Original Research Paper

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Evaluation of Three- Dimensional Rhombic Plate in Open Reduction and Internal Fixation of Subcondylar Fractures of Mandible: A Pilot Study

Abstract:

Background: Fractures of condyle of mandible are quite common and it constitutes about 25% to 50% of mandibular fractures. Open reduction and internal fixation (ORIF) of these fractures may range from use of 1 or 2 miniplates to the use of 3- dimensional (3-D) titanium plates. In recent times 3-D plates of different geometrical configurations are being used. These geometrical configurations are delta, trifix, rhombic and trapezoidal. This study was done to explore the efficacy of 3-D rhombic plate for ORIF of subcondylar fractures of the mandible.

Aim & Objectives: The aim of the study was to evaluate the efficacy of 3-D rhombic plate for ORIF of subcondylar fractures of mandible in terms of stability of fixation and to document the associated postoperative complications.

Material & Methods: This non-randomized clinical trial was conducted in 10 patients having isolated mandibular subcondylar fracture with disturbed occlusion. The ORIF of subcondylar fracture was done by using transparotid approach followed by fixation with 3-D titanium rhombic plate & 6 mm titanium screws. The primary outcome variables assessed were stability of fixation (as indicated by stable occlusion), restoration of jaw function in terms of mandibular movement (as assessed by maximum mouth opening) and bite force registration. The secondary outcome variables were postoperative complications such as infection, wound dehiscence, parotid fistula, facial nerve injury and hardware failure. Additionally, these complications were categorized according to degree of severity and recovery pattern with or without management. The parameters under evaluation were assessed at different time intervals at 1st, 7th, 15th day, 1 month and 3 months postoperatively. The data obtained was statistically analysed by Statistical Package for Social Sciences (SPSS) software package (SPSS 16 Inc, Chicago IL, USA).

Results & Observations: The age of the patients involved in the study ranges from 19 to 50 years with the mean age of 28.4±8.9 years. Out of 10 patients, 8 were males (80%) and 2 were females (20%). The occlusion was disturbed pre-operatively in all the patients enrolled in the study which was an essential inclusion criterion of the study. At 1st and 7 postoperative day the occlusion was stable in 7 patients (70%) and was deranged in 3 patients (30%). After elastic traction the occlusion was achieved and maxilla-mandibular fixation (MMF) was applied for 1 week. The occlusion remains stable in all the patients at 1st and 3rd months postoperatively. When maximum mouth opening was assessed, it wasrestricted at 1st postoperative day. There was statistically significant improvement in mouth opening at each time interval postoperatively. When bite force was evaluated post-operatively, there was statistically significant improvement at each time interval. When postoperative complications were considered, there was only 1 case of wound dehiscence and 1 case of facial paralysis. We have not encountered any case of postoperative infection, parotid fistula and hardware failure postoperatively.

Conclusion: The use of rhombic plate for ORIF of subcondylar fractures is quite promising and is associated with fewer complications. However, long term studies with larger sample size are necessary to make some definite recommendations.

Key-words: Mandible; Condyle; Subcondylar; Fracture; Reduction; Fixation; Rhombic;ORIF

Introduction:

Trauma to the face can lead to hard and soft tissue injuries or both. The incidence of fracture and its pattern may vary depending on geographical, environmental, cultural and social attributes.[1] The common cause of mandibular fracture are road traffic accidents, fight, fall from height, sports injury

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etc.[2] Due to prominent position of the mandible itis commonly involved in trauma of maxillofacial region. It constitutes about 65% to 70% of facial bone fractures.[3] The study conducted by Haug & Assael reported that condylar fractures can contribute to 30.3% of mandibular fractures.[4]

The treatment protocols for the management of condylar fractures are still controversial and are not universally accepted. The three strategies for management of condylar fractures are; functional therapy with or without maxillo-mandibular fixation (MMF), closed reduction by MMF and open reduction & internal fixation (ORIF) with or without MMF. The treatment of condylar fractures should take its complex anatomy, biomechanical behaviour and healing capability into account. The recent recommendations are in favour of ORIF especially when there is deviation of $>10^0$or shortening of ramus height by >5mm irrespective of level of fracture.[5]

Biomechanically, the mandibular condyle behaves as a complex, viscoelastic and anisotropic material. Various types of stresses that develop in it on functional loading are tension, compression and torsion. Therefore, there is an on-going search to find a fixation device that is easy to adapt according to its anatomy and can resist various strains based on functional considerations.[6]

Champy et al. (1976) in an experimental study identified the strain lines that developed in symphysis, parasymphysis and body region of mandible on functional loading.[7] These lines are considered as "the ideal lines of osteosynthesis" and it is recommended that the fixation device should be placed along these lines for predictable and better outcomes.[6]Meyer et al. (2022) also proposed similar strain lines that developed in condylar region on functional loading.[8]

The most widely used technique for ORIF of subcondylar fracture is use of two 2-dimensional (2-D) mini-plates. However, failure rate up to 35% have been documented in literature. Farmand in 1995, developed 3- dimensional (3-D) plating system for semi-rigid fixation of subcondylar fractures to minimize complications.[9] The term 3-D fixation in true sense is a misnomer, as these fixation devices are not 3- dimensional geometrically, but can resist the strains developed within the condyle in 3 dimensions during function. The basic concept of 3-D fixation revolve around the use of a closed geometry that is secured to the fractured bone.[6]In this regard, the design of 3-D rhombic plate can address the biomechanical and functional consideration of condylar region. Its 3-D geometrical form is characterized by two arms (anterior &posterior) and a window within the two arms(Figure- 1).[10]

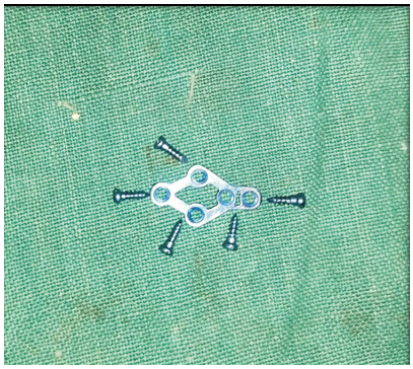

Figure 1- 3-D Rhombic plate

Many studies reported the superiority of 3-D plating system over 2-D miniplates for ORIF of subcondylar fractures. These studies involve 3-D plates of variable geometry such as delta, trapezoidal, trifix, and A shaped plate. However, fewer studies were available regarding the use of 3-D rhombic plates in the management of these fractures. Therefore, this clinical trial was done to evaluate the efficacy of 3-D rhombic plate in ORIF of subcondylar fracture of mandible.

Aim & Objectives:

The aim of the study was to evaluate the efficacy of 3-D rhombic plate for ORIF of subcondylar fracture of mandible in terms of stability of fixation and to document the associated postoperative complications.

Material & Methods:

This non-randomized clinical trial was conducted in 10 adult patients having isolated unilateral subcondylar fractureof mandible with disturbed occlusion as evident clinically and there was indicationfor ORIF (deviation $>10^0$ or shortening of ramus height by >5 mm) as evident radiographically(Figure 2).

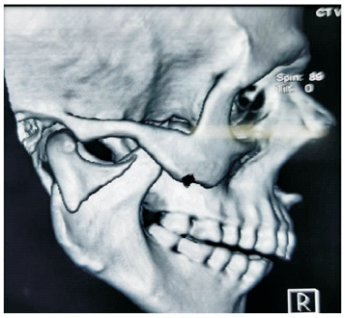

Figure 2- Three Dimensional Computed tomographic image demonstrating fracture of subcondylar region with posterior gagging of occlusion and reduction in ramus height.

Patients with condylar head or neck fractures and subcondylar fractures with mandibular fracture at additional sites were excluded. The ORIF of subcondylar fracture was done under general anaesthesia. The standard transparotid approach was used for exposure of fracture site. The incision line was marked followed by infiltration of 2% lidocaine with 1:2 lakh Adrenaline. Incision was made with No. 15 surgical blade through skin and subcutaneous tissue followed by undermining in all directions to facilitate better exposure. After exposure of parotid capsule, blunt dissection was carried through the parotid gland to expose the pterygo-masseteric sling. The sling was sharply dissected and the fractured segments were exposed. The fractured segments were reduced and fixation was done by 3-D rhombic plate (2.0 mm) and titanium screws of 6 mm length**(Figure- 3)**.

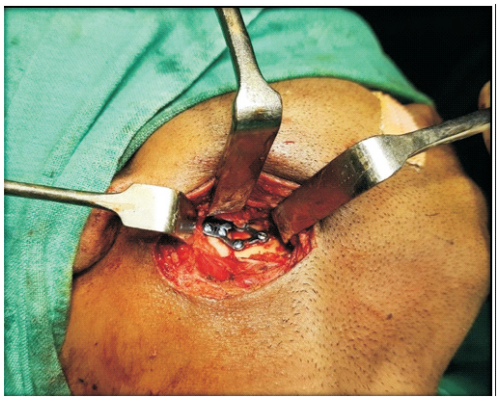

Figure 3- ORIF of subcondylar fracture using 3-D rhombic plate.

The wound was irrigated with betadine solution. The pterygo-masseteric sling was closed using 3-0 vicryl suture followed by tight closure of parotid capsule to decrease to chances of parotid sialocele or fistula. Closure of subcutaneous tissue was done followed by closure of skin using 4-0 Prolene suture. Pressure dressing was applied and standardized regimen of antibiotics and analgesics was used post-operatively for 5days. Post-operative orthopantomograph (OPG) was taken to assess the reduction of fracture and positioning of 3-D rhombic plate **(Figure- 4)**.

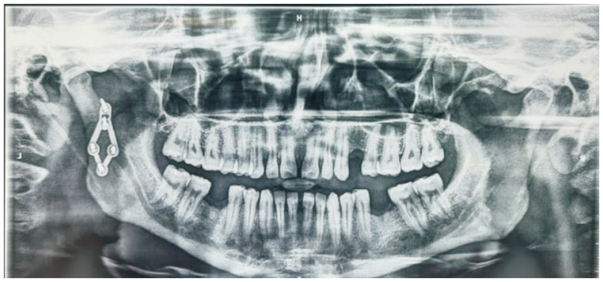

Figure 4- Postoperative OPG view demonstrating reduction of fractured condyle.

The primary outcome variables assessed were stability of fixation (as indicated by stable occlusion), restoration of jaw function in terms of mandibular movement (as assessed by maximum mouth opening) and bite force registration. The occlusion was assessed clinically by intraoral inspection. The maximum mouth opening was assessed by measuring the distance between the mesial side of incisal edge of maxillary and mandibular central incisors (in mm). The bite force was registered by use of a Goldtechbite registration device and was measured as numerical units**(Figure- 5)**.

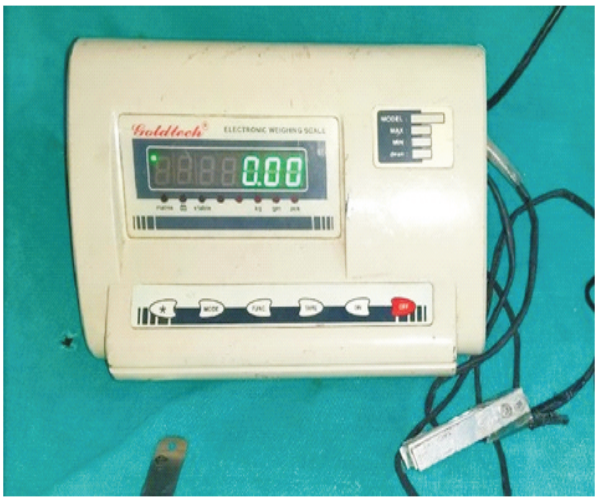

Figure 5- Bite force registration device.

The secondary outcome variables were postoperative complications such as infection, wound dehiscence, parotid fistula, facial nerve injury and hardware failure. Additionally, these complications were categorized according to degree of severity and recovery pattern with or without management. The parameters under evaluation were assessed at different time intervals such as 1st, 7th, 15th day, 1 month and 3 months postoperatively. The data obtained was statistically analysed by Statistical Package for Social Sciences (SPSS) software package (SPSS 16 Inc, Chicago IL, USA). The normality of data was tested by Shapiro Wilk's test. The values obtained was statistically analysed within the groups by paired t test to get the level of significance. The level of significance and confidence interval was 5% and 95% respectively, i.e. $p < 0.05$ is considered significant.

Results & Observations:

The age of the patients involved in the study ranges from 19 to 50 years with the mean age of 28.4±8.9 years**(Table- 1)**. Out of 10 patients 8 were males (80%) and 2 were females (20%)**(Table- 2)**.

Table 1- Age range of patients enrolled in the study

Descriptive Variable	Number (n)	Minimum (In Years)	Maximum (In Years)	Mean (In Years)	Standard Deviation
Age	10	19	50	28.40	8.897

Table 2- Distribution of patients based on Gender.

Gender	Number (n)	Percentage (%)
Male	8	80%
Female	2	20%

The occlusion was disturbed pre-operatively in all the patients enrolled in the study. After ORIF the occlusion was assessed at 1st and 7th postoperative day and was found to be stable in 7 patients (70%) and was deranged in 3 patients (30%). As there were no signs of improvement in occlusion, elastic traction was applied to achieve the occlusion followed by MMF for 1 week. MMF was released after 1 week (15th day postoperatively), and the occlusal was found to be stable at 1 month and 3 months postoperatively. All the patients with stable occlusion during initial evaluation showed no discrepancy in all the follow up examinations **(Table- 3)**.

Table 3- Comparison of occlusion at different follow up time intervals postoperatively.

Occlusion		Frequency	Percentage
1st Postoperative Day (T1)	Intact	7	70%
	Deranged	3	30%
7th Postoperative Day (T2)	Intact	7	70%
	Deranged	3	30%
15th Postoperative Day (T3)	Intact	10	100%
1 Month Postoperatively (T4)	Intact	10	100%
3 Months Postoperatively (T4)	Intact	10	100%

When maximum mouth opening was assessed postoperatively, it was restricted at 1st postoperative day. The interincisal opening at 1st postoperative day served as a base line value for future comparison. There was statistically significant improvement in mouth opening at each time interval postoperatively when compared to mouth opening recorded at previous time interval**(Table-4).**

Table 4- Comparison of Interincisal Mouth Opening at Different Time Intervals

Time Frame	Mean (mm)	Std. Deviation	Time Interval	Mean ± Std error of mean	t value	p Value
T1	21.00	3.771	-	-	-	-
T2	25.30	4.057	T2-T1	4.300±0.667	6.442	0.000**
T3	28.60	2.716	T3-T2	3.300±0.761	4.337	0.002**
T4	33.60	3.373	T4-T3	5.000±1.308	3.822	0.004**
T5	36.30	4.322	T5-T4	2.700±0.955	2.827	0.020*
T5	36.30	4.322	T5-T1	15.300±1.001	15.292	0.000**

NS- Not significant, * Significant p<0.05, ** Highly Significant p<0.01

When bite force was evaluated post-operatively, there was statistically significant improvement in bite force at each time interval postoperatively when compared to bite force registered at previous time interval except on 15th postoperative day. There was no statistically significant improvement in bite force from 7th to 15th postoperative day **(Table-5).**

Table 5- Comparison of Bite Force Registration at Different Time Intervals

Time Frame	Mean	Std. Deviation	Time Interval	Mean ± Std error of mean	t value	p Value
T1	20.7090	5.30083	-	-	-	-
T2	25.0380	5.82963	T2-T1	4.3290±0.9600	4.509	0.001**
T3	29.0390	6.25127	T3-T2	4.0010±0.9560	4.185	0.002**
T4	30.4220	10.20673	T4-T3	1.3830±3.1217	0.443	0.668^{NS}
T5	39.7960	4.75412	T5-T4	9.3740±2.9769	3.149	0.012*
T5	39.7960	4.75412	T5-T1	19.0870±1.5517	12.301	0.000**

NS- Not significant, * Significant p<0.05, ** Highly Significant p<0.01

When postoperative complications were considered, there was only 1 case of wound dehiscence. In this case there was limited dehiscence of wound on removal of pressure dressing. No surgical intervention was required and the wound heal by secondary intension by using simple measures of wound care.

We encountered only one case of facial paralysis as assessed by House and Brackman Scale. There was mild neurapraxia of buccal branch as evident by inability to blow properly. It might be attributed to the traction applied for exposure of fracture site. The muscle recovered quickly within 7 days without any active intervention.

We have not encountered any case of postoperative infection, parotid fistula and hardware failure postoperatively.

Discussion:

When fractures of maxillofacial region are considered, the incidence of mandibular fracture is quite high.[11,12] The management of condylar fracture differ from any other joint of the body due to its variable anatomy and functional characteristics. Restoration of anatomy and function of temporomandibular joint (TMJ) requires skilled management so as to achieve harmony of stomatognathic system comprises of hard (bone, teeth) and associated soft tissues (muscles). ORIF of condylar fracture is a topic of debate among maxillofacial and plastic surgeons. Now a day, displaced condylar fractures leading to greater deviation and shortening of ramal height are treated by ORIF.[9]Walker described that the main goal of management of condylar fracture is to achieve stable occlusion and symmetrical & pain free mandibular movements.[13]

Apart from the surgical approach used for management of condylar fracture, it is equally important to consider an osteosynthesis device that have the capability to withstand and disperse the functional stresses applied on this biomechanically complex anatomical region. The biomechanical factors such as buttressing bone effect, loss of fractured segment leading to gap formation and greater degree of comminution have a significant impact on the stability of fixation device.[6]The evaluation of stability of various fixation devices must consider the complex movements of the mandible leading to generation of various types of functional stresses.[14]

The study conducted by Choi et al. showed that ORIF of condylar fracture by using two miniplats is better as compared single miniplate in term of biomechanical stability.[15] The predominant factor that can affect the stability of fixation device in condylar region is inadequate reduction and fixation due to poor plate adaptation. The use of 2 miniplates is most commonly accepted, however, there is greater difficulty in its use due to limited visualization of condylar neck region. Therefore, there is high risk of inadequate reduction and poor plate fixation. Failure rates up to 35% have been reported with the use of two miniplates including hardware failure.[12,16,17] Meyer et al, in an experimental study demonstrated that the use of 2 miniplates may be inefficient to withstand the functional stresses in subcondylar region in many instances.[17]

During mandibular function, there is development of tensile strains along antero-lateral border and compressive strain along posteromedial border leading to leatero-medial bending of condyle.[4] This necessitate the use of a fixation device that can neutralize and resist these functional stresses for better stability of fracture segments and can provide early restoration of function.[6]

In this regard, the design of 3-D rhombic plate can address the biomechanicaland functional considerations of condylar region. Its geometrical form is characterized by two arms (anterior & Posterior) and a window within the two arms. The anterior arm of 3-D rhombic plate which lies in close proximity to the sigmoid notch can resist the tensile strains, which are greatest along anterior and lateral border of the condyle. The posterior arm is secured to more robust posterior border of the condyle and will help in even distribution of compressive forces and better stability of fractured proximal segment to facilitate healing during function.[10]

In our study we have used 3-D rhombic plate for ORIF of subcondylar fractures in 10 patients. The adaptation of 3-D rhombic plate was easy in all the patients. The miniature design of the rhombic plate makes its adaptation to fracture segments relatively easy. The occlusion was slightly disturbed in 3 patients at 1, 7 days postoperatively. The severity of malocclusion was very mild and we were able to achieve occlusion in 1 day by elastic traction. After 1 week of MMF it remained stable throughout the study period. There was statistically significant improvement in maximum mouth opening and bite force on subsequent follow up examinations. There was wound dehiscence in 1 patient, which was a failure of closure rather than directly related to plating. Additionally, we encountered only 1 case of mild facial nerve weakness. This complication can be attributed to poor surgical technique and traumatization of facial nerve branches or greater dissection, retraction required for better exposure essential for adaptation and fixation of 3-D plate. The miniature design of rhombic plate is beneficial in decreasing the incidence of facial nerve injury.

Conclusion:

The use of 3-D rhombic plate for ORIF of subcondylar fractures is quite promising in terms of occlusal stability and early restoration of function. Additionally, its use is associated with fewer complications of mild severity. However, long term studies with larger sample size are necessary to make some definite recommendations.

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