

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/04/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 one 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 in 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 that could occur; the graft may fail to integrate with the receiving area; if that happened, the receding gums would return to their 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?
Dr Jihad Al-Rashed
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 II 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

Previous study design:

Single-centre single-blind randomized controlled trial with split-mouth technique

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Mazzeah Highway

Damascus

Syria

DM20AM18

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

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other