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Management of receding gums using tissue obtained from the roof of the mouth, a comparison of two techniques

Submission date 31/12/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/01/2020	**Overall study status** Completed	
Last Edited 16/04/2021	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Gingival recession, also known as receding gums, is the exposure in the roots of the teeth caused by a loss of gum tissue and/or retraction of the gum from the teeth. The usual treatment is to firstly graft tissue obtained from the roof of the mouth (palate) to make the loss area more resistant to recession (known as a free gingival graft) , the second stage after about three months includes another graft obtained from the deeper tissue of the palate to cover the loss (connective tissue graft).
This study will investigate the use of a newly developed technique that combines the two stages into one, combining the two tissue grafts before attaching to the gum area.

Who can participate?
Adults aged 18 – 55 years with gingival recession on both sides of the mouth

What does the study involve?
Participants will have on side of their mouth treated with the usual method, and the other side of the mouth treated with the new method. Participants will not know which treatment is being used on which side of the mouth.

What are the possible benefits and risks of participating?
The main benefit of enrolling the trial is getting stronger gums in the affected areas and getting rid of gums receding by covering the root's exposure by the grafts.
There is one risk could occur; the graft may fail to integrate with receiving area; if that happened, the receding gums would return to its primary shape before surgery and the patient may have a little bit of pain and malaise.

Where is the study run from?
Damascus University, Dentistry College, Department of Periodontology, Syria

When is the study starting and how long is it expected to run for?
January 2020 to June 2021

Who is funding the study?
Damascus University, Syria

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
Approval of Dentistry college council- damascus university no. 677 date 28/5/2019

Study information

Scientific Title
Management of gingival recession of Miller's class || using two techniques: Combined Gingival Graft (FGG + CTG) and Free Gingival Graft

Acronym
CGG

Study objectives
There are statistical differences in the averages of the studied variables between the two surgical procedures at the end of every period of follow-up periods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2019, Ethics Committee - Dental College - Damascus University (Mazzeh Highway, Damascus, Syria; +963 1133923486; sr.srd@damasuniv.edu.sy), ref: no.3518

Study design
Current study design as of 18/02/2020:
Single-centre single-blind randomized trial with split-mouth technique

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Previous study design:
Single-centre single-blind randomized controlled trial with split-mouth technique

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gingival recession of Miller's class II

Interventions
This study will try a new surgical technique to cover Miller's class II gingival recession.

Those patients are usually treated by free gingival graft harvested of the palate to increase attached gingiva width and after 3 months if the result is not as desirable they would undergo second surgical procedure including harvesting connective tissue graft from the palate to cover the entire recession simultaneously with coronally advanced flap.

The present study will integrate the two procedures in one surgical procedure and confirm the desirable last result from the first hour after surgery.

The new technique depends on harvesting full-thickness graft from the palate and de-epithelializing a part of it and removing the connective tissue from the second part; this way one graft includes free gingival graft and connective tissue graft connected together.

Participants will receive the traditional technique (free gingival graft) for one side of the mouth (control sample) and the newly described technique for the other side.

The total duration of treatment and follow-up for all the study arms is 8 months.

Randomization method; throwing a dice, if less than or equal to 3, the right side of patient's mouth will be treated by the new technique (combined gingival graft), if greater than 3, the right side will be treated by traditional technique (free gingival graft).

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 18/02/2020:
1. Gingival recession measured by periodontal probe from a stable point (acrylic splint made for each patient) to the gingival margin at three time points: date of surgery, after one month, and after 3 months)
2. Width of attached gingiva measured by periodontal probe at three time points: date of surgery, after one month, and after 3 months

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Previous primary outcome measure:
1. Gingival recession measured by periodontal probe from a stable point (acrylic splint made for each patient) to the bottom of gingival sulcus at three time points: date of surgery, after one month, and after 3 months
2. Width of attached gingiva measured by periodontal probe at three time points: date of surgery, after one month, and after 3 months

Secondary outcome measures
Gingival Biotype (the thickness of gingiva) measured by periodontal probe at three time points: date of surgery, after one month, and after 3 months

Overall study start date
15/01/2020

Completion date
05/06/2021

Eligibility

Key inclusion criteria
1. Age between 18 - 55 years
2. There is no systematic disease that affects the wound healing
3. Good oral hygiene with no symptoms of gingivitis
4. No smoking habit
5. Gingival recession of Miller's class II on two sides of the mouth
6. No previous periodontal surgery in the targeted area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 patients (twenty surgical sites)

Total final enrolment
10

Key exclusion criteria
1. Systemic disease that affects wound healing.
2. Gingival or periodontal disease
3. Uncontrolled plaque accumulation
4. Pregnancy and breast-feeding
6. Previous periodontal surgery in the targeted area

Date of first enrolment
20/01/2020

Date of final enrolment
27/02/2021

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Dentistry College, Department of Periodontology
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Sponsor information

Organisation
Damascus University

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University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
Planned to be published in Periodontology 2000 Journal.

Intention to publish date
20/08/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other