# The use of a blood protein (A-PRF) to enhance the replacement and recovery of gum tissue around tooth implants

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
17/08/2020		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/08/2020	Completed	[X] Results		
<b>Last Edited</b> 30/04/2021	Condition category Oral Health	[] Individual participant data		

## Plain English summary of protocol

Background and study aims

Mucogingival surgery is a form of plastic surgery used to correct the effects of recession caused by gum disease (periodontitis) or poor developmental anatomy or traumatic toothbrushing. It is usually indicated to improve the gum thickness to reduce the risk of further recession, reduce dental sensitivity, in some cases cover the roots. In severe cases, it can improve the life span of the teeth treated. The ability to achieve root coverage reduces with increasing extent of recession. Mucogingival surgery usually involves transfer of a small amount of gum from the palate to the area in question. This will provide an area of tough and thick gum that will be easier to maintain clean and in turn reduce the risk of the recession worsening. Whereas, the donor site in the palate will heal very readily with new tissue.

Advanced Platelet Rich Fibrin (APRF) is a new advanced technology that helps heal wounds anywhere in the body, including those involved in oral surgery, using the patient's own blood. The aim of this study was to evaluate the efficacy of Advanced platelet-rich fibrin (A-PRF) with Apically Positioned flap (APF) compared to Free Gingival Grafts (FGG) with APF.

Who can participate?

Adults over 20 years of age requiring a replacement for missing teeth

What does the study involve?

As this is a split-mouth study, each participant will receive two different treatments, one on each side of the mouth (order chosen randomly). Participants are followed up for 6 months.

What are the possible benefits and risks of participating? Benefit: recovery of function to the affected area Risks: The procedure and recovery can be painful

Where is the study run from? Faculty of Dental Medicine, Damascus University (Syria)

When is the study starting and how long is it expected to run for? December 2018 to December 2019

Who is funding the study? Investigator self-funded and partially funded by Damascus University

Who is the main contact? Jihad ALsahli, dr.jihad1992@gmail.com

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Jihad Yasin ALsahli

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

3296\m

# Study information

#### Scientific Title

Evaluation of apically positioned flap with A-PRF vs free gingival grafts to enhance the width of keratinized tissue around dental implants: a randomized clinical split-mouth study

## Study objectives

There is a significant difference between using apically positioned flap with A\_PRF Vs. free gingival grafts to enhance the width of keratinized tissue around dental implants

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 06/08/2018, Ethical Committee of the Faculty of Dental Medicine (Damascus University, Damascus, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: 3296\m

## Study design

Randomized clinical split-mouth study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Partially edentulous and requiring a replacement for missing teeth

#### **Interventions**

Test group (Apical position flap + Advanced platelet rich fibrin) Control group (Free gingival graft)

Both test and control groups were treated in the same surgical session and patients were scheduled for postoperative follow up after 1 week, 4 weeks, 8 weeks, and 6 months after the surgery for both groups.

Patients were randomly assigned to a test group (A-PRF) or a control group (FGG) in a split mouth design, via a randomization table; by a computer-generated randomization list (SPSS v23. 0). The treatment methods (15 for A-PRF test group / 15 for FGGs control group).

## Intervention Type

Procedure/Surgery

## Primary outcome(s)

- 1.Width of keratinized tissue was measured using a vacuum stent with periodontal probe from the lingual edge side of the stent to the mucogingival junction at baseline, immediately after the surgery, and 8 weeks later
- 2. Gingival thickness (phenotype) was measured using an acrylic stent, with an average of three measurements, at baseline, 8 weeks, and 6 months after the surgery

## Key secondary outcome(s))

Postoperative pain was measured using a visual analog scale (VAS) from 0 (absence of pain) to 100 (most severe pain) on the day of surgery, and afterwards daily until day 6

## Completion date

12/12/2019

# **Eligibility**

## Key inclusion criteria

- 1. Older than 18 years old
- 2. Less than 2 mm of KT at the buccal site from the ridge crest on bilateral implants
- 3. Patients have a thick gingival phenotype ( $GT \ge 2 \text{ mm}$ )
- 4. Adequate oral hygiene (API≤1) (API= Approximal Plaque Index) and good general health

## Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

All

#### Total final enrolment

14

#### Key exclusion criteria

- 1. Smokers and alcoholics (≥10 cigarettes/day)
- 2. Patients with systemic diseases that could interfere with the healing
- 3. Patients undergoing bisphosphonate treatment and patients who previously received radiotherapy for the jaws
- 4. Patients with moderate to severe periodontitis
- 5. Pregnant women and breastfeeding mothers

#### Date of first enrolment

01/01/2019

#### Date of final enrolment

05/06/2019

## Locations

#### Countries of recruitment

Syria

## Study participating centre

#### **Damascus University**

Faculty of Dental Medicine Almazah Highway 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** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/03/2021	30/04/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes