Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Effect of Flowable Resin Composite on Pain and Wound Healing After Bilateral Standardized Palatal Soft Tissue Harvesting: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the Effect of Flowable Resin Composite on Pain and Wound Healing After Bilateral Standardized Palatal Soft Tissue Harvesting

Design

a double-blind clinical trial in 10 patients, and each participant serves as their own control.

Settings and conduct

Patients eligible for gingival grafting who will attend the Urmia Dental School during the study will be enrolled in the trial. The surgery is performed on both sides of the palate. Each side is assigned to one of two methods: dressing with composite flow or dressing alone. This study will be conducted as a double-blind trial, such that neither the patients nor the data assessor will be informed about the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Clinical need for bilateral free gingival grafting in the mandibular premolar/molar region. Age 18–65 years. Good general health. Ability to follow postoperative instructions and attend follow-up visits. Exclusion criteria:Smoking or other behaviors that impair wound healing. Known allergy to materials used in the study.

Intervention groups

Free gingival grafting is an effective soft tissue grafting method for increasing the width and thickness of keratinized gingiva and correcting mucogingival defects. In this study, one palatal side will be selected as the control side. The wound resulting from tissue harvesting will be covered with a sterile gelatinous collagen sponge (Hemospon, Maquira Dental Group) and then secured with non-absorbable monofilament sutures (SUPALON, supa medical devices).The contralateral side will be covered similarly with a gelatinous collagen sponge; however, additionally, a layer of light-curable composite resin (Denfil, Vericom Co) will be applied over the sponge and polymerized. Postoperative Care: Patients will receive one Novafen capsule (325 mg acetaminophen, 200 mg ibuprofen, and 40 mg caffeine) every 6 hours as a pain reliever. This will be administered uniformly to all patients.

Main outcome variables

Degree of wound healing؛ Postoperative pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260502069226N1**
Registration date: **2026-06-22, 1405/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-22, 1405/04/01**
Update count: **0**

Registration date

2026-06-22, 1405/04/01

Registrant information

Name
Amin Ebrahimi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-21, 1405/02/31

Expected recruitment end date
2026-08-22, 1405/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Flowable Resin Composite on Pain and Wound Healing After Bilateral Standardized Palatal Soft Tissue Harvesting: A Randomized Clinical Trial

Public title
The Effect of Flowable Composite Application Following Palatal Soft Tissue Harvesting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical Indication for Bilateral Free Gingival Graft in the Mandibular Premolar/Molar Region Age between 18 and 65 years Desired General Health Ability to Comply With Postoperative Instructions and Attend Follow-Up Appointments
Exclusion criteria:
Smoking or other behaviors known to impair wound healing Pre-existing allergy to the materials used in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each patient, one side of the palate served as the control, while the other side served as the intervention
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Following the confirmation of inclusion and exclusion criteria, informed consent will be obtained from the patients. Then, the right or left side of each patient will be randomly assigned to receive either the intervention or the standard dressing. Patients will be informed of the difference in the dressings on the two sides, but they will remain blinded to which side is assigned to the intervention or the control group. To maintain the blinding of the assessor, pain intensity on the VAS will be recorded by an individual who solely evaluates the pain of each side separately without being aware of the intervention type. Furthermore, before the clinical assessment and EHI scoring, the dressings on both sides will be removed by a separate individual to ensure the assessor remains blinded to the treatment allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Orzhans Alley, Resalat St. ,Urmia
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urmia
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Approval date
2026-01-28, 1404/11/08
Ethics committee reference number
IR.UMSU.REC.1404.463

Health conditions studied

1

Description of health condition studied
Free Gingival Graft
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Degree of wound healing
Timepoint
Clinical assessment of the wound 14 days after the intervention.
Method of measurement
Modified Early Wound Healing Index score

2

Description
Postoperative pain intensity
Timepoint
On days 1, 3, 7, and 14 post-intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Free gingival graft (FGG) is one of the effective soft tissue grafting methods for increasing the width and thickness of keratinized gingiva and correcting mucogingival defects. In this study, one palatal side will be randomly selected as the intervention side for the harvest of keratinized gingiva. After tissue harvesting, the site will be covered with a gelatinous collagen sponge (Hemospon® ,Maquira Dental Group). This will then be secured with interrupted 5-0 monofilament sutures (SUPALON, supa medical devices). Additionally, a thin layer of light-curable flowable composite resin (DenFil Flow,Vericom Co.) applied using an applicator tip, will be placed over the sponge. This application aims to ensure complete coverage of the wound area without creating excess thickness that could cause discomfort. To mechanically stabilize the flowable composite resin on the dressing, sutures passed around or through the collagen sponge will be arranged in a cross-linked network or matrix. The composite resin will be placed within and upon this suture network, ensuring the material is firmly fixed in the wound site. The composite will then be polymerized using a dental light-curing unit for the duration recommended by the manufacturer (typically 20-40 seconds). Post-operative Care: Patients will receive one Novafen capsule (a combination drug containing 325 mg acetaminophen, 200 mg ibuprofen, and 40 mg caffeine) every 6 hours as a pain reliever. This will be administered uniformly to all patients to eliminate any confounding factors.
Category
Treatment - Surgery

2

Description
Control group: The contralateral side of the palate will be designated as the control. The wound will be covered with a gelatinous collagen sponge (Hemospon® ,Maquira Dental Group) and then secured with interrupted, non-absorbable 5-0 monofilament sutures (SUPALON, supa medical devices), ensuring complete adaptation without tension. Unlike the intervention side, this will not be covered with a flowable composite. Post-operative Care: Patients will receive one Novafen Iran Daru capsule (a combination drug containing 325 mg acetaminophen, 200 mg ibuprofen, and 40 mg caffeine) every 6 hours as a pain reliever. This will be administered uniformly to all patients to eliminate any confounding factors."
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Oroumia 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
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Sajad Farrokhi
Position
Associate professor of Periodontology
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available