Healing process of periapical lesion after endodontic obturation with warm gutta-percha technique in combination with a bioceramic sealer

Abstract

Aim
The objective of this clinical study was to collect short-term endodontic outcomes of endodontic-treated teeth (ETT) obturated with of a bioceramic sealer used in combination with warm gutta-percha obturation techniques in roots with and without periapical lesion.

Methods
A total of 150 endodontic treatments were performed. At baseline, sample teeth showed periapical radiolucency; of these, 50% showed a lesion of 5 mm or bigger while lower than 5 mm in the other 50% of cases. The obturation techniques that were used in this study were: the continuous wave of condensation technique in 75% of cases, and carrier-based technique in 25%. One bioceramic sealer was used: One - Fil. Preoperative and recall radiographs of the roots were each assigned a periapical index (PAI) score by 2 blinded, independent, and calibrated examiners. The teeth were divided into outcome categories based on the following classification: healed, unhealed, and healing. The healed and healing categories were classified as success, and the unhealed category was classified as failure on the basis of loose criteria.

Results
The overall success rate was 100%, with 140 healed, 10 healing, and 0 not healed roots. Regarding the success (healed and healing) versus not healed, no significant difference was found between teeth with or without periapical lesions ($p < 0.05$). Related to the healing time, statistically significant difference in the distribution of healed, healing, and not-healed teeth was found between the groups of teeth with baseline lesions < 5 mm and > 5 mm in diameter ($p < 0.01$).

Conclusions
From the findings of this clinical study, the following conclusion can be drawn: a correct filling of root canal made with warm gutta-percha technique combined with a bioceramic sealer allows a high success rate in endodontically treated teeth.

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Keywords

periapical lesion, gutta-percha, bioceramic sealer, root canal, endodontic obturation.

INTRODUCTION

Bioceramic sealers (BS), also known as calcium silicate-based endodontic sealers, were introduced in dentistry and their mechanical, chemical, and biological properties were studied (1–5). They were launched into the dental market and their popularity progressively increased among endodontists and dental practitioners. BS cements were first used to repair root perforation and in surgical endodontics as retro filling materials (6). A fine formulation of these materials was made available and BS are now recognized as very useful in endodontic therapy. The BS are placed into the root canal using an easy technique and thanks to the filler size less than two microns, they can penetrate into the dentinal tubules sealing them. Additionally, BS can create a chemical bond with dental substrates and are sufficiently radiopaque (7–9) and have antibacterial properties (10–12). Additionally, BS showed to be osteoinductive and biocompatible: these characteristics might help in bone regeneration of periapical lesions (13,14). Because of their biocompatibility and intrinsic osteoinductive capacity, when an overfill happens, an inflammatory response will not take place and during hardening, when they come in contact with tissue fluids, calcium hydroxide reacts with phosphatase enzymes, resulting in the formation of hydroxyapatite (15).

Regarding their capacity to seal the apex, no significant differences were found in the quality of obturation when single-cone, warm condensation, and carrier-based techniques using bioceramic sealers were used (16,17). Although the single cone technique needs a large amount of cement, and that can have voids and bubbles within the sealer itself, it was advocated as the main obturation technique in combination with BS (18). Another aspect that supported combining the single cone technique with BS was that these materials should be used without the heat in order to not accelerate their setting (19,20). Moreover, their hydraulic capability to penetrate into the dentinal tubules can enhance the retention of the sealer and create a mechanical barrier able to prevent bacteria leakage (7).

The long-term success of endodontic treatments is based on adequate 3-dimensional (3D) cleaning, shaping, and 3-dimensional obturation of the complex root canal system (21,22).

The role of endodontic sealers in combination with different types of endodontic obturation techniques was investigated and BS were proposed into the market as indicated only in combination with single-cone technique because the BS are unadvisable to come into contact with heat (19,23,24). Otherwise, they can harden instantly. However, a recent study evaluated the use of several BS in combination with warm gutta-percha techniques, showing promising results (16).

Predictable and reliable results may be obtained only with clinical trials. Clinical trials are much more reliable than in laboratory studies made in both retrospective and prospective ways (25,26). When a prospective clinical trial is made, only a few specific parameters are evaluated in a limited number of specimens and they take place in specialized centers. Through a retrospective study, a wider number of specimens can be collected and it may reflect more the clinical behavior of practitioners. The objective of this study was to evaluate outcomes of endodontically treated teeth (ETT) obturated with a BS used in combination with warm gutta-percha obturation techniques in roots with and without periapical lesion.

The tested null hypotheses were: (1) there was no difference in the endodontic success of ETT with and without periapical leison; (2) there was no difference in the endodontic success of ETT with periapical lesions showing different sizes of the lesion (more or less than 5 mm).

MATERIALS AND METHODS

Study Population

Over a 24 months period (September 2023 to December 2024), one expert endodontist (DP) conducted 150 endodontic treatments in 100 patients; follow-ups were done with reference to the dental records. Patients were all in need of different endodontic therapies. Consecutive patients were selected from the authors' offices. Only primary endodontic treated teeth or nonsurgical retreatments, with a follow-up of at least 24 months or longer, were included in this survey, with patients who returned for oral hygiene recalls in 2023, 2024 and 2025.

All procedures performed in this study involving human participants, were in accordance with the ethical standards of the institutional committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed written consent was obtained from all individual participants included in the study. Collection and analysis of the data were approved by the Ethical Committee of the University of Siena.

Inclusion criteria were the following: age: 46 (±17) years (range 18 to 64); sex: 68 F, 82 M; periodontally healthy or successfully treated patients in need of one or more endodontic treatments.

Exclusion criteria were the following: individuals who were not yet adults (< 18 years), pregnancy, disabilities, previous prosthodontic restorations of abutment teeth, deep restoration (close to pulp, < 1 mm distance), or pulp capping, heavy occlusal contacts or history of bruxism, systemic disease or severe medical complications, allergic history concerning methacrylates, rampant caries, xerostomia, lack of compliance.

Factor/Demographic	n	Healed, n (%)	Healing, n (%)	Not healed, n (%)	Success, n (%) Total	P value (n=100)
Sex						
Male	62					
Female	48					
Age (ETT)						
<50	70	54	15			100
>50	80	61	20			100
Treatment type						
Initial	62	62	-			100
Retreatment	88	53	35			100
Lesion						
Present	138	103	35			100
Absent	12	12				100
Lesion size						
<5 mm	79	73	6			100
>5 mm	71	42	29			100
Sealer extrusion						
Present	45	24	21			100
Absent	95	81	14			100
One - Fil	150	115	35			100

Tab. 1 Treatment Outcome by Factors and Demographics

Sample Characteristics

A total of 150 teeth were included in the study, of which, partially mandibular posterior and mandibular anterior, and maxillary anterior and maxillary posterior (Table 1).

Several endodontic peculiarities were analyzed. At baseline, some sample teeth showed symptoms (tenderness/pain to percussion) and others had periapical radiolucency. Periapical radiolucency was 5 mm or bigger in around 50% cases while others lower than 5 mm. Regarding ETT with radiolucency, 50% of them were in coincidence with their need for retreatment and other 50% were necrotic teeth.

The most frequently used obturation techniques were Continuous Wave of Condensation in 74% (112) of cases, and Carrier Based in the other 26% (38), mainly when very curved and long canals were treated.

After being endodontically treated, ETT were restored by direct resin composite restorations or indirect partial/full crowns.

Original Endodontic Therapy Procedure

For each tooth, the following preoperative data were recorded: demographic data, tooth location, previous endodontic treatment, clinical signs and symptoms, vitality tests, and radiographic periapical status. Based on these findings, the preoperative condition was classified as one of the following: vital or not-vital without periapical lesion, not-vital with periapical lesion, endodontically treated teeth with or without periapical lesion, and symptomatic or asymptomatic.

For each tooth, the following intra-operative data were recorded: number of treatment sessions; inter-appointment dressing (if used); the occurrence of procedural complications such as perforation, breakage of files and flare-up; length of canal filling (at apical level, 1 mm short or more and beyond); and temporary restoration placed. A conservative endodontic cavity (CEC) access was performed using a long shaft round diamond bur and endodontic dedicated ultrasonic tips were used for finishing the cavity access and smooth the walls of the pulp chamber. After straight-line access preparation was obtained, root canals were negotiated with pre-curved stainless steel K-type files (Maillefer, Bailague, Switzerland), size 0.8 or 10 ISO (International Standard Organization) to the major apical foramen. Working length was measured using an electronic apex locator (Root ZX Morita, Tokyo, Japan), established at electronic 0 and, in most cases, checked with an intraoperative x-ray. Shaping techniques and instruments have been used were the following: a mixed technique was adopted: pre-flaring and glide path were performed to length with a nickel-titanium #10 tip size and 0.04 taper rotary file, followed by a nickel-titanium #15 tip size and 0.05 taper rotary file (Mtwo, Sweden e Martina, Italy). All canals were shaped with the M-Wire alloy rotary instruments (ProTaper Next X1 and X2, Maillefer

,Bailague Switzerland) to length of up to a #25 tip size and a variable taper. The apical diameter was measured (apical gauging) using nickel-titanium manual K-type files, NiTi Flex (Maillefer, Bailague, Switzerland), and the shaping of the apical third was refined, where needed. Irrigation was copious and frequent using heated 5.25% sodium hypochlorite NiClor 5 (NiClor 5, Ogna, Milan, Italy) deposited with side-vented 30-G needles. Ultrasonic activation was done for 1 minutes at least. After instrumentation, the root canals were irrigated with 10% EDTA solution Tubuliclean (Ogna, Milan, Italy), for 3 minutes, followed again by several 1-minute irrigations with heated 5.25% sodium hypochlorite solution.

The canals were dried with dedicated sterile paper points, filled with dedicated gutta-percha cones ProTaper Next (Maillefer, Bailague, Switzerland), and four different bioceramic sealers (One-Fil, Ogna, Milan, Italia) using a continuous wave of condensation technique (70%) or a carrier-based technique (Thermafil, Dentsply, Konstanz, Germany) in roots with curve canals, depending on the root canal anatomy. A post was placed when the remaining coronal structure was less than 50% (25). A temporary restoration was performed using zinc oxide base cement placed on the pulp chamber floor covered by a layer of glass ionomer cement (GCem, GC Co, Tokyo, Japan).

The post space was prepared using the drill provided by the manufacturer. Fiber-reinforced composite post was adapted to the anatomy of the root. Post length was adapted to the length of the post space. The post surface was cleaned with phosphoric acid and treated with a silane-coupling agent. For adhesive cementation, the dentinal surface was etched with phosphoric acid for 10 seconds and pretreated with a dual-cure adhesive before the post was cemented with a dual-cure resin. GC fiber posts, in combination with G-Premio Bond and Gradia Core (GC Co), were used 2018. Zirconia full crowns were luted with G-Cem adhesive cement (GC Co).

When direct restorations were placed, cuspal coverage was made, and the restorations were made using resin composite materials in combination with proprietary bonding systems. A combination between G-aenial resin composite (GC Co) and G-Premio Bond (GC Co) was used.

Follow-Up

For each tooth, the following postoperative data were recorded: the treatment and recall period, the presence or absence of signs and symptoms, the presence or absence of apical lesion, the presence and type of restoration, and the type of build-up with or without a post. Only primary endodontic treated teeth or nonsurgical retreatments with a follow-up of at least 18 months or longer were included in this survey.

The follow-up sessions were performed with patients who returned to the offices during oral hygiene recalls during 2024. Among all patients who returned for a recall, 210 teeth were selected for this survey. All of the recorded information from the files were transferred to a computerized database. The clinical follow-up examinations were performed by the primary author (DP). For teeth examined more than once, only the findings of the final examination during 2024 were considered. Traumatized teeth, injured with luxation, intrusion, extrusion, avulsion, or horizontal fractures, and teeth requiring endodontic surgery, were excluded from this study.

Criteria of Evaluation

When only the endodontic treatments were evaluated, the following criteria of the European Society of Endodontology 1994 were used to judge the success rate of root canal therapy: (1) clinical examination: the absence of pain, swelling, and other symptoms, no sinus tract, and no loss of function; and (2) radiographic examination: the periodontal ligament space was normal on the original diagnostic radiograph, and it remained unchanged on recall radiographs, or healing of a radiolucent area visible on the original preoperative radiograph was observed and the periodontal ligament space returned to normal. For radiographic examination, entity of the lesion was recorded and evaluated.

Postoperatively the same preoperative data were collected also accordingly with Pontoriero et al. (27): the treatment and recall period, the presence or absence of signs and symptoms, the presence, change or absence of periapical lesion, the presence and type of restoration, and the type of build-up with or without a post. The clinical follow-up examinations were performed by the primary author (D.I.K.P.). For teeth examined more than once, only the findings of the final examination during 2022 were considered.

The radiographic and clinical evaluation of the healing process was made accordingly with the criteria of the European Society of Endodontology 2006 (28).

However, to evaluate the efficacy of the endodontic treatments made with both bioceramic and/or traditional sealer, the Peri Apical Index (PAI) was scored (29,30) by 2 blinded, independent, and calibrated examiners (D. I.K. P., M.F.) 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.

Each endodontically treated tooth received the highest score for any of the roots.

Therefore, cases were considered as failures in the presence of pain, swelling, and sinus tract. Radiographically, failures were identified when a lesion appeared after endodontic treatment, when a preexisting lesion increased in size, and when a lesion remained the same. Multi-rooted teeth were assessed according to the root that appeared the worst. The teeth were divided into outcome categories based on the following classification:

1. Healed: Functional, asymptomatic teeth with no or minimal radio- graphic periradicular (apical) pathosis (radiolucency)
2. Nonhealed: Nonfunctional, symptomatic teeth with or without radiographic periradicular (apical) pathosis (radiolucency) or asymptomatic teeth with unchanged, new, or enlarged radiographic periradicular (apical) pathosis (radiolucency)
3. Healing: Teeth that are asymptomatic and functional with a decreased size of radiographic periradicular (apical) pathosis (radiolucency) xamples of each outcome category are shown in Figure 1.

Outcome Assessment

The outcome assessment was dichotomized. Both healed and healing cases were considered success, and not healed cases were considered failure. Several patient-, tooth-, and treatment-related variables were evaluated to identify possible prognostic factors. Patient factors examined included sex and age of the patient. Tooth-related factors included tooth type, pulpal and periapical diagnosis, pocket depths, sinus tract, presence/absence of periapical lesion, lesion size and preoperative percussion and palpation sensitivity. Treatment factors evaluated included treatment type (initial treatment or

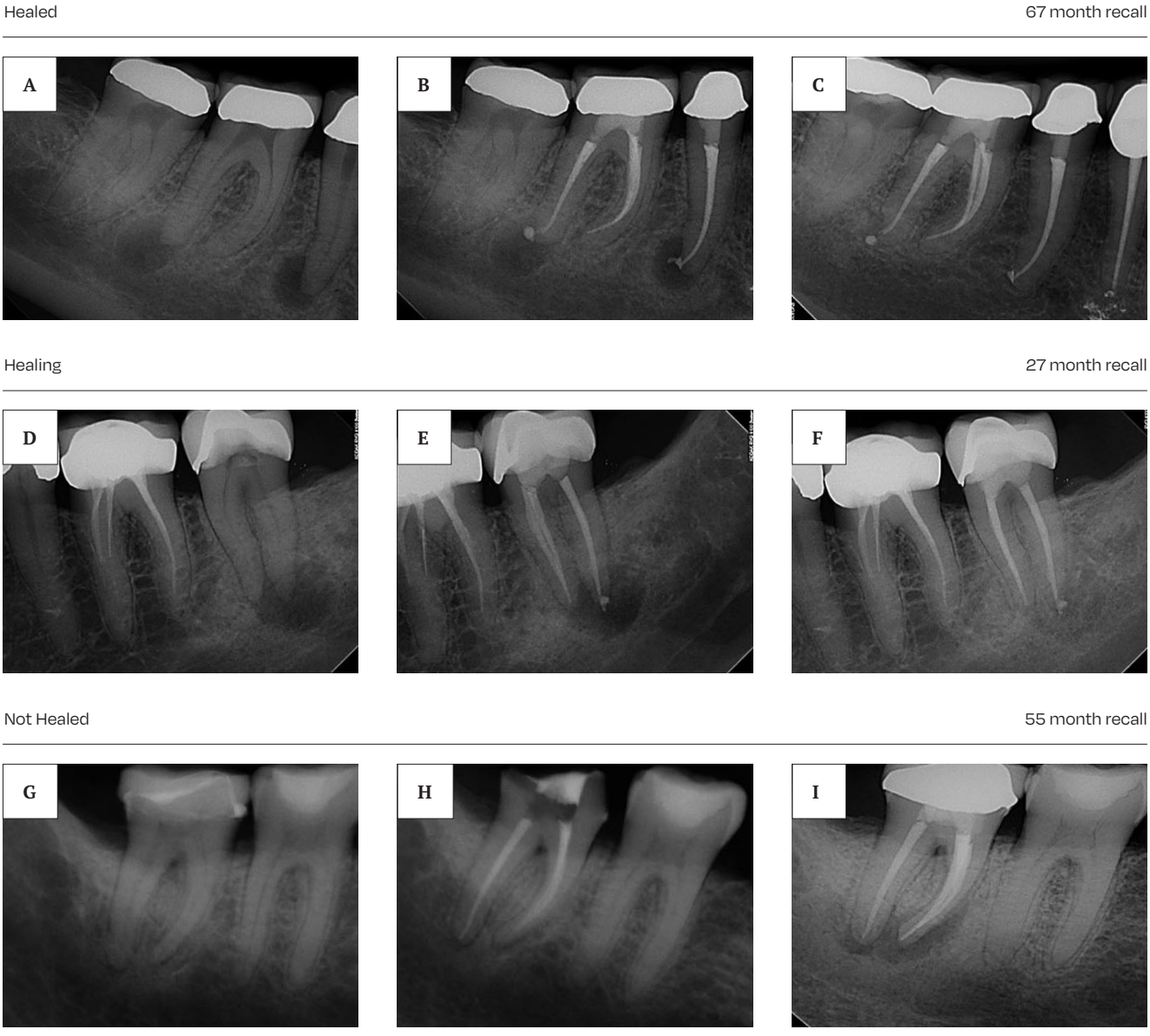

Fig. 1 Examples of healing scores.

Factor/ Demographic	n	Healed, n (%)	Healing, n (%)	Not healed, n (%)	Success, n (%)	P value	Total (n=100)
Sex							
Male	62						
Female	48						
Age (ETT)							
<50	70	61	7				100
>50	80	69	12				100
Treatment type							
Initial	62	62	-				100
Retreatment	88	69	19				100
Lesion							
Present	138	119	19				100
Absent	12	12	-				100
Lesion size							
<5 mm	79	78	1				100
>5 mm	71	53	18				100
Sealer extrusion							
Present	45	33	12				100
Absent	95	88	7				100
One-Fill	150	131	19				100

Tab. 2 Treatment Outcome by Factors and Demographics at two years recalls

Factor/ Demographic	n	Healed, n (%)	Healing, n (%)	Not healed, n (%)	Success, n (%)	P value	Total (n=100)
Sex							
Male	62						
Female	48						
Age (ETT)							
<50	70	66	4				100
>50	80	74	6				100
Treatment type							
Initial	62	62	-				100
Retreatment	88	78	10				100
Lesion							
Present	138	128	10				100
Absent	12	12					100
Lesion size							
<5 mm	79	79	-				100
>5 mm	71	61	10				100
Sealer extrusion							
Present	45	40	5				100
Absent	95	95	-				100
One-Fill	150	140	10				100

Tab. 3 Treatment Outcome by Factors and Demographics at three years.

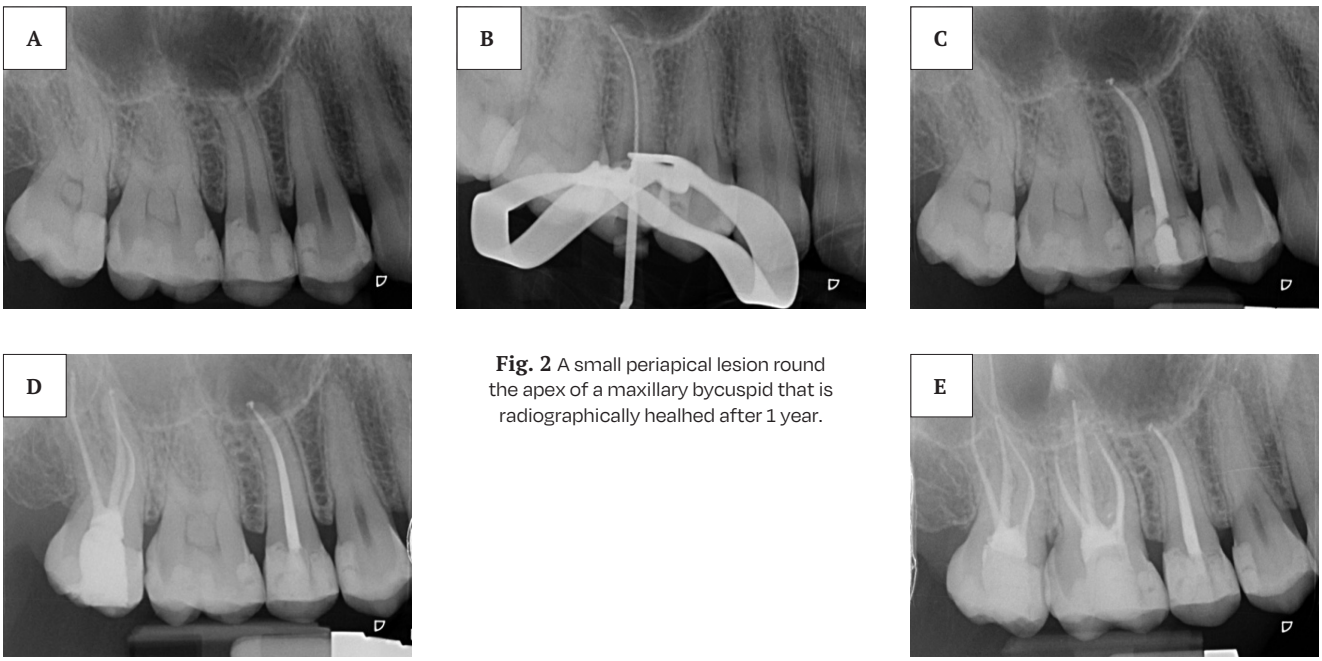

Fig. 2 A small periapical lesion round the apex of a maxillary bycuspid that is radiographically healhed after 1 year.

retreatment), type of bioceramic sealer, sealer extrusion, follow-up time, and type of restoration at recall (access restoration, crown, or bridge).

Analysis of Data

For statistical analysis, the Pearson chi-square test was used to analyze the effect of each prognostic factor after the data were grouped. A P value <.05 was considered significant, and all tests were 2-sided. Statistical tests were performed with SPSS v23.0 software (IBM Corp, Armonk, NY).

RESULTS

After 3 years of clinical service, the overall success rate was 100%, with 140 healed roots, 10 still healing, and 0 not healed. The success rate was 100%. (Tables 2 and 3). Regarding the success (healed and healing) versus not healed, no significant difference was found between teeth with or without periapical lesions.

A statistically significant difference in the distribution of healed, healing, and not-healed teeth was found between the groups of teeth with baseline lesions < 5 mm and >5 mm in diameter ($p < 0.01$), showing that when the lesions were smaller, the healing process was faster than those with lesions that were bigger than 5 mm in diameter.

After being endodontically treated, 125 (59.5%) ETT were restored by direct resin composite restorations using mainly a fiber reinforced flowable resin composite (EveryXFlow GC Co., Tokyo, Japan). A total of 35 direct restorations remained as final restoration, 45 single crowns, 80 partial crowns.

At two years recall there is an improvement of healing process of 16 teeth and only 19 are still in healing process. All of them are retreatment cases with an original periapical lesion of more than 5 mm in diameter.

At 30 months recall there is another improvement of healing process and only 10 are still in healing process. All of them are retreatment cases with an original periapical

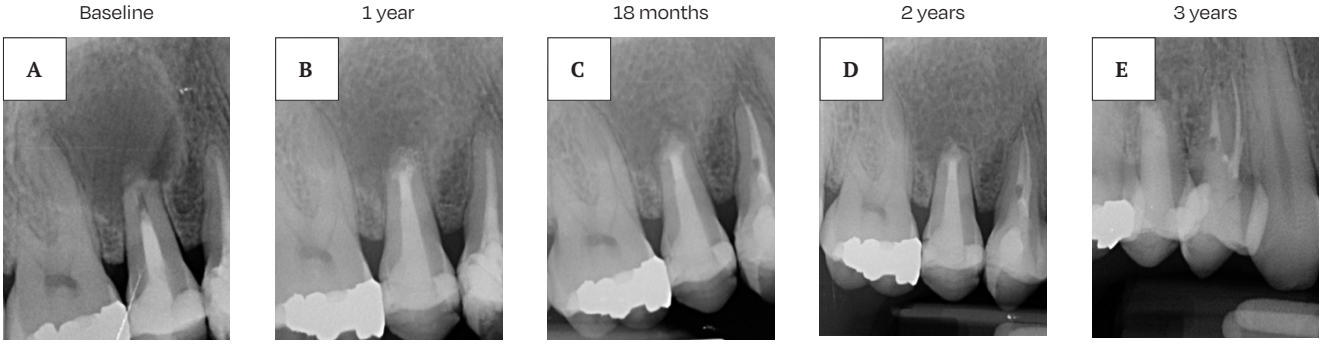

Fig. 3 A small periapical lesion round the apex of a maxillary bycuspid that is radiographically healhed after 3 year. The size of the periapical lesion can directly influence the healing time of the bone.

lesion of more than 5 mm in diameter. (Figs. 2 and 3).

DISCUSSION

Recently, BS were used in clinical trials under controlled conditions (31). Some authors highlighted that there were no differences between BS and resin and/or zinc phosphate sealers (32–40), which was also in case of unintentional apical extrusion of sealers (40).
The BS were used with single cone obturation technique (32,34–41) versus zinc phosphate or resin sealers in combination with warm vertical compaction, and the clinical results were always very good.
In the present clinical study, success (healed and healing), and failure (not healed) rates were, respectively, 100% and 0%. Also there was no difference in the endodontic success of ETT with and without periapical leison: for that the first hypothesis was accepted.
Although only one type of BS was tested in this study, its success rates was similar to those the same Authors recently reported for 4 other BS (31-33).
Regarding the second tested null hypothesis, i.e., that there was no difference in the endodontic success of ETT with periapical lesion of more or less 5 mm in size at the beginning of the treatment was accepted, and the cumulative success rate (healed and healing) showed no statistical significance difference.
However, the size of the periapical lesion showed to be very important; when the lesion was lower than 5 mm in diameter, the healing process was faster than when was wider than 5 mm.
It was also noted that extrusion was usually present when the apex was already opened by the necrosis and was combined with the periapical lesion. From a clinical point of view, it was observed that the presence of postoperative pain was not influenced by the sealer's extrusion (26).
From the other side, the cases were classified as a success, and these excellent results can be due to the appropriate shaping and cleaning of root canals (34,43), the obturation procedure (34), the hydraulic effect that pushes the bioceramic sealer into the dental tubules sealing them (44–46), and the osteogenic characteristic of this new material (47).
Being all the roots were obturated using warm techniques, voids were never noted within the obturation. Additionally, no one root showed short obturation in length.
The clinical evaluation of endodontic outcomes that consider "success" the complete resolution of the periapical radiolucency can be "strict" (48) or "stringent" (49), while choosing a mere reduction in the size of the periapical radiolucency (29,34) was described as setting a "loose" (49) or "lenient" (48) threshold. In this study, it was decided to follow a "loose" (36) or "lenient" (37) threshold. In order to support the adoption of "loose" criteria, the radiographic assessment method was chosen (31). This system provided a scale of five scores, ranging from healthy to severe periodontitis with exacerbating features (31).
It was based on radiographs with verified histological diagnosis and can be suitable in epidemiological studies (49).
Additionally, the endodontic failure usually occurs within the first years of clinical service (49).
However, it must be noted that the observation time was short, too short to permit complete healing of wide periapical radiolucency (28,49).
However, the expected success rates using the "strict" criteria would be lower than those based on the "loose" criteria (28,29).
All the patients collected in this study were in a recall program to confirm, or disprove, the outcomes under a longer observation period.
Comparing the outcomes of this study with those recently published by the same authors (27, 32), it may be noted that the skill and knowledge of the operators can allow high quality of endodontic treatment and good prognosis. The "operator" could be considered one of the most important factors concerning the outcomes in dentistry and in endodontics. Regarding the type of build-up, the findings of this study confirmed that the materials and procedure used do not affect the final outcome (50).
Some limitations of this study can be underlined. Firstly, the wider number of ETT should be enrolled; also, the good outcomes of this study were related to the skill and knowledge of one single expert, and it would be of some interest to extend the number of endodontists. Additionally, the limited observation time was short and the patients of this study were in a recall program to collect longer data and to confirm the reported outcomes.
Finally, a multicenter prospective study is desirable to confirm the findings of this study.

CONCLUSIONS

From the findings of this clinical study, the following conclusion can be drawn: a proper obturation of root canals made with warm gutta-percha technique combined with a bioceramic sealer allows a high success rate in endodontically treated teeth.
A periapical lesion does not compromise the quality of the final outcomes.

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