Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of accuracy between standard surgical splint and modified interpretative adjustable splint in transferring of anteroposterior position of maxilla during Le Fort I osteotomy

Protocol summary

Study aim

Comparison of the efficiency of the adjustable surgical wafer compared to the standard intermediate wafer, in the transfer of the anterior-posterior position of maxilla during Lefort I osteotomy

Design

Horizontal osteotomy line on the bone first will be marked with a cutter, on the area of the canine and molar teeth two vertical lines are drawn on it.Then osteotomy performed and the maxilla will be broken down. The standard wafer is placed first and the upper jaw is moved upwards with hand pressure so that the two pieces are reattached in the osteotomy line and the vertical line displacement on the moving piece (Down fractured maxilla) is shifted. The vertical line is measured on the fixed piece. If this shift is to the front, it is displayed with positive numbers, and if it is backwards, it is displayed with negative numbers. Now the adjustable wafer is set and the displacement of the lower vertical line is measured relative to the upper. This process will be repeated with wafers made in positions 1-a, 2-a, 3-a, as well as 1-p, 2-p, and 3-p.

Settings and conduct

Clinical trials at Besat Hospital in Hamadan in 2020 will be performed on patients who require lefort1 osteotomy surgery in because of maxillary symmetry.

Participants/Inclusion and exclusion criteria

Patients with problems in the sagittal dimension of maxillary classified as class 2 and 3 according to the classification of the maxillary- skeletal relationship. criteria for not entering the study: Patients with a history of previous orthognathic surgery, teeth-less patients and patients need vertical changes

Intervention groups

Intervention group: Adjustable surgical wafers will be used to determine maxillary position during Lefort 1 surgery. Control group: Standard surgical wafers will be used to determine maxillary position during Lefort 1 surgery.

Main outcome variables

Changes in the maxillary reference lines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N7**
Registration date: **2020-06-13, 1399/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-13, 1399/03/24**
Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

Name
Abbas Moradi
Name of organization / entity
Hamedan University of Medical Of Science
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of accuracy between standard surgical splint and modified interpretative adjustable splint in transferring of anteroposterior position of maxilla during Le Fort I osteotomy

Public title
Le Fort I osteotomy for transferring of anteroposterior position of maxilla
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Problem in sagittal dimension of Jaw Class 2 & 3 Jaw skeletal connection Need to change just in sagittal dimension
Exclusion criteria:
Patients with previous history of orthognathic surgery Toothless patients Patients need vertical changes
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
We made 20 cards and write letter A on 10 for adjustable splint and on the other 10 letter S for the standard surgical splint group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the letters will be randomly selected and opened, based on selected letter (A or S) patients will be assigned to adjustable surgical splint or standard surgical splint group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Science
Street address
Shahid Fahmideh Avenue
City
Hamadan
Province
Hamadan
Postal code
6517838697
Approval date
2020-05-23, 1399/03/03
Ethics committee reference number
IR.UMSHA.REC.1399.214

Health conditions studied

1

Description of health condition studied
Asymmetry of maxillary and mandibular
ICD-10 code
M26.11
ICD-10 code description
Maxillary asymmetry

Primary outcomes

1

Description
Maxillary movement
Timepoint
before and after Surgery
Method of measurement
The measurement is made with a ruler

Secondary outcomes

1

Description
Maxilla displacement in sagittal dimension
Timepoint
before and after surgery
Method of measurement
The measurement is made with a ruler

Intervention groups

1

Description
Intervention group: In each patient, first the upper and lower jaw casts will be prepared and transferred to the

articulator using Face bow. Then, based on the data obtained from the clinical analysis, photography and lateral cephalometry, the position of the upper and lower jaw is determined. Then, the patient's sergeant model is started and the upper jaw cast will be fixed at the designated position (position 0). For this purpose, first a standard (thin) wafer is made and then this wafer is removed and another wafer will be made using the made device (adjustable wafer). The upper jaw will be detached from the articulator base and fixed one millimeter stronger to the base (position 1-a) and a standard wafer and a thick adjustable wafer will be made for it. This process is in the position of two millimeters more anterior (position 2-a) and 3 mm more anterior (position 3-a), one millimeter more posterior (position 1-p), two millimeters more posterior (position 2-p) and three A more posterior millimeter (3-p position) will be repeated. In each case, a standard wafer and an adjustable wafer are made. During surgery, a horizontal osteotomy line is first marked on the bone with a milling cutter, and two vertical lines are drawn on the canine and molar teeth in the first area. An osteotomy is performed and the maxilla is broken down. At this time, the standard wafer will be placed first and the upper jaw will be moved upwards with the pressure of the hand so that the two pieces in the osteotomy line come together again and the amount of vertical line movement on the moving piece (Down fractured maxilla) The vertical line will be measured on the fixed piece. If this shift is to the front, it will be displayed with positive numbers, and if it is backwards, it will be displayed with negative numbers. Now the adjustable wafer is set and the displacement of the lower vertical line is measured relative to the upper. This process will be repeated with wafers made in positions 1-a, 2-a, 3-a, as well as 1-p, 2-p, and 3-p. If any error occurs, this error is the same on both devices. will be. Therefore, it will not affect the comparison of the two devices. In addition, all necessary measures are taken to control these rotations during operation.

Category

Treatment - Devices

2

Description

Control group: The surgical procedure in this group is similar to the intervention group, except that a standard splint will be used instead of an adjustable splint to determine the maxillary position during the Lefort I osteotomy surgery.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

dr Mohammad Reza Jamalpour

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Saeid Bashirian

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person
Abbas Moradi

Position
Coach

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Mohammad Reza Jamalpour

Position
Assistant Professor

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Specialist

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Dentistry

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Person responsible for updating data

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Abbas Moradi

Position
Nonacademic staff of community Medicine

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Master

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared except for authors names

When the data will become available and for how long
From 2021 onward it is permissible

To whom data/document is available
Researchers in all fields

Under which criteria data/document could be used
To develop research and science

From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document
Send and receive email

Comments