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

Submission date
17/08/2020

Recruitment status
No longer recruiting

Registration date
20/08/2020

Overall study status
Completed

Last Edited
30/04/2021

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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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
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 ≥ 2 mm)
4. Adequate oral hygiene (API≤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
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-

Sponsor information

Organisation
Damascus University

Sponsor details
Damascus
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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