#### CONSORT RANDOMIZED CLINICAL TRIAL

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# Clinical Efficacy of Sealer-based Obturation Using Calcium Silicate Sealers: A Randomized Clinical Trial



# **SIGNIFICANCE**

A sealer-based obturation with calcium silicate sealers could be a possible alternative to a continuous wave of condensation technique with a resin-based sealer. Sealer extrusion and postoperative pain negatively affect outcome of root canal treatment.

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## **ABSTRACT**

**Introduction:** This randomized controlled clinical trial compared the clinical efficacy and outcome of a sealer-based obturation technique (SBO) with calcium silicate sealers and a continuous wave of condensation technique (CWC) with a resin-based sealer.

**Methods:** Root canals were prepared using rotary instruments and 2.5% sodium hypochlorite. At the next visit, patients were enrolled and randomly assigned into 2 groups on the basis of the obturation protocol: CWC with AH Plus sealer and SBO with Endoseal TCS. Patients were assessed for the level of postoperative pain using a numeric rating scale. The quality of root canal obturation was evaluated in terms of the sealer extrusion, root-filling voids, and level of root filling. The participants were recalled after at least 6 months. Healing of the teeth was determined as a decrease in Periapical Index score and resolution of symptoms. The results were statistically compared by using the  $\chi^2$  test or Fisher exact test, followed by multivariate analysis with logistic regression. Results: A total of 74 teeth were included in the analysis (79% recalls), and the mean follow-up period was 17 months (6–29 months). Two groups expressed identical distribution of postoperative pain (P = .973) and similar quality of root canal obturation. The total success rates were 93.2% (CWC 92.3%, SBO 94.3%) by loose criteria and 60.8% (CWC 51.3%, SBO 71.4%) by strict criteria, with no significant differences between the 2 groups. The success rate by loose criteria in teeth with sealer extrusion was significantly lower than those in teeth without sealer extrusion (P = .049). Conclusions: SBO using an Endoseal TCS could be a possible alternative to CWC using AH Plus. Sealer extrusion and postoperative pain were found to negatively impact prognosis of the endodontic treatment. (J Endod 2022;48:144–151.)

## **KEY WORDS**

Outcome; postoperative pain; root canal treatment; sealer-based obturation; warm vertical condensation

The quality of root fillings was found to be a significant factor in the success rates of nonsurgical root canal treatment (NSRCT), with the highest odds ratio among numerous affecting factors<sup>1</sup>. Various types of endodontic sealers and filling techniques have been advocated to accomplish satisfactory root filling, and until now, warm vertical compaction with the epoxy resin-based sealer AH Plus sealer (Dentsply DeTrey GmbH, Konstanz, Germany) has been recognized as the gold standard<sup>2,3</sup>. Recently, a sealer-based obturation technique (SBO) using calcium silicate sealers (CSS) has become popular because it is less technique sensitive, requires less armamentarium, and is easier to perform<sup>4</sup>. CSS has been reported to have hydrophilic properties and a bioactivity similar to that reported for mineral trioxide aggregate (MTA)-type materials<sup>5,6</sup>. Some authors have suggested that the filling quality of the SBO is not inferior but rather superior to continuous wave of condensation techniques (CWC)<sup>4,7</sup>. On the other hand, other authors have claimed that the SBO may result in more voids in irregularly shaped canals<sup>8,9</sup>, which can negatively impact the outcome of primary root canal treatment<sup>1</sup>.

Clinical techniques or materials need to be verified in preclinical and clinical studies. CSS have been experimentally evaluated in many *in vitro* studies<sup>10–15</sup> but are rarely tested in clinical trials. The first clinical study of NSRCT using CSS was reported in 2018, which used the EndoSequence Bioceramic Sealer (BC) (Brasseler USA, Savannah, GA) and showed a favorable success rate of 90.9% <sup>16</sup>. The study was a

retrospective study without a control group, and thus far no more clinical studies on success rate of treatment using CSS have been published. With traditional sealers, SBOs are usually inferior to other compaction techniques<sup>1</sup>. However, SBO with CSS has never been compared with traditional compaction techniques.

Therefore, the purpose of this study was to evaluate the clinical efficacy and outcome of SBO when used in conjunction with CSS and compare them with CWC with a resin-based sealer.

#### **MATERIALS AND METHODS**

# **Study Design and Population**

This study was designed as a randomized controlled clinical trial to compare postoperative pain, quality of root canal obturation, and short-term clinical outcomes. The study was approved by the Institutional Review Board of Yonsei University Dental Hospital (IRB number: 2-2018-0009) and registered at the CRIS (clinical research information service; no. KCT0006230; https:// cris.nih.go.kr/cris/search/detailSearch.do?all\_ type=Y&search\_page=L&pageSize=10& page=1&seq=19547&search\_lang=E). Patients were enrolled from the outpatient clinic of the Department of Conservative Dentistry, College of Dentistry, Yonsei University, Seoul, Korea, between April and September 2018. All patients participating in this study had teeth with fully formed apices requiring root canal therapy. The subjects were all older than 18 years of age and in good health (American Society of Anesthesiologists classification I or II)17. The exclusion criteria were as follows:

- Patients who were unable to communicate their symptoms because of psychological disorders, etc.
- The tooth was affected by cracks, severe periodontal bone loss due to chronic periodontitis accompanying mobility of the tooth, etc.
- The root canal was not negotiable within 2 mm of the radiographic apex.
- The tooth was not ready for root canal filling at the next visit after canal enlargement because of signs and symptoms.

# Sample Size Determination

The required sample size was calculated using G power 3 software (Franz Faul, University of Kiel, Germany) to facilitate comparison of 2 experimental groups with significance level of 5%, statistical power of 80%, equivalence limit of 15%, and effect size of 0.58, which was

based on a previous study<sup>18</sup>. A sample size of 50 teeth per group was determined.

# Treatment Procedure and Randomization

Teeth were treated by 6 dentists including 5 postgraduate residents and 1 professor at the Department of Conservative Dentistry, College of Dentistry, Yonsei University, Seoul, Korea. All procedures were performed over at least 2 visits.

On the first visit after local anesthesia with 1.8 mL 2% lidocaine with 1:80,000 epinephrine (Huons, Sungnam, Korea) and rubber dam isolation, an access opening was made, and the working length was determined using an electronic apex locator (Root ZX II; J Morita, Irvine, CA). The canals were prepared using the operator's preferred rotary instrument. The master apical file size was determined by the operator on the basis of the initial apical file size. The canals were irrigated using 2.5% sodium hypochlorite with a 27gauge or 30-gauge side-vented needle. In some cases, passive ultrasonic irrigation (Endosonic Blue; Maruchi, Wonju, Korea) was performed to remove severe contamination. All endodontic procedures were performed under an operating microscope (OPMI PICO; Carl Zeiss, Göttingen, Germany).

If there were no or only minor signs and symptoms at the next visit, the patients were invited to participate in the study. Those who agreed to participate and signed the informed consent form were included in this study. An assistant blinded to the study objectives created a computer-generated list of random numbers using the Sealed Envelope website (https://www.sealedenvelope.com/), 1:1 allocation, and using random block sizes of 6. To ensure concealment, this list was placed in a file cabinet, kept confidential, and opened by the blinded assistant only after the inclusion of the participants in the study and before the intervention. According to the random numbers on the list, each participant was provided with an enrollment number and randomly assigned to 1 of the 2 groups based on the obturation protocol: CWC with AH Plus and SBO with Endoseal TCS (Maruchi, Wonju, Korea).

Gutta-percha cones were fitted, and a periapical radiograph was taken to confirm the working length. The canals were dried using paper points. For the SBO group, the Endoseal TCS was dispensed into the middle third of the canal using a 24-gauge needle tip. A single gutta-percha cone (DiaDent, Cheongjusi, Korea) was inserted into the canal following an up-and-down motion 3 times to allow the sealer to penetrate better. For wide

canals, 1 or 2 additional gutta-percha cones were inserted to optimize sealing. After cutting the gutta-percha cone at the orifice level, Obtura S-Kondenser (Obtura Spartan, Earth City, MO) was used to vertically compact the gutta-percha.

For the CWC group, gutta-percha cones were coated with AH Plus sealer and inserted into the prepared root canals. A heated plugger (SuperEndo Alpha 2; B & L Biotech, Ansan, Korea) that can penetrate 4 or 5 mm short of the working length was inserted into the canal and used to cut and compact the master cone. Backfill of the canal was performed by a thermoplastic injection technique using SuperEndo Beta 2 (B & L Biotech).

# Outcome Variables Postoperative Pain

Patients recorded their pain on a 0–10 numeric rating scale (NRS), with 0 indicating no pain and 10 indicating the worst pain. Patients were required to report their pain level via wired or wireless communication according to the patients' preference at the following time points: 4, 24, and 48 hours after canal obturation. The highest pain score recorded at 3 consecutive time points was selected and then sorted into 4 larger categories:

- None (NRS 0): The treated tooth was asymptomatic, and the participant had no pain at all.
- Mild (NRS 1–3): The tooth was slightly painful, but there was no need to take analgesics.
- Moderate (NRS 4–7): The tooth caused discomfort and pain that were somewhat tolerable but sometimes required analgesics.
- Severe (NRS 8–10): The pain caused by the treated tooth disturbed normal activity or sleep, and analgesics had little or no effect.

# **Quality of Root Canal Obturation**

The quality of root canal obturation was evaluated in terms of sealer extrusion, root-filling voids, and the level of root filling. The 2 blinded and calibrated examiners (J. K., Y. C.) evaluated the periapical radiographs taken immediately after canal obturation. Sealer extrusion and root-filling voids were classified as either absent or present. If there was sealer extrusion or root-filling voids in at least 1 root for multirooted teeth, the teeth were regarded as the "presence" of sealer extrusion or root-filling voids. Because cases with short working length were excluded from the present study, the level of the root filling was recorded as

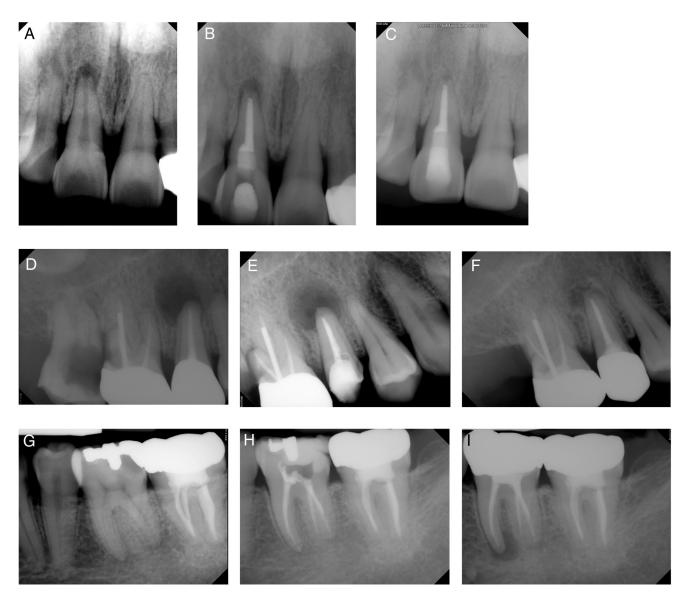


FIGURE 1 - Representative Images for Healed (a, b, c), Healing (d, e, f), and Diseased (g, h, i) cases.

"adequate" and "long". Fillings beyond the radiographic apex were sorted as long 19, and the rest were considered adequate. Any disagreement regarding sealer extrusion, root-filling voids, and level of root filling was resolved by a discussion until final consensus was reached.

#### **Healing Outcome**

The participants were recalled after at least 6 months, and radiographic and clinical examination of the treated tooth was performed. Preoperative and recall radiographs of the roots were each assigned a Periapical Index (PAI) score<sup>20,21</sup> by 2 blinded, independent, and calibrated examiners (J. K., Y. C.) as follows:

PAI 1: Normal periapical structure.

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

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

PAI 4: Well-defined apical radiolucency.

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

Multirooted teeth were assigned the highest score for any of the roots. Clinical examination included the presence or absence of pain, swelling, other symptoms, and sinus tract, in addition to functionality. Healing was determined as a decreased PAI score and lack of symptoms.

The teeth were divided into outcome categories on the basis of the following classification (Fig. 1):

- Healed: functional, asymptomatic teeth with PAI ≤2
- Healing: teeth that are asymptomatic and functional, with a decreased size on radiographic periradicular radiolucency
- 3. Diseased: nonfunctional, symptomatic teeth with PAI  $\geq$ 3.

The Healed and Healing categories were classified as success, and the Diseased category was classified as failure on the basis of loose criteria. According to strict criteria, the Healing and Diseased categories were considered as failure, and only the Healed category was regarded as success<sup>18</sup>. Examples of each outcome category are shown in Figure 1. Any disagreement regarding radiographic and clinical examination was resolved by a discussion until final consensus was reached.

TABLE 1 - Distribution of Postoperative Pain and Quality of Root Canal Obturation and Bivariate Associations with Filling Techniques

	Total (n = 74)		cwc	(n = 39)	SBO (n = 35)			
Index	N	%	N	%	N	%	P value	
Postoperative pain							.973	
None	22	29.7	12	30.8	10	28.6		
Mild	44	59.5	22	56.4	22	62.9		
Moderate	3	4.0	2	5.1	1	2.9		
Severe	5	6.8	3	7.7	2	5.7		
Sealer extrusion							.263	
Absent	48	64.9	23	59.0	25	71.4		
Present	26	35.1	16	41.0	10	28.6		
Void							.563	
Absent	49	66.2	27	69.2	22	62.9		
Present	25	33.8	12	30.8	13	37.1		
Filling length							.495	
Normal	72	97.3	37	94.9	35	100		
Long	2	2.7	2	5.1	0	0		

#### **Statistical Analysis**

Postoperative pain and quality of root canal obturation according to either technique were analyzed by using the  $\chi^2$  test or Fisher exact test. The outcomes were statistically compared by using the  $\chi^2$  test or Fisher exact test according to the variables, followed by multivariate analysis with logistic regression. Statistical analyses were performed by using SAS version 9.2 (SAS Institute, Cary, NC).

## **RESULTS**

Of the 90 patients enrolled, 3 were excluded because of advanced periodontitis (2 patients) or unrestorable fracture of the treated tooth (1 patient), and 19 patients were lost to follow-up within 6 months. Accordingly, 68 patients and 74 teeth were included in the final analysis (79% recall), and the mean follow-up period was 17 months (6–29 months).

The kappa score for interexaminer agreement after the first radiographic evaluation was 0.8, and the score for intraexaminer agreement was 0.9 after the second radiographic evaluation performed 1 week later, both indicating good agreement<sup>22</sup>.

Sixty-six of the 74 teeth (89.2%) showed no or mild pain, and 8 teeth (10.8%) triggered moderate to severe pain after root canal obturation (Table 1), and the 2 groups expressed identical distribution of postoperative pain (P = .973). Sealer extrusion and long filling length were found more frequently in the CWC group than in the SBO group (41.0% vs 28.6%, 5.1% vs 0%), but the differences were not statistically significant. Voids were found in two thirds of the total cases and were similar in both groups (Table 1).

The total success rate of the root canal treatment was 93.2% (69/74) on the basis of loose criteria. The CWC and SBO groups showed 92.3% (36/39) and 94.3% (33/35) success rates, respectively, and no statistical differences between groups were observed (P > .999). Teeth with necrotic pulp had the highest success rate (100%, 29/29), followed by retreated teeth (95.5%, 21/22) and teeth with vital pulp (82.6%, 19/23), with significant difference (P = .034). Teeth with sealer extrusion showed a significantly lower success rate than those without sealer extrusion (present 84.6%, absent 97.9%; P = .049). Postoperative pain negatively and significantly affected the outcome of root canal treatment (P = .012) (Table 2). Multivariate analysis using logistic regression identified sealer extrusion (P = .078) and postoperative pain (P = .090)as possible predictors of treatment failure, although those were insignificant (Table 3). According to strict criteria, the total success rate of the root canal treatment was 60.8% (45/74). The SBO group showed higher success rate (71.4%) than CWC group (51.3%), but the difference was not significant (P = .097). Preoperative sensitivity (absent = 73.0%, present = 48.6%) and sealer extrusion (absent = 68.8%, present = 46.2%) revealed differences in success rates of more than 20%, but both were insignificant. Multivariate analysis using logistic regression did not identify any significant predictors.

# **DISCUSSION**

This clinical trial aimed to compare the efficacy of SBO with CSS with that of CWC with resinbased sealer. To the best of our knowledge, this is the first prospective study to compare the outcomes of NSRCT incorporating SBO

and CSS. The overall success rate of this study on the basis of loose criteria was 93.2%, which was higher than the success rate of a welldesigned systematic review (85.2%)<sup>23</sup> and that of the first study using BC sealer and singlecone technique (90.9%)<sup>16</sup>. The evaluation criteria used in this study were comparable with the loose radiographic criteria in the systematic review, which is a reduction in the size of apical radiolucency rather than the absence of apical radiolucency of the strict criteria<sup>23</sup>. The overall success rate of this study on the basis of strict criteria was 60.8%, which is lower than the pooled weighted success rate that is based on strict criteria of the systematic reviews (74.7% and 76.7%)<sup>18,23</sup>. One of the limitations of this study regarding the outcome evaluation is a short follow-up period, with an average of 17 months (6-29 months), which might include more healing cases rather than possible healed cases, because the systematic review revealed that the success rates increased with longer follow-ups<sup>23</sup>. The first bioceramic root canal sealer was introduced in 2007, and various CSS have been evaluated for a long time<sup>24</sup>. This is the reason why clinical studies of bioceramic root canal sealer are rare, and the follow-up duration of this study was short.

The success rates of the obturation techniques were 92.3% in the CWC group and 94.3% in the SBO group on the basis of loose criteria, which were both promising and statistically insignificant. Many factors affect the outcome of NSRCT, and root canal sealer is not known to be a significant factor. A systematic review reported the outcome of NSRCT according to sealers, where zinc oxide eugenol–based sealers and resin-based sealers showed similar success rates of 86.5% and 87.3%, respectively. Glass ionomer–based sealer revealed the highest success rate

TABLE 2 - Characteristics of Included Patients and Bivariate Associations between the Investigated Variables and Outcomes Based on Loose and Strict Criteria

		Loose criteria						Strict criteria				
		otal = 74		ccess = 69)		ailure = 5)			ccess = 45)		ailure = 29)	
Variables	N	%	N	%	N	%	P value	N	%	N	%	P value
Age (y)							.499					.210
≤50	49	66.2	45	91.8	4	8.2		27	55.1	22	44.9	
>50	25	33.8	24	96.0	1	4.0		18	72.0	7	28.0	
Sex							.183					.343
Female	35	47.3	31	88.6	4	11.4		19	54.3	16	45.7	
Male	39	52.7	38	97.4	1	2.6		26	66.7	13	33.3	
Tooth type							.403					.720
Anterior	16	21.6	15	93.8	1	6.3		9	56.3	7	43.7	
Premolar	19	25.7	19	100.0	0	0.0		13	68.4	6	31.6	
Molar	38	52.7	35	92.1	4	10.5		23	59.0	16	41.0	
Vitality							.034					.464
Necrotic	29	39.2	29	100.0	0	0.0		19	65.5	10	34.5	
Vital	23	31.1	19	82.6	4	17.4		15	65.2	8	34.8	
Retreatment	22	29.7	21	95.5	1	4.5		11	50.0	11	50.0	
Preoperative PAI		20.1		00.0		1.0	.512		00.0		00.0	.435
1	18	24.3	15	83.3	3	16.7	.012	11	61.1	7	39.8	.400
2	14	18.9	13	92.9	1	7.1		11	78.6	3	21.4	
3	8	10.8	8	100.0	0	0.0		5	62.5	3	37.5	
4	26	35.1	25	96.2	1	3.8		15	57.7	11	42.3	
5	8	10.8	8		0			3		5		
	0	10.6	0	100.0	U	0.0	.390	3	37.5	5	62.5	.630
Preoperative pain	4.4	50 F	40	05.5	0	4 -	.390	00	CO C	10	00.4	.030
Absent	44	59.5	42	95.5	2	4.5		28	63.6	16	36.4	
Present	30	40.5	27	90.0	3	10.0	. 000	17	56.7	13	43.3	050
Preoperative sensitivity	07	<b>50.0</b>	0.4	04.0	0	0.4	>.999	07	70.0	4.0	07.0	.056
Absent	37	50.0	34	91.9	3	8.1		27	73.0	10	27.0	
Present	37	50.0	35	94.6	2	5.4		18	48.6	19	51.4	
Treatment type		=					>.999					.298
Initial	52	70.3	48	92.3	4	7.7		34	65.4	18	34.6	
Retreatment	22	29.7	21	95.5	1	4.5		11	50.0	11	50.0	
Apical patency							.651					.473
Absent	41	55.4	39	95.1	2	4.9		23	56.1	18	43.9	
Present	33	44.6	30	90.9	3	9.1		22	66.7	11	33.3	
Filling technique							>.999					.097
CWC	39	52.7	36	92.3	3	7.7		20	51.3	19	48.7	
SBO	35	47.3	33	94.3	2	5.7		25	71.4	10	28.6	
Sealer extrusion							.049					.081
Absent	48	64.9	47	97.9	1	2.1		33	68.8	15	31.3	
Present	26	35.1	22	84.6	4	15.4		12	46.2	14	53.8	
Void							>.999					.454
Absent	49	66.2	46	93.9	3	6.1		28	57.1	21	42.9	
Present	25	33.8	23	92.0	2	8.0		17	68.0	8	32.0	
Filling length							.131					.150
Normal	72	97.3	68	94.4	4	5.6		45	62.5	27	37.5	
Long	2	2.7	1	50.0	1	50.0		0	0.0	2	100.0	
Postoperative pain	_	=	•	****	•		.012	-		_		.500
None	22	29.7	22	100.0	0	0.0	- <b></b>	13	59.1	9	40.9	.000
Mild	44	59.5	42	95.5	2	4.5		29	65.9	15	34.1	
Moderate	3	4.0	2	66.7	1	33.3		1	33.3	2	66.7	
Severe	5	6.8	3	60.0	2	40.0		2	40.0	3	60.0	
OEVELE	υ	0.0	<u> </u>	0.0		40.0			40.0	J	00.0	

The bold font indicates the statistical significance.

of 94.4%, but the results were collected from only 1 study<sup>1</sup>. Unlike the root canal sealers used, the root canal filling technique was reported to be a significant factor in the outcome of NSRCT<sup>3</sup>, and vertical compaction is mostly superior or equal to lateral compaction<sup>3,25</sup>. It should be noted that all the results regarding filling techniques and

outcomes were related only to traditional sealers such as zinc oxide— or resin-based sealers, and a comparison of filling techniques using a CSS and other sealers has not been reported. Voids were found to be insignificant to the outcome that was based on both loose and strict criteria, which is in agreement with the previous studies <sup>19,25</sup>. A systematic review

reported significant differences of success rates between teeth with satisfactory and unsatisfactory root fillings; however, the criteria included inadequate seal as well as radiographic presence of voids with high heterogeneity 1.

Apical disturbance is defined as instrumentation beyond the apical foramen or

TABLE 3 - Multivariate Logistic Regression Model Identifying Predictors of Treatment Failures Based on Loose Criteria

Variables	OR	95% CI	P value
Vitality			
Necrotic	1		
Vital	5.258	0.283-97.659	.266
Retreatment	3.332	0.165–67.4	.433
Sealer extrusion			
Absent	1		
Present	5.697	0.826-39.303	.078
Postoperative pain			
None	1		
Mild	2.457	0.131-46.129	.548
Moderate	13.777	0.244–778.807	.203
Severe	21.531	0.62–747.751	.090

CI, confidence interval; OR, odds ratio.

extrusion of calcium hydroxide or root canal sealer, and teeth with apical disturbance showed 15.6% lower success rate after root canal treatment than those without apical disturbance (72.6% vs 88.2%) in a systematic review<sup>1</sup>. Although some other individual studies revealed that sealer extrusion did not significantly affect the outcome 16,26, it was found to be 1 of the 2 possible predictors in multivariate regression analysis in our study. Interestingly, in our study, 4 of the total 5 teeth of failure showed sealer extrusion, and 3 had vital pulp without preoperative apical radiolucency (PAR); therefore, the success rate of teeth with sealer extrusion and PAR was 94.4% (17/18), and that with sealer extrusion and no PAR was 62.5% (5/8) on the basis of loose criteria. No study has yet analyzed the effect and relation of sealer extrusion on the outcome of NSRCT. However, it is worth considering that overfilling induced a worse effect in teeth without PAR (odds ratio = 3.72) than in teeth with PAR (odds ratio = 1.74) on the outcome of NSRCT<sup>1</sup>. Up-regulated proinflammatory and anti-inflammatory cytokines such as tumor necrosis alpha, interleukin 6, transforming growth factor  $\beta$ , and interleukin 4<sup>27,28</sup> and activated macrophages<sup>29,30</sup> in apical granuloma might be more helpful in resisting extruded foreign materials such as sealer and gutta-percha than in normal apical tissue without those cytokines and activated macrophages.

Acute flare-up during treatment is known to have no influence on treatment outcome <sup>19,31</sup>, because it is a transient phenomenon and there is an upcoming chance to remove contaminated material before root canal obturation. On the other hand, a more recent prospective study reported that interappointment pain or swelling occurred in 18% of cases and significantly reduced the success rate of treatment, which

is believed to be because flare-up was caused by extrusion of contaminated material, which may elicit a foreign body reaction or extraradicular infection resulting in treatment failure<sup>25</sup>. We therefore evaluated postoperative pain after root canal obturation, which significantly reduced the success rate of the treatment. Postoperative pain might indicate transient inflammation, foreign body reaction, or extraradicular infection as interappointment pain or swelling; however, postoperative pain could be more significant to treatment outcome because there is no longer any option to remove the infection source. Pain is a subjective indicator, and sensitivity to pain varies from patient to patient, and then one should be very cautious to incorporate painrelated criteria and draw a conclusion from the result. In this study, patients were asked their signs and symptoms after first visit, and only the patients reporting no or minor signs and symptoms were recruited. This process could have the effect of standardizing the enrolled patients in terms of sensitivity to pain.

Five postgraduate endodontic residents and 1 endodontic specialist participated in this study. Multiple operators produce different skill and outcome with preferred instrument, and this point is a limitation of this study. However, a systematic review revealed that postgraduate students and specialists had the highest weighted pooled estimate of success, regardless of strict or loose criteria<sup>23</sup>. We included the 5 postgraduate students who were all third-year residents and 1 endodontic specialist for operators, and then the influence of the operators in this study would be minimal.

We enrolled the patients when there were no or minor signs and symptoms at the next visit after canal enlargement. This is different from the time points of enrollment of other prospective studies in which patients are enrolled before treatment<sup>3,25,26</sup>. We aimed to

evaluate the effect of obturation technique and sealer and then enrolled the patients just before obturation when the other factors were standardized.

This study did not fulfill the required sample size because of the limited time for patient recruitment. This study was funded by the government, and there was a limited time to use the fund. To reward the participants, a small amount of transportation expenses was applied for every visit. Unfortunately, because the time to use the fund was limited, we could not enroll as many participants as we calculated to ensure the proper power of the study.

# CONCLUSION

Within the limitations of this study, it was found that SBO using Endoseal TCS can be a possible alternative to CWC using AH Plus. Sealer extrusion and postoperative pain negatively affect outcome of root canal treatment. Further follow-up and other studies with larger sample sizes are needed for better reliability.

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

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