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A new material for treatment of single receding gums

Submission date	Recruitment status	[_] Prospectively registered
13/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2025	Oral Health	

Plain English summary of protocol

Background and study aims
Receding gums (also known as gingival recession) is when the gum tissue surrounding the teeth wears away or pulls back, exposing more of the tooth or its root. The aim of the study is to increase root coverage and soft tissue thickness using different treatment methods.

Who can participate?
Healthy adults aged 18 years or older and with no contraindications to surgical intervention.

What does the study involve?
Participants are randomly allocated to one of two treatment methods, one will involve Xenogeneic dermal matrix (Mucoderm) with coronal advanced flap, while the other involves subepithelial connective tissue graft with coronal advanced flap for treatment of Miller type I, II gingival recession. Participants are followed up to measure gingival recession and soft tissue thickness at 3 and 6 months.

What are the possible benefits and risks of participating?
The benefit is proven the effectiveness of full coverage of the roots and an increase in the thickness of the keratinized gingiva by applying Xenogeneic dermal matrix (Mucoderm), as similar as to subepithelial connective tissue graft. The methods are safe and there are no expected risks.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2021 to April 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mohammad Alabed
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2508/S.M

Study information

Scientific Title
Clinical comparison of coronally-advanced flap plus Xenogeneic Porcine-derived acellular dermal Matrix (Botiss Mucoderm®) and subepithelial connective tissue graft in the treatment of single tooth recessions

Study objectives
There is no difference between Mucoderm and subepithelial connective tissue graft for root coverage and increased soft tissue thickness.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 02/08/2021, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, Syria +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: 2508/S.M

Study design
Split-mouth interventional double-blinded randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Gingival recession

Interventions
Participants defects will be randomly divided into two groups by obaque sealed invelope method: control group (will be treated with Coronal Advanced Flap (CAF) + subepithelial Connective Tissue Graft (sCTG) and test group (will be treated with Coronal Advanced Flap (CAF) + Xenogeneic Dermal Matrex Mucoderm (XDM). Participants are followed up at 3 and 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Gingival recession depth measured using a UNC-15 probe at baseline, 1, 3, 6 months
2. Gingival recession width measured using a UNC-15 probe at baseline, 1, 3, 6 months
3. Keratinized Tissue Thickness measured using an anesthesia needle attached to a silicone disc stop at base line, 3 , 6 months.

Secondary outcome measures
1. Probing depth measured using a UNC-15 probe at baseline, 3, 6 months
2. Relative attachment level measured using a UNC-15 probe at baseline, 3, 6 months
3. Keratinized tissue height measured using a UNC-15 probe at baseline, 3, 6 months
4. Healing measured using a healing index at 1, 2 weeks and 1 month after surgery
5. Plaque presence measured using a plaque index at baseline, 1, 3, 6, months
6. Pain measured using a visual analogue scale (VAS) at 1 week after surgery

7. Bleeding measured using a visual analogue scale (VAS) at 1 week after surgery
8. Dentine hypersensitivity measured using a visual analogue scale (VAS) at baseline, 1, 3, 6 months

Overall study start date
10/03/2021

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Good general health.
2. No contraindications for periodontal surgery.
3. Presence one localized gingival recession in each side of the maxilla and/or mandible, All recessions will be Class I or II defects (Miller 1985).
4. The cemento–enamel junction (CEJ) will be visible in the teeth for root coverage procedures.
5. All patients demonstrating adequate plaque control.
6. All patients will be at least 18 years of age.
7. No previous periodontal surgery in the area.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 sites (15 for each group)

Key exclusion criteria
1. Patients smoking more than 10 cigarettes per day.
2. Patients with insulin-dependent diabetes.
3. Patients with a history of malignancy, radiotherapy, or chemotherapy for malignancy.
4. Patient pregnant or nursing during the past 5 months.
5. Patients taking medications or having treatments with an effect on mucosal healing in general (e.g. steroids, large doses of anti inflammatory drugs).
6. Patients with a disease affecting connective tissue metabolism.
7. Patients allergic to collagen.
8. Presence more than one localized gingival recession in each side of the maxilla and/or mandible.

Date of first enrolment

01/09/2021

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of periodontology
Faculty of Dentistry
Damascus
Syria
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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.
Additional documents (such as study protocol, statical analysis plan, etc.) will be available.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr. Suleiman Dayoub suleimandayoub@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			24/01/2022	No	No
Results article		12/07/2024	12/03/2025	Yes	No