

## Six and 12 months' evaluation of a self-etching primer versus two-stage etch and prime for orthodontic bonding: a randomized clinical trial

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**SUMMARY** The aim of the study was to compare the mean clinical chair-side time required for bracket bonding and the mean bond failure rate at 6 and 12 months of stainless steel brackets with a micro-etched base bonded with a light-cured composite using a self-etching primer (SEP) or a two-stage etch and prime system.

Fifty-one subjects who required upper and/or lower pre-adjusted edgewise fixed appliances were recruited in a single centre randomized clinical trial. The trial was a single-blind design, involving a within-patient comparison of the two bonding systems with each patient randomly allocated the two bonding systems for each side of the mouth (all teeth except molars). The two bonding techniques used were standardized throughout the trial and all bracket bonding was performed by a single operator. Bonding time was recorded using a digital timer. The bond failure rate of a strictly paired sample was recorded at 6 and 12 months for each patient.

The mean bracket bonding time per patient with the SEP was significantly less than that with the two-stage bonding system (mean difference 24.9 seconds; 95 per cent confidence interval 22.1–27.7 seconds; paired *t*-test  $P < 0.001$ ). The overall bond failure rates at 6 and 12 months with the SEP were 0.8 and 1.6 per cent, respectively, and for the two-stage etch and prime 1.1 and 3.1 per cent, respectively. At 6 months, the mean bond failure rate per patient with the SEP was 0.81 per cent and with the two-stage bonding system 0.96 per cent ( $P = 0.87$ ; Wilcoxon signed rank test). At 12 months, the mean bond failure rate with the SEP per patient was 1.54 per cent and with the two-stage bonding system 2.78 per cent ( $P = 0.33$ ; Wilcoxon signed rank test).

The mean bracket bonding time with the SEP per patient was significantly shorter than that of the two-stage bonding system ( $P < 0.001$ ). The difference between the overall bond failure rate and the mean bond failure rate per patient for the two bonding systems was not statistically nor clinically significant at 6 and 12 months ( $P = 1.00$  and  $P = 0.125$ , respectively; McNemar's test).

### Introduction

Conventional orthodontic bracket bonding with composite relies on a reproducible etch pattern by phosphoric acid to allow mechanical retention for the adhesive (Buonocore, 1955; Hobson and McCabe, 2002). Although composite, glass ionomer (conventional and resin modified) and compomer have been assessed for bracket bonding, composite resin remains the most effective and reliable adhesive available for bonding orthodontic attachments (Mandall *et al.*, 2002). Both chemical- and light-cured adhesive resins are used routinely as part of fixed appliance therapy using conventional two-stage enamel etching and priming (O'Brien *et al.*, 1989; Sunna and Rock, 1998).

The continuing developments in dental materials science have led to improvements in adhesive bonding formulations, resulting in the current availability of a wide range of products, including single-step etch/ primer solutions. These bonding systems combine an

etchant conditioner and a primer resin agent for simultaneous use (Nishida *et al.*, 1993). The main feature of the single-step etch/primer bonding systems is that no separate acid etching of the enamel is required; the liquid adhesive agent itself has an acid component that demineralizes the tooth structure in the same manner as the 30–50 per cent phosphoric acid used in a conventional acid-etching technique (Miller, 2001). The combination of etching and priming into a single procedure means fewer stages in the bonding process, resulting in time saving for the clinician, which has cost implications (Bishara *et al.*, 2001).

One new self-etching primer (SEP) is produced by 3M Unitek (Monrovia, California, USA) (Brosnihan and Safranek, 2000). Originally developed as the Prompt L Pop adhesive system (ESPE America Inc., Plymouth, Pennsylvania, USA), it has been modified and is now marketed by 3M Unitek. The SEP can only be used with light-cured composites (Bond and Croll,

2001). Since its introduction, the SEP has been used in many dental applications (Croll, 2000).

Bracket bonding with the SEP has been compared with a conventional two-stage bonding system in laboratory studies. Brackets bonded with the SEP were found to have a significantly lower mean shear bond strength compared with those bonded with a conventional two-stage adhesive system (Bishara *et al.*, 2001; Aljubouri *et al.*, 2003). However, following the application of mechanical stress, the mean survival time for brackets bonded with either the SEP or the conventional two-stage bonding system was similar (Aljubouri *et al.*, 2003). Furthermore, the *in vitro* mean bonding time of brackets bonded with the SEP was significantly less than that of the conventional two-stage etch and prime group (Aljubouri *et al.*, 2003).

It would appear that only one clinical trial has compared the clinical performance of brackets bonded with the SEP or a conventional two-stage bonding system (Asgari *et al.*, 2002). Brackets bonded with the SEP were found to have a significantly lower failure rate than those bonded with the two-stage system. That study, however, did not use a randomized clinical trial design and did not compare bonding time for each adhesive group.

The aim of this randomized clinical trial was to compare the mean clinical chair-side time required for bracket bonding and the mean bond failure rate at 6 and 12 months of stainless steel brackets with a micro-etched base (3M Unitek) bonded with a light-cured composite using the SEP or a two-stage etch and prime system (Transbond XT, 3M Unitek).

## Materials and methods

### Sample size estimation

**Bonding time.** Data from a previous *in vitro* investigation (Aljubouri *et al.*, 2003) were used to estimate the standard deviation of the within-subject differences in bonding time per tooth for the two bonding systems at 20 seconds. Based on this estimate, a sample of 45 subjects was required in order to have 80 per cent power to detect a difference of 10 seconds

between the mean bonding times per tooth between the two bonding systems.

**Failure rate.** Two samples of 350 teeth bonded with each bonding system were required for the comparison of bond failure rates; this corresponds to approximately eight brackets bonded with each bonding system in 45 patients. Previous studies (Millett *et al.*, 1998; Littlewood *et al.*, 2001) estimated a 6 per cent failure rate with the two-stage system (Transbond, 3M Unitek). The sample proposed for this study had 80 per cent power to detect a reduction in failure rate from 6 to 2 per cent for the two-stage system. This calculation is approximate and does not account for the pairing of teeth within subjects, as no information is available about intra-cluster correlation of these two bonding systems.

To allow for some sample size attrition, 51 consecutive subjects awaiting upper and/or lower fixed appliance therapy with a pre-adjusted edgewise system were invited to participate in the present trial. The inclusion and exclusion criteria are listed in Table 1.

### Ethical approval and clinical trial design

Ethical approval was obtained from the Local Area Dental Ethical Committee. The study was a prospective randomized clinical trial which used a single-blind design, involving a within-subject comparison of two bonding systems, with each subject randomly allocated two bonding systems for each side of the mouth. All subjects who were eligible for inclusion were interviewed and the purpose of the trial outlined. When informed consent was obtained, the operator (YDA) randomly allocated the upper right and lower left quadrants to be bonded with either the SEP or the two-stage conventional etch and prime bonding system. Randomization was undertaken by opening a sealed envelope, prepared by the trial statistician, containing the treatment allocation. The Battenburg design was employed in treatment allocation, i.e. if the upper right/lower left quadrants were bonded with the SEP, then the upper left/lower right quadrants were bonded using the two-stage etch and prime system.

**Table 1** Inclusion and exclusion criteria for the trial subjects.

Inclusion criteria	Exclusion criteria
Good general health	Subjects not wishing to participate in the study or withholding consent
Brushed his/her teeth at least twice daily and had good oral hygiene	Subjects with poor medical health; physical or mental handicaps
Required upper and/or lower fixed appliance therapy with a pre-adjusted edgewise system	Subjects with cleft lip and palate and craniofacial syndromes
Willing and able to comply with the trial regime	Poor oral hygiene and/or poor periodontal health
Had given informed written consent (from the parent/guardian or from the patient)	Gross or uncontrolled caries
Incisors, canines and premolars fully erupted	Enamel hypoplasia and existing enamel demineralization

### *Blinding*

The patient was not aware which bonding system (SEP or conventional two-stage bonding system) was used on each side of the mouth. It was not possible to blind the operator to the type of bonding agent used, as the bonding technique differed between the two systems.

### *The bonding procedure*

Prior to bracket bonding, the labial/buccal surfaces of the incisors, canines and premolars were cleaned using a fluoride-free, oil-free prophylaxis paste (Dentsply, DeTrey, Konstanz, Germany), washed with water and dried in a stream of oil-free compressed air. The same operator (YDA) carried out all bonding procedures in an attempt to standardize the effect of bracket and operator variables on bond performance. The SEP was available in the UK market only a few weeks prior to the start of the present trial. The operator, therefore, had no previous experience with the SEP system.

For each case, self-retaining cheek retractors were placed for bracket bonding and isolation was maintained with cotton wool rolls and high vacuum suction.

A conventional light-cured resin, Transbond XT, was used for bracket bonding. The resin adhesive was applied to the bracket base following tooth conditioning with either the SEP or the conventional two-stage etch and prime system. Tooth etching and priming for each bonding system and subsequent bracket placement was carried out according to the manufacturer's instructions. One quadrant was bonded at a time.

A 0.022 inch slot stainless steel pre-adjusted edgewise bracket with a micro-etched base (modified Roth prescription, 3M Unitek) was bonded to the mid-buccal surface of each tooth. The brackets were kept in the manufacturer's packaging until immediately prior to bonding and were handled at all times with bonding tweezers to avoid contamination of the bonding base.

### *Brackets bonded using the SEP*

The buccal surface of each tooth was etched/primed in a single stage by rubbing the enamel with the micro-brush applicator for 5 seconds, followed by drying lightly using oil-free compressed air as recommended by the manufacturers. Composite resin (Transbond XT) was then applied to the bracket base and the bracket positioned firmly on the tooth surface. Excess composite was then removed from around the bracket base with a sharp dental probe prior to curing with an Ortholux light unit (3M Unitek) for 40 seconds (20 seconds from the mesial and 20 seconds from the distal aspect of each bracket).

### *Brackets bonded with the conventional two-stage etch and prime system*

The mid-buccal enamel of each tooth was etched for 15 seconds with 37 per cent orthophosphoric acid gel applied by a sponge pledget. Following rinsing with distilled water and drying (until the enamel appeared 'frosty') with oil-free compressed air, Transbond XT primer was applied to the etched surface and light cured for 10 seconds using an Ortholux light unit. Transbond XT composite was then applied to the bracket base, the bracket placed firmly in position and excess composite removed prior to light curing, as described for the SEP.

Molar bands were cemented to molar teeth with a glass ionomer cement (Aqua-Cem, DeTrey Dentsply, Weybridge, Surrey, UK).

For each case, following the placement of all brackets and bands, the initial archwire (0.012 or 0.014 Titanol, Ortho-Care Ltd, Bradford, Yorkshire, UK) was tied into the bracket slots. Care was taken to check for any occlusal interferences to the brackets following the bonding procedure. Where an occlusal interference was noted, a thin layer of glass ionomer cement (AquaCem, Dentsply) was placed on the occlusal surfaces of the posterior teeth sufficient to relieve any trauma from occlusion to the bonded brackets. Each subject was given standard verbal and written instructions regarding care of the fixed appliances and was issued with a fluoride mouth rinse (Fluorigard, Colgate-Palmolive Ltd, Guildford, Surrey, UK). Review appointments were scheduled at 4–8 week intervals throughout treatment. Each subject was specifically instructed to inspect the appliances on a daily basis for any loose brackets and to contact the department immediately should this occur.

As far as possible, a similar archwire sequence and approach to treatment mechanics was adopted for each case. All subjects were followed for at least 12 months into treatment to record bracket failure.

The following information was recorded for each patient: date of birth and sex; which teeth had bonded orthodontic brackets; date of placement of bonded orthodontic brackets; teeth with bracket failure.

### *Outcomes measures*

**Bonding time.** The time (in seconds) required to bond brackets with each bonding system was recorded using a digital timer (Whatman International Ltd, Maidstone, Kent, UK). The time spent in the preparation of teeth for bonding (prophylaxis, washing and drying) was not recorded. Timing for each quadrant was recorded from application of the SEP or the etching gel until all brackets were placed and the composite light cured. The mean bonding time of each bonding system for each patient was calculated by dividing the time taken to

bond brackets in each quadrant by the number of teeth bonded in that quadrant.

**Failure rate.** All bond failures were recorded carefully in the patient's case notes for later transfer to a data collection form. Every effort was made to identify as accurately as possible the date of any bond failure. When a subject presented with a bond failure, he/she was questioned as to the date of failure and if certainty existed as to when this was, the date was noted. When a subject was unsure as to the date of bond failure, the date of presentation for appliance repair was taken as the date of bond failure and this was used in the analyses. The tooth which had become debonded and the type of bonding material used (SEP or conventional two-stage bonding system) were also noted. Only the first bond failure was recorded for each bracket.

### *Statistical analysis*

As a within-subject comparison was made between the two bonding systems using paired data (i.e. each subject received both bonding systems), mean bonding times were compared using a paired *t*-test as the data were normally distributed.

A Wilcoxon signed rank test was used to compare the mean bond failure rate of the two bonding systems per patient. Furthermore, each subject was classified as having no bond failures or at least one bond failure in each bonding system and McNemar's test was used to compare the proportions with at least one failure.

## **Results**

### *Profile of the clinical trial*

In total, 777 brackets were bonded; 389 with the SEP and 388 with the two-stage bonding system. Of these, 353 brackets bonded with each bonding system were strictly paired. The paired and unpaired brackets, for both bonding systems, were included in the calculation of mean bonding time analysis, but only those which were strictly paired were used for bracket bond failure rate assessment.

### *Profile of the participants*

No patient withdrew or dropped out of the trial over the 12 month observation period. Of the 51 patients who participated in the clinical trial, 16 were male and 35 were female. Thirty-nine patients had mandibular and maxillary bonded appliances; four had lower arch treatment only and eight had maxillary appliances alone.

There were 32 participants younger than 15 years of age (13 male and 19 female subjects) and 19 participants

15 years or older (three male and 16 female subjects). One adult patient had previous orthodontic treatment with fixed appliances which was completed approximately a decade prior to enrolment in the trial.

The malocclusions present were as follows: 15 patients (six males, nine females) had a Class I malocclusion; 22 patients (seven males, 15 females) a Class II division 1 malocclusion; three patients (one male, two females) a Class II division 2 malocclusion; and 11 patients (two males, nine females) a Class III malocclusion.

### *Bonding time*

The mean bracket bonding time per patient with the SEP was 81.7 seconds (range 64–122.9 seconds) compared with 106.6 seconds (range 74–148.6 seconds) with the two-stage bonding system. The mean difference between the two bonding systems was 24.9 seconds (95 per cent confidence interval 22.1–27.7 seconds) which was statistically significant ( $P < 0.001$ ).

### *Failure rate of paired brackets*

Over the first 6 months of the trial, seven bonded brackets failed; three had been bonded with the SEP and the other four with the conventional two-stage bonding system. In addition, four brackets were repositioned (electively debonded and then rebonded) to improve bracket position and tooth alignment during this period. At 6 months, the overall bond failure rate with the SEP was 0.8 per cent and for the two-stage etch and prime system 1.1 per cent. The mean bond failure rate per patient with the SEP was 0.81 per cent and with the two-stage bonding system 0.96 per cent ( $P = 0.87$ ; Wilcoxon signed rank test).

During the second 6 months of the trial, 10 bonded brackets failed; three had been bonded with the SEP and the other seven with the conventional two-stage bonding system. Furthermore, 20 brackets were electively repositioned during this period.

In total, the failure rate of paired brackets following at least 12 months included six bonded with the SEP and 11 bonded with the two-stage bonding system. The overall bond failure rate at 12 months with the SEP was 1.6 per cent and for the two-stage etch and prime system 3.1 per cent. The mean bond failure rate per patient with the SEP was 1.54 per cent and with the two-stage bonding system 2.78 per cent ( $P = 0.33$ ; Wilcoxon signed rank test). The distribution and profile of bracket failure rate for each bonding system is outlined in Table 2.

McNemar's test (Table 3) confirmed no significant difference in bond failure rate between the two systems for each patient at 6 ( $P = 1.00$ ) and 12 ( $P = 0.125$ ) months.



**Table 2** Distribution and profile of the failure rate (first failure) of the paired bonded brackets.

	Initial number of paired brackets	Paired brackets failed at 6 months	Number of paired brackets at 6 months	Paired brackets failed between 6 and 12 months	Number of paired brackets at 12 months	Total number of paired brackets failed at 12 months
SEP	353	3 (0.8%)	342	3 (0.8%)	312	6 (1.6%)
Two-stage system	353	4 (1.1%)	342	7 (2%)	312	11 (3.1%)

SEP, self-etching primer.

**Table 3** McNemar's test comparing bond failure at 6 and 12 months for the self-etching primer (SEP) and the two-stage etch and prime system.

0–6 months			
	SEP		
Two-stage	No failures	≥1 failure	Total
No failures	44	3	47
≥1 failure	4	0	4
Total	48	3	51

McNemar's test,  $P = 1.00$ .

0–12 months			
	SEP		
Two-stage	No failures	≥1 failure	Total
No failures	40	1	41
≥1 failure	6	4	10
Total	46	5	51

McNemar's test,  $P = 0.125$ .

## Discussion

### Bonding time

The mean difference in bracket bonding per patient between the two bonding systems was almost 25 seconds, i.e. on average, each bracket bonded using the SEP took 25 seconds less than the two-stage bonding system. In a case requiring 20 brackets to be bonded, the average reduction in clinical chair-side time would be around 8.5 minutes when compared with the conventional two-stage etch and prime system. The shorter bracket bonding procedure using the SEP is probably more convenient for both clinicians and patients.

The SEP combines etching and priming procedures into a single step; it also eliminates the rinsing procedure following acid etching, which leads to fewer stages in the bonding process. Bonding brackets with the SEP will, therefore, not only reduce clinical chair-side time for both clinicians and patients and offer increased patient comfort related to reduced chair-side time (Bishara,

2001), but will also help improve overall clinical cost-effectiveness.

### Failure rate

A short-coming of several previous controlled clinical and randomized clinical trials which have compared two bonding agents is that the overall rather than the per subject bond failure rate has been quoted. As each patient is the unit of assessment for both bonding systems, it is more correct to report the mean bond failure rate per patient rather than the overall bond failure rate which may obscure the true nature of the data. This aspect has been highlighted in a recent systematic review (Mandall *et al.*, 2002).

Only the first bond failure was recorded in the present trial to eliminate possible variation in bond strength introduced from rebonding, which may affect failure rate results (Sunna and Rock, 1998). In addition, when a bracket failed or elective bracket repositioning was performed, the contralateral bracket was simultaneously withdrawn from the data in order to continue to monitor bond failure in a strictly paired sample.

The overall and per patient bond failure rates of each adhesive system were close to 1 per cent at 6 months. At 1 year the overall bond failure rate with the SEP was 1.6 per cent while that of the two-stage etch and prime system was 3.1 per cent. Although this indicates that the overall bond failure rate of the two-stage system was nearly double that of the SEP at 12 months, the mean bond failure rate per patient with the SEP was 1.54 compared with 2.78 per cent with the two-stage bonding system. The percentage difference in bond failure rates between the two systems was not clinically or statistically significant. This was confirmed by McNemar's test. The similar failure rate of the two bonding systems may be explained by a similar etch pattern of the SEP when compared with the two-stage bonding system, despite the SEP producing a lesser depth of enamel etching when compared with the orthophosphoric acid etch (Miller, 2001; Hannig *et al.*, 2002).

The results of the present trial compare well with those of another clinical study that reported on bond failure rates with the SEP. Asgari *et al.* (2002) found the overall bond failure rate of the SEP at 6 months to

be 0.57 per cent compared with 4.6 per cent using a conventional two-stage system. Only 20 patients were included in the trial which consisted of 174 brackets bonded with each adhesive system. There appears to be no consideration of the likely paired nature of the data in statistical analyses. Another important difference between the present study and that trial is the number of operators. There were six operators in that study compared with a single operator in the present investigation. The latter standardized operator variables on bond performance.

The overall bond failure rate of light-cured composite used with a conventional two-stage bonding system has been reported in randomized clinical trials to be between 2.7 and 23 per cent (Lovius *et al.*, 1987; O'Brien *et al.*, 1989; De Saeytjij *et al.*, 1994; Sunna and Rock, 1998; Littlewood *et al.*, 2001) depending on the type of light-cured composite used, the length of the observation period and the trial design. It is difficult, however, to make direct comparisons of bracket failure rate between studies due to the variation in the number of operators, bonding techniques and materials, research designs and trial duration (O'Brien *et al.*, 1989).

In the study by O'Brien *et al.* (1989), 52 patients were followed until the completion of orthodontic treatment. From a total of 542 bonded brackets, 35 failed; all failures occurred within the first 12 months of treatment. The overall failure rate for brackets bonded with the light-cured composite in that trial was 4.7 per cent at 6 months. While the present trial monitored first bond failures only of a strictly paired sample, O'Brien *et al.* (1989) counted their first and subsequent bond failures together.

Although O'Brien *et al.* (1989) recorded 82 per cent of bond failures within the first 6 months of bracket bonding, Sunna and Rock (1998), who followed their patients for at least 12 months, found only 60 per cent of bond failures occurred during the first 6 months. The first bond failures of 7118 brackets bonded with Transbond light-cured composite for 548 patients by six operators have been reviewed (Millett *et al.*, 1998). An overall bracket failure rate of 6 per cent was recorded.

The low bond failure rate recorded with each bonding system in the present trial is possibly due to the careful bonding technique which was adopted in accordance with the manufacturer's instructions. Taking measures to remove any occlusal interferences with the bonded brackets was adopted for each patient in this trial and is an important factor in preventing early bond failure. Instructions issued to the patient with regard to appliance care are also critical in minimizing the bond failure rate. Standardized written instructions were given to all participants in this trial.

The results of the present randomized clinical trial encourage the routine use of the SEP for orthodontic bracket bonding as a viable alternative to the conventional two-stage bonding system.

## Conclusions

The mean bracket bonding time with the SEP per patient was significantly shorter than that of the two-stage bonding system ( $P < 0.001$ ).

The difference between the overall bond failure rate and the mean bond failure rate per patient of the two bonding systems was not statistically or clinically significant at 6 and 12 months ( $P = 1.00$  and  $P = 0.125$ , respectively; McNemar's test).

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