DOI: 10.4274/TurkJOrthod.2026.2025.145

TURKISH JOURNAL OF
ORTHODONTICS

Original Article

Effect on Bracket Bonding of Polishing with Fluoride-Containing Prophy Paste Before Enamel Pretreatment with Orthophosphoric Acid: A Randomized Clinical Trial

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Cite this article as: Hata K, Inaba M, Uchida Y, et al. Effect on bracket bonding of polishing with fluoride-containing prophy paste before enamel pretreatment with orthophosphoric acid: a randomized clinical trial. *Turk J Orthod.* 2026; 39(2): 87-94

Main Points

- Among the 951 brackets assessed in this trial, the bond failure rate was 2.7%.
- Polishing with fluoride prophy paste resulted in fewer bracket bond failures than polishing with non-fluoride prophy paste, and the failure rates were much lower than those previously reported.
- Survival analysis showed that patient age and the presence of fluoride in the prophy paste affected bracket bonding.

ABSTRACT

Objective: This randomized clinical trial assessed the effects of polishing enamel with fluoride prophy paste before enamel pretreatment with orthophosphoric acid on bracket bond outcomes.

Methods: The study included 49 patients with a mean age of 24.6 years. Participants were randomly allocated to two groups in an approximate 1:1 ratio: 25 participants in the fluoride group (Group 1) and 24 in the non-fluoride group (Group 2). All patients' tooth surfaces were polished with prophy paste, etched, and fitted with brackets. Patients were followed up for 6 months. Outcome measures included bracket bond survival and the number of bond failures, along with questionnaire items collected from all subjects, such as history of fluoride varnish and mouthwash use, age, and sex. Survival time analysis was used to characterize bond failure outcomes.

Results: A total of 951 brackets were tested; the overall bond failure rate was 2.7%. Group 2 (non-fluoride polishing) had a bond failure rate of 4.0%, while Group 1 (fluoride polishing) had a significantly lower failure rate of 1.5%. These failure rates were much lower than those reported previously. Survival analysis, accounting for patient-level variability through random effects, revealed that age and fluoride prophy paste were significant risk factors. The hazard ratio for bond failure associated with the use of fluoride-containing prophy paste was 0.26.

Conclusion: Polishing with fluoride-containing prophy paste did not affect the bracket-bond failure rate when it was followed by phosphoric acid etching.

Keywords: Dental etching, dental enamel, Kaplan-Meier estimate

INTRODUCTION

In bracket bonding procedures, tooth polishing is typically performed before enamel pretreatment with orthophosphoric acid to remove organic pellicles.[1] Fluoride-free prophy paste is commonly used during this polishing because it is thought that fluoride-containing toothpaste might inhibit bonding by forming fluoroapatite, which

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Received: November 05, 2025 **Accepted:** May 21, 2026 **Publication Date:** June 30, 2026

resists the demineralization of enamel.[2] However, fluorapatite formation plays a crucial role in preventing white spot lesions around brackets.[3] Thus, it is important to explore the effects of fluoride varnish, toothpaste and mouthwash applications on bracket bonding.[4,5] In self-etching primer (SEP) procedures, the bracket bonding failure rate has been reported to be significantly higher when fluoride prophy paste is used for polishing, as compared to when fluoride-free paste is used.[6] In addition, some studies have reported that the bond strength between brackets and enamel is significantly lower following pretreatment with fluoride.[7,8] However, conflicting reports have suggested that adhesive strength either remains unaffected[9] or recovers over time.[10] Also, enamel etching with phosphoric acid appears to improve bracket bond strength; one study found that SEP treatment following enamel pretreatment with orthophosphoric acid yielded greater bond strength than did polishing with prophy paste alone.[11] A study using acidulated phosphate fluoride (APF) demonstrated that improvements in tooth surface properties due to fluorapatite formation require a considerable amount of time, which is why manufacturers recommend avoiding eating or drinking for at least 30 minutes following application.[10]

Thus, the changes in enamel surfaces briefly polished with fluoride-containing prophy paste and the effect thereof on bracket bonding remain uncertain. We hypothesized that fluoride-containing prophy paste would influence bracket bond failure rates, even with short-term use. This randomized clinical trial evaluated bracket bonding outcomes on enamel surfaces polished with either fluoride-containing or fluoride-free prophy paste, thereby elucidating the influence of fluoride-containing prophy paste on bracket bonding.

METHODS

Trial Design and Changes After Trial Commencement

This study was a prospective, single-center, randomized controlled clinical trial with a two-arm, parallel-group design and a 1:1 allocation ratio. The study protocol was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000056470).

Participants, Eligibility Criteria, and Setting

Recruitment for the bracket bonding study commenced in December 2022. Participants were recruited from among patients requiring orthodontic treatment with fixed appliances (standard 0.022-inch slot edgewise appliances) based on the following eligibility criteria:

Inclusion Criteria

1. Patients requiring orthodontic treatment with fixed appliances who had not previously undergone orthodontic treatment.
2. Patients with complete permanent dentition (excluding the third molars).
3. Teeth with intact enamel on the labial and buccal tooth surfaces intended for bracket bonding, and without dental caries, significant wear, enamel deficiencies (e.g., hypoplasia), or restorations or fractures.
4. Patients who agreed to comply with the trial protocol.

Exclusion Criteria

1. Patients with bonded brackets that interfered with occlusion.
2. Patients with craniofacial abnormalities (e.g., cleft lip and palate).
3. Patients who did not consent to participate in the study.

The study was conducted at a dental hospital affiliated with Nihon University School of Dentistry. A total of 49 patients (mean age, 24.6 years) with malocclusion who were scheduled for orthodontic treatment were enrolled. The bonding procedures were performed by 15 orthodontic residents, and bond-failure assessment was conducted by orthodontic specialists.

This study was approved by the Nihon University School of Dentistry Ethics Committee (approval number: EP22D014, date: 17.11.2024). The principal investigator (KH) initially screened the patients for eligibility. Participants who met the inclusion criteria were provided with detailed information about the study, including the patient information sheet and consent form. The consent form outlined the study's purpose, procedures, and potential risks and benefits in a question-and-answer format. Written informed consent was obtained from all participants or, in the case of minors, by their parents or guardians after the minors provided assent.

Sample Size Calculation

The sample size was calculated based on the ability to detect a 6.46% difference in the risk of bond failure (primary outcome) between the two trial arms (2.6% vs. 9.06%; α=0.05; power: 80%). Grover et al.[2] reported failure rates of 2.6% for bracket bonding with pumice and 9.06% for bracket bonding with fluoride varnish. These values were used as a reference for sample size calculation, indicating a requirement of 442 brackets in each arm, which was rounded up to 951 to account for loss to follow-up.

Interventions

Participants were randomly allocated to one of two groups. Group 1 (intervention group) (n=25) comprised 25 patients whose teeth were polished with a 1450-ppm fluoride-containing prophy paste before bracket bonding. Group 2 (control group) (n=24) comprised 24 patients whose teeth were polished with a fluoride-free prophy paste before bracket bonding. Before the start of the study, all orthodontic residents were instructed in the bonding protocol before study commencement. Prior to bonding, the teeth were polished using either a 1450-ppm fluoride-containing prophy paste (Check-Up Strea, Lion, Tokyo, Japan) or a fluoride-free prophy paste (Merssage AP Pro, Shofu, Shiga, Japan) (Figure 1), applied with a rubber cup or brush attached to a low-speed handpiece. The enamel surface was subsequently etched with 35% phosphoric

acid (FinEtch, Spident, Incheon, Korea) for 30 seconds, rinsed with water to ensure complete removal of the etching agent, and dried. A light-cured adhesive primer (Transbond XT Light Cure Adhesive Primer, 3M Unitek, Monrovia, CA, USA) was then applied to the etched surface.

The following bracket systems were used: Invu (TP Orthodontics, IN, USA), Shine M (Mitsuba Ortho Supply, Tokyo, Japan), and Standard Edgewise Bracket (Tomy International, Tokyo, Japan). Brackets were bonded using Transbond XT Paste (3M Unitek) according to the manufacturer's instructions. Patients received dietary and oral hygiene instructions following bracket attachment. A total of 951 brackets were bonded during the study: 482 in Group 1 and 469 in Group 2.

Questionnaire

Information on prior fluoride varnish application and fluoride mouthwash use was collected from all participants via a questionnaire administered by the same researcher. The questionnaire included the following items:

1. How old are you?

2. Mark your sex:

a) Male

b) Female

3. Did you ever receive fluoride varnish at the dental office during childhood?

a) Yes

b) No

4. Did you ever use fluoride mouthwash at home during childhood?

a) Yes

b) No

Outcomes and Post-Commencement Trial Changes

Patients were examined at 3-4 week intervals to evaluate the presence or absence of bond failure. In addition, if a participant attended the clinic because of bracket detachment, between scheduled appointments, the event was recorded immediately as a bond failure. Following bond failure, the affected tooth was polished using conventional fluoride-free prophy paste, and the bracket was rebonded using a resin composite after phosphoric acid etching and primer application.

Interim Analyses and Stopping Guidelines

Not applicable.

Randomization and Allocation Concealment

Participants were randomly assigned to one of two groups using a computer-generated random-number generator (https://www.randomizer.org/). Allocation was performed by an investigator (KH) who was not involved in bracket bonding or outcome assessment. Before allocation, the operators informed the allocator of the number of teeth requiring bracket bonding and received the assigned prophy paste. The operators remained unaware of the type of prophy paste provided. Outcome assessment was performed by a separate investigator (YN), who was independent of both allocation and treatment procedures.

Blinding

The fluoride-containing and fluoride-free prophy pastes were visually indistinguishable and were transferred into identical, unlabeled containers before use (Figure 1). These containers were distributed to the operators to maintain blinding throughout the bonding procedures. The outcome assessor was also blinded to group allocation and analyzed the data using records identified only by randomly assigned participant numbers.

Statistical Analysis

Statistical analysis was conducted using software based on R and R Commander (EZR on R Commander, version 1.61; Jichi Medical

Figure 1. Prophy polishing pastes used in the study: paste containing fluoride (left) and paste without fluoride (right).

University, Saitama, Japan). Bracket survival during the 6-month follow-up period was estimated using the Kaplan-Meier method, with survival curves compared statistically via the log-rank test. Questionnaire-based experience with fluoride products, sex, age, and fluoride prophy paste were included as fixed effects, while patient-specific variation was modeled as a random effect (intraoral units). Statistical significance was set at $p<0.05$.

RESULTS

Participant Recruitment

A total of 80 patients were assessed for eligibility. Of these, 49 met the inclusion criteria, provided informed consent, and were allocated to the study. Group 1 received polishing with fluoride prophy paste before bracket bonding, and Group 2 received polishing with non-fluoride prophy paste before bracket bonding. Participant recruitment began in December 2022 and concluded in November 2023. Follow-up was completed in June 2024. All 49 enrolled patients completed the trial were included in the analysis. Figure 2 presents the CONSORT flow diagram for participants.

Baseline Participant Data

The mean age of participants was 24.6 years; 15 were aged 20 years or younger 65.3% were female and 34.7% were male (Table 1).

Experience With Fluoride Varnish And Fluoride Mouthwash

Table 1 lists participants' experience with fluoride varnish and fluoride mouthwash. The majority of participants reported no prior experience with either fluoride treatment. A higher proportion of participants had experience with fluoride varnish alone than with fluoride mouthwash; 6.1% had experience with both treatments.

Bond Failure Probabilities

A total of 951 brackets were evaluated during the study period. The overall bracket failure rate was 2.7%. The failure rates in Groups 1 and 2 were 1.5% and 4.0%, respectively (Table 2). Bond failures occurred more frequently in the mandibular arch. In the maxillary arch, posterior teeth exhibited a higher probability of bond failure than anterior teeth (Table 3).

Bond Failure By Group

Table 4 lists the bond failure probabilities by group, and Figure 3 presents the survival curves. The survival rates for Groups 1 and 2 were 0.985 [95% confidence interval (CI): 0.970-0.993] and 0.959 (95% CI: 0.937-0.974), respectively; both rates were very high. The probability of bond failure was significantly higher in Group 2 than in Group 1; the survival curve for Group 2 showed a slight decline during the early period.

Hazard Ratios Estimated Via Survival Analysis

The results of the survival analysis are shown in Table 5. When accounting for patient-level variability through random effects, age and type of prophy paste were identified as significant predictors of bond failure. The hazard ratios for age and fluoride prophy paste were 0.9208 and 0.2579, respectively.

The hazard ratio for bond failure with fluoride paste was 0.26 relative to that for non-fluoride prophy paste.

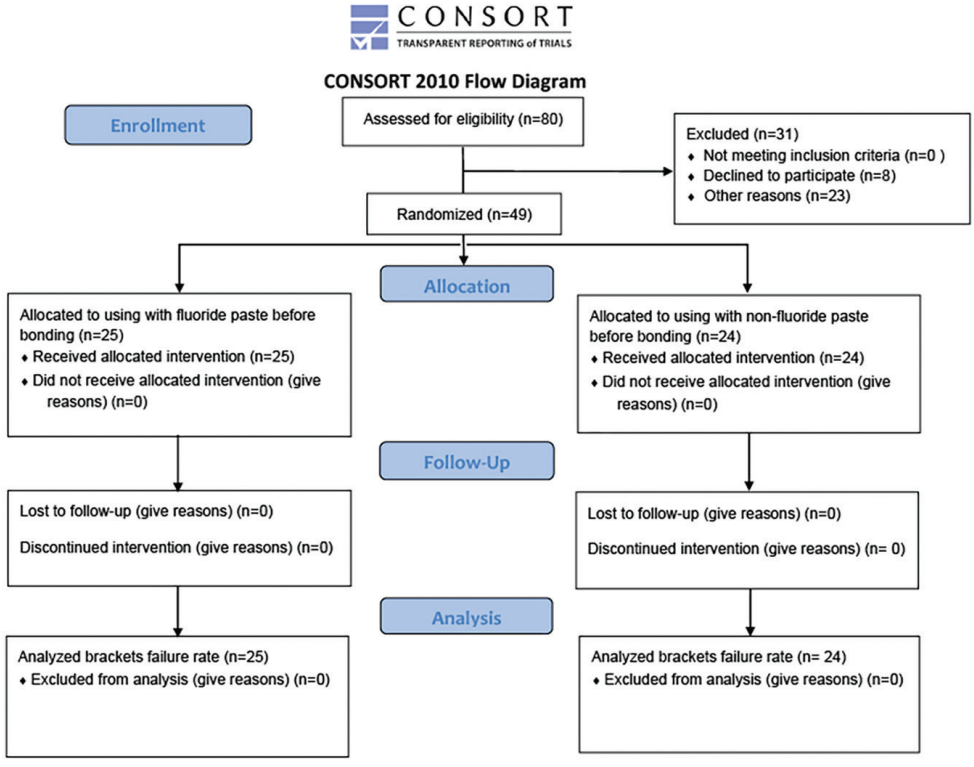

Figure 2. CONSORT flowchart diagram illustrating the recruitment, allocation, and follow-up of participants in this clinical trial.

Table 1. Patients' age, sex and experience in fluoride

	Number	Proportion (%)
Age (average age: 24.6 years) ≤20 years	15	30.6
>20 years	34	69.4
Sex Female	32	65.3
Male	17	34.7
Fluoride experience		
Only fluoride varnish	20	40.8
Only fluoride mouthwash	1	2.0
Experienced in both	3	6.1
No experience with both	25	51.1

Table 2. Bond failure probability in each group

	Brackets (n)	Failed brackets (n)	Failure proportion (%)
Randomized trial Group 1: intervention	482	7	1.5
Group 2: control	469	19	4.0
Total	951	26	2.7

Table 3. Bond failure in each area

	Number of bond failures
Upper	
Right posterior teeth	4
Right anterior teeth	0
Left anterior teeth	0
Left posterior teeth	7
Lower	
Right posterior teeth	6
Right anterior teeth	4
Left anterior teeth	4
Left posterior teeth	1

DISCUSSION

This study evaluated whether polishing with fluoride prophy paste prior to enamel pretreatment with orthophosphoric acid on bracket bonding and bond failure rates, finding that bond failure rates were significantly lower in Group 1 (fluoride prophy paste) than in Group 2 (non-fluoride prophy paste). The results demonstrated significantly lower bond-failure rates in the fluoride prophy paste group than in the non-fluoride prophy paste group. Therefore, the null hypothesis was rejected.

These findings differ from those of a previous study that reported a higher bond failure rate-of 8.0%-when brackets were bonded after fluoride polishing using SEP.[6] The overall proportion of bond failures in this study was substantially lower, at 2.7%, likely due to differences in the bonding protocol.

A conventional three-step bonding method, which consists of phosphoric acid etching, primer application, and curing of the resin composite were used. Previous research has suggested that this conventional method results in greater surface roughness and more pronounced enamel tags, leading to higher bond strength than SEP systems; it also leaves more residual adhesive on the enamel surface after debonding.[12] Therefore, although polishing with fluoride prophylaxis paste before bonding may reduce bond strength with SEP, the conventional method used in this study appeared to mitigate such adverse effects.

Bond failure was analyzed in relation to explanatory variables, including age, sex, prophy paste use, and prior fluoride exposure (fluoride varnish and fluoride mouthwash use). Based on the results of survival analysis, the use of fluoride prophy paste was associated with a statistically significant reduction in the risk of bond failure, lowering the hazard by approximately 74.2%. These findings contradict previous assertions that fluoridated abrasive pastes inhibit bracket bonding. In addition, age was also identified as an a significant predictor of bond failure. Younger individuals typically have softer enamel, whereas older individuals have harder enamel, which may affect bonding outcomes.[13] Studies have also reported that bond failure rates are higher in teenagers than in adults, primarily due to lower compliance with orthodontic instructions, thicker gingiva, ongoing tooth eruption, and oral habits.[14]

Table 4. Survival analysis results

	N	Failure number	Survival	Standard error	95% confidence interval	Logrank test
Randomized trial Group 1	482	7	0.985	0.00545	0.970-0.993	p=0.0146*
Group 2	469	19	0.959	0.00910	0.937-0.974	

*In the randomized trial, a significant difference (p<0.05) was detected between fluoride pumice polishing intervention and control groups.

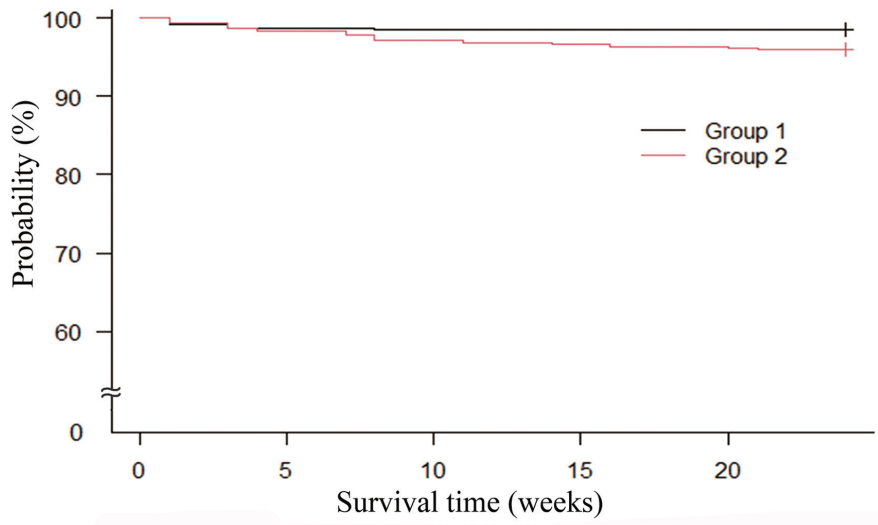

Figure 3. Kaplan-Meier survival curve depicting bracket survival times for each study group.

Table 5. Hazard rations for bracket failure using a frailty model

	Coef	Se (coef)	Exp (coef)	Chi-sq	DF	p
Prophy paste	-1.35515	0.47547	0.2579	8.12	1	0.0044
Sex	-0.13442	0.44731	0.8742	0.09	1	0.7600
Age	-0.08248	0.03542	0.9208	5.42	1	0.0200
Varnish	-0.35300	0.50545	0.7026	0.49	1	0.4800
Mouthwash	0.14653	0.77622	1.1578	0.04	1	0.8500
Frailty (patients)				0.00	0	0.8200

*In the prophy paste and age, a significant difference ($p<0.05$) was detected.

The participants were, therefore, categorized by age to account for these factors. Survival analysis showed that bond failure was significantly reduced in older individuals (coefficient =0.08). One explanation for the significantly lower failure rate observed with fluoride prophy paste compared with non-fluoride prophy paste is that 58% (11/19) of the individuals in the non-fluoride prophy paste group were teenagers. The age-related risk factors in these patients may have influenced the failure, rather than the fluoride itself.

Prior fluoride exposure was another key variable. Previous studies have suggested that enamel surfaces may be temporarily affected after APF treatment, and have recommended delaying bracket bonding for at least 21 days after APF application to allow the enamel to regain its original hardness.[10] In our study,15 bond failures were observed among the 470 brackets bonded to participants with prior fluoride exposure, corresponding to a failure rate of 2.7%. This finding implies that by the time brackets were bonded, the participants' enamel surfaces had returned to their original hardness, given that at least a few years had passed since their last fluoride treatment.

The locations where bond failures occurred were consistent with the findings of previous studies.[14,15] In the present study, bond failures occurred more frequently in the maxillary and mandibular molars and in the mandibular anterior teeth. This pattern may be attributed to the stronger biting forces applied to lower teeth during mastication and difficulty in maintaining moisture control in the maxillary molar region due to salivary gland activity.[16,17] Although bond failures are commonly reported to occur within the first month after bracket bonding,[15] bracket survival remained relatively stable during this period in both groups. Previous studies that using Kaplan-Meier survival analysis and log-rank tests to compare conventional adhesives with self-etching systems have reported conflicting findings. Ome authors observed lower survival rates with conventional adhesives,[18,19] whereas others reported superior long-term performance of conventional adhesives, particularly under conditions simulating clinical aging, such as thermal cycling.[20,21] The survival curves observed in the present study are consistent with these latter findings, exhibiting the relatively flat trajectory characteristic of conventional adhesives. Application of fluoride prophy paste did not appear to influence the survival curves, indicating that fluoride exposure had no significant effect on bracket adhesion when the conventional bonding protocol was used.

Study Limitations

This study had several limitations. First, the sample size was determined based on the number of brackets tested in Grover

et al.,[2] who investigated the effect of fluoride varnish on bracket adhesion using SEP specifications and found that fluoride varnish resulted in a significantly higher rate of adhesion failure compared to pumice. In this study, because the analysis was based on the number of brackets rather than on the number of subjects, data were clustered by subject (per mouth) to account for potential heterogeneity. Nevertheless, the relatively small number of participants may have reduced the precision and generalizability of the findings.

Second, the generalizability of the results may be limited by a single-center design, which may not fully represent diverse patient populations or clinical settings. Surveys regarding fluoride varnish and mouthwash experience with may be limited by recall bias. Additionally, the use of multiple operators may have introduced inter-examiner variability. However, all operators were instructed on the bonding protocol prior to the commencement of the study. Furthermore, the follow-up period was limited to 6 months and may not fully reflect long-term bracket survival. Furthermore, the study evaluated only a conventional phosphoric acid etch-and-rinse bonding protocol and did not investigate alternative surface-conditioning methods, such as SEPs. Therefore, the findings cannot be generalized to all orthodontic bonding systems. Moreover, the choice of brackets and adhesives was limited to a single type, which may restrict the applicability of the results to other orthodontic materials. The potential effects of tooth-surface modification through polishing with fluoride or non-fluoride prophy pastes were not extensively evaluated, which may have affected the assessment of enamel surface changes and their influence on bonding.

CONCLUSION

This randomized trial evaluated bracket bonding to enamel surfaces briefly polished with fluoride-containing and fluoride-free prophy pastes, demonstrating that the bracket-bonding failure rate was significantly lower in the fluoride prophy paste group than in the non-fluoride prophy paste group. In addition, the failure rates were lower than those reported in some previous studies using conventional bonding protocols. The higher failure rate associated with non-fluoride prophy paste polishing may be attributed to age-related risk factors. The findings suggest that the use of fluoride-containing prophy paste before phosphoric acid etching does not adversely affect bracket bonding and may be associated with improved bracket survival when a conventional etch-and-rinse bonding protocol is used.

Ethics

Ethics Committee Approval: This study was approved by the Nihon University School of Dentistry Ethics Committee (approval number: EP22D014, date: 17.11.2024).

Informed Consent: All participants were informed about the study protocol and signed the consent form.

Footnotes

Author Contributions: Concept - K.H., Y.N., M.M.; Design - K.H., Y.N.; Data Collection and/or Processing - K.H., M.I., Y.U., Y.N.; Analysis and/or Interpretation - F.K., Y.K., Y.N.; Literature Search - K.H., M.I., Y.U., Y.N.; Writing - Y.N.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: This work was supported in part by the Sato Fund, Nihon University School of Dentistry (SATO-2023-18; SATO-2024-18).

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