Original Article

Clinical bond failure rates of adhesive precoated self-ligating brackets using a self-etching primer

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ABSTRACT

Objective: To comparatively assess the failure rate of adhesive precoated (APC) self-ligating metal brackets bonded with two different enamel surface preparation techniques: self-etching primer (SEP) and conventional two-step etch and primer method (CM).

Materials and Methods: Fifty-seven patients with complete permanent dentition were included in this study. A total of 1140 APC self-ligating brackets (3M Unitek, Monrovia, Calif) were bonded using a split-mouth design. For each patient, SEP (Transbond Plus SEP, 3M Unitek) and CM (37% phosphoric acid) were used in alternate quadrants. All brackets were bonded by the same investigator after pumicing and rinsing of all of the teeth. The number, site, and date of first-time bracket failures were monitored throughout orthodontic treatment (mean, 22 months). The survival rates of the brackets were estimated by Kaplan-Meier and log-rank tests ($P < .05$). The adhesive remnant index was used to determine the bond failure interface.

Results: The bond failure rates were 2.97% and 2.18% for the CM and SEP, respectively. No statistically significant difference in failure rates was found between the groups. The bond failure sites were predominantly at the enamel-adhesive interface in both groups.

Conclusion: This long-term in vivo study showed that the combined use of SEP and the APC bracket system can be used effectively for bonding brackets after pumicing the enamel surfaces in clinical orthodontics. (*Angle Orthod.* 2014;84:155–160.)

KEY WORDS: Self-etching primer; Adhesive precoated brackets

INTRODUCTION

In orthodontic practice, obtaining a reliable adhesive bond between brackets and enamel is essential for efficient orthodontic treatment.[1] The enamel-etching technique is commonly used with composite resin when attaching brackets to the tooth enamel.[2] Despite the fact that the acid-etching technique is a useful procedure in the orthodontic field, there is a need to simplify the technique to reduce the number of steps and to improve the bonding procedure in order to maintain clinically useful bond strengths.[3]

Self-etching primers (SEPs) are popular in orthodontic bonding because they combine the conditioning and priming agents into a single acidic primer solution.[4] This method eliminates the need for separate etching, rinsing, and drying stages, which are necessary with the conventional method (CM), saving clinical time, reducing procedural errors, minimizing technique sensitivity, providing adequate bonding to enamel, and, most importantly, ensuring the patient's comfort during the bonding stages.[1,3,5] In addition, a more conservative etching pattern is obtained with SEP.[6]

In another attempt to save clinical chair time and perform simpler bonding procedures, brackets have been precoated with composite resin.[2,7,8] The precoated adhesive contains different percentages of the same components as the original Transbond XT adhesive (3M Unitek, Monrovia, Calif) used with the uncoated brackets.[3,9] Suggested advantages of the adhesive precoated (APC) brackets over conventional systems include consistent quality and quantity of adhesive, faster bonding, easier cleanup after bond-

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ing, improved asepsis, reduced waste, and better inventory control.[7]

These products save time and require less effort in clinical practice. However, there is always concern with regard to whether they achieve the same level of bond strength as conventional products. Bond failure rates obtained by in vitro studies might not mirror the real world of clinical practice. For this reason, clinical bond failure studies are the only means of obtaining clinically relevant data for evaluating new products.[10] In the literature, several in vivo studies[4,11–16] were published regarding bond failure rates with SEP. However, there are a limited number of studies[2,12,17] on the clinical performance of the combined use of both products—SEP and APC brackets. These clinical studies evaluated the short-term clinical performance associated with the combined use of the two products for up to 6 months. To date, no long-term study has been reported that evaluated the bracket failure rate of combined use of SEP and the APC bracket system during the entire active orthodontic treatment.

Accordingly, the purpose of this study was to evaluate the clinical performance of APC self-ligating stainless-steel brackets bonded with either SEP or CM for the entire treatment period. For the purposes of this study, the null hypothesis assumed that there is no difference in the bond failure rates of APC brackets bonded with either SEP or CM, applied with pumice prophylaxis before orthodontic bonding.

MATERIALS AND METHODS

The research protocol was approved by the Regional Research Ethics Committee of Ondokuz Mayis University. A total of 57 patients (39 girls and 18 boys) with complete permanent dentitions who met the inclusion criteria were selected. The characteristics of the participants included in this study are shown in Table 1. All of the patients required fixed appliance therapy. Both extraction and nonextraction patients participated; extraction patients were included if their extractions were balanced. The patients did not have any enamel defects, hypoplasia, or restorations on the buccal surfaces of the teeth that could affect bracket bond strength.

A total of 1010 APC Smart-clip self-ligating brackets (3M Unitek) were bonded. A split-mouth design was used. For each patient, SEP and CM were used in alternating quadrants, so that they were distributed equally on the left and right sides. Before performing the bonding procedure, the buccal surfaces of the teeth were pumiced, washed with a spray, and dried with compressed air. The same clinician carried out all of the bonding procedures in an effort to standardize the effect of operator variable on bond performance.

Table 1. Sample Characteristics

	Number	%
Number of patients	57	–
Distribution of patients by gender		
Female	39	68
Male	18	32
Distribution of patients by age		
≤12 y	4	7.1
12–13 y	10	17.5
14–15 y	19	33.3
16–18 y	15	26.3
≥18 y	9	15.8
Mean age: 16 y		
Number of brackets	1010	–
Distribution of brackets by bonding procedure		
Conventional method	505	50
Self-etching primer	505	50
Distribution of brackets by gender		
Female	686	67.9
Male	324	32.1
Distribution of brackets by jaws		
Upper	500	49.5
Lower	510	50.5
Distribution of brackets by tooth type		
Upper incisors	228	22.6
Lower incisors	228	22.6
Upper canines	114	11.3
Lower canines	114	11.3
Upper premolar	158	15.6
Lower premolar	168	16.6

In the CM quadrants, the teeth were etched with 37% phosphoric acid etchant liquid-gel (3M ESPE, St Paul, Minn) for 30 seconds, then rinsed and dried. After the etching protocol, a thin, uniform coat of primer (Transbond XT Primer; 3M Unitek) was applied, after which the APC Smart-clip self-ligating brackets were immediately positioned on the enamel surface. Excess adhesive was removed using a small scaler. The adhesive resin was polymerized from two directions for a total of 20 seconds using a visible light-curing unit (Elipar™ FreeLight™2; 3M ESPE) with an output power of 1200 mW/cm^2. In the SEP quadrants, the SEP (Transbond Plus SEP, 3M Unitek) was used as recommended by the manufacturer: that is, it was applied to the enamel surface and rubbed for 3 seconds. Then a gentle burst of dry air was delivered to thin the primer. Bracket placement and curing protocols were performed in the same manner as for the CM group.

The initial wire placed in all patients immediately after bonding was 0.016-inch heat-activated nickel-titanium (3M Unitek), followed by various combinations of round and rectangular nickel-titanium and stainless-steel wires (3M Unitek) as treatment progressed. The intervals between appointments were 4 weeks; only first-time failures were recorded. The brackets were

Table 2. Bracket Failure Rates for Bonding Procedures, Dental Arches, Tooth Type, and Patient Gender[a]

	Number	Bracket Failures	Failure Rate, %	Log-Rank
Bonding procedure				
Conventional method	505	15	2.97	0.421 NS
Self-etching primer	505	11	2.18	
Dental arch				
Upper	500	10	2.0	0.250 NS
Lower	510	16	3.14	
Bracket location				
Incisor	456	9	1.97	0.018 *
Canine	228	1	0.43	
Premolar	326	16	4.9	
Sex				
Female	686	17	2.48	0.768 NS
Male	324	9	2.78	

[a] NS indicates not significant; *, significant.

replaced immediately after bond failure was detected; new bonded brackets were not included in the study. All patients included in this study were monitored until the debonding appointment. The mean observation period was 22 months (minimum, 10 months and maximum, 33 months).

Bond failure rates for all treatment periods were determined for each bonding procedure. The adhesive remnant index (ARI) was used to determine the bond failure interface.[18] The survival rates of the brackets were estimated by Kaplan-Meier test. Bracket survival curves with respect to bonding procedure, dental arch, tooth type, and patient gender were compared using the log-rank test, with the level of significance set at .05. The chi-square (χ^2) test was used to determine significant differences in ARI scores between bonding procedures ($P < .05$).

RESULTS

The overall failure rate was 2.57%. A total of 26 bond failures were registered in both groups in the total population of 1010 brackets during the mean 22 months of active orthodontic treatment: 15 (2.97%) in the CM group and 11 (2.18%) in the SEP group (Table 2). The χ^2 test showed no significant differences between the groups ($P > .05$). The probabilities of having bonded brackets still in place at 22 months were .970 and .978 for the CM and the SEP groups, respectively. The influences of the bonding procedures, tooth type, patient gender, and dental arches on bracket survival rate are shown in Figure 1. The failure rates were higher for the incisors (1.97%) and premolars (4.9%) compared with the canines (0.43%).

Table 3. Frequency Distribution and the Result of the χ^2 Analysis of the Adhesive Remnant Index (ARI)[a]

	0	1	2	3
Conventional method	8	5	2	0
Self-etching primer	8	2	0	1

[a] ARI scores: 0, no composite left on enamel surface; 1, less than half of composite left; 2, more than half of composite left; and 3, all of composite left. $\chi^2 = 3759$ on 3 df; $= .288$.

The frequency distribution and result of the χ^2 analysis of the ARI scores are presented in Table 3. Most failures occurred at the adhesive-enamel interface with both bonding procedures. No significant difference was observed between the bonding procedures ($P = .288$).

DISCUSSION

To date, no data have been reported with regard to the long-term clinical efficacy of the combined use of SEP and the APC bracket system, which are intended to reduce clinical chair time. In this in vivo study, the clinical performance of APC Smart-clip self-ligating brackets bonded with SEP was determined and compared to the use of CM. At the end of the observation period (mean, 22 months), bond failure rates were 2.97% for the CM group and 2.18% for the SEP group, and the overall failure rate was 2.57%. It has been suggested[19] that bond failure rates below 10% are generally considered clinically acceptable. The results of this study did not detect statistically significant differences in bond failure rate between the SEP and the CM groups. Therefore, the hypothesis that there is no difference in bond failure rate between the SEP and CM groups was not rejected.

In the literature, in vitro investigations into the bonding performance of SEPs have produced varying results.[1,3,20,21] Several authors[21–23] have reported that SEPs required a similar force to debond as that observed after conventional acid etching, whereas others[1,3,20] have found that SEPs required significantly

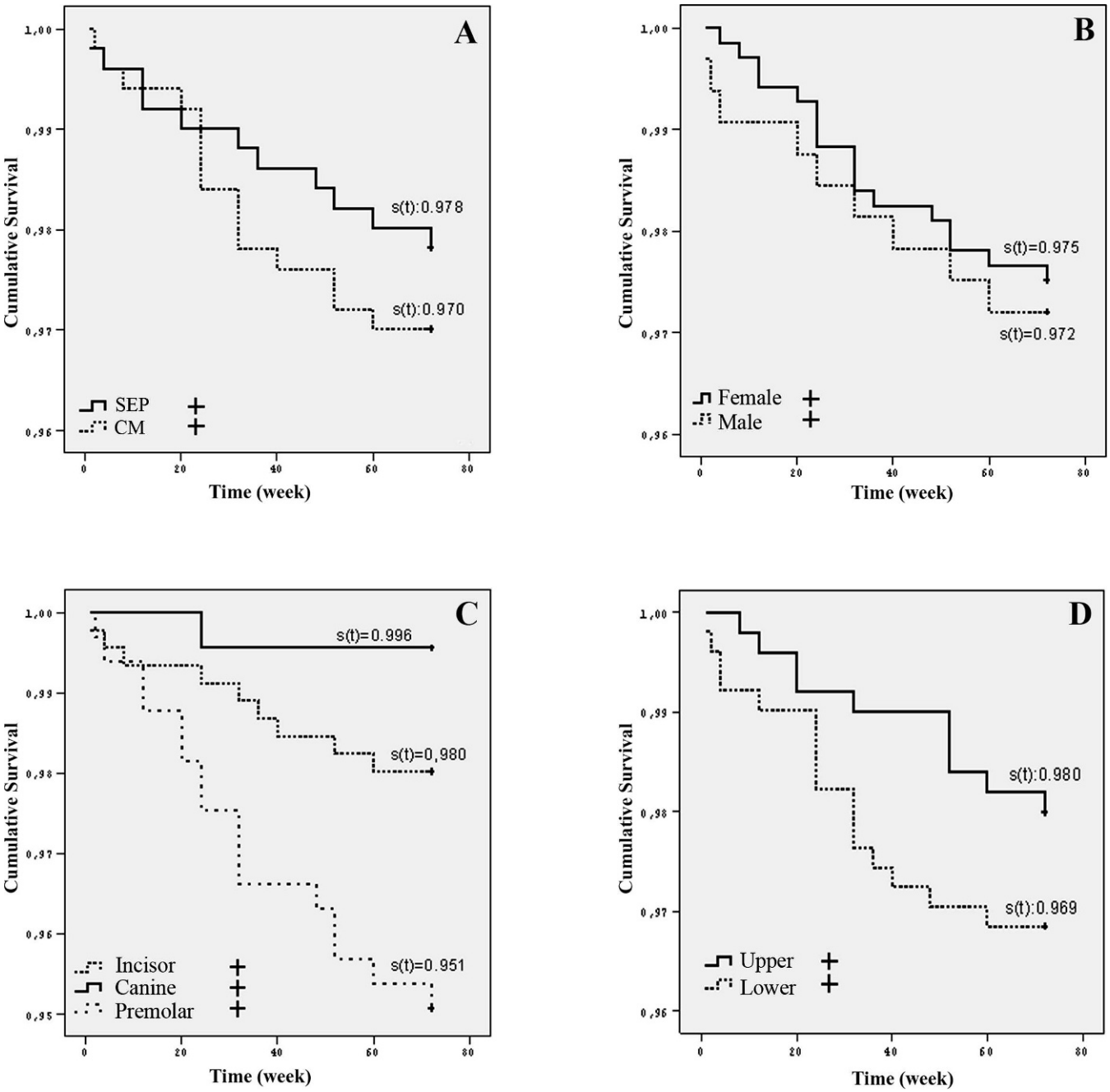

Figure 1. Bracket survival rates during treatment period (A) for bonding procedures (CM, conventional method; SEP, self-etching primer); (B) for patient gender; (C) for tooth type (incisor, canine, and premolar); and (D) for dental arches.

less force to debond. However, the SEP still produced laboratory bond strengths considered to be clinically acceptable for orthodontic bracket bonding.[24] Nevertheless, laboratory tests can never truly replicate oral conditions.[25] Failure and survival rates are a widely accepted means of assessing bracket performance clinically, allowing effective comparison with the results of other studies.[26]

In the literature, it has been noted that direct comparison of results between investigations testing identical materials should be interpreted with caution, because there is no standardized protocol for clinical studies.[27] In in vivo studies, the outcomes might be affected by the socioeconomic and dental statuses of the subjects, malocclusion types, and resultant mechanotherapies.[28] Masticatory forces that vary with facial type, culturally influenced dietary habits, and sex differences may also influence the results.[28] Furthermore, it is difficult to make direct comparisons of bracket failure rates between studies as a result of the variation

in the number of operators, bonding techniques and materials, research designs, and observation periods.[27]

Several clinical studies[4,11–16] have been published that compared the bond failure rates of CM and SEP using operator-coated brackets. These studies also reported contradictory results. Some of the authors reported significantly lower[11] or higher[12,13,16] bond failure rates for SEP, whereas others[4,14,15] observed no significant difference between SEP and CM. Contradictory results also have been reported in previous studies evaluating APC brackets, which have been shown to produce similar[23,29] or lower[9,30] bond strengths than operator-coated brackets. In addition, in vivo studies have shown conflicting findings regarding the clinical bond failure rate of APC orthodontic brackets. Two previous studies[31,32] found no significant differences in bond failure rates between operator-coated and APC brackets, another study[33] found a significantly higher failure rate with APC brackets, and other authors[8] reported significantly fewer failures with APC brackets.

To our knowledge, only a few clinical studies have evaluated the clinical performance of the combined use of APC brackets and SEP.[12,17] Ireland et al.[12] found significantly higher APC bracket failure rates with SEP (10.99%) than with CM (4.95%) after 6 months. In another study, Talic[17] reported that the failure rates of the combined use of APC brackets and SEP bonded to teeth prepared with pumice and fluoridated paste were, respectively, 4.8% and 11.2% over a 6-month period. The results of our study showed that there was no statistically significant difference in bond failure rate between SEP (2.18%) and CM (2.97%). The findings of the current study conflict with the findings of the clinical studies by Ireland et al.[12] and Talic.[17]

In the bond failure studies, long-term monitoring increases the clinical relevancy of the findings. In the majority of the research evaluating the clinical performance of SEP or the APC bracket system, the observation periods were 6 or 12 months.[4,5,12,13,16,17,24,31] Only two studies[10,34] monitored the clinical performance of SEP over 18 months. The mean observation period of 22 months in the present study was longer than that of the previous clinical studies.

In this study, the influence of several parameters on the failure rates of the brackets was also evaluated; these parameters included arch location, tooth type, and sex of the patients. Bracket failure rate was not influenced by any factor investigated, except for tooth type. The highest bond failure rate in this study was for the premolars (4.9%). These results agree with those of other studies[27,31] that concluded that posterior teeth suffer more bracket failures than do anterior teeth. Previous studies have reported a higher failure rate for premolars[5,16] and have related this higher failure rate to several factors, such as more aprismatic enamel on premolars,[35] poor moisture control,[36] and higher occlusal forces exerted on the posterior teeth during mastication.[31]

To ensure adequate bond strength, the bonding surface of the teeth should be free of plaque, debris, and organic pellicle. Cleaning of the tooth surface is most frequently performed using pumice prophylaxis. However, previous studies[37,38] have shown that the pumice step was not important for successful bonding with conventional acid-etch systems; the importance of pumice prophylaxis was more important for SEP.[17,39] Pandis and Eliades[28] suggested that a clean surface was more important for SEP because the chalky appearance of enamel that results from traditional etching, signaling that the surface is well prepared, is not visible clinically when using SEP. In the present study, the insignificant failure rates between CM and SEP might be related to pumice prophylaxis being applied before bonding in both groups.

Previous investigations have shown conflicting results regarding the amount of residual adhesive on teeth bonded with SEP. Some investigations have reported more residual adhesive with SEP than with CM, whereas others have found significantly less.[1,3,13,16,39] In the present study, the bond failure sites were predominantly at the enamel-adhesive interface (score 0) in both groups. This mode of failure is clinically beneficial, as there is less adhesive to remove from the enamel after debonding.

CONCLUSIONS

- There was no difference between the clinical bond failure rates of APC self-ligating metal brackets bonded with SEP or CM.
- This long-term in vivo study showed that the combined use of SEP and the APC bracket system can be used effectively for bonding brackets after pumicing the enamel surfaces in clinical orthodontics.

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