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# How soft tissue augmentation after tooth extraction improves implant health: findings from a clinical trial

**Submission date**
14/07/2024

**Recruitment status**
No longer recruiting

**Registration date**
15/07/2024

**Overall study status**
Completed

**Last Edited**
05/08/2025

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
This study aims to compare the outcomes of dental implants placed at sites augmented with a novel cross-linked collagen matrix (Fibro-Gide®), traditional connective tissue grafts, or spontaneous healing following tooth extraction.

Who can participate?
Adults aged 18 years or older who have had a posterior mandibular (back tooth in jaw) extraction

What does the study involve?
Participants will be allocated to receive soft tissue augmentation with a xenogenic collagen matrix (XCM), connective tissue graft (CTG), or no biomaterial placed within the socket after tooth extraction. At 6 months after surgery, the participants will receive a dental implant.

What are the possible benefits and risks of participating?
This study will determine the effectiveness of using XCM and CTG in soft tissue augmentation before implant placement on the health of peri-implant tissues, compared to not applying any material within the socket. 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?
June 2023 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Ammar Ibrahim AmmarIbrahimISRCTN@gmail.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
Dr Ammar Ibrahim

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
0000

# Study information

### Scientific Title
Impact of soft tissue augmentation on peri-implant health post-extraction: a randomized controlled trial

### Study objectives
Does the use of xenogenic collagen matrix or connective tissue graft, compared to spontaneous healing, affect the health of peri-implant tissues?

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 17/07/2023, Damascus University Ethics Committee (Damascus, Damascus, 0000, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: 22486

### Study design
Comparative interventional randomized controlled study

## Primary study design
Interventional

## Study type(s)
Prevention, Quality of life

## Health condition(s) or problem(s) studied
Pre-implant placement soft tissue augmentation

## Interventions
The method used for randomization was a closed envelope method. The envelopes were opened prior to the soft tissue augmentation procedure, allocating the patient into one of the three groups.

Following extraction, the subjects underwent one of three randomly assigned treatments: soft tissue augmentation with connective tissue graft (CTG), xenogenic collagen matrix (XCM), or spontaneous healing (SH) without soft tissue augmentation. Six months subsequent to these interventions, dental implants were placed.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
1. Pocket depth (PD) assessed using a periodontal probe gauged from the edge of the mucosa to the base of the pocket at two timepoints (baseline and 6 months after functional loading) at six distinct points around each implant, mesio-buccal (mb), buccal (b), disto-buccal (db), mesio-oral (mo), oral (o), and disto-oral (do), to ensure a thorough evaluation.
2. Marginal bone level (MBL) evaluated at two key intervals: initially at the time of implant insertion (baseline) and subsequently after a period of 6 months. For each dental implant (DI), standardized periapical radiographs were captured at baseline and at the 6-month mark, employing a paralleling apparatus. The quantification of marginal bone loss (MBL) involved measuring the span from the inaugural point of bone contact with the implant to the crest of the implant. The assessment of bone loss incorporated both the mesial and distal dimensions of each DI.

## Key secondary outcome(s))
1. Plaque Accumulation Index (PAI): adapted from the methodology proposed by Löe and colleagues (LÖE et al., 1972). this index was evaluated using a periodontal probe at six points around each implant: mesio-buccal (mb), buccal (b), disto-buccal (db), mesio-oral (mo), oral (o), and disto-oral (do), to ensure a thorough evaluation at baseline and 6 months after functional loading.
2. Bleeding on Probing (BOP): a binary assessment indicating the presence or absence of bleeding, evaluated using a periodontal probe at six points around each implant: mesio-buccal (mb), buccal (b), disto-buccal (db), mesio-oral (mo), oral (o), and disto-oral (do), to ensure a thorough evaluation at baseline and 6 months after functional loading.
3. Mucosal recession (MR): distance from the edge of the restoration to the gingival margin was evaluated using a periodontal probe at the mid-buccal surface at baseline and 6 months after functional loading.

## Completion date

23/04/2024

# Eligibility

### Key inclusion criteria
1. Had extraction sites that conformed to Type ST1 classification, as per Steigmann et al. (Steigmann et al., 2022), where both facial soft and hard tissues were preserved at levels consistent with the cementoenamel junction
2. Possessed at least 2 mm of keratinized tissue on the buccal aspect of the extraction site
3. Demonstrated commendable oral hygiene
4. Aged 18 years or above

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
45 years

### Sex
All

### Total final enrolment
30

### Key exclusion criteria
1. Exhibited buccal alveolar bone defects, such as dehiscence or fenestration, or experienced loss of the facial bone plate during extraction
2. Had systemic conditions that could impede bone healing
3. Were pregnant at the time of the study
4. Were classified as heavy smokers, defined as those consuming over 10 cigarettes daily

### Date of first enrolment
23/08/2023

### Date of final enrolment
23/03/2024

# Locations

### Countries of recruitment
Syria

**Study participating centre**
**Damascus University**
Almazzeh highway
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

# 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 Ammar Ibrahim (AmmarIbrahimISRCTN@gmail.com) and in the publication related to it after the end of the research.
Type of data that will be shared: demographic information (age, gender), location of the tooth to be extracted, clinical and radiographical measurements, photos of clinical procedure.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 06/08/2024 | 05/08/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |