

Fixation Of Mandibular Angle Fracture Using 3D Titanium Miniplate Versus Standard Two Plate Fixation: A Randomized Clinical Trial

**Protocol submitted to
Faculty of Dentistry, Cairo University
for partial fulfillment of the requirements For the Master's Degree in
Oral and Maxillofacial Surgery**

By :Ahmed Jassim alsubaya

BDS . BDS Oral & Dental Medicine , KING FISAL University .

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Head of department's signature :

Supervisors' signature

1- Associate Professor Dr/ Mohamed Atef
Abdelrasoul

2- Lecturer. Dr. Salma Hassan

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2.				
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I. Administrative information:

1. Title:

**Fixation Of Mandibular Angle Fracture Using 3D Titanium
Miniplate Versus Standard Two Plate Fixation: A Randomized
Clinical Trial**

2. Protocol Registration:

This study will be registered at clinical trials.gov by ID number ...

3. Protocol version:

4st version.

4. Funding:

The trial is totally self-funded whether on a financial or a non-financial basis. Equipment units and some consumables are provided by the Department of Oral and Maxillofacial surgery, Faculty of Dentistry Cairo University.

5. Roles and responsibilities:

1) Associate Professor Dr/ Mohamed Atef Abdelrasoul

- Professor of Oral and Maxillofacial Surgery, Cairo University.
- Main supervisor.
- Responsible for auditing and main surgical supervision.

2) Lecturer. Dr. Salma Hassan

- Lecture of Oral and Maxillofacial Surgery, Cairo University.
- Assistant supervisor.
- Responsible for allocation, outcome assessment and supervising all surgical procedures.

II. Introduction:

6. Background and rationale:

Research question:

Does fixation of mandibular angle fracture using 3D titanium miniplate provide better occlusal bite force than standard two plate fixation?

Statement of the problem:

The management of facial trauma is one of the most challenging aspects for maxillofacial surgeons (**McCormick and Putnam, 2021**). The prominent position and configuration of the mandible make it one of the most frequent facial bones to be fractured. Open reduction and internal fixation are the preferred treatment methods for mandibular fractures (**Panesar and Susarla, 2021**). Mandibular fractures represent approximately two-thirds of all the maxillofacial fractures (nearly 70%) out of which fractures of mandibular angle represent 26-35% (**Nardi et al., 2020**).

So, the aim of the study is to evaluate whether fixation of mandibular angle fractures using a 3D titanium miniplate results in better occlusal bite force compared to standard two-plate fixation.

Rationale for conducting the research:

Mandibular fractures comprise most of the traumatic injuries, which are treated by an oral and maxillofacial surgeon (**Shah et al., 2019**). The most common etiological factor is road traffic accidents (RTA) (45.3%) followed by falls (42.6%), assaults (8.9%), sport injuries (2.2%), and gunshot wounds (0.89%) (**Alharbi et al., 2020**).

The mandible is frequently fractured because of its prominence, where it occupies a central and vulnerable position in the face (**Saad et al., 2017**). Its architecture is complex, consisting of an articulation with the cranial base, making it the only freely movable bone of the facial skeleton. It is subjected to strong biomechanical distractions by its intimate association with the facial musculature (**Elrewany et al., 2020**).

There are several reasons proposed for the increased occurrence of mandibular angle fracture: The abrupt change in the anatomy at mandibular angle region which is 20° in the vertical plane and 90° in the horizontal plane at the upper border, the presence of impacted mandibular third molars, less cross-sectional area due to the large amount of space occupied by the crypt of mandibular third molars and biomechanical consideration of angle as a lever area of mandible (**Barsoum et al., 2024**).

Previously the most popular method for mandibular fracture treatment was closed reduction plus intermaxillary fixation and open reduction with internal fixation with wire osteosynthesis, necessitating an average of 6 weeks of Intermaxillary fixation (IMF) for satisfactory healing.

This long period of IMF causes bad oral hygiene, increases the caries incidence and difficulty in speech and mastication (**El-Anwar, 2018**).

However, open reduction and internal fixation is the preferred treatment method of mandibular fractures but at the same time it is very expensive and needs an experienced surgeon to get the optimum results (**Ahmad et al., 2024**).

The use of double mini plates or a combination of mini and microplates for the treatment of mandibular body fractures is considered the gold standard treatment modality (**Mittal et al., 2020**). However, the disadvantages of the conventional mini plate system in mandibular body fractures include the precise adaptation required between the plate/bone interface, the requirement of an additional second plate at the superior border to counteract the tension forces, and the theoretically increased interferences in cortical blood supply (**Hu et al., 2019**).

Three-dimensional (3D) miniplates have been used in the treatment of mandibular fractures. Their geometry conceptually allows stability in three dimensions, and resistance against forces while maintaining a low profile and malleability (**Mohd et al., 2019**). It has been found that fixation of non-comminuted mandibular angle fractures with a 3D-miniplate was predictable. This plate is low in profile, strong yet malleable, facilitating reduction and stabilization at both the superior and inferior borders (**Mehra et al., 2023**).

There are a few studies comparing 3D miniplate versus conventional miniplate in treatment of mandible fractures. So, the aim of this study is to compare the transoral using 3D titanium miniplate and extraoral using two miniplates approaches for fixation of mandibular angle fractures.

Explanation for choice of comparators:

Due to the prominent position and configuration of the mandible, it is one of the most frequent facial bones to be fractured. Because of the mandible's contribution to speech, mastication, deglutition and to the form of the lower portion of the face, fractures of this structure must receive careful consideration. Successful treatment of mandibular fractures results in an anatomic bony union with restoration of normal occlusion and function.

7. Objectives:

The aim of this study is to compare the using 3D titanium miniplate and extraoral using two miniplates approaches for fixation of mandibular angle fractures.

Hypothesis:

We hypothesize that fixation mandibular angle fracture using 3D titanium miniplate will provide better occlusal bite force than intra oral fixation using two miniplates.

8. Trial design:

- Randomized clinical trial.
- Parallel group study.
- Allocation ratio 1:1.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

This study will be conducted in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry.

10. Eligibility criteria:

Inclusion Criteria:

- Age from 20 to 50 years.
- Males.
- Patients with mandibular angle fractures.

Exclusion criteria:

- Patients with contraindication to general anesthesia
- Patients with comminuted angle fractures.
- Patients with relevant systemic diseases contraindicating surgery or affecting bone healing.
- Patients with infected condyle and coronoid fractures.
- Gun-shot injuries.
- Edentulous fractures.
- Pathological fractures.

11. Interventions

All patients involved in this study will be divided randomly to two different groups:

- Group A: Patients will be managed through open reduction and internal fixation using a 3D titanium plate.
- Group B: Patients will be managed using 2 miniplates of titanium at tension and compression at osteosynthesis line.
- After taking a full history of the causal injury, all patients will be examined clinically by inspection and palpation both extra-orally and intra-orally to detect any associated maxillofacial fractures.

Surgical procedure:

- Complete laboratory investigations and medical consultations will be requested to reveal patients' fitness to undergo surgery under general anesthesia. An intraoral Obwegesser incision or extra oral submandibular approach will be done, and the fracture line will be exposed and reduced.
- Fixation will be done in group-I, 3-D titanium miniplate according to the extent and severity of fracture. Diagonally opposite screws were placed first, followed by the remaining two screws. Three-dimensional plate was contoured across the fracture line in such a way that the horizontal

crossbars were perpendicular to the fracture line and vertical struts were parallel to fracture line. In angle fractures, the upper crossbar was placed subapically to teeth. placing 3-D plates, proper adaptation and subapical placement of plate with monocortical screw fixation will be on the lateral cortex or on external oblique ridge.

-
- In Group II: two mini plates of titanium Mini-System will be used for fixation of the fracture; the first plate will be placed at the inferior border of the mandible from the buccal side, using biocritical screws to engage both the buccal and lingual cortices achieving proper fixation. In contrast, the second plate will be placed about 5 mm superior to the inferior plate or lateral to the external oblique ridge_ using monocortical screws engaging only the buccal cortex to avoid injuring teeth roots.

Intra-oral suturing will be done in both groups in a standard fashion using Vicarly 4/0, and the maxillomandibular fixation will be released.

Postoperative care and follow-up:

- Postoperative care and follow-up:
- All patients will receive the prescribed medications after surgery, including antibiotics, analgesics, anti-edematous, and mouthwash.
- All patients will be followed up and assessed clinically, one week, , one month, three months and 6 months. Postoperatively regarding different parameters such as wound healing, degree of mouth opening, the extent of postoperative edema, infection, and numbness of the lower lip and chin.
- All patients will be measure maximal incisal opening clinically by scall , after surgery ,after 3 months and after six months follow-up .
- All patients will be assessed occlusal force – Bite force measurement device on one- day , three-months and six- months follow-up.

PICO:

Does fixation of mandibular angle fracture using 3D titanium miniplate provide better occlusal bite force than the standard two plate fixation ?

PICO:

(P): Populations: Patients with mandibular angle fractures.

(I): Intervention: Fixation using a 3D titanium miniplate.

(C): Control: 2 miniplates of titanium.

(O): Outcomes

. Outcomes:

Prioritization of Outcome	Outcome	Method of Measurement	Unit of Measurement
Primary outcome	Occlusal force	bite force measurement device	N
Secondary outcomes	Patient satisfaction	visual analogue scale (VAS)	Number
	maximal incisal opening	Scale	mM

Outcome measurements will be done at two intervals at one week and three months postoperatively to assess the following parameters:

Patient satisfaction, pain, occlusal bite force, the accuracy of reduction, occlusal discrepancy, and the operating time.

Patient satisfaction will be measured on a visual analogue scale (VAS) with zero being unsatisfied and ten being satisfied.

- **The occlusion force** on the bite force will be measured by bite force measurement device: one after surgery, three-months and six-months follow-up.

13. Participant timeline

Figure. Example template of recommended content for the schedule of enrolment, interventions, and assessments.*

TIMEPOINT**	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
	-t ₁	0	t ₁	t ₂	t ₃	t ₄	etc.	t _x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
[List other procedures]	X							
Allocation		X						
INTERVENTIONS:								
[Intervention A]			←————→					
[Intervention B]			X		X			
[List other study groups]			←————→					
ASSESSMENTS:								
[List baseline variables]	X	X						
[List outcome variables]				X		X	etc.	X
[List other data variables]			X	X	X	X	etc.	X

14. Sample size:

- The outcome used (State 1ry or 2ry): **primary (occlusion force measurement at the end point 6 months)**
- Values used for outcome (e.g. mean difference, percentage, proportion etc.): **mean difference and standard deviation**

Entry 1: (mean difference between 2 groups, mean and standard deviation of group 1, proportion 1 or estimated prevalence): **mean and SD of control group = 596.8± 70.578**

- **Mean of Group 1 = 596.8**
- **SD of Group 1 = 70.578**

- Entry 2: (standard deviation of control group, mean and standard deviation of group 2, proportion 2 clinically important difference): **minimal clinical important difference estimated to be 105**

Alpha level of significance: **(5%) (0.05)**

Effect size used in calculation:

Power of the study: **(80%) (0.8)**

Statistical test used: **Independent t-test**

The calculated sample size: **8 patients per group with the total sample size 16 patients (2 groups).**

Increased number for anticipated missing data: **10 subjects in each group to compensate for a drop-out rate of 25%. (total sample size 20).**

Sample size calculation was performed using PS power

15. Recruitment:

- Patients' data will be enrolled in database of the Outpatient clinics of the Department of Oral & maxillofacial surgery, Faculty of Dentistry, Cairo University.
- If there is a potential eligibility, the patient will be examined thoroughly as described before.
- Consecutive sampling is done through screening of patients. This will continue until the target population is achieved.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

Principal investigator will carry out the randomization process using A software www.random.org with a ratio 1:1.

16b. Allocation concealment mechanism:

Sequential numbers for each card will be placed in opaque & sealed envelopes. These envelopes will be placed in a container.

16c. Implementation

All the patients whom provide an informed consent for participation as fulfill the inclusion criteria will be randomized.

DR.Mohamed Atef will generate the allocation sequence as well as assign the participants to will enroll the participants .

17. Masking/blinding:

This trial is considered a randomized single blind clinical trial due to the following:

- **The participants** will be blinded to the technique that will be used during the surgical procedure.
- **The operator** will not be blinded for both techniques during the surgical procedure as the two techniques are different.

The outcome assessor Dr. Salama Hassan cannot be blinded

C) Data collection, management, and analysis:

18. Data collection methods

18. Data collection methods

- Dr. Dr. Salama Hassan will be responsible for data collection. The collected data whether personal or statistical will be stored on paper and on electronic spreadsheets.
- The phone numbers and addresses of the patients included in the study will be recorded from them or extracted from the patient's file.
- Assessment and collection of baseline data is recorded pre-operatively, while assessment of outcome will be done immediately postoperative as well as 3 months and six months postoperatively.
- Measurements of primary outcome will be compared to the baseline data occlusion force bit device .
- Measurement of secondary outcome will measurement immediately ,three months and after six months .

Plans to promote participant retention and complete follow up.

- Telephone numbers of all patients included in the study will be recorded as a part of the written consent.
- A periodic regular follow up recalls will be planned after 3 months and 6 months
- All patients will receive a phone call at the time of the pre-determined follow up.

Plans for data collected from participants who discontinue or deviate from intervention protocols

- The patient is allowed to drop at any time from the study.
- Participant withdrawal will be recorded and the patient will be excluded from the study.
- A percentage in the sample size will be calculated to make up for any losses.
- The investigator may also withdraw participants from the study – only under certain strict conditions – and only if the proposed therapy were considered harmful to the patient.

Primary outcome:

- Occlusal force

Secondary outcome:

- Patient satisfaction.

- maximal incisal opening

19. Data management:

All these procedures will be done by Dr Salma Hassan .

- Data will be recorded on a diagnostic chart for each patient separately and will be saved with photographs and patient's questionnaire.
- Patient files are to be stored in numerical order and stored in secure and accessible place.
- All data will be saved electronically on the investigator laptop secured with a password.
- All data will be maintained in storage for 1 year after completion of the study.
- The electronic data and the scans of the patient will be backed up to a Google Drive folder for ensuring back up and ease of accessibility.

The supervisors will have access to the data when needed

Data transmission and editing:

The assessor data entry will be transmitted from the assessor to data base officer (as blind separate datasheets) who in return, will record them in a participant chart before sending them to the statistician.

Security and back up of data:

All forms of the procedures related to the study data will be kept in the project secure folder. Access to the study data will be restricted to the database officer.

A complete back-up of the primary database will be performed twice a month.

Back up of the periodic data analysis file will be kept secure.

20. Statistical methods:

Categorical data will be represented as frequency (n) and percentage (%) and will be analyzed using chi square test. Numerical data (N) will be explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. If the data was found to be normally distributed, it will be presented as mean and standard deviation values and independent t-test will be used for the analysis. If the assumption of normality was found to be violated; the data will be presented as median and range values and will be analyzed using Mann-Whitney U test. The significance level will be set at $p \leq 0.05$ for all tests. Statistical analysis will be performed with IBM® SPSS® Statistics Version 26 for Windows.

D) Data monitoring:

21. Monitoring

® IBM Corporation, NY, USA.

®SPSS, Inc., an IBM Company.

The main supervisor Dr Mohamed Atef will be responsible for data monitoring. he will evaluate the outcome measures and any possible side effects that might affect the outcome.

22. Harms

Intra operative complication or harms	Avoidance and treatment
Bleeding	Care should be taken during injection, avoid undesirable pressure and force. Give instructions to the patient to avoid any sudden movement. If needle breakage occurs, it must be retrieved.

Postoperative harms	Avoidance and treatment
Infection	Prevention requires disinfection of the skin before starting and adhering to the principles of sterility and prophylactic antibiotics.

Other possible adverse effects of the intervention which might be caused by the inaccurate translation of injection plan include edema, pain, and prolonged preparation time preoperatively. These may either be permanent or temporary.

23. Audit

Auditing of the study design will be done by the evidence-based committee - Faculty of Oral and Dental Medicine Cairo University.

IV. Ethics and dissemination

24. Research ethics approval

This protocol and the template informed consent will be reviewed by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University.

25. Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit to the patient or may affect patient's safety including changes of study objectives, study design, sample sizes, study procedures or significant administrative aspects will require a formal amendment to the protocol.

Such an amendment will be agreed upon by the council of oral and maxillofacial surgery department.

26. Informed consent

Researchers will introduce and discuss the trial to the patients who will be shown a video regarding the main aspects of the trial. Patients will then be able to have an informed discussion with the participating consultant Dr. Mohamed Atef
Researchers will obtain written consent from the patients willing to participate in the trial. All consent forms will be translated into Arabic.

27. Confidentiality

All study-related information such as photos, radiographs, forms, and charts will be stored in a password protected folder in the department database.

The password will be available to the team.

But any personal information related to the patient's ID will be stored in and will acquire a coded ID with access only to the database officer.

28. Declaration of interest

The study is self-funded and there is no conflict of interest to declare.

29. Access to data

All the research team will have access to the data set. All data sets will be password protected.

30. Post-trial care

All patients will provide the primary contact number in case there is any emergency. Follow up will continue until all patients are satisfied.

31. Dissemination policy

Study results will be published as a partial fulfillment of the requirements for Master Degree in Oral and Maxillofacial Surgery.

Topics suggested for presentation or publication will be circulated to the authors.

V. Appendices

32. Informed consent

Diagnostic chart:

First name: _____ Last name: _____ Date: _____

Birth date: _____ Age: _____ Gender: _____ Number: _____

Address: _____ Phone: _____

• **Medical history:**

- How would you describe your health? Excellent Good Fair Poor

- When did you have your last physical examination? _____

- **Are you currently being treated for any illness or medical condition?** Yes _____ No _____

If yes, please describe _____

- Have you ever had any kind of surgery? Yes _____ No _____ When did you have it? _____

What type of surgery did you have? _____

Have you ever had any trouble with **prolonged bleeding** after surgery? Yes _____ No _____- Do you have a **pacemaker** or any kind of artificial joint? Yes _____ No _____- **Are you taking any medication or drugs at this time?** Yes _____ No _____

What medications, drugs, or herbs are you taking? _____

Why are you taking these medications? _____

- **Ever had a reaction or complication to local anesthetic or drug (like penicillin)?** Yes _____ No _____

If yes, please explain _____

- **Please circle any present or past illness you now have or had in the past:**

Alcoholism/Addictions/Drug dependence	Cancer/ Tumor/ Neoplasm	Hepatitis/ Liver	Migraines/ Headaches
Allergies (Penicillin/Antibiotic, Aspirin/Tylenol, L.A., N2O/O2, Latex, other)	Diabetes	Herpes	Sinus Trouble/ ENT
	Epilepsy/ Fainting	HIV/ AIDS	Throid/Hormonal
	Glaucoma/ Visual	Immunosuppression	Ulcers/ Digestive
Anemia/bleeding	Head/Neck Injuries	Infectious Diseases	Venereal disease
Asthma/Respiratory	Heart Disease/ Angina/ Coronary/ Surgery/ pacemaker Rheumatic	Kidney	
Blood pressure /Hypertension/ circulatory	Fever/Murmur	Mental Illness/ Neural	Other

- **If female, are you pregnant?** Yes _____ No _____

Is there any other information that should be known about your health? _____

Signature of Patient (or Parent) _____ Date _____

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