

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of marginal bone level around bone-level and tissue-level short implants in posterior maxilla

Protocol summary

Summary

The aim of this study is to compare marginal bone loss around tissue-level and bone-level short dental implants in posterior maxilla. Study is designed as randomized controlled clinical trial. Patients who seek dental implant in posterior area of maxilla, with approximately 6-10 millimeters of bone height in desired area for implant insertion, and sinus augmentation is not indicated for them are included in the study. Patients with active periodontal disease are excluded. After obtaining informed consent from patient, one or more (depending on the treatment plan) short implant/implants are inserted in posterior sextant of maxilla which are chosen as bone-level or tissue-level randomly. A standardized parallel periapical radiograph is then obtained. After healing period, prosthesis is delivered and a standardized periapical radiograph is taken. Six months later another standardized periapical radiograph with the same adjustments is taken. Marginal bone level is compared between radiographs for each implant and the mean of marginal bone loss -as primary outcome- for bone-level group and tissue-level group are compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021025662N2**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Solmaz Akbari

Name of organization / entity

Dental school, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 88249184

Email address

soolmaz.akbari@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2018-10-01, 1397/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of marginal bone level around bone-level and tissue-level short implants in posterior maxilla

Public title

Evaluation of marginal bone level around short maxillary implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Edentulous area of at least one tooth missed in the posterior sextant of maxilla; which is considered to be treated with implant supported fixed prosthesis; available bone height of at least 6 mm and less than 10 mm below the maxillary sinus in the area

planned for implant insertion, as observed in CBCT radiograph; available bone width of at least 6 mm in the area planned for implant insertion as observed in CBCT radiograph; sinus augmentation not planned, because of medical reasons or patient's unwillingness; and patient's willing for cooperation with the study. Exclusion criteria: Active periodontal disease (Probing pocket depth ≥ 4 mm with bleeding on probing); full mouth plaque score $>20\%$ at time of implant placement; full mouth bleeding score $>20\%$ at time of implant placement; smoking >10 cigarettes/day; systemic disease or conditions which influence bone metabolism; and bruxism or clenching.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tehran University of Medical Sciences

Street address

Keshavarz blvd, Ghods ave, Head quarter of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2017-03-25, 1396/01/05

Ethics committee reference number

IR.TUMS.VCR.REC.1396.1988

Health conditions studied

1

Description of health condition studied

Dental implant

ICD-10 code

Z96.5

ICD-10 code description

K00-K14 Presence of tooth-root and mandibular implants

2

Description of health condition studied

Edentulous ridge atrophy

ICD-10 code

K08.2

ICD-10 code description

Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description

Marginal bone level changes

Timepoint

At implant placement, prosthesis delivery and 6 months later

Method of measurement

a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. the distance between bone to implant contact and platform of each implant, at mesial and distal of implants were calculated at each intervals.

Secondary outcomes

1

Description

Probing depth

Timepoint

At prosthesis delivery and 6 months later

Method of measurement

O' Michigan, Williams marking probe

2

Description

Bleeding on probing

Timepoint

At prosthesis delivery and 6 months later

Method of measurement

Bleeding on probing with O' Michigan, Williams marking, which may happen till 30 seconds later

3

Description

Implant survival rate

Timepoint

At prosthesis delivery and 6 months later

Method of measurement

Percentage of remained implants in oral cavity at the end of study

Intervention groups

1

Description

Intervention group: Patients who meet inclusion criteria, after signing an informed consent enter the study. Surgery for implant placement: Patients rinse their mouth with chlorhexidine 2.2% mouthrinse. Local anesthesia is applied. Then, buccal flap is reflected and before reflecting palatal one, mucosal thickness of palatal tissue in center area of placing implant is measured and recorded. Now, an assistant opens the envelope which determines due to randomization, which type of implant should be inserted for the patient. Implant of Eurotekhnika brand are to be used in this study; test group will receive Aesthetica tissue-level implants. The length of implant chosen is 6 or 8 millimeters, depending on the available bone. Drilling and placing implant at desired level relative to bone crest is done according to manufacturer's instruction. One week later, after suture removal, a standardized parallel periapical radiograph is obtained from study implants. For this, a digital sensor, mounted on an XCP film holder- which is bound to a piece of putty material for registering the exact position of the sensor and tube relative to the implant- is used. The putty can then be used in two other radiographs to provide identical geometry as the first one. Three months after inserting implants, impression making begins and prosthesis is delivered. Type of prosthesis to be used is cemented porcelain-fused-to- metal crowns. At the time of prosthesis delivery, probing depth and bleeding on probing around implant, and full mouth plaque index are recorded, and a standardized radiograph, as described before, is taken. Six months later, PD, and BoP of the implant, and FMPI are recorded, and a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. First, each radiograph is given a code by a blind person out of the study, then one of the investigators make measurements on the image. The measurements to be made are: 1-"Bone level": the distance between the most coronal point of implant-bone contact to the most coronal point of implant platform in either mesial and distal sides. 2- the distance between implant apex and its shoulder, which is used to calibrate other measurements of the graph. Differences in bone level between the radiographs is obtained after calibrating the measures [primary outcome]. Mean marginal bone loss for the test group -tissue level implants- is calculated and compared to the control's.

Category

Treatment - Surgery

2

Description

Control group: Patients who meet inclusion criteria, after signing an informed consent enter the study. Surgery for implant placement: Patients rinse their mouth with chlorhexidine 2.2% mouthrinse. Local anesthesia is applied. Then, buccal flap is reflected and before reflecting palatal one, mucosal thickness of palatal tissue in center area of placing implant is measured and recorded. Now, an assistant opens the envelope which determines due to randomization, which type of implant should be inserted for the patient. Implant of Eurotekhnika brand are to be used in this study; control group will receive Natea bone-level implants. The length of implant chosen is 6 or 8 millimeters, depending on the available bone. Drilling and placing implant at desired level relative to bone crest is done according to manufacturer's instruction. One week later, after suture removal, a standardized parallel periapical radiograph is obtained from study implants. For this, a digital sensor, mounted on an XCP film holder- which is bound to a piece of putty material for registering the exact position of the sensor and tube relative to the implant- is used. The putty can then be used in two other radiographs to provide identical geometry as the first one. Three months after inserting implants, impression making begins and prosthesis is delivered. Type of prosthesis to be used is cemented porcelain-fused-to- metal crowns. At the time of prosthesis delivery, probing depth and bleeding on probing around implant, and full mouth plaque index are recorded, and a standardized radiograph, as described before, is taken. Six months later, PD, and BoP of the implant, and FMPI are recorded, and a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. First, each radiograph is given a code by a blind person out of the study, then one of the investigators make measurements on the image. The measurements to be made are: 1-"Bone level": the distance between the most coronal point of implant-bone contact to the most coronal point of implant platform in either mesial and distal sides. 2- the distance between implant apex and its shoulder, which is used to calibrate other measurements of the graph. Differences in bone level between the radiographs is obtained after calibrating the measures [primary outcome]. Mean marginal bone loss for the control group -bone level implants- is calculated and compared to the test's.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of periodontics, Tehran University of Medical Sciences, School of Dentistry

Full name of responsible person

Mina Taheri

Street addressTehran university dental school, North Amirabaaad,
Tehran**City**

Tehran

Fax**Email**

mtaherim@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Department of periodontics, Tehran University of
Medical Sciences, School of Dentistry**Full name of responsible person**

Soolmaz Akbari

Position

Assistant professor

Other areas of specialty/work**Street address**Tehran university dental school, North Amirabaaad,
Tehran**City**

Tehran

Postal code**Phone**

+98 21 8835 1170

Fax**Email**

soolmaz.akbari@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Tehran University of
Medical Sciences**Full name of responsible person**

Dr Amirreza Rokn

Street addressTehran university dental school, North Amirabaaad,
Tehran**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Tehran University of Medical
Sciences**Proportion provided by this source**

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**Department of periodontics, Tehran University of
Medical Sciences, School of Dentistry**Full name of responsible person**

Mina Taheri

Position

Postgraduate student

Other areas of specialty/work**Street address**Tehran university dental school, North Amirabaaad,
Tehran**City**

Tehran

Postal code**Phone**

+98 21 8835 1170

Person responsible for updating data**Contact****Name of organization / entity**Department of periodontics, Tehran University of
Medical Sciences, School of Dentistry**Full name of responsible person**

Mina Taheri

Position

Postgraduate student

Other areas of specialty/work**Street address**Tehran university dental school, North Amirabaaad,
Tehran**City**

Tehran

Postal code**Phone**

+98 21 8835 1170

Fax**Email**

mtaherim@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty