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

Submission date	Recruitment status	[X] Prospectively registered
14/11/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/11/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/06/2025	Oral Health	

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

Contact name
Dr Mohammad Tamer Abbara

ORCID ID
https://orcid.org/0000-0003-3664-0248

Contact details
Al-Mazzeh St
PO Box 3062
Damascus
Syria
20872
+963 (0)932759240
tamer92.abbara@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

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

Study type(s)
Treatment

Participant information sheet
https://drive.google.com/file/d/1xZL8OOcvoqsAsztO7ghSvKAdZHTqxLpm/view?usp=drivesdk

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 measure
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

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

Overall study start date
18/05/2020

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 mm^2

Participant type(s)
Patient

Age group

Adult

Lower age limit
25 Years

Upper age limit
44 Years

Sex
Both

Target number of participants
90

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-Mazzeh St
PO Box 3062
Damascus
Syria
20872

Sponsor information

Organisation
Damascus University

Sponsor details

Al-Mazzeh St
PO Box 3062
Damascus
Syria
20872
+963 (0)114452627
dl.srd@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/12/2022

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