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Allogeneic demineralized dentin matrix to preserve the alveolar dimensions after teeth extraction

Submission date
28/03/2025

Recruitment status
No longer recruiting

Registration date
28/03/2025

Overall study status
Completed

Last Edited
28/03/2025

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
Following tooth extraction, various physiological healing processes are unavoidable. Alveolar resorption will be most pronounced within the first 6 months after extraction. However, it will persist throughout the lifetime. It often leads to adverse modifications in both the quality and quantity of bone in the alveolar ridge, posing significant challenges for future dental implant placement. This study aims to investigate the efficacy of the allogeneic DDM (AlloDDM) prepared from human-extracted teeth in preserving the dimensions of the alveolar ridge after extraction compared with natural physiological healing with no grafting materials.

Who can participate?
Healthy participants aged 18-40 years that required bilateral simple extraction of mandibular teeth.

What does the study involve?
The study sample consisted of thirty-four bilateral mandibular alveolar sockets for eight patients whose teeth were indicated for extraction. The sample was randomly divided into two groups:
Group 1 (control): The teeth were extracted, and the socket was left empty. Sutures were applied to close the socket to preserve the blood clot (n = 17).
Group 2 (AlloDDM): The teeth were extracted, the AlloDDM was replaced, the flap was released, and the graft was sutured without placing any membrane (n = 17).

What are the possible benefits and risks of participating?
Participants will benefit from being provided with extraction treatment. However, the risks include receiving painful therapy.

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

When is the study starting and how long is it expected to run for?
October2023 to December 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Allogeneic demineralized dentin matrix prepared from human-extracted teeth as a bone graft to preserve the alveolar dimensions after teeth extraction: A randomized controlled trial

Study objectives
The null hypothesis is that AlloDDM would not preserve the dimensions of the alveolar ridge.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/02/2022, The Biomedical Research Ethics Committee (BMREC) of Damascus University (Mazzeh, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N450

Primary study design
Interventional

Study design
Randomized double-blind split-mouth active-controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Preservation of the alveolar ridge dimensions

Interventions
The study sample consisted of thirty-four bilateral mandibular alveolar sockets for eight patients whose teeth were indicated for extraction. The sample was randomly divided into two groups:
• Group 1 (control): The teeth were extracted, and the socket was left empty. Sutures were applied to close the socket to preserve the blood clot (n = 17).
• Group 2 (AlloDDM): The teeth were extracted, the AlloDDM was replaced, the flap was released, and the graft was sutured without placing any membrane (n = 17).

This study utilized a double-blind design, ensuring that both the participants and the outcome evaluators were unaware of the group assignments as well as the study's objectives. Nonetheless, it was not possible to blind the surgeon. Subsequently, alveolar sockets were randomly assigned to either the control group or the AlloDDM group for each patient, using a split-mouth model.

Procedure
A sample of teeth was collected to prepare the AlloDDM. The ultrasonic tip (Scaling Tip S3, J. Morita Corp., California, United States) was used to clean the teeth. A tungsten carbide bur (E 0521, Dentsply Maillefer, Ballaigues, Switzerland) was utilized to reduce the apical cellular cementum and the superficial enamel. The teeth were sectioned with a diamond disc (88613, orthodontic & Specialist Dental Supplies, Bristol, United Kingdom) to facilitate the extraction of the dental pulp. The sectioned teeth were placed in a plastic container filled with 5.25% sodium hypochlorite solution (EAU DE JAVEL, Akka Brothers Co. Carmel Detergent, Damascus, Syria) and subjected to ultrasonic vibrations for 30 min to eliminate any remaining pulp. Once all pulpal tissue was confirmed to be removed, the teeth were rinsed with buffered saline and soaked in 95% ethanol (Ethanol 95% Denatured, ChemWorld International Ltd., Inc., New Jersey, USA) for 10 min. The sectioned teeth underwent partial demineralization in 2% Nitric acid (5432-32 Nitric Acid, 2.00 Normal, RICCA Chemical Company, Texas, USA) for 20 min. The AlloDDM was subsequently crushed using a manual bone grinder (Dental Bone Crusher Mill Grinder Implant Bone Graft Implant Augmentation Tool, Dyna International, Punjab, Pakistan) into particles of 1000 µm, which were then packed into well-sealed graft glass bottles at a volume of 1 cc and sterilized with gamma rays at the Atomic Energy Commission in Syria. The graft was subsequently stored in a refrigerator at -20°C until needed.

Local anesthesia was administered utilizing 2% lidocaine with epinephrine 1:80,000 solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam, Korea). Regarding the control group, atraumatic flapless extraction was performed. The figure-of-8 suturing technique was performed at the top of the socket to fix the blood clot without any grafting materials using 4:0 nylon suture (ETHILON* Nylon Sutures Black 45cm 4-0 PC-5 19mm - Box/12, Ethicon Inc., New Jersey, United States). Regarding the AlloDDM group, an intracellular incision and a mucoperiosteal release of the vestibular flap were made around the tooth to be extracted from both the lingual and buccal sides. Releasing incisions were made if necessary, and the tooth was extracted. The socket was then grafted with particles of AlloDDM, and the flap edges were sutured with 4:0 nylon suture.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The dimensional radiographic changes in width and height of the alveolar ridge were evaluated utilizing a cone beam computed tomography (CBCT) scan. The first CBCT scan was obtained immediately postoperatively (t1), and the second CBCT scan six months later (t2).

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
15/12/2024

Eligibility

Key inclusion criteria
1. Healthy participants.
2. Participants aged 18-40 years.
3. Participants required bilateral simple extraction of mandibular teeth.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Participants with cystic and/or large periapical lesions at the site of extraction.
2. Participants with periodontal diseases and/or poor oral hygiene.
3. Pregnant or breastfeeding women.
4. Heavy smokers, alcoholic participants, and/or tobacco chewers.
5. Patients recently underwent radiation or chemical therapy.

Date of first enrolment
02/10/2023

Date of final enrolment

20/01/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh
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 upon request from Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request