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A study of the gums and orthodontic tooth movement after a connective tissue graft

Submission date
16/07/2022

Recruitment status
No longer recruiting

Registration date
02/08/2022

Overall study status
Completed

Last Edited
02/08/2022

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
This study aims to measure the effects of using connective tissue grafts on orthodontic patients (with crowding in the lower front teeth) with a thin gingival (gum) biotype at risk of periodontal (gum) problems, compared to patients receiving only orthodontic treatment.

Who can participate?
Patients aged 15-40 years who want to align their teeth with orthodontic treatment and have a thin gingival biotype

What does the study involve?
Participants are randomly allocated to be treated with a connective tissue graft and orthodontic treatment (the experimental group) or orthodontic treatment only (the observational group).

What are the possible benefits and risks of participating?
Participants may benefit from increased gingival thickness and width of attached gingiva and faster orthodontic movement. The procedure doesn't involve any risks. It may prevent gingival problems during orthodontic treatment in patients with a thin gingival biotype.

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

When is the study starting and how long is it expected to run for?
May 2021 to December 2022

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
Dr Mai Souliman, maisouliman001@gmail.com

Contact information

Type(s)
Principal Investigator

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Dr Mai Souliman

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
M.S /513/

Study information

Scientific Title
A study of gingival parameters and acceleration of orthodontic movement after implementation of connective tissue graft using the tunnel technique on patients with crowding in the lower anterior teeth and thin gingival biotype

Study objectives
The aim is to study gingival parameters and acceleration of orthodontic movement after implementation of connective tissue graft using the tunnel technique on patients with crowding in the lower anterior teeth and thin gingival biotype

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/09/2021, Damascus University Rector (Baramkeh, Damascus, Syria; +966 (0)55 506 3806; email: not available), ref: 3391 MS

Study design
Randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Gingival diseases in patients with thin gingival biotype and treated by orthodontics

Interventions
This study is a randomized controlled trial. Patients are randomly selected according to their order of arrival, and the odd numbers are only treated by orthodontics. The even numbers have braces installed then the connective tissue graft (tunnel technique) will be performed. After 1 week the suture will be removed and the wire added to start the orthodontic treatment.

The duration of treatment is 2-3 weeks (to test and select the appropriate patient, set up the braces then implement the connective tissue graft) and the follow-up is during the orthodontic treatment which ranges between 4-6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Acceleration of the orthodontal movement assessed by Little's irregularity index before and every month after the connective tissue graft until the end of the orthodontic treatment
2. Gingival thickness assessed by an endodontic spreader before and after the treatment
3. Width of the attached gingiva assessed by William's prober before and after the treatment

Secondary outcome measures
Gingival parameters measured using the root coverage esthetic score (RES) before and after the treatment:
1. GM (gingival margin): zero points = failure of root coverage (gingival margin apical or equal to the baseline recession); 3 points = partial root coverage; 6 points = complete root cover
2. MTC (marginal tissue contour): zero points = irregular gingival margin (does not follow the CEJ); 1 point = proper marginal contour/scalloped gingival margin (follows the CEJ)
3. STT (soft tissue texture): zero points = scar formation and/or keloid-like appearance; 1 point = absence of scar or keloid formation
4. MGJ (mucogingival junction): zero points = MGJ not aligned with the MGJ of adjacent teeth; 1 point = MGJ aligned with the MGJ of adjacent teeth

Overall study start date
14/05/2021

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Aged between 15-40 years old
2. Crowding in the lower anterior teeth (4-6 mm)
3. Thin gingival biotype (less than 1 mm)
4. Non-smoking
5. No general diseases
6. Good oral hygiene
7. No problem with gingival recession

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
The target number of participants will be determined after finishing the pilot study (5 patients) using the G power program. It is expected to be 20 patients (10 for the experimental cluster and 10 for the observational cluster).

Key exclusion criteria
1. Children (under 15 years old) and old age
2. Crowding in the lower anterior teeth (more than 6 mm)
3. Thick gingival biotype
4. Smoking
5. General diseases
6. Bad oral hygiene
7. Periodontitis

Date of first enrolment
05/11/2021

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Periodontology Department
Faculty of Dentistry
Mazzeh Highway
Damascus
Syria
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Sponsor information

Organisation
Tishreen University

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

Alternative Name(s)
October University, Université Tichrine, , TU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mai Eissa Souliman (maisouliman001@gmail.com). The data will become available in 2023.

IPD sharing plan summary
Available on request