Outcome of Sealer-based Obturation Using Calcium Silicate Sealers: A 5-year Follow-up of a Randomized Clinical Trial

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Outcome of Sealer-based Obturation Using Calcium Silicate Sealers: A 5-Year Follow-up of a Randomized Clinical Trial

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ABSTRACT

Outcome of Sealer-based Obturation Using Calcium Silicate Sealers: A 5-Year Follow-up of a Randomized Clinical Trial

The selection of an effective root canal obturation method remains a critical component of nonsurgical endodontic practice, continually evolving alongside improvements in sealing materials. Although the continuous wave of condensation (CWC) filling technique using AH plus is still regarded as the gold standard, identifying optimal filling techniques remains in the limelight of ongoing research.

Previously, a short-term randomized controlled trial comparing CWC with AH Plus to sealer-based obturation (SBO) with Endoseal TCS was reported. In this study, the same patient cohort was followed up for five years to analyze the long-term clinical and radiographic findings of CWC and SBO. This follow-up study aimed to assess healing progression and investigate factors influencing long-term success, offering one of the few long-term evaluations of SBO techniques utilizing calcium silicate sealers.

For comparing the healing outcomes, chi-square tests or Fischer's exact tests were used. For identifying the predictors of healing outcomes, multivariate logistic regression analysis with a stepwise method was employed. Kaplan–Meier analysis accompanied with the log-rank test was performed to compare the success probability between the CWC and SBO group over the 5-year-follow-up period. A significance level of $\alpha = 0.05$ was used.

Of the 96 teeth included in the previous study, 60 teeth (recall rate: 62.5%) were available for final analysis after five years, with a mean follow-up period of 62 months. Four teeth were extracted for reasons unrelated to root canal treatment, leaving 56 teeth (CWC: 33; SBO: 23) for clinical and radiographic evaluation. The success rate by loose criteria was 83.9% (CWC: 81.8%; SBO: 87.0%), and by strict criteria was 76.8% (CWC: 75.8%; SBO: 78.3%), with no significant differences observed between the groups.

In this study, none of the analyzed factors demonstrated a significant correlation with 5-year long-term success. Notably, sealer extrusion and post-obturation pain within two days after treatment—factors previously associated with success—did not show a significant relationship under either the loose (extrusion: OR = 6.584, p = 0.066; moderate pain: OR = 2.761, p = 0.520; severe pain: OR = 0.0, p = 0.999) or strict criteria (extrusion: OR = 4.005, p = 0.099; moderate pain: OR = 2.611, p = 0.522; severe pain: OR = 1.543, p = 0.794). Kaplan-Meier analysis and the log-rank test indicated no statistically significant difference in healing outcome between the two groups under either criterion ($\chi^2 = 1.323$, p = 0.250 for the loose criteria; $\chi^2 = 1.286$, p = 0.257 for the strict criteria).

This five-year follow-up study reaffirms that SBO technique with Endoseal TCS can be a viable alternative to the CWC technique with AH Plus.

Key words: **Outcome; root canal treatment; calcium silicate sealer; sealer-based obturation**

1. Introduction

The choice of an effective method for root canal obturation is a vital part of nonsurgical endodontic practice, which continually adapts to the advancements in new sealer materials and their properties. Although the warm vertical compaction technique using epoxy-resin-based sealers like AH plus is considered the gold standard[1,2], the field of endodontic research is actively exploring optimal canal filling methods. This exploration is motivated by developments in calcium silicate sealers and those derived from mineral trioxide aggregate (MTA), alongside improvements of rotary nickel–titanium (NiTi) instruments, representing significant progress in the endodontic field.

Gutta-percha (GP) alone is insufficient for completely sealing the canal; it is typically used with sealers to address the minor discrepancies between the GP and the canal walls, as well as the complexities of the root canal systems. Traditionally, epoxy-resin-based sealers have been favored for their ability to maximize the volume of GP used while minimizing the sealer's presence within the root canal, due to their limitations related to microleakage, dimensional stability, and biocompatibility. Therefore, while it is recommended to apply the minimal necessary amount of traditional sealers to overcome their limitations, calcium silicate sealers (CSS) stand out as they are not constrained by the quantity used, offering a notable advantage in endodontic treatments. The initial clinical application of non-surgical root canal treatment (NSRCT) using CSS was documented in 2018 utilizing EndoSequence Bioceramic Sealer (Brasseler USA, Savannah, GA), which demonstrated a promising success rate of 90.9%[3]. This retrospective study lacked a control group, and subsequent clinical research on CSS success rates is yet to be published. Although sealer-based obturation techniques (SBO) with traditional sealers generally shows lower success compared to other compaction techniques, SBO using CSS has not been adequately compared to these methods[4].

In clinical settings, the emerging preference for SBO techniques, particularly those using CSS, is evident due to their hydrophilicity, ease of use, adaptability in treatment, biocompatibility, and reduced susceptibility to technique-related errors.[5-7] However, concerns persist about potential issues such as sealer washout in the apical region due to the unique properties of CSS and the risk of void formation in irregular canal morphologies.[8,9]

Although CSS has been the subject of numerous laboratory investigations highlighting their performance, their clinical application is still in the nascent stages with few prospective clinical trials substantiating their effectiveness in real-world scenarios. In vitro studies focusing on CSS are prevalent, yet clinical trials remain scarce

This study is significant as it provides an in-depth analysis of a 5-year follow-up dataset from a clinical trial initiated in 2018[10], markedly enriching the existing literature with insights into the long-term efficacy of contemporary canal filling techniques. The goal of this randomized prospective clinical trial was to evaluate the clinical and radiographic outcomes of root canal treatments using a SBO technique with a calcium silicate sealer compared to the conventional root canal filling by Continuous wave of condensation (CWC) technique with resin-based sealer.

This research builds on the initial short-term findings by evaluating the five-year performance and reliability of two specific endodontic obturation techniques: CWC and SBO. The original study established a baseline for immediate postoperative outcomes and identified critical predictors of treatment success and failure[10]. This follow-up study aims to verify the sustainability of these outcomes and identify additional long-term predictors, thus offering a deeper understanding of the durability of endodontic treatments.

2. Materials and methods

This randomized clinical trial was initially approved by the Institutional Review Board of Yonsei University Dental Hospital (no. 2-2018-009) and registered with the Clinical Research Information Service (CRIS, no. KCT0006230: 2021/06/08). The initial study, conducted in 2018, aimed to compare the pain levels during the first 2 days after obturation, the quality of root canal obturation, alongside the short-term clinical outcomes, adhering to the Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) guidelines (Nagendrababu et al., 2020). Informed consent was obtained from all participants.

Following this short-term study, a five-year follow-up was conducted and analyzed to evaluate long-term clinical outcomes in the same cohort. This follow-up was approved by the Institutional Review Board of Yonsei University Dental Hospital (no. 2-2023-0035). Participants were recalled to the clinic for comprehensive follow up assessments, including clinical and radiographic examinations. Through this, the determination of the sustained efficacy and success of the treatment over an extended period was possible.

2.1. Patient Selection

The study was conducted with patients recruited at the clinic of the Department of Conservative Dentistry, College of Dentistry, Yonsei University, Seoul, Korea, from April to September 2018. Eligible participants were over 18 years of age, healthy (American Society of Anesthesiologists classification I or II)[11], and exhibited teeth with fully formed apices that required either initial root canal therapy or retreatment. Prior to participation, each subject provided written informed consent after a thorough explanation of the study's objectives and procedures. Diagnostic evaluations, including periapical radiographs, periodontal probing, percussion testing, and sensibility assessments, were performed. Teeth diagnosed with asymptomatic irreversible pulpitis and/or pulp necrosis, with or without chronic apical periodontitis, were included in the study. The exclusion criteria were as follows:

1. Patients with impairments in communicating their symptoms due to psychological disorders
2. The teeth affected by cracks, severe periodontal bone loss due to chronic periodontitis, accompanied by tooth mobility, etc.
3. Teeth with root canals not negotiable within 2mm of the radiographic apex
4. Teeth showing signs and symptoms indicating they were not ready for root canal filling at the subsequent visit after canal enlargement.

In the previous 2018 study, the required sample size was calculated with G*Power 3 software (Franz Faul, University of Kiel, Germany). The determined sample size facilitated the adequate comparison between two experimental groups, with parameters set to a 5% significance level, 80% statistical power, an equivalence limit of 15%, and an effect size of 0.58, based on prior research[12].

The calculated sample size for the initial randomized clinical trial was 50 teeth per group. Building on this previous short-term study, our current research conducted a follow-up of the same cohort to assess the long-term outcomes.

2.2. Preoperative clinical and radiographic evaluations

Prior to treatment initiation, a detailed clinical and radiographic assessment was performed on each tooth of the patients. This evaluation included percussion testing and periodontal probing, along with search for any sinus tracts. Pulp sensibility was determined through both cold and electric pulp tests to verify the necessity for root canal treatment. At access opening, the lack of vital tissue in the pulp chamber signified pulp necrosis, and bleeding in the pulp chamber indicated vital pulp. Additionally, the periapical status was evaluated and categorized according to the criteria of periapical index (PAI) score.

2.3. Treatment procedure and randomization

This study serves as a follow-up to the previously published research titled 'Clinical Efficacy of Sealer-based Obturation Using Calcium Silicate Sealers: A Randomized Clinical Trial (JOE (2022)[10])', employing the same treatment protocols and patient cohort for a comprehensive 5-year evaluation. Root canal treatments were carried out by a team of six dentists from the Department of Conservative Dentistry, College of Dentistry, Yonsei University, Seoul, Korea, comprising five postgraduate residents and one professor. All procedures were completed over a minimum of two visits.

During the first visit, local anesthesia was administered using 1.8 mL of 2% lidocaine with 1:80,000 epinephrine (Huons, Sungnam, Korea), followed by rubber dam isolation. After access opening, working length measurements were obtained with an electronic apex locator (Root ZX II;

J Morita, Irvine, CA). Each operator prepared the canals using their chosen rotary instrument, with the master apical file size determined based on the initial apical measurement. Irrigation was performed with 2.5% sodium hypochlorite delivered via a 27-gauge or 30-gauge side-vented needle. In cases of severe contamination, passive ultrasonic irrigation (Endosonic Blue; Maruchi, Wonju, Korea) was used. All procedures were conducted under magnification with an operating microscope (OPMI PICO; Carl Zeiss, Göttingen, Germany).

Patients showing minimal or no signs and symptoms at the subsequent check- up included in the study. Participants who provided written informed consent were enrolled. Participants who provided written informed consent were included in the study. A research assistant, unaware of the study's specific objectives, generated a randomized list following the protocol outlined in the previous short-term clinical trial (Kim et al., (2022)[10]) according to the Sealed Envelope website. For proper allocation concealment, the list was stored securely and was only accessed by the assistant after participants were enrolled but prior to treatment allocation. Participants received an enrollment number and were randomized into one of two obturation groups: CWC with AH Plus or SBO with Endoseal TCS (Maruchi, Wonju, Korea).

For root canal obturation, adaptation of gutta-percha cone (DiaDent, Cheongjusi, Korea) followed by taking a periapical radiograph was carried out to verify the adequate filling length. To dry the canals, sterilized paper points were applied before obturation. In the SBO group, Endoseal TCS was applied by a 24-gauge needle tip into the middle third of the canal. The adapted individual gutta-percha cone was placed and moved up and down three times to ensure optimal sealer distribution. If needed, additional gutta-percha cones were added to enhance sealing of wide canals. The gutta-percha was cut at the orifice and vertical force was applied with the Obtura S-Kondenser (Obtura Spartan, Earth City, MO) for compaction.

In the CWC group, AH Plus sealer was applied on the surface of gutta-percha cones before being inserted into the canals. SuperEndo Alpha 2 (B & L Biotech, Ansan, Korea), a heated plugger was then used to cut and compact the master cone, stopping 4–5 mm short of the working length. This was followed by the backfill of the canal using the thermoplastic injection technique with SuperEndo Beta 2 (B & L Biotech, Ansan, Korea).

2.4. Post-operative and 5-year follow up

In the follow-up of the initial short-term study, majority of the participants attended regular recall visits where the radiographic and clinical assessments were performed on the treated tooth. For those who did not attend these visits, 5-year follow-up appointment was scheduled through phone calls. Participants were reassessed after five years to evaluate the long-term outcomes of the endodontic treatments. Three primary outcomes were the main focus of the evaluation: the pain levels during the first 2 days after obturation, the quality of root canal obturation, and healing outcomes. Assessments of residual pain to determine any long-term discomfort and examining the quality of the root canal fillings via radiographs to ensure their continued integrity. Additionally, healing outcomes were assessed for signs of periapical recovery or any adverse changes. For patients who did not attend follow-up visits, phone calls were made to inquire about symptoms and whether the tooth had been extracted. When possible, records from other dental clinics were obtained, and the reasons for extraction were documented. This long-term analysis aimed to validate the effectiveness and reliability of the CWC with AH Plus sealer and SBO with Endoseal TCS previously administered, providing insights into their sustained impacts on patient outcomes.

2.5. Outcome variables

2.5.1. Preoperative and postoperative pain assessment

Before administering local anesthesia at the initial visit, patients rated their pain on a 0–10 numeric rating scale (NRS), where 0 indicated no pain and 10 the worst possible pain. A modified Wong-Baker FACES scale was also provided to patients to assist them in rating their pain along with the numeric scale. This rating provided a numerical measure of the patient's preoperative pain levels.

Additionally, preoperative sensitivity was clinically evaluated through a detailed percussion test. This involved gently tapping the treated tooth to assess for tenderness or discomfort, which could indicate sensitivity or inflammation. The test was conducted with care to ensure that any sensitive response was accurately recorded.

After canal obturation, the patients reported their pain levels via their preferred method of communication, either wired or wireless, at predetermined intervals: 4-, 24-, and 48-hours following canal obturation. The highest pain score noted across these three consecutive time points was then classified into one of four broader categories[13]:

1. None (NRS 0): The patient experienced no discomfort, indicating that the treated tooth was completely asymptomatic.
2. Mild (NRS 1–3): The patient experienced slight pain at the treated tooth, but the discomfort did not necessitate the use of analgesics.
3. Moderate (NRS 4–7): The patient experienced discomfort and pain at the treated tooth which was generally bearable; however, analgesics were occasionally required.

4. Severe (NRS 8–10): The pain was intense enough to disrupt normal activities or sleep, and analgesics were either ineffective or provided minimal relief.

The highest pain score recorded across these three time points is defined as " the pain levels during the first 2 days after obturation," clarifying that it specifically refers to the peak pain experienced shortly after the root canal procedure, not pain occurring at later follow-up stages.

2.5.2. Quality of root canal obturation

The quality of root canal obturation was assessed based on the presence or absence of sealer extrusion, as well as the presence of root-filling voids and the level of root filling. Periapical radiographs, taken immediately after canal obturation, were reviewed by two blinded, calibrated examiners (S.K. and M.S.). Sealer extrusion and root-filling voids were each categorized as either “present” or “absent”. In the case of multirooted teeth, the occurrence of either sealer extrusion or root-filling voids in any root was classified as “present” for the entire tooth.

As the study excluded cases with inadequate working length, specifically those where the root filling was not within 2mm of the radiographic apex, the level of the root filling was documented as either “adequate” or “long”. Root fillings that extended beyond the radiographic apex were classified as long, while all others were considered “adequate”.[14] In cases of initial disagreement between examiners on the classification of sealer extrusion, root-filling voids, or root-filling level, a consensus was reached through discussion.

2.5.3. Periapical evaluation & Healing outcomes

The participants were recalled after a minimum of five years, and at the appointment, radiographic and clinical examinations of the treated tooth were conducted. For patients missed the regular recall visits, appointments were scheduled by phone to ensure follow-up.

The periapical status of root-filled teeth was assessed using the Periapical Index (PAI) scoring system described by Ørstavik et al.[15], which categorizes periapical health on a five-point scale. This system classifies periapical health on a five-point scale, ranging from healthy periapical bone structures to severe apical periodontitis (AP). The scoring is based on reference radiographs supported by verified histological findings. To maintain consistency, additional verbal descriptive guidelines from both Ørstavik et al.[15] and Kirkevang et al.[16] were incorporated in addition to these visual references. Preoperative and follow-up radiographs were independently assessed for PAI scores by two independent, blinded, and calibrated examiners (S.K., M.K.). The descriptive guideline for PAI scoring were defined as follows:

PAI 1: Normal periapical structures or normal apical periodontium

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 radiating expansion of bone structural changes.

For multirooted teeth, the final assessment was based on the highest PAI score recorded among all roots. Any discrepancies in radiographic or clinical evaluations between the examiners were resolved through discussion until a consensus was reached.

Healing was defined as the reduction in lesion size along with the absence of clinical symptoms. Clinical evaluations included assessments for pain, swelling, sinus tract presence, and tooth functionality. Following the previously established research, teeth were categorized into the following three evaluation criteria based on the changes observed in the size of the apical radiolucency, indicating success or failure.[4, 17, 18]

1. 'Strict' radiographic criteria of success: Asymptomatic tooth with no detectable apical radiolucency at follow-up examination (Fig.1).

2. 'Loose' radiographic criteria of success: Asymptomatic tooth showing a reduction in the size of apical radiolucency at follow-up examination (Fig.1).

3. Failure: Non-functional, symptomatic teeth with no change or an increase in size of radiographic apical radiolucency (Fig.2).

A discussion resolved disagreements regarding radiographic and clinical examination until a final consensus was reached.

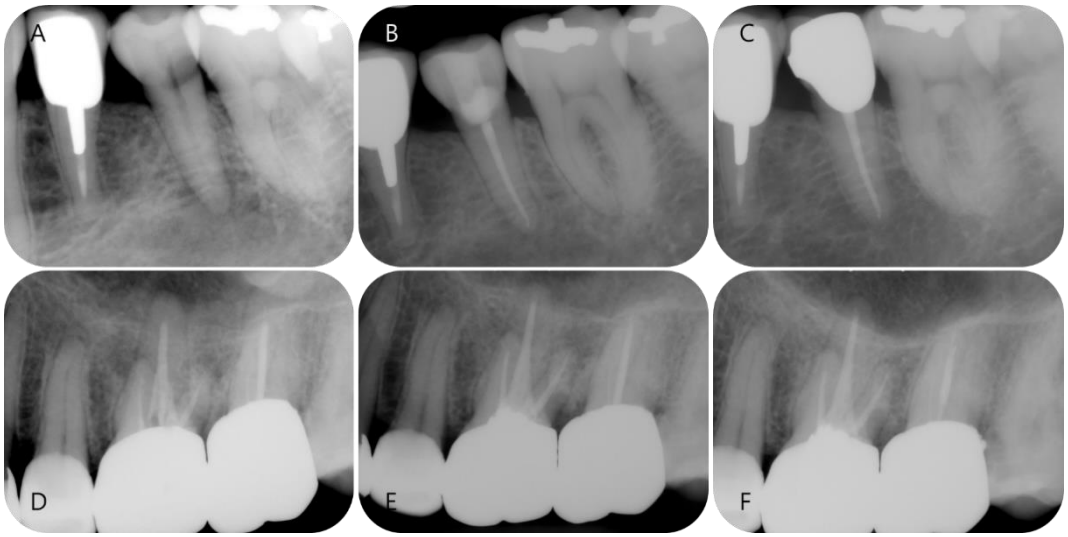

Figure 1. Representative periapical radiographs of cases in each category of success.

A. Preoperative radiograph of the mandibular left first premolar with a periapical lesion. B. Postoperative radiograph after treatment with the Continuous wave of condensation technique. C. The 64-month follow-up radiograph shows a normal contour of the periodontal ligament, with no clinical signs and symptoms. The outcome is considered "successful" under strict criteria.

D. Preoperative radiograph of the maxillary left first molar with a periapical lesion. E. The tooth was treated with the Continuous wave of condensation technique. F. The 60-month follow-up radiograph shows a reduction of the former radiolucency, and the tooth was asymptomatic at the time of clinical examination. The outcome is considered 'successful' only under loose criteria.

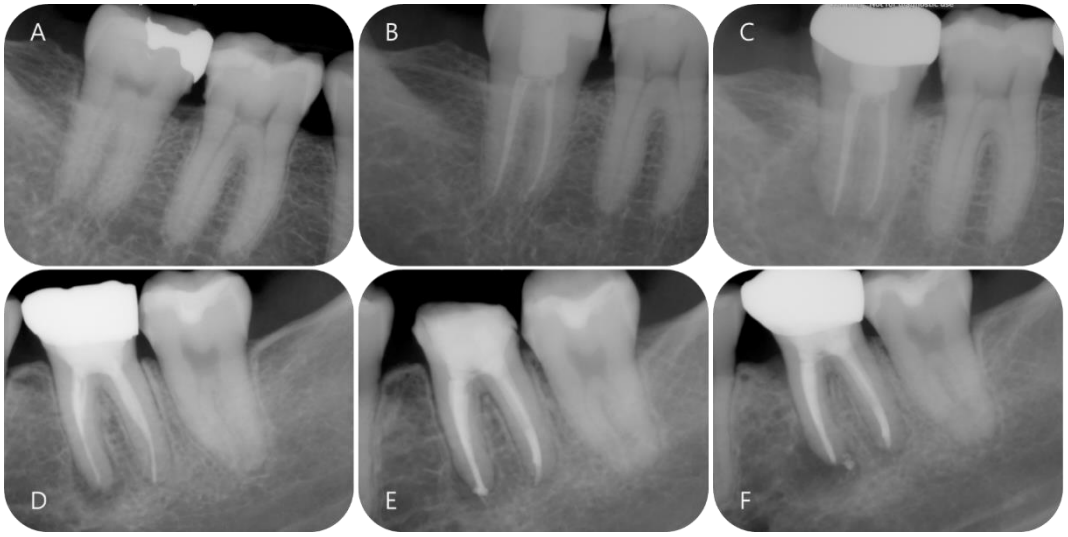

Figure 2. Representative periapical radiographs of cases in the category of failure.

A. Preoperative radiograph of the mandibular right second molar with a periapical lesion. B. Postoperative radiograph after treatment with the Continuous wave of condensation technique. C. In the 63-month follow-up radiograph, while the apical radiolucency around the distal root has decreased, an increase in radiolucency around the distal root can be observed. The outcome is

considered ‘failure’. D. The preoperative radiograph of the mandibular left first molar with a periapical lesion. E. The tooth was treated with the Sealer based obturation technique. F. The 63-month follow-up radiograph still shows radiolucency around the apex of mesial and distal root. The outcome is considered ‘failure’.

2.6. Statistical analysis

Demographic characteristics, the pain levels during the first 2 days after obturation, and the quality of root filling between the two groups were analyzed using the Chi-square or Fisher’s exact test. The healing outcomes were statistically compared using the same test. Variables with a p-value <0.20 from the bivariate analysis were included in a binary logistic regression model to identify the predictors of outcomes; a stepwise method was employed to investigate the factors associated with the outcome. The Kaplan-Meier survival curve was constructed to show the cumulative risk of failure associated with two obturation methods. This analysis included patients who did not complete the five-year follow-up, incorporating data up to their last examination. Statistical analyses were performed using SPSS software (version 27; IBM Corp, Armonk, NY, USA).

3. Results

3.1. Data Distribution

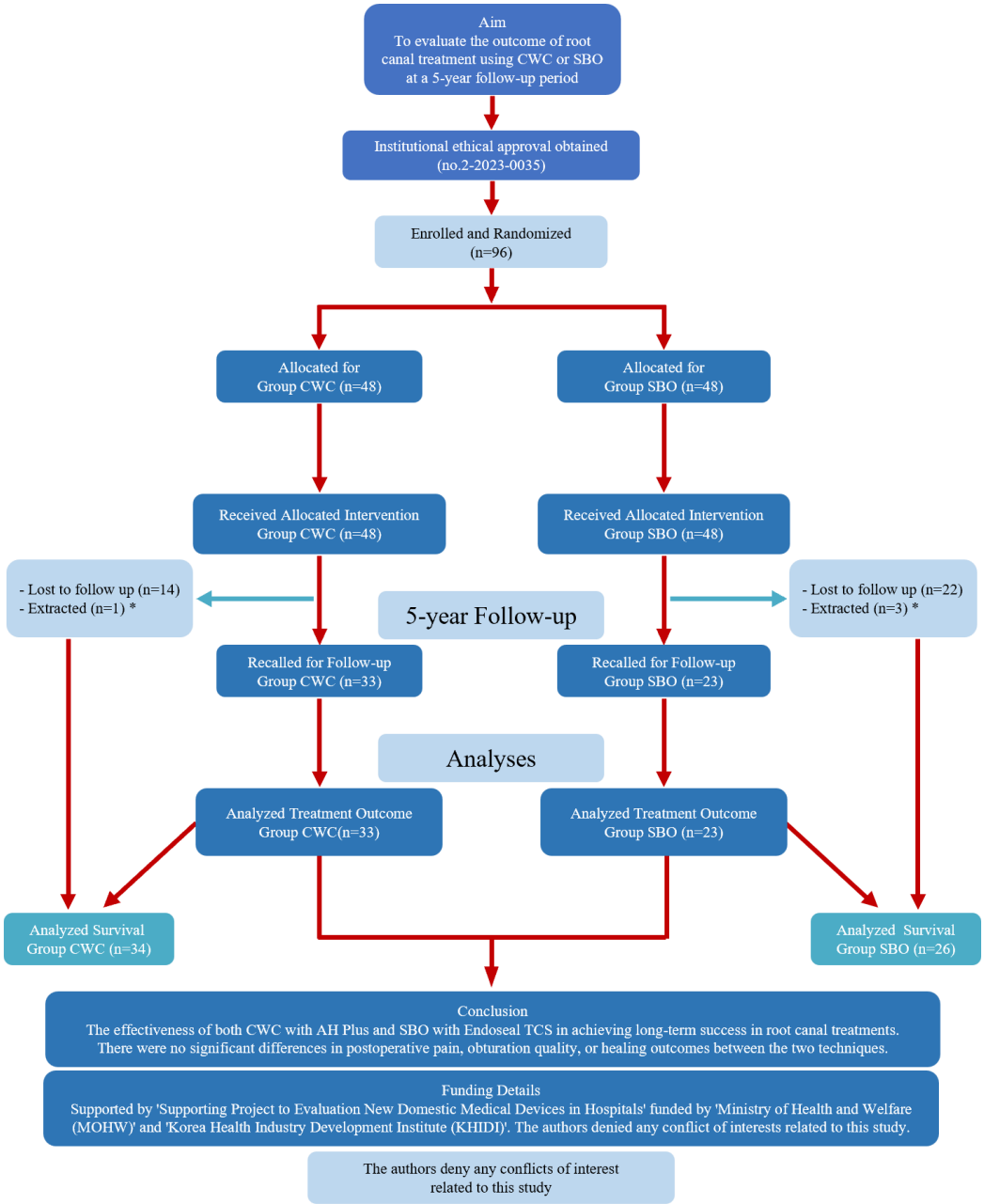

Figure 3. PRIRATE 2020 flowchart

Initially, 90 participants (96 teeth) were enrolled in this clinical trial. However, 34 participants (36 teeth) did not complete the 5-year follow-up, leaving data from 56 participants (60 teeth) for analysis, resulting in a recall rate of 62.5%. The recall rate was higher in the CWC group (34 out of 48 teeth, 70.8%) than in the SBO group (26 out of 48 teeth, 54.2%). However, a chi-squared test showed no statistically significant difference in recall rates between the two groups ($p = 0.091$). The mean follow-up period was 62 months (range: 60–67 months), excluding cases of early failure.

Three teeth were extracted in the SBO group and one tooth in the CWC group, with the reasons for extraction provided in Table 1. None of the teeth were extracted due to endodontic complications. Tooth survival was 97.0% in the CWC group and 88.5% in the SBO group ($p = 0.186$). Of the extracted teeth, two were molars, and the remaining two were premolars.

Table 1. The rationale for extraction

Category	**Pulp Status**	**CWC** (*n = 1*)	**SBO** (*n = 3*)
Vertical root fracture	Necrosis		1
Periodontal disease progression	Vital		1
Fracture of the crown	Vital		1
No information available	Previously Treated	1	

Accordingly, 56 teeth were included in the analysis of healing outcomes, with an average follow-up of 62 months (range: 60–67 months), excluding 4 cases that required extraction within 5 years. The characteristics of these 56 teeth are presented in Table 2.

Of the 56 teeth analyzed in this study, 54 had permanent restorations up to the crown, with no evidence of marginal caries or leakage. Additionally, two teeth were only restored with a resin core and had not yet received permanent crown restorations. However, clinical and radiographic examinations confirmed the absence of marginal caries or leakage in these cases.

Table 2. Characteristics of patients 5 years after the obturation

		CWC (*n = 33*)		SBO (*n = 23*)		Total (*n* = 56)		
Category		N	%	N	%	N	%	***P* value**
Mean age		43.7±17.5		44.5±15.2		44.0±16.6		
Age	<50	20	60.6%	15	65.2%	35	62.5%	0.726
	≥50	13	39.4%	8	34.8%	21	37.5%	
Gender	Female	17	51.5%	10	43.5%	27	48.2%	0.554
	Male	16	48.5%	13	56.5%	29	51.8%	
Location	Maxilla	17	51.5%	12	52.2%	29	51.8%	0.961
	Mandible	16	48.5%	11	47.8%	27	48.2%	
Tooth	Anterior	8	24.2%	3	13.0%	11	19.6%	0.661
	Premolar	7	21.2%	6	0.0%	13	23.2%	
	Molar	18	54.5%	14	60.9%	32	57.1%	
Treatment Type	Initial	26	78.8%	14	60.9%	40	71.4%	0.144
	Retreatment	7	21.2%	9	39.1%	16	28.6%	
Pulp status	Vital	12	36.4%	4	17.4%	16	28.6%	0.198
	Necrosis	14	42.4%	10	43.5%	24	42.9%	
	Previously Treated	7	21.2%	9	39.1%	16	28.6%	
Pain levels during the first 2 days after obturation	None	6	18.2%	6	26.1%	12	21.4%	0.929
	Mild	21	63.6%	14	60.9%	35	62.5%	
	Moderate	4	12.1%	2	8.7%	6	10.7%	
	Severe	2	6.1%	1	4.3%	3	5.4%	
Sealer extrusion	Absent	20	60.6%	18	78.3%	38	67.9%	0.164
	Present	13	39.4%	5	21.7%	18	32.1%	
Void	Absent	25	75.8%	18	78.3%	38	67.9%	0.129
	Present	8	24.2%	5	21.7%	18	32.1%	
Filling length	Normal	31	93.9%	21	91.3%	52	92.9%	1.00
	Long	2	6.1%	2	8.7%	4	7.1%	

CWC, Continuous Wave Condensation Technique; SBO, Sealer Based Obturation Technique

The distribution of the pain levels during the first 2 days after obturation and quality of root canal obturation, along with the bivariate associations with filling techniques, were analyzed. The pain levels during the first 2 days after obturation showed no significant differences between the CWC and SBO groups ($p = 0.929$). Sealer extrusion occurred more frequently in the CWC group compared to the SBO group, but the difference was not statistically significant ($p = 0.164$). Void was more common in the SBO group than in the CWC group, but this difference also did not reach statistical significance ($p = 0.129$). There was no statistically significant difference in filling length between the two groups ($p = 1.000$).

3.2. Treatment Outcome

The demographic and clinical characteristics of the patients revealed no significant differences between the CWC and SBO groups. Both groups displayed similar mean age, gender distribution, tooth locations in the maxilla or mandible, and types of teeth treated. Regarding treatment type, although the proportion of retreatment cases was higher in the SBO group (39.1%) compared to the CWC group (51.2%), this difference was not statistically significant ($p = 0.144$). Overall, the baseline characteristics were balanced between the groups, indicating comparability at the start of the study.

The Kappa score for inter-examiner agreement of the preoperative radiographic evaluation was 0.88, and that of the 5-year follow-up radiographic evaluation was 0.97. The score for the intraexaminer agreement was 0.88 and 0.86 for the preoperative radiographic evaluation, and 0.97 and 0.94 for the 5-year follow-up radiographic evaluation, respectively, after the second radiographic evaluation performed one week later, indicating good agreement.

Table 3. Characteristics of Included Patients and Bivariate Associations between the Investigated Variables and Outcomes Based on Loose and Strict Criteria

			Loose Criteria			Strict Criteria		
	Total		Success			Success		
	n = 56		n = 47 (83.9%)			n = 43 (76.8%)		
Variables	**N**	%	N	%	p value	N	%	p value
Age (y)					0.459			0.101
≦50	**35**	62.5	28	80.0		24	68.6	
>50	**21**	37.5	19	90.5		19	90.5	
Gender					0.073			0.084
Female	**27**	48.2	20	74.1		18	66.7	
Male	**29**	51.8	27	93.1		25	86.2	
Tooth type					0.077			0.056
Anterior	**11**	19.6	10	90.9		8	72.7	
Premolar	**13**	23.2	13	100		13	100	
Molar	**32**	57.1	24	75.0		22	68.8	
Pulp status					0.274			0.443
Necrotic	**16**	28.6	15	93.8		14	87.5	
Vital	**24**	42.9	18	75.0		18	75.0	
Retreatment	**16**	28.6	14	87.5		11	68.8	
Preoperative PAI					0.811			0.685
1	**15**	26.8	12	80.0		12	80.0	
2	**13**	23.2	10	76.9		10	76.9	
3	**5**	8.9	5	100		5	100	
4	**18**	32.1	15	83.3		13	72.2	
5	**5**	8.9	5	100		3	60.0	
Preoperative pain					0.725			0.643
Absent	**29**	51.8	25	86.2		23	79.3	
Present	**27**	48.2	22	81.5		20	74.1	
Preoperative sensitivity					0.493			0.609
Absent	**25**	44.6	20	80.0		20	80.0	
Present	**31**	55.4	27	87.1		23	74.2	

Treatment type					1.00			0.486
Initial	**40**	71.4	33	82.5		32	80.0	
Retreatment	**16**	28.6	14	87.5		11	68.8	
Filling technique					0.723			0.827
CWC	**33**	58.9	27	81.8		25	75.8	
SBO	**23**	41.1	20	87.0		18	78.3	
Sealer extrusion					0.129			0.31
Absent	**38**	67.9	34	89.5		31	81.6	
Present	**18**	32.1	13	72.2		12	66.7	
Void					0.703			0.514
Absent	**38**	67.9	31	81.6		28	73.7	
Present	**18**	32.1	16	88.9		15	83.3	
Filling length					0.514			1.00
Normal	**52**	92.9	44	84.6		40	76.9	
Long	**4**	7.1	3	75.0		3	75.0	
Pain levels during the first 2 days after obturation					0.129			0.258
None	**12**	21.4	10	83.3		9	75.0	
Mild	**35**	62.5	31	88.6		29	82.9	
Moderate	**6**	10.7	3	50.0		3	50.0	
Severe	**3**	5.4	3	100		2	66.7	

* Statistically significant ($p < 0.05$) by t-tests, chi-square tests, or Fisher's exact tests.

The overall 5-year success rate for root canal treatment was 83.9% (47/56) based on loose criteria and 76.8% (43/56) under strict criteria. The CWC group showed a slightly lower success rate of 81.8% (27/33) compared to the SBO group's success rate of 87.0% (20/23) under the loose criteria, with no statistically significant difference between the groups (p = 0.723). According to the strict criteria, the success rate in the CWC group was 75.8% (25/33), comparable to the SBO group with 78.3% (18/23) (p =0.827).

The bivariate analysis showed no statistically significant differences between the treatment groups for both loose and strict criteria, with comparable success rates for CWC and SBO. Gender differences were not significant but indicated a trend towards higher success for male patients. Tooth type and pulp status also did not show significant associations, though necrotic teeth tended to have better outcomes. The pain levels during the first 2 days after obturation and sealer extrusion were non-significant predictors as well. Based on these results, multivariate logistic regression was performed, incorporating treatment group, gender, tooth type, pulp status, the pain levels during the first 2 days after obturation, and sealer extrusion to identify potential predictors of long-term success or failure.

Table 4. Multivariate Logistic Regression Model Identifying Predictors of Treatment Failures Based on Loose Criteria

Variables	OR	95% CI	*P* value
Pulp status			
Necrotic	1		0.500
Vital	0	0	0.998
Retreatment	4.864	0.349-67.794	0.239
Sealer extrusion			
Absent	1		
Present	6.584	0.885-48.989	0.066
Pain levels during the first 2 days after obturation			
None	1		0.157
Mild	0.156	0.015-1.620	0.120
Moderate	2.761	0.125-60.948	0.520
Severe	0	0	0.999

Pseudo-R^2 = 0.461; OR, Odds ratio; CI, Confidence interval; * $p < 0.05$

Table 5. Multivariate Logistic Regression Model Identifying Predictors of Treatment Failures Based on Strict Criteria

Variables	OR	95% CI	*P* value
Pulp status			
Necrotic	1		0.991
Vital	0	0	0.998
Retreatment	1.128	0.193-6.598	0.894
Sealer extrusion			
Absent	1		
Present	4.005	0.770-20.822	0.099
Pain levels during the first 2 days after obturation			
None	1		0.139
Mild	0.221	0.032-1.530	0.126
Moderate	2.611	0.139-49.198	0.522
Severe	1.543	0.060-39.881	0.794

Pseudo-R^2 = 0.389; OR, Odds ratio; CI, Confidence interval ; * $p < 0.05$

A multivariate logistic regression analysis was conducted to determine factors influencing treatment failure based on loose (Table 4) and strict criteria (Table 5). In the logistic regression analysis, variables such as treatment group, gender, tooth type, pulp status, pain levels during the first two days after obturation, and sealer extrusion were initially included as potential predictors of long-term success or failure. However, following the stepwise selection process, only pulp status, sealer extrusion, and pain levels during the first two days after obturation were retained as the most explanatory factors in the final model. This stepwise method identifies the variables that contribute most significantly to the model while excluding those that do not improve its predictive power.

Although treatment group was considered in the initial analysis, it was not included in the final logistic regression model because it did not demonstrate a substantial contribution to explaining the

variance in treatment outcomes. This exclusion aligns with the results of the bivariate analysis, which showed no statistically significant differences in success rates between the CWC and SBO groups under either loose or strict criteria. Similarly, variables like gender and tooth type, despite showing some trends in the bivariate analysis, were also not retained in the final model due to their limited explanatory impact.

This methodological approach ensures that the logistic regression model focuses on the most relevant factors influencing treatment failure. As a result, the treatment group is absent from the logistic regression tables (Tables 4 and 5) since it was not identified as a key predictor of long-term outcomes based on the criteria set for the analysis.

The results of the final model indicate that pulp status, sealer extrusion, and pain levels during the first two days after obturation were the primary variables assessed for their influence on treatment outcomes. While none of these factors reached statistical significance, they remained in the model as they contributed to the overall evaluation of potential predictors of treatment failure. For example, retreated teeth showed a trend towards higher failure rates, as reflected in the odds ratios (OR: 4.864, 95% CI: 0.349-67.794, p = 0.239 under loose criteria; OR: 1.128, 95% CI: 0.193-6.598, p = 0.894 under strict criteria), although these trends were not statistically significant. Similarly, sealer extrusion and pain levels during the first 2 days after obturation did not exhibit significant effects on treatment outcomes under either criterion.

Kaplan-Meier analysis was used to estimate success rates for healing outcomes under both loose and strict criteria. This method included cases that, while not part of the 5-year follow-up, had their status verified during shorter follow-up intervals. A total of 44 teeth from the CWC group and 38 teeth from the SBO group were analyzed to provide a more comprehensive view of expected

success probabilities, incorporating all cases evaluated during the short-term follow-up. For this analysis, "failure to heal" was defined as the event of interest. The Kaplan-Meier survival curves, illustrating these findings, are shown below.

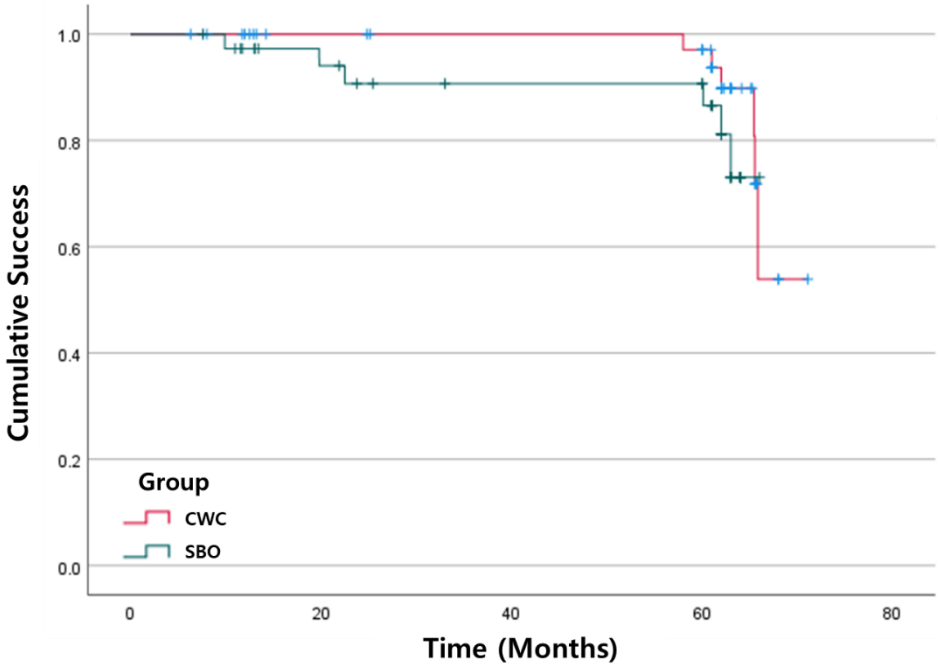

Figure 4. Kaplan-Meier Curves for the Cumulative Success of Treatment Based on Loose Criteria

Kaplan-Meier analysis showed that the 5-year survival rate according to the loose criteria was 97.1% in the CWC group and 86.6% in the SBO group, while the 5-year survival rate according to the strict criteria was 89.8% in the CWC group and 84.4% in the SBO group. The log-rank (Mantel-Cox) test indicated no statistically significant difference in survival between the two groups under either criterion ($\chi^2 = 1.323$, $p = 0.250$ for the loose criteria; $\chi^2 = 1.286$, $p = 0.257$ for the strict criteria).

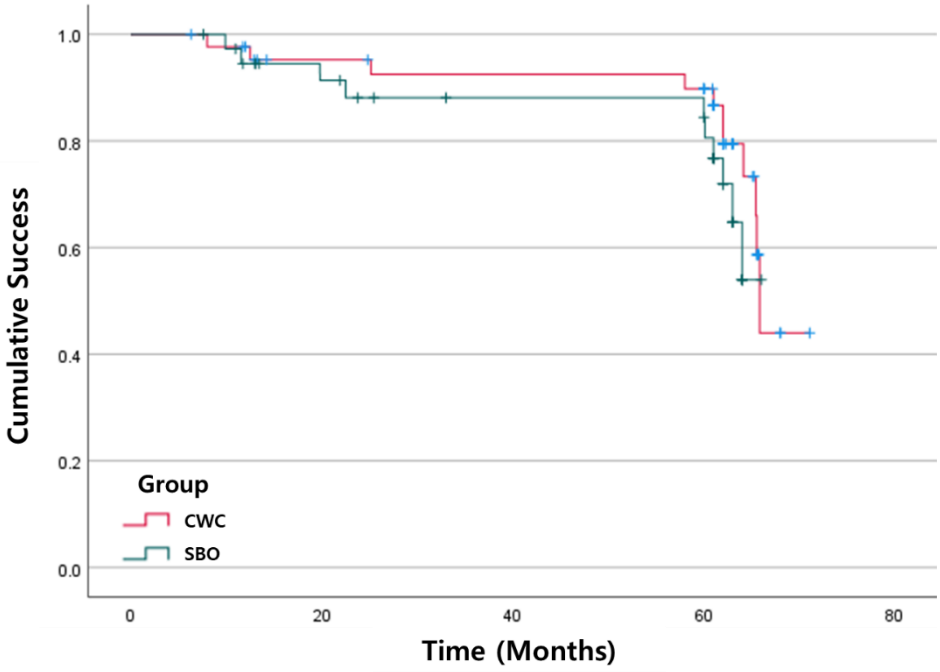

Figure 5. Kaplan-Meier Curves for the Cumulative Success of Treatment Based on Strict Criteria

4. Discussion

This study evaluated the 5-year follow-up outcomes of patients treated with two different root canal obturation techniques, CWC with a resin-based sealer and SBO with CSS. Building on a short-term study involving the same patient cohort, this analysis aimed to identify key factors impacting long-term success and failure. The study is particularly significant as it offers rare insights into the long-term performance of SBO techniques utilizing CSS.

The importance of extended observation periods is well-documented. Ng et al. (2007)[4] highlighted that shorter follow-ups, such as six months, often report higher success rates compared to longer-term studies. Professional guidelines similarly emphasize the need for long-term follow-

up. For example, the American Association of Endodontists[19] advises clinical and radiographic evaluations for four to five years, including an assessment on tooth functionality. The European Society of Endodontology (2006)[20] recommends follow-ups of at least one year, with annual evaluations for up to four years for cases with uncertain healing before determining failure. These recommendations trace back to the foundational work of Strindberg (1956)[21] and highlight the necessity of long-term monitoring, especially for cases where initial healing may be incomplete or reversed due to infection or reinfection.

While recent meta-analyses[17] report slightly higher success rates than those in our study, our findings align with the general trends. The systematic review, which included studies published between 2003 and 2020, reported weighted pooled success rates of 92.6% under loose criteria and 82% under strict criteria. In comparison, our 5-year follow-up yielded success rates of 83.9% for loose criteria and 76.8% for strict criteria. The observed decline in success rates over five years may be attributed to the extended observation period of the same patient cohort. Although previous meta-analyses have often included studies with follow-ups as brief as one year, our study's five-year duration offers a more comprehensive assessment of the long-term stability and efficacy of endodontic treatments.

The comparison of the 1-year and 5-year follow-up results highlights some important findings and trends. The initial short-term study[10], with an average follow-up of 17 months (range: 6–29 months), demonstrated a high overall success rate of 93.2% based on loose criteria, with no significant difference between the CWC (92.3%) and SBO (94.3%) groups. This suggested favorable short-term outcomes for both techniques. In contrast, our 5-year follow-up revealed a slight decrease

in overall success rates. The 5-year success rates under loose criteria were 83.9% overall, 81.8% for the CWC group, and 87.0% for the SBO group, with no significant difference ($p = 0.723$).

On the other hand, under strict criteria, the initial short-term study demonstrated a success rate of 60.8%, with no significant difference between the CWC (51.3%) and SBO (71.4%) groups. The result of 5-year follow up has yielded that under strict criteria, the overall success rates elevated to 76.8%, while shown as 75.8% for the CWC group and 78.3% for the SBO group, again without statistical significance ($p = 0.827$).

This long-term follow-up offers deeper insights into healing dynamics, as periapical lesions can take up to four years to fully resolve after nonsurgical root canal therapy. Initial radiographic improvements may not always reflect stable outcomes, and extended monitoring reveals changes in the healing process (Cheung, 2002)[22]. The following cases highlight the differences between short and long-term results, showcasing the variability in healing over time.

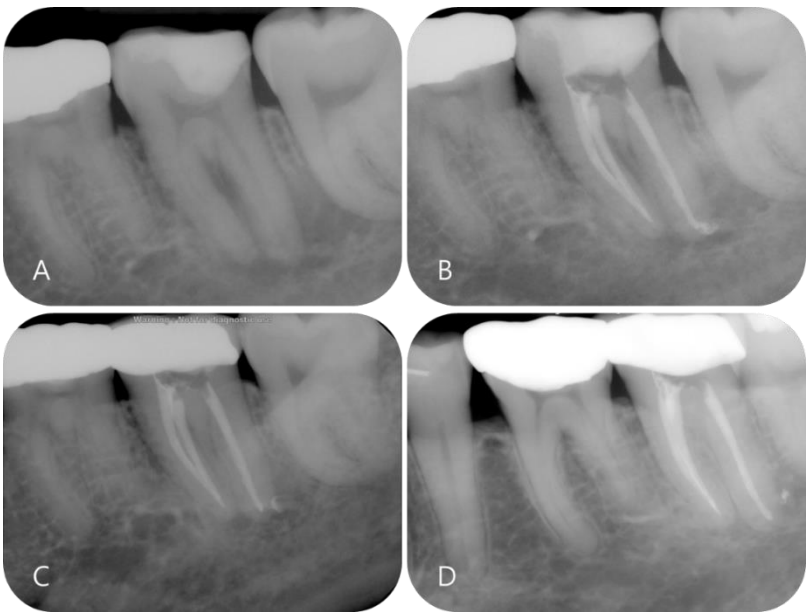

Figure 6. Representative periapical radiographs of a CWC case, showing healing progression

A. Preoperative radiograph of the second molar exhibiting a periapical radiolucency. B. Postoperative radiograph following treatment with the CWC technique. C. One-year follow-up radiograph indicating a reduction in periapical radiolucency, although the lesion has not fully resolved, classifying the case as a success only by loose criteria. D. Five-year follow-up radiograph demonstrating full resolution of the periapical radiolucency, thereby indicating success under strict criteria.

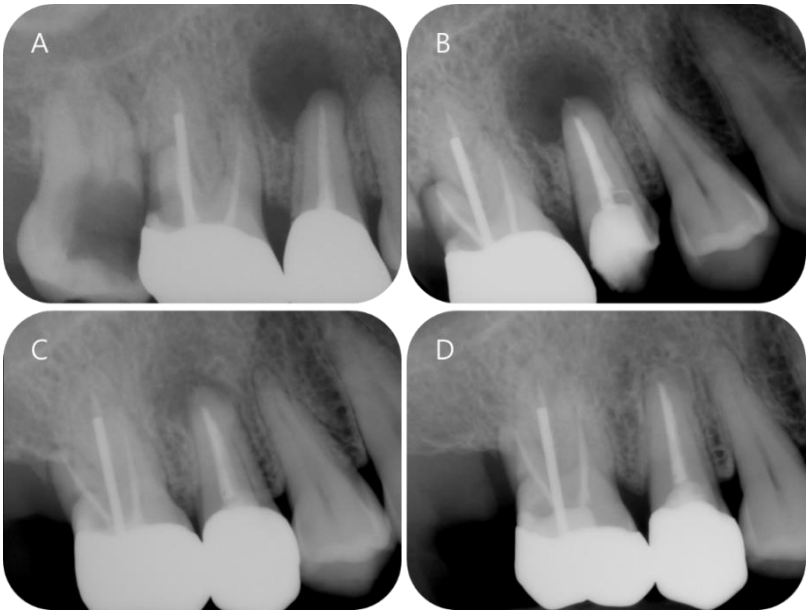

Figure 7. Representative periapical radiographs of an SBO case showing healing progression

A. Preoperative radiograph of the second premolar with periapical radiolucency. B. Postoperative radiograph following treatment with the SBO technique. C. One-year follow-up radiograph indicating a reduction in periapical radiolucency, although the lesion has not fully resolved, classifying the case as a success only by loose criteria. D. Five-year follow-up radiograph demonstrating full resolution of the periapical radiolucency, thereby indicating success under strict criteria.

A 36-year-old female in the CWC group presented with a nonvital mandibular molar

requiring initial root canal therapy (Figure 6). Preoperatively, the tooth exhibited tenderness to percussion without pain. Postoperative radiographs showed sealer extrusion with no voids and adequate filling length. In the SBO group, a 47-year-old male with a previously treated second premolar (Figure 7) presented with preoperative pain and tenderness to percussion. Post-treatment radiographs for both cases revealed sealer extrusion without voids and adequate filling lengths. At the one-year follow-up, all three cases demonstrated partial healing with reduced periapical radiolucency, meeting success under loose criteria, but not under strict criteria. By the five-year follow-up, complete lesion resolution was observed in all cases, indicating successful healing under strict criteria.

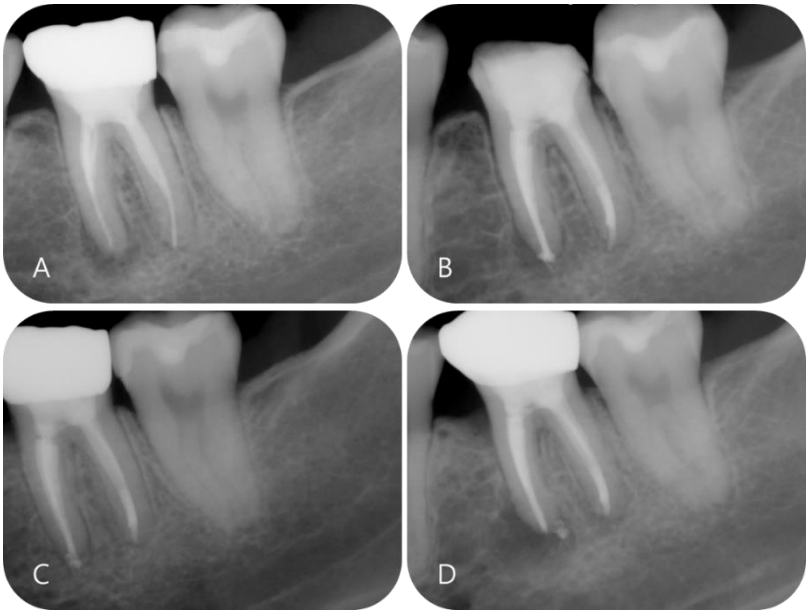

Figure 8. Representative periapical radiographs of a CWC case showing failure of healing

A. Preoperative radiograph of the previously treated first molar exhibiting a periapical radiolucency. B. Postoperative radiograph following treatment with the CWC technique. C. One-year follow-up radiograph indicating a reduction in periapical radiolucency, with the full resolution of periapical

lesion, classifying the case as a success under strict criteria. D. Five-year follow-up radiograph demonstrating recurrence of the periapical radiolucency, thereby classified as ‘failure’ of healing.

On the other hand, a 60-year-old female in the CWC group presented with a previously treated mandibular molar requiring endodontic retreatment (Figure 8). While preoperatively asymptomatic with sensitivity to percussion, the patient reported mild postoperative pain and postoperative radiographs showed sealer extrusion with no voids. Complete resolution of periapical radiolucency in one year suggested strict criteria success. At the one-year follow-up, full resolution of the periapical radiolucency was shown at the periapical radiograph, suggesting successful healing under strict criteria. However, recurrence of periapical radiolucency at five years indicated failure to sustain initial healing under any criteria.

These cases highlight the importance of extended follow-up in endodontic treatment, as short-term radiographic improvements may not reliably indicate long-term stability. The cases from the SBO group (Figures 7) and the CWC group (Figure 6) demonstrated partial healing at the one-year follow-up, meeting success only under loose criteria, while complete resolution of periapical radiolucency by the five-year follow-up fulfilled success under strict criteria. On the other hand, the five-year follow up of the CWC case in **Figure 8** demonstrates the recur of periapical lesion, thereby indicating failure of healing. Initially, the healing outcome observed at the one year follow up appeared successful under strict criteria. This highlights how treatment outcomes can change over time, emphasizing the need for longer-term radiographic monitoring to fully understand the effectiveness and stability of endodontic procedures. Notably, radiographic changes in the SBO group appear to occur more gradually, further underscoring the importance of extended follow-up periods to accurately evaluate the long-term outcomes of endodontic treatments, particularly in the

context of the cases observed in this study.

According to the bivariate analysis, this study did not find statistically significant differences in success rates between the CWC and SBO group under both loose and strict criteria, although the CWC group had a slightly lower success rate. As noted above, long-term follow-up could have contributed to an overall decrease in success rates due to extended observation periods, and the recall rate of CWC group was higher than that of SBO group. In addition to this factor, the higher decrease rate in the success rate of CWC group may be attributed to changes in the proportion of pulp status among the teeth followed up. The 5-year follow-up results demonstrated that the difference in success rates between teeth with different pulp status was not statistically significant ($p = 0.274$, loose criteria; $p = 0.443$, strict criteria). However, a comparison with our initial 1-year follow-up study highlights some notable trends. In the previous research, necrotic pulp cases showed the highest success rate at 100%, followed by retreatment cases at 95.5%, and vital pulp cases at 82.6%, with a statistically significant difference ($p = 0.034$). The current study contained a greater proportion of vital cases in the CWC group (36.4%, 12 out of 33) compared to the SBO group (17.4%, 4 out of 23). While this distribution difference was not statistically significant, it may have contributed to the lower success rates observed in the CWC group. Recent evidence, such as the study by Zahran et al. (2022)[23], emphasizes the importance of stringent contamination control protocols to improve outcomes, especially in vital pulp cases. Their findings showed that an enhanced infection protocol (EnP), involving the replacement of barriers and equipment before obturation, significantly reduced residual microbial contamination compared to a standard protocol. Specifically, the EnP reduced the observed microbial species and overall diversity, supporting the need for more rigorous aseptic techniques to minimize iatrogenic contamination during treatment.

This insight is particularly relevant for vital pulp cases, where maintaining a sterile environment may play a critical role in long-term success.

According to the bivariate analysis, gender differences showed a trend toward lower failure rates in males, but this was not statistically significant and may have been influenced by a higher number of male patients who underwent tooth extraction and were excluded from the analysis. Pulp status followed a similar pattern, with necrotic teeth exhibiting higher success rates than vital teeth, though these differences were also not statistically significant.

Post-obturation pain within two days after treatment did not differ between the two groups, nor significantly influence long-term healing outcomes, as no statistically significant differences were observed between the CWC and SBO groups ($p = 0.929$) nor under both loose and strict criteria in bivariate analysis. This contrasts with the earlier short-term study (Kim et al., (2022)[10]), which suggested a significant association between early post-obturation pain and treatment outcomes. A notable distinction of this study lies in its examination of the relationship between early postoperative pain and long-term treatment outcomes. Unlike prior research[24-27] emphasizing short-term observations, this five-year follow-up demonstrates that early postoperative discomfort is not a reliable predictor of long-term healing outcomes in endodontic treatment. While the short-term follow-up study (Kim et al. (2022)[10]) suggested a potential association between early postoperative pain and treatment success, our findings indicate that early discomfort is not a reliable predictor of long-term success in endodontic treatment.

Consistent with previous research (Yu et al. (2021)[28]; Kim et al. (2022)[10]), sealer extrusion was observed at a higher rate in the CWC group compared to the SBO group, though not statistically

significant. In the previous short-term study (Kim et al., 2022[10]), sealer extrusion was identified as a potential predictor of treatment failure, showing significantly lower success rates in cases with extrusion compared to those without (present: 84.6%, absent: 97.9%; $p = 0.049$).

In contrast, sealer extrusion observed immediately after root canal obturation was found to no longer have a statistically significant impact on treatment outcomes in our current five-year follow-up study. One possible explanation is that, particularly in the SBO group, the extruded material was gradually absorbed over the five-year period, promoting bone healing in that area. These findings suggest that the adverse effects of sealer extrusion observed in the short term may diminish during longer observation periods, particularly in the SBO group. A potential association between the absorption of CSS and improved long-term outcomes warrants further investigation to better understand this relationship. The following cases illustrate instances of sealer extrusion in the SBO group where gradual absorption of the extrusion material and associated bone healing were observed over the five-year follow-up period.

Figure 9. Representative periapical radiographs of an SBO case showing absorption of sealer

A. Preoperative radiograph of the second premolar exhibiting a periapical lesion. B. Postoperative radiograph following treatment with the SBO technique. C. Five-year follow-up radiograph demonstrating full resolution of the periapical radiolucency, indicating success by strict criteria.

In **Figure 8**, which represents a case treated with the CWC technique using AH Plus sealer, the postoperative radiograph (**Figure 8D**) shows that the extruded sealer remains in the periapical area even at the five-year follow-up. Accompanied by the persistence of the sealer, the surrounding bone demonstrates failure of healing, given the increase of periapical and the reversed stability of periapical bone structures compared to the 1 year follow up. On the other hand, **Figure 9** highlights a case from the SBO group. This case features a 25-year-old male patient with a previously treated mandibular molar with no preoperative pain or sensitivity. The re-treatment procedure resulted in sealer extrusion, but no voids were observed, and the filling length was adequate. Notably, the patient reported no postoperative pain. The radiograph at the five-year follow-up (**Figure 9C**) reveals partial absorption of the extruded sealer. Additionally, there is evidence of bone regeneration and complete periapical healing. This outcome underscores the advantages of bioactive sealers, which do not appear to impede bone healing, even in cases of minor sealer extrusion.

Over the five-year follow-up, several cases in the SBO group demonstrated gradual absorption of extruded sealer accompanied by bone healing, suggesting a potential link between calcium silicate sealer absorption and improved long-term outcomes. While it remains uncertain whether these findings are solely attributable to sealer absorption, the study's results indicate that healing progression and radiographic changes in the SBO group tend to occur at a slower pace.

Additionally, despite the higher proportion of retreatment cases in the SBO group (39.1%, 9 out of 23) compared to the CWC group (21.2%, 7 out of 33), the more favorable healing outcomes observed in the one-year short-term clinical study were consistently maintained in the five-year follow-up. Retreatment cases are generally associated with lower success rates, a finding supported by previous studies, such as Sjögren et al. (1990), who reported that only 62% of periapical lesions healed following retreatment. Despite this, our study’s success rates for retreatment cases were

consistent with or higher than those reported in earlier literature, indicating that while retreatment remains a risk factor, outcomes have improved compared to historical data. These findings suggest that the SBO technique may be particularly effective even in retreatment cases, further supporting its potential as a reliable option for challenging clinical scenarios.

This, again, highlights the importance of long-term follow-up, particularly for cases treated with the SBO technique, to accurately evaluate treatment outcomes and monitor the healing process. Although a direct relationship cannot be confirmed, further research is warranted to determine whether the unique properties of calcium silicate sealers contribute to these observations. Investigating the possibility of SBO technique reducing the impact of sealer extrusion could guide future improvements in materials and methods to enhance long-term success of root canal treatment.

Kaplan-Meier survival analysis incorporated data from not only patients who completed the 5-year follow-up but also those who were assessed for shorter observation periods. As a result, the calculated success rates provide a dynamic and continuous view of treatment effectiveness, rather than being limited to outcomes measured solely at the 5-year mark. Kaplan-Meier analysis and the log-rank test indicated no statistically significant difference in healing outcome between the two groups under either criterion ($\chi^2 = 1.323$, $p = 0.250$ for the loose criteria; $\chi^2 = 1.286$, $p = 0.257$ for the strict criteria). The absence of statistically significant differences between the two techniques suggests that both may serve as viable options for long-term root canal obturation, depending on clinical judgment and patient-specific factors. However, accurately determining the timing of endodontic treatment failure in this study was challenging, as continuous short-interval re-examinations were not feasible. Kaplan-Meier analysis ideally requires precise failure dates to

generate accurate survival estimates. As a result, our estimated survival times might be inflated, introducing a potential bias in evaluating long-term success.

Studies with high percentages of patients lost to follow-up may present an overestimated success rate. Wu et al. (2009)[29] emphasized that recall rates lower than 50% are particularly prone to this form of overestimation. In contrast, a systematic review by Ng et al. (2007)[4] found that only 62% of studies included in their analysis reported re-examination rates, with a median rate of 52.7%. A more comprehensive review later noted that 85.7% of studies provided re-examination rates, which ranged broadly from 23% to 100%, with six studies still falling below the 50% mark[17].

Our study achieved a recall rate of 62.5%, which is higher than the threshold identified as problematic by Wu et al. (2009)[29]. This rate compares favorably with those reported in prior research, thereby strengthening the reliability of our findings. Nevertheless, the loss of some participants during the follow-up period still introduces a potential source of bias. To address this, we employed calibrated examiners and adhered to standardized success criteria to ensure methodological rigor. Despite these efforts, the long-term success rates should be interpreted cautiously, acknowledging the impact of follow-up losses.

Our study, which adheres to established standards, provides valuable insights into the factors affecting the long-term success of root canal treatments by comparing outcomes over an extended observation period. We encountered some challenges in achieving the planned sample size due to a restricted recruitment window. The study was funded by a government grant that imposed a strict timeline for resource utilization. To boost participation, we offered small transportation reimbursements for each visit. However, the limited funding period constrained our ability to enroll a sufficient number of participants to ensure the desired statistical power. Additionally, the lengthy

follow-up period led to a higher dropout rate, further complicating our efforts to meet the target sample size.

These findings indicate that both techniques maintain relatively high success rates over an extended period, with a slight increase in success under strict criteria and a decrease under loose criteria observed over five years compared to the short-term results. The lack of statistically significant differences between the CWC and SBO groups across both short-term and long-term evaluations supports the hypothesis that both methods are similarly effective in achieving favorable endodontic outcomes. Factors that significantly influenced success rates at the one-year follow-up were not found to be significant at the five-year follow-up, suggesting that their impact may diminish over time. The observed changes in success rates over time underscores the importance of long-term monitoring and suggests that future studies should continue to explore factors that may influence the durability of root canal treatments over extended periods. Additionally, further clinical research is warranted to better understand the long-term outcomes of the SBO technique.

5. Conclusion

Within the limitations of this study, the five-year follow-up confirms the effectiveness of both CWC with AH Plus and SBO with Endoseal TCS in achieving long-term success in root canal treatments. There were no significant differences in the healing outcomes between the two techniques. However, the gradual absorption of extruded sealer observed in the SBO group, accompanied by bone healing over time, highlights a potential advantage of calcium silicate-based sealers in facilitating long-term periapical healing. Additionally, the slower progression of

radiographic changes in the SBO group underscores the importance of extended follow-up to fully assess its efficacy. Based on these findings, SBO demonstrates the potential to serve as a viable alternative to CWC, offering comparable clinical outcomes and advantages in certain cases. Further research is warranted to validate these observations and optimize material selection in root canal treatments.

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Abstract in Korean

칼슘 실리케이트 실러를 사용한 실러 기반 근관충전의 임상적 효능: 무작위 임상시험의 5 년 추적 연구

본 연구는 5 년 동안 레진 기반 실러를 사용한 continuous wave condensation 충전법과 칼슘 실리케이트 실러를 사용한 sealer based obturation 충전법으로 치료된 치아의 장기적인 임상적 및 방사선학적 결과를 평가하고자 하였다.

총 96 개의 성숙한 영구치가 두 그룹으로 무작위 배정되었으며, 동일한 전통적 근관 와동 형성을 시행했다. 근관은 회전 기구와 2.5% 차아염소산나트륨을 사용하여 준비되었으며, 후속 방문에서 환자들은 무작위로 AH Plus 실러를 사용하는 CWC 그룹과 Endoseal TCS 를 사용하는 SBO 그룹으로 나누어졌다. 근관 충전 후 통증 수준은 숫자 평정 척도(NRS)를 사용하여 기록되었고, 근관 충전의 품질은 실러 돌출, 공극 존재 여부, 충전의 정도를 평가하여 분석하였다. 최소 5 년 후 해당 환자들을 대상으로 추적 관찰을 시행하였으며, 치아는 임상적 및 방사선학적 검사를 통해 평가되었다. 데이터 수집은 근관 충전 후 통증, 근관 충전의 품질, 그리고 Periapical Index(PAI)를 이용하여 치근 주위 치유를 평가하는 데 중점을 두었다. 치유는 치근단 방사선 투과성 병소 크기의 감소와 증상 해소로 판단되었다. 통계적 분석은 카이제곱 검정 또는 피셔의 정확 검정을 사용하였으며, 다변량 분석은 로지스틱 회귀분석을 통해 수행되었다. 또한, 누적 치유 성공률 분석을 위해 카플란-마이어 생존 분석과 로그-랭크 검정을 수행하였다.

환자들은 수술 후 통증을 수치 평가 척도로 평가받았으며, 근관 충전의 품질은 실러 압출, 근관 충전재의 공극, 그리고 충전 길이 정도를 기준으로 평가되었다. 참가자들은 최소 5 년 후에 재방문하였으며, 결과는 엄격한 기준과 느슨한 기준에 따라 각각 성공 또는 실패로 이분화 되었고, 카이제곱 검정 또는 피셔의 정확 검정을 사용해 통계적으로 비교한 후, 로지스틱 회귀 분석을 통한 다변량 분석을 수행하였다.

본 5 년 추적 연구에는 근관 치료를 받고 포함 기준에 부합한 60 개의 치아가 포함되었으며 (회수율 62.5%), 평균 추적 기간은 62 개월(60-67 개월)이었다. 임상 및 방사선학적 추적 관찰 결과 56 개의 치아가 발치 없이 온전하게 유지된 것으로 나타났다. 느슨한 기준에 따른 전체 성공률은 83.9% (CWC 81.8%, SBO 87.0%) 였으며, 엄격한 기준에 따르면 76.8% (CWC 75.8%, SBO 78.3%)으로 나타났으나, 두 그룹 간 유의미한 차이는 발견되지 않았다.

본 연구에서 분석된 요인들 중 5 년 장기 성공률과 유의한 상관관계를 보이는 것은 없었다. 이전 임상 연구와 비교했을 때, 다변량 로지스틱 회귀 분석에서는 실러 돌출이 전체 집단에서 실패의 유의한 예측 인자로 나타나지 않았는데, 이는 느슨한 기준(OR = 6.584, p = 0.066)과 엄격한 기준(OR = 4.005, p = 0.999) 모두에서 동일하게 나타났다. 이전 연구에서는 실패의 주요 예측 인자로 확인되었던 치료 후 2 일 이내의 통증도 느슨한 기준(중등도 통증: OR = 2.761, p = 0.520; 심한 통증: OR = 0.0, p = 0.999)과 엄격한 기준(중등도 통증: OR = 2.611, p = 0.522; 심한 통증: OR = 1.543, p = 0.794) 모두에서 유의한 예측 인자로 나타나지 않았다. 카플란-마이어 생존 분석과 로그-랭크 검정 결과, 두 군 간의 누적 치유 성공률에 있어 느슨한 기준(χ^2 = 1.323, p = 0.250)과

엄격한 기준(χ^2 = 1.286, p = 0.257) 모두에서 통계적으로 유의한 차이를 확인할 수 없었다.

이 연구의 한계 내에서, 이 5 년 추적 연구는 AH Plus 를 사용한 CWC 와 Endoseal TCS 를 사용한 SBO 가 근관 치료에서 장기적인 성공을 달성하는 데 효과적임을 확인하였다. 두 기술 간 근관 충전 시, 치료 결과에 유의미한 차이는 없었다.

핵심되는 말 : 치료 결과; 근관 치료; 칼슘 실리케이트 기반 실러; 실러 기반 근관충전