CONSORT RANDOMIZED CLINICAL TRIAL

Five-Year Outcomes of Root Canal Treatment Comparing Sealer-Based Obturation With Calcium Silicate-Based Sealer to Continuous Wave of Condensation: A Randomized Controlled Trial

Minkyeong Seog, DDS, MSD, Seung-Kyung Kwon, DDS, PhD,* Dohyun Kim, DDS, PhD,* Su-Jung Shin, DDS, PhD,† and Il-Young Jung, DDS, MSD, PhD**

ABSTRACT

Introduction: While sealer-based obturation (SBO) with calcium silicate-based sealers has shown promise in short-term studies, including a previous randomized controlled trial comparing it to the continuous wave of condensation (CWC) technique, long-term evidence on its clinical performance remains limited. This study addresses this critical gap by following the same patient cohort for 5 years to evaluate the long-term clinical and radiographic outcomes of both techniques and investigate factors influencing long-term success. **Methods:** Patients were initially randomized at the time of obturation into 2 treatment groups, based on the obturation protocol: CWC with AH Plus sealer and SBO with Endoseal TCS (TriCalcium Silicate). Postobturation pain was assessed using a numerical rating scale. Root canal obturation quality was evaluated for sealer extrusion, filling voids, and root filling level. Five-year follow-up examinations assessed healing based on periapical index score reduction and symptom resolution. Statistical analysis included chi-square or Fisher's exact tests and multivariate logistic regression. **Results:** Of the initial 93 teeth, 60 (64.5% recall rate) were available for analysis after 5 years (mean follow-up: 62 months). Four teeth were extracted for nonendodontic reasons, leaving 56 teeth (CWC: 33; SBO: 23) for evaluation. Success rates showed no significant differences between groups under both loose (overall: 83.9%; CWC: 81.8%; SBO: 87.0%) and strict criteria (overall: 76.8%; CWC: 75.8%; SBO: 78.3%). No analyzed factors significantly correlated with long-term success. **Conclusion:** The SBO technique with Endoseal TCS demonstrated comparable 5-year outcomes to the CWC technique, supporting its potential as a less technique-sensitive and clinically viable alternative for root canal obturation. *(J Endod 2025;■:1–9.)*

SIGNIFICANCE

Five-year follow-up demonstrated that sealer-based obturation with Endoseal TriCalcium Silicate achieved similar success rates (87.0% loose/78.3% strict criteria) to continuous wave of condensation with AH Plus (81.8% loose/75.8% strict criteria, $P > .05$), providing a simplified obturation alternative.

KEY WORDS

Calcium silicate-based sealers; long-term outcome; root canal obturation; sealer-based obturation

The primary cause of apical periodontitis is microbial infection within the root canal system[1,2]. While canal irrigation and shaping are critical components in the prevention and treatment of apical periodontitis[3], these procedures alone cannot ensure complete disinfection[4]. Consequently, root canal obturation is necessary to entomb residual irritants within the canal system and to minimize coronal leakage from the oral environment[5]. This perspective is supported by a meta-analysis demonstrating that the quality of root canal obturation is one of the factors influencing the outcome of endodontic treatment[6].

Gutta-percha remains the most widely used core material for obturation[5], and AH Plus sealer (Dentsply, DeTrey GmbH, Konstanz, Germany) has been considered as the gold standard in endodontic research[7,8]. In recent years, calcium silicate-based sealers (CSS) have gained significant attention due to their bioactive and biocompatible characteristics[9–11]. Notably, a sealer-based obturation (SBO) using

From the *Microscope Center, Department of Conservative Dentistry and Oral Science Research Center, Yonsei University College of Dentistry, Seoul, Republic of Korea; and †Department of Conservative Dentistry, Gangnam Severance Dental Hospital, Yonsei University, Seoul, Republic of Korea

Address requests for reprints to Il-Young Jung, DDS, MSD, PhD, Microscope Center, Department of Conservative Dentistry and Oral Science Research Center, Yonsei University College of Dentistry, Seoul, Korea 50-1 Yonsei-Ro, Seodaemun-Gu, Seoul 03722, Republic of Korea.
E-mail address: juen@yuhs.ac
0099-2399

https://doi.org/10.1016/j.joen.2025.02.001

CSSs has become popular due to their favorable properties, including hydrophilicity, slight expansion, and high biocompatibility[12]. Although a limited number of clinical studies have reported treatment outcomes for the use of CSSs with SBO, a meta-analysis showed that the SBO with CSS provides similar results compared to other obturation materials and techniques in facilitating the healing of apical periodontitis[13].

Our previous randomized controlled trial also demonstrated that SBO with Endoseal TCS (TriCalcium Silicate) (Maruchi, Wonju, Korea), a novel CSS, could be an alternative to continuous wave of condensation technique (CWC) with AH Plus[14]. However, both our study[14] and other investigations included in the meta-analysis[13] were limited to short-term observations of less than 30 months. While Ng et al.[15] reported that the majority of periapical lesions healed completely within 2 years, the validation of new materials may require extended observation periods. This is exemplified by Resilon, which showed promising short-term results[16], but demonstrated higher failure rates compared to conventional gutta-percha in long-term follow-up studies[17,18]. Consequently, extended clinical observation is essential for proper validation of CSS as a novel material.

The present study followed the same patient cohort from our previous short-term clinical trial[14] for more than 5 years, comparing CWC with AH Plus to SBO with Endoseal TCS, to evaluate long-term clinical and radiographic outcomes. Additionally, we examined associations between healing outcomes and various factors at the 5-year mark.

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, registration no. KCT0006230, registered June 8, 2021). The 5-year follow-up study of the same cohort received subsequent approval from the same institution.

For this study, a noninferiority trial design was employed to compare the success rates between the control and experimental groups. The success rate of the control group was set at 93.3%, as reported in a previous study by Ng et al[19]. The sample size calculation was performed using the methodology described by Blackwelder[20], with a significance level of 5%, a statistical power of 80%, and a noninferiority margin of 15%. The required sample size was determined to be 35 participants per group. To account for a 30% drop-out rate, the sample size was increased to 50 per group, resulting in a total of 100 participants. The present study followed the same patient cohort from the initial trial.

Healthy participants aged 18 years or older, classified as American Society of Anesthesiologists I or II[21], who were asymptomatic or exhibited mild symptoms prior to root canal obturation, were recruited between April and September 2018. Following informed consent, participants were randomly assigned to one of 2 treatment groups.

Randomization was performed using a computer-generated sequence created through the Sealed Envelope website (https://www.sealedenvelope.com/) by a research assistant blinded to the study objectives. The randomization employed a 1:1 allocation ratio with random block sizes of 6. To ensure allocation concealment, the randomization sequence was secured in a locked cabinet and accessed only by the blinded assistant after participant enrollment and immediately before intervention. Based on this randomization sequence, each participant was randomly assigned to one of the 2 groups based on the obturation protocol: CWC with AH Plus sealer or SBO with Endoseal TCS.

In the CWC group, AH plus sealer was applied to gutta-percha cones before insertion into the prepared canals. A heated plugger (SuperEndo Alpha 2; B & L Biotech, Ansan, Korea) was used to cut and compact the master cone 4–5 mm short of the working length. Canal backfilling was then completed using thermoplastic injection with SuperEndo Beta 2 (B & L Biotech, Ansan, Korea). For the SBO group, Endoseal TCS was introduced into the middle third of the canal using a 24-gauge needle. A gutta-percha cone (DiaDent, Cheongju-si, Korea) was then inserted with up-and-down motions to ensure proper sealer penetration. After cutting the gutta percha cone at the orifice level, vertical compaction was performed using an Obtura S-Kondenser (Obtura Spartan, Earth City, MO).

Patients recorded postobturation pain on a 0–10 numerical rating scale (NRS) at three consecutive time points: 4, 24, and 48 hours. Pain intensity was categorized based on the highest NRS score recorded across these time points as follows.

1. "None" (NRS 0): Complete absence of symptoms or discomfort
2. "Mild" (NRS 1–3): Slight discomfort without requiring pain medication
3. "Moderate" (NRS 4–7): Notable discomfort requiring occasional analgesics.
4. "Severe" (NRS 8–10): Debilitating pain affecting daily activities, unresponsive to analgesics.

Five-year follow-up examinations were scheduled via telephone contacts. Participants underwent both clinical and radiological examinations. Preoperative and follow-up radiographs were evaluated independently by two calibrated examiners (S.K., M.K.) who were blinded to the treatment groups. Radiographic evaluations employed the Periapical Index (PAI) scoring system[22]:

PAI 1: Normal periapical structure.

PAI 2: Bone structural changes indicating, but not pathognomonic for apical periodontitis.

PAI 3: Bone structural changes with some mineral loss characteristic for apical periodontitis.

PAI 4: Well-defined apical radiolucency.

PAI 5: Radiolucency with radiating expansion of bone structural changes.

In multirooted teeth, the highest PAI score among all roots was used for the final assessment. Discrepancies between examiners in radiographic evaluations were resolved through discussion until consensus was achieved.

According to previous research[23], treatment outcomes were classified into three categories based on clinical symptoms and PAI changes.

1. "Strict" criteria of success: Absence of clinical symptoms and complete resolution of periapical radiolucency (Fig. 1*C*).
2. "Loose" criteria of success: Absence of clinical symptoms with reduction in size of periapical radiolucency (Fig. 1*F*).
3. Failure: Nonfunctional or symptomatic teeth exhibiting either no change or increased periapical radiolucency (Fig. 2*C*, *F*)

STATISTICAL ANALYSIS

Statistical comparisons between the 2 groups regarding demographic characteristics, postobturation pain, and root filling quality were conducted using Chi-square or Fisher's exact tests. These tests were also applied to compare healing outcomes. Variables with a P value $< .20$ from the bivariate analysis were included in both univariate and multivariate logistic regression models to identify predictors of treatment outcomes. A stepwise method was employed to investigate the factors associated with success or failure. All statistical analyses were performed using SPSS software version 27 (IBM Corp, Armonk, NY, USA).

RESULTS

At the time of initial patient enrollment, 90 participants (96 teeth) were assessed for

eligibility. The unit of randomization was teeth, with stratification accounting for patients contributing multiple teeth. After applying exclusion criteria, 93 teeth were randomly allocated to either the CWC (47 teeth) or SBO group (46 teeth). At the five-year follow-up, 60 teeth (from 56 participants) were available for evaluation, yielding a recall rate of 64.5% (Fig. 3). The mean follow-up period was 62 months (range: 60–67 months), excluding cases of early failure. The CWC group showed a higher recall rate (34/47 teeth, 72.3%) compared to the SBO group (26/46 teeth, 56.5%), but this difference was not statistically significant ($P > .05$).

Four teeth were extracted before the 5-year follow-up (3 from the SBO group, one from the CWC group). None of these extractions were attributed to endodontic complications; specific reasons for extraction are detailed in Table 1. The survival rates were 97.0% and 88.5% for the CWC and SBO groups respectively ($P > .05$). The extracted teeth included 2 molars and 2 premolars. Healing outcomes were assessed in 56 teeth (characteristics summarized in Table 2). Of these, 54 teeth received permanent crown restorations, while 2 remained with resin cores only. Clinical and radiographic examinations showed no evidence of marginal caries or leakage in any teeth, regardless of restoration type.

No significant differences were observed between the CWC and SBO groups in demographic and clinical characteristics, including age, sex distribution, tooth location, and tooth type ($P > .05$ for all comparisons). Although retreatment cases were more prevalent in the SBO group (39.1%) compared to the CWC group (21.2%), this difference did not reach statistical significance ($P > .05$).

No significant differences were observed between groups in technical parameters: postobturation pain ($P > .05$), filling length ($P > .05$), sealer extrusion (more frequent in CWC group; $P > .05$), and presence of voids (more common in SBO group; $P > .05$). Overall, baseline characteristics and technical parameters were well-balanced between groups, ensuring appropriate comparability (Table 2).

Radiographic assessments demonstrated high inter-examiner reliability, with Kappa scores of 0.88 and 0.97 for preoperative and 5-year follow-up evaluations, respectively. Intra-examiner reliability was also excellent, with 1-week reassessments yielding Kappa scores of 0.88 and 0.86 for preoperative evaluations, and 0.97 and 0.94 for 5-year follow-up evaluations.

The 5-year success rates were 83.9% (47/56) and 76.8% (43/56) under loose and strict criteria, respectively (Table 3). Under loose criteria, the SBO group demonstrated a slightly higher success rate (87.0%, 20/23) than the CWC group (81.8%, 27/33), though this difference was not statistically significant ($P > .05$). Success rates under strict criteria were also comparable between groups (CWC: 75.8%, 25/33; SBO: 78.3%, 18/23; $P > .05$).

Multivariate logistic regression analysis initially examined variables including obturation technique, sex, tooth type, pulp status, postobturation pain, and sealer extrusion. Following stepwise selection, the final model retained pulp status, postobturation pain, and sealer extrusion as the most explanatory factors under both loose and strict criteria (Table 4). While not reaching statistical significance, retreated teeth demonstrated a trend toward higher failure rates (loose criteria: odds ratio = 4.864, 95% CI: 0.349–67.794, $P > .05$; strict criteria: odds ratio = 1.128, 95% CI: 0.193–6.598, $P > .05$). Treatment outcomes were not significantly influenced by sealer extrusion or postobturation pain levels under either criterion.

DISCUSSION

This randomized controlled trial evaluated 5-year outcomes of root canal treatments

FIGURE 1 – Representative periapical radiographs demonstrating success criteria (*A*). Preoperative radiograph shows a mandibular left second premolar with a periapical lesion. (*B*). Immediate postoperative radiograph following root canal treatment using the Continuous Wave of Condensation technique. (*C*). At 64-month follow-up, radiograph demonstrates normal periodontal ligament contour without clinical signs or symptoms, meeting strict criteria for success. (*D*). Preoperative radiograph reveals a maxillary left first molar with a periapical lesion. (*E*). Immediate postoperative radiograph after root canal treatment using the Continuous Wave of Condensation technique. (*F*). At 60-month follow-up, radiograph shows reduced periapical radiolucency without clinical symptoms, meeting loose criteria for success.

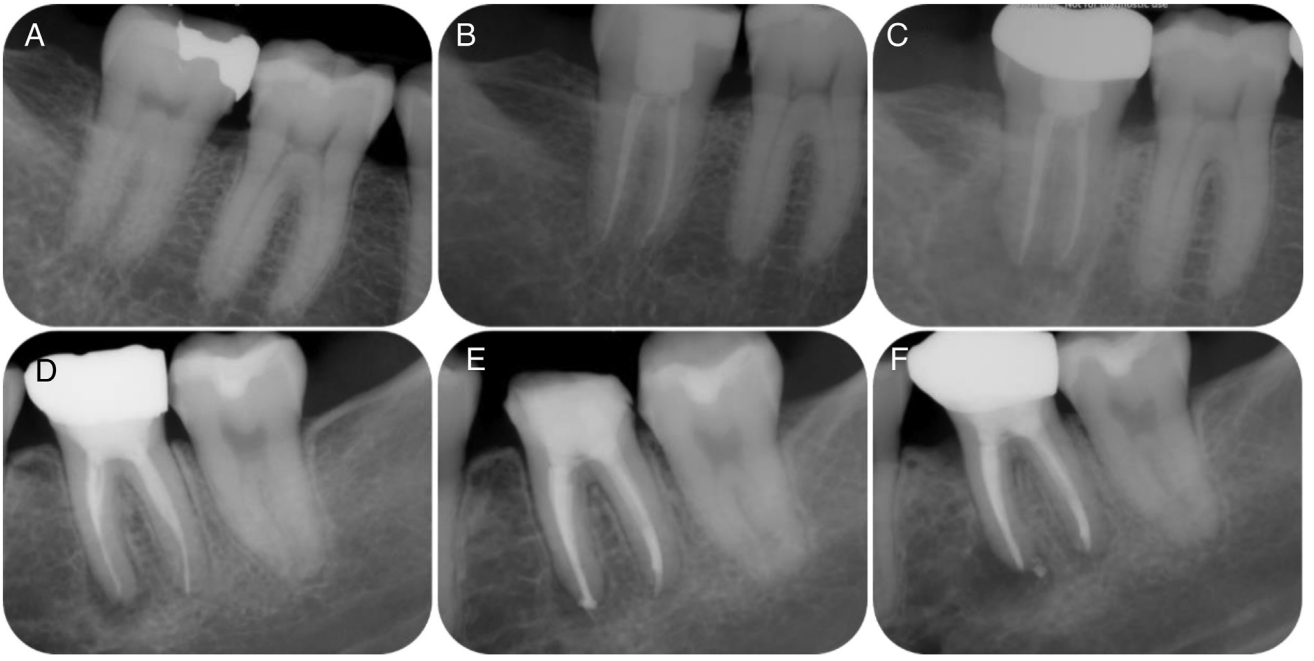

FIGURE 2 – Representative periapical radiographs of treatment failures (*A*). Preoperative radiograph shows a mandibular right second molar with a periapical lesion. (*B*). Immediate postoperative radiograph following root canal treatment using the continuous wave of condensation technique. (*C*). At 63-month follow-up, radiograph demonstrates an increased radiolucency in the distal root region, classified as failure. (*D*). Preoperative radiograph reveals a mandibular left first molar with a periapical lesion. (*E*). Immediate postoperative radiograph following root canal treatment using the sealer-based obturation technique. (*F*). At 63-month follow-up, radiograph shows persistent periapical radiolucencies around both mesial and distal roots, classified as failure.

performed using either SBO with Endoseal TCS or CWC technique with AH Plus. Success rates were comparable between techniques, with no significant differences under both loose and strict criteria. This study provides the first long-term comparative data on SBO technique using CSS against conventional obturation methods through randomized allocation.

The importance of long-term evaluation for novel materials has been clearly demonstrated through the case of Resilon[18]. While initial short-term studies (<25 months) showed comparable outcomes between Resilon/Epiphany sealer and gutta-percha/Kerr Pulp Canal Sealer based on PAI scoring and clinical symptoms[16], subsequent studies documented higher failure rates in Resilon-obturated teeth, initially observed at 5.8 years of follow-up[17] and later confirmed in an extended study exceeding 12 years[18]. Although no consensus exists regarding the optimal evaluation period for new materials, our study's mean follow-up time of 5.2 years aligns with that of Barborka et al[17], providing a meaningful addition to long-term data on obturation techniques. Our statistical analyses,

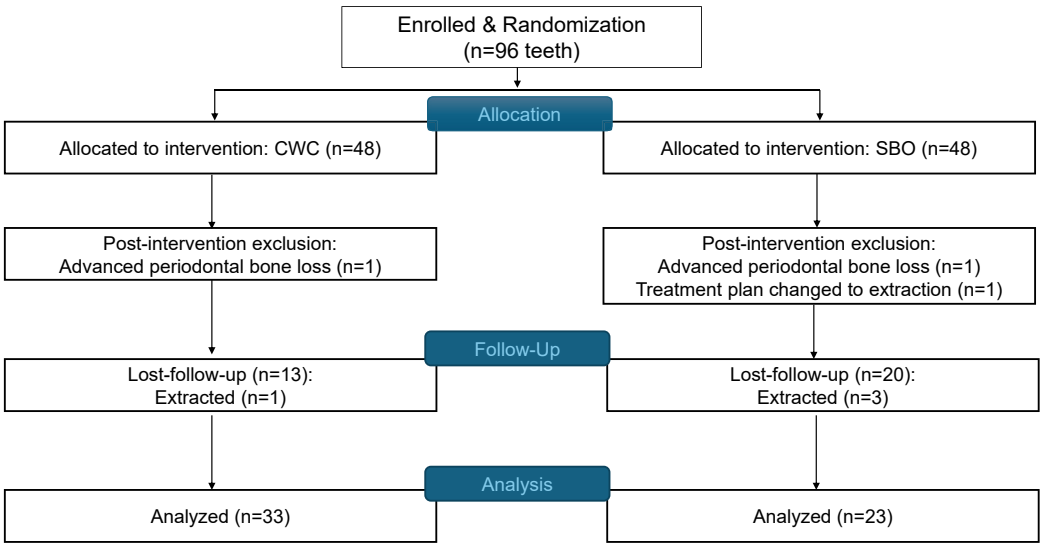

FIGURE 3 – A flow diagram of the study. CWC, continuous wave of condensation technique; SBO, sealer-based obturation.

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	

CWC, continuous wave of condensation technique; SBO, sealer-based obturation.

incorporating both chi-square tests and multivariate logistic regression, demonstrated that the SBO technique with Endoseal TCS represents a viable alternative to the CWC technique with AH Plus.

A systematic review analyzing studies from 2003 to 2020 reported weighted pooled success rates of 92.6% and 82% under loose and strict criteria, respectively[24]. The present study demonstrated success rates of 83.9% and 76.8% under loose and strict criteria. Compared to our previous findings from the same cohort[14], the strict criteria success rate increased from 60.8%, while the loose criteria success rate decreased from 93.2%. The higher strict criteria success rate in this study was anticipated, given that our previous study included a substantial number of short-term recall cases. The lower long-term success rates under loose criteria, though not statistically significant in our study ($P > .05$), has been attributed to various factors in the literature, including sealer disintegration, undetected filling voids, infection through lateral canals or dentinal tubules, and coronal leakage[25,26].

The survival rate in the present study was 93.3%, accounting for 4 extracted teeth. This rate exceeds the 83.4% reported by Dahlstrand Rudin et al[27] with a similar recall period, while aligning with the 90.85% 5-year survival rate reported in a population-based analysis from Korea[28]. Moreover, when compared to the 87% survival rate documented in 10-year follow-up studies[29,30],

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%	.73
≥50	13	39.4%	8	34.8%	21	37.5%	
Sex							
Female	17	51.5%	10	43.5%	27	48.2%	.55
Male	16	48.5%	13	56.5%	29	51.8%	
Location							
Maxilla	17	51.5%	12	52.2%	29	51.8%	.96
Mandible	16	48.5%	11	47.8%	27	48.2%	
Tooth							
Anterior	8	24.2%	3	13.0%	11	19.6%	.66
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%	.14
Retreatment	7	21.2%	9	39.1%	16	28.6%	
Pulp status							
Vital	12	36.4%	4	17.4%	16	28.6%	.20
Necrosis	14	42.4%	10	43.5%	24	42.9%	
Previously Treated	7	21.2%	9	39.1%	16	28.6%	
Postobturation pain							
None	6	18.2%	6	26.1%	12	21.4%	.93
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%	.16
Present	13	39.4%	5	21.7%	18	32.1%	
Void							
Absent	25	75.8%	18	78.3%	38	67.9%	.13
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 of condensation technique; SBO, sealer-based obturation technique.

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

	Total		Loose criteria Success			Strict criteria Success		
	n = 56		*n* = 47 (83.9%)			*n* = 43 (76.8%)		
Variables	**N**	**%**	**N**	**%**	***P* value**	**N**	**%**	***P* value**
Age (y)					.459			.101
≦50	35	62.5	28	80.0		24	68.6	
>50	21	37.5	19	90.5		19	90.5	
Sex					.073			.084
Female	27	48.2	20	74.1		18	66.7	
Male	29	51.8	27	93.1		25	86.2	
Tooth type					.077			.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					.274			.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					.811			.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					.725			.643
Absent	29	51.8	25	86.2		23	79.3	
Present	27	48.2	22	81.5		20	74.1	
Preoperative sensitivity					.493			.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			.486
Initial	40	71.4	33	82.5		32	80.0	
Retreatment	16	28.6	14	87.5		11	68.8	
Filling technique					.723			.827
CWC	33	58.9	27	81.8		25	75.8	
SBO	23	41.1	20	87.0		18	78.3	
Sealer extrusion					.129			.31
Absent	38	67.9	34	89.5		31	81.6	
Present	18	32.1	13	72.2		12	66.7	
Void					.703			.514
Absent	38	67.9	31	81.6		28	73.7	
Present	18	32.1	16	88.9		15	83.3	
Filling length					.514			1.00
Normal	52	92.9	44	84.6		40	76.9	
Long	4	7.1	3	75.0		3	75.0	
Postobturation pain					.129			.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	

CWC, continuous wave of condensation technique; PAI, Periapical Index; SBO, sealer-based obturation technique.

our findings demonstrate a consistent pattern of tooth loss.

Wu et al[31] noted that recall rates below 50% are particularly susceptible to overestimation bias. Although our study achieved a recall rate of 64.5%, exceeding their suggested threshold, the loss to follow-up reduced our effective sample size and consequently affected the precision of our estimates. However, baseline comparisons between the CWC and SBO groups revealed no significant differences in key variables (age, sex, tooth type, and initial treatment parameters), suggesting that the differential attrition rates did not introduce systematic bias. While our relatively modest sample size was sufficient for primary outcome analysis, it limited our ability to perform detailed subgroup analyses. Nevertheless, several methodologic strengths support the validity of our findings:[1] randomized controlled design minimizing selection bias[2], standardized treatment protocols ensuring procedural consistency[3], calibrated evaluators reducing assessment bias, and[4] comprehensive documentation of all clinical procedures. These methodological strengths support the reliability of our

TABLE 4 - Multivariate Logistic Regression Model Identifying Predictors of Treatment Failures Based on Loose and Strict Criteria

	Loose criteria			Strict criteria		
	Pseudo-R^2 = 0.461			Pseudo-R^2 = 0.389		
Variables	**OR**	**95% CI**	***P* value**	**OR**	**95% CI**	***P* value**
Pulp status						
Necrotic	1		.5	1		.991
Vital	0	0	.998	0	0	.998
Retreatment	4.864	0.349–67.794	.239	1.128	0.193–6.598	.894
Sealer extrusion						
Absent	1			1		
Present	6.584	0.885–48.989	.066	4.005	0.770–20.822	.099
Postobturation pain						
None	1		.157	1		.139
Mild	0.156	0.015–1.620	.12	0.221	0.032–1.530	.126
Moderate	2.761	0.125–60.948	.52	2.611	0.139–49.198	.522
Severe	0	0	.999	1.543	0.060–39.881	.794

CI, confidence interval; OR, odds ratio.

conclusions despite the sample size limitations. However, as a single-center study conducted at a university-based institution in Korea, with treatments performed by supervised endodontic residents and participants recruited from an urban population, the generalizability of our findings to other clinical settings, practitioner groups, and patient populations may be limited.

Although our short-term study[14] identified postobturation pain and sealer extrusion as significant factors associated with lower success rates, neither variable showed correlation with treatment failure in this long-term evaluation. In particular, the lack of impact from sealer extrusion may be attributed to the gradual resorption of extruded material over the 5-year period, especially in the SBO group, potentially facilitating bone healing in the affected areas.

In conclusion, this 5-year randomized controlled trial demonstrated that SBO technique with Endoseal TCS achieved statistically equivalent success rates to CWC technique with AH Plus (loose criteria: 87.0% vs 81.8%, $P = .723$; strict criteria: 78.3% vs 75.8%, $P = .827$). While larger scale randomized controlled trials would strengthen these findings, our long-term results support the clinical viability of SBO technique with Endoseal TCS for root canal obturation.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Minkyeong Seog: Writing – original draft, Data curation, Formal analysis, Investigation, Visualization. **Seung-Kyung Kwon:** Data curation, Formal analysis, Visualization. **Dohyun Kim:** Writing – review & editing, Formal analysis, Methodology, Software, Validation. **Su-Jung Shin:** Writing – review & editing, Formal analysis, Methodology, Software, Validation. **Il-Young Jung:** Writing – review & editing, Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Supervision, Validation.

ACKNOWLEDGMENTS

This work was supported by "Supporting Project to Evaluation New Domestic Medical Devices in Hospitals" funded by "Ministry of Health and Welfare (MOHW)" and "Korea Health Industry Development Institute (KHIDI)."

The authors deny any conflicts of interest related to this study.

We affirm that we have no financial affiliation (eg, employment, direct payment, stock holdings, retainers, consultantships, patent licensing arrangements or honoraria), or involvement with any commercial organization with direct financial interest in the subject or materials discussed in this manuscript, nor have any such arrangements existed in the past 3 years.

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