ISRCTN34968827 https://doi.org/10.1186/ISRCTN34968827

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/02/2020	**Overall study status** Completed	
Last Edited 09/09/2021	**Condition category** Oral Health	

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
lauramrhej@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Laura Mrhej

ORCID ID
https://orcid.org/0000-0002-7210-4998

Contact details
Damascus University
Mazzeh HIghway
Damascus
Syria
-
+963 993422870
lauramrhej@gmail.com

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. 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

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 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 measure
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

Secondary outcome measures
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 Attachement 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 Attachement Level (CAL) : is measured by a UNC periodontal probe from a stable point (acrylic splint) to the bottom of the gingival sulcus

Overall study start date
01/02/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 patients (twenty surgical sites)

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

Sponsor details
Mazzeh Highway
Damascus
Syria
DM20AM18
+963 112121635
info@damascusuniversity.edu.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 to be published in Periodontology 2000 Journal.

Intention to publish date
15/11/2021

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