Effect of minimally invasive root canal preparation on the outcome of initial endodontic treatment
: A randomized clinical trial

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: A randomized clinical trial

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어떠한 일이 있어도 사랑과 지지로 저를 응원해 주시는 가장 사랑하는 아버지, 어머니와 언니 덕분에 힘든 순간에도 다시 일어서고 이 과정을 끝까지 마칠 수 있었습니다. 언제나 제 삶에 가장 큰 힘이 되어주셔서 감사합니다. 그리고 항상 든든한 힘이 되어주는 권규범에게도 감사를 전합니다.

마지막으로 긴 기간 항상 저와 함께해주었던 의국 동기들, 선후배들에게도 감사의 마음을 전합니다. 제가 얻은 도움을 먼저 베풀고 전문적 지식과 사랑을 전할 수 있는 사람이 되겠습니다.

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ABSTRACT

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Minimally invasive endodontic treatment has been an important topic of discussion in recent years, particularly for root canal preparation as well as access cavities. However, its clinical applicability remains a concern, and no randomized trials have yet evaluated treatment outcomes. This randomized prospective clinical trial aimed to assess outcomes after at least two years following two distinct root canal treatment (RCT) protocols: (1) conventional treatment protocol (CP) and (2) minimally invasive protocol (MP), with focus on the amount of root canal preparation.

With an identical conventional access cavity design, 175 mature permanent teeth (with either vital or necrotic pulp) were randomly assigned to one of two groups. The CP group was treated using ProTaper Gold systems and the continuous wave condensation technique, while the MP group underwent treatment with TruNatomy, ultrasonic-associated irrigation, calcium hydroxide ($Ca[OH]_2$), and a sealer-based obturation technique. RCT was completed in two or more visits. Postoperative pain was measured using a numeric rating scale, while the quality of root canal filling was evaluated based on sealer extrusion, root canal filling voids, and filling level. The patients were recalled after a minimum of two years, and the outcome was dichotomized into success or failure according to strict and loose criteria, respectively. The results were analyzed statistically through chi-squared, Fisher's exact tests or t-tests, followed by multivariable logistic regression analysis.

A total of 125 teeth were analyzed, with a recall rate of 67.4% and an average follow-up period of 36 months (24–46 months). No significant differences were observed between the two groups in terms of postoperative pain distribution (p=.163), root canal filling voids (p=.833), or the level of root canal filling. However, sealer extrusion exhibited a significant difference between the two treatment groups (p=.001). The overall success rates were 84.8% for loose criteria (CP 91.9%, MP 77.8%) and 80.8% for strict criteria (CP 88.7%, MP 71.4%), with statistically significant differences observed between the groups (p=.027 and p=.016, respectively). When analyzed using the loose criteria, multivariable logistic regression analysis showed that, in addition to the MP group (OR=7.59, p=.009), the absence of sealer extrusion (OR=0.09, p=.012) and the presence of a sinus tract (OR=7.14, p=.021) were associated with a higher risk of failure. In contrast, when analyzed using strict criteria, the MP group (OR=6.75, p=.002), the presence of a sinus tract (OR=6.59, p=.007), and male gender (OR=3.27, p=.022) increased the risk of failure. Therefore, the multivariable logistic regression analyses revealed that both the MP group and sinus tract

involvement were associated with a greater risk of failure under both loose and strict criteria.

Within the limitations, the two-year success rate of initial endodontic treatment was lower in the MP group than in the CP group. The presence of a preoperative sinus tract was also a significant predictor of treatment outcomes for both criteria. Sealer extrusion and the male gender, which have not previously been reported as significant predictors of treatment outcomes, affected the results under only one of the two criteria used in this study.

Key words : **root canal treatment; ultrasonic-associated irrigation; minimally invasive endodontics; calcium hydroxide; outcome; sealer-based obturation**

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1. Introduction

The concept of minimally invasive treatment, a widely recognized concept in dentistry, is based on a large body of scientific evidence and is widely applied in the treatment of dental caries (Murdoch-Kinch & McLean 2003). The minimally invasive concept prioritizes preserving the

structural integrity of original tissues, reducing patient harm, and enhancing the immune system's natural self-healing ability to combat disease (Silva et al. 2022a). In endodontics, this approach has notably influenced access cavity preparation, reflecting a shift toward minimally invasive treatments. In the area of endodontics, this approach has notably influenced access cavity preparation, reflecting a shift toward minimally invasive treatments (Silva et al. 2022a). Accordingly, research has explored the impact of various access cavity preparation designs on subsequent endodontic (Yuan et al. 2016; Khare et al. 2024). However, the majority of studies have focused on access cavity preparation design (Silva et al. 2022a; Vorster et al. 2023), and the impact of the apical instrumentation and taper during canal shaping remains underexplored and requires further research.

Preserving more dentin, particularly in the coronal third of the root, has been identified as a key root canal preparation strategy for minimally invasive endodontics. A small taper preparation of the coronal third of the root canal may reduce the risk of fractures in the cervical part of the tooth (Yuan et al. 2016; Sabeti et al. 2018). Therefore, in keeping with the minimally invasive concept of endodontics, manufacturers have produced instruments with a low taper, one of which is the TruNatomy™ Rotary System (TN, Dentsply Sirona, Ballaigues, Switzerland), which consists of nickel-titanium (Ni-Ti) wire instruments with a fluted diameter reaching up to 0.8 mm and a unique heat treatment (Peters et al. 2020). This instrument features an off-centered parallelogram cross-section with a regressive taper, allowing for the preservation of radicular dentin during mechanical preparation (Peters et al. 2020; Mustafa et al. 2021).

However, in cases where the TN file is used for root canal shaping, the amount of preparation in the coronal portion of root canal is reduced, resulting in a smaller taper compared to conventional techniques. This reduction can complicate the insertion of a metal plugger into the root canal, particularly when the required depth is 4–5 mm shorter than the working length during the filling

process. Consequently, the continuous wave technique may present clinical challenges. In such situations, the sealer-based obturation (SBO) technique, employing a newly developed calcium silicate-based bioceramic sealer, could serve as a more practical alternative. This approach is supported by a recent meta-analysis of root canal filling techniques, which demonstrated that the calcium silicate-based bioceramic sealer applied in the single-cone obturation technique yielded results comparable to those of other materials and techniques in promoting the healing of periapical pulpitis (Sabeti et al. 2024).

Since the introduction of this file, many studies have been performed on it. Recent laboratory research has also reported better preservation of dentin in the coronal third part of the root shaped with TN compared to controls, although it is unknown whether the results have clinical significance (Ribeiro et al. 2023; Sarıyılmaz et al. 2024). On the other hand, there are concerns that minimally invasive endodontic instrumentation can compromise root canal cleanliness (Lee et al. 2019; Plotino et al. 2019; Lima et al. 2020). There is uncertainty about which factor is more important for cleanliness, the apical preparation size (Rodrigues et al. 2017, Plotino et al. 2019) or its taper (Augusto et al. 2020; Lima et al. 2020) and the extent to which both factors are involved in root canal cleanliness (Moshari et al. 2015; Usta et al. 2023), with conflicting conclusions.

Against this backdrop, and given the concerns regarding residual bacterial biofilms (Rodrigues et al. 2017), it is necessary to consider additional disinfection procedures, such as ultrasonic-associated irrigation (UI) combined with medicament placement within the root canal system (Căpută et al. 2019; Lee et al. 2019; Ahmad et al. 2022). However, while the application of intracanal calcium hydroxide did not show a clear benefit in a recent systematic review (Karaoğlan et al. 2022), other research had reported that it is effective in eliminating microorganisms from the root canal (Evans et al. 2002). In addition, UI has been shown to be superior to conventional

irrigation and improve intracanal cleanliness in a recent systematic review (Chalub et al. 2023), yet a randomized clinical trial had failed to demonstrate efficacy (Liang et al. 2013).

Another concern is that although there have been many studies conducted using minimally invasive endodontics, specifically TN files, only three clinical studies have been published to date, all of which were designed to evaluate postoperative pain (Bhojwani et al. 2022; Valliappan et al. 2023; Kim et al. 2024). There is a lack of clinical studies, especially randomized clinical trials, on the healing outcome of the treatment protocol.

A recent systematic review by Ng et al. (2007, 2008) emphasized rigorous study designs to evaluate endodontic outcomes and standardize results, and reported success rates with standardized evaluation methods (85.2% and 74.7% for loose and strict criteria, respectively). In addition, a minimum follow-up period of two years is required, as a study has shown that most periapical lesions heal within two years (Ng et al. 2007).

Therefore, this prospective randomized clinical trial aimed to assess the outcomes of two distinct root canal treatment (RCT) approaches over a minimum follow-up period of two years: (1) the conventional treatment protocol (CP), which involved ProTaper Gold® systems (PTG, Dentsply Sirona) and continuous wave condensation technique (CWC), and (2) the minimally invasive treatment protocol (MP) utilizing TN and SBO.

2. Materials and methods

This clinical trial received approval from the Institutional Review Board of Yonsei University Dental Hospital (no. 2-2020-0003) and was registered with the Clinical Research Information Service (CRIS, no. KCT0005351: 25/08/2020). It followed the Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) guidelines (Nagendrababu et al. 2020). Between April 2020 and March 2021, we methodically recruited healthy individuals aged 18 to 82 for this study. Each participant provided written consent after receiving comprehensive information detailing the objectives and procedures of the study.

2.1. Patient selection

The inclusion criteria specified healthy individuals aged 18 or older with mature permanent teeth in need of RCT. Exclusion criteria included teeth that had previously undergone treatment or initiation, periodontal pockets extending beyond the apical third of the root, recent analgesic use within 24 hours before treatment, communication difficulties, and root canals that could not be negotiated within 2 mm of the radiographic apex.

2.2. Sample size determination and randomization

This clinical trial aimed to assess two main outcomes: short-term postoperative pain, previously reported in another publication (Kim et al. 2024), and the long-term success rates of the protocols described in this study. Sample size determination incorporated both endpoints, with the larger of the two servings as the definitive criteria. To determine the required sample size for comparing

postoperative pain between the groups, we utilized G*Power 3.1 software (Franz Faul, University of Kiel, Germany) with a 5% significance level, 80% statistical power, and an effect size of 0.5. The calculation for success rate comparisons was informed by results from a previous clinical trial investigating nonsurgical root canal treatment (Flight & Julious 2016). Kim et al. (2022) reported success rates with loose criteria as 92.3% and 94.3% used with the continuous wave condensation method with resin-based sealer and the calcium silicate sealer applied using a sealer-based obturation method, respectively. This equivalence trial was planned with a 10% equivalence limit, a 5% significance level, and 90% statistical power. Using these parameters, the calculated sample size per group was 75. To allow for a 20% dropout rate, the final estimated sample size was increased to 180 cases.

This study adhered to a thorough methodology to ensure fairness in the allocation process. Random numbers were generated by an independent assistant through the Sealed Envelope website (https://www.sealedenvelope.com/) using a 1:1 allocation ratio and random block sizes of six. The resulting allocation list was securely stored in a locked cabinet to maintain confidentiality. Access to the list was restricted to the independent assistant, who referred to it after participant inclusion but before the intervention phase. Participants were assigned an enrolment number, determining their allocation to either the CP or MP treatment groups as per the predetermined protocol.

2.3. Preoperative clinical and radiographic evaluations

Prior to treatment, all teeth were subjected to a detailed clinical and radiographic evaluation. Percussion testing and periodontal probing were performed, and the presence of any sinus tract was documented. Pulp sensibility was assessed using cold-pulp and electric-pulp tests to verify the

necessity for RCT. Observing bleeding within the pulp chamber was crucial for determining pulp vitality. The absence of vital tissue within the pulp chamber indicated pulpal necrosis. Periapical radiographs were captured using extension cone paralleling devices, ensuring greater dimensional accuracy in the resulting dental X-ray images.

2.4. Treatment protocols

All procedures were carried out in a single facility by ten clinicians, including three professors and seven skilled residents from the Department of Conservative Dentistry, utilizing a dental operating microscope (OPMI pico®; Carl Zeiss, Göttingen, Germany). RCT protocols strictly adhered to rubber dam isolation and were completed over two or more appointments. In the CP group, during the initial visit, an access cavity was prepared under local anesthesia (infiltration and/or block anesthesia) using high-speed burs, and the working length was determined with an electronic apex locator (DentaPort Root zx II®, Morita, Irvine, USA) and confirmed by periapical radiography. Root canal shaping was performed sequentially with PTG files (S1, S2, F1, F2), finishing with PTG F2 (25/.08) for curved canals and PTG F3 (30/.09) for straight canals. During this process, the canals were irrigated with a 2.5% sodium hypochlorite (NaOCl) solution using a 30-gauge notched-tip needle (Sungshim Medical Co., Bucheon-si, Korea). The access cavity was temporarily sealed with a cotton pellet and restorative material (Caviton®, GC Corporation, Tokyo, Japan). At the root canal filling appointment, reinstrumentation was performed using the final shaping file, followed by irrigation with 1 mL of 18% ethylenediamine tetraacetic acid (EDTA) solution and 3 mL of NaOCl. Properly sized gutta-percha cones (GPC) were fitted and checked via periapical radiography. The canals were soaked with NaOCl for 15 seconds, replacing the irrigant

three times to standardize final irrigation across both groups. The canals were dried using paper points, and obturation was carried out using CWC technique. The GPC was coated with AH Plus® sealer (Dentsply Sirona) and placed into the prepared canals. A heated plugger (SuperEndo Alpha 2®, B & L Biotech, Ansan, Korea) was used to compact and cut the master cone, stopping 4-5 mm short of the working length. Backfilling was achieved using a thermoplastic injection system (SuperEndo Beta 2®, B&L Biotech).

In the MP group, access cavity preparation, working length determination, and canal irrigation followed the same procedures as implemented in the CP group. For canal shaping, the TN system was utilized in the sequence recommended by the manufacturer: Orifice Modifier (20/.08), Glider file (17/.02), and Prime file (26/.04). If the Prime file could not reach the working length easily, Small files (20/.04) were used during canal preparation at the clinician's discretion. The final shaping instruments were TN Prime shaping files for curved canals and Medium files (36/.03) for straight canals. After the final instrument was used, additional disinfection procedures, such as UI and calcium hydroxide ($Ca[OH]_2$), were performed. Passive UI was performed using a size 15 Ni-Ti file with a 0.02 taper (Endosonic Blue®, Maruchi, Wonju, Korea) positioned 2 mm short of the working length for 15 s. After drying the canals, premixed syringe-type calcium hydroxide ($Ca[OH]_2$) paste (Cleanical®, Maruchi) was applied to the middle third of the canal, and its distribution along the canal walls was achieved with a GPC slightly smaller than the prepared canal size. The access cavity was temporarily sealed with a cotton pellet and restorative material (Caviton®, GC Corporation). During the subsequent visit for root canal filling, the $Ca(OH)_2$ paste was removed using the final file from the previous visit, and the canals were flushed with 1 mL of EDTA followed by 3 mL of NaOCl. The fit of the GPC was verified through periapical radiography. Passive UI with NaOCl was carried out for 15 seconds per canal, repeated three times for uniform final irrigation. After drying the canals,

a calcium silicate-based sealer (Endoseal TCS®, Maruchi) was dispensed into the middle third of the canal with a 24-gauge needle tip. Matching-taper gutta-percha cones (DiaDent®, Cheongjusi, Korea) were inserted up to the working length, and the GPC was sealed at the orifice level using a heated plugger. Vertical compaction of the GPC was performed with an Obtura S-Kondenser (Obtura Spartan®, Earth City, MO, USA).

2.5. Outcome variables

2.5.1. Preoperative and postoperative pain assessment

At their initial visits, prior to recieving local anesthesia, patients were instructed to rate their preoperative pain levels on a 0-10 numerical rating scale (NRS). To assist with scoring, a modified Wong-Baker FACES scale was also provided. Patients were also contacted via phone one day after root canal filling and requested to report their pain scores.

2.5.2. Quality of root canal filling

The quality of root canal fillings was assessed based on three criteria: sealer extrusion, root canal filling voids, and root canal filling level. Periapical radiographs taken immediately after the root canal filling procedure were independently reviewed by two blinded and calibrated examiners (S. K. and M. S.). Both sealer extrusion and root canal filling voids were classified as either present or absent. In multirooted teeth, the presence of sealer extrusion or voids in at least one root was categorized as "present." The root canal filling level was also evaluated. Any discrepancies between the examiners regarding sealer extrusion, filling voids, or filling level were resolved through discussion to reach a final agreement.

2.5.3. Healing outcomes

Patients underwent annual recall appointments, which included clinical and radiographic evaluations of the treated teeth. The presence of caries or marginal leakage associated with coronal restorations was assessed by clinical inspection and periapical radiography. Only patients who completed at least 24 months of follow-up were included in the healing outcome analysis. Two blinded, independent, and calibrated examiners (S. K., M. S.) independently evaluated the preoperative and recall periapical radiographs for the periapical index (PAI) as described by Orstavik et al. (1986) and Orstavik (1996). The PAI scores were as follows (Table1).

Table1. Description of PAI scores

PAI Score	Description
PAI 1	Normal periapical structure
PAI 2	Bone structural changes indicating but not pathognomonic for apical periodontitis
PAI 3	Bone structural changes with mineral loss in apical periodontitis
PAI 4	Well-defined apical radiolucency
PAI 5	Radiolucency with the radiative expansion of bone structural changes

For multirooted teeth, the maximum score among the roots was recorded. Clinical assessments included the evaluation of pain, swelling, the presence of sinus tract, other symptoms and overall functionality. Healing criteria were defined as a decrease in the PAI score along with the absence of clinical symptoms. According to previous research, teeth were categorized into the following three evaluation criteria based on the success or failure in analyzing the change in the PAI (Ng et al. 2007).

1. ‘Strict’ radiographic success criteria: Asymptomatic tooth with no evidence of apical radiolucency during the follow-up assessment (Figure 1).

2. ‘Loose’ radiographic success criteria: Asymptomatic tooth showing a reduction in apical radiolucency size during the follow-up assessment (Figure 1).

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

Disagreements in radiographic and clinical assessments were addressed through discussion until a consensus was reached.

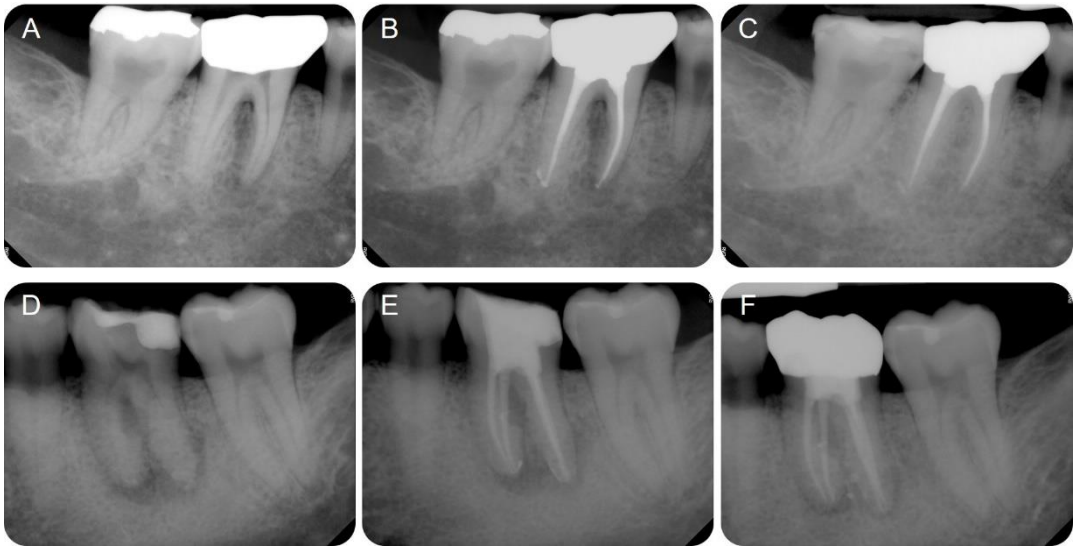

Figure 1. Representative periapical radiographs of cases in each category of success.

A. Preoperative radiograph of the first right mandibular molar tooth with a periapical lesion.

B. Postoperative radiograph after treatment with the minimally invasive protocol.

C. The 39-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 first left mandibular molar tooth with a periapical lesion.

E. The tooth was treated with the conventional treatment protocol.

F. The 25-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.

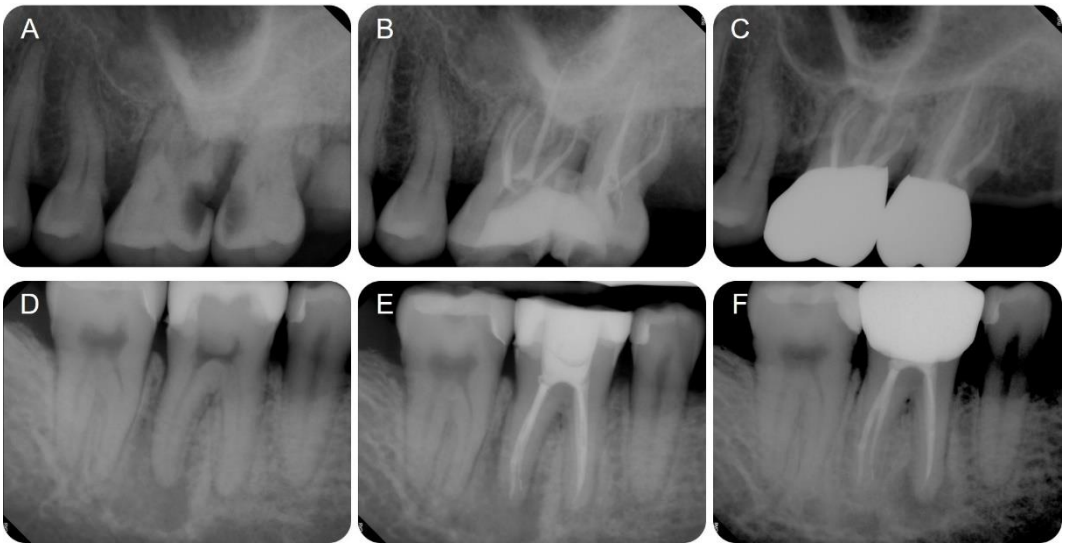

Figure 2. Representative periapical radiographs of cases in category of failure.

A. Preoperative radiograph of the first maxillary molar tooth with a periapical lesion.

B. Postoperative radiograph after treatment with the minimally invasive protocol.

C. The 35-month follow-up radiograph still shows radiolucency around the apex of mesiobuccal root. The outcome is considered ‘failure’.

D. The preoperative radiograph of the first mandibular molar tooth with a periapical lesion.

E. The tooth was treated with the conventional treatment protocol.

F. In the 38-month follow-up radiograph, while the periapical radiolucency around the distal root has decreased, an increase in radiolucency around the mesial root can be observed. The outcome is considered ‘failure’.

2.6. Statistical analysis

The t-test, Chi-square test, or Fisher's exact test were used to analyze demographic characteristics, postoperative pain, and root canal filling quality between the two groups. Observer agreement was assessed using Cohen's kappa test, and the healing outcomes were statistically compared through bivariate analysis, including the Chi-square test and Fisher's exact test. Variables with a *p*-value of <.30 from the bivariate analysis were incorporated into a binary logistic regression model to identify predictors of outcomes. A stepwise method was applied to identify factors associated with the ourcome. All statistical analyses were conducted utilizing SPSS software (version 27; IBM Corp, Armonk, NY, USA).

3. Results

Initially, 172 participants (185 teeth) were included. Seven participants (10 teeth) were excluded because they either withdrew from the study or did not meet the inclusion criteria. After 24 months, 46 patients (49 teeth) failed to comply with the follow-up requirements, and one tooth in the MP group was extracted with no data on the periapical status (Figure 3). Accordingly, 118 participants and 125 teeth were analyzed in the final evaluation, resulting in a recall rate of 67.4%. The average follow-up duration was 36 months (range: 24–46 months), except for four cases with early failure within two years. All teeth analyzed in this study had permanent restorations with no evidence of marginal caries or leakage.

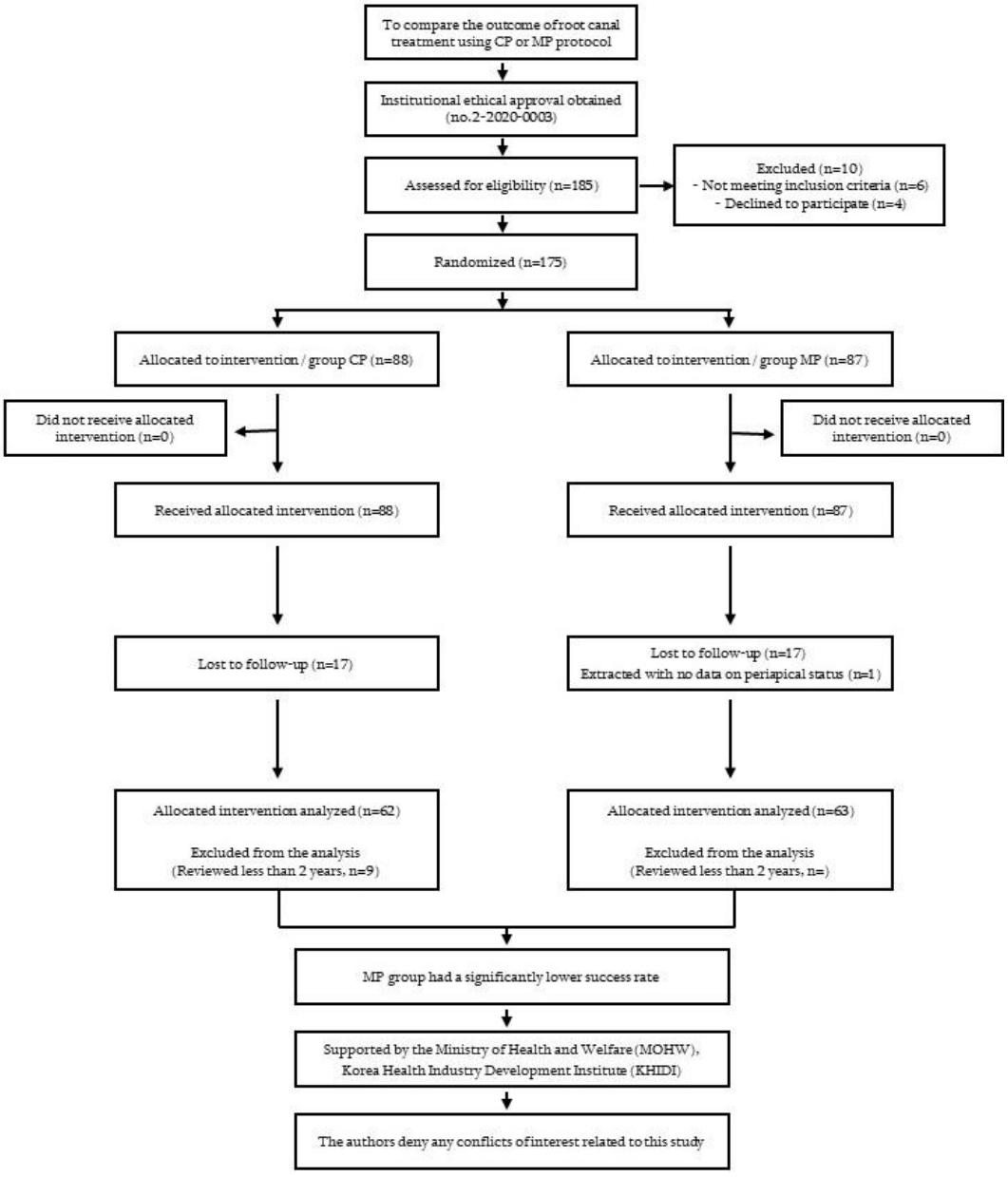

Figure 3. PRIRATE 2020 flowchart

The inter-examiner agreement for preoperative radiographic evaluation showed a Kappa score of 0.87, while the follow-up radiographic evaluation demonstrated a score of 0.79. These inter-examiner kappa values indicate 'substantial' to 'almost perfect' agreement, as defined by Landis & Koch (1977) in Table 2. The intra-examiner scores for the two evaluators, obtained from the second radiographic evaluation conducted one week later, were 0.96 and 0.95, respectively, indicating an 'almost perfect' level of agreement (Landis & Koch, 1977).

Table2. Kappa value definitions (adapted from Landis & Koch 1977)

Kappa value	Strength of agreement
<0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.00	Almost Perfect

The preoperative demographic characteristics were comparable between the two treatment groups, except for the presence of a sinus tract (Table 3). A total of one hundred-one teeth (80.8%) underwent RCT over two visits. The number of visits required to complete treatment did not significantly differ between the groups (p=.063). Postoperative pain showed identical distributions in both groups (p=.163). All cases achieved appropriate root canal filling levels, with the GPC located within 0–2 mm from the radiographic apex. However, sealer extrusion rates showed a significant variation between the groups (p=.001), while voids were similar between the groups (p=.833) (Table 3).

Table 3. The distribution of baseline demographic and clinical characteristics of patients

Preoperative factors			
Factors	CP (N=62)	MP (N=63)	*p* value
Mean age	48.0±16.7	54.1±17.7	.050
Gender			.519
Female	37 (59.7%)	34 (54.0%)	
Male	25 (40.3%)	29 (46.0%)	
Location			.940
Maxilla	36 (58.1%)	37 (58.7%)	
Mandible	26 (41.9%)	26 (41.3%)	
Tooth			.382
Anterior	12 (19.4%)	14 (22.2%)	
Premolar	15 (24.2%)	21 (33.3%)	
Molar	35 (56.5%)	28 (44.4%)	
Visits			.063
2	46 (74.2%)	55 (87.3%)	
≥3	16 (25.8%)	8 (12.7%)	
Preoperative pain (NRS)	1.87±2.54	1.98±2.64	.808
Pain on percussion			.653
No	29 (46.8%)	32 (50.8%)	
Yes	33 (53.2%)	31 (49.2%)	
Pulp status			.526
Vital	27 (43.5%)	31 (49.2%)	
Necrosis	35 (56.5%)	32 (50.8%)	
Sinus tract			.023*
Absence	48 (77.4%)	58 (92.1%)	
Presence	14 (22.6%)	5 (7.9%)	

PAI index (Preop)			.179
≤2	27 (43.5%)	35 (55.6%)	
≥3	35 (56.5%)	28 (44.4%)	
Intraoperative factors			
Sealer extrusion			.001*
No	29 (46.8%)	47 (74.6%)	
Yes	33 (53.2%)	16 (25.4%)	
Void			.833
No	53 (85.5%)	53 (84.1%)	
Yes	9 (14.5%)	10 (15.9%)	
Postoperative pain (NRS)	1.42±1.78	0.98±1.69	.163

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

The overall success rate of the RCT was 84.8% (106/125) based on loose criteria. The CP group demonstrated a significantly higher success rate of 91.9% (57/62) compared to 77.8% (49/63) in the MP group (p=.027). Based on strict criteria, the overall success rate of the treatment was 80% (100/125). Similarly, the CP group achieved a success rate of 88.7% (55/62), which was significantly greater than the 71.4% (45/63) observed in the MP group (p=.016).

According to bivariate analysis using loose criteria, teeth without sealer extrusion had a significantly lower success rate (77.6%) compared to those with sealer extrusion (95.9%, p=.005). However, bivariate tests based on strict criteria showed that gender was a significant factor in success (p=.019). Additionally, patients without a sinus tract had a higher success rate (84%) than those with a sinus tract (57.9%) (Table 4).

Table 4. Characteristics of included patients and bivariate associations between the investigated variables and outcomes based on loose and strict criteria

	Recalled (*n* = 125)					
	Total success (N, %)					
	Loose criteria (*n* = 106, 84.8%)			**Strict criteria (*n* = 100, 80%)**		
Variables	**N**	**%**	***p* value**	**N**	**%**	***p* value**
Group			**.027***			**.016***
CP	**57**	**91.9**		**55**	**88.7**	
MP	**49**	**77.8**		**45**	**71.4**	
Age			.070			.073
≤50	47	78.3		44	73.3	
>50	59	90.8		56	86.2	
Gender			.057			.019*
Female	64	90.1		62	87.3	
Male	42	77.8		38	70.4	
Location			.961			.785
Maxilla	62	84.9		59	80.8	
Mandible	44	84.6		41	78.8	
Tooth type			.290			.278
Anterior	24	92.3		23	88.5	
Premolar	28	77.8		26	72.2	
Molar	54	85.7		51	81.0	
Visits			.053			.089
2	89	88.1		84	83.2	
≥3	17	70.8		16	66.7	
Preoperative pain			.164			.374
Mild	78	87.6		73	82.0	
Moderate /Severe	28	77.8		27	75.0	

Pain on percussion			.526			.929
Negative	53	86.9		49	80.3	
Positive	53	82.8		51	79.7	
Pulp status			.554			.473
Necrotic	58	86.6		52	77.6	
Pulpitis	48	82.8		48	82.8	
Sinus tract			.166			.024*
Absence	92	86.8		89	84.0	
Presence	14	73.7		11	57.9	
PAI index (Preop)			.661			.104
1	27	87.1		27	87.1	
2	25	80.6		25	80.6	
3	26	89.7		26	89.7	
4	20	87.0		15	65.2	
5	8	72.7		7	63.6	
Sealer extrusion			.005*			.200
No	59	77.6		58	76.3	
Yes	47	95.9		42	85.7	
Void			.488			.212
Absence	91	85.8		87	82.1	
Presence	15	78.9		13	68.4	
Postoperative pain			.349			.654
Absence	57	87.7		53	81.5	
Presence	49	81.7		47	78.3	

* Statistically significant ($p < 0.05$) by t-tests, chi-square tests, or Fisher's exact tests. The bold indicates the statistical significance.

Multivariable logistic regression analysis was performed based on both loose and strict criteria to exclude the possibility that these variables were associated with each other (Table 5 and 6). After adjusting for other variables, the MP group (odds ratio [OR]=7.59, p=.009) and the absence of sealer extrusion (OR=0.09, p=.012), and presence of a sinus tract (OR=7.14, p=.021) significantly increased the risk of failure based on the loose criteria. However, the MP group (OR=6.75, p=.002), presence of a sinus tract (OR=6.59, p=.007), and male participants (OR=3.27, p=.022) significantly increased the risk of failure, based on strict criteria.

Table 5. Results of multivariable logistic regression analysis for the effect of various factors on the outcome of each treatment based on loose criteria

Variables	**OR**	**95% CI**	***p* value**
Group			
CP			
MP	7.59	1.66-34.62	.009*
Sealer extrusion			
No			
Yes	0.09	0.01-0.58	.012*
Sinus tract			
Absence			
Presence	7.14	1.34-37.96	.021*
Visits			
2			
≥3	3.25	0.85-12.41	.084
Age	0.97	0.94-1.00	.091

Pseudo-R^2 = 0.330

OR, Odds ratio; CI, Confidence interval

* $p < 0.05$

Table 6. Results of multivariable logistic regression analysis for the effect of various factors on the outcome of each treatment based on strict criteria

Variables	**OR**	**95% CI**	***p* value**
Group			
CP			
MP	6.75	1.97-23.09	.002*
Sinus tract			
Absence			
Presence	6.59	1.69-25.70	.007*
Gender			
Female			
Male	3.27	1.18-9.01	.022*
Age	0.97	0.94-1.00	.064

Pseudo-R^2 = 0.284

OR, Odds ratio; CI, Confidence interval

* $p < 0.05$

4. Discussion

This study evaluated the clinical outcomes of MP, which utilized $Ca(OH)_2$, UI, and calcium silicate cement, in comparison to CP. To address the limitations of the small taper of TN in root canal shaping and to achieve successful clinical outcomes, we established a set of protocols (MP) using TN with $Ca(OH)_2$, UI, and the SBO with a calcium silicate sealer based on several studies. We aimed to evaluate the effectiveness and long-term outcomes of MP with those of conventional root canal treatment using PTG and the continuous wave condensation technique. This study is particularly significant because, to our knowledge, no prospective clinical studies have comparatively evaluated the long-term outcomes following MP.

Studies on minimally invasive root canal treatment have focused on access cavity preparation design. In contrast, in this study, both groups had the same design as the conventional access cavity, and only the root canal preparation and subsequent procedures were different.

The TN system used in the MP group preserves cervical part of root dentin better than PTG (Silva et al. 2022b; Sarıyılmaz et al. 2024). However, previous microbiological studies have shown that the TN has results similar to or worse than those of other instrument systems in terms of bacterial reduction (Loyola-Fonseca et al. 2023; Usta et al. 2023). Given the potential disadvantage of using minimal root canal instrumentation, namely, its effect on the undisturbed, bacterial biofilm, we included an additional disinfection protocol in the MP group. Although these additional procedures introduced confounding variables into the design of this clinical study, we had to comply with IRB requirements for ethical reasons. The root canal filling method also varied between the two groups, as inserting a metal plugger into the root canal to a depth 4–5 mm short of the working length can

be difficult, particularly when the TN Prime shaping file is used as the final instrument in curved canals. Therefore, the SBO method was used in the MP group. For ethical reasons of the treatment done to the patient and for clinically successful outcomes, a treatment protocol for small tapers was established. This resulted in further differences in treatment between the CP and MP groups, but we aimed to compare the protocols themselves.

A minimum follow-up period of two years was chosen for this study based on research showing that most periapical lesions heal completely within this time frame (Ng et al. 2007). The study achieved an overall success rate of 84.8% according to loose criteria and 80% when evaluated using strict criteria.. These rates are similar to the success rates of systematic review (85.2% and 74.7%, respectively) (Ng et al. 2007). However, this systematic review included data ranging over more than 50-60 years (Setzer & Kim 2014). A recent systematic review analyzed treatment outcomes published between 2003 and 2020 and found that the weighted pooled success rate for primary endodontic treatment with at least one year of follow-up was 92.6% (21 studies) on the basis of loose criteria and 82% (39 studies) on the basis of strict criteria (Burns et al. 2022). These success rates are higher than those in our study, but given the fact that systematic reviews have shown that success rates increase with longer follow-up (Ng et al. 2007), this study may have underestimated the success rate because the follow-up period was longer than two years but not longer than four years.

A systematic review by Ng et al. (2007, 2008) emphasized the importance of standardizing study designs to ensure standardized presentation of outcome data, including mandatory definitions of success criteria (strict and loose), the use of at least two calibrated observers, and reporting kappa scores. The present study followed the aforementioned procedure to standardize the results, and the kappa scores in this study indicated 'substantial' to 'almost perfect' agreement based on Landis & Koch's (1977) criteria. Wu et al. (2009) noted that “recall” rates below 50% could lead to

overestimated results. This study had a recall rate of 67.4%, which is more reliable than other studies with shorter recall periods. On the other hand, a limitation of this study is that the treatment protocol was carried out by ten clinicians, whose varying levels of proficiency may have influenced the findings. Additionally, although most clinicians were slightly more accustomed to PTG than TN, all participants had at least two years of experience with various Ni-Ti file systems, minimizing the potential impact on outcomes.

Interestingly, the MP group exhibited significantly lower success rates compared to the CP group under both loose and strict criteria. Due to concerns about the effects of bacterial biofilm, we applied $Ca(OH)_2$ and the UI system in the MP group. While recent clinical studies and systematic reviews (Sathorn et al. 2007; Penesis et al. 2008; Karaoğlan et al. 2022) have not demonstrated a definitive advantage of $Ca(OH)_2$, other research indicates its effectiveness in eradicating microorganisms within the root canal system (Shuping et al. 2000; Evans et al. 2002). A retrospective study also found that long-term $Ca(OH)_2$ use was associated with poor outcomes in teeth with periapical periodontitis (Best et al. 2021). The UI system employed in this study was the Endosonic Blue®, comprising a handheld ultrasonic device paired with a size 15 Ni-Ti file featuring a 0.02 taper. A recent systematic review showed that UI has better antimicrobial efficacy and improved intracanal cleanliness than conventional irrigation (Virdee et al. 2018; Susila & Minu 2019; Chalub et al. 2023). However, a randomized clinical trial failed to demonstrate that UI contributes significantly to periapical healing (Liang et al. 2013). Regarding the root canal filling technique, a recent meta-analysis suggested that the single-cone obturation technique with a calcium silicate-based bioceramic sealer achieves outcomes comparable to those of other root canal filling materials and techniques in promoting the healing of apical periodontitis (Sabeti et al. 2024). As such, it is unlikely that the use of UI, $Ca(OH)_2$ medication, and SBO with a calcium silicate-based bioceramic sealer,

specific to the MP group, negatively affected the success rate. Instead, the markedly lower success rates in the MP group are more likely attributed to the dimensions of the prepared root canal system.

Although the PTG typically has a larger taper than the TN, a laboratory study found that these two systems have similar performances regarding untouched canal walls (Silva et al. 2022b). An ex vivo study on root canal disinfection revealed that using TN yielded bacterial reductions comparable to those achieved with PTG (Usta et al. 2023), and Moshari et al. (2015) demonstrated that taper differences do not significantly affect the amount of bacterial reduction. However, one study showed that larger tapers moved the irrigation needle significantly closer to the apex (Albrecht et al. 2004). In clinical situations, a wider taper allows deeper penetration of the irrigation needle and allows a greater volume of irrigant to reach the apical area. Although the manufacturer of TN recommends using a flexible polypropylene needle for irrigation, we used a comparatively stiff 30-gauge stainless-steel (SS) needle in this study. It can be difficult to insert such SS needles deeply into the root canal, particularly if the coronal third of the canal is not adequately removed. In contrast, PTG removes more dentin at the coronal level of the mesial roots than TN (Silva et al. 2022b). This difference may allow for deeper insertion of the irrigation needle into the apical portion of the root canal system in the PTG group, potentially affecting the healing outcomes. The taper of the shaped root canal can also affect the efficacy of UI (Lee et al. 2004; van der Sluis et al. 2005). In this study, the UI used may not enhance the cleaning effectiveness in the smaller tapered canals of the MP group.

However, the impact of root canal taper can be influenced by the initial size of the canal and the operator's experience, making it difficult to independently compare canals prepared using different tapers. For the clinical studies, Hoskinson et al. (2002) and Ng et al. (2011) used strict criteria and found no significant difference in treatment outcomes between small root canal tapers

(.05) and wide root canal tapers (.10). By contrast, using loose criteria, Smith et al. (1993) reported a significantly higher success rate for "flared" preparations (wide taper) compared to "conical" preparations (narrow taper). In addition, a recent randomized clinical trial involving 120 patients with mandibular first molars and asymptomatic apical periodontitis revealed that a canal preparation with a small taper (.04), and less extensive apical enlargement was associated with a significantly lower success rate (57.1%) that with a larger taper and preparation size at 1-year follow-up (Fatima et al. 2021).

When analyzed using the loose criteria, multivariable logistic regression analysis showed that, in addition to the MP group (OR=7.59, 95% CI=[1.66, 34.62], p=.009), the absence of sealer extrusion (OR=0.09, 95% CI=[0.01, 0.58], p=.012) and the presence of a sinus tract (OR=7.14, 95% CI=[1.34, 37.96], p=.021) were associated with a higher risk of failure (Table 5). In contrast, when analyzed using strict criteria, the MP group (OR=6.75, 95% CI=[1.97, 23.09], p=.002), the presence of a sinus tract (OR=6.59, 95% CI=[1.69, 25.70], p=.007), and male gender (OR=3.27, 95% CI=[1.18, 9.01], p=.022) increased the probability of failure (Table 6). In other words, MP group and sinus tract involvement were found to have a negative impact on success rates consistently for both analysis criteria, a result that suggests that these factors are likely to contribute to clinical differences in practice.

The negative impact of the MP group is thought to be due to the small taper, as previously mentioned. The presence of sinus tract is also consistent with previous studies showing that sinus tract negatively affects periapical healing (Ng et al. 2011). The sinus tract is a clinical manifestation of chronic periapical disease, indicating that the host tissue is locally overwhelmed. Although the exact reasons for the reduced treatment success in these conditions remain unclear, they are likely associated with long-standing root canal infections.

Additionally, under loose criteria, the absence of sealer extrusion was associated with an increased risk of failure. Sealer extrusion appears to occur more frequently with CWC compared to SBO (Yu et al. 2021; Kim et al. 2022). In this study, the CP group, which had a higher success rate, employed CWC and exhibited more instances of sealer extrusion (Table 3). Thus, it is suspected that sealer extrusion was investigated as a contributing factor because the proportional distribution of sealer extrusion rates and success rates differed between the CP and MP groups. Further research is necessary to determine whether sealer extrusion acts as a causal factor or correlates with the outcome.

An analysis based on strict criteria showed that the male gender was linked to a higher likelihood of failure, which contradicts the findings of a recent systematic review (Ng et al. 2008). However, one study suggested that there may be differences in pain perception due to gender differences (Macfarlane et al. 2002), and that there is a loss of protective pulpal reflexes due to a reduction in important protective feedback and pulpal proprioception in male patients (Awawdeh et al. 2017). Therefore, several potential factors could account for the statistically significant differences between the male and female treatment outcomes, and a more comprehensive investigation of their interactions is required. Furthermore, the relatively small number of cases analyzed in this study and the nature of clinical research, confounding variables were not fully controlled, so we cannot exclude the possibility that the finding of gender as a significant factor could be due to sample characteristics or coincidence. Additionally, the multivariable logistic regression analysis revealed wide confidence intervals and relatively low odds ratios compared to other factors, suggesting that its clinical impact is unlikely to be as significant as other factors.

Therefore, the logistic regression analysis results, consistent across both criteria, highlight the clinical significance of the MP group and sinus tract as important factors to consider in practice. On the other hand, the significance of sealer extrusion and gender, which showed significance in only

one of the two criteria, should be interpreted with discretion, and their effects need to be validated in further studies rather than concluded definitively.

5. Conclusion

Considering the limitations of this study, minimally invasive root canal preparation had a lower success rate. Additionally, a preoperative sinus tract was also identified as a significant predictor of treatment outcomes under both criteria. Sealer extrusion and the male gender, which have not been previously reported as significant predictors of treatment outcomes, affected the results under only one of the two criteria in this study, suggesting their clinical impact is less substantial compared to other factors.

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Abstract in Korean

최소 침습적 근관 성형이 초기 근관 치료 결과에 미치는 영향 : 무작위 배정 임상 시험

최근 몇 년간 최소 침습적 근관 치료는 중요한 논의 주제가 되어왔으며, 특히 근관 와동 형성 시의 보존 뿐 만 아니라 근관 성형 시의 치질 보존에 대한 관심이 높다. 그러나 이의 임상 적용 가능성에 대한 우려가 존재하며, 치료 결과를 평가한 무작위 임상 시험은 아직까지 보고된 바가 없다. 본 전향적 무작위 임상 시험은 두 가지 상이한 일련의 근관 치료 체계, 즉 (1) 전통적인 근관 치료 체계와 (2) 최소 침습 근관 치료 체계의 결과를 최소 2 년 후 평가하는 것을 목적으로 하였으며, 근관 성형 시의 치질 삭제량에 중점을 두었다.

총 175 개의 성숙한 영구치(생활 치수를 가진 치아 및 치수 괴사된 치아 포함)가 두 그룹으로 무작위 배정되었으며, 동일한 전통적 근관 와동 형성을 시행했다. 전통적인 치료 체계 그룹에서는 ProTaper Gold(PTG, Dentsply Sirona) 기구 체계과 연속 가압 충전법이 사용되었고, 최소 침습 치료 체계 그룹에서는 TruNatomy(Dentsply Sirona, Ballaigues, Switzerland) 기구 체계, 초음파 세척법, 수산화칼슘($Ca[OH]_2$) 첩약, 및 실러 기반 충전법이 사용되었다. 근관 치료는 두 번 이상의 내원에서 완료되었다. 환자들은 수술 후 통증을 수치 평가 척도로 평가받았으며, 근관 충전의 품질은 실러 압출, 근관 충전재의 공극, 그리고 충전 길이

정도를 기준으로 평가되었다. 참가자들은 최소 2 년 후에 재방문하였으며, 결과는 엄격한 기준과 느슨한 기준에 따라 각각 성공 또는 실패로 이분화 되었다. 결과는 카이제곱 검정 또는 피셔의 정확 검정을 사용해 통계적으로 비교한 후, 로지스틱 회귀 분석을 통한 다변량 분석을 수행하였다.

총 125 개의 치아가 분석에 포함되었으며 (회수율 67.4%), 평균 추적 기간은 36 개월(24-46 개월)이었다. 두 그룹 간의 수술 후 통증 분포 (p=.163), 근관 충전재의 공극 (p=.833), 충전 길이 정도에서는 유의미한 차이가 나타나지 않았다. 그러나 실러 압출의 존재 여부는 두 치료 그룹 간에 유의미한 차이를 보였다 (p=.001). 전체 성공률은 느슨한 기준에 따르면 84.8%(CP 91.9%, MP 77.8%), 엄격한 기준에 따르면 80.0%(CP 88.7%, MP 71.4%)로, 두 그룹 간에 유의미한 차이가 있었다(p=.027 및 p=.016). 다변량 로지스틱 회귀 분석 결과, 최소 침습 치료 체계과 술전 누공의 존재가 느슨한 기준과 엄격한 기준 모두에서 실패 위험이 높아지는 요인으로 나타났다.

이 연구의 한계 내에서, 최소 침습 치료 체계는 전통적 근관 치료 체계에 비해 초기 근관 치료의 2 년 성공률이 더 낮았다. 최소 침습적 근관 치료 체계와 술전 누공의 존재는 치료 결과에 부정적인 영향을 미치는 것으로 나타났다.

핵심되는 말 : 치료 결과; 근관 치료; 최소 침습적 근관 치료; 초음파 보조 세척; 수산화칼슘; 실러 기반 충전법