Effects of Different Irrigation Activation Techniques on the Healing of Large Periapical Lesions: A Randomized Controlled Study Date: 01.06.2023

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 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 rubber dam isolation, the guta percha was removed with RT files (EndoArt RT, inci 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 randomly determined (www.randomizer.org). The randomization was conducted with a blocked design, by a researcher not involved in the study.

The sealed envelope indicating the group to which the patient was assigned was opened at the final irrigation stage. The operator was blind to the irrigation protocol to be applied until this stage.

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 updown 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 tip 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 μ s, 0.3 W, 15 Hz and 20 mJ) with the air and water settings turned off.

Group 5 (AutoSWEEPS)

A Fotona Er:YAG laser device (SWEEPS 600, Fotona) with an 8.5 mm long and 600 μ m diameter tapered fiber tip was used for activation. The device was set to AutoSWEEPS mode with two ultrashort micropulses (25 μ s) 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 NaOCI and EDTA. Afterward, 2 mL of 2.5% NaOCI solution (MICROVEM, Turkey) was activated for 20 s, and this procedure was repeated 3 times for a total of 6 mL of NaOCI 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 \geq 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 2). The sequence of steps followed when FD analysis was performed was as follows (Figure 3): 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.