

# Investigating how well a new type of covering for the gums, called periodontal dressing, helps in the healing of wounds on the roof of the mouth

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<b>Registration date</b> 11/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/03/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Gingival recession also known as receding gums, is defined as the apical displacement of the gingival margin in relation to the cemento-enamel junction (CEJ). The usage of connective tissue graft (CTG) with the Coronally Advanced Flap (CAF) is considered the gold standard for gingival recession and root coverage treatment. However, this technique requires a secondary surgical site, which can increase the postoperative pain.

The aim of this study is to evaluate the efficacy of using an attachable periodontal dressing (Ora\_Aid) to protect the injury from mechanical harm, postoperative bleeding, or inflammation and to alleviate postoperative pain.

### Who can participate?

Healthy adults aged 19 and over who are non-smokers.

### What does the study involve?

Participants are randomly allocated to one of two treatment methods. One involves applying the gingival graft (CTG) with Coronally advanced flap (CAF), followed by applying the adhesive periodontal dressing on the donor site of the graft in the palatal area and over the flap. While the other involves applying (CAF) with (CTG) without applying dressing.

### What are the possible benefits and risks of participants?

The possible benefits for participants are achieving less postoperative pain and better healing. The methods are safe and there are no expected risks.

### Where is the study run from?

Damascus University (Syria)

### When is the study started and how long is it expected to run for?

May 2022 to December 2023

Who is funding the study?  
Damascus University (Syria)

Who is the main contact?  
Dr Remaz Abd Alkader, rymazoad@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Evaluation of the effect of attachable periodontal wound dressing (Ora-Aid) In the healing of the soft tissue during gingival recession treatment

### Study objectives

The dressing is expected to alleviate the Patient's pain sensation and enhance the healing process of the palatal wound.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 09/05/2022, Damascus university - faculty of dental medicine (Damascus-Almazah, Damascus, -, Syria; +963113341864; manger@hcsr.gov.sy), ref: 223445

## **Study design**

Interventional randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

University/medical school/dental school

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Bilateral class I or II of Miller classification of gingival recession.

## **Interventions**

Participants are randomly assigned using a sealed envelope method.

Two treatment methods will be implemented.

The first will involve applying a connective tissues graft (CTG) with a coronally advanced flap (CAF) and managing the donor site in the palatal by suturing, while the second will involve applying the connective tissue graft (GTG) with the Coronally advanced flap (CAF) with applying an adhesive periodontal dressing (Ora\_Aid) on the donor site in palatal and over the Flap.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

1. Pain using the visual analogue scale (VAS) 0-100 at 1 week after surgery
2. Wound healing assessment (Landry et al., 1988) at 1,2,3,4 weeks after surgery

## **Secondary outcome measures**

1. Keratinized tissue width measured from gingival margin to mucogingival junction with the help of periodontal probe (UNC 15 probe) at baseline 1 and 3 months
2. Epithelization test at baseline 1 and 3 months
3. Relative attachment level measured using (UNC 15 probe) at baseline 1 and 3 month
4. HEALING INDEX (Huang, Neiva, & Wang, 2005) at baseline 1 and 3 months

## **Overall study start date**

09/05/2022

## **Completion date**

09/12/2023

# Eligibility

## Key inclusion criteria

1. Good general health.
2. There are no contraindications to periodontal surgery.
3. Complaint of receding gums at least in the upper jaw and/or mandible.
4. All Recessions of class I OR II Miller.
5. The appearance of the Cementoenamel junction in the teeth that need to cover the root.
6. All patients achieve adequate control of the microbial plaque.
7. All patients are over 18 years old.
8. The patient has not been subjected to any surgery around the tooth in the area to be worked on

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

50 Years

## Sex

Both

## Target number of participants

20 sites (10 for each group)

## Key exclusion criteria

1. Previous periodontal surgery
2. Use of any drug that might affect periodontal health
3. Tooth mobility ,bruxism
4. Patients with a history of malignancy

## Date of first enrolment

01/10/2022

## Date of final enrolment

10/10/2023

# Locations

## Countries of recruitment

Syria

**Study participating centre**

Damascus university Department of periodontology faculty of dentistry

Mezzah

Damascus

Syria

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## Sponsor information

**Organisation**

Damascus University

**Sponsor details**

Albaramka

Damascus

Syria

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**Sponsor type**

University/education

**Website**

<https://damasuniv.edu.sy>

**ROR**

<https://ror.org/03m098d13>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Damascus University

**Alternative Name(s)**

University of Damascus, , DU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Syria

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/12/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are/will be available upon request from prof. Dr Tarik Kasim (prof.tarekkasem@hotmail.com)

All of data of the patients will be available on request.

Consent from participant was obtained.

**IPD sharing plan summary**

Available on request