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ORIGINAL ARTICLE

Three-year Clinical Outcome of Root Canal Treatment Using a Single-cone Technique and Ceraseal Premixed Bioceramic Sealer: A Prospective Cohort Study

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ABSTRACT

Objective: To evaluate the outcome of teeth filled with a single cone technique and a premixed bioceramic sealer at 3 years of follow-up.

Methods: Healthy patients were consecutively treated by a cohort of postgraduate operators. Root canal filling procedures were performed with NiTi rotary instrumentation, while non-surgical retreatments were performed using NiTi reciprocating instruments. Root canal filling procedures were performed using Ceraseal and the single cone technique. Post-endodontic restorations were performed after 15 days. Provisional and definitive crowns were positioned in case of non-sufficient coronal structure. Periapical radiographs were made before treatment, after filling, and at each follow-up visit (6, 12, 24 and 36 months). The periapical Index (PAI) was used to assess the presence of periapical lesions and their modifications over time. Success (absence of periapical radiolucency, PAI <3) and survival rates were evaluated. The presence of apical extrusion was also radiographically assessed. Linear regression analysis was used to investigate changes in mean PAI scores, and logistic regression analysis was used to investigate changes in the percentage of healed cases. All analyses were replicated using two distinct approaches: per protocol (PP) (treatments who completed the follow-up) and intention to treat (ITT) (all root canal treatments). A significance level of 5% was used for all statistical tests (α=0.05).

Results: Fifty-eight endodontic treatments in 52 patients were performed (ITT). Thirty-eight endodontic treatments in 33 patients completed the 3 years of follow-up with a survival rate of 92.7%. The success rate was 85.4% (PP).

Conclusion: The use of Ceraseal associated with the single cone technique was safe in maintaining endodontically affected teeth.

Keywords: Apical extrusion, CaSi sealers, periapical healing, premixed bioceramic sealer, single cone technique

HIGHLIGHTS

- This study supports the use of Ceraseal in combination with the single cone technique as a safe and effective method for preserving endodontically affected teeth.
- Teeth with necrosis and periapical lesions showed 100% healing at 36 months.
- The morphology modification of periapical sealer extrusion can be a possible event over time.

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INTRODUCTION

Hydraulic calcium silicate-based materials have gained increasing popularity in endodontic treatment due to their favourable biological, physical, and clinical properties, such as biocompatibility (1, 2), good flowability (3), and minimal post-obturation pain (4). Traditionally, these materials have been utilised in a powder-liquid form, requiring a careful preparation but reliable setting.

In recent years, thanks to the properties of calcium silicate-based materials (5–7), the use of the single cone technique has gained new popularity and makes them suitable to be used as root canal sealers for cold obturation techniques, overcoming the limitations of the traditional single cone technique associated to epoxy resin based or zinc oxide eugenol sealers, such as its inability to control the filling of the irregularities of the root canal and the consequent possibility of leaving many gaps between the sealer and the gutta-percha (8, 9).

Recently, a new category of premixed and ready-to-use root canal sealers (bioceramics) has been developed (10). Among these, Ceraseal is a premixed calcium silicate-based bioceramic sealer that contains tricalcium silicate (20–30%) as bioactive components. The radiopacifier used in Ceraseal is zirconium dioxide (45–50%). The chemical, physical, and biological properties of Ceraseal have been examined in just a few studies (5, 11, 12). These studies found that Ceraseal had lower radiopacity and setting time compared to AH Plus, while its flowability was similar. Furthermore, Ceraseal can release calcium ions and alkalise the surrounding environment (5, 12). These sealers' characteristics could prove a great advantage in relation to extensive bone defects, such as in the presence of acute or chronic periapical lesions. Finally, a recent study with a confocal laser scanning microscope demonstrated that the sealer showed significant penetration into dentinal tubules and produced effective endodontic sealing (13).

Despite their promising characteristics, the available clinical investigations are limited to short-term studies up to 24 months (14–16). No studies have prospectively investigated the single cone technique associated with Ceraseal premixed sealer in a longer follow-up. Further research is necessary to comprehensively understand their long-term clinical outcome.

This prospective cohort study aimed to evaluate the three--year results of teeth treated with Ceraseal using the single-cone technique. Furthermore, the study analysed the impact of pre-, intra-, and post-operative factors on the outcome.

MATERIALS AND METHODS

Study Design and Sample

This single-arm prospective cohort study was conducted from May 2019 to June 2023. The patients were treated in the endodontic department of the Bologna University. A group of postgraduate students, under the rigorous supervision of experienced master tutors, provided the treatments following established standard protocols. The local ethical committee approved this study (OUTENDOPROSP; CE 20079).

All patients were treated in alignment with the modified 2013 principles of the Declaration of Helsinki (17). Before enrolment, the clinical staff delivered oral and written explanations to the patients, who then provided written consent in agreement with the stated principles and consented to follow the treatment plan and the hygiene regimen. The design of this study adhered to the STROBE checklist (18) and followed the guidelines published by Dodson in 2007 (19).

Patient Enrolment

Table 1 reports the inclusion and exclusion criteria. Patient enrolment started in May 2019 and ended in February 2020. During this period, 67 patients attended the endodontic clinical section requiring root canal treatment. Fifteen patients were excluded as they were unable to attend regular follow-up examinations due to geographical location or medical condition. In the end, 52 patients requiring 58 root canal treatments were enrolled.

Root Canal Treatment Procedures

Local anaesthesia (Carboplyne 30 mg/ml, Dentsply, Germany) and isolation with a rubber dam were used in all treatments. After the pulp chamber opening, the working length (WL) was established using an electronic apex locator (Root ZX, Morita Europe, Dietzenbach, Germany). The WL was confirmed with a periapical radiograph with a K-file inserted in the root canal at the WL established by the apex locator. The initial glide path was created with stainless steel K-File instruments up to size #15.02. A sequence of NiTi instruments (Mtwo, VDW, Munich, Germany or Rotate, VDW) was used for canal shaping. A total of 5 mL of 5% NaOCl (Niclor 5, OGNA, Muggiò, Italy) was used as an irrigant solution. In the presence of calcified root canals, 3.0 mL of 10% EDTA solution was used as a chelating agent. Before the root canal filling procedure, a final rinse with 1.0 mL of sterile water was performed.

Retreatments were performed with a reciprocating NiTi system (Reciproc Blue, VDW) and a Silver Reciproc Endomotor (VDW) set to the "Reciproc All" mode. The instrument was inserted into the canal to remove the coronal portion of the previous gutta-percha filling material, then retracted to clean the material from its threads using a sterile sponge. Apical enlargement was performed using a Reciproc Blue #25 or #40 instrument, applying careful force toward the apex to minimise pressure on the canal walls. In cases where an apical size larger than 40 was suspected after using the Reciproc Blue #40 instrument, the apical preparation was meticulously completed using manual stainless-steel K-files. A total of 5 mL of 5% NaOCl (Niclor 5, OGNA, Muggiò, Italy) was used for irrigation. In the presence of calcified root canals, 3.0 mL of 10% EDTA solutions were used as a chelating agent. A final rinse with 1.0 mL of sterile water was done before the root canal filling procedures.

Root Canal Filling Technique

A premixed calcium silicate-based root canal sealer (Ceraseal, MetaBiomed, Cheongju, South Korea) was used with a single-cone technique and gutta-percha cones (Mynol, Gyeonggi-do, South Korea).

TABLE 1. Patients eligibility for the study

Inclusion criteria
Age 18–75 years No use of antiresorptive or antiangiogenic drug Healthy status (ASA 1 or 2) Needing one or more root canal treatment Teeth with less than 2 walls of structural integrity
Exclusion criteria
ASA >3 Any pathology that could compromise bone healing or the immune response, Pregnancy or breast feeding Heavy smoking (>15 cigarettes/day) Wxposure to radiation therapy focussed on the head and neck region and malignant disease directly involving the jaws Lacks of occlusal contacts

ASA: American Society of Anesthesiologists) physical status classification system

A paper point was used to dry the root canal before applying the sealer. A sterile stainless-steel K-file was inserted into the canal up to 3 mm short of the WL and was then rotated gently along the canal walls to spread the sealer. A specifically chosen single gutta-percha cone was then inserted slowly into the canal, ensuring it reached the working length and had an appropriate tug-back. Excess gutta-percha was cut using a heated instrument and then compacted vertically using a plugger.

To protect the integrity of the treated tooth until the final restoration, a cotton pellet was placed in the access cavity, followed by a thin layer of temporary restorative material (Coltosol, Coltene, Altstaetten, Switzerland).

Tooth Restoration

One week after root canal filling procedures, a post-endodontic restoration was performed using a rubber dam. A self-etching dentinal bonding agent (Clearfil SE BOND, Kuraray, Osaka, Japan) was applied as a primer and bonding agent, followed by photopolymerisation (Elipar, 3M ESPE, St. Paul, MN, USA) for 30 seconds. This step was succeeded by the incremental application of flowable (G-Aenial Flow, GC Corporation, Tokyo, Japan) and composite resins (G-Aenial, GC Corporation), each layer measuring approximately 1.5 mm. A post was placed in cases where the coronal structure was insufficient. Provisional crowns were positioned 1–3 months after tooth restoration. Definitive prosthetic crowns were positioned around 6 months or more after the root canal filling procedures. A temporary paste-paste zinc oxide-based cement (Temp Bond, Kerr, Scafati, Italy) was used for provisional crowns, while a powder liquid polycarboxylate-based cement (Heraeus Kulzer GmbH) was used for definitive crowns.

Radiological Evaluation

Periapical radiographs were obtained preoperatively and intraoperatively (to ensure the working length) immediately after the filling procedures and during the recall follow-up program using a parallel technique. Radiographs were processed in a standard unit (Euronda s.p.a., Vicenza, Italy) at a temperature of 25°C, adhering to the manufacturer's instructions with 12 seconds for development and 25 seconds for fixation. Patients were requested to undergo another radiograph if these specific parameters were not met.

The root canal filling quality was considered "adequate" if the gutta-percha was positioned within 0–2.0 mm of the radiological apex. Instances of overfilling, underfilling, and sealer extrusion were meticulously recorded.

Patients were monitored at intervals of 6, 12, 24, and 36 months during routine hygiene appointments by trained endodontists. The periapical radiographs were digitised using a scanner with a resolution of at least 960 dpi.

The Periapical Index (PAI) (20) was used for scoring at the initial and final evaluation stages. Two independent evaluators conducted these assessments in a single-blind at the outset and then at 6-, 12-, 24-, and 36-months follow-up. Any sealer extrusion was recorded and measured in millimetres along the longitudinal axis on each periapical radiograph using Image J, an open-source software (Bethesda, MD, USA). The calibration process for the PAI followed a set of precise and comprehensive guidelines.

Definition of Success And Survival Criteria

Teeth were categorised following previously published studies (21–23) and defined as:

Healed: Teeth that are free from symptoms and do not exhibit any periapical radiolucency.

Healing: Symptom-free teeth that demonstrate a reduction in the size of radiographic periapical lesions.

Not healed, may or may not show radiographic periapical lesions, be non-functional, or present symptoms. Alternatively, they may be symptom-free but display unchanged, newly formed, or enlarged radiographic periapical lesions.

TABLE 2. Baseline characteristics of the root canal treatments included in the study (n=58)

Characteristic	n	%	Characteristic	n	%
Sex			Apical diameter		
Male	23	39.7	≤40	31	53.4
Female	35	60.3	>40	27	46.6
Age group (years)			Obturation quality		
<30	9	15.5	Underfilled	5	8.6
30–65	21	36.2	Adequate filling	50	86.2
>65	28	48.3	Overfilled	3	5.2
Tooth type			Initial PAI		
Incisor	14	24.1	≤2	24	41.4
Canine	8	13.8	>2	34	58.6
Premolar	15	25.9	Sealer extrusion		
Molar	21	36.2	No	44	75.9
Tooth location			Yes, without resorption	11	19.0
Maxilla	43	74.1	Yes, with resorption	3	5.2
Mandible	15	25.9	Definitive restoration		
Diagnosis			Composite	42	72.4
Pulpitis	21	36.2	Post	1	1.7
Pulp necrosis	14	24.1	Crown	15	25.9
Exacerbated periapical lesion	23	39.7			

PAI: Periapical index

Statistical Analysis

Numerical data were presented as mean values with standard deviation, while categorical variables were expressed in terms of frequencies and percentages.

We performed linear regression analysis to investigate changes in mean PAI scores at each evaluation time point and logistic regression analysis to investigate changes in the percentage of healed cases, that is, with PAI ≤2. Because multiple evaluations per tooth and multiple teeth per patient existed, standard errors, individual significance statistics, and confidence intervals were adjusted for two-way clustering (teeth and patients) using a one-step approach described by (24). Time was treated as a categorical covariate to examine possible nonlinear trends, which resulted in the inclusion of four dummy variables for time in the model. Predicted means and probabilities resulting from regression models were displayed using bar charts with capped spikes representing 95% confidence intervals (CIs).

For the secondary analysis, the Barnard Convexity, Symmetry, and Minimisation test (Barnard CSM) (25) was utilised to evaluate the correlation between each baseline characteristic and the Periapical Index (PAI) at the 36-month follow-up. The outcomes were categorised as either ≤2 (healed) or >2 (suggestive of ongoing healing). The Barnard test is a highly recommended exact unconditional test for analysing 2×2 tables, acclaimed for its effectiveness in maintaining power and accuracy of test size (25, 26). The magnitude of the effects was quantified as the variance in percentages, with 95% Confidence Intervals (CIs) calculated by aligning them with the p-values from the Barnard CSM analysis.

All analyses were replicated using two distinct approaches: per protocol and intention to treat. The per-protocol analysis was restricted to root canal treatments who completed the follow-up and had known PAI scores at 36 months, while the intention-to-treat analysis was extended to all root canal treatments irrespective of whether they had missing outcomes at 36 months. The last-observation-carried-forward (LOCF) method was used to impute missing follow-up data.

The significance level was set at 5%, and all tests were two-sided. No baseline characteristics exhibited a significantly increased or decreased risk of being lost to follow-up (Appendix). All data were analysed using Stata 18 (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC) and R 4.3.1 (R Core Team. 2023. R: A language and environment for statistical computing. Vienna, AT: R Foundation for Statistical Computing).

RESULTS

A total of 52 patients undergoing 58 root canal treatments (14 incisors, 8 canines, 15 premolars, 21 molars) were enrolled in the study. The pre-, intra-, and post-operative characteristics of the study sample are summarised in Table 2. At the baseline, a high number of teeth show a periapical lesion (58.6%) due to pulp necrosis (24.1%) or a previous treatment failure (exacerbated apical lesion) (34.5%). Sealer extrusion was observed in 14 out of 58 treatments (24.2%). Three of these showed a complete radiographical resorption of the sealer over time. A high number of teeth with an apical diameter >40 were included (46.6%).

Thirty-eight out of 58 root canal treatments (65.5%) completed the follow-up within 36 months. The other 20 (34.5%) were lost to follow-up for premature death in 2 cases (3.5%), for extraction due to horizontal root fracture in 3 cases (5.2%), and for unknown reasons in the remaining 15 cases (25.9%). As a result, after excluding deaths and dropouts for unknown reasons, the observed survival rate was 38 out of 41 (92.7%).

TABLE 3. Results of linear regression analysis on mean periapical index (PAI) from baseline to 36 months of follow-up

	Mean PAI		Actual difference (Δ)		p
	Estimate	95% CI	Estimate	95% CI	
Intention to treat (n=58)					
Baseline	2.5	2.1, 2.9	Ref.		
6 months	2.1	1.8, 2.4	-0.4	-0.6, -0.2	0.001
12 months	1.7	1.4, 2.0	-0.8	-1.1, -0.5	<0.001
24 months	1.5	1.3, 1.8	-1.0	-1.4, -0.6	<0.001
36 months	1.5	1.3, 1.8	-1.0	-1.4, -0.6	<0.001
Per protocol (n=38)					
Baseline	2.4	2.0, 2.9	Ref.		
6 months	1.8	1.4, 2.3	-0.6	-0.9, -0.3	<0.001
12 months	1.4	1.1, 1.8	-1.0	-1.4, -0.6	<0.001
24 months	1.2	1.0, 1.4	-1.3	-1.7, -0.8	<0.001
36 months	1.2	1.0, 1.4	-1.3	-1.7, -0.8	<0.001

Intention-to-treat analysis includes all cases by carrying the last observed PAI score forward in order to replace the missing outcome; per-protocol analysis includes only cases with available PAI scores at 36 months. PAI: periapical index, CI: Confidence interval

As shown in Table 3 and Figure 1, using an intention-to-treat approach, we found a mean PAI of 2.5 (95% CI 2.1 to 2.9) at baseline and of 1.5 (95% CI 1.3 to 1.8) after 36 months, with a significant reduction of −1.0 (95% CI −1.4 to −0.6). As shown in Table 4 and Figure 1, we also found that the proportion of cases with PAI ≤ 2 was 41.4% (95% CI 29.1 to 54.8) at baseline and 79.3% (95% CI 66.5 to 88.1) after 36 months, with a significant odds ratio of 5.43 (95% CI 2.74 to 10.76).

As shown in Table 3 and Figure 1, using a per-protocol approach, we found a mean PAI of 2.4 (95% CI 2.0 to 2.9) at baseline and of 1.2 (95% CI 1.0 to 1.4) after 36 months, with a significant reduction of −1.3 (95% CI −1.7 to −0.8). As shown in Table 4 and Figure 1, we also found that the proportion of cases with PAI ≤ 2 was 42.1% (95% CI 27.2 to 58.7) at baseline and 92.1% (95% CI 77.5 to 97.5) after 36 months, with a significant odds ratio of 16.04 (95% CI 4.79 to 53.74).

As shown in Table 5, patient-related characteristics (age, sex, tooth location, and type) did not influence the healing percentage. The type of treatments influenced the outcome at 36 months, with 100% success in the case of pulpitis, 100% success in the case of pulp necrosis, and 80.0% in the case of retreatment. Using an intention-to-treat protocol, we report 100% success in the case of pulpitis, 71% in the case of necrosis, and 65% in the case of retreatment (Fig. 2). No post-surgical clinical symptoms such as post-operative pain, fistulas, or swelling were noted. Representative cases are reported in Figures 3, 4.

DISCUSSION

This clinical study tested the use of a premixed sealer with a single-cone technique with a clinical success rate of over 90% after 36 months. The data were comparable to a previously published retrospective study that used a single-cone technique with another premixed sealer (27).

Only three clinical studies with a shorter follow-up reported the clinical outcome of endodontic treatments performed with Ceraseal. A study with a mean follow-up of 19.7 months reported a 99.1% overall success rate in treatments using warm gutta-percha obturation techniques combined with Ceraseal (loose criteria) (16). Similarly, another author reported a final success of 87% healing and 100% survival at 3 months using a single cone technique (14). Another paper reported a 97.8% survival rate (loose criteria) at 24 months using a carrier-based technique associated with Ceraseal (15).

Few more studies analysed the outcome of treatments performed with other CaSi-based sealers with shorter follow-ups (3 months-1 year) (14, 28, 29). Some studies proposed the use of a premixed sealer (14, 27, 29), while others used a powder-to-liquid CaSi-based sealer (28) with a single-cone technique. Only one study reported a mean follow-up of 30.1 months (27). No longer follow-up is available in the literature.

The study comprised teeth with different endodontic pathologies, namely the presence of a primary root canal treatment with no apical exacerbation (teeth affected by pulpitis or initial pulpal disease with no infection of the periapical area), teeth with primary periapical infection (pulpal necrosis and infection of the periapical area) and teeth with a previous root canal treatment (exposition of the gutta-percha due to fractures or deep caries with the presence of periapical infection or exacerbated apical lesion). According to a recent systematic review, a periapical infection is one of the main factors associated with the healing outcome of a root canal treatment (30).

Therefore, we analysed the success rate of root canal treatments according to these 3 groups. Our study confirms that root canal treatment performed in teeth with no lesions had a significantly higher percentage of healed status at 36 months (100% of the teeth that reached the end line were healthy with a PAI of 1–2). Differently, teeth with a previous root canal treatment showed a lower healing rate at 36 months (80%). Interestingly and unexpectedly, all teeth diagnosed with pulp necrosis and a previous periapical lesion showed a 100% healing rate at 36 months.

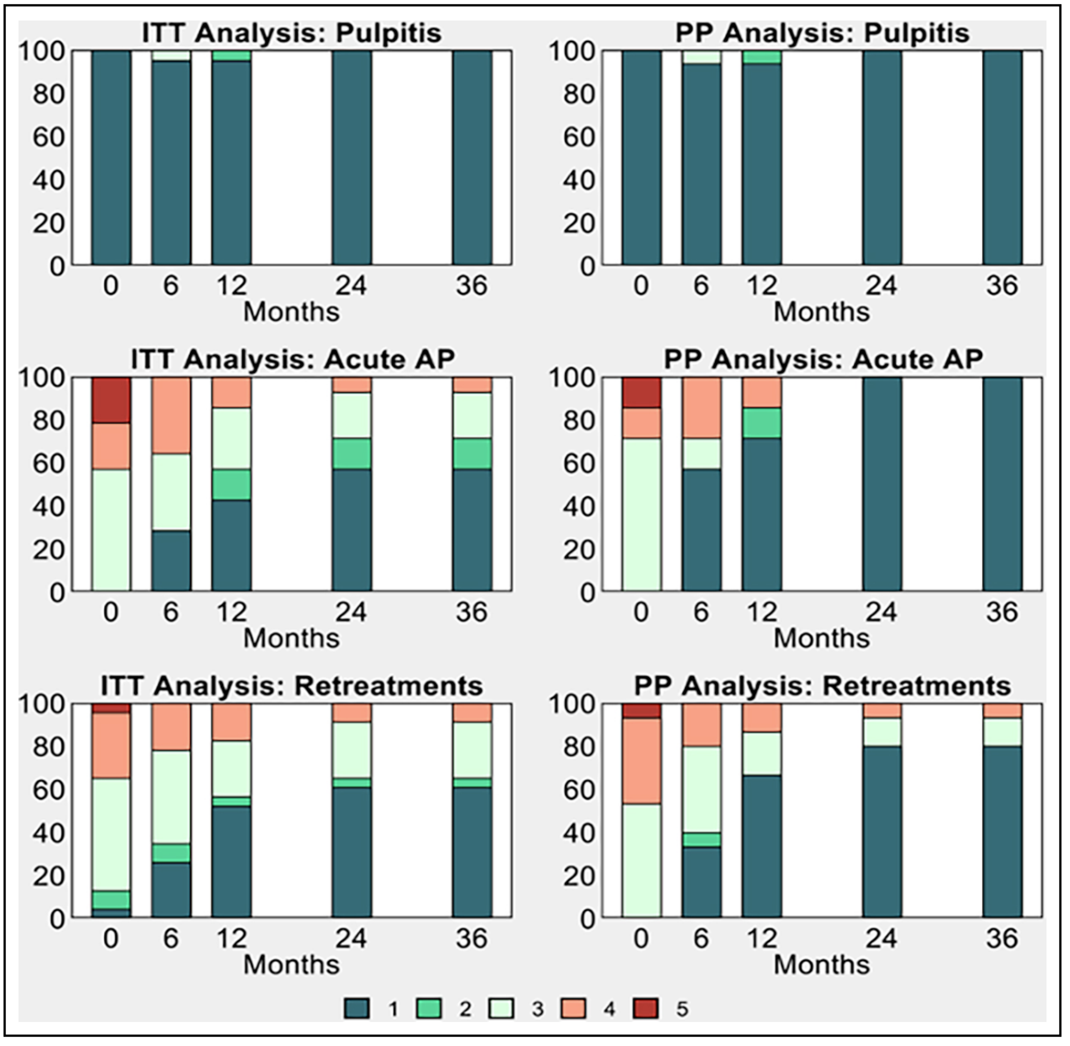

Figure 1. Results of regression analysis: mean periapical index (PAI) and percentage of healed cases (PAI ≤2) from baseline to 36 months of follow-up

95% confidence limits are displayed with capped spikes around point estimates. Intention-to-treat (ITT) analysis includes all cases by carrying the last observed PAI score forward in order to replace the missing outcome; per-protocol (PP) analysis includes only cases with available PAI scores at 36 months. AP: Apical periodontitis

TABLE 4. Results of logistic regression analysis on the percentage of healed cases (PAI ≤2) from baseline to 36 months of follow-up

	Cases with PAI ≤2 (%)		Odds ratio		p
	Estimate	95% CI	Estimate	95% CI	
Intention to treat (n=58)					
Baseline	41.4	29.1, 54.8	Ref.		
6 months	55.2	41.6, 68.0	1.74	1.12, 2.72	0.014
12 months	72.4	58.9, 82.8	3.72	2.05, 6.74	<0.001
24 months	79.3	66.5, 88.1	5.43	2.74, 10.76	<0.001
36 months	79.3	66.5, 88.1	5.43	2.74, 10.76	<0.001
Per protocol (n=38)					
Baseline	42.1	27.2, 58.7	Ref.		
6 months	65.8	48.8, 79.5	2.64	1.41, 4.95	0.002
12 months	84.2	68.0, 93.0	7.33	3.04, 17.72	<0.001
24 months	92.1	77.5, 97.5	16.04	4.79, 53.74	<0.001
36 months	92.1	77.5, 97.5	16.04	4.79, 53.74	<0.001

Intention-to-treat analysis includes all cases by carrying the last observed PAI score forward in order to replace the missing outcome; per-protocol analysis includes only cases with available PAI scores at 36 months. PAI: Periapical index, CI: Confidence interval

TABLE 5. Baseline characteristics of the root canal treatments according to healing status (PAI≤2 vs. PAI>2) at 36 months of follow-up

Characteristic	Intention to treat (n=58)						Per Protocol (n=38)					
	PAI≤2 (n=46)		PAI>2 (n=12)		Diff. in %s Est. (95%CI)	p	PAI ≤2 (n=3 5)		PAI>2 (n=3)		Diff. in %s Est. (95%CI)	p
	n	%	n	%			n	%	n	%		
Sex												
Male	17	37	6	50			11	31	2	67		
Female	29	63	6	50	+13 (-17, +41)	0.391	24	69	1	33	+35 (-14, +69)	0.153
Age group (years)												
<30	8	17	1	8	+9 (-18, +23)	0.566	5	14	0	0	+14 (-42, +28)	0.936
30–65	17	37	4	33	+4 (-28, +28)	0.825	14	40	2	67	-27 (-61, +23)	0.436
>65	21	46	7	58	-13 (-40, +18)	0.498	16	46	1	33	+12 (-37, +48)	0.815
Tooth type												
Incisor	11	24	3	25	-1 (-31, +20)	0.956	10	29	2	67	-38 (-72, +12)	0.127
Canine	7	15	1	8	+7 (-20, +21)	0.709	6	17	0	0	+17 (-39, +31)	0.906
Premolar	12	26	3	25	+1 (-30, +22)	0.886	8	23	0	0	+23 (-33, +37)	0.707
Molar	16	35	5	42	-7 (-37, +21)	0.678	11	31	1	33	-2 (-51, +33)	0.865
Tooth location												
Maxilla	33	72	10	83			27	77	2	67		
Mandible	13	28	2	17	+12 (-19, +30)	0.494	8	23	1	33	-10 (-60, +24)	0.414
Diagnosis												
Pulpitis	21	46	0	0	+46 (+18, +59)	0.002*	16	46	0	0	+46 (-12, +61)	0.221
Pulp necrosis	10	22	4	33	-12 (-41, +12)	0.379	7	20	0	0	+20 (-36, +34)	0.765
Exacerbated periapical lesion	15	33	8	67	-34 (-57, -2)	0.034*	12	34	3	100	-66 (-79, -8)	0.023*
Apical diameter (mm)												
≤40	26	57	5	42			19	54	1	33		
>40	20	43	7	58	-15 (-43, +16)	0.415	16	46	2	67	-21 (-56, +29)	0.524
Obturation quality												
Underfilled	3	7	2	17	-10 (-37, +6)	0.170	3	9	0	0	+9 (-49, +21)	0.988
Adequate filling	41	89	9	75	+14 (-5, +43)	0.195	30	86	2	67	+19 (-15, +68)	0.253
Overfilled	2	4	1	8	-4 (-30, +8)	0.320	2	6	1	33	-28 (-77, +5)	0.115
Sealer extrusion												
No	38	83	6	50	+33 (+3, +59)	0.028*	28	80	1	33	+47 (-3, +80)	0.066
Yes, without resorption	5	11	6	50	-39 (-65, -11)	0.003*	5	14	2	67	-52 (-85, -3)	0.037*
Yes, with resorption	3	7	0	0	+7 (-17, +16)	0.602	2	6	0	0	+6 (-52, +17)	0.995
Definitive Restoration												
Composite	36	78	6	50	+28 (0, +55)	0.045*	26	74	1	33	+41 (-9, +75)	0.104
Post	1	2	0	0	2 (-20, +10)	0.891	0	0	0	0	0 (-63, +8)	1.000
Crown	9	20	6	50	-30 (-57, -1)	0.036	9	26	2	67	-41 (-75, +9)	0.104

Intention-to-treat analysis includes all cases by carrying the last observed PAI score forward in order to replace the missing outcome; per-protocol analysis includes only cases with available PAI scores at 36 months. *: p≤0.05.
PAI: Periapical index, CI: Confidence interval

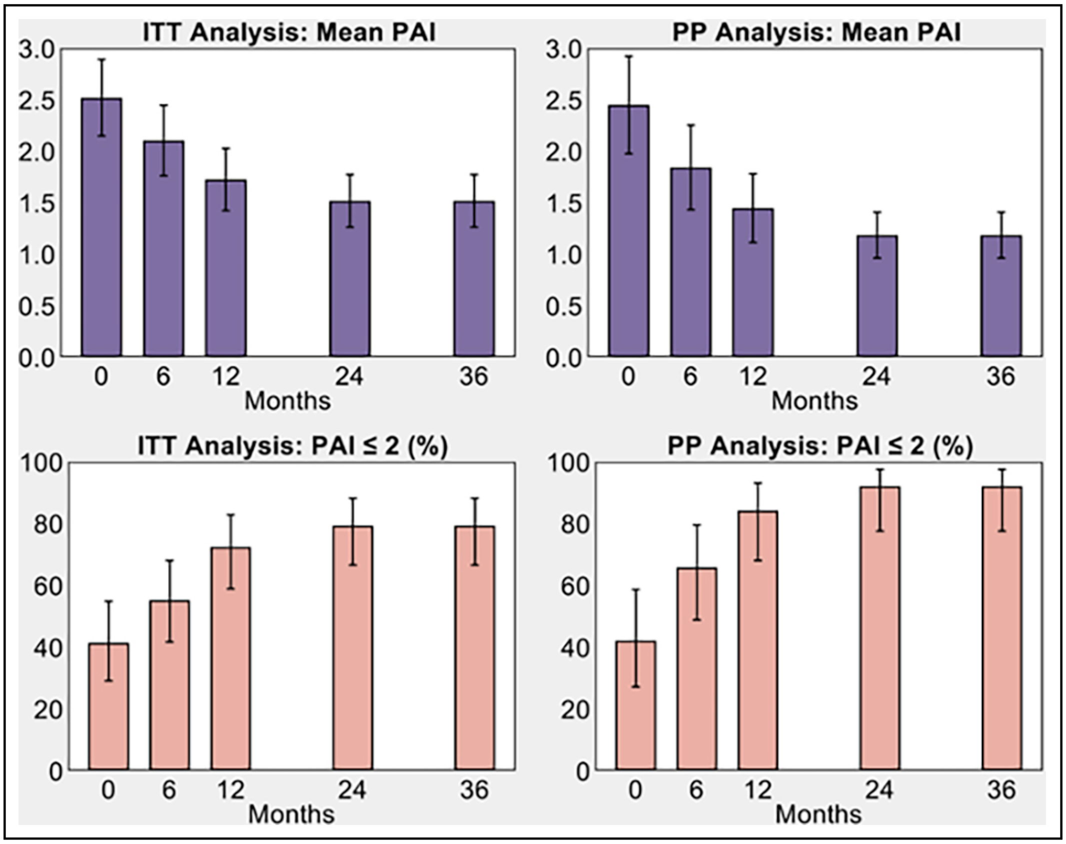

Figure 2. Percentage distribution of periapical index (PAI) from baseline to 36 months of follow-up, by diagnosis

Intention-to-treat (ITT) analysis includes all cases by carrying the last observed PAI score forward in order to replace the missing outcome; per-protocol (PP) analysis includes only cases with available PAI scores at 36 months

This data supports the use of premixed bioceramic sealers (i.e., Ceraseal) in the presence of periapical lesions and a necrotic pulp, where apical diameter and wet apices may hinder the complete set of hydrophobic sealers (such as epoxy-resin based sealers) (31). This data should be supported by longer follow-ups.

Another aim of the study was to evaluate the extrusion frequency of premixed sealers used with single cone technique and their radiographical modifications during time. Recent investigations evidenced a higher extrusion rate of CaSi-based sealers compared to epoxy resin (32). It is important to note that several clinical studies have shown that the extrusion of epoxy-resin-based sealer is not associated with a higher percentage of long-term failure (33, 34). This can be justified as the resin-based sealers remain bioinert after their complete set (35). On the other hand, the extrusion of calcium silicate-based sealers can have a positive clinical rationale due to their bioactive, osteoconductive, and osteoinductive properties that justify the expected good clinical outcome.

Interestingly, radiographical modification of apically-extruded sealers was observed for premixed bioceramic sealers, including Endosequence BC sealer (27), Ceraseal (15), and AH Plus Bioceramic (36). Our study reported a moderate number of extrusions (24%) with a relatively low number of radiographical resorption events (21% of the extrusions were completely resorbed). These percentages are similar if we consider the same sealer associated with warm techniques (15% extrusions, 50% of these were completely resorbed) (15) but markedly lower if we consider AH Plus Bioceramic sealers with warm techniques (46% of extrusions, 50% of these were completely resorbed) (36). It is interesting to note that it was reported a higher percentage of sealer extrusion (47.4%) and sealer resorption (50% of the extruded sealer showed a partial or complete absorption of sealer) using the same technique (single cone) but a different premixed bioceramic sealer (Endosequence BC sealer) (27). The different compositions of sealers, in terms of Calcium silicates and radiopacifiers percentages, could influence the physical properties of the materials. This is supported by recent laboratory studies that reported a marked higher solubility, flowability, and apparent porosity of AH Plus bioceramic Sealer compared to Ceraseal (5).

All treatment procedures were performed by experienced postgraduate operators and closely monitored by University Dental School tutors. Remarkably, the level of technical expertise did not affect the treatment outcomes, as there were no reported iatrogenic complications.

The university setup, adoption of strict and validated operative protocol, and the possibility of having a regular follow-up could have influenced the study results. Our clinical protocol standardised rotary NiTi instrumentation for primary root canal treatments, while secondary treatments were performed using a reciprocating system. The decision to use a reciprocation system for retreatment procedures was based on its abil-

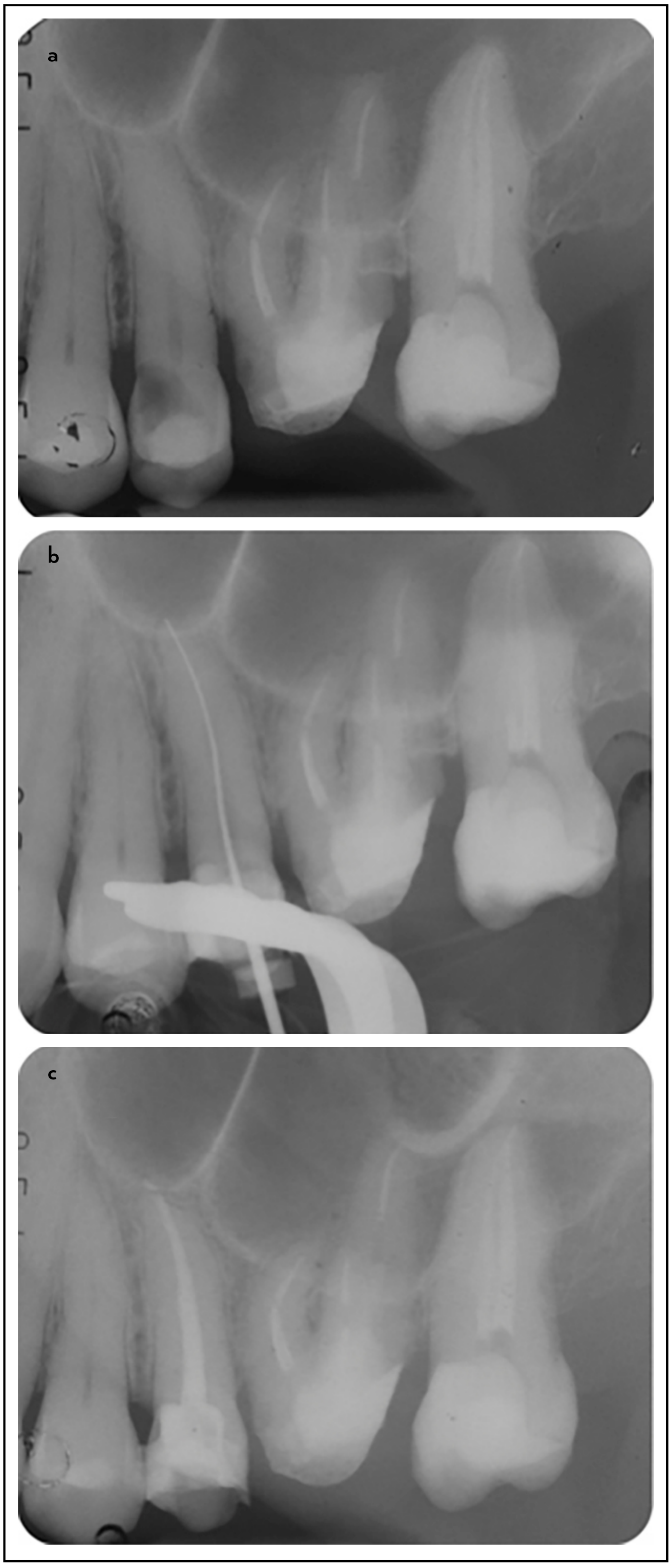

Figure 4. (a) Necrotic upper premolar with a deep carious lesion. (b) Working length. (c) Follow-up at 36 months

Figure 3. (a) Preoperative radiograph. Acute irreversible pulpitis of a lower second molar with a deep carious lesion. (b) Root canal obturation. (c) Healthy tooth at the 36 month follow-up

ity to extend a NiTi file's life by enhancing cyclic fatigue resistance (37), reducing the working time (37, 38), and removing gutta-percha also in root canals with anatomical complexities such as oval-shaped canals (39, 40). Additionally, the operators were trained in the reciprocating technique.

The present study has some limitations, which include the absence of a control group, a limited patient cohort, and a relatively brief follow-up (36 months). The absence of a control group limits our ability to directly compare with a traditional sealer.

The lack of a cone beam computed tomography could appear as a limitation in assessing the healing outcome of root canal treatments. However, the feasibility of performing multiple cone beam computed tomography at different follow-up periods conflicts with the ALARA (As Low as Reasonably Achievable) principles. Recent literature also confirmed the prognostic value of the PAI score (41). A follow-up period of 36 months might be considered insufficient for the complete resolution of teeth previously affected by a previous periapical lesion. According to the guidelines set forth by the European Society of Endodontology (ESE), a minimum observation period of four years is recommended to conclusively determine healing (42).

From future perspectives, our study opens several investigation paths. The comparison of Ceraseal effectiveness versus other bioceramic sealers and traditional obturation materials in the long-term would provide more definitive evidence of its clinical performances.

Additionally, further research could focus on the biological mechanisms regarding the healing observed with Ceraseal, particularly in teeth with pulp necrosis and periapical lesions, to elucidate the sealer's role in periapical tissue regeneration.

Robust clinical scientific evidence could further endorse the application of a premixed flowable bioceramic sealer with a single cone technique.

CONCLUSION

The study demonstrated that:

- Roots filled with single cone technique and Ceraseal premixed bioceramic sealer showed high survival and healing rates after 36 months.
- All teeth with an initial diagnosis of pulpal disease or pulpal necrosis were completely healed after 36 months.
- A high percentage of teeth with a previous root canal treatment and periapical exacerbation were healed.

The findings of the study support the clinical use of Ceraseal premixed bioceramic sealer in association with the single cone technique, suggesting a potential therapeutic indication in clinical situations of pulpal necrosis.

Disclosures

Appendix File: https://jag.journalagent.com/eurendodj/abs_files/EEJ-75537/EEJ-75537_(0)_EEJ-2024-01-02_supplementary.pdf

Ethics Committee Approval: The study was approved by the Emilia central area "CE AVEC" Ethics Committee (no: OUTENDOPROSP; CE 20079, date: 08/07/2020).

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