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ORIGINAL ARTICLE

Treatment Outcome Comparison Between two 3-Dimensional Plates (Y-Shaped Plate Versus Trapezoidal Condylar Plate) in Management of Mandible Condylar Fracture: A Randomized Control Trial

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Abstract
Aim To compare the treatment outcomes (clinical, functional and radiographical) using the two different 3-Dimensional plates in open reduction internal fixation of mandibular condylar fracture (MCF). Assessment of ease of fixation and fixation time were also performed.
Methodology 20 MCF patients were divided equally into two groups (Group A: Trapezoidal Condylar Plate and Group B: Y-shaped plate) and the treatment outcomes were compared. Intraoperatively time required for fixation was also compared. The patients were followed up at different timelines till 3 months.
Result Baseline parameters had statistically insignificant distribution in both groups implying effective randomization and balanced confounding factors. Intraoperatively, adequate anatomical reduction was achieved in both groups with statistically insignificant difference in time required for fixation. Postoperatively, no statistically significant difference was found in radiographic and functional parameters. None of the patients in either group reported with facial nerve injury, condylar resorption, Temporomandibular Disorders. However, 02 patients in Group A and 01 patient in Group B presented with infection, parotid fistula, and hardware failure respectively with statistically insignificant difference.
Conclusion This study concluded that the treatment outcomes were satisfactory with the use of both 3-D plate, but further studies with larger sample size and longer follow up are required.

Keywords Mandibular condyle fracture · 3-dimensional plates · Y-shaped plate · trapezoidal condylar plate

Introduction

Mandibular condyle fracture (MCF) is the second most common fracture in the maxillofacial region [1, 2], accounting for almost 29–52% of all mandibular fractures [3, 4]. Trauma to MC leads to changes in normal physiology and anatomy of MC as well as temporomandibular joint (TMJ) [5]. Reconstruction objective to achieve pre-injury status may avoid many complications like malunion, malocclusion, reduced facial asymmetry, temporomandibular joint derangement manifesting as chronic pain, ankylosis [6].

Management of MCF can either be addressed by closed reduction or open reduction with internal fixation (ORIF). In recent times there is a shift of debate from closed versus open reduction involving specific numbers and patterns of fixation devices [7].

MCF can be treated with multiple options, such as axial screws, single miniplate, double miniplates, 3-dimensional (3-D) plates and resorbable plates. Two straight miniplates and 3-D plates have proved its superiority over the others [8]. There are variable designs of 3-D fixation devices available [9], and they have an edge of better design configuration for complex biomechanics in condylar region,

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smaller size, ease of application and manoeuvrability even with distant retromandibular access. Meyer et al. first proposed the concept of the Trapezoidal Condylar Plate (TCP) and found satisfactory stability and rigidity for fixation of subcondylar fracture in various in vivo and in vitro studies [10, 11]. Y-shaped plates in in vitro studies have shown better control over the reduction and stabilization of condylar stump probably due to two arms which conforms to the ideal lines of osteosynthesis at the condylar region [12].

To the best of our knowledge till date, there has not been a single in vivo study assessing the treatment outcomes of MCF patients treated by ORIF comparing two different 3-D plates, i.e. Y-shaped plate versus TCP. Thus, a randomized controlled trial (RCT) comparing the clinical and radiographical treatment outcomes of Y-shaped plate versus TCP in ORIF of MCF was planned.

Material and Methodology

Trial Design and Ethical Approval

This study was designed as a single-centre, prospective, double-arm, parallel-group with active control, and open labelled RCT performed in accordance with the Declaration of Helsinki regarding medical research, as revised in 2016. This trial was carried out strictly according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines after obtaining ethical clearance from the Institutional Ethics Committee (AIIMS/IEC/2018/1550), and this trial was registered in Clinical Trials Registry-India (CTRI) registration (CTRI/2019/01/017116).

Study Participants and Settings

All the patients with MCF presenting to the Trauma and Emergency and Dental department of AIIMS, Jodhpur, were analysed from 21st January 2019 to 21st September 2020, and 20 patients were included in the study applying eligibility criteria.

Eligibility Criteria

Patients with unilateral and bilateral MCF with ASA I & II, in age range of 16–65 years with the absence of infection were included in our study after taking written informed consent. Patients with condylar head fracture, pan-facial fractures and uncontrolled systemic co-morbidities were excluded from the study.

Twenty patients were randomly allocated with a permuted block design using a computerized randomization allocation software 2.0 by an individual "A" with an allocation ratio of 1:1 into Group A (Control, $n = 10$): MCF fixation was performed with TCP and Group B (Cases, $n = 10$): MCF fixation was performed with Y-shaped plate. Allocation concealment was ensured by using sequentially numbered opaque envelope (SNOE) and different Individual "B" for patient recruitment. Both the individuals were unrelated to the trial. For electromyography (EMG) comparison for trauma patients, a random group of 20 people with comparable demographics was selected as a healthy volunteer group.

Intervention for ORIF

As per the randomization code ORIF of reduced fracture fragments after transparotid-retromandibular incision was done using Y-shaped or TCP (Stryker CMF plating system) (Figs. 1 and 2). After fracture exposure, occlusion was achieved through intermaxillary fixation with arch bars. Intraoperative time was measured with the stopwatch from point of fracture reduction to the last screw placement was noted. Layered-wise closure of parotid capsule, fascia and skin was done, and patients were followed for the following outcome parameters with a pre-structured proforma in both the groups at preoperatively (T0), intraoperatively (T1), postoperatively 1st day (T2), 1st week (T3), 1st month (T4) and 3rd month (T5).

1. Baseline demographic variables including age, sex, aetiology, fracture type on basis of classification and Computed Tomography (CT) characterization were noted at T0. The angular parameters (in degrees) included condylar angulation (CA)—angulation between the line drawn from the lateral pole to medial pole of condylar head to the line perpendicular to mid-

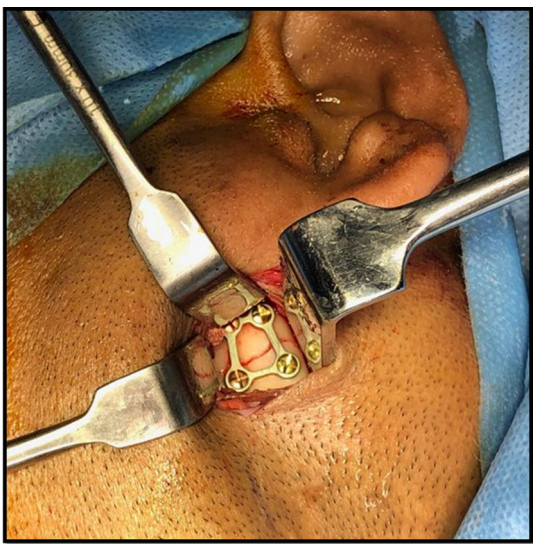

Fig. 1 Intraoperative photograph of TCP

Fig. 2 Intraoperative photograph of Y-shaped plate

coronal line and passing tangentially to postero-medial surface of condylar head was calculated, and proximal distal segment angulation (PDSA)—in coronal plane, proximal distal stump angulation was measured. Linear parameter (in mm) included condylar distance (CD)—the distance between medial pole and mid-sagittal plane (line passing through nasal septum and through foramen magnum).

Intrarater Reliability - 10 random CT scans of the patients were re-evaluated again by the same assessor after 2 weeks. The discrepancy in 2 observations was found to be minimal (kappa coefficient <0.9), and thus CT evaluation was found to be reliable and acceptable for the study.

2. Functional parameters of maximum mouth opening (MMO), lateral excursive movements, occlusion, pain with Visual Analogue Scale (VAS) score and pre-existing temporomandibular disorders (TMD) were recorded at T0, T2, T3, T4 and T5
3. Electromyography (3rd month postoperatively): EMG signal was acquired using Bioamplifier module of Power Lab 4/35 system (AD Instruments, Australia) at 1 kHz. Raw EMG signal was filtered in a separate channel using Band-pass filter 20–500 Hz. Root mean square amplitude of the signal was calculated in third channel using a window of 0.5 Seconds. Data were visualized in real time using Lab Chart Software version 8.1.13 (AD Instruments, Australia). With the leads placed, the patient was asked to clench and bite (on cotton bite block) for a duration of 20 s three times on each side with a gap of 30 s.
4. Complications like facial nerve injury, swelling, parotid sialocele, infection, hardware failure and development of TMDs were assessed at T3, T4 and T5.

Statistical Analysis

Data collected were tabulated in an excel sheet. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). Normality test was done using Shapiro–Wilk's test, skewness and kurtosis analysis. Data were expressed as mean ± standard deviation/error. Intragroup comparison for MMO, VAS, lateral excursion was analysed using one-way ANOVA along with Tukey HSD Post Hoc test. Categorical data were compared using student chi square test, while difference between mean was determined using student t test in both the groups. The level of significance was set at $p < 0.05$.

Results

The participant flow, enrolment, and group allocation are shown in the CONSORT diagram in Fig. 3.

Baseline distribution of study participants including age, sex distribution, aetiology of trauma, fracture types based on Lindahl classifications and CT characteristics, MMO, lateral excursive movements, occlusion status, VAS score, pre-existing TMD were found to have statistically insignificant differences between the two groups except for age median where the difference was found to be statistically significant ($p = 0.02$) (Table 1).

At T1 reduction was achieved in all the patients (100 percent) in both the groups. Mean intraoperative time in plate fixation (20.90 ± 9.79 min) in group A and in group B (22.30 ± 10.35 min) was found to be statistically insignificant (p value = 0.76) (Table 2).

In both groups, the range of mandibular movements was lower in the initial postoperative phase (T2 and T3), which gradually increase at each follow-up and reached normal range of mandibular movements at T5, between the group mean MMO at T5 in Group A (34.10 ± 7.2 mm) and in Group B (36.6 ± 5.8 mm), right lateral movement in Group A (6.40 ± 0.7 mm) and in Group B (6.40 ± 1.3 mm) and left lateral movement in Group A (6.8 ± 0.8 mm) and in Group B (6.2 ± 1.7 mm) were achieved; however, these movements were insignificant on intergroup comparison ($p = 0.40, 1, 0.31$). Occlusion was acceptable in all patients except one patient in group B

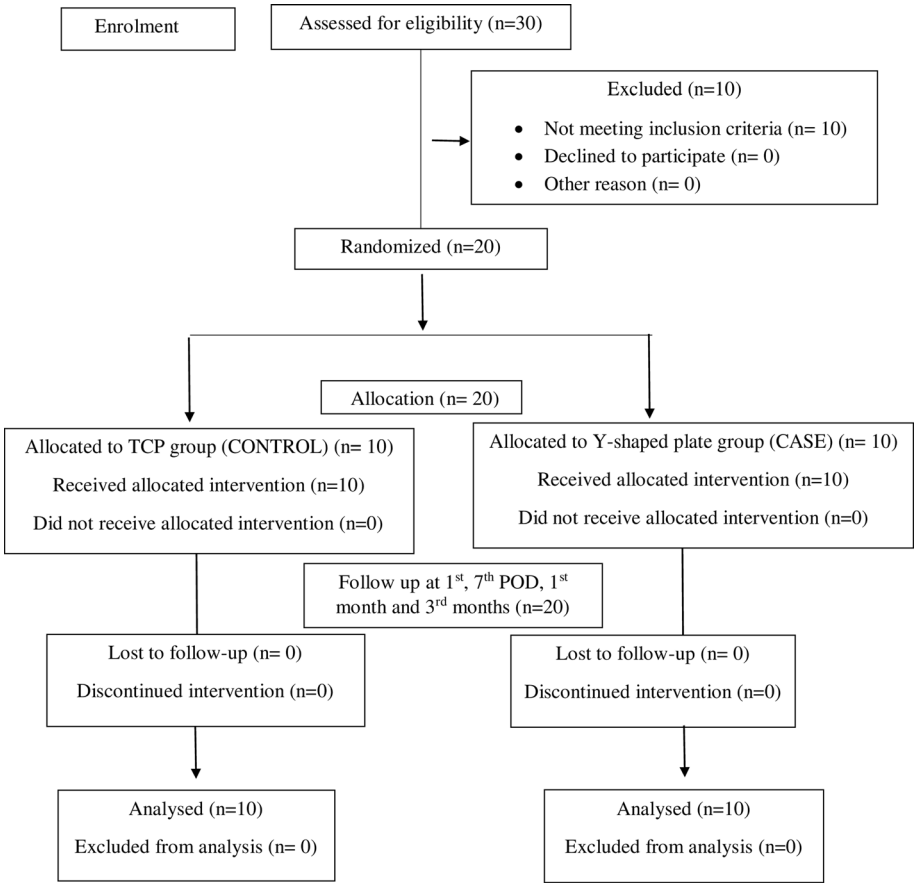

Fig. 3 Flow chart of the study

Table 1 Baseline demographic, clinical, and radiographic parameters of the study participants

Parameters	Total (n = 20)	Group A	Group B	p Value
Age (years)[c]	23.5	30	21	0.02
Male/Female[a]	19/01 (95/05)	9/1 (90/10)	10/0 (100/0)	0.31
Fracture classification[a]				
Subcondylar fracture	20/20 (100)	10/10 (100)	10/10 (100)	NA
Computed Tomography parameters[b]				
Fractured condylar angulation	a. 36.28 ± 6.47	a. 37.73 ± 4.76	a. 34.85 ± 7.81	a. 0.33
Fractured condylar distance	b. 34.63 ± 2.13	b. 34.38 ± 1.67	b. 34.88 ± 2.59	b. 0.61
Fractured proximal distal segment angulation	c. 146.43 ± 11.84	c. 149.54 ± 9.68	c. 143.32 ± 13.46	c. 0.25
Temporomandibular *Joint disorder*[a]	0/20 (0)	0/10 (0)	0/10 (0)	NA
Mouth opening[b]	14.35 ± 5.50	14.49 ± 6.09	14.30 ± 5.19	0.97
Lateral excursion[b]				
Right	a. 2.4 ± 1.23	a. 2.60 ± 1.35	a. 2.20 ± 1.13	1. 0.48
Left	b. 2.4 ± 1.39	b. 2.60 ± 1.51	b. 2.20 ± 1.32	2. 0.54
Occlusion[a]				
Stable	1. 0/20 (0)	1. 0/10 (0)	1. 0/10 (0)	NA
Deranged	2. 20/20 (100)	2. 10/10 (100)	2. 10/10 (100)	

[a]n (%)

[b]Mean ± SD

[c]Median

Table 2 Intraoperative and postoperative clinical and radiographic values

Variables	Group A	Group B	*P* value
Intraoperative treatment outcomes			
Anatomical reduction achieved[a]	10	10	1
Time in plating (minutes)[b]	22.30 ± 10.3	20.90 ± 9.8	0.8
Postoperative treatment outcomes			
Maximum mouth opening[b]	34.10 ± 7.2	36.60 ± 5.8	0.4
Lateral excursion[b]			
Right	6.40 ± 0.7	6.40 ± 1.3	1
Left	6.80 ± 0.8	6.20 ± 1.6	0.31
Occlusion deranged[a]	0	1	0.31
VAS score[b]	2.10 ± 1.3	2.30 ± 1.4	0.11
Computed tomography parameters[b]			
Condylar angulation	27.5 ± 4.7	27.1 ± 4.2	0.84
Condylar distance	37.9 ± 2.3	38.9 ± 2.1	0.30
Proximal distal segment angulation	165.9 ± 4.9	164.64 ± 4.8	0.54
Complications			
Swelling[a]	0	0	1
Infection[a]	0	0	1
Parotid fistula[a]	0	0	1
Hardware failure[a]	0	1	0.31
Facial nerve injury[a]	0	0	1
Development of TMDs[a]	0	0	1

[a]*n*

[b]Mean ± SD

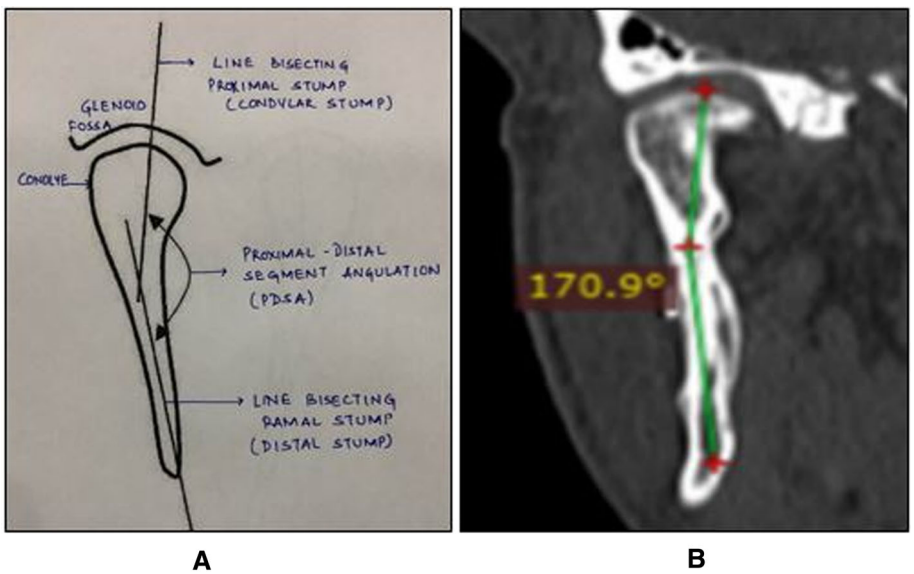

Fig. 4 **a** Depicting graphical representation of PDSA measurement and **b** Depicting actual calculation of PDSA from coronal section of patient's CT scan

with plate fracture in group at T5. The difference was statistically insignificant ($p = 0.31$) (Table 2).

Satisfactory fracture reduction and fixation were assessed with the CT evaluation at T4, which showed the effective stability in both the groups where the mean CA was found to be 27.46 ± 4.67 degrees in Group A and 27.05 ± 4.27 degrees in Group B which was comparable to non-operated side. Same results were seen in CD

Table 3 Electromyography values between MCF patients to Healthy control and Inter-group comparison

Variables	Condylar fracture patient[a]	Healthy control[a]	*p* Value[b]
Clench	631.30 ± 243.01	693.70 ± 245.78	0.37
Bite	582.40 ± 235.30	675.80 ± 234.53	0.19
	Group A[a]	Group B[a]	*P* value[b]
Clench	573.7 ± 232.2	688.9 ± 622.8	0.34
Bite	542 ± 219.6	622.8 ± 254.9	0.52

[a]Mean ± SD

[b]Student *t* test

(37.91 ± 2.24 in group A, 38.95 ± 2.11 in group B) and PDSA (165.99 ± 4.89 in group A, 164.64 ± 4.79 in group B) (Table 2). Figure 4 (A and B) depicts PDSA measurement.

EMG evaluation of masseter muscle in clench and bite in condylar fracture patients at T5 was statistically comparable to healthy volunteer masseter muscle function ($p = 0.37$, 0.19). In inter-group comparison between groups A and B, the difference in muscle function during clench and bite was found to be statistically insignificant ($p = 0.34$, 0.52) (Table 3).

All the complications assessed had statistically insignificant distribution in both the groups. None of the patients presented with facial nerve injury. Swelling was presented in 12 patients till T2 and only two had till T3. These 2 patients were of sialocele in group A (20%) and none of the patients of group B. Infection developed in sialocele in one of the patients in group A However, this difference was also not statistically insignificant ($p = 0.17$; $p = 0.31$). As a part of delayed complication none of the patients reported to have objective finding of the TMD at T3. While one patient (10%) in group B reported with malocclusion on day 40, further investigations radiographically revealed hardware failure in form of plate fracture at the bifurcation of arms of 'Y' shape design (Table 2).

Discussion

ORIF in MCF has been proved to have better treatment outcomes compared to closed reduction in terms of aesthetic and functional rehabilitation according to recent literature [13, 14]. However, there is no standard choicest plate type for complex MCFs. This trial aimed to compare treatment outcomes of fixation in MCF using two different types of 3-D plates (TCP vs Y-shaped plate).

All the baseline parameters of patients' demographics, fracture types on the basis of classification, CT parameters, functional status (as assessed by occlusion, MMO, lateral excursions, pain using VAS score) had statistically insignificant distribution in both the groups. A robust study design with near perfect randomization, allocation, concealment is the biggest strength of our study. This is evident from homogenous distribution of patient population in both the groups minisculing the patient-related confounding factors.

Intraoperatively, adequate reduction was achieved and time required for plating was comparable within the groups. Surgeons preferred Y-shaped plate over TCP due to its easy manoeuvrability, especially if fracture line location is upward towards the condylar neck. This is in line with varied research on 3-D plates having compact design and easy manoeuvrability even with distant small access [15].

Condyle forms an important bony component of TMJ; its anatomical and functional reduction is prudent for achieving a complete range of painless movements including maximum MMO, lateral excursions and functional occlusion. Preoperatively, all these parameters were deranged, progressively improved postoperative at each follow-up to normal range at T5, thus confirming adequately restored TMJ movements in both the groups. Hence, it can be concluded that both these 3-D plates were able to counteract the physiological forces and complete recovery of functional movements was witnessed.

In our study, VAS score of total population was severe at T0 [7.95 ± 0.99] which reduced to moderate at T2 and T3. Severe pain at T0 was in line with nociception due to periosteal nerve fibres stimulation caused by micro-movements of bony fragments [16, 17] after fracture and the moderate pain at T2 and T3 could be due to post-surgical localized inflammation caused because of the surgical dissection while accessing the fracture site [16]. However, as a part of good functional rehabilitation all the patients had mild pain [VAS score 2.20 ± 1.4] in 1st- and 3rd-month follow-up in all TMJ movements.

This achieved functional rehabilitation was objectively assessed with EMG in our study [18, 19]. It was found that at T5 postoperatively the muscle function of condylar fracture patients was comparable to healthy control implying that probably muscular contractility and physiology are restored with time to healthy level. More so when a comparison of operated and non-operated site was done in all the MCF the difference was statistically insignificant (p value > 0.05) depicting that neuromuscular adaptation in each patient was functionally adequate on both the sides. It seems that plate type used for fixing the condylar stump did not have any effect on the EMG functions as perceived by statistically insignificant difference; this could be ascribable as both 3-D plates are miniplates holding the fragments passively together.

Occlusion can be taken as an indirect indicator to assess the maintenance of anatomical reduction in the condyle once the muscular and pain factors are under control. Preoperatively occlusion was deranged in all of the included patients. In immediate post-operatively [1–7 days] occlusion was deranged in 3 patients (30 percent), which came to normal on guiding elastics; this finding could be attributable to the fact that even after adequate ORIF, neuromuscular settling takes some time [20]. However, at T4, all patients had perfect occlusion except for 01 patient which reported with plate fracture leading to occlusion derangement in group B on day 40.

CT Scan 3D evaluation was used for the assessing reduction and anatomical restoration of distorted morphology of fractured condyle radiographically [21, 22]. Statistical significant difference (p value < 0.05) in between the preoperative fractured and preoperative non-fractured CA, CD and PDSA implied altered condylar anatomy after trauma. At T5, CT characteristic comparison between the preoperative non-fractured condyle and post-operative fractured condyle had statistically insignificant difference signifying that the reduction in both groups was adequate and both the plates were able to restore the distorted anatomy back to pre-trauma status. Restoration of PDSA was satisfactory in our study as was assessed on CT, which provides better radiological evaluation of condylar anatomy restoration compared to 2-D evaluation on orthopantomogram [21, 22]. Intrarater reliability was also taken care of.

ORIF is a direct and precise treatment of any fracture with the only point of concern being associated with surgical complications. Thus, early and late complications were thoroughly recorded in our study. None of the complications differed statistically according to the type of plate used and no severe complication was found. While reported incidence of facial nerve injury varies from 0 to 20% temporary and less than 1% permanent in MCF [1, 13, 23] none of the patients in our study reported with any form of facial nerve weakness or Frey's syndrome. Swelling was present (19 patients) in the immediate post-operative period which could be attributed to the surgical insult to the localized site and progressively swelling subsided in all cases except 02 patients who had parotid sialocele with fistula. This was dealt with glycopyrrolate (1 mg twice daily for 5–7 days) and pressure dressings, and which completely regressed by POD 23 and did not require any further intervention. Only one patient in group A reported with surgical site infection as a sequela to parotid fistula which subsided with use of antibiotics on day 16.

None of the patients had TMD in pre-trauma stage and irrespective of the fracture fragment dislocation seen, none of our patient developed any sign of TMD in follow-up. TMDs have been found to have incidence of 10.3% in patients undergoing the ORIF treatment for MCF, especially in cases of dislocation as suggested by Suhas et al. [24]. Ilzuka et al. reported that signs of condylar resorption and osteoarthrosis were markedly more severe in cases treated by rigid fixation with miniplates than in cases treated using transosseous wiring [25]. None of our patients presented with any radiographic sign of condylar resorption. In our study, one patient reported with hardware failure (plate fracture) in Group B leading to deranged occlusion on POD 45.

Implication and Future Recommendations

With this study, we would like to conclude that Y-shaped plate and TCP are comparable in achieving anatomical reduction and functional rehabilitation in MCF patients. Although there was one case of Y-shaped plate fracture, larger trials with larger sample size and greater follow-up duration are mandatory. There is a need to objectify muscular strength assessment with EMGs on temporalis and pterygoids on a larger sample size, keeping a close follow-up for longer duration.

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Declarations

Conflict of interest None of the authors have any conflict of interest to declare.

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