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The effect of changing the length and thickness of the free gingival graft on palatal wound healing

Submission date
25/08/2020

Recruitment status
No longer recruiting

Registration date
27/08/2020

Overall study status
Completed

Last Edited
27/08/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A gingival graft is a surgical procedure for patients with gingival recession (receding gums). It involves removing tissue from the patient's palate (palatal donor sites) and then grafting it onto the site of the recession (missing gum). Different graft harvesting procedures have been used. Wound healing and re-epithelialization are the most important factors which affect the level of discomfort (morbidity) that patients may feel. This study aims to assess re-epithelialization (healing) and wound closure of palatal donor sites after free gingival graft surgery with different graft sizes.

Who can participate?
Patients aged over 20 with gingival recession

What does the study involve?
Participants are randomly allocated to be treated with grafts of one of four different sizes. Re-epithelialization is assessed on the 7th, 14th, 21st, 28th, 35th, 42nd, 48th and 54th days after surgery using blue staining and taking photographs of the surgical sites.

What are the possible benefits and risks of participating?
Expected benefits from this study are receiving treatment for gingival recession, while the risks are pain, delayed bleeding and discomfort.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
August 2018 to June 2019

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
3137\t.m

Study information

Scientific Title
Effect of graft dimensions on palatal wound re-epithelialization evaluated by toluidine blue stain

Study objectives
H0: There is no effect of the length and thickness of the free gingival graft on re-epithelialization.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 12/06/2018, University Of Damascus Dental School Local Ethics Committee (Damascus University, Damascus, Syria; +963 (0)94040840; Osama.aljabban@gmail.com), ref: 3137/t.m

Study design
Randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Mucogingival problems qualifying them for surgery: thin biotype, a narrow zone of keratinized gingiva (≤1 mm) and multiple gingival recession on the facial aspect of the mandibular anterior area

Interventions
Following enrollment, participants are assigned to treatment groups using balanced block randomization. The surgeon, the observers and the patients are blinded. To meet the assumptions of randomization, a number of sealed non-transparent coded envelopes are prepared with letters A, B, C or D printed on them. Each patient is then required to choose one. If A is chosen, the patients are assigned to group L1. A patient choosing B is assigned to the group L2. Patients choosing C are assigned to group T1, while D is assigned to group T2.

In group L1 the graft is 10-15 mm long (16 patients) and in group L2 the graft is more than 15 mm long (16 patients). The width and thickness of the graft site are 8 mm and 1.5-2 mm. In group T1 the graft is ≤2 mm thick (16 patients) and in group T2 the graft is >2 mm thick (16 patients).

The graft is obtained from the distal part of the canine to the mesial part of the first molar and 2 mm apical to the gingival margin. The length and width of the graft site are 14 mm and 8 mm, respectively.

Re-epithelialization is assessed using 1% Toluidine Blue solution according to its application protocol. The patient is asked to rinse with water for 20 seconds to eliminate the food remnants, then to rinse with 1% acetic acid for 20 seconds to eliminate saliva components. 1% Toluidine Blue is then applied with a piece of cotton for 20 seconds. Then again, participants rinse with 1% acetic acid for 20 seconds. After that, a syringe is used to rinse for 20 seconds with sterilized water. When the wound turns a dark blue color, it indicates the staining of the connective tissue cells and the absence of the keratinized epithelium. A light blue color or the absence of the color indicates the formation of keratinized epithelium.

The results are recorded on the 7th, 14th, 21st, 28th, 35th, 42nd, 48th and 54th day post-surgery by taking standardized photographs of the surgical sites by using a specially designed device and a mouth mirror to ensure that the researchers had the same reference position during the follow-up period. Then each photograph is analyzed using computer software (Image National Institutes of Health, USA) to calculate the surface area of re-epithelialization.

Graft surface area is calculated directly after harvesting and it equals the wound surface area at baseline. The surface area of the dark blue color on the photograph is measured. Finally, the re-epithelialization surface area is calculated by subtracting the dark blue area from the total wound area.

Intervention Type
Procedure/Surgery

Primary outcome measure
Re-epithelialization assessed using Toluidine Blue staining on the 7th, 14th, 21st, 28th, 35th, 42nd, 48th and 54th day post-surgery

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
12/08/2018

Completion date
22/06/2019

Eligibility

Key inclusion criteria
1. Older than 20 years
2. Presenting bilateral class I or II Miller gingival recession in the mandibular incisor region
3. Included teeth are vital and have no caries or restorations
4. Plaque and the gingival index scores less than 1
5. Systematically healthy and non-smokers

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
64

Total final enrolment
64

Key exclusion criteria
1. Periodontal probing depth higher than 3 mm
2. Patient receiving medical therapy that interferes with wound healing process
3. Pregnant and lactating woman
4. Patient with a previous surgical procedure in the study area and patients undergoing orthodontic therapy

Date of first enrolment
08/09/2018

Date of final enrolment
16/04/2019

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dental Medicine
Al-Mazzah Highway
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Sponsor information

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Government

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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 publication in a high-impact peer-reviewed journal. Currently there are no additional documents for this trial.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date