Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effectiveness of a composite dressing in pain and bleeding control of the palatal graft donor site and comparison with collagen sponge

Protocol summary

Study aim

Evaluation of the effect of using a composite dressing in combination with a collagen sponge on controlling bleeding and pain at the palatal donor site, compared to the use of a collagen sponge alone.

Design

A randomized, double-blind, controlled clinical trial with parallel groups will be conducted on 40 patients, using permuted block randomization.

Settings and conduct

This randomized, double-blind trial at Mashhad Dental School will assign eligible patients who sign the informed consent form, to either the intervention (composite dressing + collagen sponge) or control group (collagen sponge alone). A blinded assessor will record palatal wound management time. Patients will report daily pain and delayed bleeding via Visual Analogue Scale for 7 days post surgery. After one week, analgesic intake (mg), discomfort, chewing difficulty, stress, and willingness to treat will be assessed using Visual Analogue Scaleby a blinded evaluator.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with mucogingival defects requiring graft surgery, Palatal soft tissue thickness ≥ 2 mm, Palatal vault depth ≥ 12 mm. Exclusion Criteria: Any medical contraindications or systemic conditions affecting periodontium, Smoking, alcohol use, plaque index > 20%, Known allergies, prior palatal autogenous graft harvesting, Palatal lesions or use of maxillary palatal appliances/dentures.

Intervention groups

In the control group, a collagen sponge alone will be applied to the palatal donor site and in the intervention group, both a collagen sponge and a composite shield will be used to manage bleeding and pain at the donor site.

Main outcome variables

Pain measurement based on the Visual Analogue Scale index and the amount of ibuprofen consumed by the patient during the first week after surgery (mg)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250513065721N2**
Registration date: **2025-06-21, 1404/03/31**
Registration timing: **prospective**

Last update: **2025-06-21, 1404/03/31**
Update count: **0**

Registration date

2025-06-21, 1404/03/31

Registrant information

Name

zahra Moslehitabar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of a composite dressing in pain and bleeding control of the palatal graft donor site and comparison with collagen sponge

Public title
The effect of composite dressing on pain and bleeding control at the gingival graft donor site
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mucogingival defects (including lack of keratinized gingival width, gingival recession, insufficient vestibular depth) around teeth and implants, who require gum grafting surgery. The minimum thickness of the patient's palatal soft tissue should be 2 mm. The minimum height of patient's palatal vault should be 12 mm.
Exclusion criteria:
The presence of debilitating systemic disease, coagulation disorders, or any disease that has a significant impact on periodontal tissues (such as diabetes) Patients with known allergy to any of the materials used in the study Patients with gagging reflex patients with ongoing orthodontic treatment with palatal appliance Patients who wear maxillary dentures or overdentures that cover the palatal area. Patients with history of previous palatal soft tissue harvesting Presence of oral lesions in the palate Inability to maintain oral hygiene with at least 80% of plaque-free surfaces. Smoking and alcohol consumption.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used to ensure equal allocation of participants into the two study groups. Since the study includes two groups, the possible block permutations will be AB and BA. One of these blocks will be randomly selected, and participants will be assigned sequentially based on the selected block. For instance, if block AB is selected, the first participant will be allocated to Group A, the second to Group B, and the process will continue accordingly until all participants are assigned. This method ensures that both groups will have an equal number of participants. To maintain allocation concealment, the surgical information for each participant will be prepared in advance and placed in sealed, opaque, sequentially numbered envelopes. These envelopes will be handed to the surgeon by the surgical nurse immediately prior to each procedure.
Blinding (investigator's opinion)
Double blinded
Blinding description
The surgeon and patients cannot be blinded due to the nature of the surgery and the physical differences in the procedures. Data analysts are unaware of the group allocation to avoid any bias. The induviduals responsible for recordinf patient-reported outcomes related to pain and bleeding during follow-up visits are also blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Vakilabad Boulevard, Ferdowsi University West Gate, Faculty of Dentistry
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2025-06-07, 1404/03/17
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1404.032

Health conditions studied

1

Description of health condition studied
palatal donor site for gingival graft
ICD-10 code
Z52.89
ICD-10 code description
Donor of other specified organs or tissues

Primary outcomes

1

Description
Postoperative pain
Timepoint
Daily during the first 7 days and on day 14 postoperatively
Method of measurement
Using the patient-reported Visual Analog Scale and the amount of ibuprofen consumed (in milligrams)

Secondary outcomes

1

Description
Donor site working time
Timepoint
during surgical process
Method of measurement
with stopwatch

2

Description
Presence and severity of post surgical delayed bleeding
Timepoint
Daily for the first 7 days post surgical
Method of measurement
Patient-reported Visual Analogue Scale

3

Description
postoperative complications (including necrosis, infection, and hematoma) in the palatal donor site
Timepoint
on day 7 post surgical
Method of measurement
visual clinical evaluation

4

Description
The patient's willingness to undergo the same surgery again if needed
Timepoint
on day 7 post surgical
Method of measurement
Patient-reported Visual Analogue Scale

5

Description
Postoperative discomfort and Inability to chew
Timepoint
on day 7 post surgical
Method of measurement
Patient-reported Visual Analogue Scale

6

Description
Gingival graft dimensions (length, width, thickness)
Timepoint
after harvesting the graft from palatal site
Method of measurement
Using a periodontal probe (in millimeters)

7

Description
Palatal soft tissue thickness at the mesial, distal, and central parts of the designated graft site
Timepoint
during surgical process before harvesting the graft from palatal site
Method of measurement
Using a local anesthesia needle with a stopper and a gauge accurate to 0.1 mm.

Intervention groups

1

Description
Intervention group: Patients with mucogingival defects requiring gingival graft surgery will receive a composite dressing in combination with a resorbable collagen sponge to control bleeding and pain at the palatal donor site. After harvesting the autogenous gingival graft from the palate, a hemostatic collagen sponge will be placed over the wound, followed by placement of a pre-fabricated composite dressing. This dressing will be stabilized using a cross-mattress suture. The composite shield will be chairside-fabricated before surgery. First, the graft harvesting area is outlined. A rectangular frame is formed around this area using flowable composite and light-cured. The interior of the frame is then filled with additional flowable composite and cured. The fabricated composite dressing is gently removed from the palate and stored for placement at the end of surgery.
Category
Treatment - Surgery

2

Description
Control group: Patients with mucogingival defects requiring gingival graft surgery will receive only a resorbable collagen sponge to manage bleeding and pain at the palatal donor site. In this group, the wound will be covered with a resorbable collagen sponge with local hemostatic properties and stabilized using a cross-mattress suture.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Mashhad University of Medical

Sciences

Full name of responsible person
Zahra Moslehitabar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Mashhad University of Medical Sciences

Full name of responsible person
Moein Khojaste

Position
استادیار

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity
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دانشیار

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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رزیدنت

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data related to age, gender, baseline and follow-up photographs of the donor site, palatal soft tissue thickness, dimensions (length, width, thickness) of the harvested graft, exact graft harvesting location on the palate, the amount of ibuprofen consumed by patients, and patient-reported Visual Analog Scale (VAS) scores at specified time points can be shared while maintaining confidentiality and excluding any personally identifiable information.
When the data will become available and for how long
The data access period will begin 6 months after the publication of the study results.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
If other researchers require access to the data, methodology, or analyses used in this study for the purpose of writing articles or theses, the data can be shared while maintaining confidentiality and excluding any patient-identifying information.
From where data/document is obtainable
The data can be shared upon request via email at z.moslehi99@gmail.com
What processes are involved for a request to access data/document
The data will be provided within a short period after the request is received.
Comments