

Treatment of retracted gums using tissues which underline the roof of the mouth with two surgical scalpels

Submission date 03/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/09/2021	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 is a retraction of tissues which cover the teeth, this retraction causes aesthetic problems, teeth sensitivity and caries.

As usual we can solve this problem by a surgical procedure (we extract a tissue from the roof of the mouth, it's name is a connective tissue graft) by a traditional surgical tool by a traditional technique, but this approach may causes more pain and less satisfaction for the patient, a long time-surgery and longer time healing.

So in our study we will use a new tool with a new technique (Double Bladed Scalpel) to obtain better tissue from the roof of the mouth to improve our results and to make our patient more satisfied at all levels.

Who can participate?

Adults aged 18 – 55 years with gum tissues retraction on both sides of the jaw.

What does the study involve?

Participants who will be treated by a traditional tool and a traditional approach on one side of their jaw while they will be treated by a new tool on their other side of the jaw. 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 is a root coverage and an aesthetic aspect improvement.

the possible risk is a graft failure caused by lack of maintenance of the patient so the receding gum will return to its primary shape before surgery

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?

February 2020 to August 2021

Who is funding the study?
Damascus University, Syria

Who is the main contact?
Dr Laura Mrhej
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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. 686 date 18/06/2019

Study information

Scientific Title
Connective tissue graft harvesting with double bladed scalpel and traditional scalpel for treatment of gingival recession. a comparative randomized clinical trial

Acronym
CTG

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

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 05/08/2019, Ethics Committee- Dental College- Damascus University (MazzeH Highway, Damascus, Syria; +963 1133923486; sr.srd@damasuniv.edu.sy), ref: no.3889

Study design

Single-center single-blind comparative randomized clinical 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 I

Interventions

This study will compare between two scalpels to harvest a connective tissue graft for treatment of gingival recession.

The first one will be used in (test group) is double bladed scalpel (5 DOUBLE-BLADED SCALPEL HANDLE, 1MM, 1013005D1, Hu-Freidy). The handle of this scalpel holds two blades with a 1mm separation between them, this will provide me with a graft slightly thicker of around 1.2-1.5 mm after harvesting. After anesthetizing the area, we will make a horizontal incision 2.5 mm apical to gingival margins of the teeth with a 15 or 15c bard parker blade then we will Elevate a short full thickness flap of 3 mm to 4 mm approximately in order to allow exposure of the connective tissue area apical to the incision and insert the double blade knife mounted with two bard parker 15 blades (not the 15c blades!- they are too thin and will bend) into the thickness of the detached palatal flap at its distal end. After that we will take them to the desired apicoronal depth, and then move slowly towards the mesial. In the end we will Cut the perimeter of the graft with a mesial and a distal vertical incision, and a horizontal apical incision aimed to bony surface will be made to liberate the graft.

This technique will consistently provide a graft of predetermined and uniform thickness that will help me to decide the size, thickness, and composition of the graft we desire, and harvest it accordingly.

In control group, we will use a traditional scalpel to harvest the graft with (single incision technique) : The anterior and posterior borders of this rectangle will be located in the canine region and at the palatal root of the first molar. Incision will be made at a 90-degree angle to the bone. 2 mm away from the gingival margin then we will change it to 135 degrees to prepare a partial thickness flap towards the median, then we will use a periosteal elevator to detach the graft from the bone surface. In the end we will extract it by a mesial, distal and median incisions.

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 (the double bladed scalpel), if greater than 3, the right side will be treated by the traditional technique (the traditional scalpel).

Intervention Type

Procedure/Surgery

Primary outcome(s)

Current primary outcome measure as of 09/09/2021:

1. Recession Depth (RD) is measured by a UNC15 periodontal probe from a stable point (acrylic splint made for each patient) to the gingival margin at two time points: date of surgery, and after three months
2. Keratinized Tissue Width (KTW) is measured by a UNC15 periodontal probe at two time points: date of surgery, and after three months

Previous primary outcome measure:

1. Recession Depth (RD): is measured by a UNC15 periodontal probe from a stable point (acrylic splint made for each patient) to the gingival margin at two time points: date of surgery, and after three months
2. Gingival Width (GW) :is measured by a UNC15 periodontal probe at two time points: date of surgery, and after three months

Key secondary outcome(s)

Current secondary outcome measures as of 09/09/2021:

1. Gingival Thickness (GT) is measured by a UNC15 periodontal probe at two time points: date of surgery, and after three months
2. Clinical Attachment Level (CAL) is measured by a UNC periodontal probe from a stable point (acrylic splint) to the bottom of the gingival sulcus at two time points: date of surgery, and after three months
3. Surgical procedure time measured from the beginning of the surgery to the end of suturing
4. Pain level after surgery measured using vascular analogue scale (VAS) after three months
5. Patient satisfaction with esthetic results after surgery measured using vascular analogue scale (VAS) after three months

Previous secondary outcome measures:

1. Gingival Thickness (GT) : is measured by a UNC15 periodontal probe at two time points: date of surgery, and after three months
2. Clinical Attachment Level (CAL) : is measured by a UNC periodontal probe from a stable point (acrylic splint) to the bottom of the gingival sulcus

Completion date

15/08/2021

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. Bilateral side of gingival recession (Miller's class I)
6. At least 1mm of attached gingiva.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

12

Key exclusion criteria

1. Systemic disease or medication that affects wound healing
2. Gingival or periodontal disease or uncontrolled plaque accumulation
3. Pregnancy and breast-feeding

Date of first enrolment

06/02/2020

Date of final enrolment

22/08/2021

Locations**Countries of recruitment**

Syria

Study participating centre**Damascus University**

Dentistry College

Department of Periodontology

MazzeH 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