The healing process of periapical lesions: hydraulic vs traditional endodontic sealers

Abstract

Objectives
Aim of this prospective study was to assess the healing process of endodontically treated teeth with periapical lesions when hydraulic or traditional endodontic sealers were used.

Methods
Three hundred and fifty endodontic treatments were performed on 295 patients. The sample teeth were randomly divided into two groups according to the endodontic sealer was used (Group 1 Hydraulic Endodontic Sealer and Group 2 Zinc oxide-eugenol based sealer). All teeth were obturated with a warm gutta-percha technique. The healing process was documented at 1 and 2 years by intraoral X-ray using the Peri Apical Indexes. At last recall only 291 patients for 343 canal treatments were reevaluated with a recall rate of 98%. The statistical analysis evaluated the change of periapical size lesion in the time of both Groups, for each type of teeth, for each arch, the teeth with successful outcomes at T2, and the speed of the healing process between the two groups. Pearson chi-square test was used and the P value was set at <0.5.

Results
The rate of success was 97,6%; the healed teeth were 80,5%, the healing 17,2%, and not healed only 2,3%. The success rate was 98,8% for periapical lesions less than 5 mm and 96,4 % for periapical lesions bigger than 5 mm. When the teeth classified as successful were compared with not healed teeth, no significant difference was noted between the two Groups. However, 276 teeth were recorded as healed and 59 as healing and 8 others did not show any healing process and were classified as failure. Of these failures, four were recorded in Group 1 and four in Group 2.

Significance
The healing process of teeth treated with Hydraulic Endodontic Sealer was faster than that obturated with zinc phosphate sealer within the first year of clinical service but statistically significant difference. The size of the periapical lesion does influence the healing process time.

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Keywords

Clinical trial, endodontic outcomes, endodontically treated teeth, hydraulic sealers, hydraulic endodontic sealer.

INTRODUCTION

Periapical lesions are very frequent clinical signs of pulpal necrosis but can also be combined with previous endodontic treatments, modification of root canal anatomy due to previous treatments, direct trauma, missed canals, etc (1-3).
The patient with a periapical lesion may present pain to compression of the tooth, pain on touching the occlusal surface, abscess, and fistula (1-3). The diagnosis of a periapical lesion and the evaluation of the size of the lesion itself must be confirmed by radiographic examination (4).
Different systems were proposed to classify the periapical lesions (5-7), but the Peri Apical Indexes system (PAI) is frequently used for this purpose (6,7).
All periapical lesions must be treated, mainly redoing an orthograde endodontic therapy or less frequently with periapical surgery (8,9). After the tooth with the periapical lesion is retreated, the pathological area at the apex might recover in a time related to the size of the lesion itself (10-12). However, most periapical lesions retreated endodontically can heal within 4 years, and the healing process can be monitored by endo-oral radiograph at each recall to properly follow the possible healing process performed, using the PAI (6).
The endodontic sealers are basically zinc oxide eugenol-based and epoxy resin-based. When a warm gutta-percha obturation technique is used a small amount of endodontic sealer can extrude from the apex and/or lateral canals. In case of extrusion from the root canal both endodontic sealers are irritating. Also, the most used endodontic sealer in combination with a warm gutta-percha obturation technique is the zinc oxide eugenol-based but has limited biocompatibility. In the last years, the so-called hydraulic endodontic sealers (HES) become very popular among practitioners and endodontists and their popularity is progressively increasing (13-16).
Because of some in vitro studies, the HES were originally proposed in combination with the single-cone obturation technique (17-19), whilst more recently other in vitro investigations showed that also warm gutta-percha obturation techniques can be used with this new family of materials (20-22). However, the HES are different in composition and properties (13).
Clinically, trials confirmed the possibility of obtaining for good results when both obturation techniques (cold and warm gutta-percha obturation procedures) were used (23-29) although more evidence is on the single cone obturation technique.
The aim of this clinical study was to compare the speed and effectiveness of the healing process of teeth affected by the periapical lesion(s) when obturated with a warm gutta-percha technique in combination with a hydraulic or a traditional endodontic sealer.
The following null hypotheses were tested: 1. There are no differences between HES and traditional sealers at one year recall and 2. There are no differences between HES and traditional sealers regarding last 2-year recall.

MATERIALS AND METHODS

Study Design

Between March 2020 and June 2021, 350 endodontic treatments were performed by one expert operator (DIKP). Two hundred ninety-five patients were treated (139 men, 151 women, age range: 18 to 75 years, media 47 years). Patients were selected when in need of retreatment or treatment because of pulp necrosis and teeth showed a periapical lesion at the apex of different sizes. Surgical retreatments were excluded and orthograde reinterventions and primary root canal procedures were collected with a recall x-ray and visit of at least 12 months or longer (mean follow-up period of 24.6 months). After the endodontic treatment, all patients were placed in a periodical recall program for oral hygiene. The cases were collected from the authors' dental offices consecutively. In accordance with a size of population of 500 people who needed to receive root canal treatment or retreatment the sample size was determined with a margin of error of 5%, and a confidence level of 95%. The trial was conducted accordingly with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All patients received information about the study and gave their written consent. The University of Siena with its Ethical Committee approved this study on October 21st, 2019 (PR001).

Patient selection

Inclusion Criteria: This study included patients in good general status, without systematic diseases, who had no periodontal disease and one or more tooth with periradicular lesion of endodontic origin, therefore in need of an endodontic treatment or retreatment.
Exclusion Criteria: As far as exclusion criteria are concerned, it was decided not to include in this study: patients who were not at least 18 years old, pregnant women, patients with some kind of disability, previous prosthodontic restorations of abutment teeth, teeth with deep periodontal pockets, teeth that were previously undergone to pulp capping procedures, patients who have motor activity commonly known as bruxism or teeth with heavy occlusal contacts, people with systemic problems or severe medical issues, patients with allergies to methacrylates, patients with problems of xerostomia and cariogenicity, lack of compliance, need for surgical endodontic retreatment.

Baseline registration

A total of 350 teeth were collected among them, 125 were upper posteriors, 146 were lower posteriors and 35 upper anterior teeth and 44 lower anterior teeth. Of

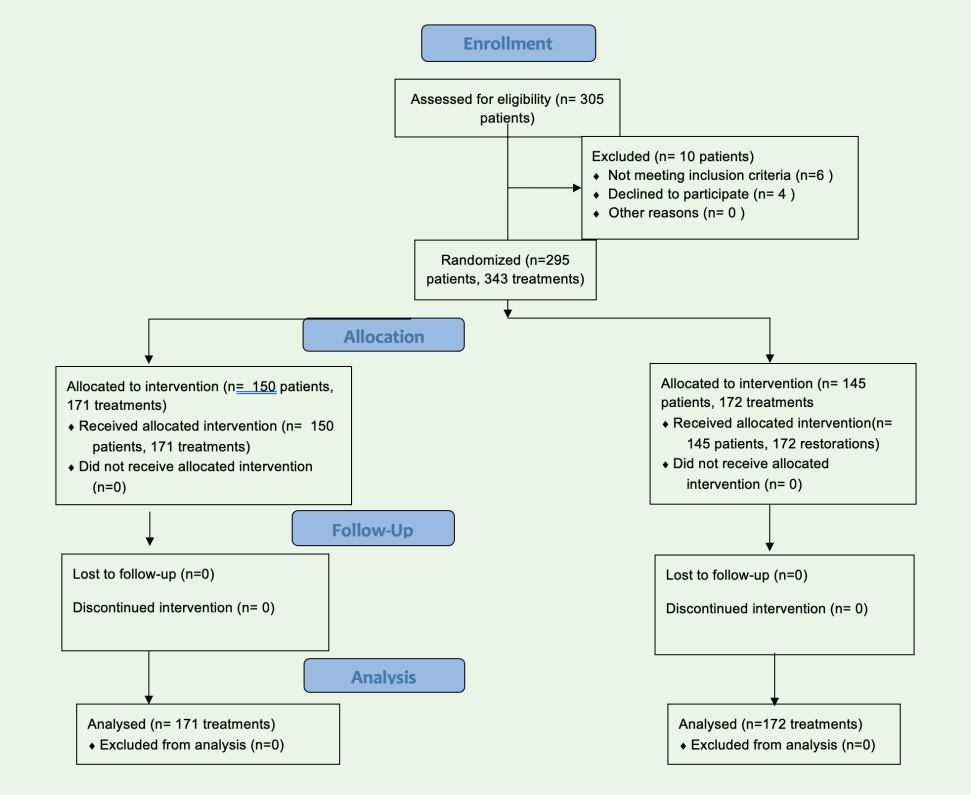

Fig. 1
CONSORT 2010 Flow Diagram

all these Endodontic Treated Teeth (ETT 186 (54,5%) were mandibular teeth and 157 (45,5%) were maxillary teeth. At baseline (T0), 275 teeth (80,2%) presented signs and symptoms (pain, abscess, sinus tract and fistula), all 343 showed periradicular radiolucency and 174 presented a periradicular lesion of 5 mm or bigger whilst 169 showed a periraducular lesion lower than 5 mm. Among all these ETTs, 299 needed to be retreated and 44 were necrotic and needed a first root canal treatment. Then, recalls were made at 10-12 months (T1) and 22-24 months (T2).

The sample teeth were randomly divided into two groups: Group 1: the teeth were obturated with a hydraulic endodontic sealer (CeraSeal, MetaBiomed, Co., LTD., Cheongju-si, Korea). Group 2: the teeth were obturated with a zinc phosphate sealer (Argoseal, Ogna Srl, Muggio, MB, Italy).

Treatment assignment was noted in the registration and the treatment assignment form was kept by the study. Allocation concealment was performed by using opaque, sealed and sequentially numbered envelopes. The statistician made the allocation sequence by means of a computer-generated random list and instructed a different subject to assign a sealed envelope containing the type of LD material to be used. The opaque envelope was opened immediately before material selection and communicated to the operator before the treatment.

In the record of each patient, the following data was listed: number of appointments needed to perform a correct root canal treatment, use of intracanal medications, intra-operative issues (i.e perforations, files separation, ledges, stripping, apical transportation or any other alteration of the original Endodontic anatomy of the tooth) also, the length of the obturation was recorded (at apex, 1 mm short or more and beyond)and possible post-operative complications(i.e. pain on biting, tenderness on percussion, swelling or other manifestations of flare-up).

Endodontic treatment

The endodontic treatment and the restoration of ETT were made accordingly with Pontoriero et al. (32) as reported below. In summary, the pulp chamber penetration was performed with a long shaft round diamond bur (Hager and Meisinger GmbH, Germany) mounted on a high speed handpiece and then finished with no.2 ultrasonic StartX tip (DENTSPLY Konstanz, Germany). All canals were scouted at first with pre-curved stainless steel hand instruments K-type files (Maillefer, Baillague, Switzerland), size 0.8 or 10 ISO (International Standard Organization) to reach the apex; after measuring the working length with an electronic apex locator (Root ZX Morita, Tokyo, Japan), pre-flaring and glide path were performed with Mtwo number 10 0.4 taper and Mtwo number 150.5 taper NiTi rotary files (Sweden e Martina, Le Due Carrare, Italy) bringing them to working length approaching the apex gradually in continuous rotation at 250 rpm and brushing movements, where in presence of dentinal

interferences. Then, all root canals were shaped by rotary instruments ProTaper Next (DENTSPLY Konstanz, Germany). Irrigation was performed with heated 5.25% sodium hypochlorite delivered into the canal with a 5ml syringe and a 27-gauge side-vented needle, passive ultrasonic activation of the irrigants was performed with ultrasonic dedicated tip (Irrisafe,Acteon Satelec)a 2 minutes irrigation with EDTA solution 17% (Ogna, Bologna, Italy) was performed before a last 3 minutes irrigation with heated 5.25% sodium hypochlorite NiClor (NiClor, Ogna, Bologna, Italy) was done. The shaped canals were dried with dedicated paper points (ProTaper Next DENTSPLY Konstanz, Germany) and then obturated with dedicated gutta-percha cones (DENTSPLY Konstanz, Germany) in combination with one of the two endodontic sealer with the continuous wave of condensation technique or a carrier-based procedure (Thermafil, Dentsply, Konstanz, Germany) accordingly with the root canal anatomy. The Continuous Wave of Condensation Technique was performed using a dedicated guttapercha cone of the same size as the last rotary instrument brought at the apex of the root canal. The cone fit was done when the root canal was still filled with sodium hypochlorite and the tug back was checked. Then the tip of the cone was cut to about 0.5 mm in length. The plugger fit was performed by choosing the widest one that arrived at 4-6 mm from the working length without touching the root canal walls. The canals were then dried with dedicated paper points. The traditional sealer was placed in the canal in a small layer covering directly the master cone, while the pre-mixed HES was placed with its provided plastic cannula in the coronal-middle third in a small amount and then distributed on the canal walls by the master cone. The EQ-V (Meta Systems CO., South Korea) device was used and set at 180 °temperature and the plugger was heated in CUT-OUT mode to perform the obturation of the apical third while the middle and coronal third were obturated with the EQ-V FILL gun set at 180°.

The temporary restorations were made using adhesive flowable resin composite (G-Bond and GenialFlow, GC Co) in order to proper seal the coronal margins. A fiber post was placed only when the remained coronal structure was less than 50%, otherwise the ETT were restored with a fiber reinforced flowable resin composite (EverXFlow, GC Co., Tokyo, Japan).

The restorations were performed covering the cusps using a resin composite material combined with an adhesive system (G-aenial resin composite, GC Co., and G-Premio Bond, GC). The finalization of the build-up and a zirconia crown were made only when the PAI was improved showing a complete or at least partial healing of the original periapical lesion. After preparing the post space into the root canal, the restorative procedure was performed with a fiber-reinforced composite post or a fiber-reinforced flowable resin composite material accordingly with Pontoriero et al. (32).

Follow-up

Standardized periapical X-rays were taken preoperatively, after root canal filling and at each recall using a customized tray for each ETT. Recall rate was 100%.

At each recall the same data that were originally collected before the treatment were evaluated accordingly with Pontoriero et al. (32): mainly the presence of symptoms and the size of the periapical lesion. At each recall always the same operator performed the clinical evaluations (D.I.K.P.). All cases were radiographically evaluated by two operators (D.I.K.P., M.F.) and an agreement was found for each clinical case.

The radiographic and clinical evaluation of the healing process was made according to the criteria of the European Society of Endodontology 2006 (5).

However, to evaluate the efficacy of the endodontic treatments made with both hydraulic and/or traditional endodontic sealers, the Peri Apical Index (PAI) was scored (6,7) by 2 blinded examiners (D. I.K. P., M.F.) after being calibrated as follows:

PAI 1: Normal periapical structure. PAI 2: Bone structural changes indicating but not pathognomonic for apical periodontitis. PAI 3: Bone structural changes with some mineral loss characteristic for apical periodontitis. PAI 4: Well-defined apical radiolucency. PAI 5: Radiolucency with a radiating expansion of bone structural changes.

For each tooth the highest score was recorded.

The following classification was followed (23):

1. Healed: Functional, asymptomatic teeth with no or minimal radiographic peri-apical lesion.
2. Not Healed (Failure): Nonfunctional, symptomatic teeth with or without radiographic lesion or asymptomatic teeth with not changed, new, or wider lesion.
3. Healing: Asymptomatic and functional roots with a lower periapical lesion and no symptoms.

The Healed and Healing categories were classified as Success and the Not Healed category was classified as Failure based on loose criteria (Figs. 2a-2c).

In case of disagreement between the two evaluators, an agreement was found after discussion.

Figures 2a-2c show examples of Healed, Healing and not Healed outcomes.

Outcome Evaluation

In Table 2 the outcomes of sample teeth are reported and summarized (28). To identify possible prognostic factors, many variables related to the tooth and the treatment were evaluated. Tooth-related factors were reported. The type of sealer and follow-up time were considered as main clinical factors.

Statistical Analysis

The statistical analysis evaluated the change of periapical size lesion in the time of both Groups,

Fig. 2A. Healed lower first molar after 12 and 24 months.

Fig. 2B. A upper second premolar in the healing process after 12 and 24 months.

Fig. 2C. Not healed of the first upper molar.

for each type of teeth, for each arch, the teeth with successful outcomes at T2, and the speed of the healing process between the two groups.
Pearson chi-square test was used to compare the distribution of values in the different cells. A P value <.05 was considered significant, and all tests were 2-sided. Statistical analysis was performed with SPSS v26.0 software (IBM Corp, Armonk, NY) (Tables 2, 3).

RESULTS

Two hundred nighty eight teeth were obturated with the Continuous Wave of Condensation Technique. The demography of selected patients is reported in Table 1. At last recall 5 patients for 7 root canal treatments did not show and for that the recall rate was 98%. At last recall 343 root canal treatments were evaluated.
The overall success rate was 97,6%, with 80,5% healed, 17,2% healing, and 2,3% not healed. The success rate was 98,9% for periapical lesions less than 5 mm and 96,2% for periapical lesions higher than 5 mm. Regarding the success (healed and healing) versus not healed, no significant difference was found between the two Groups/endodontic sealers. However, 276 ETT were classified as healed and 59 ETT as healing and 8 roots did not show any healing process and were classified as failure. Seven of the 8 recorded failures were found when the lesion was < 5 mm. Of the eight failure roots, four were recorded in Group 1 (HES) and four in Group 2 (traditional sealer).
A statistically significant difference in the distribution of healed, healing, and not healed teeth was found between the two groups of teeth with baseline (T0) lesions <5 mm and >5 mm in diameter (P <0.01), showing that when hydraulic endodontic sealer (Group 1) was used the healing process was faster (T1) than those when the traditional sealer was used (Group 2), although at last recall after 2 years of clinical service (T2), no difference between the two Groups was recorded (Table 2).
Nonetheless, the 8 failures that were recorded were distributed 4 in Group 1 and 4 in Group 2. (P<0.01). Five of them were found in molars, whilst three were in premolars.
After being endodontically treated, 290 (84,5%) ETT were restored by direct resin composite restorations using mainly a fiber-reinforced flowable resin composite (EveryXFlow GC Co. Tokyo, Japan), and in 53 (15,5%) posts were placed accordingly with the amount of remained coronal residual structure. A total of 165 (48,1%) direct restorations remained as final restoration, 58 single crowns (16,9%), 80 (23,3%) partial adhesive crowns, and 40 (11,7%) abutments of fixed bridges were the final treatments.

Sex (n=295)	Male 144 (48.8%)	Female 151 (51.2%)	
Age	>50 125 (42.3%)	<50 170 (57.7%)	
Type of Treatment (n=350)	Initial RCT (necrotic) 48 (13.8%)	ReTx 302 (86.2%)	
Tooth Type (n=350)	Anterior 74 (21.1%)	Molars 186 (53.2%)	Premolars 90 (25.7)
Upper teeth (n=160) (45,7%)	Anterior Upper 34 (21.3%)	Molars Upper 85 (53.1%)	Premolars Upper 41 (25.6%)
Lower teeth (n=190) (54,3%)	Anterior Lower 44 (23.2%)	Molars Lower 99 (52.1%)	Premolars Lower 47 (24.7%)
PAR Presence	Present 350 (100%)	Absent /	
Lesion Size (n=350)	>5 mm 153 (43.7%)	<5 mm 197 (62.4%)	
Sealer (n=350)	HES (CeraSeal) 175 (50%)	Traditional 175 (50%)	

Table 1. Population demographics and type of treatment. (PAR: periapical radiolucency; RCT: root canal treatment; ReTx: retreatment)

	Cement	N	Media	Standard Deviation	Media standard error
PAI T1	HES	171	2.01 [a]	.767	.074
	Zinc Phosphate Sealer	172	1.48 [b]	.550	.050
PAI T2	HES	171	2.51 [a]	.989	.093
	Traditional Zinc Phosphate Sealer	172	2.54 [a]	1.070	.089

Table 2. The table reports the differences between Traditional and HES sealers at T1 and T2, pointing out that HES showed a faster healing process at T1, whilst at T2 the healing process was similar (no statically significant difference). The success rate of the two used sealers was not statistically significantly different (Table 3).

DISCUSSION

Clinical outcome

In the last years, HES were clinically tested and when compared with zinc phosphate sealers did not show clinical differences (24-31). HES were often used in combination with single-cone obturation technique (23,30) versus zinc phosphate or resin sealer in combination with a warm gutta-percha obturation technique with good outcomes (32). From the outcomes of the present trial it can be assumed that HES can be used also in combination with a continuous wave of condensation techniques. In fact, the sample teeth that showed success (combining Healed and Healing cases) were 99,46% when warm gutta-percha in combination with HES was used and 98,7% when traditional sealer was used. Also, when the periapical lesion was >5 mm the success rate was high when HES or traditional sealer were used respectively, and similarly when was <5 mm for both Groups. These findings can be related to the different sizes of the periapical lesions and the longer time needed to recover by the bigger lesions.

However, when the speed of the healing process was evaluated, it was noted that the tested Group with HES was statistically faster than the traditional sealer Group at the first recall (1 year) whilst at the second recall (after 2 years) there was not statistically significant difference between the two groups (Table 3). The accelerated periapical bone healing process that was noted when HES was used can be explained by the osteo-inductive properties of HES used in this study that can create best conditions for the healing process. Also, it must be considered that when the endodontic treatment is performed properly independently from the type of sealer used, the healing of the periapical lesion can be expected within a few years. For that, the first null hypothesis, that there are no differences between HES and traditional endodontic sealer at 1 year recall was rejected. Also, accordingly with reported outcomes, the second null hypothesis, that there are no differences between HES and traditional endodontic sealer at last recall was accepted.

Looking more in detail, from the outcome of this clinical study it might pointed out that the size of the periapical lesion affects the results: when the original periapical lesion was bigger than 5 mm, 76,1% of roots were classified as Healed in Group 1 and 68,8 % in Group 2, but when the periapical lesions were lower than 5 mm almost 100% of Healed was recorded in both Groups. The 2 failures were recorded in Group 2 where traditional sealer was used and 1 in Group 1. However, because no statistically significant difference was found between the two groups, this finding cannot be related to the type of sealer used. Also it can be noted that 2 of the 3 failures were recorded when the periapical lesion was <5 mm; this fact might be due to the difficulty of completely cleaning the root canal space and the persistence of bacteria out of the apex.

A warm gutta-percha technique was used (continuous wave technique) in combination with two different endodontic sealers and no differences were found between the roots obturated with these two materials. That can be because warm gutta-percha technique did not over stress the HES with high temperature and consequently the sealer preserved its mechanical, chemical, and biological properties. When the

Factors/ Demography		Healed	Healing	Not Healed	Success (Healed + Healing)	P Value
	Total (n=343)	276 (80,5%)	59 (17,2%)	8 (2,3%)	335 (97,6%)	
Treatment type (n=343)						Not applicable
Initial (necrotic) (n=44) (12.8%)		43 (97.7%)		1 (4.4%)	43 (97.7%)	
ReTx (n=299) (87.2%)		239 (79.9%)	53 (17.7%)	7 (2.4%)	292 (97.6%)	
Group 1 and 2						
Lesion size	>5 mm (n=169)	122 (72.1%)	41 (24.2%)	6 (3.6%)	163 (96.4%)	
	<5 mm (n=174)	154 (88.5%)	18 (10.4%)	2 (1.1%)	172 (98.8%)	
Group 1: Hydraulic Endodontic Sealer (n=171 roots)						<0.01
Lesion size	>5 mm (n=79)	59 (74.7%)	17(21.5%)	3 (3.8%)	76 (96.2%)	
	<5 mm (n=92)	85 (92.4%)	6 (6.5%)	1 (1.1%)	91 (98.9%)	
Group 2: Zinc Phosphate Sealer (n=172 roots)	Group 2					<0.01
Lesion size	>5 mm (n=82)	55 (67.1%)	24 (29.2%)	3 (3.7%)	79 (96.3%)	
	<5 mm (n=90)	77(98.5%)	12 (13.3%)	1 (1.1%)	89 (98.8%)	

Table 3 The outcomes at final recall.

temperature generated on the surface of System B continuous wave plugger was assessed, the temperature recorded was much lower than the set temperature of the device with the highest increase in temperature at the plugger shank (33). Also other recent studies showed that mimicking the in vivo temperature dissipation, intracanal temperatures ranging below 60°C during warm vertical compaction approaches and the use of a carrier-based warm obturation techniques resulted in even lower intracanal temperature rises affecting the sealer with temperature of less than 10°C thermal (34). Also Atmeh et al. showed that heat carriers reached temperature levels below 60 degrees when used in cut-out mode (18).

All samples of roots were obturated with warm gutta percha technique, none of them showed radiographically short obturation in length and this data agrees with those already reported (31). All obturations closed the major apex of treated teeth. Because of the short observation time of this trial, it was decided to follow the "loose" (36) or "lenient" (35) clinical endodontic. For that, the radiographically based PAI scores system was chosen (6). If the "strict" criteria were applied, the success rates would be lower than that found (5). The short observation time also limited the number of healed: to observe the complete healing process of all sample teeth, the patients are recalled periodically to confirm the expectation of a wider number of Healed cases. When a periapical lesion is present, according to ESE guidelines, the healing result can be observed after 4 years of clinical service (37).

The success rate of both Groups can be related also to the skill and knowledge of the operator who already performed high-quality of outcomes and prognosis (31,32). These findings should be confirmed by similar clinical trials performed by a higher number of operators.

Patient-related factors

When reporting on endodontic treatments of teeth with periapical lesions such as the current study, it should always be considered that there are many variables that can influence the results as age, gender, type of tooth and position in the mouth, the degree of infection, proper instrumentation, cleaning of root canal system, filling material and technique, a well condensed root filling, root anatomy and its complexity, number of canals and curvatures, position of apical foramina (38-40). All these confounders factors can affect the outcomes. In this clinical study the variable related to the health status of the patients, the different steps of the endodontic treatment, the number of sample teeth were under control, while all types of teeth and root anatomy were included. For that multicenter prospective studies are advocated to confirm the outcomes of this clinical study.

The final restorations made in the patients of these two groups were not clinically scored because the build-up and then the finalization with the direct or indirect restoration was made only after the 1-year recall when the healing process was evident. This clinical behavior determined a too short observation time to evaluate the restorations. However, the patients are in a recall program and the restorations will be clinically evaluated along next years.

CONCLUSIONS

From the outcomes of this clinical trial, these conclusions can be drawn HES can be clinically used in combination with warm gutta-percha technique allowing a high success rate.

The use of HES can make a faster healing process than zinc phosphate sealer within the first year of clinical service. The two types of endodontic sealers used in combination with warm gutta-percha obturation technique showed a high success rate at 2-year recall, without any statistically significant difference.

The size of the periapical lesion does influence the healing process time.

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