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# Report- Dr.Pavithra

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# COMPARATIVE EVALUATION OF PAIN EXPERIENCED WITH NEEDLELESS JET INJECTOR (INJEX) AND CLASSICAL NEEDLE INFILTRATION DURING SCALING AND ROOT PLANING IN PATIENTS WITH PERIODONTITIS- A SPLIT MOUTH RANDOMIZED CONTROLLED CLINICAL TRIAL

## Abstract

**Background:** The treatment of periodontitis primarily consists of mechanical debridement carried out by means of thorough scaling and root planing that might sometimes be a painful procedure which requires the administration of some form of local anesthesia. INJEX is needleless jet injector which deliver local anesthesia without subjecting the patient to the unpleasant experience of feeling the pain of "the needle". Thereby, the jet syringe enables the patient to develop a more positive approach towards the dental treatment by eliminating his/her greatest fear.

**Objective:** The present study evaluates the efficacy of Jet anesthesia (INJEX) and compare with the classical needle infiltration for pain caused during administration and after the completion of scaling and root planing.

**Methodology:** 30 patients with probing depth of 5mm or more and visual analogue scale (VAS) score of ≥30mm on probing were selected and asked to assess the pain by VAS immediately after administration of anesthesia and after completion of the treatment.

**Results:** VAS score during administration of anesthesia in Group 1 was lower compared to Group 2 ($p < 0.03$) and onset of anesthesia was faster in Group 1 ($p<0.01$). No statistically significant results seen in VAS score during scaling and root planing among both groups.

**Conclusion:** Thus, the data suggest that administration of anesthesia using INJEX was less painful, equally efficacious in anesthetic effect, which was seen during scaling & root planing. INJEX was also found to be faster in induction of anesthesia compared to classical needle infiltration.



**Keywords**: Needleless anesthesia, INJEX, Jet anesthesia

**Introduction:**

Treatment of periodontal disease includes measures such as self-performed plaque control, professional scaling, root planing and surgical management of periodontal pockets. The success of it, depends mostly on the effective removal of supragingival and subgingival bacterial biofilms and the smear layer, which contains bacteria, bacterial endotoxins, and contaminated root cementum.[1]

Mechanical non-surgical therapy, or Scaling and Root planing (SRP), is the most commonly performed procedure which can be painful.[2] To make the procedure comfortable for the patient and to facilitate the clinician's ability to provide care, requires the use of local anesthesia.[3] A large proportion of scaling and periodontal debridement procedures performed involve nerve block or infiltration anaesthesia.[1]

Injection anaesthesia may be carried out alone or in conjunction with topical anaesthesia.[1] One of the most distressing aspects of dentistry for the average dental patient is the fear and anxiety caused by the dental environment, particularly the dental injection, i.e., syringe and needle which is referred as "NEEDLE PHOBIA" or BLENOPHOBIA.[2] The pain of needle insertion, duration of action and inconvenience of soft tissue anaesthesia limit patient acceptance. Efficacy, uncontrolled spreading and undesirable taste limit the use of topical agents (Milgrom et al. 1997). There is therefore a need for a fast-acting anaesthetic that is simple to apply and painless.[1]

Needleless devices have been developed as an alternative medium to deliver anesthesia which uses pressure to force the anesthetic solution safely into oral tissues. The anesthetic solution infiltrates the tissue in the tiny droplet form, which is immediately taken up by the myelin sheath of the nerve with an onset of action of approximately in 1 milli second. This amount is most effective in localizing its effect without producing an effect on systemic blood level hence helpful in cardiac patients. In dentistry it can be successfully used as anesthetic

device for curettage and scaling, mental and nasopalatine blocks, cementing crowns, jackets, bands and clamps; copper tube impressions, gingivectomies, direct pulp injections, biopsies and pointing abscesses for incision and drainage procedures.[2]

The objective of the needless jet injection is to deliver local anesthesia without subjecting the patient to the unpleasant experience of facing the "needle" and to achieve adequate anesthesia that should be acceptable to the patients.

The present study was conducted with an aim to assess the pain experienced during administration of jet anesthesia and during scaling and root planing and compare it with classical needle infiltration anaesthesia.

**Materials and methods:**

This present randomized controlled split mouth clinical trial was conducted on both male and female individuals in the age group of 18-70 years, who reported to Department of Periodontics, Dayananda Sagar College of Dental Sciences, Bangalore. All selected patients were explained about the need, design of the study and its potential benefits who signed an informed written consent prior to commencement of the study. The study was approved by the Ethical Committee of the Institution, Dayananda Sagar College of Dental Sciences, Bangalore. A split-mouth design was followed and the anesthesia was administered in maxillary or mandibular quadrants, which were chosen randomly, in each subject. Thirty subjects in the age group between 18-60 years with minimum five teeth in each quadrant that had not received periodontal debridement in last 12 months and pocket depth of more than or equal to 5mm but less than 8 mm on at least 2 or 3 teeth adjacent to each other on both sides either maxilla or mandible excluding third molars and with VAS score of 30-80mm on probing were included in the study. Subjects who are allergic to local anesthetic agents, on pain medication who have ulcers or abscess, who are in immediate need of surgery, with systemic diseases or conditions, pregnant or lactating, smokers, alcoholics, drug abusers and with CNS depression were excluded from the study.

**Procedure:**

Based on the above-mentioned inclusion and exclusion criteria, total of 30 subjects were selected and randomly allocated into two groups making it a total of 60 sites in a split mouth design. Ultrasonic scaling was performed for all the patients in the first visit and the patient was recalled after 1 week for root planing. Local infiltration anesthesia is administered through jet injector (INJEX) in group 1 (Experimental) with 30 sites both buccal and palatal aspect. INJEX, needle free jet injector was used in this study. The injector consists of a head assembly with glass fill chamber holding up to 0.3 ml of local anesthetic solution, the body with a cocking

lever and discharge button and extend a tip and sheath which can be changed between each patient. The glass chamber was filled with 2% lidocaine with 1:80000 adrenaline. INJEX was gently placed perpendicularly against the area to be injected with sheath in complete contact with the gingiva.

Local infiltration anesthesia is administered through classical needle injection technique in group II (control), that is, the opposite side of experimental group. The same volume and concentration of anesthesia was used in group II.

The onset of anesthesia was assessed in both the groups immediately after the administration of anesthesia using timer every 10 seconds until the numbness have been achieved, following which root planing was performed using Gracey's area specific curettes. Pain assessment was done immediately after administration of anesthesia and immediately after root planing, by asking the patient to mark his level of pain on VAS scale of 100mm length, with the left end point marked "no pain" and right end marked "worst pain imaginable".

The sample size has been estimated using the G Power software v. 3.1.9.2 Considering the effect size to be measured (d) at 47% for one-tailed hypothesis and 95% confidence interval, power of the study at 80% and the margin of the error at 5%, the total sample size needed is 30.

Computer assisted software will be used to generate random sequence (Block Random allocation) which will follow random allocation of teeth requiring root planing to either group I or group II. Random allocation will be done by the person who is not involved in the study. Allocation Concealment will be done by concealing the allocation sequence from the operator in an envelope and will be revealed by the third person at the moment of assignment.

Statistical analysis was performed using Chi- square test, Mann whitney test and Wilcoxon Signed rank test.

**Observation and Results:**

The present study was designed as single blinded, Split mouth, Randomized controlled clinical trial. A total number of 30 patients reporting to Department of Periodontology, Dayananda Sagar College of Dental Sciences, Bangalore were enrolled based on the inclusion and exclusion criteria and were included in the study between January 2020 and September 2021. Computer assisted software was used to generate random sequence (Block Random allocation) which followed random allocation of teeth requiring root planing to either group I or group II. Random allocation was done by the person who is not involved in the study.

In 30 patients included in the study, 60% were males and 40% were females with mean age of 37.50 ± 10.13 years.(Table1).

The mean duration of onset of anesthesia on buccal aspect in group 1 was 32.52 seconds and in group 2 was 48.76 seconds. The mean difference of onset of anesthesia on buccal aspect was -16.24 seconds (P<0.001). The mean duration of onset of anesthesia on Lingual/Palatal aspect in group 1 was 28.62 seconds and in group 2 was 45.48 seconds and the mean difference was -16.86 seconds (P<0.001) which was statistically significant. (Table 2)

VAS score in group 1 during administration of anesthesia was 1.93±1.82 and in Group 2 was 2.90±1.35 and the mean difference was found to be -0.97 (P<0.03) which was statistically significant.

VAS score during Scaling and Root planning in Group 1 was 0.30±0.54 and in Group 2 was 0.13±0.51 with mean difference of 0.17 (P<0.06) with test group experiencing more pain during treatment compared to control group. However, the difference was not statistically significant. (Table 3).

In test group, mean VAS score of 1.93±1.82 was found during administration of anesthesia and during the treatment, VAS score of 0.30±0.54 was observed with P<0.001. In control group,

VAS score of 2.90±1.35 and 0.13±0.51 with P<0.001 during administration and during Scaling and root planing was observed, respectively. (Table 4).

**Discussion:**

The present study was designed to assess the efficacy of needle-less jet injector (INJEX) in providing a pain free experience during administration of anesthesia and during Scaling and root planing as well as to assess the onset of anesthesia. Subjects were asked to assess their pain perception using VAS during the administration of anesthesia and during the procedure. In the present study, a baseline VAS pain score of ≥ 30 mm during probing is included, which was in accordance with the study conducted by Magnusson et al, 2003 and Gupta et al, 2017.

Periodontal probing was used at baseline to screen for pain sensitivity, whereas the effect of the anesthesia was assessed during SRP.

The primary means of determining efficacy of jet injector was the measurement of treatment-associated pain. The use of the VAS for scoring pain has been validated in a variety of studies for different conditions including rheumatoid arthritis (Scott & Huskisson 1976) and temporo-mandibular disorder pain (Le Resche et al. 1988). The reliability of the VAS has been demonstrated previously by Luria in 1975, by using the test/re-test method for repeated measures of subjective sensations. The reliability of the VAS was shown to be excellent (kappa 0.82). Thus, the VAS represents appropriate methods for measuring subjective pain. However, the subject nature of VAS may over or underestimate the efficacy of the test group.[1]

The results of this study indicate that the mean value of VAS in control and test group was 2.90±1.35 and 1.93±1.82 respectively. The difference between the VAS scores of control and test group is statistically significant ($P < 0.03$). The VAS score of test group (INJEX) was much lower than control group. In a study conducted by Gupta et al, 2017, where they have compared the effectiveness of EMLA and needleless jet injection "MADAJET XL" for non-surgical periodontal debridement, the mean VAS values were lowest with Jet injection among the three groups ($p<0.001$) which is in accordance to our study. Additionally, the difference of this study is that we evaluated the efficacy of INJEX during Scaling and Root planing in a split-

mouth design. The advantage of the split-mouth design is the fact the comparison of anesthesia in the same individual eliminates the effect of confounding variables, as each participant serves as his/her own control.[4]

The mean age of male subjects (n = 18) was 37.3 and the mean age of female subjects (n = 12) was 37.6. There are no statistical differences between age and gender-related efficiency and acceptance of these two methods which correlates with findings of Saravia et al. (1981) who reported no age differences on method preference.[5] This study included equal number of maxillary and mandibular teeth (n=30 each) and there was no statistical difference between maxillary and mandibular scores.

The results of our study are contrary to Arapostathis et al. 2010, who reported more negative experiences with pressure anesthesia using INJEX as 73% children preferred the traditional needle method.[2] Similarly, Dabarakis et al. 2007, in their study reported only 17.6% patients' preference for pressure anesthesia; whereas 52.8% patients preferred classical injection technique.[6] Geenan L et al, 2004, also concluded that non needle phobia patients in their study did not prefer the needle free INJEX system above the classical local injection for restoration.[7] Makade et al.2014, with Madajet also demonstrated higher discomfort but significantly less fear with jet injection in adult patients.[2] Oliveira et al. 2019 with Comfort-In and Ocak et al.2020 with Injex on the other hand found no difference in pain during anaesthesia when comparing these devices with conventional anaesthesia.

Needleless jet injectors offer some advantages over traditional needle syringe, especially that it is fast and easy to use.[5] In this study, the onset of anesthesia on both buccal and lingual aspect with INJEX was much lower compared to Needle infiltration which is in accordance to the study by Sachin Makade, et al, 2014, where the total duration of anesthesia was significantly more ($P < 0.001$) with classical needle infiltration (mean $50 \pm 9.32$ min) when compared to pressure anesthesia ($20.75 \pm 3.53$ min). However, Dabarakis et al, 2007, concluded that there

was no statistically significant difference between Injex and the needle injection technique in onset of anesthesia to achieve pulpal anesthesia.

Various anesthetic solutions such as lidocaine, articaine, mepivacaine with different concentration ranging from 2% to 5% have been used in previous studies. The type, amount and concentration of anesthetic solution along with the amount of vasoconstrictor affect the anesthetic result. Dabarakis et al. 2007, in their study found that 3% mepivacaine used with pressure anesthesia did not produce pulpal anesthesia.[2] Hence, in our study, 2% lignocaine with epinephrine 1:80,000 was used with both the anesthetic techniques for completion of scaling and root planing.

Bennett et al. 1971, in their radiographic and histologic study supported pressure anesthesia as it provides penetration and infiltration roughly comparable to that produced by needle injection to near 1 cm depth, with the use of quantities up to 0.2 ml/injection; as it is the concentration gradient of anesthetic solution diffusing into the surrounding tissue determines how much anesthetic reaches a nerve. According to literature provided by manufacturer very little anesthetic solution is needed to form a wheal which effectively gives adequate anesthesia to carry out restorative procedures. Hence, 0.3 ml of anesthetic solution was deposited buccally and lingually.[2]

There were few limitations experienced with INJEX. According to the manufacturer, the ampoule has to be placed on the attached gingiva at an angle of 90° directly above the tooth to be anesthetized. There was difficulty in positioning the device perpendicular to the gingival tissue, particularly in palatal/Lingual region. No problems were noticed during anaesthesia of the buccal aspect of the maxillary and mandibular anterior teeth and maxillary posterior teeth, while there was difficulty to adequately use the device for delivering anesthesia on the lingual/palatal aspect of these teeth which resulted in leakage of anaesthetic solution and bitter taste. This can be avoided if the anaesthetic delivering segment forms a 45° angle with the

mainbody of the device, as per MADAJET XL design, which may permit better and easier positioning to the gingival tissue such that there is complete contact of the entire device's tip surface with the gingival tissue, which may result in less chance of leakage of anaesthetic solution). Other limitation of the device that was experienced during the study is that the few subjects indicated fear during the delivery of anesthesia via INJEX due to "pop" sound, produced due to the release of pressure during the administration. Further, treatment procedures where wide area needs to be anesthetized, INJEX may not be ideal option for administering anesthesia as it can be used only for administering infiltration anesthesia.

Within the scope of the study, we may conclude that needleless jet injection (INJEX) can be considered as an alternative technique for administering infiltration anesthesia for Scaling and root planing.

**Conclusion:**

From the results of this study, it can be concluded that,

Pain was not there during administration of anesthesia using Jet Injector (INJEX) & the anesthesia procedure was comfortable. However, mild discomfort was experienced by the patient during administration of Infiltration anesthesia using classical needle injection.

Though pain during Scaling and root planing was not there with both techniques, INJEX induced anesthesia faster as compared to classical needle infiltration.

Overall, INJEX not only provided sufficient anesthesia necessary for Scaling and Root planing, but also made the process of administration pain-free. Thus, needleless jet Injector (INJEX) appears to show promise which can be explored with further studies.

The jet syringe might enable the patient to develop a more positive approach towards the dental treatment by eliminating his/her greatest fear & this too can be evaluated in future studies.

**Funding-** No funding was obtained for this study

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## Tables:

**Table 1. Age and Gender**

| Table 1. Age and gender distribution among study subjects | | | |
|---|---|---|---|
| Variable | Category | n | % |
| Age | 18-30 yrs. | 6 | 20.0% |
| | 31-40 yrs. | 16 | 53.3% |
| | > 40 yrs. | 8 | 26.7% |
| | | Mean | SD |
| | Mean & SD | 37.50 | 10.13 |
| | Range | 18 – 64 | |
| Gender | Males | 18 | 60.0% |
| | Females | 12 | 40.0% |

**Table 2. Onset of Anesthesia:**

| Table 2. Comparison of mean duration of onset of Anaesthesia (in secs) on buccal & Lingual / Palatal region between 2 groups using Mann Whitney Test | | | | | | |
|---|---|---|---|---|---|---|
| Region | Group | N | Mean | SD | Mean Diff | P-Value |
| Buccal | Group 1 | 30 | 32.52 | 11.97 | -16.24 | 0.001* |
| | Group 2 | 30 | 48.76 | 19.41 | | |
| Lingual / Palatal | Group 1 | 30 | 28.62 | 10.47 | -16.86 | 0.001* |
| | Group 2 | 30 | 45.48 | 19.40 | | |

**Table 3. VAS Scores between two groups**

| Table 3. Comparison of mean VAS scores during administration of anaesthesia & during SRP between 2 groups using Mann Whitney Test | | | | | | |
|---|---|---|---|---|---|---|
| Time | Group | N | Mean | SD | Mean Diff | P-Value |
| During administration | Group 1 | 30 | 1.93 | 1.82 | -0.97 | 0.03* |
| | Group 2 | 30 | 2.90 | 1.35 | | |
| During SRP | Group 1 | 30 | 0.30 | 0.54 | 0.17 | 0.06 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Group 2 | 30 | 0.13 | 0.51 | | |

**Table 4: VAS Scores among each group**

| Table 4. Comparison of mean VAS scores between during administration of anaesthesia & during SRP in each group using Wilcoxon signed rank Test | | | | | | |
|---|---|---|---|---|---|---|
| Group | Time | N | Mean | SD | Mean Diff | P-Value |
| Group 1 | During administration | 30 | 1.93 | 1.82 | 1.63 | <0.001* |
| | During SRP | 30 | 0.30 | 0.54 | | |
| Group 2 | During administration | 30 | 2.90 | 1.35 | 2.77 | <0.001* |
| | During SRP | 30 | 0.13 | 0.51 | | |

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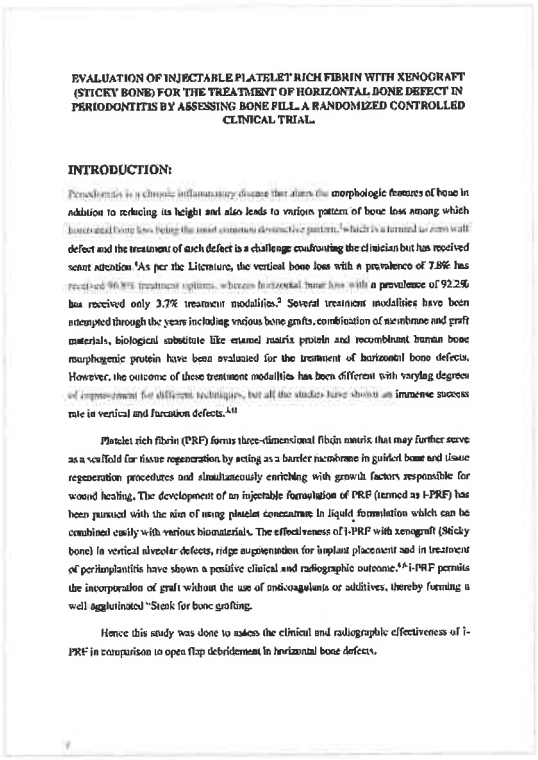

EVALUATION OF INJECTABLE PLATELET RICH FIBRIN WITH XENOGRAFT (STICKY BONE) FOR THE TREATMENT OF HORIZONTAL BONE DEFECT IN PERIODONTITIS BY ASSESSING BONE FILL. A RANDOMIZED CONTROLLED CLINICAL TRIAL.

INTRODUCTION:

Periodontitis is a chronic inflammatory disease that alters the morphologic features of bone in addition to reducing its height and also leads to various pattern of bone loss among which horizontal bone loss being the most common destructive pattern,[1] which is termed as zero wall defect and the treatment of such defect is a challenge confronting the clinician but has received scant attention [1]As per the Literature, the vertical bone loss with a prevalence of 7.8% has received 90.8% treatment options, whereas horizontal bone loss with a prevalence of 92.2% has received only 3.7% treatment modalities.[2] Several treatment modalities have been attempted through the years including various bone grafts, combination of membrane and graft materials, biological substitute like enamel matrix protein and recombinant human bone morphogenic protein have been evaluated for the treatment of horizontal bone defects. However, the outcome of these treatment modalities has been different with varying degrees of improvement for different techniques, but all the studies have shown an immense success rate in vertical and furcation defects.[3,4]

Platelet rich fibrin (PRF) forms three-dimensional fibrin matrix that may further serve as a scaffold for tissue regeneration by acting as a barrier membrane in guided bone and tissue regeneration procedures and simultaneously enriching with growth factors responsible for wound healing. The development of an injectable formulation of PRF (termed as i-PRF) has been pursued with the aim of using platelet concentrate in liquid formulation which can be combined easily with various biomaterials. The effectiveness of i-PRF with xenograft (Sticky bone) in vertical alveolar defects, ridge augmentation for implant placement and in treatment of periimplantitis have shown a positive clinical and radiographic outcome.[5,6] i-PRF permits the incorporation of graft without the use of anticoagulants or additives, thereby forming a well agglutinated "Stenk for bone grafting.

Hence this study was done to assess the clinical and radiographic effectiveness of i-PRF in comparison to open flap debridement in horizontal bone defects.

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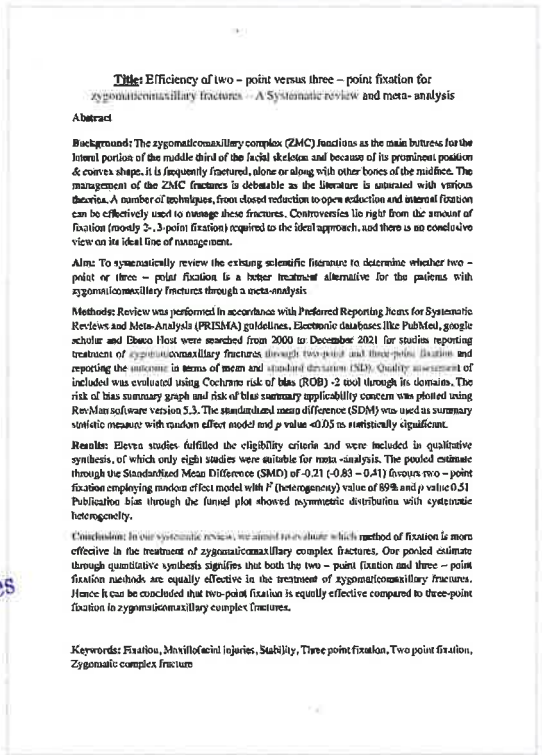

**Title:** Efficiency of two – point versus three – point fixation for zygomaticomaxillary fractures – A Systematic review and meta- analysis

**Abstract**

**Background:** The zygomaticomaxillary complex (ZMC) functions as the main buttress for the lateral portion of the middle third of the facial skeleton and because of its prominent position & convex shape, it is frequently fractured, alone or along with other bones of the midface. The management of the ZMC fractures is debatable as the literature is saturated with various theories. A number of techniques, from closed reduction to open reduction and internal fixation can be effectively used to manage these fractures. Controversies lie right from the amount of fixation (mostly 2-, 3-point fixation) required to the ideal approach, and there is no conclusive view on its ideal line of management.

**Aim:** To systematically review the existing scientific literature to determine whether two – point or three – point fixation is a better treatment alternative for the patients with zygomaticomaxillary fractures through a meta-analysis

**Methods:** Review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Electronic databases like PubMed, google scholar and Ebsco Host were searched from 2000 to December 2021 for studies reporting treatment of zygomaticomaxillary fractures through two-point and three-point fixation and reporting the outcome in terms of mean and standard deviation (SD). Quality assessment of included was evaluated using Cochrane risk of bias (ROB) -2 tool through its domains. The risk of bias summary graph and risk of bias summary applicability concern was plotted using RevMan software version 5.3. The standardized mean difference (SDM) was used as summary statistic measure with random effect model and $p$ value <0.05 as statistically significant.

**Results:** Eleven studies fulfilled the eligibility criteria and were included in qualitative synthesis, of which only eight studies were suitable for meta -analysis. The pooled estimate through the Standardized Mean Difference (SMD) of -0.21 (-0.83 – 0.41) favours two – point fixation employing random effect model with $I^2$ (heterogeneity) value of 89% and $p$ value 0.51 Publication bias through the funnel plot showed asymmetric distribution with systematic heterogeneity.

**Conclusion:** In our systematic review, we aimed to evaluate which method of fixation is more effective in the treatment of zygomaticomaxillary complex fractures. Our pooled estimate through quantitative synthesis signifies that both the two – point fixation and three – point fixation methods are equally effective in the treatment of zygomaticomaxillary fractures. Hence it can be concluded that two-point fixation is equally effective compared to three-point fixation in zygomaticomaxillary complex fractures.

**Keywords:** Fixation, Maxillofacial Injuries, Stability, Three point fixation, Two point fixation, Zygomatic complex fracture

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# Report- Dr.Shobha- Paper-1

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**Keywords:** Fixation, Maxillofacial injuries, Stability, Three point fixation, Two point fixation, Zygomatic complex fracture

## Introduction

The zygomaticomaxillary complex (ZMC) is the main buttress of the lateral portion of the middle third of the facial skeleton and is frequently fractured, along with the other bones of the face[1]. Zygomaticomaxillary complex (ZMC) fractures are a common form of craniofacial trauma, accounting for as much as one quarter of all facial structures. Anatomically, the ZMC is among the most prominent features of the lateral face and is responsible for the face's vertical and horizontal contours[2].

The ZMC's unique tetrapod arrangement, articulating with several bones, demarcates the anterolateral aspect of the face and delineates the midfacial width, the inferior and lateral orbital borders as well as the cheek prominence[3]. In addition to defining the facial width and cheek projection, the zygoma contributes to the lateral and some of the inferior orbital wall[4]. The zygoma shares its longest articulation with the greater wing of sphenoid bone along the lateral orbital wall; thus the zygomatico-sphenoid suture is the most sensitive indicator of fracture reduction and restoration of malar projection. However, fractures do not always occur across the 3 buttress-related sutures; thus reduction based on the "tripod" model will often fail to correct the deformity[5]. Additionally, the zygomatic arch serves as the origin of the masseter and the attachment of the superficial musculoaponeurotic system and temporoparietal fascia. The entire complex can be subjected to translational and rotational displacement in all 3 dimensions, yielding infinite combinations of pitch, yaw and roll of the fractured segements. As such, no fixation amount has been universally accepted as required to prevent post reduction displacement of ZMC fractures[6].

If these fractures are not attended to, they may lead to functional and aesthetic deficits such as loss of facial symmetry, paraesthesia by infraorbital nerve, depressed malar prominence, limited mouth opening, obstruction of lacrimal duct, epiphora, diplopia, orbital dystopia, enophthalmos and loss of vision when related to orbital floor fractures[7].

Management of these fractures is debatable and various theories supporting different treatment modalities exist. A number of techniques, from closed to open reduction and internal fixation, can be effectively used to manage ZMC fractures, but no uniform consensus exists. Management of a given ZMC fracture can vary considerably depending on the severity, the presence of comorbidities and surgeon preference[8]. Although nondisplaced fractures can sometimes be managed nonoperatively[4], displaced fractures will require reduction with or without fixation at one or more of the bony buttress[9].

The main goal of the treatment is to attain anatomic reduction and stable fixation to prevent post-operative aesthetic or functional deficits[10]. This can be accomplished by one-, two-, three- or four- point fixation of the fractured ZMC, depending on the displacement of the fractured segment, type of fracture and stability of zygoma after reduction, as mentioned in the existing litertaure[11,12]. Therefore, the aim was to systematically review the existing scientific literature to determine whether two – point or three – point fixation is a better treatment alternative for the patients with zygomaticomaxillary fractures through a meta-analysis.

# METHODOLOGY

## Protocol development

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement[13].

## Study design

The review question was to evaluate the outcome of zygomaticomaxillary fractures in patients with two – point and three – point fixations. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed "What is the efficacy of Two – point fixation compared to three – point fixation in patients with zygomaticomaxillary fractures?

The PICO criteria for this review were as follows:

**P (Participants)** – Patients with zygomaticomaxillary fractures

**I (Intervention)** – Use of two – point fixation

**C (Comparison)** – Comparison of two – point fixation with three – point fixation for treatment of zygomaticomaxillary fractures

**O (Outcome)** – correction of zygomaticomaxillary fractures

**S (Study designs)** – Clinical studies

## Eligibility Criteria

a) **Inclusion Criteria:** following were the inclusion criteria

1) Articles published in English language
2) Articles having sufficient data on two – point and three – point fixation in the treatment of zygomaticomaxillary fractures
3) Studies published between 2000 – 2021 and having relevant data on the two – point and three – point fixation in the treatment of zygomaticomaxillary fractures
4) Clinical studies and comparative studies
5) Articles from open access journals

6) Articles reporting the study outcomes in terms of mean and standard deviation

b) **Exclusion Criteria:** following were the exclusion criteria

1) Any studies conducted before 2000
2) Articles in other than English language
3) Reviews, abstracts, letter to the editor, editorials, animal studies and in vitro studies were excluded
4) Articles not from open access journals
5) Articles not reporting the study outcomes in terms of mean and standard deviation

## Data extraction

For all included studies, following descriptive study details were extracted by two independent reviewing authors and using pilot-tested customized data extraction forms in Microsoft excel sheet with the following headings included in the final analysis: author(s), country of study, year of study, mean age of the participants, study design, method of fixation used, duration of follow up, conclusion.

### Search Strategy

A comprehensive electronic search was performed till December 2021 for the studies published within the last 21 years (from 2000 to 2021) using the following databases: PubMed, google scholar and EBSCOhost to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and OpenGrey.

A manual search of oral and maxillofacial surgery journals, including the International Journal of Oral and Maxillofacial Surgery, British Journal of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, international journal of oral and maxillofacial surgery, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology, Journal of Cranio-Maxillofacial Surgery, Journal of Craniofacial Surgery, Journal of Maxillofacial and Oral Surgery and the journal of American Dental Association was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND, OR, NOT. The relevant data was searched using the following keywords and their combinations: "two – point fixation" (MeSH term) AND "zygomaticomaxillary fractures" (MeSH term); "three – point fixation" (MeSH term) AND "zygomaticomaxillary fractures" (MeSH term); "fixation" (MeSH term) AND "zygomaticomaxillary fractures" (MeSH term) AND zygoma (MeSH term); "two – point fixation" (MeSH term) AND "three – point fixation" (MeSH term) AND "zygomaticomaxillary fractures" (MeSH term); "stability" AND "zygomatic fracture" (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

**Screening Process**

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

**Quality assessment of included studies**

The methodological quality among included studies was executed by using Cochrane collaboration risk of bias (ROB) -2 tool[14]. The tool has various domains like random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipments (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases through their signalling questions in Review Manager (RevMan) 5.3 software. The overall risk for individual studies was assessed as low, moderate or high risk based on domains and criteria. The study

was assessed to have a low overall risk only if all domains were found to have low risk. High overall risk was assessed if one or more of the six domains were found to be at high risk. A moderate risk assessment was provided to studies when one or more domains were found to be uncertain, with none at high risk.

**Statistical analysis**

The standardized mean difference (SDM) with 95% CI was calculated for continuous outcomes. A fixed effects model (Mantel-Haenszel method) was used if there was no heterogeneity ($p \geq 0.05$ or I-squared $\leq 24\%$), otherwise a random effects model (Der Simonian-Laird method) was used[15]. All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). The significance level was kept at $p<0.05$.

**Assessment of heterogeneity**

The significance of any discrepancies in the estimates of the treatment effects of the different trials was assessed by means of Cochran's test for heterogeneity and the $I^2$ statistics, which describes the percentage of the total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $P < 0.1$. A rough guide to the interpretation of $I^2$ given in the Cochrane handbook is as follows: (1) from 0 to 40%, the heterogeneity might not be important; (2) from 30% to 60%, it may represent moderate heterogeneity; (3) from 50% to 90%, it may represent substantial heterogeneity; (4) from 75% to 100%, there is considerable heterogeneity[16].

**Investigation of publication bias**

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg's funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size[17].

## Results

### Study Selection

After duplicates removal, reference list of included studies was screened. Of which 121 studies were excluded. After this full text articles were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Only eleven studies fulfilled eligibility criteria and were included in qualitative synthesis. Of which only eight studies were included in meta – analysis. A flowchart of identification, inclusion and exclusion of studies is shown in **Figure 1** below.

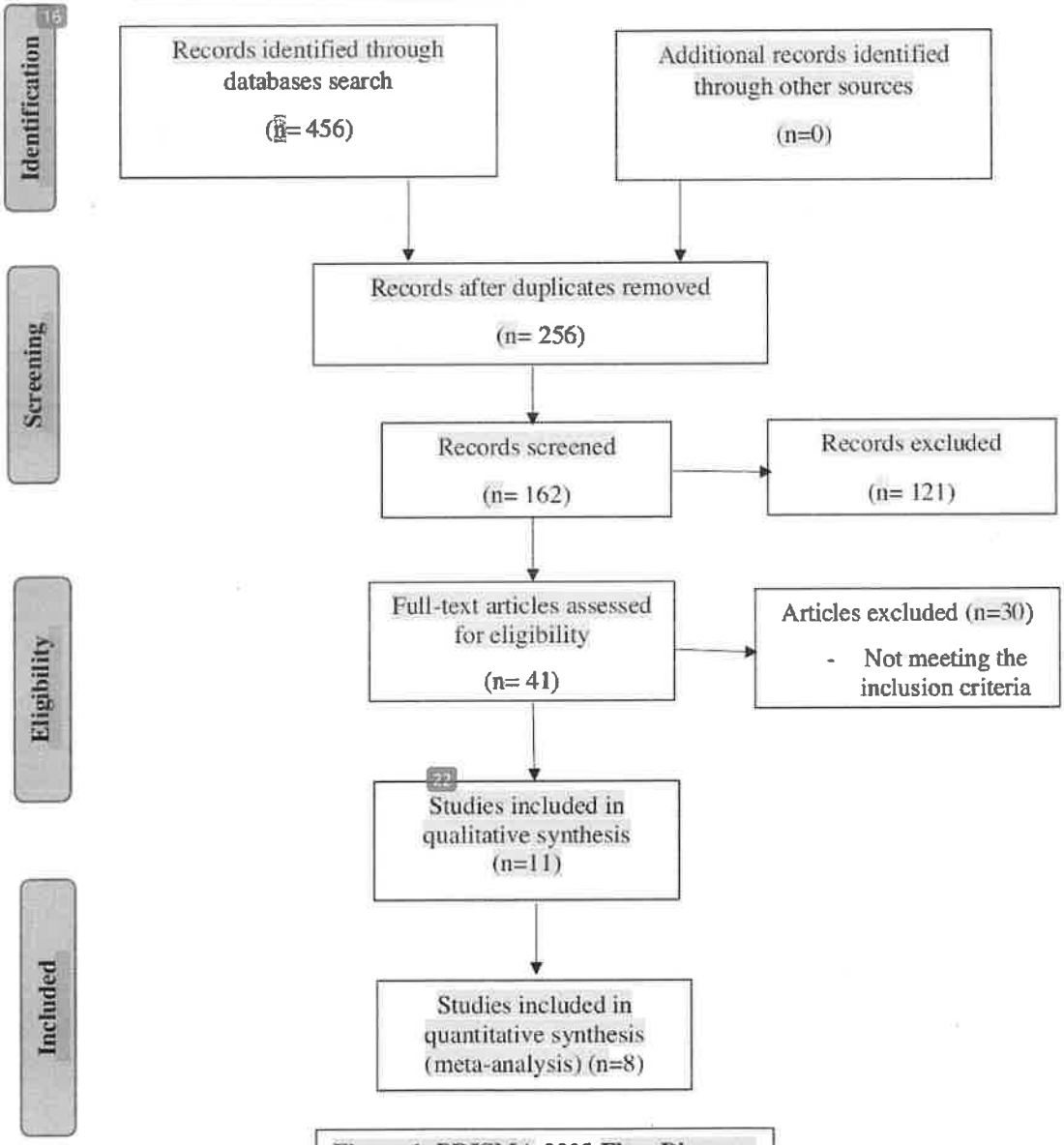


**Figure 1. PRISMA 2009 Flow Diagram**

## Study Characteristics

A summary of descriptive characteristics all included studies is shown in **Table 1.** Data was evaluated from an aggregate of 531 (n) patients with a mean age of 36.01 years. Data of two – point fixation was evaluated from 237 (n) patients while data of three – pint fixation was evaluated from 234 (n) patients. Among the included studies, four studies[19-21,26] studies were conducted in India, two studies[23, 28] were conducted in Korea, one study[18] in Pakistan, one study[22] in Brazil, one study in Saudi Arabia[24], one study in Egypt[25] and one study in Germany[27]. Among the included studies, eight studies[18-21,24,26-28] concluded that three-point fixation is better as compared to two-point fixation in zygoma fractures while two studies[23,25] concluded that two-point fixation is as effective to three-point fixation in zygoma fractures.

| S.no | Author (Year) | Country | Sample Size (n) | Mean Age (years) | Follow up | Conclusion |
|---|---|---|---|---|---|---|
| 1. | Ashraf et al (2019)[18] | Pakistan | 182 | 43.13 years | 6 months | Using three-point fixation results better as compared to two-point fixation in terms of malar height outcome |
| 2. | Candamourty et al (2013)[19] | India | 20 | 39.5 years | 4 weeks | Three-point fixations are preferred in zygomatic complex fractures to avoid rotation of fragment postoperatively in vertical or horizontal axis. P value not specified |
| 3. | Dutt et al (2018)[20] | India | 40 | 37.23 years | 6 weeks | Zygomatic bone fracture is not frequently observed among facial bone fractures, Management with three- point fixation appears better than two -point fixation |
| 4. | Gawande et al (2021)[21] | India | 20 | Not mentioned | 5 years | Alignment of the fracture at three points and fixation at two stable points provide the most accurate and satisfactory postoperative results |

| | | | | | | |
|---|---|---|---|---|---|---|
| **5.** | Hasse et al (2011) [22] | Brazil | 30 | 33 years | 16 months | The authors did not specify which form of fixation was superior in the study |
| **6.** | Kim et al (2018)[23] | Korea | 27 | 44.8 years | 12 weeks | There was little difference in post operative stability between the groups, hence the amount of displacement is not a very important consideration when deciding the fixation method, including the number and location |
| **7.** | Latif et al (2017)[24] | Saudi Arabia | 50 | 32.62 | 6 weeks | It was concluded from the study that three- point fixation technique in the treatment of zygomatic bone fractures is a better option in order to minimize the post operative complications like altered malar height and vertical dystopia |
| **8.** | Nasr et al (2016)[25] | Egypt | 40 | 29.6 years | 6 weeks | Two-point fixation modality for displaced ZMC fractures is almost as effective as three-point fixation and prevents post reduction rotation or clinical displacement with significantly lower cost. |
| **9.** | Parashar et al (2007)[26] | India | 22 | 28.45 years | One year | The authors recommended that the three-point rigid fixation of fractured zygoma after accurate reduction maintains adequate stabilization against masticatory forces during fracture healing |
| **10.** | Rana et al (2012)[27] | Germany | 100 | 31.60 years | 6 weeks | Based on this study open reduction and internal fixation using three- point fixation by miniplates is the best available |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | method for the treatment of zygoma fractures |
| **11.** | Young Ji et al (2016)[28] | Korea | Not mentioned | 40.2 years | 10 years | It was concluded from the study that three-point fixation technique in the treatment of zygomatic bone fractures is a better option in order to minimize the postoperative complications like altered malar height and vertical dystopia |

**Table 1:** showing descriptive study characteristics of included studies

## Assessment of methodological Quality of included studies

All the included studies were largely comparable in methodological quality. All the included studies had moderate to high risk of bias with all the respected domains. The highest risk of bias was seen for blinding of outcome assessment (detection bias). Among the included studies, Parashar et al 2007[26] and Rana et al 2017[27] had the high risk of bias compared to all other studies. Candamourty et al 2013[19] reported lowest risk of bias. Domains of incomplete outcome data (attrition bias) and blinding of participants and personnel (performance bias) were given at the lowest risk of bias by included studies while blinding of outcome assessment (detection bias) was given highest risk of bias. Risk of bias of included studies through Cochrane risk of bias (ROB)-2 tool is depicted in **Figure 2 and 3** as shown below.

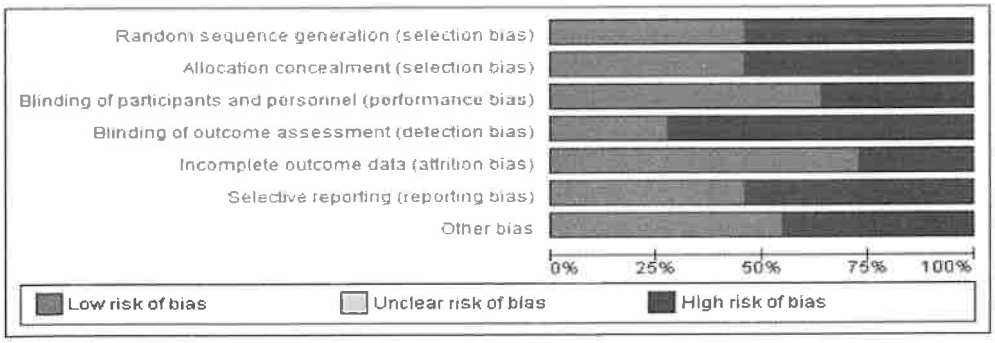


**Figure 2:** showing risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

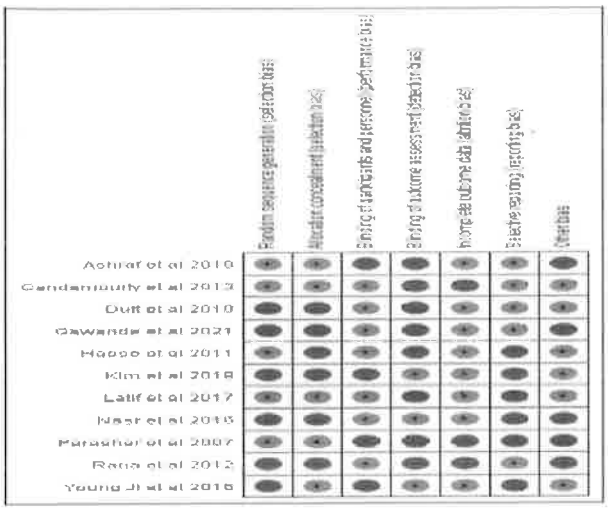


**Figure 3:** showing risk of bias summary: review authors' judgements about each risk of bias item for each included study.

## Synthesis of Result

Eight studies containing data on 471 ($n$=471) participants, of which ($n$=237) participants were evaluated by two – point fixation and ($n$=234) patients were evaluated by three – point fixation for the evaluation or the correction of zygomaticomaxillary fractures. The mean age of participants was 34.67 years. The standardized mean difference is used as a summary statistic in meta-analysis when the studies all assess the same outcome but measure it in different way. Therefore, it is necessary to standardized the results of the studies to a common scale before they can be combined to an overall pooled estimate.

As shown in **Figure 4.** the Std. Mean Difference is -0.21 (-0.83 – 0.41) and the pooled estimates favours two – point fixation. This signifies that the correction of zygomaticomaxillary fractures on an average is 0.21 times more by two – point fixation as compared to three – point fixation but it is not statistically significant ($p$=0.51). Both are more or less equally.

Among all the included studies, Ashraf et al 2019 had highest weightage at the overall pooled estimate while the lowest weightage was observed for Gawande et al 2021 at the pooled estimate. Weight of the study is directly proportional to the sample size (n) and inversely proportional to the variability. Box represents the weight of each study while the black horizontal line represents the 95% confidence limit. Bigger the size of box, more the weightage

of study at the pooled estimate and wider the horizontal line, more the presence of variability and less weightage of that individual study at the overall pooled estimate

By employing the random effect model the $I^2$ statistic showed 89%, the heterogeneity for $Tau^2$ was 0.68, $x^2$ being p<0.00001 and the overall effect for Z value being 0.66(P=0.51).

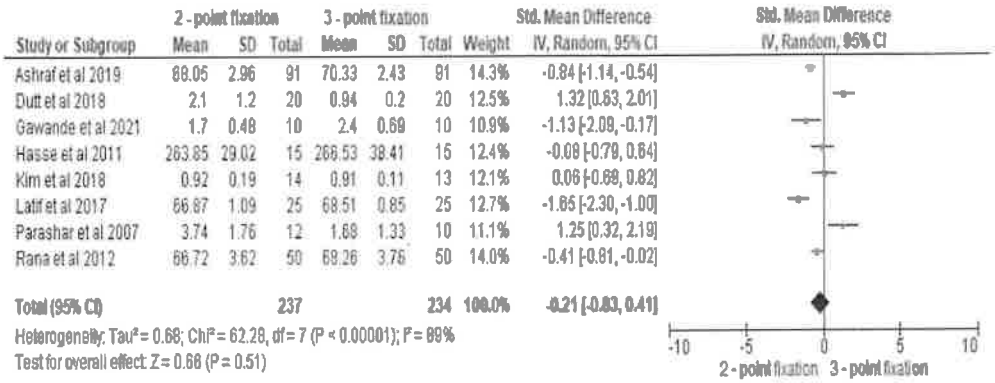


**Figure 4:** showing Forest plot showing staged arthroplasty versus simultaneous arthroplasty with regards to the inter-incisal opening

The funnel plot did show significant asymmetry, indicating presence of publication bias as shown in **Figure 5.** Funnel plot showing asymmetric distribution with systematic heterogeneity of individual study compared to the standard error, showing presence of publication bias in the meta-analysis.

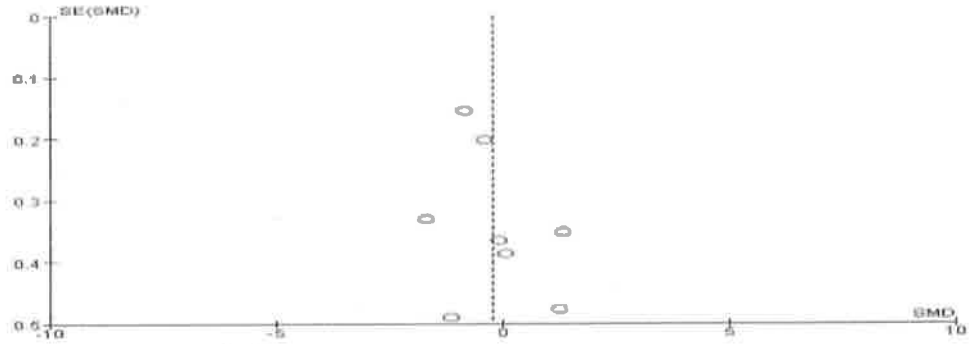


**Figure 5:** showing Begg's Funnel plot with 95% confidence intervals demonstrating asymmetric distribution with systematic heterogeneity of individual study compared with the standard error of each study, indicating a presence of publication bias.

## Discussion

The zygomaticomaxillary complex is an important part of the facial skeleton, and because of its lateral prominence is commonly injured, particularly in road traffic accidents and interpersonal violence[4]. Hence it is the second most common mid-facial bone fractured after the nasal bones and overall represents 13% of all craniofacial fractures. However, the incidence and etiology vary from area to area; another study shows that zygomatic bone fractures were commonly found among young males and the most common cause was found to be road traffic accidents[27].

These injuries can result in both functional (diplopia, trismus, and paraesthesia) and aesthetic deformities like midfacial widening, malar flattening and globe malposition[4].

Because of its importance in the facial skeleton, which dictates soft tissue overlay and harmony, zygomaticomaxillary complex fractures require suitable diagnosis and effective management to restore premorbid form and function[4].

Despite the high frequency of the zygomaticomaxillary complex (ZMC) fractures, there is no consensus among surgeons regarding the best surgical management. Thus, the surgical treatment of these fractures remains challenging. Basically, four principles must be considered when undertaking the repair of a facial fracture: namely, adequate exposure, proper reduction, stable fixation, and minimal complications[27].

The use of open reduction and internal fixation of simple displaced fractures of the zygomais an attempt to define the simplest method of achieving premorbid aesthetic and post-reduction stability.

Various surgical techniques have been described for the reduction of the zygomatic complex fracture. Open reduction with surgical incisions has been accomplished through Keen's approach, Gillie's approach, bi-coronal scalp flap approach, or the more popular Dingman's approach[27].

Historically, surgeons have focused on the number and location of buttresses that should be repaired for optimal ZMC fracture stability[12].

The need for one-point, two-point, three-point, or four-point fixation should be based on fracture stability, and applying the minimum amount of hardware to maintain fracture reduction throughout the process of healing. This approach has been termed functionally stable fixation[12].

Irrespective of the fixation used, reduced fractures are vulnerable to postoperative displacement due to masticatory forces, and hence result in a delayed malar asymmetry and vertical dystopia[12]. According to Rudderman and Mullen (1992), the displacement may occur in six possible directions of motions: translation about the x, y, z-axis and rotation about the x, y, z-axis. In spite of several academic debates that exist in the literature regarding the fixation of ZMC fractures, there is not one conclusive treatment that is used as a gold standard to treat zygomaticomaxillary complex fractures. Thus, we undertook this study to systematically review the existing literature on treatment and management of ZMC fractures using two-point vs three-point fixation techniques. The aim was to of systematically review the existing scientific literature to determine whether two – point or three – point fixation is a better treatment alternative for the patients with zygomaticomaxillary fractures through a meta-analysis.

In our review, eleven studies[18-28] were included that fulfilled the inclusion criteria. Data was evaluated from an aggregate of 531 (n) patients with a mean age of 36.01 years. Data of two – point fixation was evaluated from 237 (n) patients while data of three – pint fixation was evaluated from 234 (n) patients. Among the included studies, four studies[19-21,26] studies were conducted in India, two studies[23, 28] were conducted in Korea, one study[18] in Pakistan, one study[22] in Brazil, one study in Saudi Arabia[24], one study in Egypt[25] and one study in Germany[27]. Among the included studies, eight studies[18-21,24,26-28] concluded that three-point fixation is better as compared to two-point fixation in zygoma fractures while two studies[23,25] concluded that two-point fixation is as effective to three-point fixation in zygoma fractures.

Among the included studies, eight studies[18,20,21-24,26-27] were involved in meta-analysis. Eight studies[18,20,21-24,26-27] containing data on 471 ($n$=471) patients, of which ($n$=237) participants were evaluated by two – point fixation and ($n$=234) patients were evaluated by three – point fixation for the evaluation or the correction of zygomaticomaxillary fractures. The mean age of participants was 34.67 years. The standardized mean difference is used as a summary statistic measure. The Std. Mean Difference (SDM) is -0.21 (-0.83 – 0.41) and the pooled estimates favours two – point fixation which signifies that the correction of zygomaticomaxillary fractures on an average is 0.21 times more by two – point fixation as

compared to three – point fixation but it is not statistically significant ($p$=0.51). Both are more or less equally.

Although, eight studies[18-21,24,26-28] concluded that three-point fixation is better as compared to two-point fixation in zygoma fractures while two studies[23,25] concluded that two-point fixation is as effective to three-point fixation in zygoma fractures but our pooled estimate through quantitative synthesis signifies that both the two – point fixation and three – point fixation methods are equally effective in the treatment of zygomaticomaxillary fractures.

## Conclusion

To conclude, zygomaticomaxillary complex fractures are commonly occurring fractures of the midface that occur due to various etiological factors, with road traffic accidents being the primary cause. The literature includes a variety of different treatment modalities and methods of fixation that could be employed to treat these fractures. However, a uniform consensus is not available to date, and this remains one of the most debated topics in maxillofacial surgery.

In our systematic review, we aimed to evaluate which method of fixation is more effective in the treatment of zygomaticomaxillary complex fractures. A comprehensive search of the literature identified eleven articles that fit the inclusion criteria.

Our pooled estimate through quantitative synthesis signifies that both the two – point fixation and three – point fixation methods are equally effective in the treatment of zygomaticomaxillary fractures. Hence it can be concluded that two-point fixation is equally effective compared to three-point fixation in zygomaticomaxillary complex fractures.

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# Report- Dr.Shobha- Paper-1

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**Title:** Efficacy of nasal floor augmentation on the survival rate of dental implants: A Systematic review

**Abstract**

**Background:** Despite the fact that Nasal floor augmentation was first described more than three decades ago, the information on the literature regarding this procedure and technique and the predictability of dental implants placed in conjugation with augmented nasal floor is rather scarce

**Aim:** To systematically review the existing scientific literature, to summarize and assess the efficacy of the nasal floor augmentation on the survival rate of dental implants by systematically reviewing the available literature.

**Methods:** Review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Electronic databases like PubMed, google scholar and Ebsco Host were searched from 2000 to December 2021 for studies reporting efficacy of nasal floor augmentation and reporting outcomes in terms of survival rates of dental implants. Quality assessment of included comparative follow up studies was done using the critical checklist put forward by the Joanna Briggs Institute (JBI) was used.

**Results:** Only nine studies fulfilled the eligibility criteria and were included in the qualitative synthesis. Of these nine studies, five were case reports and four comparative follow up studies. A total of 14 implants were placed in five patients with a survival rate of 100% in included case reports while a total of 408 implants were placed in 130 patients with survival rates ranging from 89% to 100% in included comparative follow up studies. No complications were observed during follow ups and the patients were satisfied with the functional and aesthetic results of the treatment. Quality assessment of included studies showed moderate to low risk of bias with overall high quality of studies.

**Conclusion:** The results of this systematic review indicate that implant placement by nasal floor augmentation techniques can be considered as a predictable treatment modality. However, due to the scarcity of literature, more studies should be carried out on proving the efficacy of nasal floor augmentation on survival rate or success of dental implants.

**Keywords:** Dental implant, nasal floor augmentation, implant success, implant survival

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# Report- Dr.Shobha- Paper-2

*by* Dr. Shobha

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**File name:** Nasal_Floor_Augmentation_for_Dental_Implants_-_MANUSCRIPT.pdf (197.92K)
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**Title:** Efficacy of nasal floor augmentation on the survival rate of dental Implants: A Systematic review


## Abstract

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**Keywords:** Dental implant, nasal floor augmentation, implant success, implant survival

## Introduction

It was strongly suggested that a lost tooth must be replaced by the restorative procedures in order for the patients to benefit from their dentition masticatory function and aesthetics.[1] Over the years, various treatment methods have been used by the clinicians to replace lost teeth such as: removable partial dentures, resin bonded or cemented fixed partial prosthesis. These treatment methods could not fulfill the patients and clinicians demand as long as preparation of adjacent intact teeth was a main part of their procedures. Especially, in anterior region of maxilla, reestablishment of aesthetic is a crucial task which cannot be accomplished by these treatment modalities properly.[2]

The loss of teeth affects the aesthetics and function of the orofacial region and consequently compromises the patient's quality of life.[3] The goal of modern dentistry is to restore oral function, appearance, and aesthetics and to improve patient's health. Implant placement in the maxilla is often limited by insufficient bone width and height after teeth loss and by the proximity of the anatomical structures, nasal cavity, and maxillary sinus.[4] In the anterior maxilla, the alveolar ridge dimensions influence implant location, position of the lip, and the architecture of the free gingival margin.[5] Bone resorption after tooth loss is usually dramatic and irreversible, and more prominent in the first year. Resorption can be vertical or horizontal, leaving the area without sufficient bone to place implants. In the anterior maxillary region, nasal floor elevation could serve as an option for bone augmentation to enable dental implant placement.[6] Despite the anatomical proximity, rehabilitation of the anterior part of the maxilla is even more challenging. The pattern of remodelling after tooth loss leads to vertical and horizontal bone resorption, leaving an inadequate alveolar ridge for dental implantation.[7] Additionally, the high aesthetic and functional demands of the patient makes the necessity of immediate provisionalization an obstacle for large reconstructions. As the nasal cavity is usually the height limit for implant placement in the anterior area, nasal floor augmentation emerges as a possibility for rehabilitation of the anterior-superior region.[8]

Nasal floor augmentation techniques was first described by Adell et al[9] and Jensen et al[10] reported on reconstruction of the severely resorbed maxilla using nasal floor elevation with autogenous bone grafts. Lundgren et al[11] reported on a two-stage technique using autogenous bone grafts to the nasal floor for implant placement. Misch et al[12] discussed a subnasal elevation techniques for implant placement using bone substitutes but scientific production regrading this procedure and the predictability of dental implants inserted in association with this

technique are still limited. Garg et al in 1997 described nasal floor augmentation as a technique for implant placement in severely resorbed maxilla with less than 10 mm of residual ridge height. He advocated the use of intraoral donor sites for autogenous bone harvest to predictably elevate the nasal mucosa by 3 to 5 mm. He further recommended that implants be placed after consolidation of the graft.[13] A modification of this technique was reported by Hising et al, in which a mixture of autogenous bone harvested from the chin, bovine bone mineral and biologic adhesive was used for the augmentation of three nasal cavities.[14]

El-Ghareeb and colleagues recently described a study aimed to evaluate the survival and success of dental implants placed in nasally grafted maxillae and inadequate height in the anterior arch to support implants underwent nasal floor augmentation. The nasal floor was exposed through an intraoral approach and grafted with osteoconductive substitutes. Twenty-four dental implants in six patients in six patients were placed, restored with bar-retained implant- supported overdentures after a traditional healing period and followed after prosthetic loading. Three patients received nasal floor augmentation and simultaneous implant placement, whereas the other three had a mean healing period of 6. Months before implant placement. The implant survival rate was 100% with no complications.[15]

The tougher and thicker nasal mucosa is difficult to pierce and relatively easy to repair. Another advantage of nasal floor augmentation is that in nasal sites, the membrane is consistently intact, while in antral sites, this is not so. The residual bone of the nasal floor often provides adequate initial implant stability, while in posterior maxilla often presents major bone deficits, resulting in a thin, low-density antral floor (residual ridge) in which low implant stability can be expected.[16]

Despite the fact that Nasal floor augmentation was first described more than three decades ago, the information on the literature regarding this procedure and technique and the predictability of dental implants placed in conjugation with augmented nasal floor is rather scarce. Going through evidences, till date no study has provided a comprehensive, qualitative analysis on the efficacy of nasal floor augmentation on the survival rate of dental implants. Therefore, we updated our research for related articles and conducted a systematic review with the aim to summarize and assess the efficacy of the nasal floor augmentation on the survival rate of dental implants by systematically reviewing the available literature.

## Methodology

### Protocol development

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement[17].

### Study design

The review question was to evaluate the outcome in terms of dental implant survival from nasal floor augmentation. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed "In patients requiring dental implant placement, what is the effect on implant survival of nasal floor augmentation?

The PICO criteria for this review were as follows:

**P (Participants)** – Patients requiring dental implant placement

**I (Intervention)** – Patients with dental implant placement in augmented nasal floor

**C (Comparison)** – "optional"

**O (Outcome)** – success or survival of dental implants placed in maxillary anterior tooth region

### Eligibility Criteria

a) **Inclusion Criteria:** following were the inclusion criteria

1) Studies involving placement of dental implant in augmented maxillary nasal floor
2) Studies involving outcome measures as success or survival of dental implants in augmented nasal floor
3) Articles from open access journals
4) Articles published in English language
5) Articles published from 2000 – 2021
6) Study design: Comparative studies, prospective studies, follow up studies, retrospective studies, case report, case series

b) **Exclusion Criteria:** following were the exclusion criteria

1) Studies that do not involve placement of dental implant in augmented maxillary nasal floor
2) Studies not reporting study outcome measures as success or survival of dental implants in augmented nasal floor
3) Articles not from open access journals
4) Articles published in other than English language
5) Articles not published from 2000 – 2021
6) Animal studies, in vitro studies were excluded
7) Articles on dental implants placed in maxillary posterior region

**Data extraction**

For all included studies, following descriptive study details were extracted by two independent reviewing authors and using pilot-tested customized data extraction forms in Microsoft excel sheet with the following headings included in the final analysis: author(s), country of study, year of study, mean age of the participants, study design, sample size, follow up period, survival rate and conclusion

**Search Strategy**

A comprehensive electronic search was performed till December 2021 for the studies published within the last 21 years (from 2000 to 2021) using the following databases: PubMed, google scholar and EBSCOhost to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and OpenGrey.

A manual search of oral and maxillofacial surgery journals, including the International Journal of Oral and Maxillofacial Surgery, British Journal of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, international journal of oral and maxillofacial surgery, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology, Journal of Cranio-Maxillofacial Surgery, Journal of Craniofacial Surgery, Journal of Maxillofacial and Oral Surgery and the journal of American Dental Association was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND. The relevant data was searched using the following keywords and their combinations: "nasal floor" (MeSH term) AND "dental implant" (MeSH term); "implant survival" (MeSH term) AND "maxillary anterior teeth" (MeSH term); "augmentation" (MeSH term) AND "nasal floor"" (MeSH term) AND survival (MeSH term); "dental implant with survival rates" (MeSH term) AND "augmented (MeSH term) AND "nasal floor elevation" (MeSH term); "dental implant" AND "survival rates" (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

**Screening Process**

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

## Assessment of methodological quality

The quality of included studies for comparative and prospective studies was evaluated based on Newcastle Ottawa Scale and accordingly a numeric score (NOS Score) was assigned[18]. It was designed to evaluate bias based on participant selection, study group comparability in cross-sectional study, attainment of exposure in case-control studies and outcome of interest in cohort study. It is a valid and reliable tool for assessing the quality of non-randomized studies. supported by the Cochrane Collaboration for the quality appraisal of non-randomized trials. The NOS uses a nine-star rating system with a maximum of four points available for selection, two for comparability and three for the assessment of the outcome or exposure. The tool was deemed acceptable for the appraisal of cross-sectional studies as the effectiveness of an

intervention was not being measured. Quality appraisal of the included studies was undertaken by the two authors and a third author was consulted in the event of any discrepancy. A study with a score from 7 to 9 will be considered as high quality, 4 to 6 will be considered as moderate quality and 0 to 3 will be considered as low quality or very high risk of bias.

Quality assessment for the included case reports and case series, the critical checklist put forward by the Joanna Briggs Institute (JBI) was used in order to assess the quality of studies[19].

## Results

### Study Selection

After duplicates removal, reference list of included studies (n=25) was screened. Of which five studies were excluded. After this full text articles (n=20) were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Only nine studies fulfilled eligibility criteria and were included in qualitative synthesis. A flowchart of identification, inclusion and exclusion of studies is shown in **Figure 1** below.

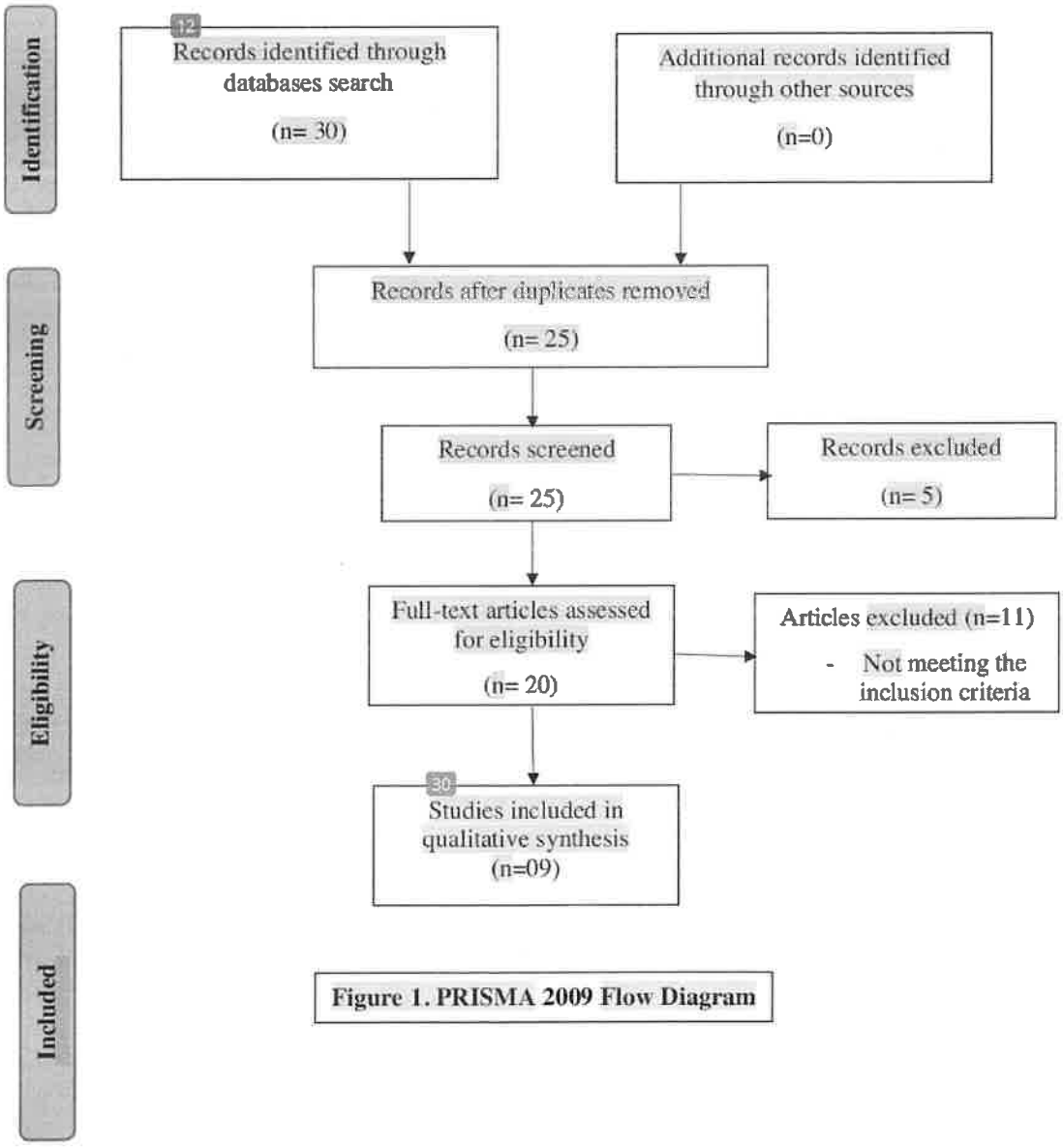


**Figure 1. PRISMA 2009 Flow Diagram**

## Study Characteristics

A summary of descriptive characteristics all included studies is shown in **Table 1.** Five case reports[20-24] and four comparative studies[25-28] describing nasal floor augmentation and implant survival or success were included. For involved case reports, data was evaluated from an aggregate of five patients with a mean age of 63.6 years with placement of 14 implants. For included comparative follow up studies, data was evaluated from an aggregate of 130 patients with a mean age of 55.25 years and with placement of 408 implants. All the case reports concluded that nasal floor augmentation proved to be a reliable method of dental implant insertion. No complications were observed during follow ups and the patients were satisfied with the functional and aesthetic results of the treatment and all studies had survival rate of 100%. For comparative follow up studies, two studies[25,27] showed 100% implant survival through the follow ups, one study[26] had 89.2% implant survival through the follow ups and one study[28] showed 96.3% implant survival. All studies concluded that nasal floor augmentation might serve as a predictable procedure and is an effective and safe procedure, which allows implant placement in areas with significant atrophy together with increased implant stability due to the bio-cortical support and nasal floor augmentation can be used for implant placement in atrophic maxillary regions with success rates that are comparable to those of implants placed in the maxillary sinus.

| S.no | Author (Year) | Country | Sample Size (n) | Mean Age of Volunteers | No. of implant placed | Follow up period | Survival rate | Conclusion |
|---|---|---|---|---|---|---|---|---|
| 1. | Kucukkurt et al, 2015[20] | Turkey | 1 | 63 years | 4 | 12 months | 100% | Nasal floor augmentationn may be a treatment modality and could serve as a feasible option for treatment of edentulous maxilla |
| 2. | Rafael et al, 2016[21] | Brazil | 1 | 48 years | 3 | Six months | 100% | Nasal floor augmentation proved to be a reliable |

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| | | | | | | | | method for dental implant |
| **3.** | Sentineri et al, 2016[22] | Italy | 3 | 67 years | 3 | Eighteen months | 100% | Nasal floor augmentation could be a minimally invasive, alternative method for vertical bone augmentation |
| **4.** | Anitua et al.2021[23] | Spain | 1 | 65 years | 2 | 10 years | 100% | Nasal floor augmentation might serve as a reliable method for Implant placement |
| **5.** | Jordan et al, 2022[24] | Croatia | 1 | 75 years | 2 | Not mentioned | 100% | Nasal floor augmentation can be considered as a predictable technique for rehabilitation in the atrophic anterior maxilla. |
| **6.** | Mazor et al, 2010[25] | Israel | 32 | 56.5 years | 100 | 28 months | 100% | Nasal floor augmentation might serve as a predictable procedure |
| **7.** | Garcia-Denche et al, 2014[26] | Canada | 14 | 65.9 years | 78 | 12 months | 89.2% | Nasal floor augmentation is an effective and safe procedure that can be used for implant placement with high success rates |
| **8.** | Lorean et al, 2014[27] | Israel | 67 | 58.7 years | 203 | 86 months | 100% | Nasal floor augmentation might serve as a reliable |

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| | | | | | | | | method for reconstruction of the anterior atrophic maxilla when residual height is insufficient |
| **9.** | Parhiz et al, 2017[28] | Iran | 14 | 40 years | 27 | 6 months | 96.3% | Implant placement by nasal floor augmentation techniques can be considered as a predictable treatment modality |

**Table 1:** showing descriptive study characteristics of included studies

## Assessment of Methodological Quality

Among the included case repots, overall quality appraisal of the included studies were high as all the questions under the checklist were answered by all the studies as **shown below in Figure 2**

| **Questions** | **Yes** | **No** | **Unclear** | **Not applicable** |
|---|---|---|---|---|
| 1. Were patient's demographic characteristics clearly described? | Present | - | - | - |
| 2. Was the patient's history clearly described and presented as a timeline? | Present | - | - | - |
| 3. Was the current clinical condition of the patient on presentation clearly described? | Present | - | - | - |
| 4. Were the diagnostic tests or assessments methods and the results clearly described? | Present | - | - | - |
| 5. Was the intervention(s) or treatment procedure(s) clearly described? | Present | - | - | - |
| 6. Was the post intervention clinical condition clearly described? | - | - | - | - |
| 7. Were adverse events identified and described? | Present | - | - | - |
| 8. Does the case report provide takeaway lessons? | Present | - | - | - |

**Figure 2:** shows quality appraisal of included case reports using Joanna Brigga Checklist

Among the included cohort studies, none of the study reached the maximum score of the Newcastle Ottawa scale. The highest overall quality score was gained only by one study[25] . Only one study[25] gained the maximum score in the selection criteria and was considered to have the highest level of quality with an estimated low risk of bias; only one study[26] had high risk of bias for comparability outcome while for outcome, all the studies had moderate to low risk of bias. Risk of bias of included cohort studies through Newcastle Ottawa scale is depicted in **Figure 3** below.

| Author, year | Selection (Max = 4) | Comparability (Max = 2) | Outcome (Max = 3) | Overall quality score (Max = 9) |
|---|---|---|---|---|
| Mazor et al, 2010[25] | **** | ** | ** | 8 |
| Garcia-Denche et al, 2014[26] | *** | * | *** | 7 |
| Lorean et al, 2014[27] | ** | ** | *** | 7 |
| Parhiz et al, 2017[28] | ** | ** | ** | 6 |

**Figure 3:** shows Risk of bias of included cohort studies through Newcastle Ottawa scale

## Discussion

The aim of this systematic review was to summarize and assess the efficacy of the nasal floor augmentation on the survival rate of dental implants by systematically reviewing the available literature. Despite the fact that Nasal floor augmentation was first described more than three decades ago, the information on the literature regarding this procedure and technique and the predictability of dental implants placed in conjugation with augmented nasal floor is rather scarce.

Going through evidences, till date no study has provided a comprehensive, qualitative analysis on the efficacy of nasal floor augmentation on the survival rate of dental implants. Therefore, we updated our research for related articles and to our knowledge conducted a first systematic review with the aim to summarize and assess the efficacy of the nasal floor augmentation on the survival rate of dental implants by systematically reviewing the available literature.

The present systematic review summarizes evidence from case reports and comparative follow up studies on human participants receiving dental implants on nasal floor augmentation with mean follow up of 24 months. The results from the identified case reports with 5 patients with placement of 14 implants had an excellent survival rate of 100% with no evidence of delayed healing or complications and all studies suggested that Nasal floor augmentation might serve as a reliable method for Implant placement while results from the comparative follow up studies with 130 patients with placement of 408 implants also had an excellent survival rate from 89% to 100%. The highest survival rate was shown by two studies[25,27] while the lowest survival rate was shown by one study[26]. All studies concluded that nasal floor augmentation might serve as a predictable procedure and is an effective and safe procedure, which allows implant placement in areas with significant atrophy together with increased implant stability due to the bio-cortical support and nasal floor augmentation can be used for implant placement in atrophic maxillary regions with success rates that are comparable to those of implants placed in the maxillary sinus.

The strengths of this systematic review include the following of strict PRISMA guidelines, the extensive unrestricted literature search, the use of robust methodology pertaining to the qualitative synthesis of data, the assessment of the quality of evidence with the Newcastle Ottawa Scale (NOS) and the critical checklist put forward by the Joanna Briggs Institute (JBI) was used. For the quality assessment all the included studies, had moderate to low risk of bias

and overall quality of included studies were high indicating absence of potential and unavoidable sources of bias with less reporting deficiencies and variability.

However, few limitations were also present. Going through the evidences, there is a scarcity and paucity of literature on efficacy of nasal floor augmentation on the survival rate of dental implants. Even after going through an unrestricted search and eligibility criteria, the number of included studies for qualitative synthesis was very less. Only nine studies were included in our systematic review. There is a need to conduct more follow up studies on the efficacy of nasal floor augmentation on the survival rate or success of dental implants. Furthermore, there should a trial of conducting a systematic review and meta-analysis, for getting an overall pooled estimate of the success rate of dental implants placed on augmented nasal floor.

## Conclusion

The results of this systematic review indicate that implant placement by nasal floor augmentation techniques can be considered as a predictable treatment modality. However, due to the scarcity of literature, more studies should be carried out on proving the efficacy of nasal floor augmentation on survival rate or success of dental Implants.

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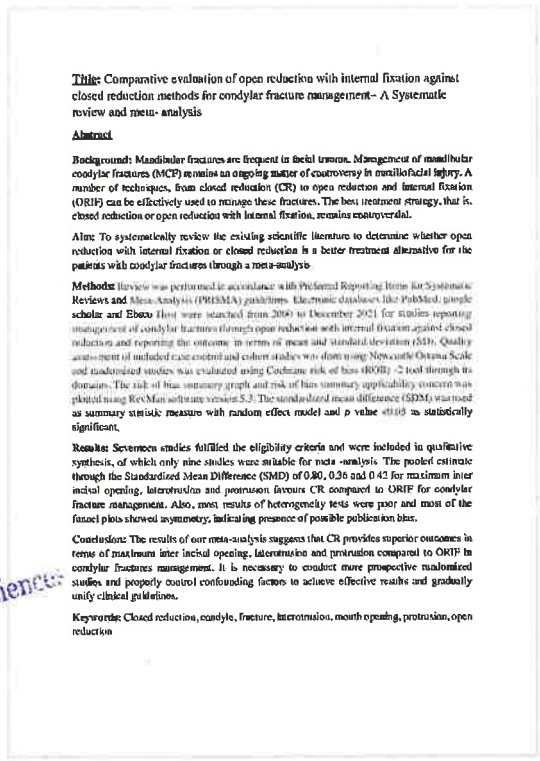

**Title:** Comparative evaluation of open reduction with internal fixation against closed reduction methods for condylar fracture management– A Systematic review and meta- analysis

**Abstract**

**Background:** Mandibular fractures are frequent in facial trauma. Management of mandibular condylar fractures (MCF) remains an ongoing matter of controversy in maxillofacial injury. A number of techniques, from closed reduction (CR) to open reduction and internal fixation (ORIF) can be effectively used to manage these fractures. The best treatment strategy, that is, closed reduction or open reduction with internal fixation, remains controversial.

**Aim:** To systematically review the existing scientific literature to determine whether open reduction with internal fixation or closed reduction is a better treatment alternative for the patients with condylar fractures through a meta-analysis.

**Methods:** Review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Electronic databases like PubMed, google scholar and Ebsco Host were searched from 2000 to December 2021 for studies reporting management of condylar fractures through open reduction with internal fixation against closed reduction and reporting the outcome in terms of mean and standard deviation (SD). Quality assessment of included case control and cohort studies was done using Newcastle Ottawa Scale and randomized studies was evaluated using Cochrane risk of bias (ROB) -2 tool through its domains. The risk of bias summary graph and risk of bias summary applicability concern was plotted using RevMan software version 5.3. The standardized mean difference (SDM) was used as summary statistic measure with random effect model and $p$ value $<0.05$ as statistically significant.

**Results:** Seventeen studies fulfilled the eligibility criteria and were included in qualitative synthesis, of which only nine studies were suitable for meta -analysis. The pooled estimate through the Standardized Mean Difference (SMD) of 0.80, 0.36 and 0.42 for maximum inter incisal opening, lateretrusion and protrusion favours CR compared to ORIF for condylar fracture management. Also, most results of heterogeneity tests were poor and most of the funnel plots showed asymmetry, indicating presence of possible publication bias.

**Conclusion:** The results of our meta-analysis suggests that CR provides superior outcomes in terms of maximum inter incisal opening, laterotrusion and protrusion compared to ORIF in condylar fractures management. It is necessary to conduct more prospective randomized studies and properly control confounding factors to achieve effective results and gradually unify clinical guidelines.

**Keywords:** Closed reduction, condyle, fracture, laterotrusion, mouth opening, protrusion, open reduction

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# Report- Dr.Shobha- Paper-3

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**Title:** Comparative evaluation of open reduction with internal fixation against closed reduction methods for condylar fracture management– A Systematic review and meta- analysis


## Abstract

**Background:** Mandibular fractures are frequent in facial trauma. Management of mandibular condylar fractures (MCF) remains an ongoing matter of controversy in maxillofacial injury. A number of techniques, from closed reduction (CR) to open reduction and internal fixation (ORIF) can be effectively used to manage these fractures. The best treatment strategy, that is, closed reduction or open reduction with internal fixation, remains controversial.

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**Conclusion:** The results of our meta-analysis suggests that CR provides superior outcomes in terms of maximum inter incisal opening, laterotrusion and protrusion compared to ORIF in condylar fractures management. It is necessary to conduct more prospective randomized studies and properly control confounding factors to achieve effective results and gradually unify clinical guidelines.



**Keywords:** Closed reduction, condyle, fracture, laterotrusion, mouth opening, protrusion, open reduction

## Introduction

Mandibular fractures are frequent in facial trauma. Condylar process fractures are highly frequent and prevalent in maxillofacial injuries and represent about 25 – 40% of all mandibular fractures[1]. Management of mandibular condylar fractures (MCF) remains an ongoing matter of controversy in maxillofacial injury. This controversy is reflected in the wide variety of opinions and proposed treatment modalities offered in the literature[2]. The best treatment strategy, that is, closed reduction or open reduction with internal fixation, remains controversial[3].

For decades, closed reduction (CR) has been the preferred treatment because the treatment is easier and less invasive and the results are comparable with no surgical complications. However, CR may employ varying periods of intermaxillary fixation (IMF) from 0 to 6 weeks followed by aggressive physiotherapy[4]. Nevertheless, CR appears to be associated with a high risk of long -term complications like temporomandibular joint (TMJ) pain, open bite, arthritis, malocclusion, deviation of mandible on opening and closing movements, TMJ dysfunction, facial asymmetry, inadequate restoration of vertical height of ramus and ankylosis may occur in condylar injuries treated closed[5].

A better understanding of the sequelae associated with closed treatment has resulted in a trend towards open treatment, allowing anatomic repositioning and internal fixation and enabling functional aftercare[6]. With the development of surgical techniques and improvement of internal fixation materials, open reduction and internal fixation (ORIF), which could be used to anatomically restore fractured condyle, has been gradually accepted and widely applied[7]. Open reduction and internal fixation (ORIF) allow anatomic repositioning and immediate functional movements of the jaw but has the potential complications of damaging the facial nerve and forming visible scars[8].

With the implementation of rigid internal fixation (IF) over the past 30 years, indications for surgical treatment of MCFs have broadened. A review of the literature revealed several studies comparing open reduction with internal fixation (ORIF) against closed Reduction (CR) in the treatment of MCFs, but there is still a continuing debate over how to best manage this type of fracture.

Going through evidences, till date no study has provided a comprehensive, quantitative analysis of comparison of open reduction with internal fixation (ORIF) against closed reduction on which best treatment option for condylar fractures could be established. Therefore, we updated

our research for related articles and conducted a systematic review with the aim to compare the open reduction with internal fixation (ORIF) against closed reduction according to the effect on maximum interincisal opening, laterotrusion and protrusion in adults with condylar fractures through a novel meta-analysis.

## Methodology

### Protocol development

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement[9].

### Study design

The review question was to evaluate the outcome in terms of maximum interincisal opening, laterotrusion and protrusion by comparing open reduction with internal fixation (ORIF) against closed reduction in management of condylar fractures. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed "What is the efficiency of open reduction with internal fixation (ORIF) against closed reduction in management of condylar fractures?

The PICO criteria for this review were as follows:

**P (Participants)** – Patients with condylar fractures

**I (Intervention)** – open reduction with internal fixation

**C (Comparison)** – Comparison of open reduction with internal fixation (ORIF) against closed reduction in management of condylar fractures

**O (Outcome)** – correction of condylar fractures in terms of maximum interincisal opening, laterotrusion and protrusion

### Eligibility Criteria

a) **Inclusion Criteria:** following were the inclusion criteria

1) Articles published in English language
2) Articles having sufficient data on open reduction with internal fixation (ORIF) against closed reduction in management of condylar fractures
3) Studies published between 2000 – 2021 and having relevant data on open reduction with internal fixation (ORIF) against closed reduction in management of condylar fractures

4) Clinical studies, case control studies, cohort studies, comparative studies
5) Articles from open access journals
6) Articles reporting the study outcomes in terms of mean and standard deviation

b) **Exclusion Criteria:** following were the exclusion criteria

1) Any studies conducted before 2000
2) Articles in other than English language
3) Reviews, abstracts, letter to the editor, editorials, animal studies and in vitro studies were excluded
4) Articles not from open access journals
5) Articles not reporting the study outcomes in terms of mean and standard deviation

**Data extraction**

For all included studies, following descriptive study details were extracted by two independent reviewing authors and using pilot-tested customized data extraction forms in Microsoft excel sheet with the following headings included in the final analysis: author(s), country of study, year of study, mean age of the participants, study design, sample size, type of condylar fracture, aetiology of fracture, treatment or fixation method.

**Search Strategy**

A comprehensive electronic search was performed till December 2021 for the studies published within the last 21 years (from 2000 to 2021) using the following databases: PubMed, google scholar and EBSCOhost to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and OpenGrey.

A manual search of oral and maxillofacial surgery journals, including the International Journal of Oral and Maxillofacial Surgery, British Journal of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, international journal of oral and maxillofacial surgery, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology, Journal of

Cranio-Maxillofacial Surgery, Journal of Craniofacial Surgery, Journal of Maxillofacial and Oral Surgery and the journal of American Dental Association was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND. The relevant data was searched using the following keywords and their combinations: "open reduction" (MeSH term) AND "condylar fractures" (MeSH term); "closed reduction" (MeSH term) AND "condylar fractures" (MeSH term); "internal fixation" (MeSH term) AND "condylar fractures"" (MeSH term) AND protrusion (MeSH term); "open reduction with internal fixation" (MeSH term) AND "closed reduction (MeSH term) AND "laterotrusion" (MeSH term); "mouth opening" AND "mandibular fracture" (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

**Screening Process**

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

**Quality assessment of included studies**

The quality of included studies for observational studies was evaluated based on Newcastle Ottawa Scale and accordingly a numeric score (NOS Score) was assigned[10]. It was designed to evaluate bias based on participant selection, study group comparability in cross-sectional study, attainment of exposure in case-control studies and outcome of interest in cohort study. It is a valid and reliable tool for assessing the quality of non-randomized studies, supported by the

Cochrane Collaboration for the quality appraisal of non-randomized trials. The NOS uses a nine-star rating system with a maximum of four points available for selection, two for comparability and three for the assessment of the outcome or exposure. The tool was deemed acceptable for the appraisal of cross-sectional studies as the effectiveness of an intervention was not being measured. Quality appraisal of the included studies was undertaken by the two authors and a third author was consulted in the event of any discrepancy. A study with a score from 7 to 9 will be considered as high quality, 4 to 6 will be considered as moderate quality and 0 to 3 will be considered as low quality or very high risk of bias.

The methodological quality among included studies was executed by using Cochrane collaboration risk of bias (ROB) -2 tool[11]. The tool has various domains like random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipments (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases through their signalling questions in Review Manager (RevMan) 5.3 software. The overall risk for individual studies was assessed as low, moderate or high risk based on domains and criteria. The study was assessed to have a low overall risk only if all domains were found to have low risk. High overall risk was assessed if one or more of the six domains were found to be at high risk. A moderate risk assessment was provided to studies when one or more domains were found to be uncertain, with none at high risk.

**Statistical analysis**

The standardized mean difference (SDM) with 95% CI was calculated for continuous outcomes. A fixed effects model (Mantel-Haenszel method) was used if there was no heterogeneity ($p > 0.05$ or I-squared $\leq 24\%$), otherwise a random effects model (Der Simonian-Laird method) was used[12]. All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). The significance level was kept at $p<0.05$.

## Assessment of heterogeneity

The significance of any discrepancies in the estimates of the treatment effects of the different trials was assessed by means of Cochran's test for heterogeneity and the $I^2$ statistics, which describes the percentage of the total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $P < 0.1$. A rough guide to the interpretation of $I^2$ given in the Cochrane handbook is as follows: (1) from 0 to 40%, the heterogeneity might not be important; (2) from 30% to 60%, it may represent moderate heterogeneity; (3) from 50% to 90%, it may represent substantial heterogeneity; (4) from 75% to 100%, there is considerable heterogeneity[13].

## Investigation of publication bias

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg's funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size[14].

## Results

### Study Selection

After duplicates removal, reference list of included studies was screened. Of which 121 studies were excluded. After this full text articles were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Only seventeen studies fulfilled eligibility criteria and were included in qualitative synthesis. Of which only nine studies were included in meta – analysis. A flowchart of identification, inclusion and exclusion of studies is shown in **Figure 1** below.

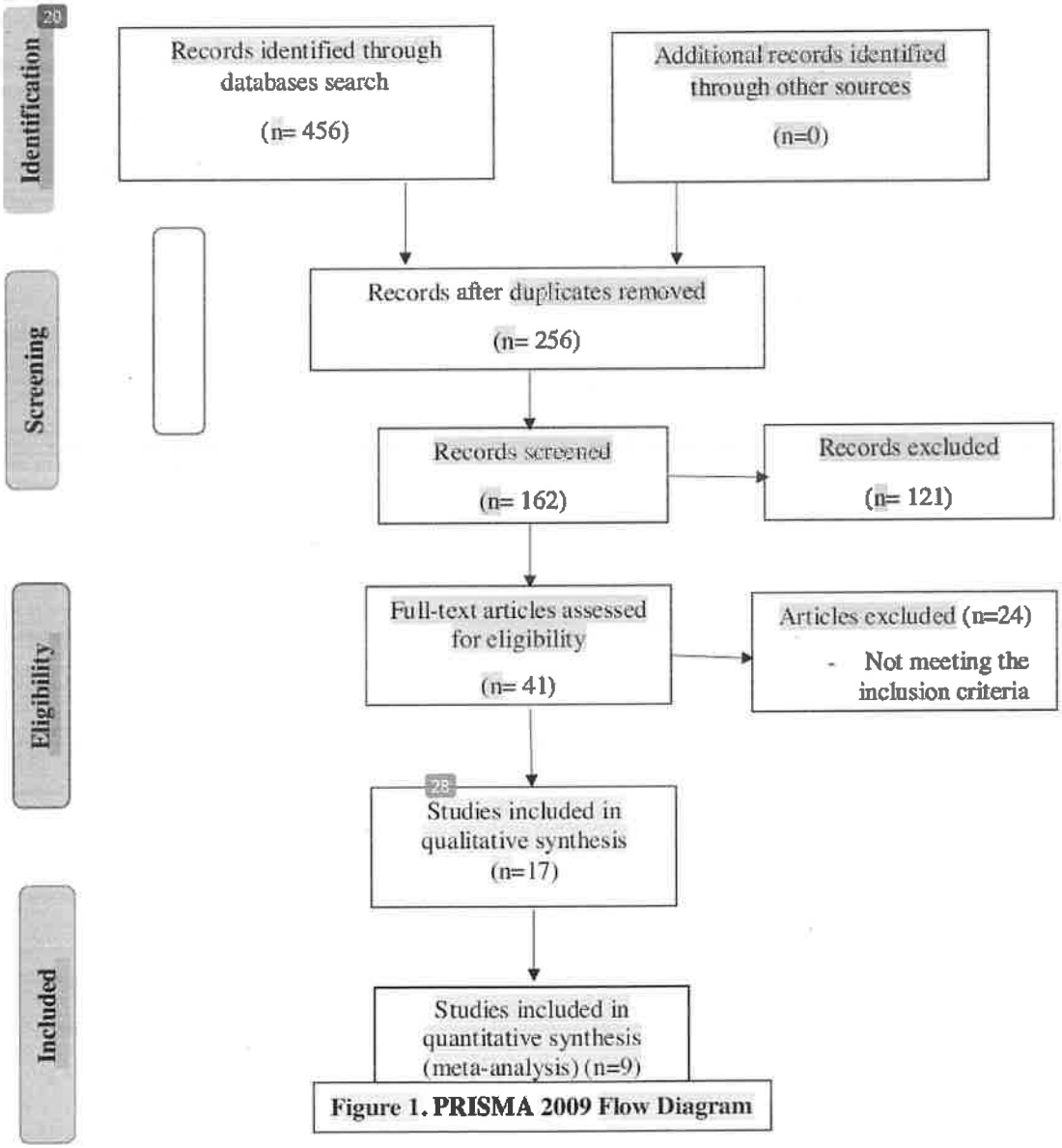


**Figure 1. PRISMA 2009 Flow Diagram**

## Study Characteristics

A summary of descriptive characteristics all included studies is shown in **Table 1.** Data was evaluated from an aggregate of 907 (n) patients with a mean age of 35.01 years. Data of open reduction with internal fixation was evaluated from 440 (n) patients while data of closed reduction was evaluated from 467 (n) patients. Among the included studies, nine studies[17,22,23-27,29,30] studies were conducted in India, four studies[19-21,28] were conducted in Germany, one study[15] in Korea, one study[16] in Brazil, one study in USA[18] and one study in Slovenia[31]. Among the included studies, three studies[15-17] had case control design, seven studies[18-24] had cohort or prospective study design while seven studies[25-31] had randomized controlled study design. All the studies evaluated patients with closed reduction and open reduction with internal fixation.

**Table 1:** showing descriptive study characteristics of included studies

| S. No. | Author (Year) | Country | Sample Size (ORIF / CR) | Mean Age of Volunteers | Study design | Type of condylar fracture | Closed reduction methods | Surgical approach |
|---|---|---|---|---|---|---|---|---|
| 1. | Yong Kim et al, 2014[15] | Korea | 33/15 | 42 years | Case control | Subcondylar | CR followed by IMF for 7 days | ORIF |
| 2. | Stypulkowski et al, 2019[16] | Brazil | 9/8 | Not mentioned | Case control | Condylar process | CR followed by IMF for 2-3 weeks | OR by retromandibular approach |
| 3. | Bansal et al, 2021[17] | India | 23/ 54 | Not mentioned | Case control | Condylar process | CR | ORIF |
| 4. | Thockmorton et al, 2000[18] | USA | 74/62 | 42 | Cohort | Condylar process | CR | ORIF |
| 5. | Landes et al, 2005[19] | Germany | 27/31 | 36 | Cohort | Subcondylar and condylar head | CT: IMF for 2 weeks | ORIF: preauricular approach |
| 6. | Jensen et al, 2006[20] | Denmark | 24/81 | 42 | Cohort | Concomitant condylar fracture | Not mentioned | ORIF |
| 7. | Kokemueller et al, 2012[21] | Germany | 44/31 | Not mentioned | Cohort | Condylar process | CR | ORIF |
| 8. | Kotrashetti et al, 2013[22] | India | 10/12 | Not mentioned | Cohort | Subcondylar | CT: IMF+ elastics for 3-4 weeks, ORIF: | ORIF: retromandibular approach |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | titanium miniplates and 2x6 mm miniplate screws | |
| 9. | Gareikpatii et al, 2021[23] | India | 25/25 | 26 | Cohort | Condylar process | CR | ORIF |
| 10. | Prakash et al, 2022[24] | India | 11/11 | 31.5 | Cohort | Condylar process | CR | ORIF |
| 11. | Karan et al, 2019[25] | India | 10/10 | Not mentioned | RCT | Condylar process and condylar neck | CR | ORIF |
| 12. | Khiabani et al, 2015[26] | India | 20/20 | Not mentioned | RCT | Subcondylar | CR with arch bars | ORIF |
| 13. | Rashid et al, 2020[27] | India | 24/25 | Not mentioned | RCT | Condylar process | CR | ORIF |
| 14. | Schneider et al, 2008[28] | Germany | 36/30 | Not mentioned | RCT | Condylar process | CT: IMF for 10 days + elastic ORIF: ORIF using 1 or 2 Miniplate/lag screw | ORIF: preauricular, transoral and retromandibular approach |
| 15. | Singh et al, 2010[29] | India | 18/22 | 25 | RCT | Subcondylar | CT: IMF+ elastic for 7 to 35 days ORIF: 2 mm titanium Miniplates+ IMF with elastic for 3-5 days | ORIF: retromandibular, anteroparotid approach |
| 16. | Singh et al, 2016[30] | India | 10/10 | Not mentioned | RCT | Subcondylar | CR + MMF | ORIF: retromandibular approach + IMF with 2mm miniplates |
| 17. | Vesnaver et al, 2011[31] | Slovenia | 42/20 | Not mentioned | RCT | Condylar process | CR | ORIF |

RCT: randomized controlled trial; ORIF: open reduction internal fixation; CR: closed reduction; IMF: intermaxillary fixation

## Assessment of methodological Quality of included studies

Among the included case control studies, none of studies reached the maximum score of the Newcastle Ottawa scale. Only one study[16] gained the maximum score in the selection criteria and was considered to have the highest level of quality with an estimated low risk of bias; two studies[15,17] had the maximum score in the comparability outcome and was considered to have the highest level of quality with an estimated low risk of bias; and all the studies had a partial score in the exposure outcome while only one study[17] had the highest score for exposure outcome having the lowest level of quality with an estimated low risk of bias. Risk of bias of included case control studies through Newcastle Ottawa scale is depicted in **Table 2** below.

| Author, year | Selection (Max = 4) | Comparability (Max = 2) | Exposure (Max = 3) | Overall quality score (Max = 9) |
|---|---|---|---|---|
| Yong Kim et al, 2014[15] | ** | ** | ** | 6 |
| Stypulkowski et al, 2019[16] | *** | * | ** | 6 |
| Bansal et al, 2021[17] | ** | ** | *** | 7 |

Among the included cohort studies, none of the study reached the maximum score of the Newcastle Ottawa scale. Only two studies[18,23] gained the maximum score in the selection criteria and was considered to have the highest level of quality with an estimated low risk of bias; only one study[19] had high risk of bias for comparability outcome while for outcome, all the studies had moderate to low risk of bias. Risk of bias of included cohort studies through Newcastle Ottawa scale is depicted in **Table 3** below.

| Author, year | Selection (Max = 4) | Comparability (Max = 2) | Outcome (Max = 3) | Overall quality score (Max = 9) |
|---|---|---|---|---|
| Thockmorton et al, 2000[18] | **** | ** | ** | 8 |
| Landes et al, 2005[19] | *** | * | *** | 7 |
| Jensen et al, 2006[20] | ** | ** | *** | 7 |
| Kokemueller et al, 2012[21] | ** | ** | ** | 6 |
| Kotrashetti et al, 2013[22] | *** | ** | ** | 7 |
| Gareikpatii et al, 2021[23] | **** | ** | ** | 8 |
| Prakash et al, 2022[24] | ** | ** | ** | 6 |

All fours RCTs were largely comparable in methodological quality. All the included studies had moderate to high risk of bias with all the respected domains. The highest risk of bias was seen for blinding of allocation concealment (selection bias). Among the included studies, three studies[26,28,31] had the high risk of bias compared to all other studies. Domains of random sequence generation (selection bias) and selective reporting (reporting bias) were given at the lowest risk of bias by included studies while allocation concealment (selection bias) was given highest risk of bias followed by blinding of outcome assessment (detection bias). Risk of bias for included randomized controlled trials through Cochrane risk of bias (ROB)-2 tool is depicted in **Figure 2 and 3** as shown below

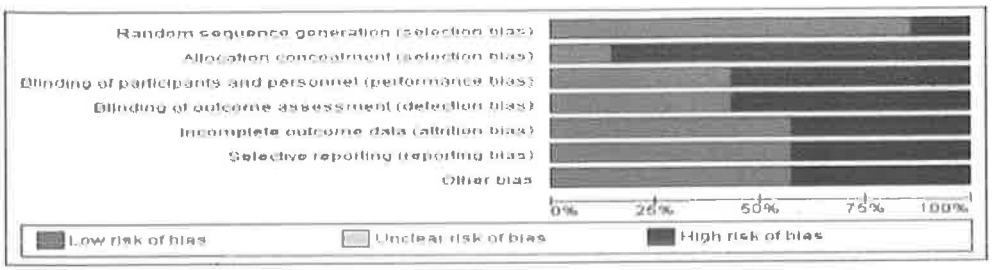


**Figure 2:** showing risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

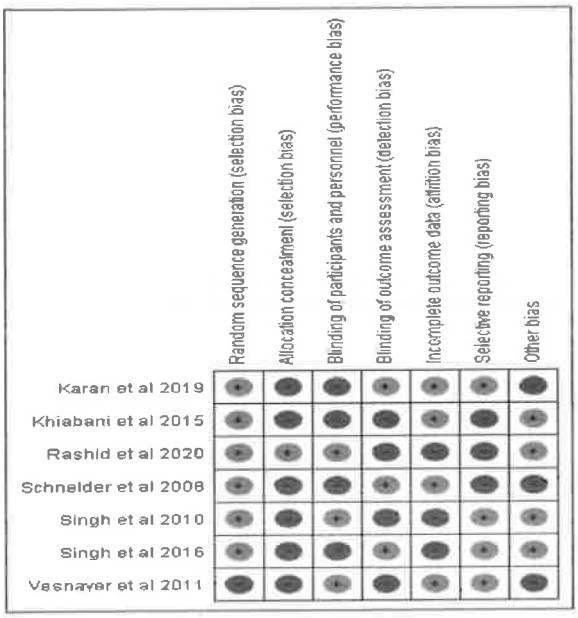


**Figure 3:** showing risk of bias summary: review authors' judgements about each risk of bias item for each included study

## Synthesis of result

Nine studies[18,19,22,26-31] containing data on 384 ($n$=384) patients, of which ($n$=197) patients were evaluated by open reduction with internal fixation and ($n$=187) patients were evaluated by closed reduction for the evaluation of management of condylar fractures. The mean age of participants was 34.67 years. The standardized mean difference is used as a summary statistic in meta-analysis when the studies all assess the same outcome but measure it in different way. Therefore, it is necessary to standardized the results of the studies to a common scale before

they can be combined to an overall pooled estimate. The outcome was assessed in terms of maximum interincisal opening, laterotrusion and protrusion.

A) **Maximum inter incisal opening**: As shown in **Figure 4**, nine studies[18,19,22,26-31] containing data on 384 ($n$=384) patients, of which ($n$=197) patients were evaluated by open reduction with internal fixation and ($n$=187) patients were evaluated by closed reduction for the maximum inter incisal opening as an outcome. The Std. Mean Difference is 0.80 (0.21 – 1.39) and the pooled estimates favours closed reduction. This signifies that the management of condylar fractures in terms of maximum inter incisal opening as an outcome is on an average is 0.80 times more by closed reduction as compared to open reduction with internal fixation but it is not statistically significant ($p$=0.008). Both are more or less equally.

Among all the included studies, Throckmorton et al 2000 had highest weightage at the overall pooled estimate while the lowest weightage was observed for Singh et al 2016 at the pooled estimate. Weight of the study is directly proportional to the sample size (n) and inversely proportional to the variability. Box represents the weight of each study while the black horizontal line represents the 95% confidence limit. Bigger the size of box, more the weightage of study at the pooled estimate and wider the horizontal line, more the presence of variability and less weightage of that individual study at the overall pooled estimate

By employing the random effect model the $I^2$ statistic showed 86%, the heterogeneity for $Tau^2$ was 0.68, $x^2$ being p<0.00001 and the overall effect for Z value being 2.65($p$=0.008).

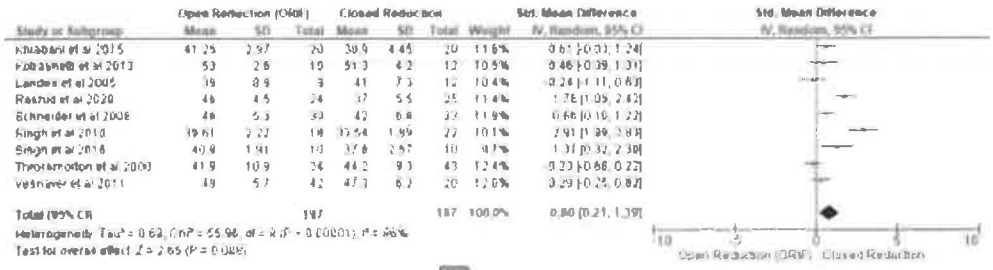


**Figure 4:** showing Forest plot showing open reduction with internal fixation versus closed reduction with regards to the maximum inter-incisal opening

The funnel plot did show significant asymmetry, indicating presence of publication bias as shown in **Figure 5.** Funnel plot showing asymmetric distribution with systematic heterogeneity of individual study compared to the standard error, showing a presence of publication bias in the meta-analysis.

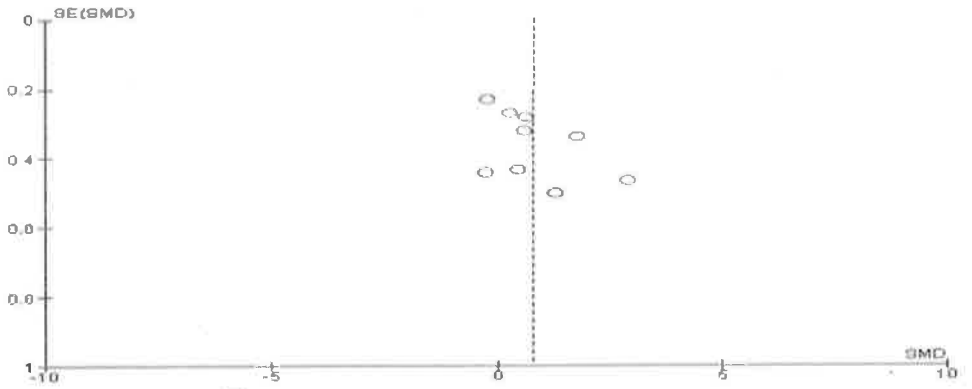


**Figure 5:** showing Begg's Funnel plot with 95% confidence intervals demonstrating asymmetric distribution with systematic heterogeneity of individual study compared with the standard error of each study, indicating a presence of publication bias.

B) **For laterotrusion**: As shown in **Figure 6,** five studies[18,19,22,28,29] containing data on 205 ($n$=205) patients, of which ($n$=99) patients were evaluated by open reduction with internal fixation and ($n$=106) patients were evaluated by closed reduction for the laterotrusion as an outcome. The Std. Mean Difference is 0.36 (-0.32 – 1.05) and the pooled estimates favours closed reduction. This signifies that the management of condylar fractures in terms of laterotrusion as an outcome is on an average is 0.36 times more by closed reduction as compared to open reduction with internal fixation but it is not statistically significant ($p$=0.30). Both are more or less equally. Among all the included studies, Throckmorton et al 2000 had highest weightage at the overall pooled estimate while the lowest weightage was observed for landes et al 2005 at the pooled estimate.

By employing the random effect model the $I^2$ statistic showed 91%, the heterogeneity for $Tau^2$ was 0.48, $x^2$ being (p=0.0004) and the overall effect for Z value being 1.05($p$=0.30).

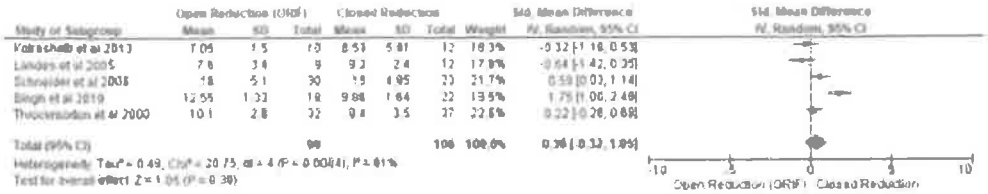


**Figure 6:** showing Forest plot showing open reduction with internal fixation versus closed reduction with regards to the laterotrusion

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in **Figure 7.** Funnel plot showing symmetric distribution with absence of systematic heterogeneity of individual study compared to the standard error, showing an absence of publication bias in the meta-analysis.

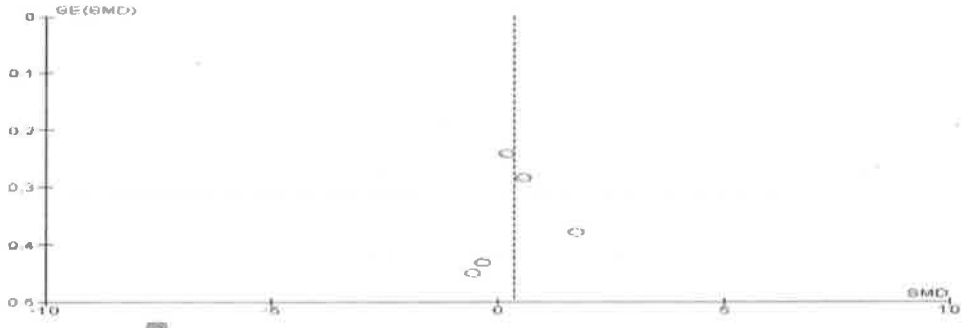


**Figure 7:** showing Begg's Funnel plot with 95% confidence intervals demonstrating symmetric distribution with absence of systematic heterogeneity of individual study compared with the standard error of each study, indicating an absence of publication bias.

c) **For protrusion**: As shown in **Figure 8,** five studies[18,19,28,29,30] containing data on 203 ($n$=203) patients, of which ($n$=99) patients were evaluated by open reduction with internal fixation and ($n$=104) patients were evaluated by closed reduction for the protrusion as an outcome. The Std. Mean Difference is 0.42 (-0.33 – 1.17) and the pooled estimates favours closed reduction. This signifies that the management of condylar fractures in terms of protrusion as an outcome is on an average is 0.42 times more by closed reduction as compared to open reduction with internal fixation but it is not statistically significant ($p$=0.27). Both are more or less equally. Among all the

included studies, Throckmorton et al 2000 had highest weightage at the overall pooled estimate while the lowest weightage was observed for Singh et al 2016 at the pooled estimate.

By employing the random effect model the $I^2$ statistic showed 84%, the heterogeneity for $Tau^2$ was 0.60, $x^2$ being ($p<0.0001$) and the overall effect for Z value being 1.09($p$=0.27).

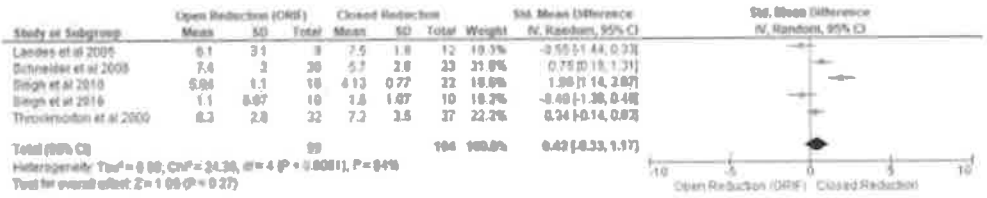


**Figure 8:** showing Forest plot showing open reduction with internal fixation versus closed reduction with regards to the protrusion

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in **Figure 9.** Funnel plot showing symmetric distribution with absence of systematic heterogeneity of individual study compared to the standard error, showing an absence of publication bias in the meta-analysis.

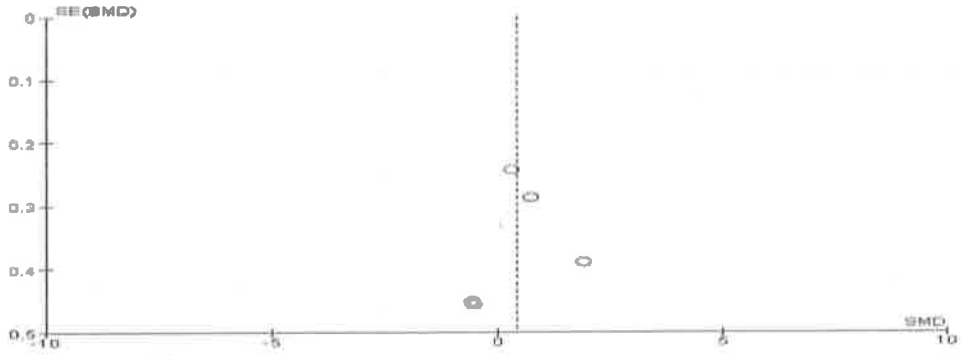


**Figure 9:** showing Begg's Funnel plot with 95% confidence intervals demonstrating symmetric distribution with absence of systematic heterogeneity of individual study compared with the standard error of each study, indicating an absence of publication bias.

## Discussion

Mandibular fractures are frequent in facial trauma. Condylar process fractures are highly frequent and prevalent in maxillofacial injuries and represent about 25 – 40% of all mandibular fractures[1]. Management of mandibular condylar fractures (MCF) remains an ongoing matter of controversy in maxillofacial injury. At present, the rational treatment regimen of condylar fractures remains controversial. This controversy is reflected in the wide variety of opinions and proposed treatment modalities offered in the literature[2]. The best treatment strategy, that is, closed reduction or open reduction with internal fixation, remains controversial[3]. A general consensus is that non-displaced condylar fractures should be treated conservatively, while displaced or dislocated condylar fractures should be treated surgically[32].

Going through evidences, till date no study has provided a comprehensive, quantitative analysis of comparison of open reduction with internal fixation (ORIF) against closed reduction on which best treatment option for condylar fractures could be established. Therefore, we updated our research for related articles and conducted a systematic review with the aim to compare the open reduction with internal fixation (ORIF) against closed reduction according to the effect on maximum interincisal opening, laterotrusion and protrusion in adults with condylar fractures through a novel meta-analysis.

Several classifications have been provided for mandibular condylar fractures, Loukota et al. 2005[33] sorted mandibular condylar fractures into three types, including condylar head fracture (diacapitular fracture), neck fracture and basic fracture, the latter two were also called extra-capsular fractures. Kozaliewicz et al. 2018[34] further divided condylar neck fracture into high neck fracture and low- neck fracture separated by the head anterior border point. Actually, the side and level of bone fractures play indispensable roles in the selection of treatment options and functional outcomes of either treatment[28].

In general, the results of this study show that closed reduction (CR) leads to improvements in measures of post operative maximum inter incisal opening, laterotrusive and protrusive movements. Meta – analysis had a total of nine studies[18,19,22,26-31] containing data on 384 ($n$=384) patients, of which ($n$=197) patients were evaluated by open reduction with internal fixation and ($n$=187) patients were evaluated by closed reduction for the evaluation of management of condylar fractures. The mean age of participants was 34.67 years. For instance, this meta – analysis revealed that CR patients had a greater postoperative maximum inter incisal opening than patients treated with open reduction (ORIF) with internal fixation with

SMD = 0.80 (0.21 – 1.39), $p = 0.008$. Laterotrusive movements was better in CR patients than ORIF patients with SMD = 0.36 (-0.32 – 1.05), $p = 0.30$ and also the protrusive movements was better in CR patients than ORIF patients with SMD = 0.42 (-0.33 – 1.17), $p = 0.27$ but these were not statistically significant. Also, most results of heterogeneity tests were poor and influenced the validity of overall effects to some extent. Most of the funnel plots showed asymmetry, indicating presence of possible publication bias.

Although, there are various guidelines regarding the management of condylar fractures of mandible by open or closed reduction, there is still a continuing debate over how to best manage these fractures. This is in part attributable to a potential misinterpretation of the literature from decades prior, a lack of uniformity of classification of the various anatomical components of the mandibular condyle, lack of scientifically-valid studies comparing treatments and a perceived potential to cause harm through the open approach based in part on the surgeon's lack of experience and critical examination of the literature[35]. Other factors confounding the strategy for the management of condylar fractures are the anatomic position of the fracture, the influence of fracture and surgery on facial growth, and the potential complications such as malocclusion, chin deviation, ankylosis and internal derangement of the joint[36].

It must be remembered that when one selects ORIF, one is increasing the cost of treatment because ORIF engenders more operating room time, more expensive hardware and a longer general anaesthetic. One is also imposing a potential set of complications that must be carefully weighed to determine if the potential benefits of open treatment are worth the potential surgical and post – surgical risks. The potential complications injury to nerves and blood vessels, sialocele, salivary fistulae, facial scarring, etc[37].

It should also be mentioned that individuals, who publish studies on the treatment of condylar fractures usually have a great experience at whatever treatment they are providing. Even though the outcomes of the studies in the existing literature might favour any possible treatment measures for many of the outcomes variables, individual practitioners may not see that benefit if their surgical experience is not great. One must be able to safely perform these treatment procedures with minimal complications if one is to see the improved outcomes[37].

## Conclusion

The results of our meta-analysis suggests that CR provides superior outcomes in terms of maximum inter incisal opening, laterotrusion and protrusion compared to ORIF in condylar fractures management. Better designed prospective randomized controlled clinical trials with adequate sample size and long follow up periods comparing open and closed treatment would be useful. Other variables such as treatment cost and patient satisfaction should be additionally studied to determine the differences between open and closed treatment of condylar fractures.

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