A randomised clinical trial to investigate bond failure rates using a self-etching primer

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SUMMARY This clinical trial evaluated, over a 12-month period, the performance of brackets bonded to teeth etched and primed with Transbond™ Plus Self-Etching Primer (SEP) when compared with a conventional separate two-step etch and primer system.

Thirty-nine randomly selected patients requiring fixed appliance therapy were entered into the study. Random allocation of each etching system, along with a 'split-mouth cross-quadrant' design was used. A total of 661 brackets were placed by two operators. The failure and survival rates of the brackets were determined for age and gender of the patients, each etching system, operator, mode of failure, tooth position in the dental arch, and number of manipulations prior to curing the adhesive.

Statistical analysis showed that SEP had a significantly higher bond failure rate (11.2 per cent) than the conventional etch and primer system (3.9 per cent) at the $P = 0.001$ level. Cox's proportional hazards regression showed the conventional etch and primer system to have a 60 per cent reduced chance of bracket failure over a 12-month observation period, while males had a 2.4 times increased risk compared with females. The predominant mode of failure was at the composite enamel interface for the SEP, while for the conventional etch and primer system, it was within the composite adhesive. No statistically significant differences were found for the failure rate with respect to the age of the patient, operator, tooth location, or the number of manipulations of the bracket.

This *in vivo* study showed that brackets bonded using SEP had an increased clinical bond failure rate compared with the conventional, separate, etch and prime system.

Introduction

The ideal bond strength of orthodontic attachments should be sufficient to withstand the typical intraoral forces that occur throughout the course of fixed appliance treatment, yet weak enough to facilitate debonding without damaging the tooth enamel, especially on previously restored teeth. Bonding of attachments is facilitated by first etching the enamel surface, as proposed by Buonocore (1955). He recommended the use of 85 per cent phosphoric acid for 30 seconds, but since then, the majority of studies have reported that an etch time of 15 seconds (Brännström *et al.*, 1982; Carstensen, 1986; Kinch *et al.*, 1989; Wang and Lu, 1991; Sheen *et al.*, 1993; Barry, 1995; Bin Abdullah and Rock, 1996) and 37 per cent phosphoric acid (Proffit, 1993; Zachrisson, 2000) appears sufficient to obtain a satisfactory bond for orthodontic attachments. By decreasing the concentrations and etchant times, the amount of superficial enamel loss and the depth of enamel penetration are reduced (Carstensen, 1993).

The newly introduced acidic primers [for example Transbond™ Plus Self-Etching Primer (SEP), 3M Unitek, Monrovia, California, USA] may be advantageous if they provide a clinically useful bond. In addition to decreasing the amount of damage to the enamel from the etching process, the number of clinical steps and time required is

also less (White, 2001). As the monomers that cause the etching are also responsible for bonding, the depth of penetration of the monomers into the enamel is exactly the same as the depth of demineralisation, resulting in a full depth polymerized layer (Miller, 2001).

Using *in vitro* studies, Arnold *et al.* (2002) and Rajagopal *et al.* (2004) found no significant difference in bond strength between a SEP and the conventional etching and primer system. Bishara *et al.* (2001, 2002) however, found Transbond™ Plus SEP to have a significantly lower bond strength than the conventional system, although on the basis of bond strength, it could still be considered to be clinically acceptable (Reynolds, 1975).

Previous *in vivo* studies, using various conventional adhesives, suggest that bracket failure rates of around 4–12 per cent are to be expected (Armas Galindo *et al.*, 1998; Fowler, 1998; Sunna and Rock, 1998). A recent study by Ireland *et al.* (2003) investigated the bond failure rate *in vivo* of a SEP system, and found that there was weak evidence to suggest a higher failure rate with the new system. Their study was limited to 20 participants over a 6-month period, and did not investigate whether age, gender, tooth position, or number of manipulations during bonding influenced the survival rate. The amount of adhesive remaining on the bracket was also not reported. The present

study aimed to investigate these factors over a total time period of 12 months.

Subjects and method

Thirty-nine patients attending the Orthodontic Clinic of the University of Otago School of Dentistry between September 2002 and June 2003 for routine orthodontic treatment participated in this study. Ethical approval was obtained prior to the start of the study from the Otago Ethics Committee. One individual declined to participate. The patients were randomly assigned to one of two operators, both of whom were in the early stages of their postgraduate training. The characteristics of the study sample are given in Table 1.

Section on sample size

Three hundred and two brackets were required in each etching group in order to have an adequate power for the study of 80 per cent to show a statistically significant difference at $P < 0.05$ between a 5 and 12 per cent bracket failure rate for the two etch/primer systems.

Patients were eligible for inclusion in the study if they required one or two arch fixed appliance therapy, did not have any gross enamel defects which could affect bracket bond strength, and both patient and parent (where appropriate) had given consent to be in the trial.

A split-mouth, cross-quadrant design (Glavind, 1977) was used to determine which etching and primer systems were applied in each quadrant. Randomization for allocation of either of the two etch and primer systems to the upper right quadrant was undertaken using a block randomization method as described by Roberts and Torgerson (1998). This randomization method guarantees that any 10 consecutive subjects will contain five subjects who have been etched

Table 1 Characteristics of the sample

	Number	%
Number of participants	39	100
Distribution of participants by gender		
Male	13	33.3
Female	26	66.6
Distribution by age		
<12	2	5.1
12–13	17	43.6
14–15	16	41.0
>16	4	10.3
Mean age: 14.4 years (SD = 2.5 years)		
Distribution of patients by operator		
Operator 1	16	41.0
Operator 2	23	59.0
Number of brackets	661	
Distribution of brackets by operator		
Operator 1	273	41.3
Operator 2	388	58.7

and primed with Transbond™ Plus SEP on the upper right and five with it on the upper left. The operators were unaware of the assignment until the patient was entered into the trial. The patients were unaware which system had been used on each side of the mouth, but as the two systems had different modes of application, it was not possible to blind the operators to the type of system being used. In total, 661 brackets were bonded. All patients were observed for the entire 12-month period apart from one 13-year-old male who moved to another city after 7 months of observation, during which time no bracket failures occurred. His data was still included in the analysis, as it was considered that it still provided useful information on bracket survival rates.

Incisors, canines, and premolars were bonded using 0.018-inch Mini-Taurus® (RMO®, Denver, Colorado, USA) pre-adjusted edgewise brackets with a vertical slot. The quadrants were either etched with Transbond™ Plus SEP or conventional 37 per cent phosphoric acid (3M Scotchbond™ Etchant, 3M Dental Products, St Paul, Minnesota, USA) and Transbond™ MIP primer (3M Unitek).

After allocation of the upper right quadrant to either of the etching systems, the teeth were cleaned with a rubber cup and water/pumice slurry, rinsed, and isolated using cheek retractors and a low volume suction evacuator. The appropriate etch and primer system for each quadrant was then applied, according to the manufacturers' instructions. The Transbond™ Plus SEP blisters were activated, the liquid rubbed onto the tooth surface for at least 3 seconds, followed by a gentle airburst directed away from the gingival margin using a 3-in-1 syringe, and it was ensured that the tooth surface retained a glossy appearance.

For the two-step 37 per cent phosphoric acid and Transbond™ MIP primer, the etchant gel was applied for 15 seconds, the tooth surface was washed for 15 seconds and dried using a 3-in-1 syringe, and finally Transbond™ MIP primer was applied.

All brackets were bonded using Transbond™ XT (3M Unitek) light cure adhesive on the base of the bracket, which was then placed with minimal movement on the buccal surface of the tooth. Any excess composite was removed with a sharp dental probe prior to curing.

Finally, the adhesive was cured using light polymerisation for 20 seconds (10 seconds mesially and 10 seconds distally), using one of two halogen curing lights (3M Curing light XL3000, 3M Dental Products, or a Coltène Coltolux 4 Curing light, Coltène/Whaledent Inc, Mahwah, New Jersey, USA). The power output of the curing lights was checked on a weekly basis.

Depending on the severity of the crowding, initial aligning archwires of either 0.014-inch NiTi (SDS Ormco, Glendora, California USA) or 0.014-inch regular grade Australian Wilcox wire (Whittlesea, Victoria, Australia) were tied into the bracket slots with elastomeric 'O' rings after completion of bonding.

At the time of bonding the following was recorded: the date the brackets were placed, which etch/primer system was used in each quadrant, and the number of minor adjustments made by the operator when placing the bracket. Each patient was then monitored for 12 months. If a bond failed, the tooth on which the failure occurred, the date of failure, and the amount of adhesive remaining on the tooth using the adhesive remnant index (Årtun and Bergland, 1984) were recorded.

The data were described with standard descriptive statistics, such as crosstabs and Kaplan–Meier survival curves, using the statistical packages Stata V8 (Stata Corporation, College Station, Texas, USA) and SPSS version II (Statistical Package for Social Sciences, Chicago, Illinois, USA). Statistical testing was carried out with models appropriate to the level of measurement of the outcome variable and allowing for the fact that some bonds were 'clustered' in the same mouth and some in different mouths. Binary outcomes were tested with logistic regression and categorical outcomes with multinomial logistic regression and were adjusted for the clustering within mouths. Kaplan–Meier estimates of survival curves were constructed since not all brackets would have failed by the end of the 12-month observation period. The survival curves for the etch/primer systems and the gender and age of the patient were compared using Cox's proportional hazards regression models, adjusted for the clustering within mouths.

Results

Bracket failure

During the 12-month observation period the bracket failure rate was 11.2 per cent for the Transbond™ Plus SEP and 3.9 per cent for the conventional 37 per cent phosphoric acid and primer. The overall bracket failure rate for all brackets in the study was 7.6 per cent. Transbond™ Plus SEP was found to have a significantly higher failure rate than the conventional 37 per cent phosphoric acid and primer ($P = 0.001$).

Patient gender ($P = 0.060$) and age ($P = 0.177$), operator ($P = 0.891$), tooth location in the dental arch ($P = 0.710$), and the number of manipulations of the bracket prior to curing ($P = 0.716$) did not significantly affect the bond failure rate. However, brackets which had been manipulated more than three times prior to curing almost doubled the failure rate with Transbond™ Plus SEP (Table 2). It appeared that upper premolar teeth and lower canines had higher failure rates with Transbond™ Plus SEP (Table 3), although this was not tested statistically due to low power.

Bracket survival

The bracket survival curves (Figure 1) and corresponding Cox's proportional hazard regression also showed Transbond™ Plus SEP to have a lower bracket survival rate ($P = 0.002$), with the conventional etch and primer system having a

Table 2 Percentage failure rate related to the number of adjustments prior to curing the adhesive*.

Etching system	≤3 adjustments (%)	≥4 adjustments (%)
Self-etching system	7.8	15.3
Conventional etching system	3.6	4.3
Total	5.8	10.8

*$P = 0.716$.

Table 3 Failure by location of bracket*. Entries are n/N (%).

Tooth	Self-etching	Conventional	Overall†
Upper incisors	6/74 (8.1)	2/74 (2.7)	8/148 (5.4)
Upper canines	4/35 (11.4)	1/35 (2.9)	5/70 (7.1)
Upper premolars	10/49 (20.4)	3/49 (6.1)	13/98 (13.3)
Lower incisors	4/78 (5.1)	4/78 (5.1)	8/156 (5.1)
Lower canines	7/39 (17.9)	1/38 (2.6)	8/77 (10.4)
Lower premolars	6/56 (10.7)	2/56 (3.6)	8/112 (7.1)

*$P = 0.710$.
†Overall percentage for each tooth type.

60 per cent less chance of bracket failure over the 12-month observation period (Hazard ratio 0.4, 95 per cent confidence 0.2–0.8).

Survival analysis for gender (Figure 2) showed that males had a 2.4 (95 per cent confidence interval 1.2–4.6) times higher chance of bracket failure than females ($P = 0.01$) but no significant differences for age or operator.

Site of failure

Analysis of the adhesive remnant scores showed that Transbond™ Plus SEP failed mainly at the enamel composite interface, indicating adhesive failure. The conventional acid and primer had a significantly higher number of failures with more than half the composite remaining on the tooth ($P = 0.026$), indicating a greater degree of cohesive failure (Table 4).

Discussion

The overall bond failure rate for this study was 7.9 per cent, which is similar to previous investigations using Transbond™ XT as the bonding adhesive and inexperienced operators as the clinicians, and that had a 12-month observation period (Sunna and Rock, 1998; Kula et al., 2002).

It has been suggested that bond failure rates below 10 per cent are generally considered to be clinically acceptable (Mavropoulos et al., 2003). The 11.2 per cent bond failure rate of Transbond™ Plus SEP may, therefore, be considered unacceptable when compared with the 3.9 per cent failure
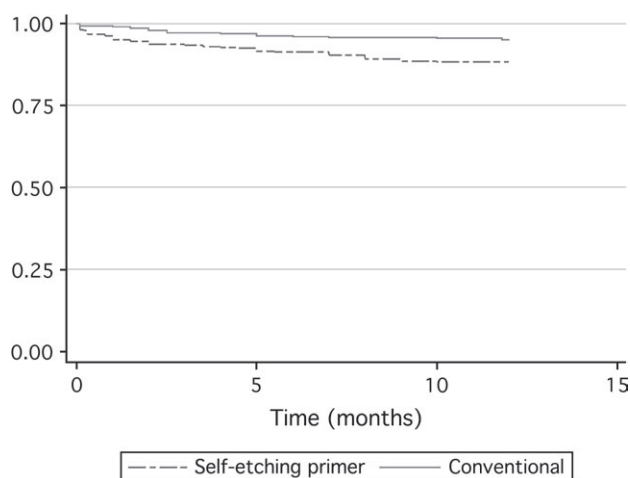
Figure 1 Bracket survival rates for both etch and primer systems plotted against time.
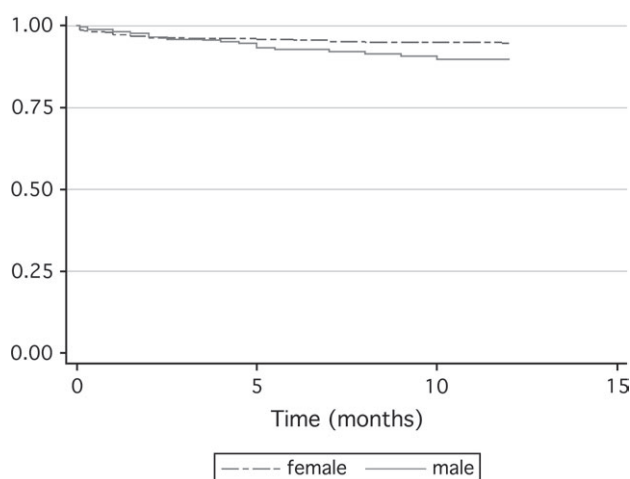

Figure 2 Bracket survival rates for patient gender plotted against time.

Table 4 Adhesive remnant index (ARI) by etching system.

Etching system	ARI score			
	0	1	2	3
	n (%)	n (%)	n (%)	n (%)
Self-etching system	26 (70.3)	9 (24.3)	2 (5.4)	0 (0)
Conventional etching system	4 (36.4)	2 (18.2)	4 (36.4)*	1 (9.0)

ARI: 0, no adhesive left on the tooth; 1, less than half of the adhesive left on the tooth; 2, more than half of the adhesive left on the tooth; 3, all of the adhesive left on the tooth, with distinct impression of the bracket mesh.*$P = 0.026$.

rate of the conventional 37 per cent phosphoric acid etch and primer system. The conventional etch and primer failure rate is at the lower end of reported failure rates for studies carried out with a 12-month observation period (Zachrisson, 1977; Fricker, 1994) and for those using Transbond™ XT as the adhesive (Millett et al., 1998; Littlewood et al., 2001).

Greater manipulation of the bracket prior to curing the adhesive had very little effect on the failure rate of the conventional system, but doubled the failure rate of the SEP group to a value of 15.3 per cent when the brackets were manipulated more than three times. A higher number of manipulations of a bracket may not be a relevant factor for an experienced clinician, but possibly adds indirect evidence to a reduced etching pattern with Transbond™ Plus SEP, as found in an in vitro study using scanning electron microscopy (Bishara et al., 1998).

The results showed that tooth location influenced the rate of bond failure in the Transbond™ Plus SEP group, but once again had very little effect on the conventional etch and primer failure rate. Previous studies have reported a higher failure rate for premolars (Kinch et al., 1988; O'Brien et al., 1989; Millett and Gordon, 1994) and related this higher failure rate to several factors, such as a larger amount of aprismatic enamel on these teeth (Whittaker, 1982), poor moisture control (Trimpeneers and Dermaut, 1996; Millett et al., 1998), and heavier occlusal forces exerted on the posterior teeth during mastication (Sunna and Rock, 1998). The highest bond failure rate in this study was for the upper premolars etched and primed with Transbond™ Plus SEP. Some 20 per cent of upper premolar brackets failed, but this was not statistically significantly different from the other teeth. This may be because the number of bracket failures for each tooth was small and it is unlikely that any differences would be found in a sample of this size.

The failure rate for the lower canines in the Transbond™ Plus SEP group was also considerably higher than the conventional etch and primer group. This increased failure rate may have been due to increased occlusal interferences. However, the initial malocclusion was not analysed as a variable and there have been conflicting results regarding the failure rate and malocclusion type in previous studies (Millett et al., 1998, 2000; Shammaa et al., 1999).

In agreement with previous investigations (Norevall et al., 1996; Marcusson et al., 1997; Millett et al., 1998, 2000) the findings of the present study showed that the age of the participants did not have a statistically significant effect on failure rate. Although logistic regression showed no gender differences, survival analysis indicated that males had a 2.4 times greater chance of bracket failure than females over the 12-month observation period. This may be a question of the different power of the two different models.

According to the adhesive remnant index (Årtun and Bergland, 1984), the site of bracket failure was predominantly

at the enamel–adhesive interface (adhesive failure) for the Transbond™ Plus SEP. This may be indicative of a reduced etch pattern and resultant reduction in the quality of the micromechanical bond. This mode of failure is clinically beneficial because there is less adhesive to remove from the enamel after debond. Although the number of failures in the conventional etch and primer group was low, there was a significant chance that more than half of the adhesive would remain on the enamel. This type of failure indicates a cohesive breakdown and may potentially expose the enamel to an increased risk of damage during the clean up process following debonding.

Other studies have reported a statistically significant difference between the survival rates for different operators (Millett and Gordon, 1994; Hitmi *et al.*, 2001), but there was no significant difference in the failure rate between the two operators in this study. This is possibly because both operators were of a similar clinical experience and is in agreement with a recent study which also had postgraduate students as operators (Mavropoulos *et al.*, 2003).

Conclusions

The results from this randomized split-mouth clinical trial demonstrated that Transbond™ Plus SEP has a significantly higher bond failure rate than the conventional separate 37 per cent phosphoric acid and primer method, and that the bond failure mode was predominately at the enamel–adhesive interface for the Transbond™ Plus SEP.

Therefore, the proposed advantage of Transbond™ Plus SEP in terms of reduced time for the bonding procedure may be negated due to extra time required to replace failed brackets.

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