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Six-month bracket failure rate evaluation of a self-etching primer

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SUMMARY The aim of this study was to compare the clinical performance of a self-etching primer (SEP) with a conventional two-step etch and primer [conventional method (CM)]. The chair time required for bonding was also evaluated.

Thirty-seven patients (14 males and 23 females) with a mean age of 16 years 5 months were included in the study. Six hundred and seventy-two brackets were bonded by one operator using a split-mouth design, with either SEP (Transbond Plus) or CM (Transbond XT). Bracket failure rates were estimated with respect to bonding procedure, dental arch, type of tooth (incisor, canine, and premolar), and gender. The results were evaluated using the chi-square test. The survival rate of the brackets was estimated with Kaplan–Meier analysis. Bracket survival distributions with respect to bonding procedure, dental arch, type of tooth, and patient gender were compared with a log-rank test. Bond failure interface was determined with the adhesive remnant index (ARI).

The failure rates were 0.6 per cent for both bonding procedures. The failure and survival rates did not show significant differences between the bonding procedures, upper and lower dental arches, or gender. However, premolar brackets displayed a higher bond failure rate and a lower survival rate than incisor and canine brackets ($P < 0.05$). The mean bracket bonding time per tooth with SEP was significantly shorter than with CM ($P < 0.001$). No significant difference was observed for the ARI scores ($P > 0.05$).

The results of this *in vivo*, randomized, cross-mouth clinical trial demonstrated a high survival rate with Transbond Plus. This finding indicates that SEP can be effectively used for bonding of orthodontic brackets.

Introduction

The introduction of acid-etch primers, such as Transbond Plus Self-Etching Primer (SEP; 3M Unitek, Monrovia, California, USA), has attracted considerable interest. A self-etching primer (SEP) combines 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 (Cinader, 2001).

SEP (Transbond Plus) demonstrates a more conservative etch pattern, a smaller amount of demineralization, and less adhesive penetration of the enamel surface when compared with 37 per cent phosphoric acid (Cal-Neto and Miguel, 2006). The thickness of the resin-infiltrated layer after enamel treatment with self-etching priming agents, as well as with the conventional method (CM), has been evaluated (Hannig *et al.*, 2002). The penetration of adhesive into porous enamel surfaces creates a new structure designated as the 'hybrid layer'. This hybrid layer ranges from 1.5 to 3.2 μm for SEPs compared with 6.9 μm for phosphoric acid (Hannig *et al.*, 2002). Pashley and Tay (2001) reported the thickness of the hybrid layer for SEPs and phosphoric acid as 4 and 8 μm, respectively. 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 when compared with the phosphoric acid etch (Hannig *et al*., 2002). These similarities could explain the potential of the SEP systems (Hannig *et al*., 2002).

Measurements of bond strengths with SEP have shown contradictory results *in vitro* (Aljubouri *et al.*, 2003; Dorminey *et al.*, 2003; Grubisa *et al.*, 2004; Turk *et al.*, 2007). However, laboratory tests can never truly replicate the oral environment (House *et al.*, 2006). Thus, clinical bond failure studies have become popular and because the examined variable is the actual survival of bonds (Pandis and Eliades, 2005).

Several *in vivo* studies have been published concerning the bond failure rates with CM and SEP (Asgari *et al*., 2002; Ireland *et al.*, 2003; Aljubouri *et al.*, 2004; Cal-Neto and Miguel, 2005; dos Santos *et al.*, 2006; Manning *et al.*, 2006; Murfitt *et al.*, 2006). However, the findings showed different results. Asgari *et al.* (2002) and dos Santos *et al.* (2006) reported significantly lower bond failure rates with SEP than with CM. Whereas, Ireland *et al.* (2003) and Murfitt *et al.* (2006) found significantly higher failure rates with SEP than with CM. On the other hand, Cal-Neto and Miguel (2005), Aljubouri *et al.* (2004), and Manning *et al.* (2006) observed no significant difference between SEP and CM at the end of a 6 month observation period.

The aim of this study was to compare the bond failure rate of stainless steel brackets bonded with SEP (Transbond Plus) and with CM over a 6 month period. The chair time required for bonding with these systems was also evaluated.

Subjects and methods

Ethical approval was obtained and the subjects and parents gave their written consent for participation. All patients required two-arch fixed appliance therapy. The buccal surfaces of the teeth did not have any hypoplasia or restorations. There was no restriction concerning the type of malocclusion, except skeletal Class III. Extraction patients were included if their extractions were balanced.

Before the beginning of fixed appliance therapy, all patients were instructed in oral hygiene and in caring for the appliances by one operator. Each was given written instructions about the care of the fixed appliances. The details of sample size, mean age, and patient distribution by gender, age, and tooth type included in the study are presented in Table 1.

All teeth, except for the molars, were bonded with 0.022-inch slot MBT prescription metal brackets (Mini Master Series; American Orthodontics, Sheboygan, Wisconsin, USA). To eliminate inter-examiner variation, one operator (TT) performed the bonding procedures. The teeth were polished with a pumice slurry prior to bonding. The bonding procedures were allocated by the split-mouth method. The mouth was divided into quadrants, and a contralateral bonding pattern was randomly alternated to ensure an equal distribution of enamel treatments between the right and left sides (Cal-Neto and Miguel, 2005).

In the CM quadrants, the teeth were etched with 37 per cent phosphoric etchant liquid gel (3M Espe, St Paul, Minnesota, USA) 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 seated on the enamel surface. Excess adhesive resin was removed with an explorer. The adhesive resin was polymerized from two directions for a total of 20 seconds using a visible-light curing unit (Hilux 200, Benlioglu Dental Inc., Ankara, Turkey) with an output power of 600 mW/cm^2.

In the SEP quadrants, the SEP was used as recommended by the manufacturer, i.e. 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 the CM.

The timing required for bonding each quadrant was recorded in seconds from application of the SEP or phosphoric acid until all brackets were seated and the adhesive light cured. The mean bonding time of each bonding system for each tooth was obtained by dividing the time taken to bond brackets in each quadrant by the number of teeth bonded in that quadrant (Aljubouri *et al.*, 2004).

Initial aligning arch wires, 0.014-inch superelastic NiTi (Sentalloy; GAC International Inc., Bohemia, New York, USA), were fitted in the upper and lower arches approximately 5 minutes after the bonding procedure. The patients were instructed to check for loose brackets on a daily basis. If bond failure occurred, they were asked to record the date of bracket failure and to return to the clinic immediately. The patients were seen every 4 weeks. Following bracket failure, the amount of adhesive remaining on the tooth was visually determined according to the adhesive remnant index (ARI; Årtun and Bergland, 1984). Only the first bond failure was registered for each bracket.

Table 1 Sample characteristics.

	Number	%
Number of patients	37	—
Distribution of patients by gender		
Male	14	37.8
Female	23	62.2
Distribution by age		
<12	3	3.2
12–13	5	13.5
14–15	7	18.9
16–18	11	29.7
>18	11	29.7
Mean age: 16 years 5 months		
Number of brackets	672	—
Distribution of brackets by bonding procedure		
Conventional method	336	50
Self-etching primer	336	50
Distribution of brackets by gender		
Male	258	38.4
Female	414	61.6
Distribution of brackets by dental arch		
Upper	325	48.4
Lower	347	51.6
Distribution of brackets by tooth type		
Upper incisors	138	20.5
Lower incisors	146	21.8
Upper canines	64	9.6
Lower canines	74	11.0
Upper premolars	122	18.2
Lower premolars	128	18.9

Statistical analysis

The mean bonding times were compared using a paired *t*-test with respect to bonding procedure and dental arch.

The survival rates of the brackets were estimated using the Kaplan–Meier test. Bracket survival distributions with respect to bonding procedure, dental arch, type of tooth (incisor, canine and premolar), and patient gender were compared using the log-rank test ($P < 0.05$). Bond failure rates during a period of 6 months were determined for each bonding procedure, dental arch, type of tooth (incisor, canine, and premolar), and patient gender. The chi-square test was used to compare the failure rates ($P < 0.05$). The differences in ARI scores between the bonding procedures were determined with chi-square analysis ($P < 0.05$).

Results

Bonding time

The mean bracket bonding time per tooth was 91.27 seconds [standard deviation (SD) = 14.39] for the CM and 65.51

seconds (SD = 10.51) for the SEP. The mean difference between the two methods was 25.76 seconds, which was statistically significant ($P < 0.001$).

Table 2 Mean bracket bonding time (seconds) per tooth and the comparison between upper and lower dental arches for both bonding procedures.

Bonding procedure	Upper		Lower		*P*
	Mean	SD	Mean	SD	
Conventional method	97.04	14.86	85.49	11.43	0.001***
Self-etching primer	68.73	11.66	62.29	8.16	0.018*

$^{*}P < 0.05$ and $^{***}P \leq 0.001$; SD, standard deviation.

Comparison of the mean bonding times between upper and lower dental arches showed significant differences for CM ($P \leq 0.001$) and SEP ($P < 0.05$) (Table 2).

Bracket survival

A total of four bond failures occurred for the 6 month observation period: two (0.6 per cent) with CM and two (0.6 per cent) with SEP. No significant difference was found between failure rates ($P = 1.00$). The corresponding bracket survival curves were plotted with the Kaplan–Meier estimate (Figure 1A). Bonding procedures did not have a significant influence on the survival rates ($P = 0.998$). The probability of having bonded brackets still in place at 6 months was 0.994 for both bonding procedures.

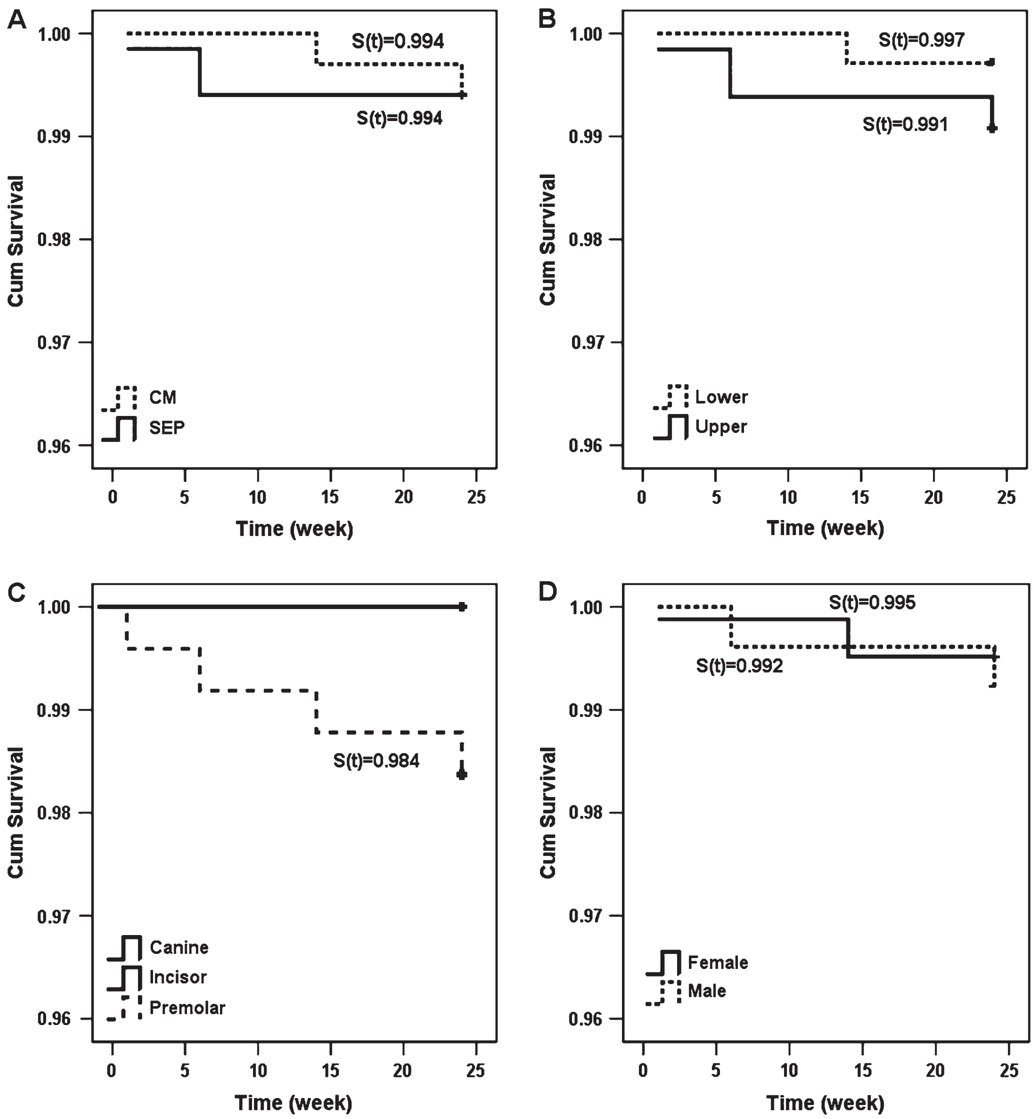

Figure 1 Bracket survival distribution for (A) bonding procedures (log-rank statistics = 0.000 on degree of freedom (df) = 1, $P = 0.998$), (B) dental arches (log-rank statistics = 1.143 on df = 1, $P = 0.285$), (C) tooth type (incisor, canine, and premolar) (log-rank statistics = 6.969 on df = 2, $P = 0.030$), and (D) patient gender (log-rank statistics = 0.227 on df = 1, $P = 0.633$).

The bond failure rates were 0.9 and 0.3 per cent in the upper and lower arches, respectively. The difference was not statistically significant ($P = 0.285$). 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 ($S[t] = 0.991$) and lower ($S[t] = 0.997$) dental arches ($P = 0.285$).

Premolar brackets showed a higher (1.6 per cent) failure rate than incisor (0.0 per cent) and canine (0.0 per cent) brackets ($P = 0.031$). Figure 1C shows the influence of arch location on bracket survival rate. The log-rank test demonstrated significant differences between the incisor, canine, and premolar teeth in terms of survival rate ($P = 0.030$).

Female patients had a 0.5 per cent failure rate, and male patients a 0.8 per cent failure rate, which were not statistically significant ($P = 0.632$). The influence of gender on the bracket survival rate is shown in Figure 1D. No significant difference between females ($S[t] = 0.995$) and males ($S[t] = 0.992$) was observed with the log-rank test ($P = 0.634$).

Site of failure

Frequency distribution and the result of the chi-square analysis of the ARI scores are shown in Table 3. No significant difference was observed among the bonding procedures ($P > 0.05$).

Discussion

In this study, the clinical performance of a SEP was evaluated and compared with a CM. The failure and survival rates of the brackets bonded with SEP were evaluated according to bonding procedure, dental arch, type of tooth (incisor, canine, and premolar), and gender. According to Hitmi *et al.* (2001), failure rates are a widely accepted means of assessing bracket performance, allowing effective comparison with the results in the literature. 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 the underlining of some significant differences, which is impossible with failure rates (Hitmi *et al.*, 2001).

Table 3 Frequency distribution and the result of the chi-square analysis of the adhesive remnant index (ARI).*

	ARI scores†			
	0	1	2	3
Conventional method	1	1	—	—
Self-etching primer	—	1	—	1

*$\chi^2 = 2.000$, $P = 0.368$.
†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.

It has been reported that most bond failures occur within the first 3–6 months following bracket placement (Hegarty and Macfarlane, 2002; Aljubouri *et al.*, 2004; O'Brien *et al.*, 1989). Aljubouri *et al.* (2004) and O'Brien *et al.* (1989) observed bracket failure rates of 50 and 82 per cent, respectively, during the first 6 months. Hegarty and Macfarlane (2002) noted failure rates of 54 per cent during the first 3 months. O'Brien *et al.* (1989) discussed three possible reasons for this increased failure rate during the first 6 months of treatment: (1) any deficiencies in the bond strength of any individual bracket/adhesive combination would become evident within this initial period of treatment, (2) 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, and (3) the initial phase of treatment may involve a period of overbite depression and, as a consequence, heavy occlusal forces may be applied to many of the bonded attachments.

In the present study, the bond failure rates were 0.6 per cent for both CM and SEP. No significant difference was found between these procedures. These findings are in agreement with the results of the clinical studies by Aljubouri *et al.* (2004) and Manning *et al.* (2006). Aljubouri *et al.* (2004) hypothesized that failure rate was due to the similar etch pattern of the SEP when compared with the two-stage bonding system. Asgari *et al.* (2002) noted significantly lower bond failure rates with SEP (0.57 per cent) than with CM (4.60 per cent). Nevertheless, Ireland *et al.* (2003) and Murfitt *et al.* (2006) observed significantly higher failure rates with SEP (10.99 and 11.2 per cent, respectively) than with CM (4.95 and 3.9 per cent, respectively).

In the present study, the survival rate was 0.994 for both bonding procedures. These survival rates did not demonstrate a significant difference. A survival rate of 0.994 implies a 99 per cent chance for a bonded bracket to be in place after 6 months. Cal-Neto and Miguel (2005) did not observe a significant difference between the survival rates of a SEP and a hydrophilic primer applied with conventional acid etching, even though the bond failure rates with SEP (5.08 per cent) were higher than with the hydrophilic primer (2.54 per cent). dos Santos *et al.* (2006) reported that the self-etch adhesive ($S[t] = 0.782$) showed a significantly higher survival rate than the conventional system ($S[t] = 0.708$).

Some clinical studies (Asgari *et al.*, 2002; Ireland *et al.*, 2003; Aljubouri *et al.*, 2004; Cal-Neto and Miguel, 2005; dos Santos *et al.*, 2006; Murfitt *et al.*, 2006) show different results to the present findings. However, direct comparison between investigations testing identical materials should be interpreted with caution, as there is no standardized protocol for clinical studies (O'Brien *et al.*, 1989). In the present investigation, the CM included etching with 37 per cent 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 (Transbond Plus) was applied according to the manufacturer's instructions in several studies (Asgari *et al.*, 2002; Ireland *et al.*, 2003; Aljubouri *et al.*, 2004; Cal-Neto and Miguel, 2005; Manning *et al.*, 2006; Murfitt *et al.*, 2006). However, dos Santos *et al.* (2006) applied the SEP for 10–15 seconds. In *in vivo* studies, socio-economic and the dental status of patients, malocclusion classification, and resultant mechanotherapy may affect the outcomes (Pandis and Eliades, 2005). Furthermore, masticatory forces varying with facial type, culturally influenced dietary habits, and gender differences may also influence the results (Pandis and Eliades, 2005).

In the present study, there was no significant difference between male and female patients, or the location of teeth, i.e. upper or lower dental arches, in terms of failure rate. These findings are in accordance with other studies (Mavropoulos *et al.*, 2003; Pandis *et al.*, 2006). Tooth type (incisor, canine, and premolar) significantly influenced the bond failure and survival rates in the present study. The brackets on one lower and three upper premolar teeth failed with a survival rate of 0.984. Mavropoulos *et al.* (2003) observed that the bracket failure rate for posterior teeth (first and second premolars) was three times higher than anterior teeth (incisors and canine). In the present investigation, only one premolar bracket failure, bonded with CM, in the lower jaw was observed. Occlusal interference was responsible for this bond failure. The remaining three failure rates were located in the upper left quadrant. It has been suggested that bracket placement on maxillary premolars is difficult due to poor visualization and access (Graber *et al.*, 2005). Furthermore, the brackets on these teeth may have been manipulated for accurate placement. In the present study, the clinician was right handed making bracket placement easier on the right side. This observation has been supported by Mavropoulos *et al.* (2003). The difficulty of bonding to upper posterior teeth, particularly on the left side, could explain these bond failures. However, it is difficult to make conclusive statements about bond failure of premolar teeth since the number of bond failures was low.

In the present clinical study, a shorter mean bonding time was obtained with SEP, with a mean difference of 25.76 seconds between CM and SEP, which is similar to the 24.9 seconds found *in vivo* by Aljubouri *et al.* (2004). Those authors reported that the average reduction in chair time was 8.5 minutes when 10 teeth were bonded in each arch. In the current study, the average reduction in chair time was approximately 9 minutes when 20 teeth were bonded. This shorter bonding time translates into reduced clinical chair time, which increases cost-effectiveness (Aljubouri *et al.*, 2004). In addition, reduced time may increase the patient's comfort.

Conclusion

The results of this *in vivo*, randomized, cross-mouth clinical trial demonstrated a high survival rate with SEP (Transbond Plus). This finding indicates that SEP can be effectively used for bonding of orthodontic brackets. Furthermore, the mean bracket bonding time with SEP per tooth was significantly shorter than with the CM.

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