SHORT COMMUNICATION

Bond failure rates with a self-etching primer: A randomized controlled trial

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Introduction: The purpose of this clinical trial was to evaluate over a 12-month period the performance of a self-etching system (SEP) (Transbond Plus SEP, 3M Unitek, Monrovia, Calif) compared with a conventional multi-step system (TBXT) (Transbond XT, 3M Unitek). **Methods:** Twenty-eight randomly selected patients were included in this study. They were randomly assigned to either the TBXT or the SEP group. A total of 548 brackets were bonded according to the manufacturer's instructions with Transbond XT adhesive paste (3M Unitek). The survival rates of brackets were estimated with the Kaplan-Meier analysis. Bracket survival distributions for bonding procedure, tooth location, dental arch, and patient sex were compared with the log-rank test. **Results:** The failure rates of the TBXT and SEP groups were 4.78% and 6.88%, respectively. No significant differences in the survival rates were observed between the bonding procedures ($P = 0.311$). When tooth location, dental arch, and sex were analyzed, only tooth location was significant. Posterior brackets were more likely to fail than anterior brackets ($P = 0.013$). **Conclusions:** Both systems had low bond failure rates and are adequate for orthodontic bonding needs. (Am J Orthod Dentofacial Orthop 2009;135:782-6)

Even though the acid-etching technique is useful in orthodontics, improved techniques are needed to maintain clinically useful bond strengths while minimizing enamel loss and to simplify the technique by reducing the number of steps.[1,2] Self-etching primers (SEPs) are popular in orthodontic bonding because they combine the conditioning and priming agents into a single acidic primer solution.[1] This eliminates the washing and drying stages, which are necessary in the conventional method, saving clininal time, reducing procedural errors, and minimizing technique sensitivity. In addition, a more conservative etching pattern is obtained with fewer resin tag penetrations.[3] But the effectiveness of these acidic primers is unclear.

Some clinical evaluations have been published concerning the bond failure rates with SEPs, but the results do not agree.[4-10] Some problems with study design were noted including lack of subject randomization, sample size, and power calculation. Occasionally, the manufacturer's instructions are not followed, making comparison with other reports inappropriate and difficult.[11]

The purpose of this randomized clinical trial was to compare the bond failure rates of brackets bonded with a SEP (Transbond Plus SEP, 3M Unitek, Monrovia, Calif) and and a conventional multi-step system (TBXT) (Transbond XT, 3M Unitek) over a 12-month period. A secondary aim was to investigate factors contributing to bracket failure—tooth location, dental arch, and patient sex. The null hypothesis was that there is no difference in the failure rates of brackets bonded with TBXT or SEP during preadjusted edgewise appliance therapy.

MATERIAL AND METHODS

The sample size for each group was estimated based on the number of brackets required, since this was the unit of measurement. A sample size of 500 brackets ($n = 250$ per group) is sufficient to detect improvement or reduction in bond failure after 12 months using a log-rank test, with 90% power and a 5% significance level (StatMate version 2.0, GraphPad Software, San Diego, Calif). To have 250 brackets per group, approximately 30 patients would be needed, since the number of teeth per patient would vary because of extractions, missing teeth, and other excluded teeth.

Thirty consecutive patients from the waiting list for treatment at the Department of Orthodontics, School of Dentistry, State University of Rio de Janeiro, Rio de

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Table I. Sample characteristics

	Number	%
Patients (n)	28	—
Distribution by bonding procedure		
TBXT	14	50
Distribution by sex		
Male	5	35.7
Female	9	64.3
Distribution by age		
11-13 years	7	50
14-16 years	4	28.6
≥17 years	3	21.4
SEP	14	50
Distribution by sex		
Male	6	42.6
Female	8	57.4
Distribution by age		
11-13 years	5	35.7
14-16 years	5	35.7
≥17 years	4	28.6
Mean age, 14 y 11 mo		
Brackets (n)	548	—
Distribution of brackets by bonding procedure		
TBXT	272	49.6
SEP	276	51.4
Distribution of brackets by dental arch		
Maxillary	268	48.9
Mandibular	280	51.1
Distribution of brackets by tooth type		
Anterior	336	61.3
Posterior	212	38.7
Distribution of brackets by sex		
Male	216	39.4
Female	332	60.6

Janeiro, Brazil, participated in this study. Ethical approval was obtained from the university's Research Ethics Committee, and parents gave their written consent for participation. Patients were eligible for the study if they (1) required 2-arch fixed therapy; (2) had no caries, fillings, or hypoplasia; (3) had no occlusal interferences to eliminate the influence of trauma on failure rate; and (4) consented to participate. They were randomly allocated with opaque numbered sealed envelopes (blocked randomization ensured equal numbers of patients in each group after every tenth subject) to either the TBXT or the SEP group. There were 15 patients in each group, but 2 patients moved and were removed from the study (1 from each group). Thus, there were 14 patients in each group. The characteristics of the study sample are given in Table I.

The operator was unaware of the assignment until the patient entered the trial, but because the 2 systems had different modes of application, it was impossible to blind the operators to the system being used.

Initially, the teeth were cleaned with a rubber cup with pumice and water slurry, rinsed, isolated with cheek retractors and a low-volume suction evacuator, and dried with oil-free air. All teeth, except the molars, were directly bonded. In the TBXT group, 37% phosphoric acid was applied to the enamel surface for 15 seconds before rinsing with water and drying until the enamel was frosty white. Transbond XT primer (3M Unitek) was then applied to the etched enamel acording to the manufacturer's instructions and given a gentle burst of air. Transbond XT adhesive paste (3M Unitek) was placed on the back of the brackets (Alexander 0.022-in stainless steel brackets [Micro-Arch, GAC International, Bohemia, NY]), and they were positioned in the center of the crown with gentle pressure applied to seat each bracket. Excess adhesive was removed with a sharp dental probe, and the brackets were light cured for 20 seconds (10 seconds mesially, 10 seconds distally), with a visible light-curing unit (Ortholux XT, 3M Unitek, 640 mW/cm^{-2}). The same curing light was used throughout the study, and its output was checked periodically.

In the SEP group, following the instructions, the material was applied to the enamel surface and rubbed for 3 seconds, and then a gentle burst of dry air thinned the primer. The adhesive paste and the brackets were placed and light cured as described for the TBXT group.

Initial aligning archwires, 0.014-in superelastic nickel-titanium (GAC) were fitted in both arches approximately 10 minutes after bonding. No bite planes were used during treatment. All patients were given verbal and written instructions about diet and care immediately after fitting the appliances.

The patients were followed for 12 months. If a bond failed, the following inforrmation was recorded: (1) site of bond failure, (2) number of failed brackets, and (3) date of bond failure. The patients were seen at 3 to 4 week intervals but were requested to come as soon as possible if case of a bond failure. When the patient was unaware of a bracket failure, the date was recorded as the date of the appointment when the failure was noted by the clinician. Subsequent failures for the same tooth were noted but not included in the study.

Statistical data analysis was carried out by using Prism (version 4.0, GraphPad Software) at the 5% level of significance. The survival rates of the brackets were estimated by using the Kaplan-Meier test. Bracket survival distributions with respect to bonding procedure, dental arch, type of tooth (anterior and posterior), and patient sex were compared by using the log-rank test.

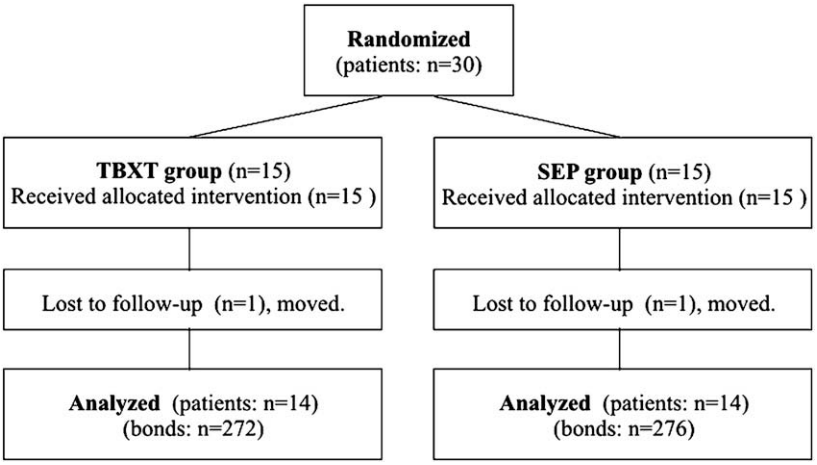

Fig 1. Flow chart of patients in the trial.

RESULTS

The flow chart of this trial is given in Figure 1. Thirty-two failures were registered during the 12-month observation period: 13 (4.78%) ocurred with the TBXT and 19 (6.88%) with the SEP (Table II). The overall failure rate for all brackets in the study was 5.84%. The corresponding bracket survival curves were plotted by using the Kaplan-Meier product-limit estimate (Fig 2, *A*). There was no significant difference in terms of bracket failure risk over the 12 months between groups (hazard ratio = 0.69; 95% confidence interval = 0.35-1.40; log rank test $P = 0.311$).

Posterior brackets (premolars) showed higher (8.96%) failure rates than anterior brackets (3.87%). Figure 2, *B,* shows the influence of tooth location on bracket survival rate. The log-rank test showed significant differences between anterior and posterior brackets in terms of survival rate ($P = 0.013$; hazard ratio = 0.42; 95% confidence level = 0.20-0.83).

The maxillary arches had a 4.85% failure rate, and the mandibular arches a 6.78% failure rate; these were not statistically significant according to the log-rank test ($P = 0.341$; hazard ratio = 0.71; 95% confidence level = 0.36-1.43). The influence of the dental arches on bracket survival rate is shown in Figure 2, *C*.

The bond failure rates were 3.70% and 7.23% in male and female patients, respectively. The influence of sex on the bracket survival rate is shown in the Figure 2, *D*. No significant difference between female subjects was observed with the log-rank test ($P = 0.088$; hazard ratio = 0.51; confidence level = 0.27-1.10).

Table II. Relationship between tooth characteristics and bracket failure over 12 months

Variable	*Number*	*Bracket failures*	*Failure rate (%)*	*Log-rank*
Bonding procedure				NS
TBXT	272	13	4.78	
SEP	276	19	6.88	
Dental arch				NS
Maxillary	268	13	4.85	
Mandibular	280	19	6.78	
Bracket location				*
Anterior	336	13	3.87	
Posterior	212	19	8.96	
Sex				NS
Male	216	8	3.70	
Female	332	24	7.23	

NS, Not significant; *significant.

DISCUSSION

The null hypothesis was not rejected. We did not find statistically significant differences in bond failure rates between the TBXT and the SEP groups. Bond failure rates below 10% are generally considered clinically acceptable.[12] The 6.88% bond failure rate of the SEP can be considered acceptable compared with the 4.78% failure rate of the conventional 2-step system.

Recent clinical trials comparing bonding systems have used the split-mouth design; the mouth of each patient is divided into quadrants, and the contralateral bonding pattern is randomly alternated from patient to patient to ensure balanced distribution of adhesives between the right and the left side of the dental arches. The advantage of this is that patient factors—eg, poor care of the appliances—will be accounted for evenly, since the patient is his or her own control. However, one bonding agent might affect the performance of the other, and the bracket bonding technique might be altered and not truly reflect clinical practice. Randomly

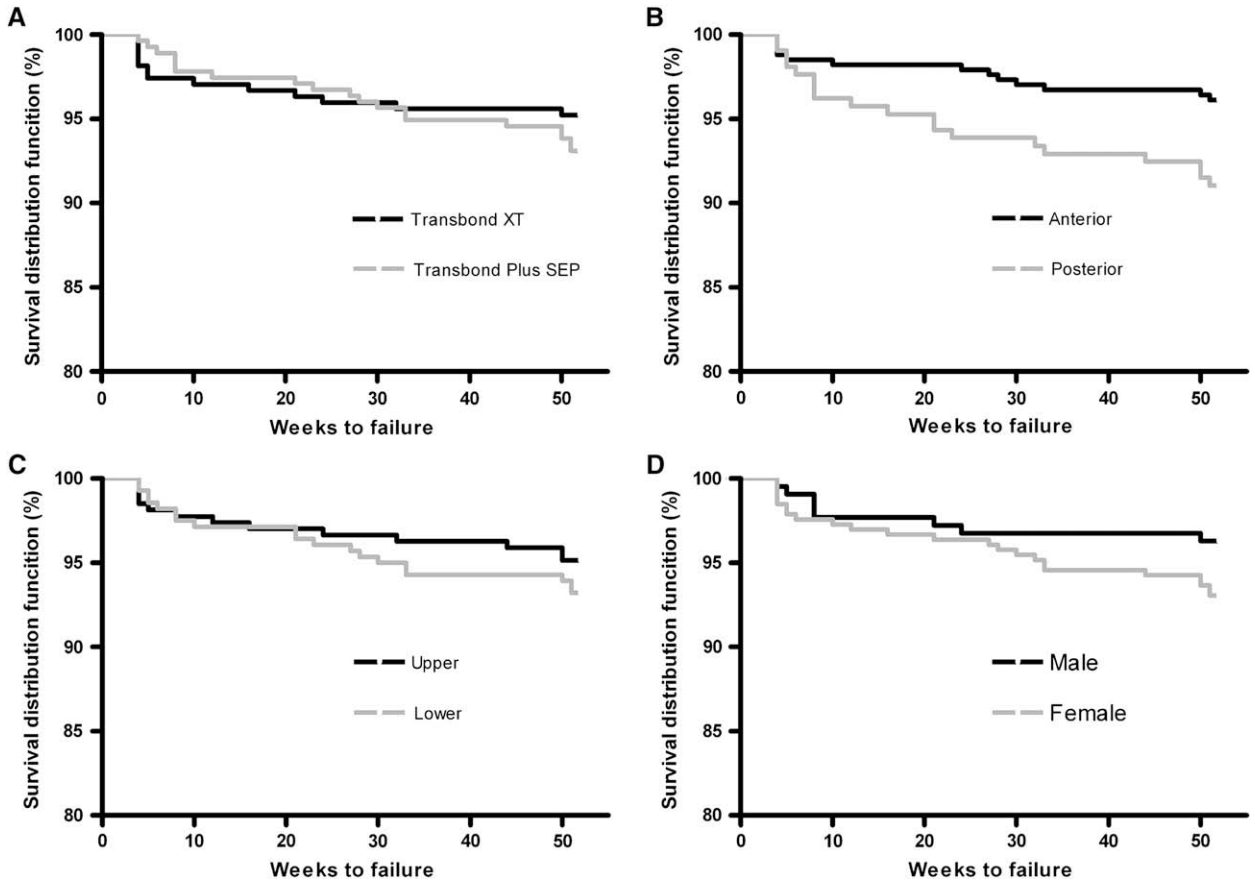

Fig 2. Graphs of Kaplan-Meier survival plots for: **A,** bonding procedure; **B,** tooth type; **C,** dental arch; and **D,** patient sex.

allocating one material to each patient eliminates this problem.[8,13,14]

When we compared our results with other studies that investigated Transbond Plus, there was agreement with the studies of Manning et al,[8] Banks and Thiruvenkatachari,[9] and Elekdag-Turk et al,[10] but not with others that observed significantly lower bond failure rates with SEP than with TBXT[4] or that noted significantly higher failure rates with SEP than with TXBT.[5,7] However, direct comparison between investigations testing identical materials should be interpreted with caution, because there is no standardized protocol for clinical studies.[15] In in-vivo studies, socioeconomic and dental status of patients, maloccusions, and resultant mechanotherapies might affect the outcomes.[6]

Bracket failure rate was not influenced by any factor investigated, except tooth location. These results agree with other studies that concluded that posterior teeth suffer more bracket failures than anterior teeth.[15,16] The possible reasons for this are higher occlusal forces on posterior teeth, more aprismatic enamel on premolars, and difficult access and isolation from moisture in the posterior regions.[15,16] However, statistical tests for subgroup analysis should be regarded with caution because these were not planned for in the original study design and are likely to be less reliable and underpowered.

Our results indicate that both the TBXT and the SEP provide adequate performance for bonding orthodontic appliances with Transbond XT adhesive paste. From a clinical standpoint, the use of a SEP can be desirable because it reduces clinical steps, saves chair time, improves adhesive procedures, and reduces the risk of salivary contamination.[17] In addition, a SEP produces a more conservative etching pattern than phosphoric acid, minimizing enamel loss.[3] The decision to use a particular adhesive will come down to clinical preference.

CONCLUSIONS

1. In this randomized clinical trial, there was no difference between the clinical bond failure rates of

brackets bonded with a SEP or a conventional multi-step system.
2. Both systems had low bond failure rates and are adequate for orthodontic bonding needs.

REFERENCES

1. Bishara SE, Von Wald L, Laffoon JF, Warren JJ. Effect of a self-etch primer/adhesive on the shear bond strength of orthodontic brackets. Am J Orthod Dentofacial Orthop 2001;119:621-4.
2. Yamada R, Hayakawa T, Kasai K. Effect of using self-etching primer for bonding orthodontic brackets. Angle Orthod 2002; 72:558-64.
3. Cal-Neto JP, Mendes-Miguel JA. Scanning electron microscopy evaluation of the bonding mechanism of a self-etching primer on enamel. Angle Orthod 2006;76:132-6.
4. Asgari S, Salas A, English J, Powers J. Clinical evaluation of bond failure rates with a new self-etching primer. J Clin Orthod 2002; 36:687-9.
5. Ireland AJ, Knight H, Sherriff M. An in-vivo investigation into bond failure rates with a new self-etching primer system. Am J Orthod Dentofacial Orthop 2003;124:323-6.
6. Pandis N, Eliades T. A comparative in-vivo assesment of the long-term failure rate of 2 self-etching primers. Am J Orthod Dentofacial Orthop 2005;128:96-8.
7. Murfitt PG, Quick AN, Swain MV, Herbison GP. A randomised clinical trial to investigate bond failure rates using a self-etching primer. Eur J Orthod 2006;28:444-9.
8. Manning N, Chadwick SM, Plunkett D, MacFarlane TV. A randomized clinical trial comparing 'one-step' and 'twostep' orthodontic bonding systems. J Orthod 2006;33:276-83.
9. Banks P, Thiruvenkatachari B. Long-term clinical evaluation of bracket failure with a self-etching primer: a randomized controlled trial. J Orthod 2007;34:243-51.
10. Elekdag-Turk S, Isci D, Turk T, Cakmak F. Six-month failure rate evaluation of a self-etching primer. Eur J Orthod 2008;30: 211-6.
11. Dos Santos JE, Quioca J, Loguercio AD, Reis A. Six-month bracket survival with a self-etch adhesive. Angle Orthod 2006;76:863-8.
12. Mavropoulos A, Karamouzos A, Kolokithas G, Athanasiou AE. In vivo evaluation of two new moisture-resistant orthodontic adhesive systems: a comparative clinical trial. J Orthod 2003; 30:139-47.
13. Hujoel PP, De Rouen TA. Validity issues in split-mouth trials. J Clin Periodontol 1992;19:625-7.
14. Hujoel PP. Design and analysis issues in split-mouth clinical trials. Community Dent Oral Epidemiol 1998;26:85-6.
15. O'Brien KD, Read MJ, Sandison RJ, Roberts CT. A visible light-activated direct-bonding material: an in vivo comparative study. Am J Orthod Dentofacial Orthop 1989;95:348-51.
16. Sunna S, Rock WP. Clinical performance of orthodontic brackets and adhesive systems: a randomized clinical trial. Br J Orthod 1998;25:283-7.
17. Cal-Neto JP, Miguel JAM, Zanella E. Effect of a self-etching primer on shear bond strength of adhesive precoated brackets in vivo. Angle Orthod 2006;76:127-31.