Effects of Different Irrigation Activation Techniques on the Healing of Large Periapical Lesions: A Prospective Clinical Study

Clinical Trial Number: NCT06991803

Date: 30.06.2024

Study Protocol

MATERIALS AND METHODS

Local ethics committee approval was obtained from the Recep Tayyip Erdoğan University Ethical Committee (No: 2023/136). All the participants were informed about the study protocol, and written informed consent was obtained. Sample size calculation The G Power 3.1.9.4 (University Kiel, Germany) program was used to calculate the effect size. The effect size was calculated on the basis of the data of Verma et al. (14), who compared the success of different irrigation techniques in healing after one year. On the basis of the chi-square test data, an effect size of 0.388 was found to be sufficient for significance, and it was calculated that a total of at least 110 samples were required with a type 1 error of 0.05 and 90% power.

Patient selection

Vertucci Class I single-rooted mandibular premolars with asymptomatic apical periodontitis and a periapical index (PAI) score of 3 or higher were included in the study. Patients with systemic diseases, bone metabolism diseases and/or drugs that affect bone metabolism (steroids and bisphosphonates) were excluded from the study. Immunocompromised patients, patients with a history of radiotherapy, pregnant patients, teeth with Miller 2 or more mobility, teeth with a periodontal pocket depth of ≥5 mm, teeth with internal and external resorption, and teeth with vertical and horizontal root fractures were excluded. Out of 150 patients aged 18 years and over, a total of 18 patients who refused to participate or did not meet the inclusion criteria were excluded from the study, and 132 patients were included. Pretreatment panoramic radiographs were obtained with a Planmeca Promax 2D S2 device (Planmeca Romexis, Helsinki, Finland). The patients were positioned so that the sagittal plane was parallel to the vertical plane of the dental panoramic machine and the Frankfurt plane was parallel to the floor. The same radiographic exposure settings (66 kVp, 8 mA and 16.6 second exposure time) were used for all patients.

For 2 each tooth, the vertical, horizontal and diagonal dimensions passing through the center of the lesion were measured via ImageJ v1.52 software (National Institutes of Health, Bethesda, United States), and the largest dimension obtained was recorded as the preoperative lesion diameter (15).

Clinical Procedure

Figure 1 shows the flow diagram of the study, summarizing the treatment methodology. After the teeth were isolated with a rubber dam, the endodontic access cavity was opened with a sterile diamond rond bur under water cooling. Then, #10-15 K-type hand files (Dentsply Maillefer, Ballaigues, Switzerland) were inserted into the canals, and after determining point 0.0 with the Root ZX mini electronic apex locator (J. Morita Co., Tokyo, Japan), the working length was determined to be 0.5 mm shorter than this point and confirmed radiographically. When a discrepancy was observed, the apex locator was considered correct. After the initial apical diameter with the largest K-type file trapped in the working length was determined, the root canals were prepared with ProTaper Next (PTN; Dentsply Maillefer, Ballaigues, Switzerland) up to 3 sizes larger than the initial diameter via a torque-controlled endodontic motor (SybronEndo, Glendora, CA, USA) in 300 rpm/2–5.2 Ncm rotation mode. Between each file, the canals were irrigated with 5 ml of 2.5% NaOCl. In retreatment cases, after opening the access cavity under rubber dam isolation, the guta percha was removed with RT files (EndoArt RT, İnci Dental, Turkey), and the rest of the procedure was performed in the same manner as for primary root canal treatment. After the preparation was completed, final irrigation was applied via the irrigation method.

Control Group (Conventional Syringe Irrigation)

In this group, the traditional syringe method was used for final irrigation of the root canals. The canals were irrigated with 6 mL of 17% EDTA solution, 2 mL of saline and, finally, 6 mL of 2.5% NaOCl, and a 30-gauge perforated irrigation needle placed 1–2 mm shorter than the working length was used. During irrigation, 1–2 mm up-down movements were made with a constant low pressure.

Group 1 (MDA)

After the root canal was filled with irrigation solution, a gutta-percha cone compatible with the master file was positioned 1 mm behind the working length and moved up and down with 100 strokes/minute for activation.

Group 2 (Sonic Activation)

Sonic activation was performed via the Easydo Activator device (EA; Easyinsmile (Weixiaomeichi, Changsha, China). While the solution was present in the canal, the needle t ip of the device was placed in the canal 2 mm behind the determined working length, and the solutions were activated at the recommended power setting.

Group 3 (PUI)

Solutions were activated via ultrasonic tips (mode:E, setting:6) (DTE, Guilin Woodpecker Co., Guilin, Guangxi, China) and an ultrasonic device (DTE S6 Led, Guilin Woodpecker Co., Guilin, Guangxi, China). An ultrasonic tip one size smaller than the master apical file was used 2 mm behind the working length without contacting the walls.

Group 4 (PIPS)

A Fotona Er:YAG laser device (LightWalker Fotona, Ljubljana, Slovenia) was used for activation. A special conical and radial fiber tip (PIPS 300/14, Fotona) was placed in the coronal part of the pulp chamber, and the irrigation solutions in the canal were activated in SSP mode (50 µs, 0.3 W, 15 Hz and 20 mJ) with the air and water settings turned off.

Group 5 (SWEEPS)

A Fotona Er:YAG laser device (SWEEPS 600, Fotona) with an 8.5 mm long and 600 µm diameter tapered fiber tip was used for activation. The device was set to SWEEPS mode with two ultrashort micropulses (25 µs) continuously changing at 0.3 W, 20 mJ, and 15 Hz. The tip was placed in the pulp chamber, and the solution was activated with the air and water settings turned off. In all the activation groups, 2 mL of 17% EDTA solution (SAVER, Prime Dental, Turkey) was activated for 20 s, and this process was repeated 3 times for a total of 6 mL of EDTA activation in 1 min. Then, 2 mL of saline was applied to the canals for 20 s to prevent the chemical interaction of NaOCl and EDTA. Afterward, 2 mL of 2.5% NaOCl solution (MICROVEM, Turkey) was activated for 20 s, and this procedure was repeated 3 times for a total of 6 mL of NaOCl solution activation in 1 minute.

After the final irrigation, the canals were dried with paperpoint (DiaDent, Heungdeok-gu, Korea) and obturated via the cold lateral compaction method via an ADSeal (Meta Biomed, Cheongju, South Korea) sealer and gutta-percha. The gutta-percha was cut 1 mm below the cemento-enamel junction, and coronal restoration was performed with composite resin (Llis, FGM, Joinville, Brazil). All procedures were performed by a single operator (M.Ç.).

Healing evaluation

PAI score and lesion diameter At the 12-month follow-up, panoramic radiographs were taken using the same settings as those used for pretreatment radiography. PAI scores of the treated teeth were recorded, and patients were classified as "healed" (PAI<3) or "unhealed" (PAI≥3). PAI scoring was performed by 2 endodontists, and in cases of disagreement, a consensus was reached by discussion. Additionally, the widest diameter of the lesion at the follow-up session was measured by an endodontist (M.Ç.) The same method was used for the preoperative measurements. The researchers who conducted the PAI and lesion size evaluations were blinded to the irrigation method and preoperative measurements.

Fractal analysis

Fractal analysis (FA) was performed by an experienced oral and maxillofacial radiologist (D.N.G.) who was blinded to the activation method and used the fractal box counting method on panoramic radiographs with ImageJ. The program was downloaded from the internet at https://imagej.nih.gov/ij/download.html. To standardize the size and location of the ROI, a parallel line forming a right angle to the apical and long axes of the tooth was placed 1 mm apical to the root apex (Figure 1). The sequence of steps followed when FD analysis was performed was as follows (Figure 2): All digital images were opened in ImageJ v. 1.52 software (National Institutes of Health), and 30x30 pixel sections were taken from the determined regions and saved in 'tif' format. After the area of interest to be analyzed was cropped, it was saved in 8-bit format and copied. A Gaussian filter (sigma= 35 pixels) was applied to the duplicated image. The blurred image was subtracted from the original image via subtraction. A value of 128 was added to each pixel location, and 128 was set as the threshold value regardless of the initial brightness of the image. The 128 brightness threshold image was converted to binary format. An erosion and dilatation process was applied. The inverted image was skeletonized, and FD analysis was applied to the skeletonized image via the 'box-counting' function. To assess intraobserver reliability, the lesion diameter and fractal measurements were conducted twice with 2-week intervals by the same researchers in 20% of the teeth involved in the study.

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Statistical analysis

The Jamovi 2.3.28 statistical program was used for statistical analysis. Normal distribution in the comparisons was evaluated by the Shapiro–Wilk test, Kolmogorov– Smirnov test, Anderson–Darling test and Q–Q graph. Homogeneity between variances was analyzed by Levene's test. Since sex data were categorical, the differences between the groups were analyzed via the chi-square test. Since the distribution of age between groups was found to be normal, it was analyzed by Welch's one-way ANOVA test. Although a normal distribution was obtained in fractal analysis, Welch's one-way ANOVA test was preferred for the comparison of irrigation groups because the variances were not homogeneously distributed, and pairwise comparisons were made with the Games–Howell test. Before and after comparisons within each group, paired sample t tests were used.

Since a normal distribution could not be obtained, the Kruskal–Wallis test was preferred for the comparison of irrigation groups for lesion size, and pairwise comparisons were made with the Dwass-Steel-Critchlow-Fligner test. Before and after comparisons within each group, the Wilcoxon rank test was used. The significance level for the statistical analysis was set to $p<0.05$. Additionally, intraobserver reliability was evaluated for fractal and lesion size measurements via the concordance correlation coefficient (CCC).

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PLEASE READ CAREFULLY!

You are invited to participate in our research. Before deciding to take part, you need to understand the purpose of the study and make a free and informed decision. Please read this information carefully and feel free to ask any questions you may have.

Participation in this study is entirely voluntary. You have the right to refuse participation or withdraw from the study at any time. Your participation will be interpreted as your consent to join the research. Do not feel any pressure while answering the questions on the forms. All information gathered will be used solely for research purposes.

PURPOSE OF THE STUDY: This study aims to compare the healing rates of single-rooted mandibular teeth with large periapical lesions of endodontic origin using different irrigation activation methods (sonic, ultrasonic, Er:YAG laser, manual dynamic activation), through fractal analysis of panoramic radiographs taken before treatment and one year after treatment.

• WHAT ARE THE CONDITIONS OF PARTICIPATION?

To be eligible for participation, the following criteria must be met:

Patients examined at Recep Tayyip Erdoğan University Faculty of Dentistry, Department of Endodontics

Patients aged 18 and over

Have accepted the Endodontic Consent Form and Study Participation Form

Diagnosed with apical periodontitis requiring primary endodontic treatment with a PAI (periapical index score) of 3 or higher in single-rooted mandibular teeth

Diagnosed with apical periodontitis requiring retreatment with a PAI score of 3 or higher in single-rooted mandibular teeth

Having good oral hygiene

Participants will be included based on the irrigation activation technique used during routine endodontic treatment.

• WHAT KIND OF APPLICATION WILL BE DONE?

Routine root canal or retreatment procedures will be applied. If necessary, irrigation activation techniques will be used.

• WHAT ARE MY RESPONSIBILITIES?

You must regularly attend treatment and follow-up appointments as part of the study.

• WHAT IS THE NUMBER OF PARTICIPANTS?

A total of 132 participants are planned to be included in the study.

• HOW LONG WILL MY PARTICIPATION LAST?

Endodontic treatment is expected to take approximately 1 hour. You will be asked to participate in a follow-up one year after treatment..

• WHAT ARE THE POSSIBLE BENEFITS EXPECTED BY PARTICIPATION IN THE STUDY?

Observing the effect of endodontic treatment and irrigation activation techniques on the healing of teeth with large lesions.

• WHAT ARE THE POSSIBLE RISKS EXPECTED BY PARTICIPATION IN THE STUDY?

No risks beyond routine root canal treatment complications are expected.

• WHAT ARE THE DRUGS/NUTRIENTS KNOWN TO BE CONTROLLED TOGETHER DURING THE RESEARCH PROCESS?

There are no known medications or foods that pose a risk.

• UNDER WHAT CONDITIONS CAN I BE EXCLUDED FROM THE RESEARCH?

You may be excluded if tooth extraction, apical surgery, or similar indications arise during treatment.

• WHO IS LIABLE/RESPONSIBLE IN CASE OF ANY DAMAGE AND WHAT WILL BE DONE?

The treating physician and their supervisor are responsible for any harm that may occur.

• WHO SHOULD I CALL FOR PROBLEMS THAT MAY ARISE DURING THE RESEARCH PROCESS?

If you have any questions or require additional information, please contact:

Name: Medine ÇİÇEK
Position: Research Assistant
Phone: +905442745525

• WILL THE EXPENSES IN THE SCOPE OF THE STUDY BE COVERED?

There is no cost to the patient for procedures covered in this study.

• IS THERE AN INSTITUTION SUPPORTING THE STUDY?

The study will be conducted within the Faculty of Dentistry at Recep Tayyip Erdoğan University.

• WILL ANY PAYMENT BE MADE DUE TO MY PARTICIPATION IN THE STUDY?

No payment will be provided.

• WHAT SHOULD I DO IF I DO NOT AGREE TO PARTICIPATE IN THE STUDY OR LEAVE THE STUDY?

Participation is entirely voluntary. Patients who do not agree to participate will not be included in follow-up measurements after routine treatment. You can withdraw at any time without having to state a reason, and without facing any negative consequences.

• CAN CONFIDENTIALITY BE PROVIDED REGARDING INFORMATION REGARDING MY PARTICIPATION?

Participant identity information will be kept confidential. Age, gender, and radiograph data will be used for statistical analysis.

Consent to Participate in the Study:

I have read the information provided above and understand the purpose and scope of the study, as well as my responsibilities as a volunteer. The researcher named below has explained the study to me both in writing and verbally, and I had the opportunity to ask questions and received satisfactory answers. I was also informed verbally of the possible risks and benefits. I understand that I may withdraw from the study at any time without having to give a reason and that doing so will not result in any negative consequences.

Under these conditions, I voluntarily agree to participate in this study without any pressure or coercion. I understand that refusing to sign this form will not affect any legal rights I may have. A signed and dated copy of this form has been provided to me.

VOLUNTEER		
NAME & SURNAME		**SİGNATURE**
ADDRESS		
PHONE & FAX		
DATE		

RESPONSIBLE RESEARCHER		
NAME & SURNAME	R.A. Medine Çiçek	**SİGNATURE**
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