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Evaluation of the efficiency of autologous albumin gel mixed with I-PRF and artificial bone graft in alveolar ridge preservation following tooth extraction

Submission date
25/05/2024

Recruitment status
No longer recruiting

Registration date
20/06/2024

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

When a tooth is lost, the surrounding bone, known as the alveolar bone, begins to deteriorate. This process, termed alveolar bone resorption, results in a decrease in both the quantity and quality of the bone, leading to a reduction in its external width and height. Ridge preservation is a treatment carried out during or after tooth extraction to mitigate this bone loss. It aims to slow down bone resorption, promote new bone formation, and enhance the healing of both bone and surrounding soft tissues. Various biomaterials have been tested for ridge preservation, including autografts (bone from the same individual), bone substitutes, blood derivatives, and bioactive agents. Platelet-rich fibrin (PRF), a second-generation platelet concentrate, has shown promise in promoting tissue regeneration by enhancing blood vessel formation, stem cell capture, immune response, and tissue closure. However, PRF is rapidly absorbed, typically degrading within 10 to 14 days, which limits its effectiveness as a long-term barrier. Recent advancements have led to the development of an injectable albumin gel combined with PRF, which prolongs the material's absorption time to 4-6 months. This new compound leverages the benefits of PRF while offering a slower degradation rate, potentially providing more sustained support for bone and tissue regeneration. The purpose of this research is to evaluate the efficacy of this innovative injectable albumin gel mixed with PRF and artificial bone graft in preserving the alveolar ridge following tooth extraction. The study will focus on 1. assessing the pain experienced by patients during the treatment; 2. measuring the radiographic density of the newly formed bone; and, 3. analyzing the changes in the dimensions of the alveolar ridge, specifically the vestibular (cheek side) and lingual (tongue side) walls, six months post-surgery. Alveolar ridge resorption is a significant issue after dental extractions, leading to aesthetic and functional problems and complicating future dental implant placement. This study aims to offer a potential solution to enhance the preservation of the alveolar structure, thereby improving patient outcomes.

Who can participate?
Adult patients aged between 22 and 50 years old requiring the preservation of the alveolar structure following tooth extraction

What does the study involve?
This study aims to compare the effectiveness of two different combinations of treatments (one with autologous albumin gel and PRF, and the other with injectable PRF) in maintaining alveolar bone dimensions post-extraction.

What are the possible benefits and risks of participating?
The benefits gained from the procedure are improved healing and more bone. There are no risks after the application of bone graft.

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

When is the study starting and how long is it expected to run for?
August 2022 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Zain Moalla, zainmoalla150@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the efficiency of autologous albumin gel mixed with I-PRF and artificial bone graft in alveolar-ridge-preservation following tooth extraction

Study objectives
Is the application of autologous albumin gel mixed with injectable platelet-rich fibrin and artificial bone graft able to improve healing, relieve pain, prevent post-extraction alveolar bone resorption, and improve the bone density of new bone?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/08/2022, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, -, Syria; +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: 4243

Study design
Comparative clinical trial with a split mouth technique

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Symmetrical teeth indicated for extraction

Interventions
The study aims to compare two different treatments for maintaining alveolar bone dimensions after tooth extraction. On one side, autologous albumin gel mixed with platelet-rich fibrin (PRF) and artificial bone graft will be applied, while on the opposite side, injectable platelet-rich fibrin (I-PRF) mixed with artificial bone graft will be used. To ensure unbiased results, the specific treatment for each side will be randomly assigned using Excel software, and blinding will be maintained by pulling papers to determine the treatment for each party. The intervention involves atraumatic extraction of two teeth from a single patient in one session, with each extraction taking 20-40 minutes. Both extraction sites will receive bone grafts, but with different PRF combinations to assess their effectiveness.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Radiographic Bone Density: ROI Region of Interest By drawing a rectangle in the extraction socket in the image taken six months after the alveolar ridge preservation procedure and recording the average value given, measured using the Ez3Di viewer program
2. Study of changes in alveolar bone dimensions: The two images are uploaded to the OnDemand3D program. We perform matching in the three axes - sagittal, frontal, and vertical - and then choose the appropriate section of the image in which the surgical intervention was performed.
3. Measuring vertical changes (alveolar ridge height): A line is drawn that connects the top of the vestibular plate to the top of the lingual or palatal plate, and from the middle of this line a line is drawn to the height of the socket. In this way, the vertical height of the socket is measured immediately after the extraction and six months after the extraction, and the amount of change that occurs is calculated after that.
4. Measuring horizontal bone changes (width of the alveolar ridge): Two horizontal lines are drawn at level 3 and level 5 mm from the edge of the alveolar bone on the image taken immediately after the extraction. These lines are fixed when measuring on the second image (six months later) after merging the two images together, and the amount is then calculated. The change is happening.

Secondary outcome measures
Pain is measured using a visual analogue scale (VAS) at baseline 24, 48, and 72 h

Overall study start date
29/08/2022

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. There are no general diseases
2. There is no periodontitis
3. There is no contraindication for local anesthesia or oral surgery
4. Extraction socket type 1 according to Elian, 2007

Participant type(s)
Patient

Age group
Adult

Lower age limit
22 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
12

Total final enrolment
12

Key exclusion criteria
1. Pregnant and breastfeeding
2. The presence of an acute abscess or vestibular fistula in the work area
3. Smoker patient
4. Alcoholics
5. Taking medications that affect bone metabolism

Date of first enrolment
01/02/2023

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
Syria

Study participating centre

Damascus University
Mazzeh highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The dataset to be generated will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Alveolar Ridge Preservation Using a Mixture of Alb-PRF and Alloplastic Bone Graft: A Case Report	13/03/2025	22/07/2025	Yes	No