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COMPARATIVE EVALUATION OF THE CLINICAL OUTCOMES OF 3D DELTA PLATES AND CONVENTIONAL MINI-PLATES FOR TREATMENT OF MANDIBULAR CONDYLAR FRACTURES IN AN ADULT POPULATION. A SYSTEMATIC REVIEW

Surgery

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ABSTRACT

Objectives: This systematic review aimed to compare outcomes between efficacy of standard non-compression mini- plate and 3-dimensional (3D) titanium plate in the open reduction internal fixation (ORIF) of the mandibular condylar fractures. **Methods:** PubMed, MEDLINE, Cochrane Library, Google Scholar and EBSCOhost databases were searched up to 30th October 2021 for randomized control trials (RCTs) comparing of standard non-compression mini-plate and 3-dimensional (3D) titanium plate the open reduction internal fixation (ORIF) of the mandibular condylar fractures . The review protocol followed the PRISMA guidelines and was registered in PROSPERO (CRD42023388639). The risk of bias of the studies was independently evaluated using Cochrane Risk of Bias tool. **Results:** Three RCTs were included. Patients treated with 3D delta plates had superior outcomes with regard to operation time, mouth opening, biting efficiency, superior fracture fragment stability and less displacement of the fractured segments compared with mini-plates. Hence, it can be concluded that the 3D Delta plate allows the stress distribution to be superior and multidimensional, leading to better post-operative stability, faster healing, and reduced complications. **Conclusion:** This study indicates that the use of delta plates yielded superior outcomes compared to conventional mini-plates. Data on intra-operative outcomes are scarce and conflicting for any definitive conclusions. Further high-quality adequately powered RCTs are required to strengthen current evidence.

KEYWORDS

mini-plates, 3D Delta plates, retromandibular incision, open reduction internal fixation (ORIF), malocclusion, mandibular condylar fracture

INTRODUCTION

Condylar fracture is the most common fracture of mandible .Condylar and sub condylar fractures constitute 25-35% of all mandible fractures[1]. The incidence of condylar fractures is high, but the management of fractures of the mandibular condyle continues to be controversial[2].

Historically, maxilla-mandibular fixation, external fixation, and surgical splints with internal fixation systems were the techniques commonly used in the treatment of the fractured mandible. Condylar fractures can be extracapsular or intra-capsular, un-displaced, deviated, displaced, or dislocated. Several indications for surgical treatment have been proposed that depend on factors such as; age, level of the fracture, degree of dislocation or displacement, malocclusion, loss of height of the ramus, facial asymmetry and the co-existence of other mandibular or maxillary fractures from which it is difficult to recover aesthetically and functionally. An appropriate treatment is required to reconstruct the shape and achieve the function of the uninjured status[3].

Despite the tremendous effort by research workers to clarify criteria for the management of condylar fractures, many surgeons find themselves in a dilemma every time they encounter one. As per recent researches in condylar fractures a lot of plate techniques and methods are developed such as mini-plates, lag screws, pin fixation, intraosseous wire (K wire).

Single mini-plate is most commonly used for open reduction and internal fixation of mandibular condylar fracture. However better results are obtained with two mini-plates[5]. To gain more stability these two plates should be placed with a sufficient distance between the screws and the fracture line[6]. But sometimes it is extremely difficult and traumatic to place two mini-plates in the narrow condylar region. Two mini-plates (double-plate technique) are the most reliable technique because these neutralize tension and pressure forces best and produce greater stability[7].

As alternative to the modified 2 mini-plate technique, specially designed plates such as the delta plate or the trapezoid plate are now available. Therefore, these plates provide sufficient stabilization for open reduction and internal fixation of sub condylar and condylar neck fractures combined with the advantage of a smaller plate. In the delta-shaped plate, the base is oriented toward the angle of the mandible; thus, the lines of tensile strength and compressive stress distribution run parallel to both sides of the plate. The plate is 1 mm thick, 20 mm long, and 5 mm wide at the top and 12 mm wide at the base. At the top of the plate is an arm with 2 longitudinally arranged holes; two more holes form the 2 corners of the base of the plate.

The aim of this study was to compare and evaluate the clinical outcomes of mini-plates with delta plates for mandibular sub condylar fracture.

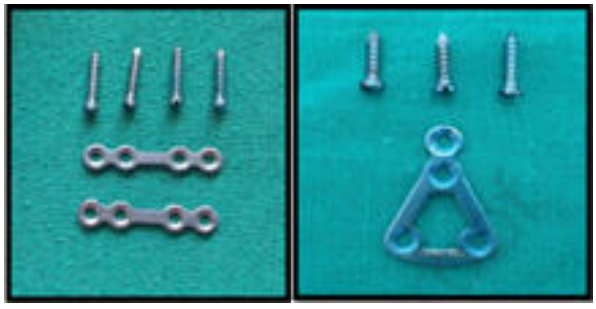

Fig 1 Conventional Mini Plate **Fig 2** 3D Plate

MATERIAL AND METHODS

Structured Registration And Protocol

This systematic review was registered under the number CRD42023388639 in the PROSPERO database, created by the University of York, responsible for the registration and dissemination of systematic reviews and carried out according to the PRISMA statement.

Focused Question

In order to perform this systematic review, the following question was elaborated:

Between 3D delta plates and conventional mini-plates which modality of treatment has a better efficacy in the treatment of mandibular condylar fractures in the age group of 16 to 60 years

Eligibility Criteria

The PICO strategy was applied in this systematic review. This acronym stands for an abbreviation of the following components: patient, intervention, comparison, and outcome, which are essential for designing all stages of an interventional systematic review.

PICO Analysis:

(P) Types of participants: Adult human patients with age group of 16-60years diagnosed with mandibular condylar fractures based on Spiessl and Schroll Classification (excluding Type 1 fractures without displacement) and where conservative therapy was not applicable.
(I) Types of interventions: ORIF with 3D delta plates and conventional mini-plates
(C) Comparison between interventions: All possible comparisons between 3D delta plates and conventional mini-plates for condylar fractures.

(O) Type of outcomes measures: Primary outcomes: operating time, Inter-incisal mouth opening, Pain on VAS, Postoperative Occlusion.
(S) Types of studies: Only randomized controlled clinical trials (RCTs) were considered

Additionally,

The Following Additional Inclusion Criteria Were Considered:

- RCT which included unilateral condylar fractures, non-comminuted with 16 years and older age group
- RCT in which Patient required ORIF
- RCT in which Patients had given signed consent for the treatment

In This SR, The Following Items Were Considered As Exclusion Criteria:

RCTs comparing variations of a same technique (i.e. delta plates vs rhomboid plates or delta plates with trapezoidal plates Case reports, descriptive studies, review articles, editorial letters, conferences, book chapters, abstracts opinion articles, animal studies, insufficient information and in vitro studies were not considered.

INFORMATION SOURCE AND LITERATURE SEARCH:

For the identification of Randomized clinical trials to be considered for inclusion in this systematic review, PubMed, MEDLINE, Cochrane Library, Google Scholar AND EBSCO host were employed as electronic databases, and a literature search was carried out with a personal computer on articles published up to and including October 2021.

Last electronic search was carried out on 30 October 2021.

Following Search Terms Alone And In Combination Were Used By Means Of PUBMED Search Builder:

(condylar fractures[All Fields] AND 3D delta plates[All Fields] AND ("conventional miniplate"[MeSH Terms] OR "delta plates"[All Fields])) AND (Conventional[All Fields] AND ("delta plates"[MeSH Terms] OR "delta plates"[All Fields])) AND ("condylar fractures"[MeSH Terms] OR ("condylar"[All Fields] AND "fractures"[All Fields]) OR "condylar fractures"[All Fields]) AND ("randomized controlled trial"[All Fields] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomised controlled trial"[All Fields] OR "randomized controlled trial"[All Fields]

No Limits and language restrictions were applied during the electronic search to include all the possible clinical trials in the potentially relevant article search phase of the systematic review. Reference list of the reviews and of the identified randomized trials were also checked for possible additional studies. The article search was then narrowed down manually by the reviewer according to the inclusion criteria of the present systematic review to include all the RCTs in English language only and the articles involving treatment of intra bony defects.

Additionally, hand search was also carried out in all relevant journals up to and including October 2021.

Journals Included For Hand Search:

International Journal of Oral & Maxillofacial Surgery British Journal of Oral & Maxillofacial Surgery Journal of Oral & Maxillofacial Surgery.

Study Selection:

Study Selection Was Conducted By Independent Reviewers In The Following Stages:

Initial screening of potentially-suitable titles and abstracts against the inclusion criteria to identify potentially relevant papers. Before initial screening, all the items found through electronic and manual searches were grouped into a single list, excluding duplicates. Independent screening of the titles and abstracts (when available) of all reports identified. When studies met the inclusion criteria or when insufficient data from abstracts for evaluating inclusion criteria were gained, full article was obtained. Full text articles which met the inclusion criteria were considered eligible in the further screening.

Data Collection Process And Data Items:

- All studies that met the inclusion criteria then underwent quality assessment and data recording.
- A standardized data chart was prepared from each included study, encompassing number of patients, demographics, definition and diagnosis of condylar fractures, clinical methods (assessment and treatment), follow-up duration, clinical and radiographic outcomes and patient-reported outcomes.
- Two review authors independently extracted data.
- When disagreement between the two reviewers was detected, consensus was achieved by discussion with the third reviewer/ statistical advisor.

Risk Of Bias In Individual Studies

The Cochrane Collaboration risk assessment tool was used for assessing the quality of included RCTs. Studies were assessed by two reviewers independently for the following:

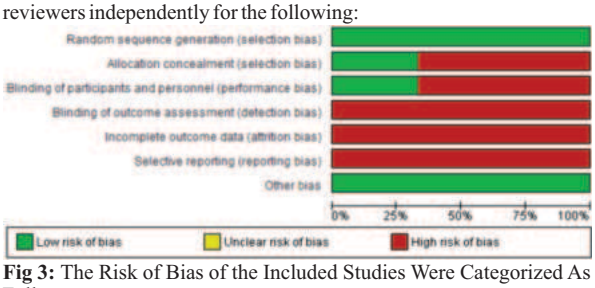

Fig 3: The Risk of Bias of the Included Studies Were Categorized As Follows

RESULTS

Study Selection:

The search strategy provided a total of 882 studies. After screening the title and abstracts, 9 studies were found to be duplicates of which 5 studies were excluded. The remaining 4 studies were potentially eligible and were screened entirely by the evaluators. At the end of the analyses, 3 articles published between 2018- 2021 met the inclusion criteria and were included in the present systematic review. The flowchart of article screening and selection process is displayed in.

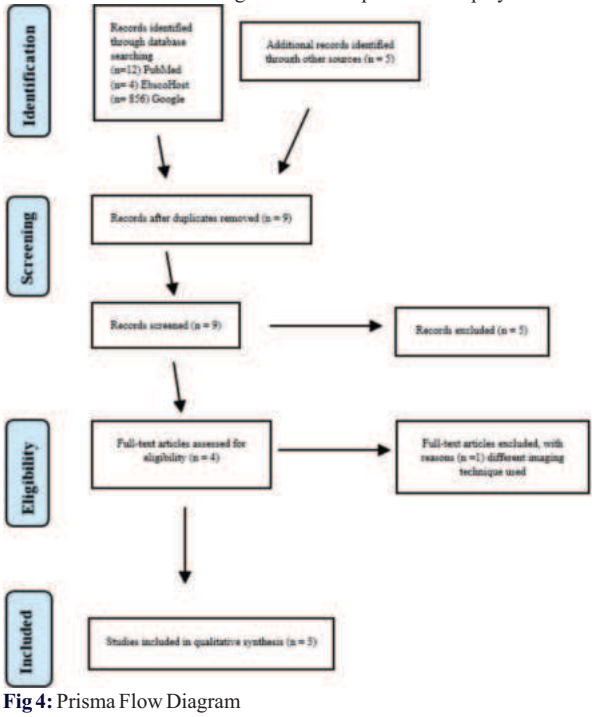

Fig 4: Prisma Flow Diagram

Study Characteristics:

Details of the included studies are presented in Table. All studies were published in the last 5 years. All three studies were conducted in India. All studies included patients with unilateral mandibular condylar fractures. The sample size of the included studies varied from 10 to 22 patients per group. All studies had measured the maximum mouth opening pre-operative and post-operatively at regular intervals. Operative time was measured with the help of stopwatch. Other variables included measurement of biting efficiency with the help of Gnatho-dynamometer and post-operative occlusion was assessed. Study carried out by Cynthia Scott et.al assessed the increase in angulation and increase in the gap between fracture segments with the help of radiographs post-operatively.

Table 1: Table Of Study Characteristics

AUTHOR	YEAR	COUNTRY	STUDY DESIGN	AGE	SAMPLE SIZE	INTERVENTION & COMPARISON	PRIMARY OUTCOME	MEASUREMENT OF PRIMARY OUTCOME	FOLLOW UP
Aneesh Ganguly et.al	2021	India	RCT	31	20	GROUP A - conventional miniplates GROUP B – 3D delta plates	operating time, Mouth opening, Biting efficiency, Postoperative pain	Operating time – stop watch Mouth opening- inter-incisal distance measured Biting efficiency - Gnatho dynamometer Postoperative pain - VAS	1 week, 1 month, and 3 month
Cynthia Scott et. al	2020	India	RCT	25.4	44	GROUP A – Conventional plates GROUP B – 3D plates	Time taken for fixation, maximum mouth opening, occlusal stability, increase in angulation and increase in the gap between fractured segments in the radiograph.	Time taken for fixation - stopwatch maximum mouth opening – inter-incisal distance, occlusal stability – measurement between the molars. increase in angulation and increase in the gap between fractured segments in the radiograph - Assessed with tracing of the OPG	7 days, 1, 3, and 6 months
Archana D. Deshpande et.Al	2018	India	RCT	29.6	20	GROUP 1 – delta plate GROUP 2 – Conventional plate	Maximum Inter Incisal Distance, Mandibular Deviation, Postoperative Occlusion	Maximum Inter Incisal Distance – inter-incisal distance measured, Postoperative Occlusion -	1 week, 1 month. 6 months

Risk Of Bias Within And Across Studies:

The methodological quality of the individual studies were evaluated using the Cochrane Risk of Bias 2.0 tool (Figure 5). Only one study showed low risk of bias with regard to selection bias and performance bias. None of the studies had blinded the outcome assessor, the participant and personnel. There were high risk of bias regarding attrition and reporting. Overall, all the studies reported as a high risk of bias.

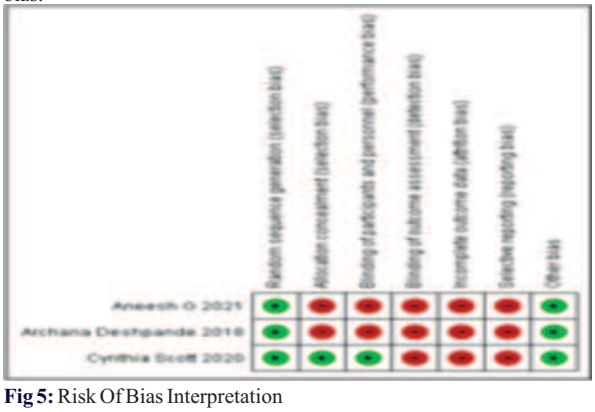

Fig 5: Risk Of Bias Interpretation

DISCUSSION

Summary Of Evidence

Condylar fractures constitute between 17.5% and 52% of all mandibular fractures and between 11% and 16% of all facial fractures. The anatomical basis of the mandible ensures that direct impact leads to a unilateral fracture namely, by allowing the weakest part of the condylar neck to fracture, thus preventing the transfer of forces to the cranium. However, most condylar fractures are not caused by direct trauma, but instead follow from indirect forces transmitted to the condyle from a blow elsewhere. Their displacement is determined by the direction, degree, magnitude, and precise point of application of the force, as well as by the state of dentition and the occlusal position. It is for this reason suggested that 72% of condylar fractures are associated with concomitant mandibular fractures, mostly para symphyseal[1].

There are four muscles of mastication, namely, the medial and lateral pterygoid, masseter, and the temporalis. Lateral pterygoid is attached to the pterygoid fovea at the condylar neck and is responsible for the displacement of the condylar fractures medially. Change in the direction of resultant forces post fracture will alter the function of the mandible during various excursion movement.

The management of condylar fracture is filled with controversies at every step of the way, starting from open versus closed reduction, extra-oral approaches versus transoral approaches, comparisons among the various types of extra-oral approaches, transoral approach with or without endoscopy, types of plating system, and so forth. However, every oral and maxillofacial surgeon would agree that an ideal treatment outcome for condylar fracture should include parameters such as pain-free mouth opening, overall good mobility, restoration of occlusion, stable temporomandibular joints, absence of pre auricular depression, osseous union, good facial and jaw symmetry, speech, deglutition, and swallowing[1].

Several studies have shown favorable clinical results with conservative treatment of condylar fractures. However, numerous studies have also shown signs of dysfunction with conservative treatment. With the advent of rigid internal fixation of the facial skeleton by small titanium plates and screws, both surgeon's acceptance and patient's expectations had led to a resurgence of interest in the open reduction and internal fixation (ORIF) of mandibular condylar fractures[6].

Open reduction and rigid internal fixation of condylar fractures ideally give the condylar process its pre-traumatic position or close to the position restoring skeletal continuity re-establishing the normal mandibular position and bringing the teeth into a proper occlusal relationship. Regardless of any type of the treatment modality used, the teeth in occlusion seem to be the most important goal along with early functional recovery[8].

Over the years, various designs of 3D plates have been developed. Many in vitro studies comparing these plate designs have found Delta plates to be superior (Lauer et al[2]. Haim et al[21]), whereas others have found trapezoidal plates to be better. Albogha et al[19] in his clinical study has stated that Delta plates are principally suitable for condylar neck fractures, whereas trapezoidal plates are suitable for wider areas such as sub condylar fractures. Although statistically insignificant, in their study they observed that there might be a tendency for deltoid plates to lead to a better outcome.

Ganguly A et al[1] reported that on comparing both groups regarding operating time, they found that Group A (conventional mini plates) (141.20 mins ± 2.59 min) had a significant statistical difference (P = 0.001) in operating time from that of Group B (3D plates) (117.2 ± 9.63 min). Similarly, Postoperative pain was measured using the Visual Analog Scale. All the patients reported pain (VAS score 3-5) which lasted for 1 week. Group A patients showed a slightly longer duration of pain, which was managed with oral analgesics. No patients had complaints of post-operative pain on subsequent follow ups. Also, permanent facial nerve injury was not observed in any of the patients. Mouth opening was significantly higher at 3 month follow-up in Group B compared to Group A (P = 0.001). Thus the authors concluded that 3D Delta plate allows the stress distribution to be superior and multi-dimensional, thereby providing better post-operative stability, and leading to faster healing and reduced complications. The Delta plate prevents the need for additional plates, thus reducing the bone-to-plate ratio without compromising fracture stability. The Delta plate can be used easily via extra oral as well as intraoral techniques, thus indicating it as a versatile plating system in the future.

Cynthia S et al[4] reported that Intraoperative time taken for fixation of the fractured segments, after reduction, was calculated. The statistical analysis was performed using the student's t test, which suggested that time taken for Group B (3D plates) was significantly lower with a P value of 0.0001. The occlusal stability was satisfactory in 12 patients (54.5%) in Group A (conventional mini plate) and 17 patients (77.2%) in Group B at the end of postoperative day 1. The P value was 0.282, which was not statistically significant. At the end of the first postoperative month, 18 patients (81.8%) in Group A and 21 patients (95.4%) in Group B had satisfactory occlusal stability. The P value was 0.154, which was not statistically significant. At the end of 6 months, all patients had satisfactory occlusal stability. Mouth opening after 1 month in Group B was significantly more with a P value of 0.032. All patients had surgical management of their fractured condyle with no persistent clinical complications. Though conventional mini-plates and 3D plates showed similar results subject to clinical parameters, there were statistically significant results with respect to the radiological parameters. Patients treated with conventional mini-plates had a significant increase in angulation and increase in the gap between the fixed fractured segments. Thus concluded that 3D plate offers superior fracture fragment stability and offers resistance to further displacement of the fixed condyle both in the mediolateral and anteroposterior direction. 3D plates also has an added advantage of the ease of adaptation and shorter operating time.

Deshpande AD et.al[6] reported that about 80% patients were classified as Spiessl and Schroll's Type II Low Fracture with Displacement. Both the groups achieved adequate mouth opening (35mm or more) with acceptable mandibular deviation (up to 5mm) after 6 months. Mean value of Mandibular deviation post operatively after 6 months in Delta plate Group was 1.0 mm whereas, it was 2.60 mm in group of patients treated with single mini plate. Deviation was towards fracture side. Improper occlusion was found in 10% patients in delta plate group immediately postoperatively where as it was 70% in case of single mini plate. They had to be given inter maxillary fixation in the form of heavy elastics for one month. These patients were advised liquid diet during this period. No active physiotherapy was given to any patient. The authors also added that the radiographic evaluation of postoperative cases showed satisfactory consolidation with some displacement of the condylar fragment (difference of up to 10^0 was considered acceptable). In cases treated with delta plate, maximum secondary displacement was 8^0 with the mean value of 6^0 whereas in cases treated with single mini plate 30% patients were having difference of angle more than 10^0 with mean value of 8^0. The p-value for difference between the two groups was significant 0.0125. Thus the authors reported, in the open reduction and internal fixation of mandibular condylar fracture with Delta condylar plate: Normal mandibular movements and occlusion were achieved. Mandibular deviation was minimal. Inter maxillary fixation was not required post operatively. Stable osteosynthesis was achieved in all cases with restoration of ramus height and condylar position. There were no complications in terms of either soft tissue infection or hardware failure. The 3 dimensional nature of Delta plate is found to provide internal stability and optimal leverage with minimal thickness of plate. Thus concluded that the Delta plate is suitable for the treatment of mandibular condylar fractures.

On reviewing data from three studies comparing outcomes between efficacy of standard non-compression mini-plate and 3-dimensional (3D) titanium plate in the open reduction internal fixation (ORIF) of the mandibular condylar fractures, 3D plate have superior outcomes with regard to operation time, mouth opening, postoperative pain and postoperative occlusion compared with mini-plates.

Limitations

Certain Limitations Of The Present Systematic Review Are:

1. The quality of the all three included studies bore high risks of bias. The studies were all randomized clinical trial, but none of them followed the required CONSORT statement. A well-designed and conducted randomized clinical trial should have strong evidence for comparing interventions, and systematic reviews of well-conducted randomized clinical trial can draw better conclusions of a specific clinical question.

2. The majority of included studies may not have adequate statistical power, as the sample size of two studies was fewer than 15 patients per group.

3. The included studies were heterogeneous for the primary outcome, Biting efficiency, occlusal stability, increase in angulation and increase in the gap between fractured segments.

4. The intra-operative outcomes may depend upon the comfort and experience of the operator with a specific surgical technique. It is, however, difficult to take into account the influence of such confounding factors on the study outcomes when pooling results from different studies.

CONCLUSION

With the advent of new surgical techniques and a growing armamentarium, there has been a paradigm shift in the management of extracapsular condylar/ sub condylar fracture from closed reduction to open reduction. In the field of open reduction internal fixation, eminent scientists and surgeons have combined efforts to research various materials and design and have developed various osteosynthesis plating systems which reduce post-operative morbidity and improve function.

Our study concludes that the 3D Delta plates yielded superior outcomes compared to conventional mini plates, as patients treated with 3D delta plates had superior outcomes with regard to operation time, mouth opening, postoperative pain and postoperative occlusion in comparison to patients treated with the conventional mini plates. The geometric pattern of the plate readily adapts to the anatomy of the fracture, allowing surgical ease in placement.

This systematic review found that 3D Delta plate allows the stress distribution to be superior and multidimensional, leading to better post-operative stability, faster healing, and reduced complications. Data on intra-operative outcomes are scarce and conflicting for any definitive conclusions. Further high-quality adequately powered RCTs are required to strengthen current evidence.

DECLARATIONS

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Competing Interest Statement:

None.

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