

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of Periosteal pocket flap technique with autogenous bone block for horizontal bone augmentation

Protocol summary

Study aim

The aim of this study was to compare the effect of Periosteal pocket flap technique with the gold standard technique, autogenous bone block on reconstruction of horizontal alveolar ridge defects.

Design

A controlled clinical trial with Individual block randomization with the random number tables with 24 sample sizes in 17 patients

Settings and conduct

The study was performed in the implant department of Mashhad Dental School. Patients were randomly divided into two groups. The periosteal pocket flap method was used in the intervention group with a horizontal incision on the periosteum. This space was then deepened using a periosteal elevator to completely separate the mucosa from the periosteum. Next, the periosteum with the periosteal elevator was raised over the bone to create a periosteal pocket between the bone and the periosteum. After biomaterial application including particulate allograft, collagen membrane was placed on the biomaterial inside the envelope. Membrane was then sutured to periosteum and buccal flap to palatal or lingual flap. In the control group, bone was harvested from the ramus of the mandible and fixed with titanium screws in the target area. The gaps between the block and the receptor area were filled by particulate allografts and collagen membrane was placed on it. The buccal flap was then sutured to the palatal or lingual flap.

Participants/Inclusion and exclusion criteria

Inclusion criteria: edentulous area requiring horizontal bone reconstruction Exclusion criteria: previous bone graft in the area, cigarette smoking, drug abuse

Intervention groups

The use of periosteal pocket flap in intervention group and autogenous bone block technique in control group

Main outcome variables

horizontal alveolar ridge augmentation in millimeter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046011N1**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **retrospective**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Leila Khodadadifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-05-19, 1398/02/29

Actual recruitment start date

2019-04-06, 1398/01/17

Actual recruitment end date

2019-05-19, 1398/02/29

Trial completion date

2019-11-20, 1398/08/29

Scientific title

Comparison of Periosteal pocket flap technique with autogenous bone block for horizontal bone augmentation		Ethics committee of Mashhad University of Medical Sciences	
Public title	Comparison of Periosteal pocket flap technique with autogenous bone block	Street address	Qom dental school, Qom university of medical science, Saheli Ave., Qom
Purpose	Treatment	City	Mashhad
Inclusion/Exclusion criteria		Province	Razavi Khorasan
Inclusion criteria:	edentulous area requiring horizontal bone reconstruction	Postal code	3713649373
Exclusion criteria:	previous bone graft in the area cigarette smoking drug abuse	Approval date	2018-12-19, 1397/09/28
Age	From 18 years old	Ethics committee reference number	IR.MUMS.DENTISTRY.REC.1397.091
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 17 More than 1 sample in each individual Number of samples in each individual: 24 edentulous area requiring horizontal bone reconstruction Actual sample size reached: 17 More than 1 sample in each individual Actual sample size in each individual: 24 edentulous area requiring horizontal bone reconstruction	ICD-10 code	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
Randomization description	Individual block randomization with the random number tables Based on the CONSORT criteria, we coded the patients based on their number and assigned a random code to each patient. We put Periosteal pocket flap and autogenic block methods in the envelope and assign a special number to it randomly based on a random number table. Then we assign the envelope to the patient based on the patient code and random number and the procedure is performed by the surgeon.	Primary outcomes	
Blinding (investigator's opinion)	Not blinded	1	
Blinding description		Description	
Placebo	Not used	horizontal alveolar ridge augmentation in millimeter	
Assignment	Parallel	Timepoint	
Other design features		before intervention, 26 weeks after surgery	
Secondary Ids		Method of measurement	
empty		cone beam computed tomography survey	
Ethics committees		Secondary outcomes	
1		empty	
Ethics committee		Intervention groups	
Name of ethics committee		1	
		Description	
		Intervention group: Using the periosteal pocket flap method, after local anesthesia, a horizontal incision is made on the periosteum to create a small space between the periosteum and the mucosa. This space is then deepened using a periosteal elevator to completely separate the mucosa from the periosteum. Vertical releases are applied only to the mucosa if needed. The mucosal flap is then separated by the periosteal elevator over the mucogingival line, and the periosteum is then elevated from the bone to create a periosteal pocket between the bone and the periosteum. After biomaterial application including particulate allograft in the size of 500-1000 micrometer (Regen Allograft- Iranian Tissue Product Company- Tehran-Iran), collagen membranes with 0.6-1 mm width (Regen Alloderm- Iranian Tissue Product Company- Tehran-Iran) are inserted over the biomaterial in the envelope. The buccal flap is then	

sutured to the palatal or lingual flap using the Vicryl 4-0 suture.

Category

Treatment - Surgery

2

Description

Control group: Bone block harvesting is done from the ramus mandibular area, then fixation of the block by titanium screws (JEIL Medical Corporation- Seoul-Korea). Flap tension is eliminated by applying periosteal-releasing at the buccal vestibule. The gaps between the block and the receptor area are filled by particulate allograft with a size of 500-1000 micrometer (Regen Allograft- Iranian Tissue Product Company- Tehran-Iran) and a collagen membrane with a width of 0.6-1 mm (Regen Alloderm-Iranian Tissue Product Company- Tehran-Iran) places over them. The buccal flap is then sutured to the palatal or lingual flap using the Vicryl 4-0 suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Implant section of Mashhad dental school

Full name of responsible person

Leila Khodadadifard

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Qom dental school, Qom university of medical science, Saheli Ave., Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Ghoum University of Medical Sciences

Full name of responsible person

Leila Khodadadifard

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information of the age, sex, and width of the alveolar ridge before and after surgery as well as will be shared as well as the enhancement of the alveolar ridge width will be share.

When the data will become available and for how long

Start of access period 6 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used to conduct a similar study.

From where data/document is obtainable

Leila khodadadifard Address: Qom dentistry school, Qom university of medical science, Qom, Iran Email address: I.khodadadifard@gmail.com

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

Sending an email request for data which containing information about the applicant for employment in academic and scientific institutions. Data file will be sent by an email within one week.

Comments