Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 parasymhysis 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 dehisence 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 Dehisence
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 statsfactory. 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 Hydrochorlide/ 0.2% Chlorhexidine Gluconate)(Platinum Pharmacueticals 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 Hydrochorlide/ 0.2% Chlorhexidine Gluconate)(Platinum Pharmacueticals 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Militray 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
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Oral and Maxillofacial Surgery
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Person responsible for updating data

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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