) [15–18]. To overcome this problem, the concept of locking bone plates was introduced. The locking plating system has been developed and popularized by AO/ASIF to obviate the main disadvantage of conventional plate system, which requires the plate to be perfectly adapted to the underlying bone to avoid gaping of the fracture and associated instability [19, 20]. Locking plate and screw systems have been available for more than three decades, but recently, interest in these systems have been rekindled. These locking plate and screw systems function as internal fixators, achieving stability by locking the screw to the plate. The hole in the bone plate is engineered to accept the screw that lock to it by a second thread under the head of the screw. Conventional bone plate and screw systems require precise adaptation of the plate to the underlying bone. Without this intimate contact tightening of the screw will draw the bone segment towards the plate, resulting in the alterations in the position of the osseous segments and the occlusal relationship. Locking plate and screw systems offer certain advantages over other systems in this regard, most significant being that it becomes unnecessary for the plate to have intimate contact with the underlying bone in all areas, thus making plate adaptation easier [21].

As the screws are tightened they lock to the plate, thus stabilizing the segments without the need to compress the bone to the plate. This obviates the risk that screw insertion will alter reduction [21].

One of the important advantages of this system is that screws are unlikely to loosen since they engage the bone plate in the screw head slot. This means that even if a screw is inserted into a fracture gap, loosening of the screw will not occur. The possible advantage of this property of a locking plate and screw system is a decreased incidence of inflammatory complications due to loosening of the hardware. It is known that loose hardware propagates an inflammatory response and promotes infection. For a locking plate and screw system to loosen, loosening of a screw from the bone or loosening of all the screws from the plate would have to occur. Both of these are unlikely events. The amount of stability provided across the fracture and osteotomy gap is greater than when standard non-locking screws are used [21].

Research continues to focus on the size, shape, number and biomechanics of plate/screw systems to improve surgical outcomes. Locking plate/screw systems have certain advantages over conventional plates and screws. Theoretical advantages proposed include less screw loosening, greater stability across the fracture site, less precision required in plate adaptation because of the less alteration in osseous or occlusal relationship upon screw tightening” [22].

Fig. 1 **a** 2.0 mm locking plate with 2 × 8 mm screws. **b** 2.0 mm Champy's titanium mini plates with 2 × 8 mm screws

With conventional bone plating systems, stability is achieved when the head of the screw compresses the fixation plate to the bone. Advocates for the locking system claim the screw/lock interface circumvents the need for precise adaptation providing an “internal external fixator.” In 1999, Gutwald et al. [23] performed the first biomechanical comparison of locking plates applied to the mandible. They concluded that a higher stability was achieved with locking plates. The purpose of this prospective study was to evaluate the efficacy and to compare standard 2.0 mm monocortical plates with 2.0 mm locking plates in the treatment of mandibular fractures.

Materials and Methods

The study sample consisted of 20 patients with fractures of mandible and were treated over a period between September 2010 and August 2012. Out of 20 patients, 14 were male and 6 were female patients. (Mean ± SD = 29 ± 7.53; age range 17–45 years)

Fig. 2 Panoramic radiograph (3 months postoperatively) of bilateral parasymphysis fracture treated with two-miniplate-fixation technique

The patients were divided into two groups:

- (a) *Group A*: Those patients who underwent osteosynthesis of the mandibular fracture by non-compression, monocortical, 2.0 mm locking plating system (Fig. 1a).
- (b) *Group B*: Those patients who underwent osteosynthesis of the mandibular fracture by non-compression, monocortical, 2.0 mm standard Champy's titanium miniplating system (Fig. 1b).

The two groups were compared for the seven different parameters that included (1) occlusion, (2) infection, (3) mobility of fracture segment, (4) pain, (5) wound dehiscence, (6) neurological deficit, (7) operating time. The patients were evaluated pre-surgically, 1 week, 1, 2, and 3 months postoperatively.

The radiographic evaluation consisted of OPG, and in required cases CT-scans with 3D reconstruction were taken pre-operatively. Postoperative OPG was taken immediate postoperative day and at 1, 2, and 3 months postoperatively. Postoperative OPG is planned to assess the approximation of the fracture fragment and to check loosening of screws and fracture of the plate (Fig. 2).

In all the cases total operating time was recorded after intubation and general anesthesia i.e. the infiltration of local anaesthesia at the site of surgery till the last suture was placed. For our study, the time taken from adaptation of the plate to the time when the last screw was placed in mandibular fracture site region was recorded.

Results were assessed for statistical significance by use of the Chi square test using an Internet based statistical calculator (www.georgetown.edu/faculty/balle/webtools/wechi.html). Statistical significance was set at a level of $p < 0.05$.

Results

Road traffic accident was the cause of mandibular fractures in 17 (85 %) cases, fall in 1 case and in 2 (15 %) cases it

Fig. 3 a 2.0 mm locking plate secured at the fracture site. b 2.0 mm standard titanium miniplate secured at the fracture site

was interpersonal violence. In our study parasymphysis (Fig. 3) was the most common site of fracture in 11 (60 %) cases, followed by symphysis, body, and angle.

In group A out of ten patients, four patients had isolated single fractures (2 parasymphysis, 1 symphysis, and 1 angle) and six patients had isolated multiple fractures (4 parasymphysis, 2 body). In group B out of ten patients, six patients had isolated fractures (2 parasymphysis, 1 symphysis, 1 body, and 2 angle) and four patients had isolated multiple fractures (3 parasymphysis, 1 symphysis).

Occlusion of the patient was evaluated preoperatively and postoperatively at 1 week, 1, 2, and 3 months (Figs. 4a–d, 5). Chi square test was applied to compare the results between the two groups. Statistical analysis did not show significant difference of incidence of malocclusion between the two groups (p value = 0.606).

◀**Fig. 4** a, b Preoperative and postoperative occlusion in group-A. c, d Preoperative and postoperative occlusion in group-B

The patients were evaluated for signs of infection. The potential possibility for infection is always a consideration when treating mandibular fractures, especially when there is communication with oral cavity. Preoperatively patients with gross infection at the site of fracture were excluded from the study. Postoperatively signs of infection were checked after 1 week and 1, 2, 3 months. Signs of infection were found in one case of both groups at 1 week postoperatively (Fig. 6). Signs of infection were found in one patient of group A, and two cases of group B had infection after 1 month. The difference is found to be statistically insignificant as per Chi square test (p value = 1.0).

In our study all 20 patients had mobility of fracture fragments preoperatively. Two patients of group A (20 %) and three patients of group B (30 %) had mobility of fracture fragments 1 week post operatively and these patients were kept on IMF for duration of 3 weeks. Statistically there is no significant difference found in both groups at 1 week post operatively. IMF was released after 3 weeks to evaluate the mobility of fracture fragments in both groups. One month post operatively mobility of fracture fragments was absent in all cases except one patient in group A and two patients in group B. There was no mobility of fracture fragments present after 2 and 3 months post operatively. Chi square test was applied to study the association between the mode of treatment and postoperative mobility. The results however showed no statistically significant difference among the two groups (Fig. 7).

The Chi square statistic is 0.3925. The p value is 0.821816. The result is not significant at $p < 0.05$.

Average operating time for the adaptation and placement of each type of plate at mandibular fracture site region was noted in minutes. The operating time required for the adaptation and fixation of locking plate ranged from 5 to 9 min with a mean time of 6.8 min and the operating time required for the adaptation and fixation of Champy's miniplate ranged from 8 to 14 min with a mean of 10.1 min. Statistical analysis using un-paired t test showed significant difference of working time between the two groups (p value = 0.00296) (Fig. 8).

Pain was recorded based on the visual analogue scale. Scores for assessment of pain was as follows, 0-no pain, 1-mild pain, 2-moderate pain, 3-severe pain. In group A preoperative pain scores were moderate in four patients where symphysis and parasymphysis fracture was present and severe in six patients in whom fracture involved parasymphysis or symphysis and other associated fracture of the mandible. In group B preoperative pain scores were moderate in two patients and severe in eight patients. The

Fig. 5 Comparison of occlusion disturbance **Fig. 6** Comparison of postoperative infection **Fig. 7** Comparison of mobility of fracture segments

Fig. 8 Comparison of operating time in group A and group B

difference is found statistically insignificant as per Chi square test preoperatively. After 1 week post operatively pain was higher in group B patients because of swelling due to more operating time required for adaptation and fixation of plates. At the end of 2 weeks pain was mild in all the patients except in four patients (two patients of group A and two patients of group B) in whom pain was moderate in three patients and severe in one patient. This was because of infection at the parasymphysis and symphysis region of the mandible in two patients. At the end of 1 month two patients from both the groups had moderate pain. However there was no significant difference between the pain scores of the two groups after 1 month postoperatively.

Intra oral wound dehiscence was most frequently seen at the mandibular angle and symphysis regions when using an intraoral incision design. Wound dehiscence was present 1 week post operatively in one patient of group A and one patient in group B and both the patients had preoperative soft tissue loss at the fracture site region. Wound dehiscence was seen 1 month post operatively in one case of group A and one case of group B. Both the patients had postoperative infection that lead to wound break down. The comparative statistical analysis showed no significant difference between the two groups.

One patient in group A had sacrificed the mental nerve at the time of trauma and one patient in group B who had angle fracture, that would result in injury to the inferior alveolar nerve, gave the symptoms of nerve paresthesia preoperatively. Patients were evaluated post operatively at 1 week, 1, 2, and 3 months for nerve function. Neurological deficit was found 3 months post operatively also because patient had comminuted fractures of mandible. Postoperatively patient showed complete nerve recovery in 1 year. Though the study period was only 3 months post-operative, patients were reviewed as long as possible. The statistical analysis showed no difference in the two groups in reference to the nerve injury.

Fig. 9 Conventional screw and locking screw. **a** Conventional screw pressing the plate against the bone. **b** Locking head screw stabilizing the plate without direct bone/plate contact

Discussion

Re-establishment of previous normal tension (alveolar border) and compression (basal portion) of functional bone trajectories is the fundamental prerequisite for the full recovery of the mechanical integrity of the mandible [15–18]. A disadvantage of conventional bone plate/screw systems is that the plate must be perfectly adapted to the underlying bone to prevent alterations in the alignment of segments and changes in occlusal plane. As the human mandible shows an uneven surface, adapting conventional miniplate to the contours of the bone can compensate for such incongruities [24]. Repeated bending may cause material fatigue and create predetermined breaking points [25]. Moreover, inaccurate adaptation of conventional plates causes displacement of the mobile bony fragments when the screws are tightened and can decrease primary stability. It causes movement and loosening of screws following failure of fracture treatment. Plate pressure causes disturbance of blood supply and bone necrosis especially around the screws which leads to loss of plate friction.

In order to improve miniplate osteosynthesis a new internal minilocking system has been developed in collaboration with the AO/ASIF- institute (Devos, Switzerland) Locking 2.0 mm miniplate utilizes double threaded screws which lock to the bone and the plate creating a mini internal fixator (Fig. 9). This results in a more rigid construction with less distortion of the fracture or osteotomy, less screw loosening and less interference with bone circulation since the plate is not too tightly pressed against the bone.

The locking screw plate system also reduces compressive forces between the undersurface of the plate and lateral bony cortex compared with a conventional mandibular plate. In a locking screw plate system, forces are generated between the threaded portion of the plate and the screw.

This limits stress shielding and creates a more stable fixation over time [26]. Theoretical advantages proposed include: less precision required in plate adaptation because of the internal/external fixator; less alteration in osseous or occlusal relationship on screw tightening; greater stability across the fracture site; and less screw loosening [27].

The locking plate/screw system has only minor additions to the instrument armamentarium. This system requires perpendicular placement of the plate/screw interface, thereby requiring a locking drill guide. The technical difficulty added to the case is fairly minor for even the inexperienced surgeon. In fact, the average operating time for the locking system was 6.8 min shorter than the standard plate/screw system. Ellis and Graham [21] treated 80 fractures in 59 patients with 102 locking plate/screw systems and no period of MMF. There were 12 complications (15 %): 6 infections, 2 malocclusions, and 4 hardware removals.

Smith [28] retrospectively reviewed 51 mandibular fractures following miniplate osteosynthesis. Fractures which had been treated delayed beyond recommended time was compared to those in which the osteosynthesis was performed within 24 h. The incidence of wound dehiscence was 2.5 %, wound infection 2.5 % and delayed union 2.5 %. It was concluded that the seating of incision lines is important in preventing wound dehiscence and infection.

Collins et al. [27] did prospective randomized clinical trial to compare 2.0-mm locking plates to 2.0-mm standard plates in treating consecutive mandible fractures and similar overall complication rates occurred between the 2.0-mm locking group (4.6 %) and the 2.0-mm standard plate group (5.2 %). The data was not statistically significant.

Singh et al. [29] did a prospective randomized clinical trial to evaluate the efficacy of a 2.0-mm locking plate/screw system compared with a 2.0-mm non-locking plate/screw system in mandibular fractures. Two complications occurred in the locking group and five in the nonlocking group with complication rates equalling 6 and 13 %, respectively. When comparing the overall complication rates according to plates used no statistically significant difference was found. The number of patients in whom post-operative MMF was required varied in both groups: seven (28 %) in group A and 17 (68 %) in group B. In our study, two patients of group A (20 %) and three patients of group B (30 %) had mobility of fracture fragments 1 week post operatively and these patients were kept on IMF for a duration of 3 weeks. Bolourian et al. [30] conducted a study to assess the efficacy of treatment of mandibular fractures using a 2.0-mm nonlocking miniplate and 2 weeks of MMF with a complication rate of 5 %. When complication rates of 2.0-mm locking plates are compared with standard 2.0-mm plates, there is no statistically significant difference. It is difficult to apply statistical analysis

to these results because of the overall low complication rate, but the data suggests no clinical advantage of 1 plate/screw system over the other.

Chiodo et al. [26] compared the failure strength of 2.0 locking compared with 2.0 conventional miniplate in a laboratory model and found no differences. They hypothesized that the type and degree of failure is more likely to be related to the quality of the bone and the surgical technique than the fixation system.

Haug et al. [31] showed superior results of a locking system when compared with conventional plates in a study on polyurethane-mandibles as only the degree of plate adaptation affected the non-locking system.

Exact plate adaptation is no longer necessary which should shorten operation times [32–34]. The operating time required for the adaptation and fixation of locking plate ranged from 5 to 9 min with a mean time of 6.8 min and the operating time required for the adaptation and fixation of Champy's miniplate ranges from 8 to 14 min with a mean of 10.1 min. Champy's mini plate (group B) required higher time because these are linear plates and two plates are required for fixation at parasymphysis or symphysis region. Since the plate did not have to be as precisely adapted to the underlying bone and indeed did not have to be compressed against the bone for stability, the bending of plates was simplified.

Wound dehiscence was present 1 week post operatively in one patient of group A and one patient in group B and both the patients had pre-operative soft tissue loss at the fracture site region. Wound dehiscence was seen 1 month post operatively in one case of group A and one case of group B. The comparative statistical analysis showed no significant difference between the two groups.

The most commonly injured nerve associated with mandibular fractures is the inferior alveolar nerve and its branches—the mylohyoid, the dental branches, the incisive branch and most particularly the mental nerve. Neurological deficit was found 3 months post operatively, because patient had comminuted fractures of mandible. One patient in group A had sacrificed the mental nerve at the time of trauma and one patient in group B who had angle fracture, that would result in injury to the inferior alveolar nerve, gave the symptoms of nerve paresthesia preoperatively. Postoperatively patient showed complete nerve recovery in 1 year. Though the study period was only 3 months post-operative, patients were reviewed as long as possible. The statistical analysis showed no difference in the two groups in reference to the nerve injury.

Tuovinen et al. [35] retrospectively analyzed 279 patients with 447 isolated mandibular fractures treated with titanium miniplates. Mandibular fractures were treated with miniplate fixation using the tension band principle of Champy et al. They reported that neurosensory disturbances were

noted preoperatively in 26.9 % of patients and 12 months post operatively in 1.4 % of patients.

The limitations to this study include a short follow-up period and the intermaxillary fixation variable added to each case. This is an acceptable follow-up period for studying mandible fractures when compared with the literature; however, long-term follow-up is desirable. It was found that the fracture site stability is dependent on the rigidity produced by the plate and screw system. Mobility of fracture fragments occurs because of infection at the fracture site. The decision to use 2.0-mm locking or standard plates should be based on cost and ease of placement. In conclusion, mandible fractures treated with 2.0-mm locking plates and standard 2.0-mm plates present similar short-term complication rates within the diagnosis and treatment parameters of this study.

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