

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 17/08/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/08/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 30/04/2021 | Condition category Oral Health | <input type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

06/12/2018

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 ($GT \geq 2$ mm)
4. Adequate oral hygiene ($API \leq 1$) (API= Approximal Plaque Index) and good general health

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

15

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

Sponsor details

Damascus

Damascus

Syria

-

+963 (0)113341864

manager@hcsr.gov.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

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

16/10/2020

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 |