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Testing a new approach for modifying the characteristics of the gums

Submission date	Recruitment status	[_] Prospectively registered
07/04/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/04/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2025	Oral Health	

Plain English summary of protocol

Background and study aims
Recently, more studies have addressed the importance of determining the characteristics of the gums (gingival phenotype) before dental procedures, as they significantly impact the outcome of restorative and regenerative therapy. The aim of this study is to evaluate the change in gum thickness and the width of gum tissue that is keratinized after treatment with either a connective tissue graft or an albumin gel-platelet-rich fibrin mixture (Alb-PRF).

Who can participate?
Patients aged 18 years and over with a thin gingival phenotype

What does the study involve?
The position of the graft is selected at random. The connective tissue graft is inserted and sutured in the first test position and an albumin gel-platelet-rich fibrin mixture (Alb-PRF) prepared from the patient's own blood is inserted in the second test area on the opposite side of the mouth.

What are the possible benefits and risks of participating?
Both CTG and Alb-PRF might improve the gingival phenotype by increasing the thickness and keratinized tissue width of the gums. 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 September 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Sara Abdulhak, dr.sara.abd.alhak@gmail.com

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
2495/S.M

Study information

Scientific Title
Clinical comparative study of autologous albumin gel mixed with liquid platelet-rich fibrin (Alb-PRF) vs connective tissue graft to modify the gingival phenotype

Study objectives
There is no difference between albumin gel-platelet-rich fibrin mixture (Alb-PRF) and connective tissue graft for increasing gingival thickness and keratinized tissue width.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/08/2021, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, Syria; +963 (0)1133923192; ap.srd@damascusuniversity.edu.sy), ref: 2495/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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Thin gingival phenotype

Interventions
In this split-mouth study, individuals with thin gingival phenotypes were randomly treated with a connective tissue graft and an albumin gel-platelet-rich fibrin mixture (Alb-PRF). Allocation will be at random using a sequentially numbered opaque, sealed envelope method. The connective tissue graft will be applied at the gingiva on one side of the mandibular anterior region, and Alb-PRF will be applied on the other side for the same patient. Clinical measurements will be taken every month during the 3-month follow-up period.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Gingival thickness measured using a no.15 endodontic spreader (inserted perpendicularly from the vestibular midpoint 1.5 mm apical of the gingival margin through the soft tissue until a hard surface is reached) and a digital caliper to assess the penetration depth at baseline, 1, and 3 months
2. Keratinized tissue width measured from gingival margin to mucogingival junction with the help of a periodontal probe (UNC 15 probe) at baseline, 1, and 3 months

Secondary outcome measures
1. Probing depth index measured using a periodontal probe to measure the periodontal pocket depth at baseline, 1, and 3 months
2. Relative attachment level measured using a UNC-15 probe at baseline, 1 and 3 months
3. Pain measured using a visual analogue scale (VAS) at 1 week after surgery
4. Healing measured using a healing index at 1, 2 weeks and 1 month after surgery

Overall study start date
11/03/2021

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Systemically healthy patients
2. Gingival thickness of the mandibular anterior teeth >1 mm
3. No pregnancy or lactation
4. Non-smokers
5. Adequate plaque control
6. 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
20 sites (10 for each group)

Key exclusion criteria
1. Active orthodontic treatment
2. Previous periodontal surgery
3. Use of any drug that might affect periodontal health
4. Malocclusion, crowding, missing or supernumerary teeth
5. Tooth mobility, bruxism
6. Patients with a history of malignancy, radiotherapy, or chemotherapy for malignancy

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
Mezzah
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

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http://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
30/09/2024

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 Tarik Kasem (prof.tarekkasem@hotmail.com).
All of data of the patients will be available on request.
Consent from participants was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/06/2024	07/05/2025	Yes	No