ISRCTN60191547 https://doi.org/10.1186/ISRCTN60191547

Comparison between two types of platelet concentrates for socket preservation after tooth extraction

Submission date
24/11/2023

Recruitment status
No longer recruiting

Registration date
28/11/2023

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Healing of the socket after tooth extraction leads to ridge resorption (loss of bone in the jaw) that can make implant installation position difficult and negatively affect functional and aesthetic outcomes. Alveolar ridge preservation (ARP) is a procedure in which biomaterials are placed in the socket of the extracted tooth at the time of extraction to minimize changes in hard and soft tissue after tooth loss. The aim of this study is to determine the effect of leukocyte-platelet-rich fibrin (L-PRF) and titanium prepared platelet-rich fibrin (T-PRF) in comparison with spontaneous healing.

Who can participate?
Adult patients aged 18 years and over who had a treatment plan of extraction and alveolar ridge preservation.

What does the study involve?
Participants will be allocated to receive L-PRF, T-PRF, or no biomaterial placed within the socket after tooth extraction. At 4 months after surgery, the participants will undergo x-rays to evaluate the effectiveness of each method.

What are the possible benefits and risks of participating?
This study will determine the effectiveness of autologous biomaterials in reducing changes in hard and soft tissue after tooth loss and compare it with not applying any material within the socket. There is a risk of not achieving good results in some cases, however, the study team can manage these cases with another method.

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

When is the study starting and how long is it expected to run for?
April 2023 to November 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Emad Aldemmari, emadalddenaldemmari@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)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of using T-PRF for alveolar ridge preservation: a randomized controlled trial

Study objectives
Is there a difference between applying platelet-rich fibrin and not applying it (spontaneous healing), and is there a difference between leukocyte-platelet-rich fibrin (L-PRF) and titanium prepared platelet-rich fibrin (T-PRF) fibrin when applied after extraction to preserve the alveolar ridge?

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 04/06/2023, Scientific Research Committee (Faculty of Dentistry, Damascus University, Mazzeh Highway, Damascus, 00000, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: 22749

Study design
Comparative interventional randomized controlled study

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Alveolar ridge preservation

Interventions
Informed consent will be obtained by investigators participating in the study, and cases will be diagnosed clinically and radiographically to ensure the matching of inclusion criteria. On the day of surgery, participants will be randomized to the control, L-PRF, or T-PRF group by one investigator using a computer-generated randomization scheme.

After sulcular incisions without flap reflection, teeth will be extracted atraumatically utilizing periotomes with care to preserve the buccal bone plate and the surrounding soft tissues. Following debridement, the socket will be closed with 4-0 non-resorbable sutures in control group (spontaneous healing), the socket will be filled with L-PRF (prepared by centrifugation of blood for 12 min at 2700 rpm) and will be closed with 4-0 non-resorbable sutures in L-PRF group, or the socket will be filled with T-PRF (prepared by centrifugation of blood for 12 min at 2800 rpm) and will be closed with 4-0 non-resorbable sutures in T-PRF group.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 24/03/2025:

1. Width of Alveolar Ridge: Superimposition between pre-treatment and 4-month post-intervention CBCT images was performed using Ondemand 3D software The measurements were conducted at three levels (4, 7, and 10 mm).

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Previous primary outcome measure as of 13/02/2025:

1. Width of Alveolar Ridge: Superimposition between pre-treatment and 4-month post-intervention CBCT images was performed using Ondemand 3D software. A pre-fabricated stent was not used for this purpose. The measurements were conducted at three levels (4, 7, and 10 mm).
2. Vertical Height to the Buccal and Palatal Alveolar Bone: Superimposition between pre-treatment and 4-month post-intervention CBCT images was performed using Ondemand 3D software to measure vertical resorption on the buccal and palatal sides. A pre-fabricated stent was not used for this purpose.

3. Radiographic Bone Density: Radiographic bone density was measured after 4 months using EZ-3D Plus software for CBCT analysis. The entire socket area was evaluated using the "Region of Interest" feature. A pre-fabricated stent was not used for this purpose.

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Previous primary outcome measure:

1. Width of alveolar ridge: at three levels (4, 7, and 10 mm), the distance between the two horizontal buccal and palatal points located at the same level. Measured using a pre-fabricated stent before extraction and 4 months after the alveolar ridge preservation.
2. Vertical height to the buccal and palatal alveolar bone: the distance between the buccal /palatal crest to the vertical point, measured using a pre-fabricated stent before extraction and 4 months after the alveolar ridge preservation.
3. Thickness of the buccal (BPT) and palatal/lingual (PPT) alveolar plates: measured using a pre-fabricated stent at the first sectional CBCT scan (before extraction).
4. Radiographic bone density: at three levels (4,7, and 10 mm), the mean density values in the three levels are taken, measured using a pre-fabricated stent after 4 months of the alveolar ridge preservation.
5. Buccal soft tissue thickness: measured using a pre-fabricated stent and its clinical reference points with the addition of an endodontic spreader with rubber stops, recorded before extraction and 4 months after the alveolar ridge preservation.

Key secondary outcome(s))

Current secondary outcome measures as of 24/03/2025:

1. Vertical Height to the Buccal and Palatal Alveolar Bone: Superimposition between pre-treatment and 4-month post-intervention CBCT images was performed using Ondemand 3D software to measure vertical resorption on the buccal and palatal sides.
2. Radiographic Bone Density: Radiographic bone density was measured after 4 months using Ondemand 3D software for CBCT analysis.
3. Wound healing recorded using the Landry Wound Healing Index weekly during the first month after the alveolar ridge preservation
4. Pain measured using visual analog scale (VAS) and the number of analgesics, recorded daily during the first week after the alveolar ridge preservation
5. Complications after tooth extraction, recorded (if present) as soon as the patient reports it.
6. Periodontal Probing Depth (PPD) and Gingival Recession (GR): Measured before extraction and at 4 months post-extraction using a UNC-15 periodontal probe at the extraction site and the adjacent mesial and distal teeth.
7. Keratinized Tissue Width (KTW): Measured using a UNC-15 periodontal probe from the gingival margin to the mucogingival junction (MGJ) at the extraction site, before extraction and at 4 months post-extraction.

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Previous secondary outcome measures as of 14/02/2025:

1. Wound healing and complete wound epithelization recorded using the Landry Wound Healing Index weekly during the first month after the alveolar ridge preservation
2. Pain measured using visual analog scale (VAS) and the number of analgesics, recorded daily during the first week after the alveolar ridge preservation
3. Complications after tooth extraction, recorded (if present) as soon as the patient reports it.

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Previous secondary outcome measures:

1. Wound healing recorded using the Landry Wound Healing Index weekly during the first month after the alveolar ridge preservation
2. Complete wound epithelization recorded by application of toluidine blue weekly during the first month after the alveolar ridge preservation
3. Pain measured using visual analog scale (VAS) and the number of analgesics, recorded daily during the first week after the alveolar ridge preservation
4. Complications after tooth extraction, recorded (if present) as soon as the patient reports it.

Completion date
05/11/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/02/2025:

1. Patients with a single rooted tooth in the maxillary arch who had a treatment plan of extraction and alveolar ridge preservation with no evidence of acute infection such as severe swelling, suppuration, abscess, and/or spontaneous bleeding, and the teeth adjacent to the tooth to be extracted must be present
2. At least 18 years old
3. Non-smoker
4. Participants treated for periodontal disease
5. Participants that show the presence of buccal plate at the extraction site as determined by a sectional cone-beam computed tomography (CBCT) scan. If the patient qualified based on the CBCT scan
6. Participants with excellent oral health (20% or less of plaque index)
7. Participants with 2 mm at least of keratinized tissue at the surgical site

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Previous inclusion criteria:

1. Patients with a single rooted tooth in the maxillary arch who had a treatment plan of extraction and alveolar ridge preservation with no evidence of acute infection such as severe swelling, suppuration, abscess, and/or spontaneous bleeding, and the teeth adjacent to the tooth to be extracted must be present
2. At least 18 years old
3. Participants smoke fewer than 10 cigarettes per day
4. Participants treated for periodontal disease
5. Participants that show the presence of buccal plate at the extraction site as determined by a sectional cone-beam computed tomography (CBCT) scan. If the patient qualified based on the CBCT scan
6. Participants with excellent oral health (20% or less of plaque index)
7. Participants with 2 mm at least of keratinized tissue at the surgical site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
56 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Lactating or pregnant female
2. Medical conditions that are contraindicated with periodontal surgery
3. Use anticoagulant drugs or steroids
4. Bleeding disorders
5. Autoimmune or immune proliferative disorders
6. Acute inflammation

Date of first enrolment
02/01/2024

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Al-Mazzeh 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 Emad Aldemmari (emadalddenaldemmari@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		05/07/2025	07/07/2025	Yes	No