A Two-Center Randomized Controlled Trial of Two Calcium Silicate-based Materials for Pulpotomy of the Mature Permanent Teeth

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감사의 말

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부족한 후배였지만 잘 알려주고 편안한 의국분위기를 만들어주어 보존과에 애정을 갖게 해준 선배 의국원들, 3년동안 힘들 때도 좋을 때도 함께 헤쳐나간 보존과 동기들, 믿고 의지해준 후배 의국원들에게 감사드립니다. 그 중에서도 항상 믿고 지지해주며 아낌없이 애정을 준 내 반려자에게 감사를 드립니다. 마지막으로 항상 사랑과 믿음으로 지켜봐주는 나의 가족들과 흔들리지 않는 내 편인 부모님께 감사의 말씀을 드립니다. 더욱 성장하여 모두에게 보답할 수 있는 사람이 되도록 노력하겠습니다.

Table of Contents

List of Figures

List of Tables

Abstract

A Two-Center Randomized Controlled Trial of Two Calcium Silicate-based Materials for Pulpotomy of the Mature Permanent Teeth

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(Directed by Professor Il-Young Jung, D.D.S., M.S.D., Ph.D.)

Recent clinical trials and systematic studies have shown that vital pulp therapy procedures, including partial and full pulpotomies, yield favorable outcomes of treating caries with vital pulp exposure in the mature permanent teeth. Endocem MTA Premixed (Maruchi, Wonju, Korea) has been developed as a premixed syringeable calcium silicate-based cement. However, studies on this material have not been conducted in the permanent teeth.

Therefore, the aim of the present study was to compare the outcomes of Pulpotomy using ProRoot MTA® (Dentsply Tulsa Dental, Tulsa, OK, USA) and Endocem MTA Premixed in teeth with normal pulp or reversible pulpitis

This was a two-center randomized clinical trial of ProRoot MTA and Endocem MTA Premixed for pulpotomy, focused on the outcome of the permanent premolars and molars. Teeth with non-restorable crown, immature roots, and inability to control bleeding within 5min after pulp exposure were excluded. After achieving hemostasis, the randomly chosen calcium silicate material was applied. A thin layer of the light-curing glass ionomer composite liner (Ionoseal, VOCO GmbH, Germany) was applied on the material, and curing was performed for 20 s. The cavity was restored with composite restoration during the same visit. The 12-months success rate and calcific bridge formation were evaluated. A chi-square test and a logistic regression analysis were used for data analysis.

Enrolled a total of 87 teeth, including 64 teeth from YUDH and 23 teeth from NHIIH. Four patients (four teeth) refused to participate after the allocated procedure; therefore 83 teeth were finally included. Four patients, including three in the ProRoot MTA group and one in the Endocem MTA Premixed group, experienced severe pain within 6 months after the pulpotomy procedure and underwent root canal treatment. 12 patients were excluded during the follow-up period. Finally, 71 teeth, including 37 in the ProRoot MTA group and 34 in the Endocem MTA Premixed group, were clinically and radiographically assessed at 1 year. This resulted in an overall recall rate of 91.0%. The overall success rate of pulpotomy was 93.9% in the ProRoot MTA and 97.1% in the Endocem MTA Premixed

group.

Among the total cases analyzed, full pulpotomy was performed in 17 teeth and partial pulpotomy was carried out in 54 teeth. The success rates of the former and the latter are 94.1%, and 94.4%, respectively. The success rates of occlusal and axial exposure were 91.7% and 95.2%, respectively, and there was no statistical significance ($p > .05$). Hard tissue barrier was formed in six (16.2%) cases in the ProRoot MTA group and 10 (29.4%) cases in the Endocem MTA Premixed group, showing no significant difference in the exposure site in the logistic regression analysis or chi-square test.

The 12-months success rate and hard tissue barrier formation of Pulpotomy did not differ significantly between ProRoot MTA and Endocem MTA groups.

Keywords : Mineral Trioxide Aggegate (MTA), Pulpotomy, Calcific bridge

A Two-Center Randomized Controlled Trial of Two Calcium Silicate-based Materials for Pulpotomy of the Mature Permanent Teeth

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I. Introduction

Treating caries with pulp exposure is a challenge in the mature teeth. However, recent clinical trials and systematic studies (1-5) have shown that vital pulp therapy procedures, including partial and complete pulpotomies, yield favorable outcomes of treating caries with vital pulp exposure in the mature permanent teeth. Pulpotomy also shows high success rates in traumatic pulp exposures (6). Although long-term outcomes remain limited, vital

pulp therapy procedures can be a treatment option for vital pulp exposure of the mature permanent teeth.

Since the introduction of the mineral trioxide aggregate (MTA) in the early 1990s (7), it has consistently shown a high success rate clinically (8). However, it has disadvantages of a prolonged setting time, poor handling properties, and potential for discoloration (8). Moreover, the adverse effect of an etching procedure with MTA restricts its use (9). In many clinical trials (2, 10, 11), a moist cotton pellet and an interim restoration were placed on top of the unset MTA material, and the final restoration was placed during a subsequent visit. However, both patients and dentists would prefer the treatment to be completed in a single appointment. The glass ionomer cement or composite resin with a bonding agent can be applied over freshly mixed MTA with minimal effects on the MTA (12, 13). In a clinical trial (3), a thin layer of resin-modified glass ionomer liner was immediately placed over the MTA, and the cavity was restored with composite restoration during the same visit. This approach reduces the cost and chairside time of the procedure significantly.

Endocem MTA Premixed (Maruchi, Wonju, Korea) has been developed as a premixed syringeable calcium silicate-based cement that contains dimethyl sulfoxide as a solvent. When the material meets moisture, dimethyl sulfoxide(DMSO) is rapidly displaced with water, and a setting reaction occurs. Because Endocem MTA Premixed does not require mixing, the cement can be administered directly from the syringe into the target area, implying that it is easy to use. According to the manufacturer, the material has a short

setting time of approximately 5 min when a moist cotton pellet is placed on the injected cement. However, studies on this material have not been conducted in the permanent teeth. Therefore, the aim of the present study was to compare the outcomes of pulpotomy using ProRoot MTA (Dentsply Tulsa Dental, Tulsa, OK, USA) and Endocem MTA Premixed in the teeth with normal pulp or reversible pulpitis (Figure 1, Table 1). The null hypothesis was that the outcome does not differ between these two tested materials.

Table 1. Detailed information of the materials tested in this study

Material	Manufacturer	Composition	Content (wt%)
ProRoot MTA®	Dentsply, Tulsa, OK, USA	Calcium oxide (CaO)	44.2
		Silicon dioxide (SiO_2)	21.2
		Bismuth oxide (Bi_2O_3)	16.1
		Aluminium oxide (Al_2O_3)	1.9
		Magnesium oxide (MgO)	1.4
		Sulphur trioxide (SO_3)	0.6
		Ferrous oxide (FeO)	0.4
Endocem MTA premixed	MARUCHI, Wonju, Korea	Zirconium dioxide (ZrO_2)	40
		Calcium silicate ($CaSiO_3$)	40
		Calcium aluminate ($CaAl_2O_4$)	0.60
		Calcium sulfate ($CaSO_4$)	0.30
		Dimethyl sulfoxide $(CH_3)_2SO$	16.33
		Lithium carbonate (Li_2CO_3)	0.17
		Thickening agents, etc.	2.60

Figure 1. Materials tested in this study. (A) ProRoot MTA®, (B) Endocem MTA premixed

II. Material and Methods

1. Study design and population

This was a two-center randomized controlled trial of ProRoot MTA and Endocem MTA Premixed for pulpotomy, focused on the outcome of the permanent premolars and molars. The independent ethics committees of the Yonsei University Dental Hospital (YUDH) and National Health Insurance Ilsan Hospital (NHIIH) approved the study protocol. The clinical trial was registered in the Clinical Research Information Service (reg. no.: KCT0005734). We enrolled systematically healthy patients aged 11–82 years scheduled for pulpotomy of the mature permanent teeth at either hospital from December 2020 to October 2021.

Inclusion criteria were: (1) no history of spontaneous pain in the tooth of interest; (2) a positive response of the tooth of interest to the cold test; (3) pulp exposure during caries removal or secondary to recent trauma; (4) negative responses to palpation and percussion of the tooth of interest; (5) a periapical index score ≤2 on the periapical radiograph; and (6) a healthy periodontium based on a probing pocket depth ≤3 mm and mobility within the normal limit. Exclusion criteria were: (1) non-restorable crown; (2) immature roots; and (3) inability to control bleeding within 5 min after pulp exposure.

Patients fulfilling the eligibility criteria were informed about the procedure, associated risks and benefits, and alternative treatment options. Subsequently, written informed consent was obtained before participation in the study.

2. Sample-size determination and randomization

All investigators and participants were blinded to patient distribution. We postulated that pulpotomy with Endocem MTA Premixed would not be inferior to that with ProRoot MTA. Pulpotomy with calcium hydroxide showed a mean 20% lower success rate compared to that with hydraulic silicate cements (HSCs). The success rate of the control group is generally considered to be >90%. Therefore, we set a success rate of 50% to 75% of −20%, i.e., −15% to 10%, as the non-inferiority margin. Further, 50 patients per treatment group were estimated to provide an 80% power to detect a non-inferiority margin of −0.12 using a one-sided α of 0.05, assuming a 20% dropout rate.

A clinical coordinator blinded to the study objectives created a computer-generated list of random numbers using the Sealed Envelope website (https://www.sealedenvelope.com/) in a stage 1 allocation using random block sizes of 6. The clinical coordinator assigned the involved permanent teeth to one of the two groups: ProRoot MTA or Endocem MTA Premixed.

3. Treatment procedure

Six dentists, including five postgraduate residents and one faculty, from the YUDH and one postgraduate resident and one faculty from the NHIIH performed the procedures.

Local anesthesia was induced with 1.8 mL of 2% lidocaine with 1:80,000 epinephrine

(Huons, Sungnam, Korea), and caries removal was performed under rubber dam isolation (Figure 3b, 4b). After pulp exposure, 2–3 mm of pulp was removed with a sterile high-speed round, tapered diamond bur (Komet Dental, Gebr. Brasseler, Lemgo, Germany) under a water coolant to a depth of 2 mm (partial pulpotomy; Figure 3c, 4c). When hemostasis could not be achieved within 5 min, the pulp tissue was amputated to the level of the root canal orifices (complete pulpotomy). Subsequently, the cavity was thoroughly washed with 5% NaOCl. After achieving hemostasis, the randomly chosen calcium silicate material was applied. In the ProRoot MTA group, MTA was freshly mixed following the manufacturers' instructions and gently placed over the pulp wound and its surrounding dentin with a thickness of 3 mm as the inflamed coronal pulp depth beneath the exposure (Figure 3d) (14). In the Endocem MTA Premixed group, the material was introduced in the target area directly using a 19-gauge needle with the same thickness (Figure 4d). Subsequently, a moist cotton pellet was placed to ensure the setting of both materials and removed after 5 min. A thin layer of the light-curing glass ionomer composite liner (Ionoseal, VOCO GmbH, Germany) was applied on the material, and curing was performed for 20 s. The cavity was restored with composite restoration during the same visit (Figure 3e, 4e). When prosthetic restoration was required, it was commenced during the next visit (Figure 3f, 4f). An immediate postoperative periapical radiograph was taken.

Table 2. Detailed information of the tested liner in this study

Material	Manufacturer	Composition	Content (wt%)
Ionoseal	Voco GmbH, Germany	Bis – GMA Urethanedimethacrylate 1,6- hexanediylbismethacrylate Triethylene glycol dimethacrylate	10-25 5-10 5-10 2.5-5

Figure 2. Light-curing glass ionomer composite liner (Ionoseal, VOCO GmbH, Germany)

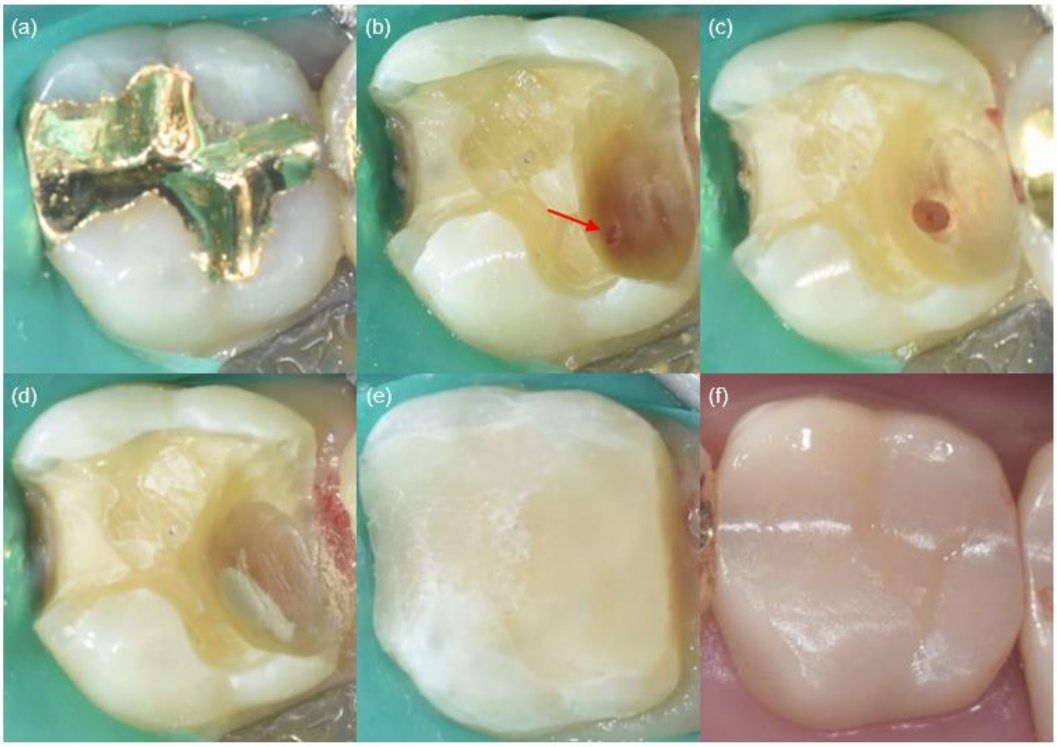

Figure 3. Partial pulpotomy clinical protocol. (a) Preoperative clinical photographs. (b) Pulp exposure after non-selective caries removal (red arrow). (c) Hemostasis achieved after several minutes by placing a cotton pellet soaked in 2.5% NaOCl, pressed against the exposed pulp tissue. (d) ProRoot MTA used to restore the exposed pulp. (e) Cavity restored with Ionoseal and Composite resin restoration. (f) Full zirconia crown final setting.

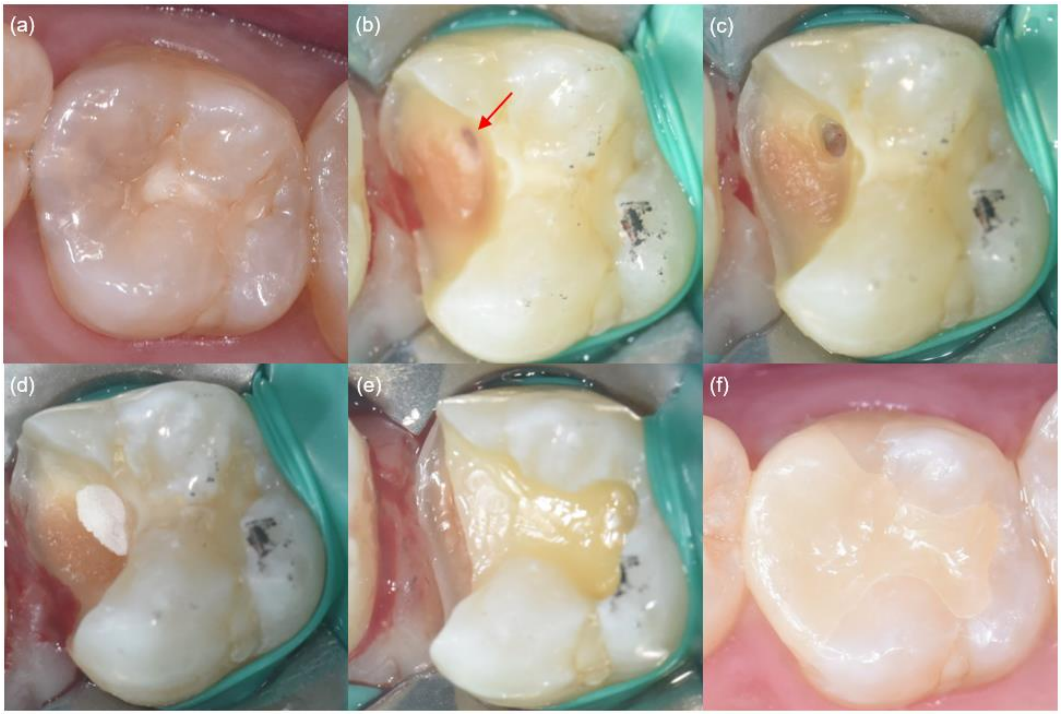

Figure 4. Partial pulpotomy clinical protocol. (a) Preoperative clinical photograph. (b) Pulp exposure after non-selective caries removal (red arrow). (c) Hemostasis achieved after several minutes by placing a cotton pellet soaked in 2.5% NaOCl, pressed against the exposed pulp tissue. (d) Endocem MTA used to restore the exposed pulp. (e) Cavity restored with Ionoseal and Composite resin restoration. (f) Ceramic inlay setting.

The participants were recalled after 3, 6, and 12 months after pulpotomy, and radiographic and clinical examinations of the treated tooth were performed. Clinical examination included the presence/absence of pain (spontaneous or on percussion, biting, or palpation),

swelling, sinus tract formation, and other symptoms. Radiographic examination included the detection of periapical radiolucency and signs of pathological root resorption and hard tissue barrier formation, except in cases of extracoronal restoration. The success of pulpotomy was determined by the absence of clinical and radiographic signs and symptoms. Two operators blinded to the type of MTA performed radiographic analyses. Clearly visible calcific bridge formation was regarded as success, whereas its absence was regarded as failure.

4. Statistical analysis

The chi-squared test was performed to assess the homogeneity of baseline characteristics of the two treatment groups. The relationships of possible explanatory variables with treatment success and hard tissue formation were analyzed using logistic regression. Statistical analyses were performed using SPSS software version 29.0 (IBM SPSS Inc., Chicago, IL, USA).

III. Results

Enrolled a total of 87 teeth, including 64 teeth from YUDH and 23 teeth from NHIIH. Four patients (four teeth) refused to participate after the allocated procedure; therefore, 83 teeth were finally included. Four patients, including three in the ProRoot MTA group and

one in the Endocem MTA Premixed group, experienced severe pain within 6 months after the pulpotomy procedure and underwent root canal treatment (Figure 6). These four cases were considered to show treatment failure. Table 3 shows the clinical and radiographic findings of these patients. Five teeth, including two with secondary caries, one with trauma, one with root fracture, and one with extraction due to orthodontic treatment, were excluded during the follow-up. Seven patients were lost to follow-up. Finally, 71 teeth, including 37 in the ProRoot MTA group and 34 in the Endocem MTA Premixed group, were clinically and radiographically assessed at 1 year (Figure 4). This resulted in an overall recall rate of 91.0%. The chi-square test revealed that demographic variables, such as sex and age group, and clinical variables, such as the types of teeth, exposure, and pulpotomy, were similarly distributed among the experimental groups (Table 4, $p > 0.05$).

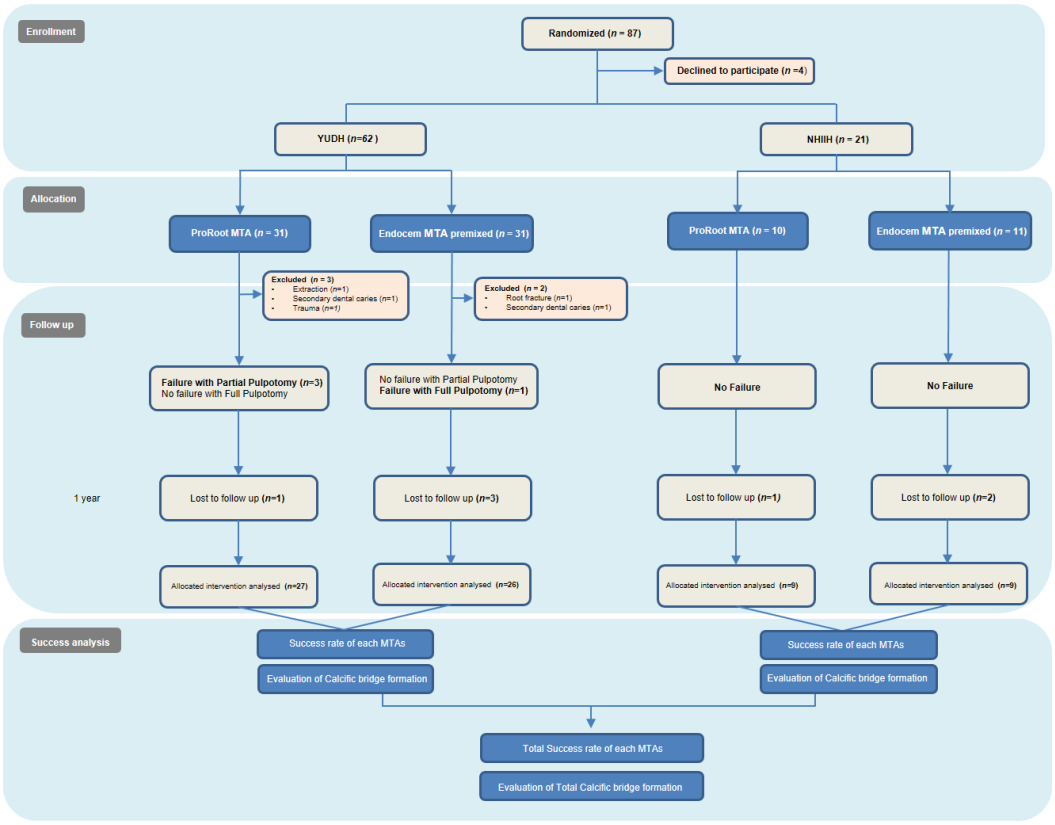

Figure 5. Flowchart of patient selection for partial pulpotomy with two materials

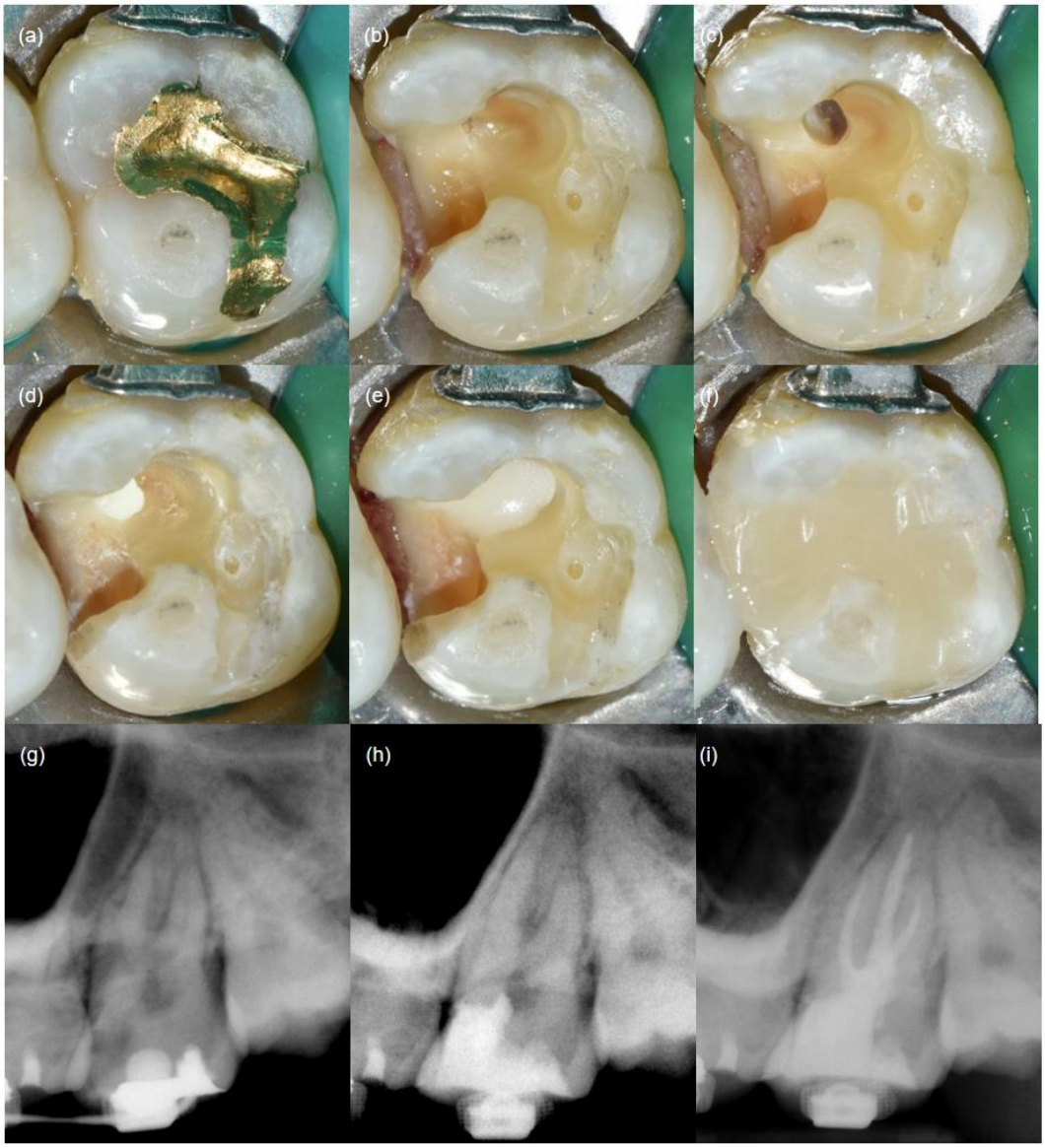

Figure 6. Failure cases of the study because of severe pain. (a,g) Preoperative view of the maxillary left second molar with a deep carious lesion. (b) Pulp exposure after non-selective caries removal. (c) Hemostasis achieved after several minutes by placing a cotton

pellet soaked in 2.5% NaOCl, pressed against the exposed pulp tissue. (d) Endocem MTA Premixed used to restore the exposed pulp. (e) Exposure site restored with a light-curing glass ionomer composite liner (Ionoseal, VOCO GmbH, Germany). (f) Cavity restored with composite resin. (h) Postoperative periapical view of the maxillary left second molar. (i) Same tooth in Figure h treated endodontically and restored with composite resin at the 6-month follow-up.

Table 3. Characteristics of failure cases during the follow-up of partial pulpotomy

Age	Tooth type	Exposure type	Site of Exposure	HSCs Material	Decision of Failure	Reason of Failure
30	Molar	Caries	Occlusal	ProRoot MTA	2 Months	Spontaneous pain
19	Premolar	Caries	Axial	ProRoot MTA	6 Months	Spontaneous pain
62	Premolar	Caries	Full pulpotomy	Endocem MTA	4 Days	Spontaneous pain
54	Molar	Caries	Axial	ProRoot MTA	6 Months	Spontaneous pain

Table 4. Baseline demographic and clinical features of all patients by treatment group

		ProRoot	Endocem	Total
Mean age		44.6±21.2	39.9±21.6	41.2±22.4
Sex	Female	22 (59.5%)	17 (50.0%)	39 (54.9%)
	Male	15 (40.5%)	17 (50.0%)	32 (45.1%)
Location	Maxillar	23 (62.2%)	26 (76.5%)	49 (69.0%)
	Mandible	14 (37.8%)	8 (23.5%)	22 (31.0%)
Tooth	Premolar	10 (27.0%)	8 (23.5%)	18 (25.4%)
	Molar	27 (73.0%)	26 (76.5%)	53 (74.6%)
Exposure	Occlusal	8 (26.7%)	4 (16.7%)	12 (22.2%)
	Axial	22 (73.3%)	20 (83.3%)	42 (77.8%)
type of pulpotomy	Partial	30 (81.1%)	24 (70.6%)	54 (76.1%)
	Full	7 (18.9%)	10 (39.4%)	17 (23.9%)

Table 5. Chi-square test and logistic regression results of the success rate of pulpotomy at the 1-year follow-up (n = 71)

Variables	Total	Success (n,%)	Failure (n, %)	*P* value[a]	*P* value[b]
Age in years					
<21	15	14 (93.3%)	1 (6.7%)		
21-40	19	18 (94.7%)	1 (5.3%)		0.88
41-60	19	18 (94.7%)	1 (5.3%)		0.98
>60	18	17 (94.1%)	1 (5.9%)	1	0.99
Gender					
Male	32	31 (96.9%)	1 (3.1%)		
Female	39	36 (92.3%)	3 (7.7%)	1	0.99
Type of tooth					
Premolar	18	16 (88.9%)	2 (11.1%)		
Molar	53	51 (96.2%)	2 (3.8%)	0.27	0.65
Arch					
Upper	49	46 (93.9%)	3 (6.1%)		
Lower	22	21 (95.5%)	1 (4.5%)	0.71	0.99
Type of HSC					
ProRoot MTA	37	34 (93.9%)	3 (6.1%)		
Endocem MTA	34	33 (97.1%)	1 (2.9%)	0.27	0.99
Site of Exposure					
Axial	42	40 (95.2%)	2 (4.8%)		
Occlusal	12	11 (91.7%)	1 (8.3%)	0.58	0.94
Type of Pulpotomy					
Full	17	16 (94.1%)	1 (5.9%)		
Partial	54	51 (94.4%)	3 (5.6%)	1	0.99

[a] *p* value of chi square test
[b] *p* value of logistic regression analysis
Chi-square test and Logistic regression analysis shows no statistic significance

Four clinical failures were determined within 6 months after the treatment (Table 3). At the 1-year follow-up, no case exhibited clinical or radiographic signs or symptoms of failure. Therefore, the overall success rate of pulpotomy was 93.9% in the ProRoot MTA group and 97.1% in the Endocem MTA Premixed group. Full pulpotomy was performed in 17 teeth, including seven in the ProRoot MTA group and 10 in the Endocem MTA Premixed group, and partial pulpotomy was performed in 54 teeth. The success rates of pulpotomies with ProRoot MTA and Endocem MTA Premixed were 94.1%, and 94.4%, respectively. The site of exposure was analyzed only in cases of partial pulpotomy. The success rates of occlusal and axial exposures were 91.7% and 95.2%, respectively, showing no significant difference ($p > 0.05$). The probability of calcific bridge formation was 3.75 times higher in the case of occlusal exposure than in the case of axial exposure (Table 6). None of the independent variables, including the type of materials, significantly influenced the success rate of pulpotomy (Table 5, $p > 0.05$). Because of extracoronal restoration, evaluating hard tissue formation was not possible in four cases, including two cases in the ProRoot MTA group and two cases in the Endocem MTA Premixed group. Hard tissue barrier was formed in six (16.2%) cases in the ProRoot MTA group and 10 (29.4%) cases in the Endocem MTA Premixed group (Figure 7), showing no significant difference in the exposure site in the logistic regression analysis or chi-square test (Table 6, $p > 0.05$).

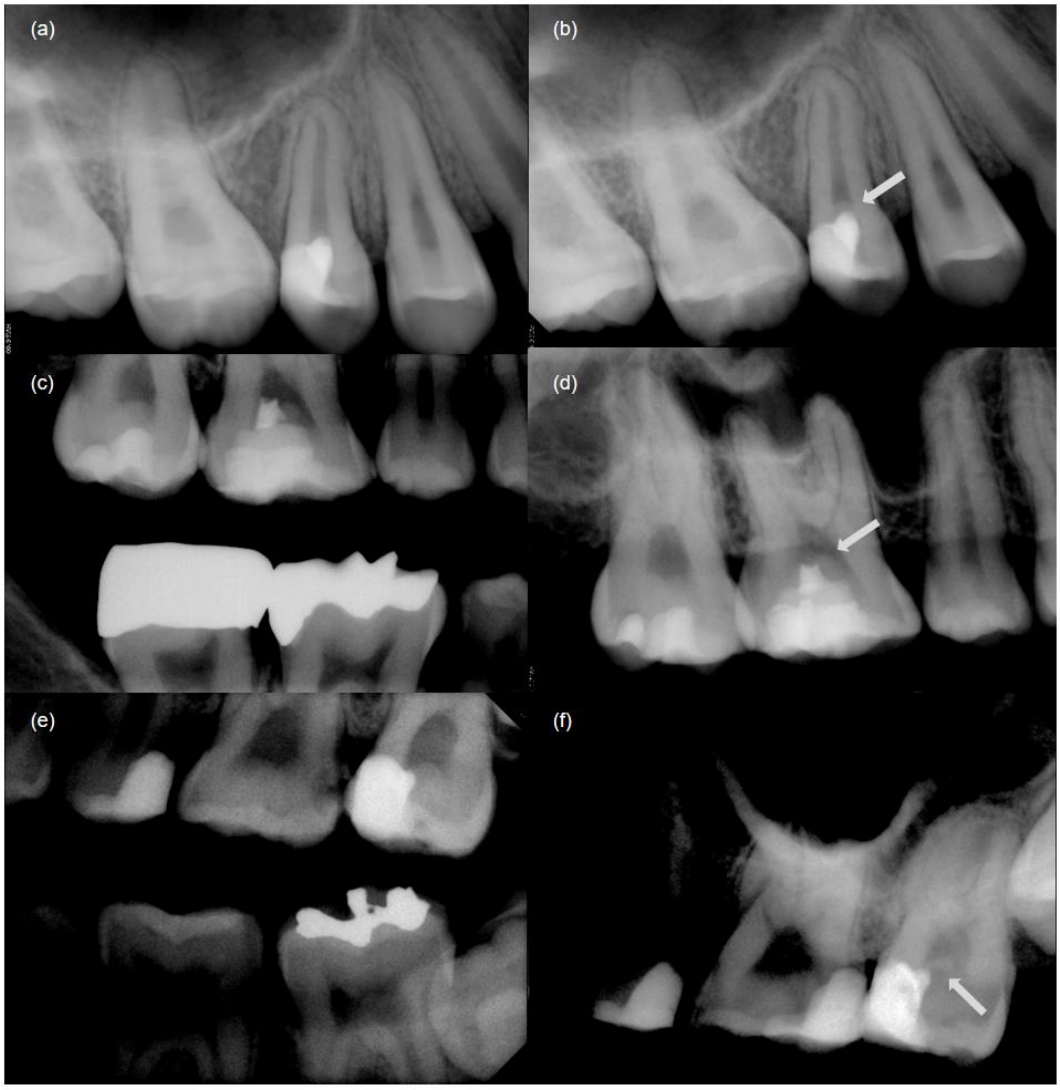

Figure 7. Radiographic evaluation of calcific bridge formation. (a,b) Calcific bridge formation (white arrow) in the maxillary right second premolar. Endocem MTA Premixed. (c,d) Calcific bridge formation (white arrow) in the maxillary right first molar. ProRoot MTA. (e,f) Calcific bridge formation (white arrow) in the maxillary left second molar.

Endocem MTA Premixed.

Table 6. Chi-square test and logistic regression analysis results of hard tissue formation at the 1-year follow-up after partial pulpotomy (n = 71)

Variables	Total	Hard tissue formation over the exposure site		*P* value	Odds ratio	*P* value [a]	95% conf. interval [b]	
		Evident	Absent					
Age in years								
<21	15	5	10		1			
21-40	19	6	13		0.37	0.32	0.054	2.589
41-60	19	3	16		0.26	0.20	0.033	2.060
>60	18	2	16	0.21	0.34	0.21	0.032	3.639
Gender								
Male	32	6	26		1			
Female	39	10	29	0.78	1.20	0.80	0.292	4.909
Type of tooth								
Premolar	18	5	13		1			
Molar	53	12	41	0.09	0.36	0.09	0.036	1.285
Arch								
Upper	49	10	39		1			
Lower	22	7	15	0.11	3.01	0.11	0.764	12.523
Type of HSC								
ProRoot MTA	37	6	31		1			
Endocem MTA	34	10	24	0.27	2.83	0.21	0.556	14.433
Site of Exposure								
Axial	42	10	32		1			
Occlusal	12	6	6	0.15	3.88	0.07	0.774	19.477
Type of Pulpotomy [c]								
Full	17	0	17					
Partial	54	16	48	1				

[a] *p* value of chi square test
[b] *p* value of logistic regression analysis
[c] Type of Pulpotomy is not analyzed because there is no evient case in full pulpotomy group.

YUDH and NHIIH had 53 and 18 cases, respectively, and all failure cases were from YUDH. At NHIIH, occlusal exposure occurred only in one case, and axial exposure occurred in the remaining 17 cases. In addition, all cases underwent partial pulpotomy,

whereas no case underwent full pulpotomy, showing no significant difference in the chi-square test (Table 7).

Table 7. Baseline demographic and clinical features of patients from YUDH (n = 53) and NHIIH (n = 18)

		YUDH			NHIIH		
		ProRoot	Endocem	Total	ProRoot	Endocem	Total
Mean age		44.7±22.0	41.2±22.8	42.9±22.5	42.4±16.5	37.8±14.9	40.1±15.9
Gender	Female	19 (70.4%)	15 (57.7%)	34	3 (33.3%)	7 (77.8%)	10
	Male	8 (29.6%)	11 (42.3%)	19	6 (66.7%)	2 (22.2%)	8
Location	Maxillar	21 (77.8%)	15 (57,7%)	36	6 (66.7%)	7 (77.8%)	13
	Mandible	6 (22.2%)	11 (42.3%)	17	3 (33.3%)	2 (22.2%)	5
Tooth	Premolar	9 (33.3%)	6 (23.1%)	15	3 (33.3%)	0 (0%)	3
	Molar	18 (66.7%)	20 (76.9%)	38	6 (66.7%)	9 (100%)	15
Exposure	Occlusal	4 (22.2%)	7 (38.9%)	11	1 (11.1%)	0 (0%)	1
	Axial	14 (77.8%)	11 (61.1%)	25	8 (88.9%)	9 (100%)	17
Type of Pulpotomy	Partial	18 (66.7%)	18 (69.2%)	36	9 (100%)	9 (100%)	18
	Full	9 (33.3%)	8 (30.8%)	17	0 (0%)	0 (0%)	0
Success	Success	24 (88.9%)	25 (96.2%)	49	9 (100%)	9 (100%)	18
	Failure	3 (11.1%)	1 (3.8%)	4	0 (0%)	0 (0%)	0
Calcific bridge	Formation	4 (14.8%)	7 (26.9%)	11	2 (22.2%)	3 (33.3%)	5
	None	23 (85.2%)	19 (73.1%)	42	7 (77.8%)	6 (66.7%)	13

Chi - sqaure test shows no statistical significance

IV. Discussion

The success rate of vital pulp therapy is high, regardless of pulpotomy being partial or full. In addition, the success rate of ProRoot MTA, the gold-standard material for vital pulp therapy, is higher than that of other materials (15). Clinicians often face the dilemma of which material is better for a clinical case. All calcium silicate substances, except the resin-containing agent, have similar biological and histological responses as ProRoot MTA (16, 17). However, randomized controlled trials of the commonly used materials have been limited. Therefore, this study was aimed at evaluating the clinical and radiographic results of pulpotomy by comparing the commonly used calcium silicate substances with the gold-standard MTA.

Unlike ProRoot MTA, Endocem MTA Premixed is delivered via a syringe and has the advantage of no error in the mixing ratio. According to the manufacturer, the setting time of the Endocem MTA Premixed is 4 minutes, which is shorter than that of ProRoot MTA, and advantageous for a single-visit treatment. Moreover, the phyllosilicate ingredient in the product is more advantageous for bleeding control owing to hemostatic action (18). However, no studies on Endocem MTA Premixed have supported these claims.

This study differed from other studies in that pulpotomy with ProRoot MTA was also

conducted in a single visit. Washout of MTA was prevented by using the light-curing glass ionomer composite liner, and final restoration was performed. However, no study has investigated how using the light-curing glass ionomer composite liner before the setting of ProRoot MTA causes the interaction between each material. In addition, the failure of MTA setting due to washout or moisture contamination of MTA could not be confirmed during the bonding process for the final restoration immediately after sealing with the light-curing glass ionomer composite liner.

Many factors influence the outcome of partial pulpotomy. Early failure is commonly associated with spontaneous pain due to inflammatory processes (19, 20). In the present study, all failures occurred within 6 months of follow-up, with one case of failure occurring within 4 days after partial pulpotomy and root canal treatment. Preoperative pulp status is a significant factor that causes early failure. Although all cases included in this study are reversible pulpitis or normal pulp state, the reason why all failure cases are early failure may have misdiagnosed the status of pulp. Additionally, to prevent early failure of partial pulpotomy, tight sealing should be achieved such that the material covering the pulp does not leak (21). In this study, the pulpotomy success rate did not differ significantly between occlusal and axial exposures. This was because the occurrence of secondary dental caries before the failure of partial pulpotomy was considered “dropout.” When restoration was improperly performed, the effect of marginal leakage was minimized because of dropout.

Delayed/late failure is caused by lack of new hard tissue formation or the newly formed hard tissue not acting as a protective barrier against bacterial microleakage (22). It occurs near the closed area of bioactive substances that contact the pulpal tissue. Continuous deposition of hard tissues can lead to canal narrowing and obliteration in several cases. Radiographic evaluation conducted in this study was limited by investigator's subjectivity, inherent limitations of periapical radiographs, and the final restoration not showing periapical radiolucency. Biological mechanisms underlying the variable response of pulp tissues for these biomaterials remain poorly understood, and further research is required. Future studies should evaluate the progression of the hard tissue barrier over longer time periods using the latest techniques, such as cone-beam computed tomography, for increased accuracy.

Hard tissue formation rate of axial exposure and occlusal exposure are 23.8%, 50.0% respectively. Also The probability of hard tissue formation according to the site of exposure was 3.88 times higher than the Axial exposure. Although there was no statistical significant, setting of MTA is considered to affect hard tissue formation. Due to difficulties of cavity sealing and isolation, setting of MTA is more difficult in axial exposure than in occlusal exposure. Therefore, hard tissue formation is more advantageous in occlusal exposure than in axial exposure. The probabilities of hard tissue formation according to the type of tooth, arch, and type of HSC were 0.36, 3.01, and 2.83 times higher than the default values,

respectively, although without statistical significance. In the future, more detailed analyses of whether or not the type of tooth, arch, and type of HSC are influencing factors should be evaluated using more samples.

Although we evaluated several potential prognostic factors, including age, sex, type of tooth, arch, type of MTA, site of exposure, and type of pulpotomy, none of them significantly affected the survival rate. Consistently, a meta-analysis of partial pulpotomy showed that the final restoration, pulp capping material, or age did not affect treatment outcomes (22). In this meta-regression analysis, the only variable significantly associated with the success rate at the 1-year follow-up was the preoperative pulp status (22). This was a randomized controlled trial involving patients screened based on the indication of partial pulpotomy. Thus, cases of inadequate pulp status were excluded. Young patient age may be associated with a high success rate. However, the definitions of "young" and "old" vary. In this study, age groups were divided based on a threshold of 40 years, considering that the study participants were aged between 11 and 82 years and that the average age was 41.2 ± 22.4 years. These age groups showed no significant differences. Therefore, age groups were classified as <20, 20–40, 40–60, and >60 years for detailed analyses. From the results of this study, we cannot conclude that the success rate was higher in young patients, because two cases, i.e., half of the four failed cases, occurred in patients in their 10s and 30s. However, age did not affect the success rate in this study significantly ($p = 0.97$), and patients in the wide age range of 11 to 82 years were treated successfully with partial

pulpotomy.

This study has several limitations. First, eight technicians participated in the randomized controlled trial, and differences in results may have resulted from differences in their proficiency. Although they are endodontic specialists, errors may have occurred in results because of differences in proficiency. Second, the follow-up duration in this study was 1 year. In a recent study, the factor causing failure during the long-term follow-up was bacterial microleakage due to the absence of a calcific barrier (23). The average time to calcific barrier formation was 21.3 months, and the presence of a calcific barrier was confirmed in 75% of the cases. In this study, the presence of a calcific barrier was confirmed only in 16 (22.5%) cases, possibly because of a short follow-up of 1 year. Calcific barrier formation of ProRoot MTA and Endocem MTA were 16.2%, and 29.4% respectively. Although there was no significant difference, Endocem MTA has higher calcific barrier formation. DMSO, a characteristic component of Endocem MTA, exhibits hemostatic action when in contact with tissue. Hemostatic action may have promoted faster calcific barrier formation by fixing not only the contacted pulp surface but also inside pulp space. Histological analysis is expected to be necessary for the accurate evaluation of this hypothesis. Long-term follow-ups are required to prevent bacterial microleakage through the formation of a calcific barrier and ProRoot MTA, which is the gold-standard material. In addition, calcific barrier formation may be judged differently depending on the subjectivity of the investigator or angle of the radiographic view. For an accurate evaluation,

a bitewing radiograph and three-dimensional reconstruction using cone-beam computed tomography are necessary.

V. Conclusion

The 12-months success rate and hard tissue barrier formation of Pulpotomy did not differ significantly between ProRoot MTA and Endocem MTA premixed.

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Abstract (In Korean)

칼슘 실리케이트 재료를 이용한 영구치 치수절단술 두 기관 무작위 대조연구

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(지도교수 정 일 영)

최신의 연구들에 따르면, 성숙한 영구치의 우식으로 인한 치수 노출 시 부분 치수절단술이나 전체 치수절단술과 같은 생활 치수치료는 우수한 성공률을 나타낸다. 본 연구에서는 주사기 타입의 칼슘 실리케이트 재료인 Endocem MTA Premixed(Maruchi, Wonju, Korea)를 정상 치수 또는 가역성 치수염을 가진 성숙한 영구치의 치수 노출 시 생활치수치료 재료로써 ProRoot MTA

(Dentsply Tulsa Dental, Tulsa, OK, USA)와 비교하려한다.

영구 소구치, 대구치를 대상으로 2개의 기관에서 ProRoot MTA와 Endocem MTA Premixed를 이용하여 치수절단술을 시행했을 때의 결과를 분석하였다. 수복이 불가능한 치아, 미성숙 근관, 치수 노출 후 5분 내의 지혈이 되지 않는 치아를 제외하였다. 치수 노출 후 지혈이 완료되면 무작위로 선택된 칼슘실리케이트 재료를 노출 부위에 적용하였고, 직후 광중합 글라스아이오노머로 이장 후 20초동안 중합하였다. 와동은 치수절단술이 시행된 날에 완료되었고, 12개월동안의 성공률과 치수 내 경조직 형성에 대해 카이검정과 로지스틱 회귀를 통해 분석하였다.

연세대학교 치과대학병원 치과보존과에서 64개의 치아, 국민건강보험공단 일산병원에서 23개의 치아가 등록되어 총 87개의 치아를 평가하였다. 4명의 환자가 연구 참여를 거부하였고, 최종적으로 83개의 치아만이 분석되었다. 치수절단술 시행 후 6개월 이내에 4명의 환자가 통증을 호소하여 근관치료를 받았고, ProRoot MTA에서 3개의 치아, Endocem MTA Premixed에서 1개의 치아가 포함되었다. 12명의 환자가 정기검진에 참여하지 않아, 최종적으로 ProRoot MTA 37개, Endocem MTA Premixed 34개로 총 71개의 치아가 1년 정기검진 후 임상적, 방사선학적으로 평가되었다. 정기검진률은 91.0%였다. 전체 성공률은 ProRoot MTA에서 93.9%, Endocem MTA Premixed에서

97.1%로 평가되었다.

부분 치수절단술은 54개의 치아, 전체 치수절단술은 17개의 치아에서 진행되었고, 각각 94.1%, 94.4%의 성공률을 나타냈다. 교합면 치수노출과 측면 치수노출간의 치수절단술 성공률은 각각 91.7%, 95.2%였으며, 통계학적으로 유의성은 없었다. ($P>.05$) 치수 내 경조직 형성은 ProRoot MTA에서 16.2%, Endocem MTA Premixed에서 29.4%가 형성되었고 통계학적으로 유의성은 없었다.

결론적으로, 치수절단술 후 1년 경과관찰 시 성공률과 치수 내 경조직형성률은 ProRoot MTA와 Endocem MTA Premixed 사이에 유의할만한 차이는 관찰되지 않았다.

핵심 되는 말 : Mineral Trioxide Aggegate (MTA), 치수절단술, 경조직형성