

# Testing a new approach for modifying the characteristics of the gums

<b>Submission date</b> 07/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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

## Contact name

Dr Sara Abdulhak

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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](mailto: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

Albaramkeh  
Damascus  
Syria  
-

+963 (0)1133923192  
info@damascusuniversity.edu.sy

### Sponsor type

University/education

### Website

<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?
<a href="#">Results article</a>		08/06/2024	07/05/2025	Yes	No