Efficacy of Er,Cr:YSGG laser with endodontical radial firing tips on the outcome of endodontic treatment: blind randomized controlled clinical trial with six-month evaluation

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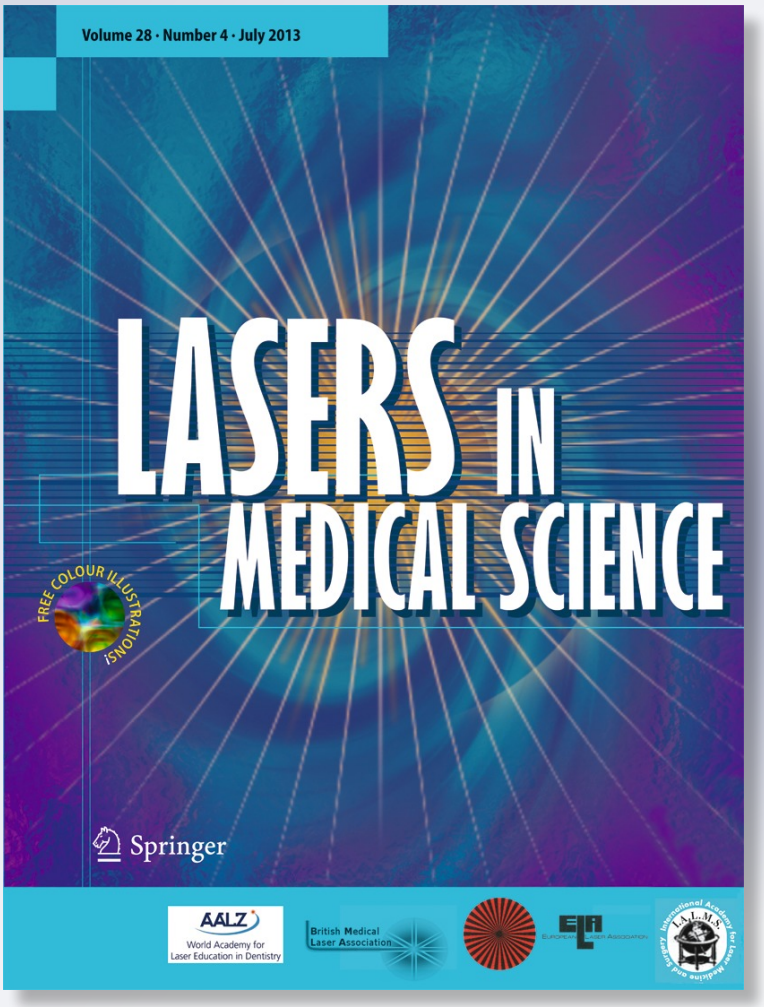

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ORIGINAL ARTICLE

Efficacy of Er,Cr:YSGG laser with endodontical radial firing tips on the outcome of endodontic treatment: blind randomized controlled clinical trial with six-month evaluation

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Abstract Clinical reports stating the efficacy of novel root canal disinfection protocols are an important focus in endodontic research. This blind randomized clinical trial assessed the clinical efficacy of the erbium, chromium:yttrium–scandium–gallium–garnet (Er,Cr:YSGG) laser radial firing tips (RFT) versus the concomitant use of 3 % sodium hypochlorite and interim calcium hydroxide paste in necrotic teeth with chronic apical periodontitis. We hypothesized to find similar or improved bone healing in the laser-assisted endodontic treatment. Thirty-six anterior and premolar teeth were randomly assigned. In group 1, teeth were prepared with 3 % sodium hypochlorite for irrigation and calcium hydroxide as inter-appointment dressing; in group 2, teeth were prepared with saline solution and irradiated with Er,Cr:YSGG laser using RFT2 (140 μs, 37.5 mJ, 20 Hz) and RFT3 (140 μs, 62.5 mJ, 20 Hz) in the first and second appointment, respectively, four times each, moving at 2 mm s^{-1} from apical to coronal. The primary outcome measure was changed in apical bone density at 6 months, using the periapical index (PAI) for blind radiographic evaluation. Twenty-nine patients were examined and subjected to statistical analysis, 12 in group 1 and 17 in group 2. There was one treatment failure in group 1. Both groups gave similar outcomes exhibiting statistically significant decreases in PAI scores.

Keywords Er,Cr:YSGG laser · Randomized clinical trial · Sodium hypochlorite · Calcium hydroxide · Apical periodontitis · Endodontics

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Introduction

Bacterial presence and maintenance within the root canal system can be considered the principal etiologic factor for the development of pulp and periapical lesions [1–3]. Moreover, the idea that absence of cultivable bacteria at the time of obturation will favor healing is consistent with the one that microorganisms could be responsible for chronic apical periodontitis (CAP) [4]. Chemomechanical preparation using sodium hypochlorite (NaOCl) as irrigant can be conventionally accepted for effective root canal disinfection [5]. To supplement these procedures and eliminate persistent bacteria, calcium hydroxide is arguably the most used intracanal medication [6, 7]. However, the effectiveness of these conventional strategies against microorganisms commonly associated with CAP remains under debate [7–10].

Despite the fact that currently used intracanal medicaments have limited antibacterial spectrum and low ability to diffuse into the dentine [11, 12], during mechanical preparation, a smear layer is produced. The smear layer can cover the root canal walls, serve as a reservoir of bacteria, and also prevent antibacterial solutions from penetrating into the dentinal tubules [13]. Thus, clinicians should ideally adopt a treatment protocol that has been shown to be effective in well-controlled studies so that a predictable outcome can be

achieved. These must include strategies that could penetrate deeper into dentinal tubules and eliminate microorganisms located beyond the host defense mechanisms [14].

Lasers have been suggested to assist endodontic treatments, being a suitable method to remove the smear layer [15, 16] and to achieve deep root canal system disinfection [17, 18]. Although laser effectiveness may depend on several factors such as wavelength, pulse power, pulse duration, and light distribution through the end of the optical fiber [15], endodontic clinical research to date has been promising but limited [19].

The erbium, chromium:yttrium–scandium–gallium–garnet (Er,Cr:YSGG) laser, at a wavelength of 2,780 nm, has been shown capable of removing the smear layer [20–22] and improving root canal system disinfection [23–25] without being hazardous to surrounding structures [25–27]. Recently, in order to improve light distribution inside root canals, modified radial firing tips (RFT) were developed and have been showing to be a valuable tool for smear layer removal using water concomitantly to root canal disinfection in dry conditions [28–30]. However, there is still no clinical evidence stating the efficacy of the Er,Cr:YSGG laser-assisted endodontic treatment while using RFTs for both purposes within the same protocol.

We hypothesized that necrotic teeth with CAP treated with Er,Cr:YSGG laser and RFTs would demonstrate similar outcomes using the periapical index (PAI) [31], when compared with teeth treated with 3 % NaOCl and calcium hydroxide dressing. In accordance, the aim of this blind randomized clinical trial was to compare radiographic evidences of periapical healing after root canal therapy, suggesting the possibility of achieving predictable outcomes using the Er,Cr:YSGG laser without the aid of any chemical substances.

Material and methods

Subject enrollment Approval for the project was obtained by the University of Porto Ethical Committee. Participants were recruited from referrals made to the university dental clinic and then referred to endodontics for initial nonsurgical root canal treatment between September 2009 and May 2010.

Patients with asymptomatic teeth with necrotic pulps and CAP verified radiographically (minimum size, ≥1.0× 1.0 mm) were consecutively enrolled in the study. Diagnosis was confirmed by negative response to thermal pulp tests. Pulp testing was performed by undergraduate students, and radiographic interpretation was verified by independent faculty members. Only anterior or premolars with mature, fully formed apex teeth were selected. Rubber dam isolation technique was mandatory. Within-person design was allowed (two patients contributed with more than one tooth).

Patients were excluded if they were younger than 12 years old, pregnant, had a positive history of antibiotic use within the past month, needed antibiotic premedication for dental treatment (for infective endocarditis or immunocompromising disorders), suffering from uncontrolled hypertension, uncontrolled diabetes mellitus, chronic renal failure, hematologic diseases, HIV, osteoporosis treated with biphosphonates, steroid therapy in excess of 5 mg/day of prednisolone, or head and neck irradiation therapy. No compulsion was allowed (e.g., terminal stages, prisoners). Teeth with abnormal root canal anatomy, longer than 26 mm in length, non restorable teeth, and teeth with advanced periodontal disease were not included in the study.

Once eligibility was confirmed, the study was explained to the patient by one endodontic resident, and the patient was invited to participate. Treatments were not subsidized, and no financial incentive was offered (i.e., patients were responsible for the usual root canal treatment fee). It was advised that root canal treatment would be performed regardless of participation in the study. After informed consent (Helsinki Declaration 1973, revised in Edinburgh 2000) was acquired, participants were randomly assigned to either test or control group using block sequences from a randomized computer generator program—generated by an independent investigator (M.A.M.)—resulting in a 1:1 ratio between the groups.

Allocation concealment and participants Neither the undergraduate clinician nor the patient was aware of the group assignment before agreeing to participate in the study. Standard patient (control/test group) allocation was done randomly according to the sequence given by the computer-randomized generated tables. When more than one tooth was allocated in the same patient (within person), randomization was done by assigning the right or more mesial tooth to the control treatment group, whereas the left or more distal tooth was allocated to the laser-assisted group.

All endodontic procedures were performed by enrolled undergraduate (4th and 5th graduation years) students always supervised by graduated, trained, and experienced professors who were not aware of the patient group assignment. Laser irradiation was provided by the main investigator (M.R.M.). Radiographic evaluation was done by experienced, previously calibrated, endodontic specialists (M.F.C., I.P.V., and J.A.C.).

Clinical procedures All treatment sessions were approximately 3 h in length and were performed by undergraduate residents following a standardized treatment protocol for each intervention. Local anesthesia (2 % lidocaine with

1:100,000 epinephrine) was administered as needed for patient comfort.

Initial carious excavation was performed and previous restorations removed. Rubber dam isolation was obtained and standard access cavity was prepared.

Initial canal working length (WL) was established at 1 mm short of the biological apex of the root, established radiographically with a size ISO #15 stainless steel file. WL was confirmed and adjusted using straight and angled radiographs.

Both groups were subjected to root canal treatments in two appointments. Finishing the first appointment, a sterile cotton pellet imbibed on Cresophène® (Septodont) solution was placed in the pulp chamber, and the access cavity was sealed with a reinforced zinc-oxide eugenol intermediate restorative material (IRM®, Dentsply).

During the second appointment, which took place 7 to 24 days after the first visit, every patient was inquired for symptom history such as pain, sensitivity to percussion, or swelling.

A minimum apical file size of #45 ISO was required for all teeth. If canals were initially large, then the master apical file size was set at least three sizes larger than the first file to bind at the WL.

Group 1–control On the first appointment, root canal instrumentation was performed using the manual step-back technique and irrigated with 5.0 mL of 3 % sodium hypochlorite after each cycle until reaching the minimum enlargement of #30 ISO K-file (Zipperer CC^{+}, VDW GmbH, Munich, Germany). Root canals were dried with sterile paper points and dressed with calcium hydroxide paste. At the second appointment, all of the calcium hydroxide paste was removed using H-files (Zipperer, VDW GmbH, Munich, Germany) and copious irrigation with 3 % sodium hypochlorite. Complete removal of the calcium hydroxide paste was confirmed by visual inspection, and manual instrumentation was completed. After final irrigation with 5.0 mL 3 % sodium hypochlorite, all canals were dried with sterile paper points, checking for the absence of suppuration or exudate.

Finally, root canals were filled with gutta-percha cones (Gutta-Percha Points, ISO Color Coded–Dentsply, Maillefer) using cold lateral condensation technique including zinc oxide eugenol handmade paste as sealer. The access cavity was sealed with a reinforced zinc oxide eugenol IRM (Dentsply) followed by taking a postoperative radiograph.

Group 2–test On the first appointment, root canal instrumentation was performed in similarity with the protocol described for group 1, while irrigation was performed with 2.0 mL of saline solution between files. After reaching the #30 ISO K-file (Zipperer CC^{+}, VDW GmbH, Munich, Germany), the main canal was filled with distilled water, and laser irradiation was performed with the 2,780 nm Er,Cr:YSGG laser (Waterlase MD; Biolase Technology, Inc, San Clement, CA) and a 270-μm-diameter radial firing tip (RFT2 Endolase, Biolase Technology, Inc; calibration factor of 0.55) with panel settings of 0.75 W, 20 Hz (37.5 mJ), 140 μs pulse, 0 % water, and air. The tip was placed at the working length, and irradiation was performed approximately at the speed of 2 mm s^{-1} until reaching the most coronal part of the canal. This irradiation procedure was repeated four times (two with the canal filled with distilled water and two in dry conditions), resting approximately 15 s between each irradiation.

On the second appointment, canal preparation was completed with saline solution as irrigant. The main canal was filled with distilled water, and laser irradiation was performed with a 320-μm radial firing tip (RFT3 Endolase, Biolase Technology, Inc; calibration factor of 0.85) with panel settings of 1,25 W, 20 Hz (62.5 mJ), 140 μs pulse, 0 % water, and air. The irradiation protocol was identical to the first appointment.

After irradiation, canals were irrigated with 5.0 mL of saline solution during approximately 1 min as final rinsing and dried with sterile paper points, checking for the absence of any suppuration or exudate. Root canals were filled with the technique described for group 1. All teeth must have been permanently restored by the referring undergraduates within a 30-day period.

Outcome classification and data analysis

All radiologic assessments were carried by one operator (M.R.M.). The long-cone paralleling technique, with one film holder, was used for the immediate postoperative and follow-up radiographs. Radiographic exposure settings were recorded for each tooth. Radiographs were all made under the same condition and exposure settings. Radiographic images were coded and stored by two investigators (V.I.P. and C.J.A.).

The primary outcome measure for this study was change in apical bone density at 6 months. The PAI [31] was used to radiographically evaluate the proportion of teeth that could be considered improved (decreased PAI score) or healed (PAI $\leq$2) in each group.

Radiographic evaluation was blind and independently performed by two experienced, previously calibrated endodontists (C.M.F. and V.I.P.). Instructions for grading images with the PAI scoring system were adapted from Orstavik et al. [31]. All images were scored in a random order in a darkened room using an illuminated viewer

box whilst mounted in a cardboard slit to block off ambient light.

For calibration, each examiner graded a series of 30 radiographic images not associated with the study sample and representing a wide range of periapical bone densities. To access intra-rater agreement, 1 week after the first session, the examiners scored the same images. This method generated four PAI scores for each image, two from each of the two examiners. The examiners then met as a group to reach consensus on cases that did not receive unanimous agreement and reviewed all scores to enhance calibration and inter-rater agreement. Consensus was reached on images that were not initially scored the same. The identifying code for each image was not broken until after consensus score was determined. Consensus score for each image was considered the true score and used for statistical analysis. Agreement between and within examiners was determined using the interclass correlation coefficient (ICC). Intra-rater reliability was measured with the single-measure ICC (SPSS 17 for Windows; SPSS Inc, Chicago, IL), and inter-rater agreement was measured with the average measure ICC (also known as the inter-rater reliability coefficient). The criteria proposed for strength of agreement by Landis and Koch [32] were used: 0.00–0.20, slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; and 0.81–1.00, almost perfect agreement.

One week following the final calibration session, both examiners (C.M.F. and V.I.P.) randomly scored the assembled study images, without knowing the treatment protocol used for each patient. If they disagreed, another independent specialist (C.J.A.) decided the final scoring.

To evaluate differences between groups, the Mann–Whitney U test was applied for both baseline (immediate postoperative) and 6-month follow-up evaluation. Change in PAI score for each group from baseline to 6-month follow-up evaluation was tested with the Wilcoxon signed rank test. The proportion of teeth in each group that could be considered improved (decreased PAI score) or healed (PAI ≤ 2) was assessed with the χ^2 Monte Carlo simulation test.

Presence of clinical symptoms or abnormal findings at 6 months (spontaneous pain, swelling, mobility, and sensitivity to percussion or palpation) were recorded but not subjected to statistical analysis.

Results

Thirty-six patients met the inclusion criteria and consented to participate in the trial. Due to deviation from protocol (no compliance), four patients were excluded from statistical analysis. Twenty-nine patients were examined and subjected to statistical analysis at the 6-month follow-up, 12 in the control group (group 1) and 17 in the test group (group 2) (Fig.1).

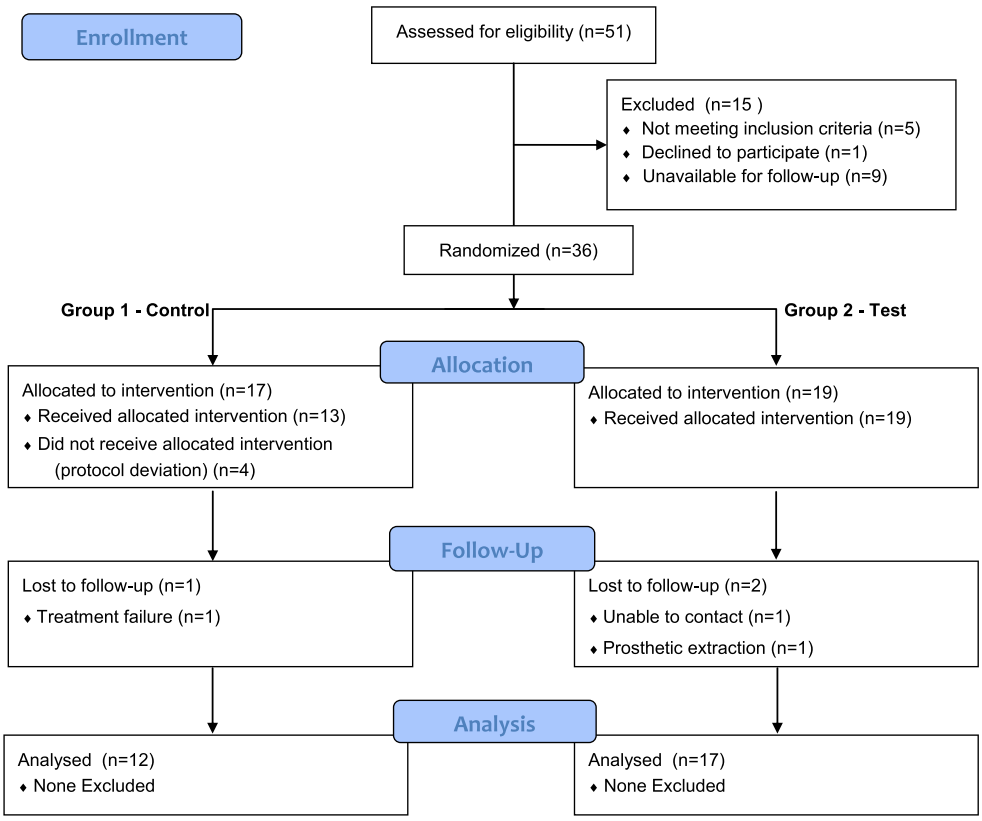

Fig. 1 Consolidated standards for reporting trials (CONSORT 2010) flow diagram

No adverse effects were found. As abnormal clinical finding, one patient (group 2) complained about swelling and sensitivity immediately after obturation which has disappeared in approximately 1 week with antibiotic and anti-inflammatory prescription.

We defined failure as the need for any additional treatment. The single failure (group 1) was related to the presence of swelling, sensitivity to percussion, and sinus tract after 3 months. In group 2, one tooth was extracted due to prosthetic reasons before the 6-month examination and was considered lost to follow-up. One additional patient was lost to follow-up. Treatment failures were not included in the primary data analysis.

Before the consensus scoring meeting, intra-rater reliability score was 0.95, and the overall inter-rater agreement was 0.85, considered as almost perfect agreement.

The mean PAI score for group 1 was 3.83 (SD=1.19) at the immediate postoperative examination and 2.17 (SD=1.47) at the 6-month follow-up, a decrease of 1.66; the mean PAI score for group 2 was 4.49 (SD=1.05) at the immediate postoperative examination and 2.47 (SD=1.23) at the 6-month follow-up, a decrease of 2.02; Both groups exhibited a statistically significant decrease in PAI score ($P<0.05$). There was no statistically significant difference between groups at either the immediate postoperative examination ($P=0.28$) or the 6-month evaluation ($P=0.38$).

In group 1, 66.67 % of teeth were considered healed (PAI ≤2) at 6 months, 83.33 % improved (lower PAI score), and 16.67 % were unchanged (same PAI score). There was one treatment failure which was not accessed to follow-up. In group 2, 58.82 % of the teeth were considered healed at 6 months, 82.35 % improved, and 17.65 % were unchanged. There was no record of increased PAI score. There was no statistically significant difference between groups ($P=0.69$).

Discussion

The limited effectiveness of sodium hypochlorite and calcium hydroxide paste against several common endodontic pathogens has caused some investigators to question its optimal concentration and use [5]. Moreover, there is still no consistent evidence that a single appointment would result in improved healing when compared to multiple-appointment root canal therapy performed with calcium hydroxide dressing [7, 33]. However, the expectation that teeth treated in two appointments without the use of chemical solutions or dressing paste would result, at least, in similar outcomes using this laser-assisted endodontic treatment protocol was confirmed.

The sample size and operators might not accurately represent the true population of patients and clinicians. The sample size can be considered typical when compared to other high-quality clinical trials [6, 34]. Thirty six from patients from an original sample of 51 were examined at the 6-month follow-up, 12 in group 1 and 17 in group 2.

Patients were randomly assigned to treatment groups, and root canal treatments were performed by undergraduates according to a standardized protocol that may represent the University of Porto consensus for both best and possible clinical practice. As residents (fourth- and fifth-year graduation students) can arguably be considered less skilled than general dentists or experienced endodontists; all treatments were performed under supervision with the opportunity for consultation and assistance as needed. Interestingly, results of treatment under quality-controlled training conditions were found similar to those performed by experienced professionals [35].

The PAI score was not used as initial inclusion criteria for this study, although the requirement that all teeth must have a visible periapical radiolucent area at least 1.0×1.0 mm assured an initial PAI score ≥2. There was an approximately equal distribution of immediate postoperative PAI score between the two groups so that difference between disinfection protocols was the only independent variable.

Results can be influenced by many unknown and uncontrolled variables (e.g., inclusion of smokers) that may suggest that these patients could experience poorer treatment outcomes. In contrast, it was decided to exclude multi-rooted teeth from the study because they appear to have lower probability of complete healing when compared to single-rooted teeth [36]. Both groups were similar regarding basic demographic characteristics (Table 1) even if small baseline differences can be considered the result of chance rather than source of bias in a randomized trial.

Table 1 Demographic characteristics for each group (age, gender, and tooth type)

	Male	Female	Age	Anterior	Premolar
Control group1 ($n=12$)	4	8	Mean=49 (range, 12 to 76 years old)	8	4
Test group2 ($n=17$)	7	10	Mean=42 (range, 24 to 67 years old)	11	6
Treatment faillure	0	1	45 years old	0	1
Lost to follow-up	1	1	26 and 56 years old	2	0
Totals	12	20	Mean=45 (range, 12 to 76 years old)	21	11

Radiographic diagnosis of apical periodontitis may be regarded as a signal task, and its prevalence in a cohort study is considered difficult to access by radiographic means [37]. Some authors have also suggested that 4 or 5 years might be necessary to adequately evaluate periapical healing after root canal therapy. However, considering the risk of losing patients during follow-ups, some studies have used shorter periods as an endpoint while others suggested simpler but accurate surrogate endpoints [9, 33].

The ICC was used to determine the agreement between and within examiners. A score of 0 represents no agreement beyond the level of agreement expected by random chance whereas 1.0 signifies perfect agreement. The inter-rater reliability score of 0.85 in this study represents an almost perfect level of agreement between examiners, even before meeting to establish the consensus scores for each image. Despite being able to support the PAI reliability to measure radiographic changes in apical bone density, there is more than one way to analyze data generated by the PAI considering that this is an ordinal scale [33]. For this study, we were most interested in differences in healing between groups by measuring changes in the mean PAI score. We considered that early evidences of periapical change in bone density should be apparent even if longer observation periods might be recommended. Such studies will soon be in progress. These may verify whether predictable outcomes can be achieved with the Er,Cr:YSGG laser-assisted endodontic treatment.

At the present stage, with a follow-up period of 6 months, in necrotic teeth with apical periodontitis and root canal therapy, there were no significant differences in terms of periapical healing between groups. Nevertheless, taking into consideration that both groups exhibited significant differences between the postoperative and final healing score, it could support the idea that the Er,Cr:YSGG laser-assisted endodontic treatment (using RFTs in wet and dry conditions) can be non-inferiority approach to perform endodontic treatments with less restrictions and adverse effects.

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