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Effect of extraction timing on alkaline phosphatase enzyme levels in the fluid around the gums during orthodontic treatment

Submission date
25/10/2025

Recruitment status
No longer recruiting

Registration date
30/10/2025

Overall study status
Completed

Last Edited
30/10/2025

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
This study aims to investigate the biological response of the periodontal (gum) tissues during orthodontic treatment with different extraction timing protocols. Specifically, it evaluates the activity of alkaline phosphatase (ALP) enzyme in the gingival crevicular fluid (GCF, the fluid that flows into the crevice around the teeth), which reflects bone and periodontal remodeling, during the alignment phase of treatment. Understanding how extraction timing affects ALP activity may help optimize the treatment of orthodontic patients.

Who can participate?
Healthy male and female patients aged 18–28 years with moderate crowding in the upper dental arch (Little's Irregularity Index between 4–6 mm) who require extraction of the upper first premolars as part of their orthodontic treatment plan.

What does the study involve?
Participants were randomly allocated into three groups:
Group A: orthodontic leveling and alignment only (delayed extraction)
Group B: extraction only (no active tooth movement during the observation period)
Group C: simultaneous extraction with leveling and alignment
Gingival crevicular fluid samples were collected from the mesial and distal sites of the upper canines at seven timepoints (baseline and weekly up to 6 weeks) to measure ALP activity. All procedures were carried out under routine orthodontic care and with informed consent.

What are the possible benefits and risks of participating?
The study aimed to improve understanding of biological markers related to orthodontic tooth movement and to help design more efficient treatment protocols.
There were minimal risks beyond standard orthodontic procedures, such as mild and temporary gum irritation during sample collection.

Where is the study run from?
The study was conducted at the Department of Orthodontics, Faculty of Dentistry, Damascus University, Damascus (Syria)

When did the study start and how long did it run for?
January 2021 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Yahya Ahmad Dakdouk, yahya1.dakdouk@damascusuniversity.edu.sy

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Yahya Dakdouk

ORCID ID
https://orcid.org/0009-0005-8076-1487

Contact details
Damascus
Damascus
Syria
10090
+963 (0)91833272
yahya1.dakdouk@damascusuniversity.edu.sy

Additional identifiers

Protocol serial number
DN-160925-H35

Study information

Scientific Title
Alkaline phosphatase activity in gingival crevicular fluid during orthodontic alignment and extraction protocols: a randomized controlled clinical trial

Acronym
ALP-Ortho

Study objectives

Primary objective:
To evaluate the effect of extraction timing on alkaline phosphatase (ALP) activity in gingival crevicular fluid (GCF) around maxillary canines during the leveling and alignment phase of orthodontic treatment.

Secondary objectives:
1. To compare ALP activity among three treatment protocols: leveling and alignment alone, extraction alone, and simultaneous extraction with leveling and alignment.
2. To explore whether extraction timing can serve as a biological factor influencing orthodontic tooth movement efficiency.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/09/2022, Research Ethics Committee – Faculty of Dentistry, Damascus University (Mazzeh Street, Faculty of Dentistry, Damascus University, Damascus, 10090, Syria; +963 (0) 991833272; ethics.dentistry@damascusuniversity.edu.sy), ref: DN-160925-H35

Study design
Randomized controlled three-arm clinical trial with a parallel-group design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Evaluation of gingival crevicular fluid alkaline phosphatase activity in patients with moderate maxillary dental crowding undergoing orthodontic treatment with different extraction timing protocols.

Interventions
Randomization was performed using sealed opaque envelopes to ensure allocation concealment. Blinding was applied to the laboratory examiner analyzing ALP activity, while operator and patients were not blinded due to the clinical nature of the interventions.
Participants will be randomly allocated into three parallel groups (n = 20 each) using sealed opaque envelopes:

Group A (levelling and alignment only – delayed extraction): fixed orthodontic appliances will be placed, and tooth alignment will be performed without extractions during the first 6 weeks.
Group B (extraction only): bilateral extraction of the upper first premolars will be performed without initiation of orthodontic treatment during the observation period.
Group C (simultaneous extraction with leveling and alignment): extractions of the upper first premolars will be carried out on the same day as the fixed appliance bonding, and alignment will begin immediately thereafter.

Gingival crevicular fluid samples will be collected from the mesial and distal sites of the maxillary canines at seven time points (baseline and weekly up to 6 weeks) to assess alkaline phosphatase (ALP) activity.

The study will be conducted at the Department of Orthodontics, Faculty of Dentistry, Damascus University, over a 6-week experimental period.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Alkaline phosphatase (ALP) activity in gingival crevicular fluid (GCF) measured using a spectrophotometric enzymatic assay (Jenway 6330, 405 nm) at seven timepoints: baseline (T0) and weekly intervals up to 6 weeks (T1–T6) during orthodontic leveling and alignment.

Key secondary outcome(s))
Changes in gingival crevicular fluid alkaline phosphatase (ALP) activity over time, measured using a spectrophotometric enzymatic assay (Jenway 6330, 405 nm) at seven time points: baseline (T0) and weekly up to 6 weeks (T1–T6).

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Healthy male and female participants aged 18–28 years
2. Presence of moderate maxillary dental crowding as defined by Little’s Irregularity Index between 4–6 mm
3. Indication for orthodontic treatment with extraction of upper first premolars for space management
4. Good oral hygiene and healthy periodontium (probing depth ≤ 3 mm, no bleeding on probing)
5. No systemic diseases or medications affecting bone metabolism
6. No previous orthodontic treatment
7. Willingness to participate and sign informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
28 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Presence of severe or mild dental crowding (Little’s Irregularity Index <4 or >6 mm)
2. Systemic diseases or conditions affecting bone metabolism (e.g., diabetes, osteoporosis, hyperparathyroidism)
3. Current or previous use of medications that influence bone turnover (e.g., corticosteroids, bisphosphonates, anticonvulsants)
4. Poor oral hygiene or active periodontal disease
5. Pregnant or lactating females
6. History of orthodontic treatment or trauma to the anterior maxillary teeth
7. Smoking or use of tobacco products
8. Refusal or inability to sign informed consent

Date of first enrolment
01/12/2022

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Department of Orthodontics
Mazzeh Street
Damascus
Syria
10090

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding author (Dr. Yahya Ahmad Dakdouk, yahya1.dakdouk@damascusuniversity.edu.sy).
The shared data will include anonymised individual participant values of alkaline phosphatase (ALP) activity in gingival crevicular fluid (GCF) and related timepoint information (T0–T6).
Data will be made available after publication of the main results and for up to five years thereafter, for research purposes only.
Participant consent included agreement for anonymised data sharing, and all ethical and legal requirements under Damascus University regulations have been observed.

IPD sharing plan summary
Available on request