

SCIENTIFIC  
SECTION

# A randomized clinical trial comparing ‘one-step’ and ‘two-step’ orthodontic bonding systems

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*Objective:* The primary objective of this prospective clinical trial was to assess the clinical bond failure rates of orthodontic brackets bonded using a self-etching primer (SEP), compared with brackets bonded using a conventional acid-etched technique with control adhesive (Transbond™). A secondary aim was to investigate whether characteristics of the operator, patient or tooth bonded had any influence on bracket failure.

*Design:* Single-centre randomized controlled clinical trial. Thirty-four patients were bonded, each being randomly assigned to either the test or control adhesive.

*Setting:* NHS Hospital Orthodontic Department, Chester, UK.

*Subjects:* Orthodontic patients requiring fixed appliance treatment.

*Main outcome measures:* Bond failure.

*Main outcome results:* Failure rates over the initial 6-month period were 2.0% (Transbond™) and 1.7% (SEP) with no statistically significant difference between the two groups. Over the duration of the fixed appliance treatment, bond failure rates increased, but remained acceptable at 7.4% (TB) and 7.0% (SEP), respectively. When operator, patient and tooth characteristics were analysed, only the bracket location was found to be significant. Maxillary brackets were more likely to fail than mandibular brackets (RR 0.47%; 95% CI 0.22, 1.03). The failure rate for brackets in our study was low when compared with previous studies.

*Conclusions:* Both the acid-etched control and self-etching primer in combination with adhesive pre-coated brackets were successful for clinical bonding. Their combined failure rate was lower than that reported in similar trials.

*Key words:* Bond failure, brackets, self-etch primer, Transbond™

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## Introduction

Bonding of orthodontic bands and brackets to enamel has greatly simplified the provision of orthodontic treatment since it was first described by Newman *et al.*<sup>1</sup> Conventional orthodontic bonding systems involve the use of acid-etching of the enamel surface to aid the retention of the bonding agent. An unfilled composite resin is then applied as an intermediate bonding layer between the etched enamel and a filled composite resin adhesive. Setting of this two-stage system can be done using a chemical-cure or light-cure initiation.

Recent advances have reduced this two-stage etch and prime adhesive system down to a one-stage

self-etching system. The manufacturers claim this combined etch-primer system, Transbond™ Plus Self-Etching Primer, can reduce the time required for the bond up of fixed appliances and is able to work effectively in a moist environment. Therefore, isolation of the enamel surface, to prevent salivary contamination, may not be as critical when using SEP. This may further reduce the chair-side time required for the bond up process. If the bond failure rate using a one-stage system (Transbond™ SEP Plus) is similar or better than conventional two-stage systems, and the clinical bond up time is reduced, it would be advantageous to use a one-stage adhesive system in everyday orthodontic practice.

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## Aim

This clinical study aims to compare the bond failure rate for a one-stage 'self-etching' adhesive (Transbond™ SEP Plus – 3M Unitek Dental Products Division, 2724 South Peck Road, Monrovia, CA 91016, USA) to a conventional two-stage orthodontic adhesive (Transbond™ XT – 3M Unitek Dental Products Division, 2724 South Peck Road, Monrovia, CA 91016, USA).

## Subjects and materials

### Ethical approval

Ethical approval was obtained from the South Cheshire local research ethics committee. The application was reviewed by the Macclesfield sub-committee and approved including the patient information sheets and consent forms used.

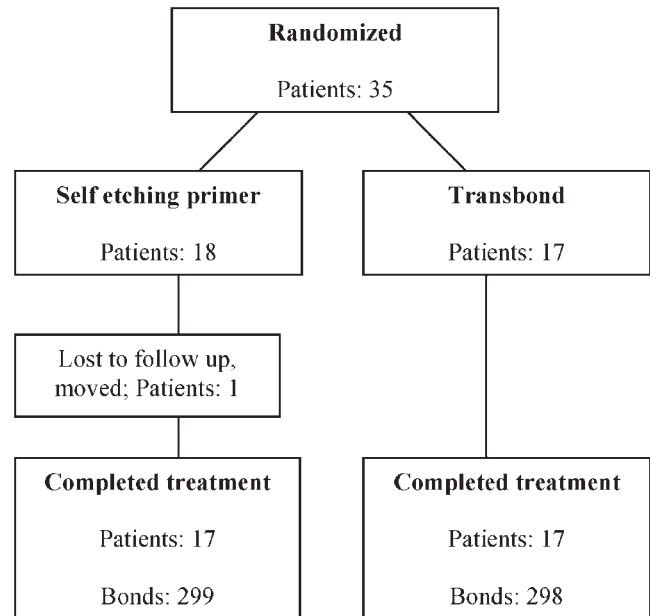
### Sample size calculation

The sample size for each group was estimated based on the number of brackets required as this was the unit of measurement. A sample size of 540 brackets (270 brackets per group) will be sufficient to detect an improvement or reduction in bond failure after 6 months of 10% from an expected 15% based on similar clinical trials of light-cured composite resins, with 80% power and a 5% significance level using a two-sided, continuity corrected chi-squared test.<sup>2</sup> At the time of setting up the trial, there were two published clinical trials using similar materials. These were by Littlewood,<sup>3</sup> and Sunna and Rock,<sup>4</sup> with reported failure rates of 6.8 and 9.4%, respectively. A higher failure rate was conservatively estimated as other larger trials of light-cured composite reported failure rates of 24.3<sup>5</sup> and 23.8%.<sup>6</sup>

To produce 270 brackets per group, approximately 32 patients would be required, as the number of teeth per patient would vary due to extractions, missing teeth and other excluded teeth.

### Study design

Thirty-five patients (Figure 1) were consecutively drawn from the treatment waiting list of the Orthodontic Department, Countess of Chester Hospital. All the patients required fixed orthodontic therapy and no effort was made to match the patients for age, sex or malocclusion to ensure a representative range of orthodontic patients. Patients requiring single arch treatments or orthognathic surgery as part of their orthodontic treatment were excluded. Patients were



**Figure 1** Flow chart of patients in the study

consented (no information was available on consent rate) and randomly allocated (using random number tables, controlled with permuted blocks to ensure equal numbers of patients in each group after every sixth subject) to either a conventional (two-stage) adhesive group (Transbond 'TB') or alternatively to the (one-stage) self-etching primer adhesive group ('SEP').

There were 18 patients in the SEP group, 17 patients in the TB group, but one patient in the SEP group was lost to follow up (the patient moved away from the area and was removed from the study). This meant there were 17 patients in each group. The initial appliance placement was performed by two operators (N.M. and S.C.). Two operators were necessary to achieve sufficient patient numbers in a reasonable time period. Overall, 597 brackets were placed, 299 with SEP and 298 with TB. The number of teeth bonded per patient varied from 20 for non-extraction cases to as few as 13 (Table 1). Teeth were excluded from the trial if they could not be bonded at the main bonding appointment. This occurred when teeth were unerupted or markedly displaced. Although these teeth were bonded acceptably at a later date, the clinical technique for bonding a single tooth varies to that for an entire arch and so it was decided not to include these in the analysis of results.

### Bonding technique

Conventional acid etch group:

- Prophylaxis with a pumice slurry and rubber cup using a slow speed hand piece.

**Table 1** Description of patient characteristics between treatment groups.

Patient characteristics	Self etching primer	Transbond
	Number (%) of patients	Number (%) of patients
<b>Overall age</b>	17	17
11	–	1 (5.9)
12	3 (17.7)	2 (11.8)
13	4 (23.5)	3 (17.7)
14	4 (23.5)	6 (35.3)
15	5 (29.4)	4 (23.5)
16	1 (5.9)	1 (5.9)
<b>Gender</b>		
Males	4 (23.5)	7 (41.2)
Females	13 (76.5)	10 (58.2)
<b>Operator</b>		
1	13 (76.5)	15 (88.2)
2	4 (23.5)	2 (11.7)
<b>Duration of follow up (days)</b>		
216–524	4 (23.5)	7 (41.2)
567–658	8 (47.1)	3 (17.7)
672–1157	5 (29.4)	7 (41.2)
<b>Difference in treatment start between upper and lower teeth (days)*</b>		
–84; –7	4 (23.5)	3 (17.7)
0	7 (41.2)	12 (70.6)
31; 175	6 (35.3)	2 (11.8)
<b>Bonded UR</b>		
5	14 (82.4)	14 (82.4)
4	12 (70.6)	10 (58.8)
3	13 (76.5)	17 (100)
2	15 (88.2)	14 (82.4)
1	17 (100)	17 (100)
<b>Bonded UL</b>		
1	17 (100)	17 (100)
2	16 (94.1)	16 (94.1)
3	14 (82.4)	17 (100)
4	12 (70.6)	12 (70.6)
5	14 (82.4)	12 (70.6)
<b>Bonded LL</b>		
5	12 (70.6)	11 (64.7)
4	15 (88.2)	14 (82.4)
3	17 (100)	17 (100)
2	17 (100)	17 (100)
1	17 (100)	17 (100)
<b>Bonded LR</b>		
1	17 (100)	17 (100)
2	15 (88.2)	17 (100)
3	17 (100)	17 (100)
4	14 (82.4)	13 (76.5)
5	14 (82.4)	12 (70.6)
<b>Total number of brackets bonded</b>		
13	1 (5.9)	–
14	–	–
15	3 (17.7)	2 (11.8)
16	2 (11.8)	7 (41.2)
17	–	–

**Table 1** (Continued).

Patient characteristics	Self etching primer	Transbond
	Number (%) of patients	Number (%) of patients
18	5 (29.4)	2 (11.8)
19	1 (5.9)	–
20	5 (29.4)	6 (35.3)
<b>Number of failed brackets</b>		
0	7 (41.2)	8 (47.1)
1	3 (17.7)	4 (23.5)
2	3 (17.7)	2 (11.8)
3	4 (23.5)	–
4	–	2 (11.8)
5	–	–
6	–	1 (5.9)

\*Lower teeth were bonded before upper teeth

- Thorough wash and dry with and oil-free air from a 3-in-1 tip.
- Isolation of the bonding surfaces using a combination of cheek retractors, cotton wool rolls and saliva ejector.
- Application of 37% phosphoric acid liquid to the enamel surface for 30 seconds.
- Thorough wash with water to remove all etch and precipitates.
- Isolation using a combination of cheek retractors, cotton wool rolls and saliva ejector.
- Dry with oil-free air to achieve a frosted enamel appearance.
- Application of a thin coating of Transbond primer to the etched enamel surface using a disposable cotton tipped applicator.
- APC bracket placed and cured for 10 seconds.
- Final cure for 20 seconds via trans-illumination method.<sup>3</sup>

SEP group:

- Prophylaxis with a pumice slurry and rubber cup using a slow speed hand piece.
- Thorough wash and dry with and oil-free air from a 3-in-1 tip.
- Isolation of the bonding surfaces using a combination of cheek retractors, cotton wool rolls and saliva ejector.
- Drying of the enamel surface without complete desiccation.
- SEP is applied to the enamel surface gently swirling for 3-5 seconds to ensure primer is transported to the enamel surface.
- APC bracket placed and cured for 10 seconds.

- Final cure for 20 seconds via trans-illumination method.<sup>3</sup>

For both groups pre-coated orthodontic brackets (3M Unitek MBT appliance, 3M Unitek Dental Products Division, 2724 South Peck Road, Monrovia, CA 91016, USA) were used. All brackets were light-cured for 30 seconds (XL 3000 light unit, 3M Unitek) and a 0.016-inch Nitinol (3M Unitek Dental Products Division, 2724 South Peck Road, Monrovia, CA 91016, USA) heat-activated arch wire was engaged fully into all of the brackets. Any bond failure was recorded on a data collection sheet on the day the patient attended with the breakage.

The first bond failure for each tooth was recorded by date and tooth number. A failure was regarded as an all or none occurrence, and subsequent failures of bonding for that same tooth were noted, but not included in the failure rate. Failed brackets were replaced using the same adhesive and bonding technique.

### Statistical analysis

Statistical data analysis was conducted on both patient and tooth level. Such an approach is useful for comparison with previous studies in reviews.<sup>7</sup> Analysis of bond failures on a patient level was done using the Mann–Whitney test. Where the tooth was the unit of analysis, it was essential to take into account the clustering that occurs within a patient. This was necessary to prevent an individual with a high number of failures from having too great an influence on the results. First, several possible models (exponential, Weibull, lognormal, log-logistic and gamma) were compared (Stata Statistical Software, Version 6.0, Stata Corporation, College Station, Texas, USA) using Akaike information criterion (AIC).<sup>8</sup> While the coefficient estimates were very similar between models, the best model was exponential. Such a model assumes that the survival time distribution is exponential, and dependent on the values of a set of independent variables ( $z_i$ ), e.g. stronger bonds tend to last longer. Exponential distribution can be expressed as:  $S(z) = \exp(a + b_1*z_1 + b_2*z_2 + \dots + b_m*z_m)$ , where  $S(z)$  denotes the survival times,  $a$  is a constant, and the  $b_i$ 's are the regression parameters. Backward stepwise selection was then applied (based on the likelihood-ratio statistic). In order to evaluate the fit of the model, Cox-Snell residuals were calculated and plotted against estimate of the cumulative hazard function. The plot showed that the model fitted the data well.

## Results

### Results for patient level

A total of 34 patients participated in this study (Figure 1), 17 in each group. Description of patient level characteristics is presented in Table 1 and includes age, gender, operator, duration of treatment, time between bonding of the upper and lower teeth, type of tooth bonded and the total number of brackets bonded per patient. The most recorded bond failures for any one patient was six. There was no statistical difference between the bonding systems and the number of brackets that failed per patient ( $P=0.758$ ).

### Results for tooth level

A total of 597 brackets were bonded, of which 43 (7.2%) failed (Table 2). There was no statistically significant difference in rate of bond failure between the two bonding systems. Also no statistically significant difference in rate of bond failure was found for operator, age of the patient and whether failures occurred left or right or anterior/posterior (Table 2, Figure 2). Lower brackets were however significantly less likely to fail [RR 0.17; 95% CI (0.07, 0.43)]. The rate of failure in females was half that of the males, but this difference was not statistically significant [RR 0.47; 95% CI (0.22, 1.03)]. When stepwise regression was performed, the only predictors of failure were tooth location and gender. A comparison of bracket failure over treatment time intervals is shown in Table 3.

## Discussion

The current study did not find a statistically significant difference in bond failure rates between brackets bonded using a self-etching primer and a conventional acid-etch and resin technique. There have been numerous clinical trials comparing orthodontic adhesive systems. Earlier trials compared chemically-cured two-stage composite bonding systems to those cured with light.<sup>9,10</sup> These studies showed that both two-stage systems and light-cure systems were equally reliable, our trial uses a proven two-stage light-cured system as the benchmark for comparison against the one-stage SEP technique.

### Study design

While the study achieved the required sample size, the original sample size calculations did not take into account aggregation of brackets within the participants, modelling using other covariates or multiple testing issues. The use of clusters (individuals in this case)

**Table 2** Relationship between tooth characteristics and bracket failure.

Variable	Number of teeth	Number (%) of bracket failures	RR (95% Confidence Interval) <sup>#</sup>
<b>Total</b>	597	43 (7.2)	–
<b>Age of participant</b>			
11–13	305	19 (6.2)	1.00
14–16	292	24 (8.2)	1.02 (0.45, 2.31)
<b>Gender of participant</b>			
Male	194	22 (11.3)	1.00
Female	403	21 (5.2)	0.47 (0.22, 1.03)
<b>Operator</b>			
1	494	33 (6.7)	1.00
2	103	10 (9.7)	1.49 (0.62, 3.57)
<b>Bonding system</b>			
Self etching primer	299	21 (7.0)	1.00
Transbond	298	22 (7.4)	0.96 (0.44, 2.12)
<b>Tooth location</b>			
Anterior	392	33 (8.4)	1.00
Posterior	205	10 (4.9)	0.61 (0.22, 1.71)
<b>Tooth location</b>			
Upper	290	36 (12.4)	1.00
Lower	307	7 (2.3)	0.17 (0.07, 0.43)
<b>Tooth location</b>			
Left side	301	24 (8.0)	1.00
Right side	296	26 (6.4)	0.81 (0.47–1.40)

<sup>#</sup>Crude (unadjusted) RR derived from exponential model taking into account clustering of teeth within patients.

reduces the power of the trial<sup>11</sup> and multiple testing increases the chance of false positive results, so an increase in sample size is required. Future RCTs in orthodontics should take these issues into account and increase the required sample size accordingly.

Recent clinical trials comparing bonding systems have used a ‘split-mouth’ design where one side or contralateral quadrants are bonded using a study adhesive, whilst the alternative side serves as the control adhesive. The advantage of this is that ‘patient factors’, such as poor care of the appliances will be accounted for evenly, as the patient acts as their own control. However, it is possible that one bonding agent will affect how the other performs, and that bracket placement will not be true

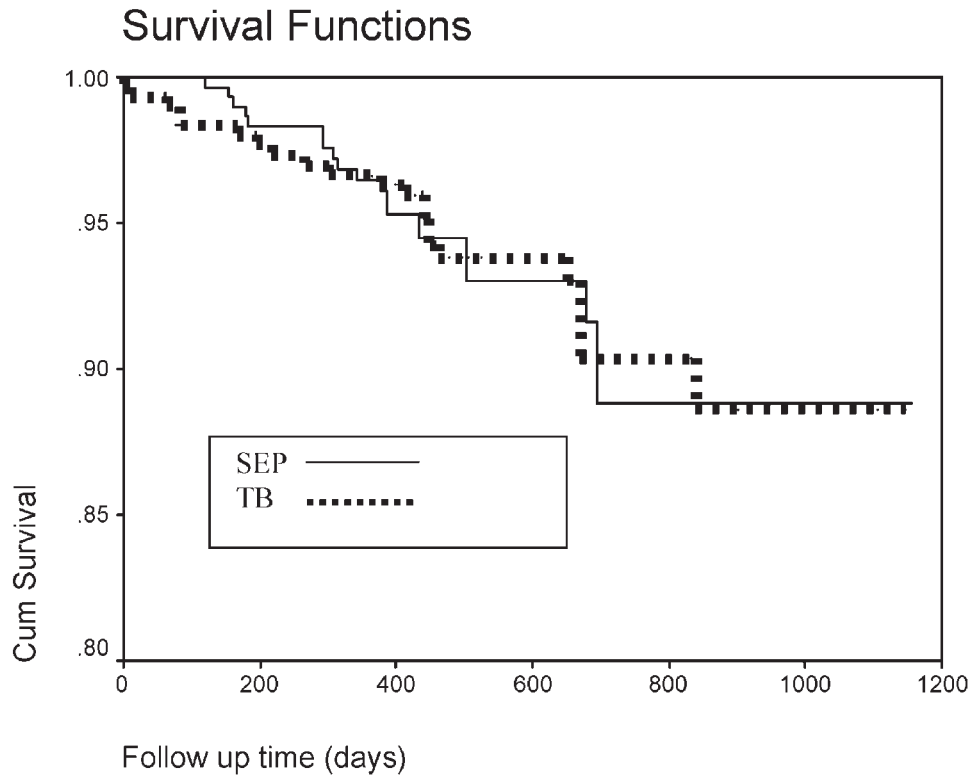
reflection of clinical practice, as the bracket placement technique will be altered during bonding when the ‘changeover’ between the bonding system occurs. Randomly allocating one material to each patient eliminates this problem.

#### *Pre-coated brackets*

Adhesive pre-coated brackets (APC) were used in this study, as this ensures a uniform consistency of adhesive on each bracket, regardless of which technique was used and so eliminates adhesive placement as a variable. Previous studies<sup>4,5</sup> found no difference in bond failure rate between APC brackets and other uncoated

**Table 3** Bracket failure over treatment time intervals.

Variable	6 months		12 months		Total treatment time	
	Number of teeth	Number (%) of bracket failures	Number of teeth	Number (%) of bracket failures	Number of teeth	Number (%) of bracket failures
<b>Bonding system</b>						
Self etching primer	299	5 (1.7)	299	10 (3.7)	299	21 (7.0)
Transbond	298	6 (2.0)	298	10 (3.5)	298	22 (7.4)



**Figure 2** Survival function (tooth level) by treatment group

brackets, and it would seem reasonable to assume that bond failure rates would be similar if uncoated brackets and Transbond adhesive were used.

#### Timing

Describing bond failure rate over the whole period of a course of treatment in randomly allocated patients means that any variation due to treatment length is eliminated. If this is not done and a set time period (e.g. 1 year) is used, it may fail to reveal if one material's performance deteriorates over time. In this study failure rates were analysed at 6 and 12 months and at completion of treatment (Table 3). Previous studies have used 6- and 12-month intervals only. Six-month studies,<sup>3,12,13</sup> using similar materials, have shown failure rates varying from 1.1 to 6.8%. Aljubouri *et al.*<sup>12</sup> compared the same materials at 6- and 12-month intervals, and found no statistical difference between them. In this study, the failure rate for SEP increased from 1.7% at 6 months to 7.0% at completion of treatment, and for Transbond the bond failure rate increased from 2.0 to 7.4%. This shows that although failure rates increased for both materials over the treatment time, there was no difference between the two materials at each time interval. A recent review of

orthodontic bonding studies performed by the Cochrane Oral Health Group<sup>7</sup> recommended that bonding studies follow all trial patients to the end of fixed appliance treatment. Our study follows that guideline and the fact that failure rate increased over the total treatment time for both materials supports this recommendation.

#### Tooth factors

Failure rates were compared between anterior and posterior teeth. The overwhelming conclusion from other studies is that posterior teeth suffer more bracket failure than incisors and canines.<sup>4-7,9,10,14-16</sup> A number of possible explanations for this are given – difficult clinical access and isolation from moisture in the posterior regions, higher occlusal forces on posterior teeth and more aprismatic enamel on premolars. This study was in contrast to these other studies in that there was a failure rate of 8.4% for anterior and 4.9% for posterior teeth; however, this was not statistically different.

There was a statistical difference in bracket failure rates between maxillary and mandibular teeth. Maxillary brackets (12.4%) were five times more likely to fail than brackets bonded to mandibular teeth (2.3%), [RR 0.17%, 95% CI (0.07,0.43)]. The reasons for this are



unclear but it would seem that brackets bonded to maxillary anterior teeth were the most likely to fail. Perhaps habits such as nail biting and pen chewing are significant in accounting for this and may outweigh dietary factors that may predispose to failure of posterior brackets under occlusal load.

### Patient factors

Patient factors – age and gender – were found not to be statistically significant in this study; however, the bond failure rate was higher for boys. Millet *et al.*<sup>17</sup> found bracket survival slightly better in males, while Norevall *et al.*<sup>14</sup> showed bracket survival better in females. Both these results were not statistically significant. Poor patient compliance with dietary instructions and lack of care of the fixed appliances is a likely cause of bracket failure rate above the mean. O'Brien *et al.*<sup>9</sup> reported five patients with three bracket failures each and Zachrisson<sup>16</sup> found 7% of patients had five or more failures. A similar trend was found in this study with one patient experiencing six bracket failures out of the 22 total recorded failures for Transbond in the entire study. All patients in the hospital department are required to have a plaque score less than 10% before being placed on the waiting list, and all attend sessions with a qualified oral health educator prior to treatment. This may mean that this group of patients are particularly well motivated and compliant in respect of care of their appliances, and this may explain the low overall bracket failure compared with other studies.

### Failure rates

At 6 months, the overall bond failure rate for both groups (1.8%) was low compared with other published studies.<sup>4,6,9,18,19</sup> The highest bracket failure rate was reported by Lovius *et al.*<sup>6</sup> at 23.8%. Studies using the pre-coated brackets showed lower failure rates. Littlewood *et al.*<sup>3</sup> studied the failure rate of pre-coated brackets bonded using the same two-step adhesive system as this study. They reported a failure rate of 6.8% after 6 months. Sunna and Rock<sup>4</sup> reported a 9.4% failure rate of pre-coated brackets. A more recent *in vitro* study<sup>20</sup> compared the same two adhesive systems used in this study and found *in vitro* bond strengths were greater for the two-step adhesive (9.8 MPa) than the one-step self-etching system (7.5 MPa). *In vitro* studies do not truly represent the clinical environment and, as both adhesives performed well clinically in this study, this would suggest that differences in *in vitro* bond strengths may be clinically insignificant. A recent paper has reported high failure rates using an alternative

self-etching primer system. Clearly, manufacturers vary in the quality of these materials.<sup>21</sup>

There was no statistical difference between the bond failure rates of both adhesive groups and both groups performed well. Using either a two-step acid-etched resin bonding system or a one-step self-etch resin bonding system resulted in low bond failure rates. The one-step system (Transbond<sup>TM</sup> Plus) is however quicker to use as it does not involve an initial acid etch/wash process. Whether this time difference is critical depends on the relative importance of timing to each individual clinician.

The lack of a washing/drying step and the fact that moisture isolation is claimed to be not so critical, means that the bonding procedure for one-step adhesives may be more comfortable for the patient and anecdotal evidence would support this. The one-step system is certainly simpler to use clinically than the two-step system. Both systems appear to perform equally well and the decision to use a particular adhesive will come down to individual clinical preference. Additional factors, e.g. cost will further influence adhesive choice.

## Conclusion

- There was no statistically significant difference found between the clinical bond failure rates for brackets bonded using a self-etching primer or a conventional acid-etch and resin technique.
- Both systems had low overall failure rates and the decision to use a particular adhesive system may come down to individual preference.

## Contributors

Kevin O'Brien was responsible for the study design, logistic and administrative support for the initial part of the study leading to the award of MSc. for Nick Manning. Nick Manning was responsible for the recruitment of patients, data collection, analysis of data and drafting of the article and critical revision of the literature. Steve Chadwick was responsible for the recruitment of participants, data collection, analysis of data, drafting of the paper and final approval of the article. Dave Plunkett was responsible for the data collection and completion of treatment of the study cohort, drafting of the article and data interpretation. Tatiana MacFarlane was responsible for the analysis of the data and advice on statistical methodology. She wrote the section on the statistical analysis of the data and was responsible for interpretation of the

data. Steve Chadwick and Kevin O'Brien are the guarantors.

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