

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Keratinized mucosa changes with buccal base modified palatal flap in maxillary anterior implants

Protocol summary

Study aim

Evaluation of Keratinized mucosa changes with buccal base modified palatal flap in maxillary anterior implants

Design

Clinical trial without control group based on community and pragmatic.

Settings and conduct

10 patients who have referred to the implant department of Tabriz Dental faculty for treatment and have inclusion criteria and no exclusion criteria will be selected. Patients in this study are randomly selected, Surgery is performed by a maxillofacial surgeon with 5 years of specialized experience

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for implant placement in maxillary central and lateral teeth, the width of the keratinized mucosa is less than 3 mm, the thick of the keratinized mucosa are less than 1 mm, the minimum width of the bone should be 4.5 mm, the minimum height of the bone is 12 mm, and more than 6 months have passed since tooth extraction. Exclusion criteria: Uncontrolled periodontal disease, presence of teeth in the implant site, uncontrolled systemic disease, smoking history in the last 6 months, pregnancy and lactation, patients with connective tissue disease, and radiotherapy and chemotherapy

Intervention groups

Intervention group: the split-thickness crestal incision is made in the top of the crest so that it is 0.5 mm towards the palatal, Supra-periosteal dissection is then given up to 2 cm on the palatal side. At the end of the palatal dissection, a periosteal incision is made and the periosteum and connective tissue are moved to the buccal that is, the palatal connective tissue is rolled and placed behind the buccal mucosa and sutured by absorbable sutures. The fixture is then placed in a standard surgical manner so that the initial torque is higher than 30n / cm

Main outcome variables

Width of keratinized gingiva; Thickness of keratinized gingiva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130710013938N6**

Registration date: **2021-08-22, 1400/05/31**

Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**

Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Mohamadali Ghavimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5968

Email address

ghavimim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Keratinized mucosa changes with buccal base modified palatal flap in maxillary anterior implants

Public title
Evaluation of modified palatal flap surgery to improve gingival health

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for implant placement in maxillary central and lateral teeth The width of the keratinized mucosa is less than 3 mm The thick of the keratinized mucosa are less than 1 mm The minimum width of the bone should be 4.5 mm The minimum height of the bone is 12 mm More than 6 months have passed since tooth extraction
Exclusion criteria:
Uncontrolled periodontal disease Presence of teeth in the implant site Uncontrolled systemic disease Smoking history in the last 6 months Pregnancy and lactation Patients with connective tissue disease Radiotherapy and chemotherapy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 10

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz dental faculty, Golgasht St.,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2021-04-15, 1400/01/26

Ethics committee reference number

IR.TBZMED.REC.1400.023

Health conditions studied

1

Description of health condition studied

Periodontal health around dental implants

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description

Thickness of keratinized gingiva

Timepoint

AT the beginning of the study, 6 weeks after completion of the intervention and 12 weeks after completion of the intervention

Method of measurement

Measured by endodontic spreader No. 25

2

Description

Width of keratinized gingiva

Timepoint

AT the beginning of the study, 6 weeks after completion of the intervention and 12 weeks after completion of the intervention

Method of measurement

Measured by a calibrated gauge.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The crestal incision is applied in a split-thickness at the top of the crest so that it is 0.5 mm towards the palatal, then the supra-periosteal dissection is given up to 2 cm towards the palatal. At the end of palatal dissection, a periosteal incision is made and the periosteum and connective tissue are moved to the

buccal base, ie the palatal connective tissue is rolled and placed behind the buccal mucosa and sutured by absorbable suture. The fixture is then placed in a standard surgical manner so that the initial torque is higher than 30n / cm. It should be noted that if the torque was lower than this value, the patient will be excluded from the study and his surgery will be performed in two stages. By placing the fixture as standard, healing abutment with a diameter of 4.5 cuff 4 and a height of 4.5 mm is placed. (One-step surgical procedure)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Ali Ghavimi

Street address

Tabriz dental faculty , Golgasht St.,

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Ghavimim@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Ghavimi

Position

Assistant Professor of Oral and Maxillofacial Surgery

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Dr Mohamadali Ghavimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be published after unidentifying individuals.

When the data will become available and for how long

3 months after publishing the results

To whom data/document is available

It will be accessible to all researchers

Under which criteria data/document could be used

The use of data with reference to the source is
unrestricted

From where data/document is obtainable

1. Dr Mohammadali Ghavimi/Ghavimim@tbzmed.ac.ir 2.
Dr Mahdi Sadeghi/ m.sadeghi13@gmail.com

What processes are involved for a request to access data/document

After receiving the email containing the data request
from the researcher, the data will be provided to the
researcher within a period of one month.

Comments