Original Article

12-Month Self-Ligating Bracket Failure Rate with a Self-Etching Primer

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ABSTRACT

Objective: To compare the clinical performance of a self-etching primer (SEP) with a conventional two-step etch and primer method (CM).

Materials and Methods: Study subjects were 39 patients with a mean age of 15 years 7 months. Six hundred and eighty-eight brackets were bonded by one operator with a split-mouth design, using Transbond Plus Self-Etching Primer or a conventional two-step etch and primer (Transbond XT). The survival rate of the brackets was estimated by the Kaplan-Meier analysis. Bracket survival distributions with respect to bonding procedure, dental arch, type of tooth (incisor, canine, and premolar) and patients' gender were compared using the log-rank test. Bond failure interface was determined using the Adhesive Remnant Index (ARI).

Results: The bond failure rates of SEP and CM were 4.7% and 1.7%, respectively. A significant difference was found between the bonding procedures using the log-rank test ($P < .05$). Furthermore, canine and premolar teeth displayed a lower survival rate than incisor teeth ($P < .05$). Survival rates did not show significant differences between the upper and lower dental arches and patients' gender ($P > .05$). No significant difference was observed for ARI scores ($P > .05$).

Conclusion: These findings indicate that the SEP (Transbond Plus) can be effectively used to bond orthodontic brackets.

KEY WORDS: Self-ligating brackets; Self-etching primer; Bracket failure; Survival rate

INTRODUCTION

The introduction of acid-etch primers, such as Transbond Plus Self-Etching Primer (3M Unitek, Monrovia, Calif), has attracted considerable interest as they combine the etching and priming steps into one, eliminating the need for separate etching, rinsing, and drying. The active ingredient of the SEP is a methacrylated phosphoric acid ester. Phosphoric acid and the methacrylate group are combined into a molecule that etches and primes simultaneously.[1]

SEP (Transbond Plus) demonstrated a more conservative etch pattern, a smaller amount of demineralization, and less adhesive penetration of the enamel surface compared with 37% phosphoric acid.[2] The thickness of the resin-infiltrated layer after enamel treatment with SEP agents as well as a conventional method was evaluated by Hannig et al,[3] who observed 1.5–3.2 μm wide, netlike resinous structures with SEPs. A similar pattern, but greater depth (6.9 μm) of enamel surface hybridization, was found with phosphoric acid.[3] The hybrid layer was measured at 4 μm for SEPs and 8 μm for phosphoric acid by Pashley and Tay.[4] Despite the less distinct enamel etching pattern, a similar etch pattern was observed with the use of SEPs by means of the nanoretentive interlocking between enamel crystallites and resin compared with the phosphoric acid etch.[3] This observed similar etch pattern and the nanoretentive interlocking could explain the potential of SEP systems.[3] Measurements of bond strengths with SEP have shown inconsistent results when tested in vitro.[5–7] It was pointed out that the clinical use of SEPs in enamel-to-resin bonding has to be confirmed by clinical studies.[3]

Several in vivo studies were published concerning the bond failure rates with CM and SEP.[8–13] In these studies the CM included etching with 37% phosphoric acid (15 or 30 seconds), primer application (Transbond MIP or XT) and bonding with Transbond XT light cure adhesive (20, 40, or 60 seconds). SEP (Trans-

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bond Plus) was applied according to the manufacturer's instructions in these studies[8–11,13] except in one study.[12] In this study the SEP was rubbed onto the enamel for 10–15 seconds instead of the recommended 3 seconds.[12]

These studies presented contradictory results.[8–13] Asgari et al[9] and dos Santos et al[12] reported significantly lower bond failure rates with SEP than with CM. Whereas, Ireland et al[10] and Murfitt et al[13] found significantly higher failure rates with SEP than with CM. On the other hand, Cal-Neto and Miguel[11] and Aljubouri et al[8] observed no significant difference between SEP and CM at the end of a 6-month and a 12-month observation period.

The aim of this study was to compare the bond failure rate of self-ligating stainless steel brackets bonded with SEP (Transbond Plus) and with CM over a 12-month period.

MATERIALS AND METHODS

From the waiting list of the orthodontic department, 40 patients were enrolled in this study. Ethical approval was obtained. All patients required two-arch fixed appliance therapy. Extraction patients were included if their extractions were balanced. The patients did not have any hypoplasia or restorations on the buccal surfaces of their teeth. There was no restriction concerning the type of malocclusion, except exclusion of open bite or Class III.

Before the beginning of fixed appliance therapy, all patients were meticulously instructed in oral hygiene and care for their braces by one operator. Furthermore, each patient was given written instructions concerning the care of the fixed appliances. Patients and parents gave their written consent for participation. The details of sample size, mean age, and patient distribution by gender, age, and tooth type are presented in Table 1. One patient had to drop out of this trial. The study was continued with 39 patients.

All teeth, except for the molars, were bonded with 0.022-inch slot self-ligating metal brackets (Time2; American Orthodontics, Sheboygan, Wis). To eliminate interexaminer variation, one operator performed the bonding procedures. The teeth were cleansed with pumice slurry before bonding. Bonding procedures were allocated by the split-mouth method. Each patient's mouth was divided into quadrants, and a contralateral bonding pattern was randomly alternated from patient to patient to ensure an equal distribution of enamel treatments between the right and left sides.[11]

In the CM quadrants, the teeth were etched with 37% phosphoric etchant liquid-gel (3M ESPE, St Paul, Minn) for 30 seconds, rinsed, and dried. After etching, a thin uniform coat of primer (Transbond XT Primer, 3M Unitek) was applied. The adhesive resin (Transbond XT Light Cure Adhesive Paste, 3M Unitek) was placed onto the bracket base, and the bracket was positioned on the enamel surface. Excess adhesive resin was removed. The adhesive resin was polymerized from two directions for a total of 20 seconds using a visible light-curing unit with an output power of 600 mW/cm^2. In the SEP quadrants, the SEP 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. Bonding with Transbond XT adhesive resin was performed as for CM.

Initial aligning arch wires, 0.014-inch superelastic NiTi (Sentalloy; GAC International, Bohemia, NY), were fitted in the upper and lower arches approximately 5 minutes after the bonding procedure. Patients were instructed to check for loose brackets on a daily basis. If bond failure should occur, they were asked to record the date of bracket failure and to visit the clinic immediately. Patients were seen every 4

Table 1. Sample characteristics[a]

	Number	%
Number of patients	39	—
Distribution of patients by gender		
Male	8	20.5
Female	31	79.5
Distribution by age		
<12 years	3	7.7
12–13 years	10	25.6
14–15 years	14	35.9
16–18 years	6	15.4
>18 years	6	15.4
Mean age: 15 years 7 months		
Number of brackets	688	—
Distribution of brackets by bonding procedure[a]		
CM	344	50.0
SEP	344	50.0
Distribution of brackets by gender		
Male	136	19.8
Female	552	80.2
Distribution of brackets by jaws		
Upper	328	47.7
Lower	360	52.3
Distribution of brackets by tooth type		
Upper incisors	146	21.2
Lower incisors	154	22.4
Upper canines	76	11.0
Lower canines	78	11.4
Upper premolars	106	15.4
Lower premolars	128	18.6

[a] SEP indicates self-etching primer; CM indicates conventional two-step etch and primer method.

Table 2. Bond failure rates for the bonding procedures[a]

	CM			SEP				
	No Failure	Failure	Failure Rate	No Failure	Failure	Failure Rate	*P*	Log-rank Test
First 6-month period	340	4	1.2%	333	11	3.2%	.068	—
Second 6-month period	338	2	0.6%	328	5	1.5%	.243	—
12-month period	338	6	1.7%	328	16	4.7%	.030*	.031

[a] SEP indicates self-etching primer; CM indicates conventional two-step etch and primer method.

* $\chi^2 = 4.696$ on 1 *df.*

weeks. After bracket failure the amount of adhesive remaining on the tooth was visually determined according to the Adhesive Remnant Index (ARI).[14] Only the first bond failure was registered for each bracket.

Bond failure rates for first 6-month, second 6-month, and 12-month periods were determined for each bonding procedure. The χ^2 test was applied to compare failure rates ($P < .05$). Kaplan-Meier estimates of bracket survival curves were plotted. Bracket survival distributions with respect to bonding procedure, dental arch, type of tooth (incisor, canine and premolar), and patients' gender were compared using the log-rank test ($P < .05$). The χ^2 test was used to determine significant differences for ARI scores between bonding procedures ($P < .05$).

RESULTS

Bracket Survival

During the first 6-month observation period 15 brackets failed: 4 (1.2%) in the CM group and 11 (3.2%) in the SEP group (Table 2). No significant difference was found between failure rates ($\chi^2 = 3.339$, $P = .068$). During the second 6-month observation period seven brackets failed: two (0.6%) in the CM group and five (1.5%) failed in the SEP group. The difference was not statistically significant ($\chi^2 = 1.363$, $P = .243$). At the end of 12 months, the failure rates were 1.7% (six brackets) for CM group and 4.7% (16 brackets) for the SEP group. A significant difference was observed between failure rates (Table 2; $P = .030$).

The bracket survival curves were plotted with the Kaplan-Meier estimate for the 12-month observation period (Figure 1A). The bonding procedures demonstrated a significant influence on the bracket survival rates (Table 2; $P = .031$). The probabilities of having bonded brackets still in place at 12 months were .983 and .953 for the CM and SEP groups, respectively.

Bond failure rates were 3.0% (10 brackets) and 3.3% (12 brackets) in the upper and lower arches, respectively. The difference was not statistically significant (Table 3; $P = .832$). The influence of the dental arches on bracket survival rate is shown in Figure 1B. The log-rank test did not show a significant difference between upper (S[t] = .970) and lower (S[t] = .967) dental arches ($P = .840$).

Bond failure rates were 5.8% (9 brackets) for canine, 4.3% (10 brackets) for premolar, and 1.0% (3 brackets) for incisor teeth (Table 4). Significant differences were observed for the failure rates of canine, premolar, and incisor teeth (Table 4, $P = .010$). Figure 1C shows the influence of arch location on bracket survival rate. The log-rank test showed significant differences between the incisor, canine, and premolar teeth in terms of survival rate ($P = .010$).

Female and male patients presented a 2.9% (16 brackets) and 4.4% (6 brackets) failure rate, respectively (Table 5). The difference was not statistically significant ($P = .369$). The influence of gender on the bracket survival rate is shown in Figure 1D. No significant difference between females (S[t] = 0.971) and males (S[t] = 0.956) was observed with the log-rank test ($P = .362$).

Site of Failure

Frequency distribution and the result of the χ^2 analysis of the ARI scores are presented in Table 6. Most failures occurred at the adhesive-enamel interface with SEP. No significant difference was observed between the bonding procedures ($P = .336$).

DISCUSSION

Laboratory tests are often used to evaluate the performance of bonding systems before proceeding with clinical trials that will determine the clinical efficacy of these systems.[15] Nevertheless, laboratory tests can never truly replicate the oral environment.[16] Thus, clinical bond-failure studies have become popular because of their clinical relevance and because the examined variable is the actual survival of bonds.[17]

In the present study, the clinical performance of an SEP was assessed and compared with that of CM. Failure and survival rates of the brackets were evaluated according to bonding procedure, dental arch, type of tooth (incisor, canine, and premolar), and gender. Failure rates are a widely accepted means of assessing bracket performance, allowing effective compari-

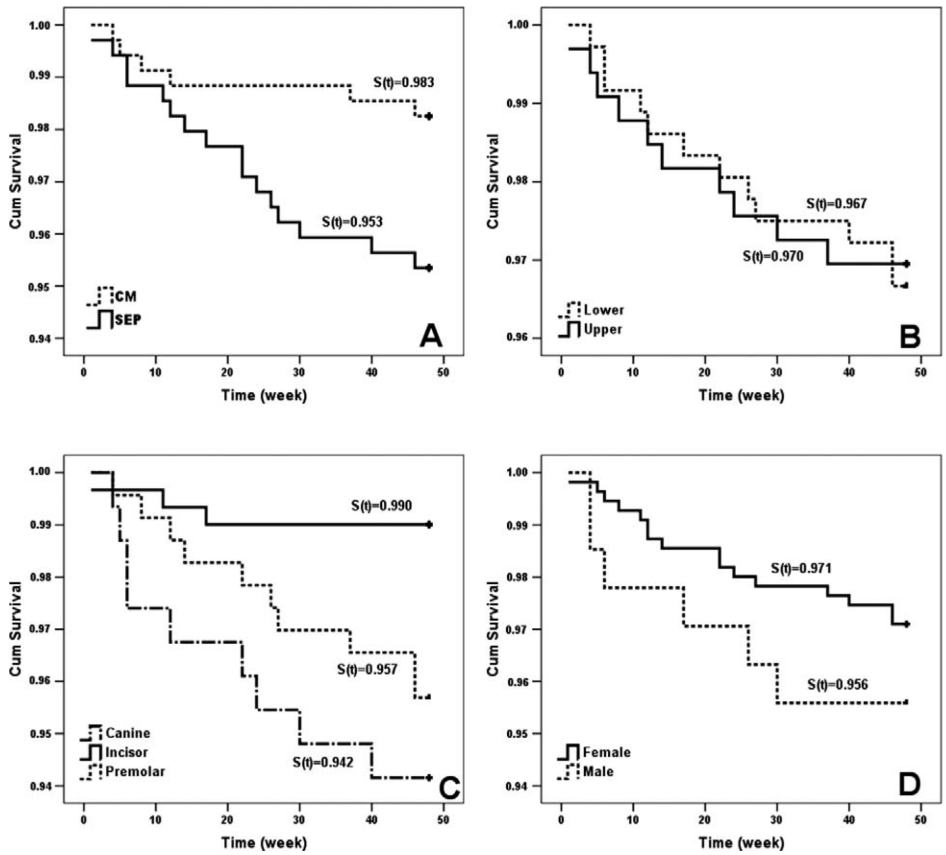

Figure 1. Bracket survival distribution during 12-month period (A) for bonding procedures; (B) for dental arches; (C) for tooth type (incisor, canine and premolar); and (D) for patients' gender.

Table 3. Bond failure rates for upper and lower dental arches*

	No Failure	Failure	Failure Rate	Log-rank Test
Upper	318	10	3.0%	.840
Lower	348	12	3.3%	

* $\chi^2 = .045$ on 1 *df*; *P* = .832.

Table 4. Bond failure rates for type of tooth (incisor, canine and premolar)*

	No Failure	Failure	Failure Rate	Log-rank Test
Incisor	299	3	1.0%	.010
Canine	145	9	5.8%	
Premolar	222	10	4.3%	

* $\chi^2 = 9.153$ on 2 *df*; *P* = .010.

Table 5. Bond failure rates for female and male subjects*

	No Failure	Failure	Failure Rate	Log-rank Test
Females	536	16	2.9%	.362
Males	130	6	4.4%	

* $\chi^2 = .807$ on 1 *df*; *P* = .369.

Table 6. Frequency distribution and the result of the χ^2 analysis of the Adhesive Remnant Index (ARI)[a]

	ARI Scores[a]			
	0	1	2	3
CM	2	2	1	1
SEP	11	1	2	2

[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 composite left. SEP indicates self-etching primer; CM indicates conventional two-step etch and primer method. $\chi^2 = 3.385$ on 3 *df*; *P* = .336.

son with the results in the literature.[18] Nevertheless, in addition to the simple event of failure, survival rate evaluation permits consideration of the time interval before failure. Thus, survival rate application allows some significant differences to be underlined, which is impossible with failure rates.[18]

In this study, bond failure rates were 1.2% and 3.2% for CM and SEP, respectively, during the first 6-month period. During the second 6-month period, bond failure rates were 0.6% and 1.5% for CM and SEP, respectively. No significant differences were found between these procedures for both observation periods.

At the end of the 12-month observation period bond failure rates were 1.7% for the CM group and 4.7% for the SEP group. These failure rates demonstrate a significant difference despite the results obtained for the first and second 6-month periods. The findings of the current study concur with the findings of the clinical studies by Ireland et al[10] and Murfitt et al.[13] Significantly higher failure rates were found by Ireland et al[10] and Murfitt et al[13] for SEP (10.99% and 11.2%, respectively) than for CM (4.95% and 3.9%, respectively).

Nevertheless, Cal-Neto and Miguel[11] did not observe a significant difference between SEP (5.08%) and CM (2.54%), even though the bond failure rates with SEP were higher than with CM. Aljubouri et al[8] reported no significant difference between SEP and CM at the end of 6 (0.8% and 1.1%, respectively) and 12 (1.6% and 3.1%, respectively) months. Aljubouri et al[8] attributed the similar bond failure rate of CM and SEP to the similar etch pattern of SEPs and phosphoric acid. Asgari et al[9] and dos Santos et al[12] noted significantly lower bond failure rates with SEP (0.57% and 7.4%, respectively) than with CM (4.60% and 10.6%, respectively).

In these clinical studies,[8–13] differences in failure rates and contradictory results are noteworthy. Thus, direct comparison between studies testing identical materials should be interpreted with caution, as there is no standardized protocol for clinical studies.[19] In in vivo studies, socioeconomic and dental status of patients, and malocclusion classification and resultant mechanotherapy may affect the outcomes.[17] Furthermore, masticatory forces varying with facial type, culturally influenced dietary habits, and sex differences may also influence the results.[17]

In the present study the survival rates were 0.983 and 0.953 for the CM and SEP groups, respectively. These survival rates show a significant difference. A survival rate of 0.953 implies a 95% chance for a bonded bracket to still be in place after 12 months for the SEP group. According to dos Santos et al,[12] the self-etch adhesive ($S[t] = 0.782$) showed a significantly higher survival rate than the conventional system ($S[t] = 0.708$). Cal-Neto and Miguel[11] did not observe a significant difference between survival rates of an SEP and a hydrophilic primer applied with conventional acid etching even though the bond failure rates with SEP (5.08%) were higher than those of the hydrophilic primer (2.54%).

Patient gender and tooth location (ie, upper or lower jaw) did not influence failure rates. This is in accordance with the clinical studies conducted by Mavropoulos et al[20] and Pandis et al.[21] Nevertheless, in the current investigation tooth type (incisor, canine and premolar) influenced the bond failure and survival rates with canine and premolar teeth demonstrating significantly higher failure rates and lower survival rates. Mavropoulos et al[20] observed that the bracket failure rate for posterior teeth (first and second premolars) was three times higher than the failure rate for anterior teeth (incisors and canine). Murfitt et al[13] reported considerable higher failures for the lower canines in the SEP group. These higher failures were attributed to occlusal interferences. In the present trial, occlusal interferences were not perceived, except for one patient.

Studies have shown that most bond failures occur within the first 3 or 6 months after bracket placement.[8,19,22] Aljubouri et al[8] and O'Brien et al[19] reported bracket failure rates of 50% and 82% during the first six months, respectively. Hegarty and Macfarlane[22] registered failure rates of 54% during the first 3 months. In the current study, bracket failure rates were 67% and 69% for the CM and SEP groups, respectively, during the first 6 months. O'Brien et al[19] presented three possible reasons for this increased failure rate during the first 6 months of treatment. First, they suggested that any deficiencies in the bond strength of any individual bracket/adhesive combination would become evident within this initial period of treatment. Second, the initial period of treatment is also a time of acclimatization and experimentation for patients concerning the type of food that can be tolerated by fixed orthodontic appliances. Finally, the initial phase of treatment may involve a period of overbite depression and, therefore, heavy occlusal forces may be applied to many of the bonded attachments.

According to the adhesive remnant index, the site of bracket failure was predominantly at the enamel-adhesive interface for the SEP. However, it is difficult to comment about the site of bracket failure for CM because the number of bracket failure was low. The adhesive failures observed for SEP at the enamel-adhesive interface may be explained with the less distinct enamel-etching pattern.

CONCLUSION

- SEP (Transbond Plus) can be effectively used to bond orthodontic brackets and can serve as a practicable alternative to the conventional two-stage bonding system.

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