

The effect of a laser on large-sized apical lesion healing

Submission date 14/11/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/06/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Apical lesions are holes that appear in the bone surrounding portals of exit from infected tooth root canal systems. Healing of large apical lesions is a long-term process. Many studies show that bio-stimulation with a diode laser may accelerate bone regeneration, so this study will evaluate the effect of diode laser bio-stimulation on the healing of large-sized apical lesions.

Who can participate?

Patients aged between 25 and 44 years old with at least one upper incisor with an apical lesion

What does the study involve?

Activated irrigation is a method to agitate and improve the flow of irrigants to the root canal system, which wash out debris and lubricate the canal. Patients will be divided into two groups. Group 1 (the control group) will be divided into three sub-groups where irrigant activation is carried out either ultrasonically, with the Xp-Endo finisher or with a diode laser. Group 2 (the study group) will be divided into three groups as the control group but with bio-stimulation by external application of a diode laser. Patients of all groups will be recalled for clinical follow-up at 1, 3, 7, and 14 days to assess pain, swelling and tooth mobility. Patients of all groups will be recalled for x-ray follow-up at 6 and 12 months, when the apical lesions will be assessed.

What are the possible benefits and risks of participating?

The expected benefits of participating are getting rid of apical lesions, accelerating the healing process and decreasing postoperative pain. There are no expected risks of participating because root canal treatment is considered a safe treatment.

Where is the study run from?

Damascus University (Syria)

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

May 2022 to December 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Mohammad Tamer Abbara, tamerabbara@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of low-level laser application on the acceleration of apical lesion healing in single-rooted teeth after using different irrigation activation protocols

Study objectives
H0: There are no significant differences between groups in apical lesion healing and postoperative pain.
H1: There are significant differences between groups in apical lesion healing and postoperative pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 18/05/2020, the Institutional Review Board (IRB) of Damascus University (Al-MazzeH St., Damascus, PO Box 3062, Syria; +963 (0)1144923000; president@damascusuniversity.edu.sy), ref: 1734

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Apical lesions of permanent upper incisors

Interventions

Following the randomization procedure, patients will be divided into two groups (45 permanent upper incisors in each group) using the simple randomization method and a random sequence created using the website <https://www.random.org/>:

Group 1 (control group) will be divided into three sub-groups:

G1-A: Irrigant activation with Ultrasonic

G1-B: Irrigant activation with Xp-Endo finisher

G1-C: Irrigant activation with Diode laser

Group 2 (study group) will be divided into three groups as the control group but with bio-stimulation by external application of diode laser.

After working length determination, instrumentation and sterilizing root canals, sodium hypochlorite (SH) and EDTA will be activated in three ways:

Ultrasonic activation groups: U-file will be inserted 2 mm before the apex, where SH will be activated for 5 minutes and EDTA will be activated for 30 seconds.

Xp-Endo Finisher groups: Xp-Endo Finisher file will be inserted to the full working length, where SH will be activated for 5 minutes and EDTA will be activated for 30 seconds.

Diode laser groups: the tip of the diode laser device will be inserted 2 mm before the apex, where SH will be activated for 5 minutes and EDTA will be activated for 30 seconds.

All groups will be irrigated with chlorhexidine as the final irrigant, obturated with Gutta-percha and Ah-plus sealer using continuous vertical waves technique, and restored with resin-bonded restoration.

As for bio-stimulation groups, mucosa opposing the peri-apical area will be irradiated with a diode laser tip for 60 seconds immediately and 2, 4, 6, 8, 10, and 12 days after finishing the treatment.

Patients of all groups will be recalled for clinical follow-up at 1, 3, 7, and 14 days by assessing postoperative pain, swelling and tooth mobility in all groups.

Patients of all groups will be recalled for radiographical follow-up at 6 and 12 months, where the volume and density of apical lesions will be determined using CBCT images and scored in all groups. Finally, data will be statistically analyzed using SPSS.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Not provided at time of registration

Primary outcome(s)

1. Postoperative pain measured using the visual analog scale (VAS) before treatment, 1, 3, 7 and 14 days
2. Swelling and tooth mobility measured according to their presence/absence before treatment, 1, 3, 7 and 14 days
3. Apical lesion volume and density measured using CBCT images before treatment, 6, and 12 months

Key secondary outcome(s)

Percentage of apical lesions healing measured using CBCT images by comparing the baseline with 6, and 12 months follow-up images

Completion date

01/12/2023

Eligibility**Key inclusion criteria**

1. Healthy patients without any systemic disease or compromised immune status
2. Patients aged between 25 and 44 years old
3. Patients with at least one permanent closed-apex upper incisor first with an asymptomatic apical lesion sized 5 to 10 mm²

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

25 years

Upper age limit

44 years

Sex

All

Key exclusion criteria

1. Patients with advanced periodontitis (more than 5 mm periodontal attachment and bone loss)
2. Untreatable teeth (root fracture, unrestorable tooth, massive internal or external resorption)
3. Smokers

Date of first enrolment

20/11/2022

Date of final enrolment

20/11/2023

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Al-Mazzeah St

PO Box 3062

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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 data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	The effect of the irrigant activation protocol on postoperative pain	03/10/2023	03/10/2023	Yes	No
Results article	The effect of diode laser on postoperative pain	14/03/2024	17/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes