Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur in thickness and width of peri-implant keratinized tissue

Protocol summary

Study aim
Comparison of the width and thickness of peri-implant keratinized tissue following the use of de-epithelialized free gingival graft using surgical blade and diamond bur

Design
The study was a single-blind splith-mouth clinical trial and the available non-random sampling method was used.

Settings and conduct
The study was performed on 20 patients referred to the periodontics department of Islamic Azad University, Isfahan Branch before receiving the final implant prosthesis. The recipient site was prepared by the envelope flap technique. to prepare the d-fgg by bur, the superficial epithelial layer removed by diamond bur and a high-speed handpiece to the depth of about 0.5-1 mm, then the tissue is separated from the palate and to prepared the d-fgg by blade, the graft is separated from the palate in partial thickness, then the superficial epithelial layer is removed using a blade. The connective tissue is guided to recipient site by absorbable monofilament 0-5 suture and sutured to the flap.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1.Partial edentulous patient with at least 2 dental implants 2.Insufficient keratinized tissue around implants (width less than 2 mm and / or thickness less than 2 mm) 3.Presence of buccal bone around the implant 4.Good oral hygiene 5.Identical implants in terms of shape and brand in each patient exclusion criteria: 1.uncontrolled systemic disease 2.Smoking more than 10 cigarettes a day 3.History of mental disorder 4.Periodontal disease or local inflammation 5.History of implant failure or tissue grafting 6.Poor oral health 7.Drugs affect on tissue repair 8.History of tissue augmentation in the area

Intervention groups
Intervention : de-epithelialization of the fgg using diamond bur Control : de-epitelialization of the fgg using surgical blade

Main outcome variables
width of keratinized tissue thickness of keratinized tissue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220427054680N1**
Registration date: **2022-06-20, 1401/03/30**
Registration timing: **retrospective**

Last update: **2022-06-20, 1401/03/30**
Update count: **0**

Registration date
2022-06-20, 1401/03/30

Registrant information

Name
nasim maghamipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 1535 4053

Email address
n.maghamipour@khuisf.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-16, 1400/07/24

Expected recruitment end date
2021-12-25, 1400/10/04

Actual recruitment start date

2021-10-17, 1400/07/25

Actual recruitment end date

2022-01-23, 1400/11/03

Trial completion date

empty

Scientific title

Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur in thickness and width of peri-implant keratinized tissue

Public title

Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Partial edentulous patient with at least 2 dental implants ready to receive prosthesis Insufficient keratinized tissue around implants (keratinized gingival width less than 2 mm and / or keratinized gingival thickness less than 2 mm) Presence of buccal bone around the implant Good oral hygiene (FMPS, FMBS <25%) Identical implants in terms of shape and brand in each patient

Exclusion criteria:

Existence of uncontrolled systemic disease Smoking more than 10 cigarettes a day History of mental disorder Periodontal disease or local inflammation History of implant failure or tissue grafting in the area Poor oral health (25%> FMBS) Consumption of drugs effective in tissue repair History of soft or hard tissue augmentation in the area

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
Case and control groups as split-mouth in one person
Actual sample size reached: **20**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Case and control groups as split-mouth in one person

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who collected the data and evaluated the outcome was someone other than the surgeon and is kept blind

Placebo

Not used

Assignment

Parallel

Other design features

split-mouth

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University - Isfahan Branch (Khorasgan)

Street address

Arghavaniyeh street, Eastern Jey Street

City

isfahan

Province

Isfehan

Postal code

8155139998

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.IAU.KHUISF.REC.1400.244

Health conditions studied

1

Description of health condition studied

peri-implant keratinized tissue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

width of keratinized tissue

Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 6 months after surgery

Method of measurement

Compass and digital caliper

2

Description

thickness of keratinized tissue

Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 6 months after surgery

Method of measurement

Endodontic file and digital caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: de-epithelialization of the free gingival graft using diamond bur
Category
Treatment - Surgery

2

Description
Control group: de-epitelialization of the free gingival graft using surgical blade
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Periodontology, Dental School,Isfahan Branch, Islamic Azad University
Full name of responsible person
Nasim Maghamipour
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Boulevard, Arghavanieh Street, Eastern Jey Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Research Vice- Chancellor of Islamic Azad University Isfahan Branch
Street address
Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Esfahan 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
Islamic Azad University
Full name of responsible person
Nasim Maghamipour
Position
Resident of periodontics
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The documentation for this study is available to other researchers. Available documents will include data related to all studied variables (except patients' personal information) and in the form of SPSS file.

When the data will become available and for how long
3 months after printing the results

To whom data/document is available
The information of this research can be shared with all academic researchers.

Under which criteria data/document could be used
For research and clinical use

From where data/document is obtainable
Ways of communication with the responsible researcher: Email: n.maghamipour@khuisf.ac.ir

What processes are involved for a request to access data/document
En After coordination with the responsible researcher, the requested data will be sent within one month.

Comments