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Clinical outcomes of nonsurgical root canal treatment using C-root SP combined with different obturation techniques in older patients: a randomized controlled clinical trial

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Abstract

Background To evaluate the clinical efficacy and outcomes of C-Root SP bioceramic-based sealers combined with different obturation techniques in nonsurgical root canal treatment for older patients.

Methods This prospective, single-center, single-blind, parallel, randomized clinical trial included 240 patients aged ≥ 60 years. Patients were randomly divided into four treatment groups. Group A: C-Root SP combined with single-cone (SC); Group B: C-Root SP combined with warm vertical compaction (WVC); Group C: C-Root SP combined with cold lateral condensation (CLC); Group D: iRoot SP combined with SC (Control). All teeth were subjected to root canal filling using the corresponding methods 7–10 days after root canal preparation and medication. The duration of obturation was recorded. Periapical radiographs were obtained immediately after obturation to determine the length of root canal filling, and postoperative pain on days 1, 2, and 7 was documented. The treatment outcomes based on clinical signs and symptoms as well as periapical index (PAI) were analyzed at 1 year postoperatively.

Results Groups A and D exhibited significantly higher filling efficiency than groups B and C ($P < 0.001$). No significant differences were observed in the length of obturation between the groups ($P > 0.05$). Postoperative pain decreased over time in all groups, with group A showing significantly lower pain rates on day 1 than the other groups ($P < 0.05$). After 1 year, all groups exhibited considerable reductions in the PAI scores, with success rates ranging from 91.23 to 94.83%; however, no significant differences were observed between them ($P > 0.05$).

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Conclusions C-Root SP combined with different obturation techniques yielded similar outcomes to iRoot SP combined with the SC technique in terms of filling length, success rate, and changes in PAI scores. The SC technique demonstrated significant advantages in terms of clinical efficiency and may reduce early postoperative pain when combined with C-Root SP.

Trial registration The study was retrospectively registered in chictr.org.cn with the identifier: ChiCTR2400092580 on 11/19/2024.

Keywords Bioceramic-based sealers, Clinical trial, Endodontic outcomes, Obturation technique, Postoperative pain

Background

Although the clinical demand for endodontic therapy is increasing among older individuals, they are more likely to undergo tooth extraction than receive periodontal and endodontic treatment and restoration [1]. Because of the lack of appropriate prevention and maintenance, along with other factors such as low salivary flow, a soft diet with high carbohydrates, and systemic diseases, older patients often present with extensive periapical infection, combined with periodontal destruction, substantial tooth defect, and root caries that would affect periapical lesion healing after nonsurgical root canal treatment (NSRCT) and subsequent tooth rehabilitation [2–4]. Furthermore, increased canal calcification with aging poses challenges in diagnosis as well as in root canal cleaning, shaping, and obturation [5]. These factors, in combination with anatomical complexities, may prolong the operation duration and cause postoperative pain and fatigue in the maxillofacial joints and muscles, affecting the patient's acceptance of the treatment [6]. Moreover, systemic disorders may contribute to the safe and successful completion of NSRCT, whereas increased patient age does not decrease its success or survival rates [5]. Therefore, aging and its associated systemic disorders do not preclude endodontic treatment in older individuals [2].

Adequate root canal instrumentation, irrigation, and medication are essential for eliminating endodontic pathogens [7], and three-dimensional obturation is crucial for preventing root canal re-infection by sealing in residual pathogens and blocking infiltration from apical tissues [8]. Thus, hermetic sealing of the root canal system is one of the preconditions to ensure successful NSRCT [9, 10]. Root canal sealers are used to enhance sealing ability by filling any voids and irregularities between the root canal wall and gutta-percha [11]. Multiple root canal sealers have been used in clinical settings in combination with different obturation techniques [12, 13]. Bioactive properties of bioceramic-based sealers can promote periapical healing and facilitate dentine mineralization. The excellent flowability of this material, high alkaline pH, and less cytotoxicity are beneficial to canal sealing, microbial elimination, hydroxyapatite formation, and subsequent periapical tissue healing [14–16]. Among them, a novel bioceramic-based sealer, C-Root SP (C-root Dental Medical Devices Co. Ltd. Beijing, China), has recently been developed using a strontium silicate–based setting system. Strontium is a trace element in bone that can increase the expression of angiogenic factors in cells, thereby stimulating angiogenesis and promoting bone tissue repair [17]. Animal experiments have confirmed that strontium can substitute calcium in bioactive materials to stimulate the proliferation, osteogenesis, and angiogenesis of bone marrow stromal cells without exerting adverse local or systemic effects [18, 19]. Furthermore, strontium ions share intracellular transport pathways with calcium, imparting them with a strong affinity for binding to the bone matrix. Strontium can reduce osteoclast activity and bone resorption in vitro [20], and it exerts immunomodulatory effects and radiopacity [21, 22]. Multiple in vitro studies have reported that C-Root SP exhibits high biocompatibility, biological activity, and low cytotoxicity in terms of cell proliferation. It also exhibits antibacterial activity against *Enterococcus faecalis* [23], superior osteogenic potential compared with AH-Plus [24–26], and reasonable marginal adaptation [27], making it a promising alternative for root canal obturation. Although C-Root SP has been in the market for > 4 years, well-controlled clinical studies on its clinical outcomes in combination with different obturation techniques are limited. This study aimed to evaluate the clinical efficacy and outcomes of C-Root SP in combination with the single-cone (SC) technique, warm vertical compaction (WVC) technique, and cold lateral condensation (CLC) technique in older patients requiring root canal therapy. iRoot SP (Innovative BioCeramix Inc., Vancouver, Canada), a calcium silicate–based sealer combined with the SC, was used as a control. Table 1 lists the composition and lot numbers of these two premixed bioceramic-based sealers [25, 26]. The null hypothesis of this study is that there is no significant difference in operation duration, postoperative pain response, obturation length, and 1-year success rate between C-Root SP combined with different obturation techniques and iRoot SP combined with SC in older patients.

Table 1 Composition of the premixed bioceramic-based sealers

Sealers	Manufacturer	Lot number	Composition
C-Root SP	C-root Dental Medical Devices Co. Ltd. Beijing, China	20230403	Strontium silicate, calcium phosphate, calcium hydroxide, zirconium dioxide, fillers and thickening agents
iRoot SP	Innovative BioCeramix Inc., Vancouver, Canada	23001SP	Tricalcium silicates, dicalcium silicates, calcium phosphate monobasic, calcium hydroxide, zirconium oxide, fillers, and thickening agents

Materials and methods

Participant enrollment

This prospective, single-center, single-blind, parallel, randomized clinical trial was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT, 2010) [28] and ethical principles of the Declaration of Helsinki. The study was approved by the Ethics Committee of the Chinese PLA General Hospital (No. S2023-141-01) and was retrospectively registered at the Chinese Clinical Trial Registry (ChiCTR2400092580; date of registration: November 19, 2024). Patients who required NSRCT were enrolled after obtaining informed consent. All patients were informed of the benefits and risks and required follow-up assessments. They were consecutively treated between January and May 2023. Follow-up assessments were performed at least 1 year postoperatively. The flow of participants throughout the study is illustrated in Fig. 1. The inclusion and exclusion criteria were as follows:

Inclusion criteria:

- Patients aged ≥ 60 years at recruitment.
- Patients classified according to the American Society of Anesthesiologists (ASA) physical status as ASA I and ASA II.
- Patients with no known allergies to any material used in the study.
- Patients diagnosed with pulp necrosis and those with radiographic evidence of apical periodontitis (< 5 mm in diameter), including symptomatic apical periodontitis, asymptomatic apical periodontitis, and chronic apical abscess.
- Periodontally healthy patients or those with a pocket depth ≤ 4 mm.
- Patients with tooth mobility limited to grade 0 or 1.
- For a participant with multiple teeth eligible for the study, only one tooth was randomly selected.

Exclusion criteria:

- Patients with severe systemic diseases, allergy to local anesthetic drugs or multiple drugs, and other absolute contraindications for the treatment.
- Patients with malignant tumors and taking oral or injected bisphosphate drugs.
- Patients with extreme fear and psychological disorders that make understanding and cooperation during treatment difficult.
- Patients with grade 2 or 3 affected tooth mobility or periodontal–endodontic lesions.
- Patients who underwent endodontic treatment (completed or not), with immature roots, with internal or external root resorption, with root fracture, or with perforation in the affected teeth.
- Patients with excessive tension in the orbicularis oris muscle and a mouth opening of less than three transverse fingers, making it highly difficult to accurately utilize the required tools in the mouth.

Sample size determination

The minimum estimated sample size was calculated using the G*Power 3.1 software (Heinrich Heine, University of Düsseldorf, Düsseldorf, Germany) based on previous research data [29, 30]. In the calculation for the similarity trial, an equivalence limit of 0.5, standard deviation of 0.73, type I error of 0.05, and power test of 0.90 were used. The sample size was increased by 20% to compensate for dropouts. Finally, 60 teeth/patients were included in each experimental condition.

Randomization

The patients were allocated to four groups according to two bioceramic-based sealers, C-Root SP and iRoot SP, combined three different obturation techniques using a randomized block design with blocks of 60 patients/teeth each. The group allocation was concealed using a predetermined computer-generated randomization list. The number of tables was prepared separately for three experimental groups, namely, group A (C-Root SP combined with the SC technique), group B (C-Root SP combined with the WVC technique), and group C (C-Root SP combined with the CLC technique), and a control group, namely, group D (iRoot SP combined with the SC technique). Table 1 presents the demographic characteristics of the study population and the distribution of treated teeth according to group. Because the present study was an interventional study, clinicians were not blinded to the procedures being performed. Patients were not informed about the treatment (control or experimental) to which they were allocated.

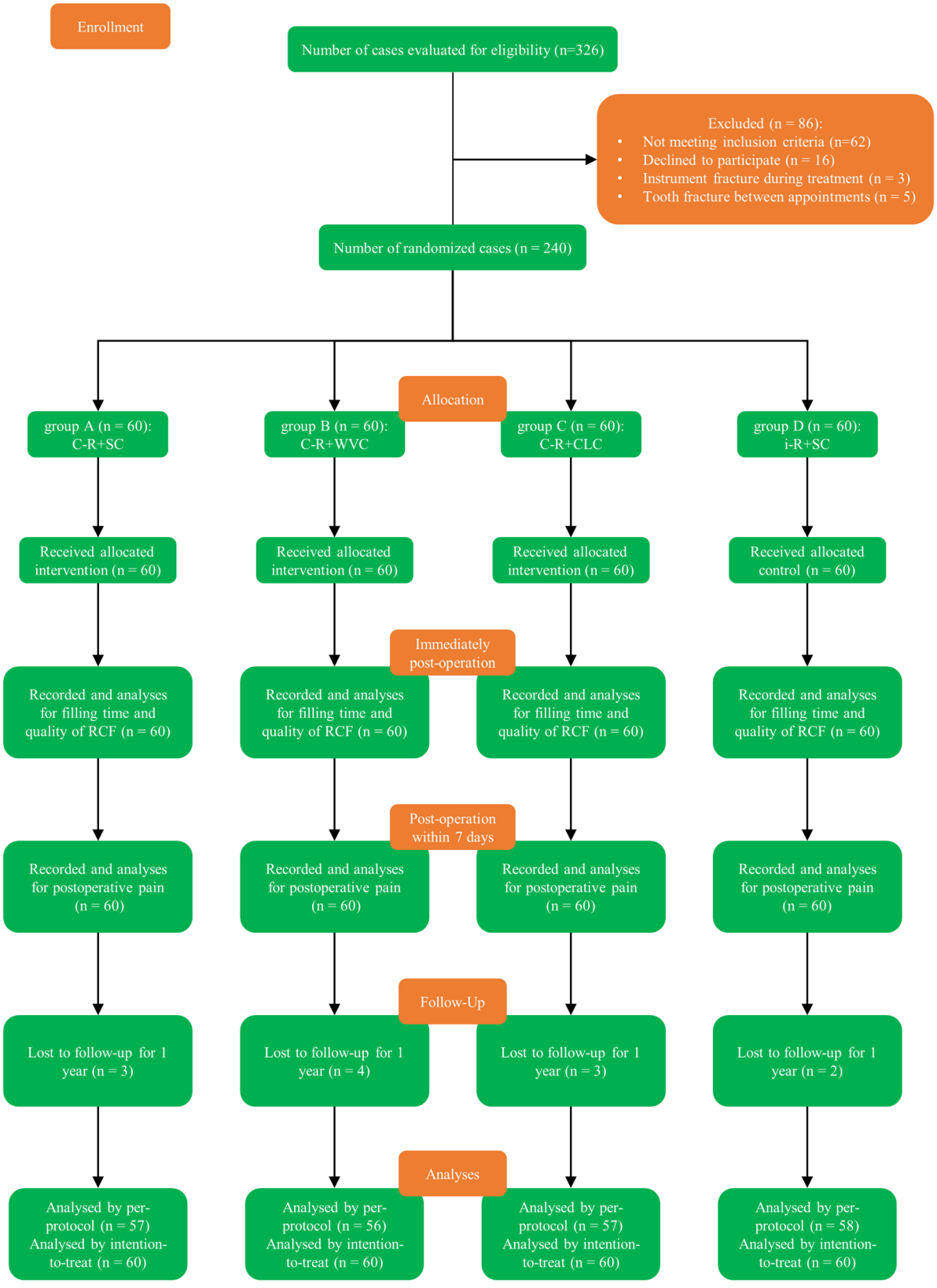

Fig. 1 Flowchart of patient allocations. C-R; C-Root SP; i-R, iRoot SP; SC, single-cone technique; WVC, warm vertical compaction technique; CLC, cold lateral condensation technique

Root Canal Preparation techniques

After a thorough clinical and radiographic evaluation based on the inclusion/exclusion criteria, teeth that met the inclusion criteria were treated in two visits. All teeth were isolated using a rubber dam during root canal treatment. The procedures were performed using a microscope (OPMI Sensera; Carl Zeiss, Germany). The working length (WL) was determined using an apex locator (Raypex 6, VDW GmbH, Germany) and validated radiographically to be 1 mm less than the radiographic apex.

For each group, apical preparation was performed using ISO stainless steel hand files (size #10–15, K-reamers, MANI, Japan), beginning with the selection of the first file to bind at the WL. Subsequently, rotary files (ProTaper Next, Dentsply Maillefer, Switzerland) with an endodontic motor (XSmart Plus, Dentsply Maillefer, Switzerland) were used for mechanical preparation according to the manufacturer's recommendations (speed: 200 rpm; torque: 2 Ncm). In the presence of EDTA gel, the rotary files were inserted into the canal up to the full WL in the following sequence: X1 (size: #17; taper: 0.04), X2 (size: #25; taper: 0.06), and X3 (size: #30; taper: 0.07). The final instrumentation file was set three sizes larger than the first file used to improve periodontitis healing [7].

The canals of all groups were extensively irrigated using a 2.5% NaOCl root canal irrigant (5 mL for 1 min), and a disposable plastic syringe equipped with a side-vented needle (0.4 × 25RW, Sungshim, Korea) was used to reach 1 mm short of the WL. An equal volume of irrigant was administered to each tooth (5 mL applied before instrumentation, 5 mL between files, and a final 5 mL flush following root canal instrumentation). Subsequently, the canals were dried using sterile paper points (Dayading Medical Appliance Co., China). The access cavity was filled with a sterile cotton pellet and temporary filling material (Coltosol F, Coltene/Whaledent, Switzerland), and a calcium hydroxide–based dressing (ApexCal, Ivoclar Vivadent, Germany) was placed in the root canals [31].

Obturation techniques

After 7–10 days, the gutta-percha (GP) master cone was selected and trimmed using a blade to ensure a snug fit in the apical root canal, and it was confirmed using a periapical radiograph (eXpert DC, Gendex Dental Systems, USA) before obturation. Similarly, all obturation procedures were performed under rubber dam isolation.

The teeth in groups A and D were filled with bioceramic-based sealers C-Root SP and iRoot SP, respectively, by injecting the sealer into the coronal third of each canal. A size 25 Lentulo spiral (Paste Carriers, MANI, Japan) coated with additional sealer was introduced 3 mm short of the WL at 300 rpm. Subsequently, a 0.06 taper GP (Dayading Medical Appliance Co., China) was dipped in the corresponding bioceramic-based sealer and introduced into the canal to the WL. A heated plugger (Alpha unit, B&L Biotech USA Inc., USA) was used to sear the GP point at each orifice.

The teeth in group B were filled with 0.06 taper GP (Dayading Medical Appliance Co., China), and C-Root SP was introduced using the master cone. A heated plugger size of 30/0.04, 35/0.04, or 40/0.04 (Alpha unit, B&L Biotech USA Inc, USA) was inserted 3–5 mm short of the WL, and the remaining canal space was backfilled with additional sealer and thermoplasticized GP using the beta unit (B&L Biotech USA, Inc., USA).

For group C, the root canals were obturated using a 0.06 taper GP cone (Dayading Medical Appliance Co., China), which was selected based on the master apical file. The cone was lightly coated with C-Root SP and placed into the canal up to the WL. Lateral compaction was performed using finger spreaders (MANI, Japan) with a size of 25. The excess filling material was removed using a heated instrument.

For each group, the time from the introduction of the root canal sealer to the completion of a single obturation was recorded, and the coronal access cavities were filled with glass ionomer cement (Fuji IX, GC America, USA) for temporary restoration. The final direct resin restoration or indirect ceramic restoration was performed on the next visit after 7–10 days, according to the European Society of Endodontology position statement [32].

Postoperative radiographic evaluations

The obturation length was classified into "deficient" (> 2 mm from the radiographic apex), "proper" (0–2 mm from the radiographic apex), or "overextension" (beyond the radiographic apex) [33]. Radiographic evaluations were conducted by two independent, blinded, and experienced endodontists who were trained and calibrated using 150 radiographs unrelated to this study. In cases of disagreement in the assessment of the results, discussions were held until a consensus was reached.

Evaluation of postoperative pain

The numeric rating scale (NRS) was used for postoperative pain assessment [9]. This scale encompasses the following grades according to pain severity: 0, no pain; 1–3, mild pain; 4–6, moderate pain; and 7–10, severe pain. On days 1, 2, and 7 after treatment, patients were asked to rate their pain level from 0 to 10. In addition, they were reminded to note the number of analgesics they used when necessary. They were contacted via telephone on day 7 to ask about postoperative pain and analgesic intake.

Follow-up evaluation of the treatment outcome

Endodontic treatments were considered failure if pain and/or swelling and/or sinus tract were present. Radiographically, if a pre-existing lesion increased in size or remained the same, the treatment was considered a failure [9]. Periapical radiographs were obtained preoperatively, postoperatively, and at 1-year follow-up. Lesions were reclassified according to the periapical index (PAI) using the following scores [34, 35]: 1, normal periapical structures; 2, small changes in bone structure; 3, changes in bone structure with some mineral loss; 4, lesions with well-defined radiolucent areas; and 5, severe lesions with exacerbating features. Two blinded, independent, and calibrated examiners (C.X. and L.W.) assessed the radiographs, and each endodontically treated tooth was assigned the highest score recorded for any of its roots.

The treated roots were categorized as follows [13, 36]:

1. Healed: Teeth that are functional, symptom-free, and exhibit no radiographic periapical lesions, with a PAI score of 1 or 2.
2. Healing: Symptom-free teeth that function well, show a reduction in the size of radiographic periapical lesions, and have a PAI score that has decreased from baseline but remains above 2.
3. Not healed: Nonfunctional teeth that have symptoms with or without radiographic periapical lesions or asymptomatic teeth with unchanged, newly developed, or enlarged radiographic periapical lesions. These teeth exhibited PAI score comparable to or worse than the baseline.

In this clinical evaluation, "success" was defined as belonging to the healed and healing categories, whereas "failure" referred to teeth that were not healed. In cases of disagreement regarding radiographic and/or clinical evaluations, discussions were held until consensus was reached. Examples of each outcome category among the four groups are presented in Figs. 2, 3, 4 and 5.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows (version 26.0, IBM Corp. Released 2019). Continuous variables were expressed as means ± standard deviations (M ± SD), and categorical variables were expressed as frequencies with percentages. Normality diagnostic plots and tests were used to test data normality. For the comparisons of the means among the four groups, a two-way analysis of variance was employed for normally distributed data and the Kruskal–Wallis test for non-normally distributed data. Pearson's chisquared test or Fisher's exact test was used for categorical variables to evaluate the group differences. Intra and interobserver agreements were examined using weighted kappa analysis.

To assess differences in postoperative pain among the four groups according to the NRS scores, the nonparametric Mann–Whitney *U* test was used to test the hypothesis that the pain difference among the four groups is not significant. The difference in postoperative pain scores within each treatment group at different time points was assessed using the nonparametric Friedman test. Given the substantial differences identified in the Friedman analysis, Dunn's test with Bonferroni correction was used for pairwise comparisons of time points within the groups [37].

Data from the PAI score change were analyzed using the Mann–Whitney *U* test for equivalence via two one-sided tests [38], as the hypothesis tested was that the two techniques were equivalent. To assess changes in periapical status, the data were subjected to both per-protocol and intention-to-treat (ITT) analyses. In the case of ITT, the PAI at baseline was repeated for the final evaluation of patients who did not attend their follow-up appointments [7]. A *P*value of 0.05 was considered statistically significant in all analyses.

Results

Demographics, tooth position distribution, and root Canal quantitative information

According to the demographic characteristics of the participants, no significant differences were observed in age ($F = 0.094$, $P = 0.963$) and gender ($\chi^2 = 0.133$, $P = 0.988$) among the groups. The positional distribution of the included teeth was similar ($\chi^2 = 0.227$, $P = 1.000$). Furthermore, no significant difference was observed in the number of root canals in each group ($\chi^2 = 0.294$, $P = 1.000$) (Table 2). Therefore, the potential impact of these factors can be ignored.

Comparison of duration and length of obturation

Comparison of the obturation duration of each group showed that the filling efficiencies of groups A and D were significantly higher than those of groups B and C ($F = 71.823$, $P < 0.001$); however, no significant difference was observed between the latter two groups. Furthermore, the use of different root canal sealers in the same obturation technique did not affect the filling duration. All obturated teeth were included in the analysis because of the absence of severely undere-xtended or over-extended obturations (> 2 mm). A comparison of the filling length in each group showed that the proper filling rates were higher in group A than in the other three groups. The overfilling rates of the groups were as follows: group A (3.33%) < group D (5.00%) < group C (6.67%) < group B (8.33%). The underfilling rates in groups B, C, and D were higher than those in group A,

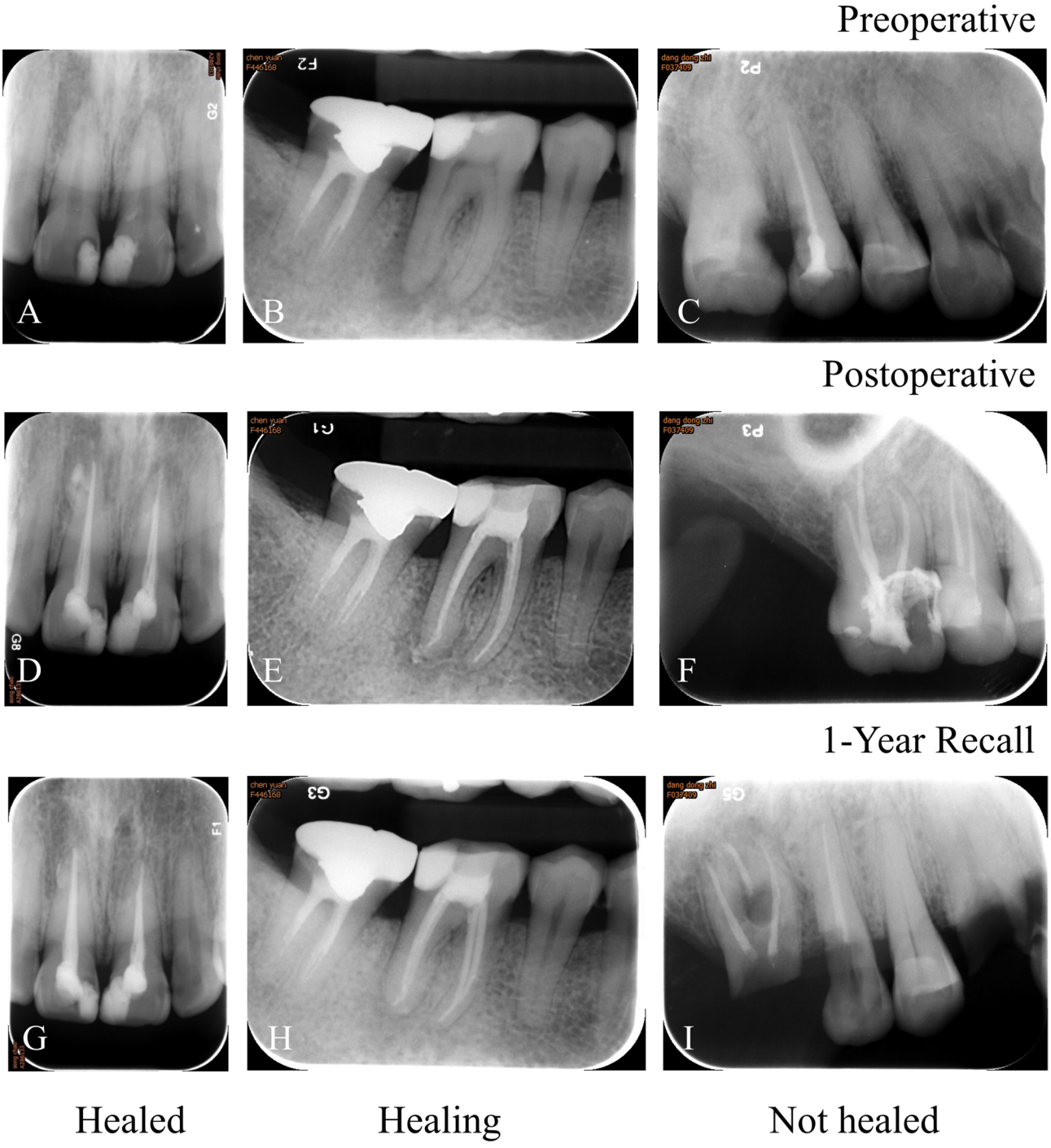

Fig. 2 Preoperative (**A**, **B**, and **C**), postoperative (**D**, **E**, and **F**), and recall (**G**, **H**, and **I**) radiographs of the outcomes of healed, healing, and not healed teeth in group A (C-R combined with SC); C-R; C-Root SP; SC, single-cone technique

but the difference was not significant ($F = 2.318$, $P = 0.907$) (Table 3).

Comparison of postoperative pain after obturation

The NRS scores of each group on days 1, 2, and 7 after the operation are presented in Table 4. The postoperative rate and degree of pain in each group decreased with time. No severe pain on days 1, 2, and 7 as well as moderate pain on days 2 and 7 were reported in any group. In addition, group A experienced no mild pain on day 7. The postoperative rate of pain (mild and moderate pain) in the groups on day 1 after obturation is as follows: group A (11.67%) < group D (28.33%) < group B (31.67%) < group C (33.33%). The postoperative pain rate

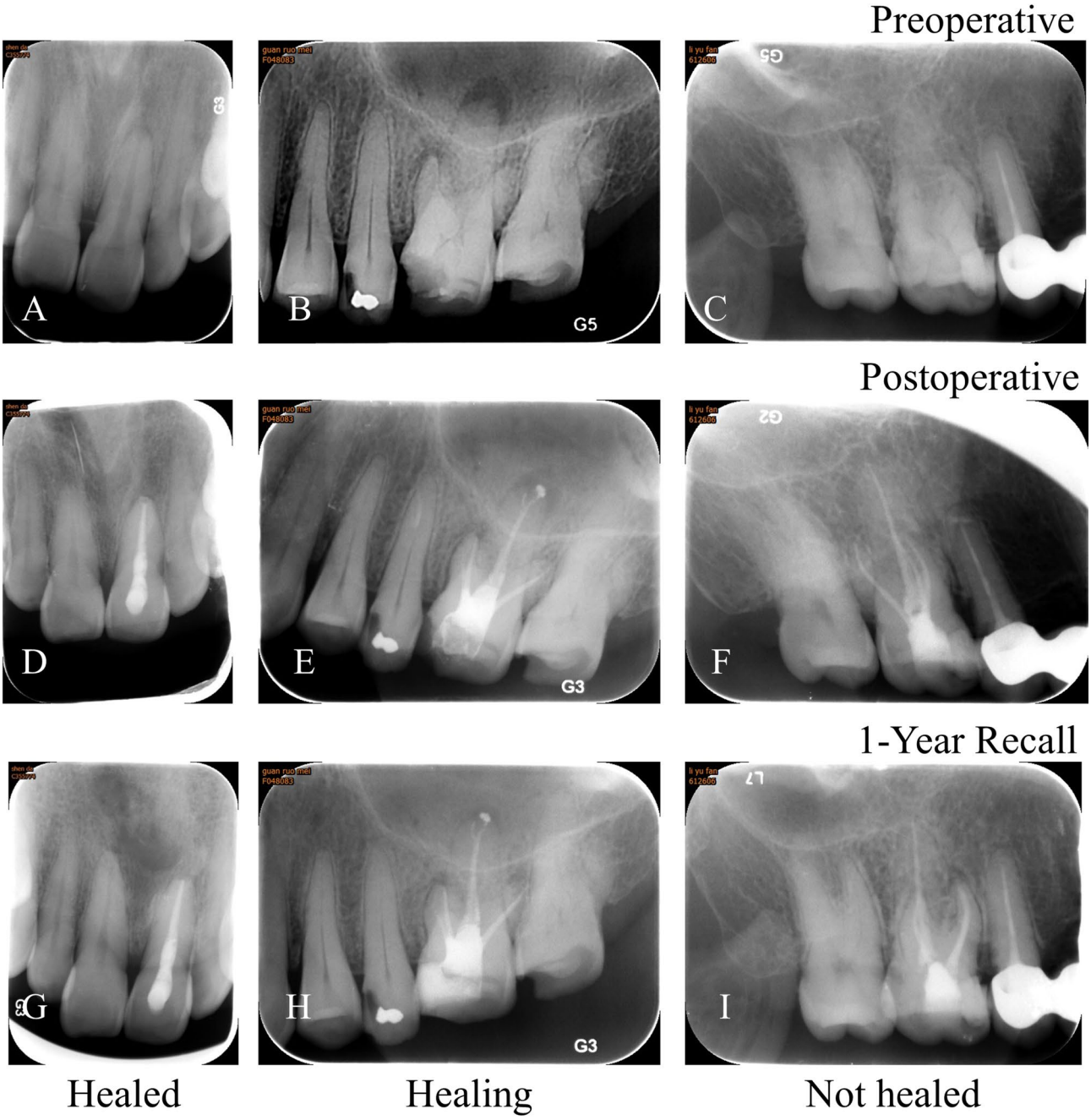

Fig. 3 Preoperative (**A**, **B** and **C**), postoperative (**D**, **E** and **F**), and recall (**G**, **H** and **I**) radiographs of the outcomes of healed, healing and not healed teeth respectively in group B (C-R combined with WVC); C-R; C-Root SP; WVC, warm vertical compaction technique

in group A significantly differed from those in groups B, C, and D ($\chi^2 = 9.19$, $P = 0.027$). No significant difference was observed between the four groups in terms of postoperative pain on days 2 ($\chi^2 = 6.565$, $P = 0.084$) and 7 ($F = 2.027$, $P = 0.904$).

Comparison of obturation efficacy after 1 year

Loss of follow-up and the results of changes in PAI scores 1 year later are presented in Table 5. The follow-up loss rates were 5.00% for Group A, 6.67% for Group B, 5.00% for Group C, and 3.33% for Group D. No significant differences were observed between the groups ($F = 0.818$, $P = 0.976$). Similar average PAI scores were observed across all groups, regardless of whether the per-protocol or ITT analysis was used ($P = 0.988$ and $P = 0.986$, respectively). All treatment approaches effectively reduced the PAI scores 1 year after treatment ($P < 0.001$ for all analyses). In general, the PAI score at baseline ranging from

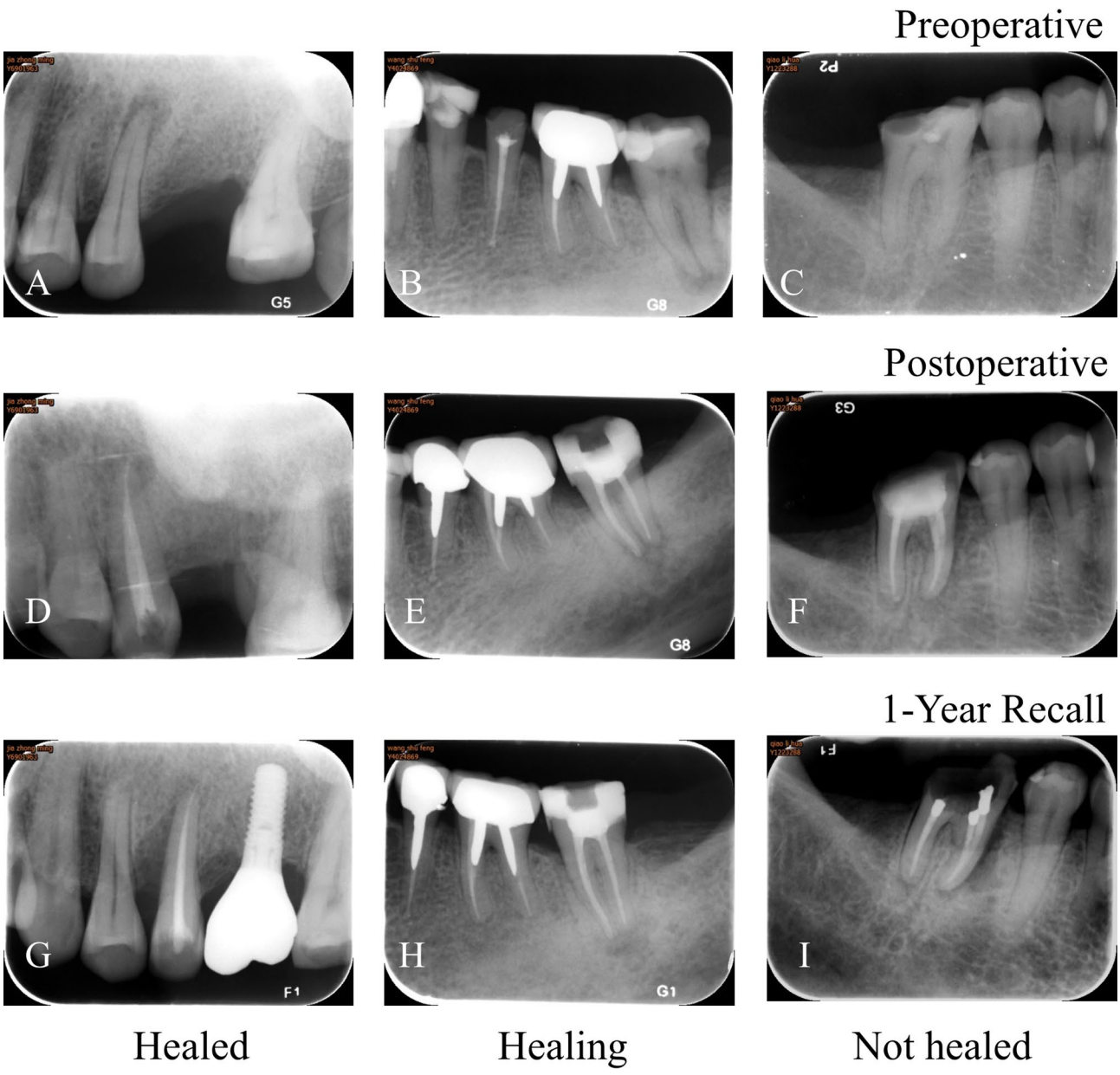

Fig. 4 Preoperative (**A**, **B** and **C**), postoperative (**D**, **E** and **F**), and recall (**G**, **H** and **I**) radiographs of the outcomes of healed, healing and not healed teeth respectively in group C (C-R combined with CLC); C-R; C-Root SP; CLC, cold lateral condensation technique

2.93 to 3.00 was reduced to 1.89 to 2.10 after 1 year of follow-up. Finally, the success rates for all groups after 1 year were in the following order: group D (94.83%) > group A (92.98%) > B group (92.85%) > C group (91.23%); however, no significant differences were observed between the groups ($F = 0.680$, $P = 0.892$).

Discussion

Various techniques for root canal obturation have been proposed, including SC, lateral condensation, and vertical compaction, and each has its advantages and disadvantages. CLC is widely used because of its low cost and simplicity; however, it lacks adaptability in irregular areas within root canal systems [39], and excessive lateral pressure may lead to root wall damage and fracture [40]. WVC has been recognized as the "gold standard" for canal obturation [41, 42]. Its good three-dimensional adaptability and filling uniformity allow the GP to flow to the irregular areas of the root canal space upon heating and pressing. However, this technique has relatively high technical sensitivity and may cause micro-leakage when microgaps occur in the root canal and the irregular apical foramen, thereby leading to the retention of chemicals and microorganisms [43]. The SC technique,

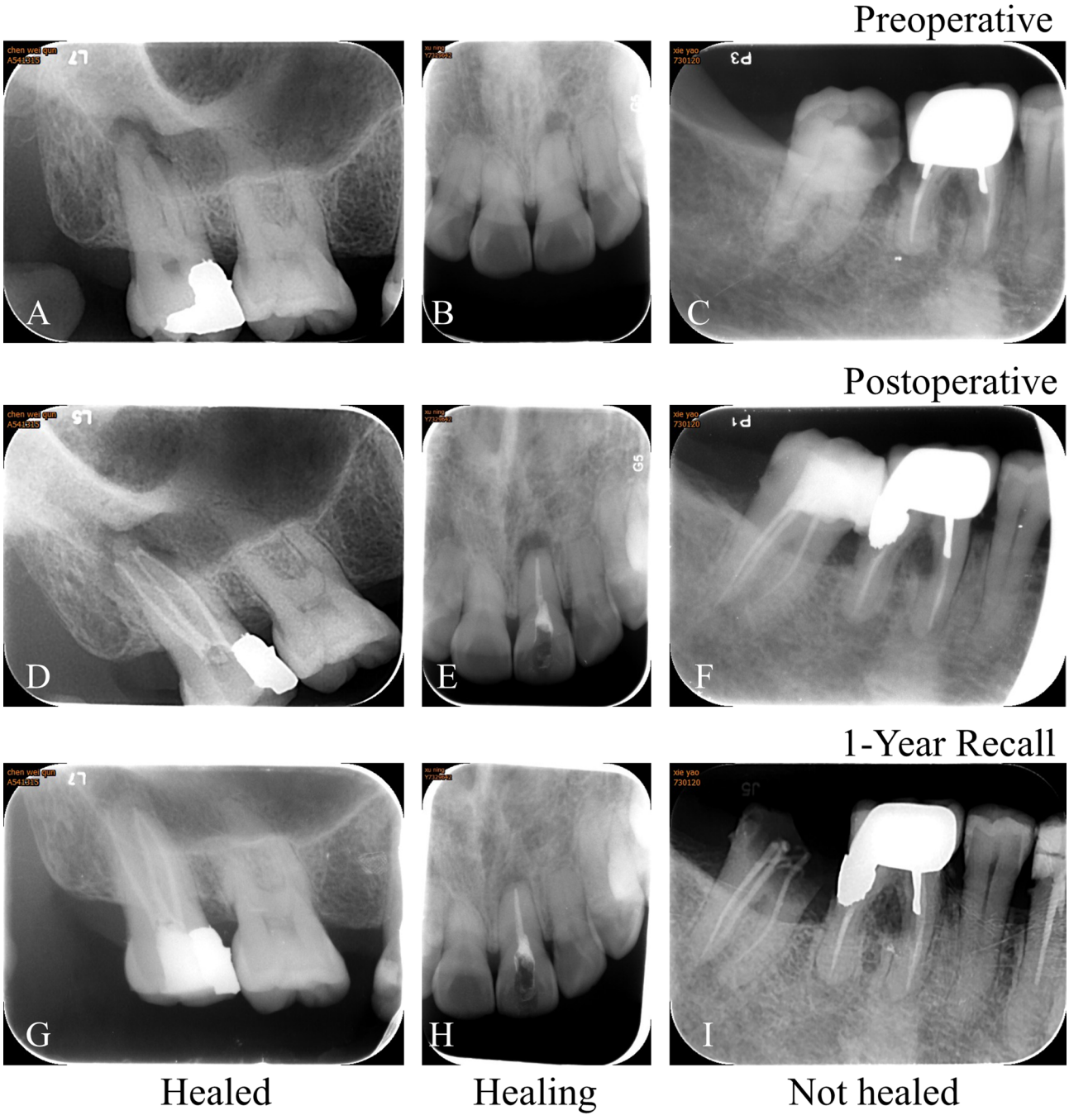

Fig. 5 Preoperative (**A**, **B** and **C**), postoperative (**D**, **E** and **F**), and recall (**G**, **H** and **I**) radiographs of the outcomes of healed, healing and not healed teeth respectively in group D (i-R combined with SC); i-R, iRoot SP; SC, single-cone technique

a simple and time-saving procedure, has been frequently used by general practitioners owing to the development of bioceramic-based sealers, which possess better fluidity and do not shrink during the setting phase to reduce pore formation [44, 45]. Evidently, the operating efficiency of SC was significantly higher than those of WVC and CLC, regardless of the selected bioceramic-based sealers. Therefore, the null hypothesis of no significant difference in the filling duration among the groups was rejected. In older patients undergoing NSRCT, the appropriate timing of filling is crucial because of their low tolerance [5].

Filling length is an important index for evaluating the quality of root canal obturation for the prevention of periapical inflammation and the creation of an environment conducive to the healing of apical inflammation. It is essential to ensure hermetic three-dimensional filling and sealing of the apical area and root canal system [46, 47]. Radiographic evaluation has been increasingly

Table 2 Demographic features of the population and the distribution of treated teeth in each group

	A	B	C	D	Total	*p*-value
Sample size	60	60	60	60	240	
Mean age (year)	68.97 ± 7.17	68.27 ± 7.75	68.53 ± 8.05	68.47 ± 6.78	68.56 ± 7.41	0.963
Gender [n] (%)						0.988
Male	29 (48.33)	30 (50.00)	31 (51.67)	30 (50.00)	120 (50.00)	
Female	31 (51.67)	30 (50.00)	29 (48.33)	30 (50.00)	120 (50.00)	
Location (number of root canals)						1.000
Anterior	20 (20)	19 (19)	19 (19)	20 (20)	78 (78)	
Premolar	19 (27)	21 (24)	20 (27)	19 (24)	79 (102)	
Molar	21 (64)	20 (56)	21 (63)	21 (63)	83 (246)	

Note: group A (C-R combined with SC), group B (C-R combined with WVC), group C (C-R combined with CLC) and group D (i-R combined with SC); C-R; C-Root SP; i-R, iRoot SP; SC, single-cone technique; WVC, warm vertical compaction technique; CLC, cold lateral condensation technique; *p* = significance value using chi-square test

Table 3 Statistics of operation time and quality of root Canal filling in each group

	A(*n* = 60)	B (*n* = 60)	C(*n* = 60)	D (*n* = 60)	Total (*n* = 240)	*p*-value
Filling time(second)	61.08 ± 12.38	81.07 ± 10.82①	87.12 ± 13.70①	61.98 ± 11.39②③	72.81 ± 16.66	< 0.001
Quality of root canal filling [n] (%)						0.907
Proper	57 (95.00)	53 (88.33)	54 (90.00)	55 (91.67)	219 (91.25)	
Overextension	2 (3.33)	5 (8.33)	4 (6.67)	3 (5.00)	14 (5.83)	
Deficient	1 (1.67)	2 (3.33)	2 (3.33)	2 (3.33)	7 (2.92)	

Note: group A (C-R combined with SC), group B (C-R combined with WVC), group C (C-R combined with CLC) and group D (i-R combined with SC); C-R; C-Root SP; i-R, iRoot SP; SC, single-cone technique; WVC, warm vertical compaction technique; CLC, cold lateral condensation technique; *p* = significance value using chi-square test; ①Compared with group A, $p<0.05$; ②Compared with group B, $p<0.05$; ③Compared with group C, $p<0.05$

Table 4 Severity and percentage of postoperative pain in each group at various timepoints (n;%)

	A(*n* = 60)	B (*n* = 60)	C(*n* = 60)	D (*n* = 60)	*p*-value
Days 1					
Mild pain	7 (11.67)	18 (30.00)	18 (30.00)	15 (25.00)	
Moderate pain	-	1 (1.67)	2 (3.33)	2 (3.33)	
Total	7 (11.67)	19 (31.67)①	20 (33.33)①	17 (28.33)①	**0.027**
Days 2					
Mild pain	2 (3.33)	10 (16.67)	8 (13.33)	8 (13.33)	
Total	2 (3.33)	10 (16.67)	8 (13.33)	8 (13.33)	0.084
Days 7					
Mild pain	-	1 (1.67)	2 (3.33)	1 (1.67)	
Total	-	1 (1.67)	2 (3.33)	1 (1.67)	0.904

Note: group A (C-R combined with SC), group B (C-R combined with WVC), group C (C-R combined with CLC) and group D (i-R combined with SC); C-R; C-Root SP; i-R, iRoot SP; SC, single-cone technique; WVC, warm vertical compaction technique; CLC, cold lateral condensation technique; *p* = significance value using chi-square test; ①Compared with group A, $p<0.05$; Severe pain on days 1, 2, 7 and moderate pain on days 2, 7 was not included in the table because no case was observed

used to examine the quality of obturation techniques because of its simplicity, reliability, and objectivity [48]. In our study, the proper filling rate of each group was between 88.33% and 95.00%, whereas the overfilling and underfilling rates were less than 8.33% and 3.33%, respectively, in accordance with those previously reported [37]. These findings indicate no significant difference in root canal filling quality among the groups, thereby validating the null hypothesis. Another critical factor affecting the three-dimensional sealing of root canal filling was the choice of root canal sealer, particularly hydrophilic bioceramic-based sealers with good fluidity and adhesion, which improves filling and sealing in irregular anatomical structures, such as isthmus, apical bifurcation, and lateral root canal [49]. The selected bioceramic-based sealers also exhibited excellent biocompatibility, antibacterial activity, low cytotoxicity, stable physicochemical properties, and radiopacity [16, 50].

Post-obturation pain is a concern in endodontic therapy, with reported incidences between 3% and 58% [51]. It can be as high as 80% in the first 24 h [52]. The factors related to postoperative pain include age, gender, pulpal and periradicular status, degree of infection, tooth type, sinus, preoperative pain, root canal preparation, irrigation and filling methods, and materials [53, 54]. Root canal sealers are in direct or close contact with the innervated periapical tissue through apical extrusion or diffusion, which may elicit an immunological response

Table 5 The efficacy of root Canal filling in each group after 1 year

	A	B	C	D	Total	Row *p*-value
Lost follow-up for 1 year [n] (%)	3 (5.00)	4 (6.67)	3 (5.00)	2 (3.33)	12 (5.00)	0.976
Per-protocol analyses						
Baseline PAI	2.96 ± 1.15	3.00 ± 0.97	2.93 ± 0.98	2.97 ± 0.97	2.96 ± 1.02	0.988
1-year PAI	1.89 ± 1.01	2.09 ± 0.96	2.04 ± 1.00	1.98 ± 0.78	2.00 ± 0.94	0.726
Column *p*-value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	-
Intention to treat analyses						
Baseline PAI	2.93 ± 1.13	2.95 ± 1.00	2.95 ± 0.98	3.00 ± 0.99	2.96 ± 1.02	0.986
1-year PAI	1.92 ± 1.00	2.10 ± 0.97	2.10 ± 1.04	2.05 ± 0.87	2.04 ± 0.97	0.698
Column *p*-value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	-
Success [n] (%)	53 (92.98)	52 (92.85)	52 (91.23)	55 (94.83)	212 (92.98)	0.892

Note: group A (C-R combined with SC), group B (C-R combined with WVC), group C (C-R combined with CLC) and group D (i-R combined with SC); C-R; C-Root SP; i-R, iRoot SP; SC, single-cone technique; WVC, warm vertical compaction technique; CLC, cold lateral condensation technique; *p* = significance value using chi-square test

and activate the trigeminal nociceptors, causing postoperative pain [55]. Previous studies have reported that bioceramic-based sealers combined with different obturation techniques were better than or comparable to resin-based sealers in terms of incidence and intensity of postoperative pain [56–59]; however, no comparison between different types of bioceramic-based sealers have been made. In the present study, C-Root SP combined with the SC technique has certain advantages in relieving postoperative pain (incidence and intensity), particularly on day 1 after operation; thus, the null hypothesis that no significant difference exists in postoperative pain response among the three groups was partially rejected. One of the reasons is that calcium silicate was replaced with strontium silicate in C-Root SP [24, 27]. In addition, Strontium Ranelate induces analgesia in patients with arthritis by inhibiting the release of inflammatory cytokines into the inflamed joints [60]. Therefore, we speculated that C-Root SP may alleviate postoperative pain following root canal filling and is partially related to strontium silicate.

Several clinical trials, retrospective studies, systematic reviews, and metaanalyses revealed that clinical outcomes of using calcium silicate–based sealers combined with different obturation techniques were similar to or better than other obturation materials and techniques. In particular, bioceramic-based sealers can play crucial roles in reducing acute inflammation and promoting periapical healing [9, 11, 61, 62]. However, the clinical effects of using strontium silicate–based sealers combined with different obturation techniques remain unclear.

This randomized clinical study aimed to investigate success rates and changes in PAI scores using C-Root SP combined with different obturation techniques in older patients. Both success rates and PAI scores were similar for the patients allocated to all groups at baseline and 1 year of follow-up using either per-protocol or ITT analysis. Our study's treatment approaches effectively reduced the PAI score from 2.93 to 3.00 at baseline to 1.89–2.10 after 1 year of follow-up ($P < 0.001$ for all analyses). Furthermore, the success rate for all four groups in the 1-year review was > 91.23%; however, no significant differences were observed between the four groups ($F = 0.680$, $P = 0.892$). This finding is consistent with those of previous studies [9, 36]; hence, the relevant null hypothesis is accepted. Therefore, the clinical efficacy of C-Root SP combined with different obturation techniques and iRoot SP combined with SC in older patients can be deemed equivalent.

Finally, several factors affect the success rate of root canal therapy in older patients, including root canal preparation, disinfection, and obturation. These steps can be effectively performed if the overall treatment is successful, particularly when considering the unique challenges posed by dental pulp aging. With age, pulp tissue undergoes changes such as increased fibrosis and reduced vascularization [63], making endodontic treatment initiation more challenging. Because this study included older patients, the root canal size was smaller because of pathological and age-related calcification. Even anterior teeth with single root canal rarely required preparation beyond X4 (40/0.06) or X5 (50/0.06). Although removing root canal infections was crucial, appropriate irrigation and disinfection strategies were also essential for infection control. Furthermore, excessive removal of the root canal wall should be avoided, as thinning increases the risk of root fractures [64]. The operator's expertise is a key factor, as their skills and knowledge in providing high-quality endodontic treatment affect the prognosis and outcomes of therapy [13].

To the best of our knowledge, this is the first clinical trial on the use of strontium silicate–based sealers combined with different obturation techniques in older patients. The limitations of this study include the relatively small number of teeth and patients, diversity of periapical tooth status, not using the splitmouth design to eliminate individual factors [58], and short observation duration. Nevertheless, the patients in this study are still

in a recall program to collect long-term data and validate the outcomes of our findings.

Conclusions

Within the limitations of this clinical randomized study, the following conclusions can be drawn: C-Root SP combined with different obturation techniques presented outcomes similar to those of iRoot SP combined with the SC technique in terms of root canal filling length, success rate, and changes in PAI scores in older patients. The SC technique could significantly improve the efficiency of clinical procedures. It may have an advantage in reducing the incidence and intensity of early postoperative pain when combined with C-Root SP. Nevertheless, multicenter prospective long-term clinical trials involving larger sample sizes and different diagnoses should be conducted to obtain specific conclusions regarding the outcomes of using these obturation techniques and sealers.

Abbreviations

NSRCT	Nonsurgical root canal treatment
SC	Single-cone technique
WVC	Warm vertical compaction technique
CLC	Cold lateral condensation technique
WL	Working length
GP	Gutta-percha
NRS	Numeric rating scale
PAI	Periapical index
ITT	Intention-to-treat

Author contributions

F.C.: conceptualization, methodology, investigation, project administration funding acquisition. L.D., J.L. and P.X.: investigation, data curation and drafting and writing the manuscript. S.H. and L.L.: investigation and data curation. C.X. and L.W.: radiographically analysis. H.H. and Q.L.: writing review & editing, and supervision. All authors contributed to the study conception and design and read and approved the final manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval for this study was obtained from the Ethics Committee of the First Medical Center of PLA General Hospital (No. S2023-141-01). The study was conducted in accordance with the Declaration of Helsinki. Informed consents were obtained from the patients in written form.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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