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Comparing collagen matrix and connective tissue grafts for improving smile aesthetics around dental implants

Submission date 06/11/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/11/2024	**Overall study status** Ongoing	
Last Edited 04/03/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
One of the challenges in implant dentistry is to achieve optimal soft tissue esthetics (appearance) around implants in the anterior region (front of the mouth). Various techniques have been proposed to increase the thickness of the peri-implant soft tissue, such as using autogenous connective tissue grafts (CTGs) or xenogenic collagen matrices (XCMs). However, there is a lack of evidence on the comparative effectiveness and patient satisfaction of these two methods. Therefore, the aim of this study is to compare the clinical and patient-reported outcomes of using CTG and XCM (Mucoderm®, Botiss Biomaterials, Germany) for simultaneous soft tissue augmentation around single implants in the esthetic zone.

Who can participate?
Adults aged 18 years or older who have a single missing tooth in the aesthetic zone of the maxilla (upper jaw).

What does the study involve?
The patients will be randomly assigned to one of the two intervention groups: the CTG group or the XCM group. Both groups will receive a single dental implant inserted with a guided implant surgery approach, the CTG group will simultaneously receive soft tissue augmentation using a tissue graft taken from their own palate, while the XCM group will simultaneously receive soft tissue augmentation using a xenogenic (animal) collagen matrix (Mucoderm®, Botiss Biomaterials, Germany). The implant surgery and soft tissue augmentation will be performed by a single experienced surgeon.

What are the possible benefits and risks of participating?
This study will determine the effectiveness of using XCM and CTG in soft tissue augmentation simultaneously with implant placement. There is a risk of not achieving optimal results in some cases but the study team can manage these cases with alternative methods.

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

When is the study starting and how long is it expected to run for?
October 2024 to May 2026

Who is funding the study?
1. Damascus University (Syria)
2. Botiss Biomaterials

Who is the main contact?
Dr Ali Omair, ali.omair.formal@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT06837688

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of xenogeneic collagen matrix versus subepithelial connective tissue graft to enhance soft tissue profile around single dental implants in the aesthetic zone

Study objectives
Is there a significant statistical difference between collagen matrix and connective tissue graft in terms of enhancing soft tissue profile around single dental implants.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, Damascus University Ethics Committee (Damascus, Damascus, 00000, Syria; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Comparative interventional randomized controlled study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Soft tissue defect

Interventions
The patients will be randomly assigned to one of the two intervention groups: connective tissue graft (CTG) group or xenogeneic collagen matrix (XCM) group. Both groups will receive a single dental implant inserted with a guided implant surgery approach, the CTG group will simultaneously receive soft tissue augmentation using an autogenous connective tissue graft harvested from the palate, while the XCM group will simultaneously receive soft tissue augmentation using a xenogenic collagen matrix (Mucoderm®, Botiss Biomaterials, Germany). The randomization will be performed by a computer-generated random number sequence. The implant surgery and soft tissue augmentation will be performed by a single experienced surgeon.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Changes in buccal soft tissue volume: an intra-oral scan will be used to analyze volumetric and profilometric changes of the buccal soft tissue at the following time points in each patient: T0 (pre-op), T1 (immediately post-op), and T2 (at 3 months). The intra-oral scan data will be processed and compared using a specific software to calculate the difference in soft tissue volume between the groups and the time points.
2. Patient-reported outcome measures: postoperative bleeding, pain, oedema, and hematoma will be assessed using a visual analogue scale (VAS) 1 week following surgery. Furthermore, the willingness of the patient to undergo the same treatment again, and the patients' aesthetic satisfaction will be assessed using a Likert scale at 3 months.
3. Aesthetic outcomes: such as mid-facial recession, pink aesthetic score, and mucosal scarring index will be evaluated at 3 months and 6 months. The mid-facial recession will be measured as the distance from the middle point of the incisal edge of the implant-supported crown to the mucosal margin. The pink aesthetic score (PES) will be used to assess the harmony of the peri-implant soft tissue with the adjacent teeth and gingiva, based on seven criteria: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color, and soft tissue texture. The mucosal scarring index (MSI) will be used to assess the presence and severity of scar formation at the graft site, based on four criteria: color, contour, texture, and vascularity.

Key secondary outcome(s))
1. Clinical outcomes: such as graft dimensions, wound closure, surgery time, and complications will be recorded by the surgeon during and after the surgery. The graft dimensions will include the length, width, and thickness of the graft before and after the placement. The surgery time will be measured from the start of the incision to the end of the suturing. The complications will include any adverse events such as infection, dehiscence, necrosis, or loss of the graft or the implant.
2. Peri-implant health parameters: such as marginal bone loss, probing depth, plaque, and bleeding on probing will be measured at the implant site at baseline, 3 months, and 6 months. The marginal bone loss will be measured on the CBCT images as the distance from the implant shoulder to the first bone-to-implant contact. The probing depth will be measured using a periodontal probe at six sites around the implant. The plaque and bleeding on probing will be assessed using the modified plaque index (mPI) and the modified bleeding index (mBI), respectively.

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Patient is older than 18 years old
2. Patient has excellent oral hygiene; less than 25% according to O'Leary index
3. Patient has a single missing tooth in the aesthetic zone of the maxilla
4. Failing tooth removed at least 3 months prior to enrolment
5. At least 5 mm of keratinized mucosa available at the single tooth gap
6. Bucco-palatal bone dimension of at least 6 mm at the central and crestal aspect of the single tooth gap as assessed on cone beam computed tomography (CBCT) to ensure complete embedding of an implant by bone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria

1. Systemic diseases
2. Smoking
3. Periodontal disease
4. Need for horizontal bone augmentation at the time of implant placement
5. Patient previously underwent soft or hard tissue augmentation at the site of the procedure

Date of first enrolment
01/02/2025

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Damascus
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Funder Name
Botiss Biomaterials

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Dr Ali Omair (ali.omair.formal@gmail.com) and in the publication related to it after the end of the research.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication