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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

Submission date
02/03/2024

Recruitment status
No longer recruiting

Registration date
11/03/2024

Overall study status
Completed

Last Edited
11/03/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 cemanto-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
Dr Remaz Abdalkader

Contact details
Dumar
Damascus
Syria
-
+963(0)951753797
rymazoad@gmail.com

Additional identifiers

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

Completion date
09/12/2023

Eligibility

Key inclusion criteria
1. Good general health.
2. There are no contraindications to peridental surgery.
3. Complaint of receding gums at least in the upper jaw and/or mandible.
4. All Recessions of class | OR || Miller.
5. The appearance of the Cemantoenamel 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

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

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

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