

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison between 3-D Plates and Conventional miniplates in the management of parasymphysis and symphysis fractures of the mandible.

Protocol summary

Study aim

To compare the surgical outcome and post op complications of symphysis and parasymphysis fractures in 3-D and conventional miniplating plating system.

Design

A single blinded, randomized control trial in which cases and controls were sampled via consecutive sampling with concealed envelope method with a sample size of 62, enrolled between August 2023 to August 2024

Settings and conduct

30 Military Dental Centre, Combined Military Hospital, Peshawar Cantt., Peshawar, KPK

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pain following history of fall/ RTA/ trauma Age range of 18-50. Both genders, Male and Female American Society of Anesthesiologist ASA Class 1 Isolated mandible fracture Exclusion criteria: Infection at site of fracture Malunited fractures Comminuted fractures Panfacial trauma Patients with a bone pathology (Osteomyelitis, Osteoporosis and Paget's Disease) Chronic Illness (Diabetes, Asthma and Hypertension)

Intervention groups

Under strict aseptic conditions, general anesthesia and local anesthesia given in fracture vicinity by a single surgical team. Temporary MMF will be done using eyelets and tie wires to achieve best possible occlusion. Plates will be adapted and secured with the help of screws. In Group A patients with 3D plates fixation the upper cross bar will lie in the subapical region.

Main outcome variables

1) Stability 2) Post op pain 3) Wound dehiscence 4) Malocclusion

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20230420057970N1**

Registration date: **2024-11-04, 1403/08/14**

Registration timing: **retrospective**

Last update: **2024-11-04, 1403/08/14**

Update count: **0**

Registration date

2024-11-04, 1403/08/14

Registrant information

Name

Aminah Khan

Name of organization / entity

Combined Military Hospital

Country

Pakistan

Phone

+92 91 5245367

Email address

aminahkhan93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-17, 1402/05/26

Expected recruitment end date

2024-08-17, 1403/05/27

Actual recruitment start date

2023-08-17, 1402/05/26

Actual recruitment end date

2024-09-04, 1403/06/14

Trial completion date

2024-09-05, 1403/06/15

Scientific title

Comparison between 3-D Plates and Conventional miniplates in the management of parasymphysis and symphysis fractures of the mandible.

Public title

3D plates in mandible fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pain following history of fall/ RTA/ trauma Age 18-50 years American Society of Anesthesiologist ASA Class 1 Isolated mandible fractures

Exclusion criteria:

Infection at site of fracture Comminuted fractures Panfacial trauma Patients with a bone pathology (osteomyelitis, osteoporosis and paget's Disease) Chronic Illness (uncontrolled diabetes, asthma and hypertension)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **62**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups using sealed envelope method. Individuals with odd numbers in the envelopes will be included in Group A and even numbers in Group B. A third person not being part of the study will open the envelopes and the patients will be allocated to the mentioned groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were blinded as they were not informed about the treatment modality used for management of their ailment, but consent was taken. An independent assessor, who will be a senior and experienced Oral and Maxillofacial Surgeon and will not be part of the study, will assess patients, he will also be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Review Committee for Dental Research, 30 MDC

Street address

2G3R+9W5, Mall Rd, 30 MDC, Peshawar Cantonment

City

Peshawar

Postal code

25000

Approval date

2022-04-29, 1401/02/09

Ethics committee reference number

3943-01

Health conditions studied**1****Description of health condition studied**

Fracture of mandible.

ICD-10 code

S02.6

ICD-10 code description

Fracture of mandible

Primary outcomes**1****Description**

Stability will be checked between both the plating systems

Timepoint

Just after plate Insertion, 1 week, 4 weeks

Method of measurement

Checked clinically by manual manipulation to assess mobility of fractured segments post-op after fixation

Secondary outcomes**1****Description**

Malocclusion

Timepoint

1st post op day, 1week, 4 week

Method of measurement

Deflection from the normal relation or alignment of the teeth to other teeth in the same arch and/or to the teeth in the opposing arch, 2mm or more space between maxillary and mandibular teeth.

2**Description**

Post op pain

Timepoint

1st post op day, 1 week, 4 week

Method of measurement

Evaluated by Visual analog scale.

3

Description

Wound Dehiscence

Timepoint

1st post op day, 1 week, 4 week

Method of measurement

Plate exposure and visibility in the oral cavity

Intervention groups

1

Description

Intervention group: Group A: Mandible fractures will be fixated with 3D plates according to Champys lines of Osteosynthesis. All cases will be treated under strict aseptic conditions, general anesthesia and local anesthesia (1.8ml 2% Lignocaine with Adrenaline 1:100,000;Septodont, USA) given in fracture vicinity by a single surgical team. Temporary MMF will be done using eyelets and tie wires (prestretched, round, stainless steel, 24 gauge, 6 inches in length) to achieve best possible occlusion. One titanium 3-D plates, square shaped 4 hole, 2mm thick [Grade 4] (Moin International CE, Pakistan) will be adapted and secured with the help of titanium monocortical screws [Grade 5] around the fracture line in the subapical region. 7mm length screws will be inserted in upper holes and 9mm in lower hole. Muscle and then mucosal closure will be done with vicryl 3.0 (Ethicon, USA) respectively. All patients will be prescribed I/V pre-op broad spectrum antibiotics (Inj I/V Augmentine 1.2g BD, Inj I/V Flagyl 500mg BD) which will be continued post-op along with analgesics (Inj I/V Toradol 30mg TDS), antiemetic (Inj I/V Maxalon 10mg STAT) and fluids (Inf I/V Ringer Lactate + 5% Dextrose over 24 hrs) for 3 days according to the ward protocol. Post-op MMF will only be done if occlusion is not satisfactory. Patient will be advised liquid diet and strict oral hygiene instructions (intraoral irrigation and suctioning, 24 hours after the procedure with Enziclor (0.15% Benzydamine Hydrochloride/ 0.2% Chlorhexidine Gluconate)(Platinum Pharmaceuticals Pvt Ltd, Pakistan) 3 times a day, after meals.

Category

Treatment - Devices

2

Description

Control group: Group B: Mandible fractures will be Fixated with conventional mini plates According to Champys line of Osteosynthesis. All cases will be treated under strict aseptic conditions, general anesthesia and local anesthesia (1.8ml 2% Lignocaine with Adrenaline 1:100,000;Septodont, USA) given in fracture vicinity by a single surgical team. Temporary MMF will be done using eyelets and tie wires (prestretched, round, stainless steel, 24 gauge, 6 inches in length) to achieve best possible occlusion. Conventional titanium miniplates (Moin International CE, Pakistan); one 4/5 hole[Grade 5] in subapical region with 7mm [Grade 4] screws and 5/6 hole [Grade 5] in inferior boarder region with 9mm

screws [Grade4] will be adapted and secured. Number of hole can Increase as per obliqueness of fracture line. Muscle and then mucosal closure will be done with vicryl 3.0 (Ethicon, USA) respectively. All patients will be prescribed I/V pre-op broad spectrum antibiotics (Inj I/V Augmentine 1.2g BD, Inj I/V Flagyl 500mg BD) which will be continued post-op along with analgesics (Inj I/V Toradol 30mg TDS), antiemetic (Inj I/V Maxalon 10mg STAT) and fluids for 3 days (Inf I/V Ringer Lactate + 5% Dextrose over 24 hrs) according to the ward protocol. Post-op MMF will only be done if per-op stability of the fractured segments is not achieved. Patient will be advised liquid diet and strict oral hygiene instructions (intraoral irrigation and suctioning, 24 hours after the procedure with Enziclor (0.15% Benzydamine Hydrochloride/ 0.2% Chlorhexidine Gluconate)(Platinum Pharmaceuticals Pvt Ltd, Pakistan) 3 times a day after meals.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital, Peshawar

Full name of responsible person

Lt Col. Chaudry Muhammad Usman

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2G3R+9W5, Mall Rd, Peshawar Cantonment

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

N/A

Grant code / Reference number

N/A

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Combined Military Hospital

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Combined Military Hospital

Full name of responsible person

Lt. Col Muhammad Chaudry Usman

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Combined Military Hospital

Full name of responsible person

Aminah Khan

Position

Trainee

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Combined Military Hospital

Full name of responsible person

Aminah Khan

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available