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Understanding root and canal structures in teenagers: a study on extracted mandibular premolars in Damascus

Submission date 17/03/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/03/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/03/2025	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The structure of dental roots is complex and varied so it's important to understand the pulp anatomy and structure for successful root canal treatment. This study looked at the number, length, and root canal structure of lower premolars taken from teenagers in Damascus.

Who can participate?
Adolescents aged 12-15 years with at least one intact lower premolar needing orthodontic extraction

What does the study involve?
The participants' premolars were measured and their root numbers were assessed and x-rayed to assess their morphology.

What are the possible benefits and risks of participating?
The main benefit is to assess the root canal structure of the Damascus population. No possible risks are proposed as this study is an observational study.

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

When is the study starting and how long is it expected to run for?
January 2023 to March 2025

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Yasser Alsayed Tolibah, yasser94.tolibah@damascusuniversity.edu.sy or Yasseralsayedtolibah@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
UDDS-361-13032023/SRC-2654

Study information

Scientific Title
An epidemiological study of root number, length, and canal morphology in extracted mandibular premolars from adolescent patients in Damascus

Study objectives
The null hypothesis proposes that gender does not influence the number of roots, their length, or the canal morphology of mandibular premolars

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/03/2023, Damascus University (Almazzeh Street, Damascus, 20872, Syria; +963 (0) 944372202; sdg@damascusuniversity.edu.sy), ref: 361

Study design
Epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

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

Study type(s)
Diagnostic

Participant information sheet
Not available

Health condition(s) or problem(s) studied
Root number, length, and root canal anatomy of extracted mandibular premolars

Interventions
The sample consisted of 250 recently extracted first and second MPs during orthodontic treatment of adolescents aged 12–15 years from Damascus at the Pediatric Dentistry, Orthodontics, and Oral and Maxillofacial Surgery Departments, Faculty of Dentistry, Damascus University. Premolars that had undergone endodontic treatment, or had internal/external resorption, deformities, open apices, or fractures during extraction were excluded. Each patient signed an informed consent form, stating that the extracted premolar would be used in an epidemiological study. Therefore, 216 first and 132 second MPs met the inclusion criteria, forming a total sample of 232 intact-root MPs. Each extracted premolar was assigned a number, and the patient's gender was recorded to accompany each premolar’s data. Soft tissues, bone fragments, and calculus were removed through scaling and polishing. At this stage, the number of roots and the maximum length of premolars were determined in millimeters with a digital caliper (WEN Digital Caliper, Performance Tool - Wilmar LLC, Kent, Washington, USA). Subsequently, two periapical radiographs were taken for each extracted premolar to provide a three-dimensional understanding of its canal morphology: one in the buccolingual direction and one in the mesiodistal direction. This was done using a portable radiographic unit (PRU) (HyperLight, Eighteeth; Changzhou Sifary Medical Technology Co., Ltd., Changzhou City, Jiangsu Province, China) with the following settings: exposure time of 0.08 seconds, 65 kVp, and 2.5 mA. The PRU was positioned perpendicular to the tooth's long axis and the surface of the digital sensor (EzSensor HD; Vatech, Gyeonggi-do, Korea) in both radiographs.

Intervention Type
Other

Primary outcome measure
1. Premolar root numbers counted immediately after premolar extraction
2. Premolar length measured in mm immediately after premolar extraction
3. Root canal morphology assessed immediately after premolar radiographing. Vertucci’s classification was adopted to assess the canal morphology in both radiographs in each premolar:
Type I (1-1): A single canal from the pulp chamber to the apex.
Type II (2-1): Two separate canals leave the chamber and merge near the apex to form a single canal.
Type III (1-2-1): A single canal leaving the pulp chamber, dividing into two, then rejoining to form

one canal.
Type IV (2-2): Two separate canals from the pulp chamber to the apex.
Type V (1-2): A single canal leaving the chamber and dividing into two separate canals at the apex.
Type VI (2-1-2): Two separate canals leaving the pulp chamber, merging in the middle of the root, and dividing again into two short, separate canals at the apex.
Type VII (1-2-1-2): A single canal dividing, merging, and then separating into two short, separate canals at the apex.
Type VIII (3-3): Three separate canals in one root from the pulp chamber to the apex.

Secondary outcome measures
The gender effects on the root number (one, two, three or more roots), their length (in mm), and the canal morphology of mandibular premolars (Vertucci classification), assessed statistically after analyzing the data

Overall study start date
15/01/2023

Completion date
15/03/2025

Eligibility

Key inclusion criteria
1. Adolescents in Damascus
2. Intact mandibular premolars

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
12 Months

Upper age limit
15 Months

Sex
Both

Target number of participants
250

Total final enrolment
250

Key exclusion criteria

1. Syndromes patients
2. Premolars fractured during the extraction process

Date of first enrolment
30/03/2023

Date of final enrolment
15/01/2025

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University, Faculty of Dentistry
Almazzeh ST, Damascus, Syria
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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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Yasser Alsayed Tolibah (yasseralsayedtolibah@gmail.com)
The type of data that will be shared: patient age and gender with all data in an Excel file
Dates of availability: by 01/01/2026
Whether consent from participants was required and obtained: consent was required and obtained

IPD sharing plan summary
Available on request