ISRCTN18692174 https://doi.org/10.1186/ISRCTN18692174

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

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Additional identifiers

Protocol serial number
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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

Primary study design
Interventional

Study design
Comparative interventional randomized controlled study

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