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Comparison of two approaches to rebuilding gum tissue around dental implants

Submission date	Recruitment status	[ ] Prospectively registered
06/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/02/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2022	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Following tooth extraction, within the first week after removing the tooth, there is a vast amount of gum loss, especially at the outer surface of bone. In order to compensate for the loss of volume, a number of surgical procedures may be necessary. Including those increasing dimensions of soft tissue, to gain additional volume. The gold standard for this type of procedure is the use of connective tissue which is generally taken from the hard palate. As this procedure leaves a second surgical site for the patient healing may be impaired. It is desirable to reduce complications and shorten the healing phase. Various soft tissue substitutes were evaluated in the past to replace autogenous tissue. Although clinical data demonstrated promising results for various substitute materials when used for gain of keratinized tissue or recession coverage, tissue augmentation in terms of volume gain cannot be achieved predictably using these collagen materials. In order to replace the harvesting of autogenous tissue, a volume stable collagen matrix were developed allowing for soft tissue volume augmentation, the porous network of Geistlich Fibro-Gide® supports formation of new connective tissue and stability of the collagen network in submerged healing. In vivo animal models have shown good integration of xenogeneic collagen matrix (Geistlich Fibro-Gide®) into the surrounding soft-tissue while maintaining stability. With Geistlich Fibro-Gide® additional harvest site is avoided, patient morbidity is reduced.

Who can participate?
Patients aged 20 years or above who have a dental implant with soft tissue recession

What does the study involve?
Control group: 15 sites will be treated by coronal advancement flap with subepithelial connective tissue graft.
Test group: 15 sites will be treated by coronal advancement flap with xenogeneic collagen matrix (Geistlich Fibro-Gide®).

What are the possible benefits and risks of participating?
Benefits:
1. Covering of the peri-implants soft tissue recessions
2. Increasing width and thickness of keratinized tissue

3. Enhancing/improving esthetic satisfaction
Risks:
Potential Graft failure could happen in case of lack of commitment to post-operative instructions

Where is the study run from?
The department of Periodontology
Faculty of Dental Medicine
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
September 2019 to July 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
3167/S.M

Study information

Scientific Title
Comparison of the peri-implant soft-tissue recession coverage and esthetic outcomes of two different approaches: xenogeneic collagen matrix (Geistlich Fibro-Gide®) and subepithelial connective tissue graft using the coronal advancement flap for the treatment of soft tissue recession

Study objectives
(Geistlich Fibro-Gide®) is an alternative to Connective Tissue Graft (CTG) due to its characteristics which are its volume stability, contains collagen, use, and indications like insufficient soft tissue volume and recession defects. Compared to CTG, it has proven a stable augmented soft tissue both in terms of quality and quantity with the additional benefits of eliminating the donor site and lowering patient pain perception when compared to CTG.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/09/2019, Medical research committee at Damascus University faculty of dental medicine (Mazzeh, Damascus, Syria; +963 40404840; Osama.aljabban@gmail.com), ref: 3167/S.M

Primary study design
Interventional

Study design
Interventional randomized controlled split mouth trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peri-implant soft tissue defects treatment

Interventions
The study contains 15 patients with bilateral soft tissue recession peri-implant ≥2mm in one implant at least in the upper or lower jaw, therefore 30 affected sites will be treated
Control group: 15 sites will be treated by coronal advancement flap with a subepithelial connective tissue graft.
Test group: 15 sites will be treated by coronal advancement flap with xenogeneic collagen

matrix (Geistlich Fibro-Gide®)
Follow up : 3 months
Randomisation process: Coin Flip

Intervention Type
Procedure/Surgery

Primary outcome(s)
Recession depth at 2 weeks, month, 3 months measured using a periodontal probe

Key secondary outcome(s)
1. Width and thickness of keratinized tissued measured using a periodontal probe at baseline and 3 months
2. Percentage of implant coverage measured using a periodontal probe at baseline and 3 months
3. Recession width measured using a periodontal probe at baseline and 3 months
4. Color and texture of treatment sites, ''equal or not equal to surrounding native tissue'' through visual observation and palpation at 2 weeks, months, and 3 months.
5. Subject esthetic satisfaction, (''unsatisfied'' to ''very satisfied'') on a five-point scale at 3 months
6. Subject pain or discomfort (''no pain'' to ''extreme pain'') on 10-cm visual analog scales at 2 hours, 24hrs, 48hrs, 72hrs and 1 week.

Completion date
04/07/2021

Eligibility

Key inclusion criteria
1. Patients with bilateral soft tissue recession peri-implant ≥2mm
2. Thin gingival biotype
3. Age ≥20 years old
4. No probing depths ≥5mm
5. Healthy implants measured by the lack of periimplantitis and mucositis
6. Good oral hygiene

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Unstable systemic diseases
2. Compromised immune system
3. Unstable bleeding disorders
4. History of radiation or cancer in the oral cavity
5. Use of intra-venous bisphosphonate or steroid medication
6. Use of tobacco products (1/2 pack per day)
7. Pregnant or breastfeeding women
8. Previous mucogingival surgery or implant placement within the past 6 months
9. Bone defects requiring grafting
10. Bad oral hygiene

Date of first enrolment
15/09/2019

Date of final enrolment
20/06/2021

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Periodontology
Faculty of Dental Medicine
Mazzeh
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

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

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