Randomized controlled trial

Do we need primer for orthodontic bonding?
A randomized controlled trial

Sarabjit Singh Nandhra*, Simon J. Littlewood**,***, Nadine Houghton****, Friedy Luther*****; Jagadish Prabhu******, Theresa Munyombwe****** and Simon R. Wood*******

*Orthodontic Department, The Royal Bournemouth Hospital, **Orthodontic Department, St Lukes Hospital, Bradford, ***Leeds Dental Institute, University of Leeds, ****Department of Orthodontics, The Charles Clifford Dental Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, *****Orthodontic Department, Peterborough & Stamford NHS Trust, ******Center for Epidemiology and Biostatistics, University of Leeds and *******Department of Oral Biology, Leeds Dental Institute, University of Leeds, UK

Correspondence to: Sarabjit Singh Nandhra, Orthodontic department, The Royal Bournemouth Hospital, Castle Lane East, Bournemouth BH7 7DW, UK. E-mail: saabsn@googlemail.com

Summary

Objective: To evaluate the clinical performance of APC™II Victory Series™ (3M Unitek) brackets in direct orthodontic bonding with and without the use of primer.

Design: A single-operator, two-centre prospective, non-inferiority randomized controlled clinical trial.

Setting: The Orthodontic departments at the Leeds Dental Institute and St Luke's Hospital, Bradford, UK.

Ethical approval: Ethical approval was granted by Leeds (East) Research Ethics Committee on 18th of December 2009 (Reference 09/H1306/102).

Protocol: The protocol was not published prior to trial commencement.

Subjects and methods: Ninety-two patients requiring orthodontic treatment with fixed appliances were randomly allocated to the control (bonded with primer) or test groups (bonded without primer). Patients were randomly allocated to either the control or experimental group. This was performed by preparing opaque numbered sealed envelopes in advance using a random numbers table generated by a computer by an independent third party. Once the envelopes were opened, blinding of the operator and the patient was no longer possible due to the nature of the intervention. Patients were approached for inclusion in the trial if they qualified for NHS orthodontic treatment requiring fixed appliances and had no previous orthodontic treatment.

Main outcome measures: Number of bracket failures, time to bond-up appliances, and the adhesive remnant index (ARI) when bracket failure occurred, over a 12-month period

Results: Failure rate with primer was 11.1 per cent and without primer was 15.8 per cent. Bonding without primer was shown statistically to be non-inferior to bonding with primer odds ratio 0.95–2.25 (P = 0.08). Mean difference in bond-up time per bracket was 0.068 minutes (4 seconds), which was not statistically significant (P = 0.402). There was a statistically significant difference in the Adhesive Remnant Index – ARI 0 with primer 49.4 per cent, no primer 76.5 per cent, (P < 0.0001).

Limitations: As the study was only performed by one operator, the results can therefore only be truly be applied to their practice. Also this study was powered to ascertain if there was no difference between the 2 groups up to 5%, however orthodontists may consider a change in the bracket failure rate of 2% to be clinically significant.
Conclusion: When bonding with APC™II Victory Series™ brackets without primer was shown statistically to be non-inferior to bonding with primer (P = 0.08). There was no significant difference in bond-up times. Bond failure was more likely to happen at the composite–enamel interface when bonded without a primer.

Conflict of interest: No conflict of interest for all authors.

Funding: No funding sources were used.

Registration: Study was not registered on external databases.

Introduction

Composite bonding in orthodontics has evolved significantly since the concept was first introduced by Buonocore (1). Primer may be used as part of the bonding process and with light-cured composite; it is usually unfilled resin. Its primary purpose is enamel surface penetration to improve the effectiveness of the final bond. According to previous reports in the literature (2–4), its purpose in orthodontic bonding includes enhancing the bond strength. If a primer could be avoided during bonding brackets, this would represent a financial saving and a potential time saving by missing a step in the bonding process.

Several in vitro studies have shown a comparable tensile bond strength with or without the use of a primer (5–9). These studies suggested that a resin phase devoid of filler particles is present in sufficient amounts on the surface of the composite resins to fill the micropores in the etched enamel surface, and the unfilled resin is not necessary. This has been confirmed further within in vitro studies that have measured the depth of penetration of resin tags using scanning electron micrographs (5, 6, 8–10).

Research has previously been carried out on bonding orthodontic brackets with no primer, with three In vitro studies (11–13), demonstrating sufficient bond strengths for bonding orthodontic brackets without primer, when bonding with chemically cured/light-cured composite.

Three in vivo orthodontic studies have also been published assessing the use of no primer: one study recorded bonded retainer failure rates (14), and two studies investigated bracket failure rates (12, 13).

The randomized controlled trial investigating bonded retainer failure rates (14) found a higher failure rate when bonding lingual retainers without primer group (27%) compared with the with primer group (4%). However, this is not truly applicable to bonding of orthodontic brackets as low viscosity composite was used for bonding lingual retainers compared with ‘normal’ composite. Therefore, previous studies observing bracket failure rates are more appropriate when analysing bonding brackets without primer.

A non-randomized clinical trial (15) found similar bracket failure rates when bonding with and without primer (4% with primer and 3% without primer). This study does offer relatively stronger evidence that primer is not required for orthodontic bonding of brackets. However, the drawbacks of this study were its lack of randomization; lack of appropriate statistical analysis of bracket failure rate; failure to consider cross-over effects; and unclear details about the duration of the study period.

A retrospective controlled study (16) found when bonding with chemically cured composite that the bracket failure rate was similar when bonding with or without primer (3.62% without primer and 6.22% with primer). The conclusions of this study were not robust due to the following features of the study design:

- Sample selection criteria were unclear.
- Upper appliances only were assessed.
- Only patients who completed treatment with full records were included (this may induce selection bias.).

The evidence available from studies in this area is weak, but the evidence that exists appears to support that it would be possible to bond orthodontic brackets without primer; therefore, further investigation of orthodontic bonding without a primer is merited.

Aims

The objective of the trial was to determine whether a primer is required as part of the bonding process. The study compared direct orthodontic bonding of APC™II (adhesive pre-coated) Victory™ brackets with and without the use of primer by investigating:

- If there is no difference in the bracket failure rates over 12 months
- If the bonding time per bracket is different between the groups
- The type of bond failure using the Adhesive Remnant Index (ARI)

Hypothesis

The null hypotheses to be tested in this study were the following:

- There is no difference in the bracket failure rate when pre-adjusted edgewise metal brackets (APC™II Victory Series™) are bonded with (control group) or without (experimental group) Transbond™ XT Primer over a 12-month period.
- There is no difference in the bonding time per bracket.
- There is no difference in the type of bond failure as assessed by the ARI.

Method of investigation

Ethical approval

Ethical approval was granted by Leeds (East) Research Ethics Committee on 18th of December 2009 (Reference 09/ H1306/102).

Sample population

Orthodontic patients referred to the Leeds Dental Institute/St Luke’s hospital, Bradford, UK.

Setting

Patients were treated in a dental teaching hospital and district general NHS hospital.

Operator characteristics

All patients were treated from the start until the end of the study period by a single postgraduate student (SN).
Sample selection criteria

Inclusion criteria
- Patients requiring single or two-arch fixed appliance therapy (no previous orthodontic treatment)
- Willing to consent to participate in the trial

Exclusion criteria
- Patients with craniofacial anomalies and those requiring orthognathic surgery
- Patients with several buccal restorations or congenital enamel defects
- Hypodontia cases (more than one tooth missing in each quadrant)

Subject withdrawal criteria
Subjects could withdraw from the study at any time without any compromise to the agreed and proposed treatment. Such a subject would have been accounted for during data and statistical analysis. Any dropout sample would not be replaced. All data pertaining to first time bracket failure was recorded as agreed until the withdrawal date for an individual sample.

Trial termination—safety reasons for abandoning the trial
The trial would have been terminated if more than 50 per cent of the brackets failed in the experimental group in at least three patients within the first review appointment (6 weeks).

Study design
A two-centre prospective single-operator, non-inferiority randomized controlled clinical trial. Individual patients were randomly allocated to either the test or control group.

Sample allocation—randomization and blinding
After informed consent was obtained (by SN), patients were randomly allocated to either the control or experimental group. This was performed by preparing opaque numbered sealed envelopes in advance using a random numbers table generated by a computer by an independent third party (GN). The operator enrolled the participants. Once the envelopes were opened, blinding of the operator and the patient was no longer possible due to the nature of the intervention. Treatment was commenced on all patients within 3 months of enrolment.

Agreed start and end points
Upper and lower arches were bonded when appropriate. If upper and lower arches were bonded at separate visits, then specific dates were considered as the start point for each arch. The follow-up period was 12 months, and the incidence of first bracket failure was recorded. The first analysis focused on the first bracket failure times. For patients who had no failures, the bracket survival time was censored until the end of fixed appliance treatment by the operator.

Bonding procedure
The same clinician performed the bonding procedure and subsequent orthodontic treatment for a period of at least 12 months. The bonding procedure was standardized as follows.

Control group
- Moisture control as deemed appropriate
- 30 second wash and 30 second dry using 3 in 1 syringe, if gross debris present
- 30 second etch with 37 per cent phosphoric acid gel
- 30 second wash and 30 second dry using 3 in1 syringe
- Application of Transbond™ XT Primer and air thinned
- Adhesive pre-coated bracket (APC™II Victory Series™, 3M Unitek) placed at long axis point on the buccal surface of the tooth
- Polymerization using a LED light; 30 seconds mesially and 30 seconds distally on each tooth
- Insertion of an appropriate sized arch wire, dependent on the severity of the patients’ malocclusion.

Test group
The process for the test group was identical, but the application of the primer was omitted.
All incisors, canines, premolars, and 1st molars are included within the study. If 2nd and 3rd molars were to be bonded, the same bonding procedure was followed; however, these teeth were not included within the data collection of this study.

Outcome measures
Primary—Bracket failure rate for test and control group within a study period of 12 months
Secondary—Bonding time per bracket, Bond failure type using the ARI index

The ARI is a point-based system ranking from 0 to 3:
0 = no composite left on tooth
1 = less than half of the composite left on the tooth
2 = more than half of the composite left on the tooth
3 = all composite left on tooth with a distinct impression of the bracket base

Sample size calculation
Calculation of sample size to demonstrate non-inferiority of control was based on a maximum difference of 5 per cent between the two groups (which represents an additional one bracket failure), and a failure rate of 15 per cent in both groups, for a power of 80 per cent, and a type I error of 10 per cent (one sided).
However, the study also had to account for clustering. Previous studies on bracket failure rates used either split-mouth designs (which have cross-over effects) or did not account for clustering or the ‘design effect’.
Ideally, an estimate of the ‘design effect’ for the indicators of interest is obtained from prior surveys. As no information was available on the magnitude of design effects for the indicators of interest, the use of a default value is recommended. In many cluster surveys, a default value of \( D = 2.0 \) is used.
This gave a sample size of 46 patients per group, giving a total sample size of 92 patients.

Statistical analysis
The test group was declared non-inferior to the control group (with primer) if the confidence interval for the difference between failure rates of Intervention and control covers only values that are smaller than the pre-determined error margin of 5 per cent.
Secondary analysis to investigate the effects of possible confounders, e.g., age, gender, etc., was conducted using multilevel logistic regression model as the outcomes are correlated (i.e., clustered within a subject). Survival curves for the test and control group were compared using the Kaplan–Meier estimate of survival function. Further analysis to investigate the effects of covariates was carried out using the frailty Cox regression model with response time to failure. A $P$ value of 0.05 or less was considered to be statistically significant.

## Results

### Participant flow

Ninety-five patients were approached for inclusion within the study, 92 patients agreed to participate in the study (53 females and 39 males), and 2 patients once enrolled withdrew from the study due to moving out of the region. Figure 1 shows the CONSORT flow diagram.

### Sample demographics

The study sample demographics are shown in Table 1.

The table demonstrates a similar demographic distribution of both study groups, with the mean age being 15.6 years.

### Bond failure rates

Bond failure rates for both groups are shown in the Table 2 for the duration of the study.

The bracket failure rate at 12 months for bonding with primer was 11.1 per cent and without primer was 15.8 per cent. The difference in the percentage failure rate between the two groups at 12 months is 4.7 per cent.

Figure 2 shows the percentage survival (in days) for brackets bonded with and without primer, with the shaded areas demonstrating the 95 per cent confidence interval for each group. It shows more bracket failures initially when bonding without primer and then both lines running parallel. The graph also shows that there is

<table>
<thead>
<tr>
<th>Table 1. Study sample demographics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>With primer</td>
</tr>
<tr>
<td>Patients</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Mean age (years)</td>
</tr>
<tr>
<td>Minimum age (years)</td>
</tr>
<tr>
<td>Maximum age (years)</td>
</tr>
<tr>
<td>Leeds Dental Institute, UK</td>
</tr>
<tr>
<td>St Lakes, Bradford, UK</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Bracket failure rate at 12 months.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study group</td>
</tr>
<tr>
<td>With primer</td>
</tr>
<tr>
<td>No primer</td>
</tr>
<tr>
<td>Overall</td>
</tr>
</tbody>
</table>
no statistically significant difference between the two groups as the 95% confidence intervals overlap.

The statistical model indicates that brackets bonded without primer are 1.47 times more likely to fail than with primer. However, statistically bonding without primer is shown to be non-inferior to bonding with primer as the P value is greater than 0.05 (P = 0.08), and the 95% confidence interval for the hazard ratio includes 1 (0.95–2.25).

**Bond failure rates excluding 1st permanent molars**

As most bonding studies are performed from premolar to premolar, further analyses were generated, which excluded 1st permanent molars.

Table 4 shows that the bracket failure rates when excluding 1st permanent molars were 10.3 per cent with primer and 14.4 per cent without primer, which is a difference of 4.1 per cent over a 12-month period.

The Cox proportional hazards model with frailty (Table 5) indicates that brackets bonded without primer are 1.41 times more likely to fail than with primer. However, statistically bonding without primer is shown to be non-inferior to bonding with primer as the P value is greater than 0.05 (0.14), and the 95% confidence interval for the hazard ratio includes 1 (0.89–2.24).

**Distribution of bond failures**

Total bond failures in relation to tooth type. Figure 3 shows a graphical demonstration of bracket failures in relation to tooth type.

The figure demonstrates that the highest percentage of bracket failures occurred on the 1st molar and the lowest on the 1st premolar. Table 6 shows a tabular description of the number failures for both study groups and the tooth position along the arch.

Figure 4 shows bracket failure rate by tooth number and study group, which shows the highest failure rate was with the 1st molars when bonded without primer. This was further analysed within the

---

**Table 3. Bracket failure by study group and tooth.**

<table>
<thead>
<tr>
<th>Tooth number</th>
<th>Central incisor</th>
<th>Lateral incisor</th>
<th>Canine</th>
<th>1st premolar</th>
<th>2nd premolar</th>
<th>1st molar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primer Censor</td>
<td>139</td>
<td>127</td>
<td>144</td>
<td>119</td>
<td>110</td>
<td>67</td>
</tr>
<tr>
<td>No primer Censor</td>
<td>16</td>
<td>21</td>
<td>8</td>
<td>8</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

---

**Figure 2.** Kaplan Meier survival graph with 95% confidence intervals.

**Figure 3.** Graphical demonstration of bracket failures in relation to tooth type.

**Figure 4.** Bracket failure by tooth number and study group.
they were more likely to fail with an ARI of 0. It also shows that when brackets were bonded without primer, the ARI was measured on bracket failure and when not recorded it was denoted as missing. Figure 5 shows a graphical representation of ARI on failure where brackets were bonded with and without primer.

Figure 5. Adhesive Remnant Index on failure.

Cox proportional hazards model with frailty. The results are shown in Table 6.

Table 6 also compares the odds ratio of failure by tooth number with the reference group being tooth number 1 (central incisor). The hazard ratios of the tooth numbers were the following:

- 2 (lateral incisor) 1.00 (95% CI 0.95–2.25)
- 3 (canine) 0.53 (95% CI 0.66–1.30)
- 4 (1st premolar) 0.46 (95% CI 0.27–0.79)
- 5 (2nd premolar) 1.06 (95% CI 0.70–1.61)
- 6 (1st molar) 1.84 (95% CI 1.18–2.88)

The teeth that were statistically significant from the 1 (central incisor) were the 4 (1st premolar) and 6 (1st molar) as the confidence interval does not include 1, and the P value is less than 0.05.

Distribution of bond failure rates with respect to gender, transversely (right or left) and between the arches

There was no statistically significant differences in bracket failure rates between the genders (P = 0.512), or between the upper and lower arches (P = 0.092) or in the transverse dimension (P = 0.926).

Time to bond brackets

Mean bonding time per tooth was calculated in minutes because some patients had different numbers of teeth bonded, dependent on whether it was an extraction or non-extraction case, and if the molars were to be banded or bonded.

The data were then checked and found to have normality of distribution and equality of variance. An independent samples’ t-test was performed to compare the means.

The mean difference of bond-up (Table 7) times per bracket was 0.068 minutes (4 seconds) with less time taken to bond without primer. This is not statistically significant as the P value is greater than 0.05 (P = 0.4), and the 95% confidence interval includes 0 (−0.09 to 0.23).

Adhesive Remnant Index

The ARI was measured on bracket failure and when not recorded it was denoted as missing. Figure 5 shows a graphical representation of ARI on failure when bonding with and without primer. It demonstrates most failures occurred in both groups with an ARI of 0 or 1. It also shows that when brackets were bonded with primer, they were more likely to fail with an ARI of 0.

Statistical analysis was performed using a binomial multilevel model and due to the low numbers of failures with a high ARI (2 or greater). This gave an odds ratio of 2.82 (95% CI 2.04–3.59), which was statistically significant (P value 0.0000000582). This result means that if a bracket fails when bonded without primer, it is 2.82 times more likely to fail with an ARI of 0 compared to a bracket bonded with primer.

Discussion

Study design

The study design was that of a non-inferiority prospective randomized controlled trial where participants were randomly allocated to each group upon enrolment in the study. This design has the effect of preventing any potential cross-over effects that occur with split-mouth studies. The challenge of this approach is that it increased the sample size required for the statistical calculation to have significant power (17).

Randomization-ensured treatment allocation cannot be predicted in advance, as predication of allocation is associated with biased treatment effects (18, 19).

Unfortunately, due to the nature of the intervention, it was not possible to maintain blinding throughout the study.

Also the results achieved are only truly representative of SN’s practice when using APC™II Victory Series™ brackets; therefore, if this was to be extrapolated to the whole of the orthodontic population, a multicentre/multi-operator trial would be required.

Clinical experience has suggested that some patients are more prone to bracket failure than others, which may be due to a multitude of factors, e.g. diet, tooth anatomy, etc. Therefore, the usual assumption of the independence of the bracket failures will be invalid (20). Violation of the assumption of independence of the observation often occurs within in the dental literature in a variety of situations, e.g. periodontal pockets, restorations, etc. This is known as clustering and is when multiple measurements belonging to the same person are likely to be correlated (21). Clustering has the effect of reducing the amount of information gathered from each sample within a cluster compared with a non-clustered study (21). To overcome this non-independence, a Cox proportional hazards model with frailty was used. This statistical model is often advocated within the medical literature for survival analyses.

The use of a frailty allows for differences in risks and thereby improves the quality of the research. An example of the frailty model in the orthodontic bracket failure setting (20) demonstrated age at the start of treatment being a statistically significant factor in a basic Cox model. However, when frailty was used, the model showed that age was no longer statistically significant. Therefore, if clustering is ignored it increases the chance of achieving statistically significant results, which may not be genuine (21).

Bracket failure rates

The bond failure rates achieved in this study were 11.1 per cent with primer and 15.8 per cent without primer (overall 13.5%) including 1st permanent molars. In comparison to previously published work, the control group (with primer) achieved a bracket failure rate of 10.3 per cent (excluding 1st molars) which is similar to the higher range of the established literature when adhesive pre-coated brackets were used, 2.7 per cent, 7.5 per cent, 8.06 percent, and 9.5 per cent (22–25).
Table 4. Bond failure rates with respect to study group excluding 1st permanent molars.

<table>
<thead>
<tr>
<th>Study group</th>
<th>Total N</th>
<th>Number of failures</th>
<th>Censored N</th>
<th>%</th>
<th>Failure rate, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>With primer</td>
<td>712</td>
<td>73</td>
<td>639</td>
<td>89.7</td>
<td>10.3</td>
</tr>
<tr>
<td>No primer</td>
<td>737</td>
<td>109</td>
<td>648</td>
<td>85.6</td>
<td>14.4</td>
</tr>
<tr>
<td>Overall</td>
<td>1469</td>
<td>182</td>
<td>1287</td>
<td>87.6</td>
<td>12.4</td>
</tr>
</tbody>
</table>

Table 5. Bracket failure as analysed by Cox proportional hazards model with frailty excluding 1st permanent molars.

<table>
<thead>
<tr>
<th>Hazard ratio</th>
<th>Standard error</th>
<th>P value</th>
<th>Lower boundary of 95% confidence interval</th>
<th>Upper boundary of 95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No primer compared with bonding with primer</td>
<td>1.412</td>
<td>0.33</td>
<td>0.142</td>
<td>0.892</td>
</tr>
<tr>
<td>Lateral incisor compared with central incisor</td>
<td>1.006</td>
<td>0.21</td>
<td>0.977</td>
<td>0.669</td>
</tr>
<tr>
<td>Canine compared with central incisor</td>
<td>0.532</td>
<td>0.13</td>
<td>0.010</td>
<td>0.329</td>
</tr>
<tr>
<td>1st premolar compared with central incisor</td>
<td>0.469</td>
<td>0.13</td>
<td>0.005</td>
<td>0.277</td>
</tr>
<tr>
<td>2nd premolar compared with central incisor</td>
<td>1.068</td>
<td>0.23</td>
<td>0.758</td>
<td>0.703</td>
</tr>
</tbody>
</table>

Table 5. Bracket failure as analysed by Cox proportional hazards model with frailty excluding 1st permanent molars.

<table>
<thead>
<tr>
<th>Hazard ratio</th>
<th>Standard error</th>
<th>P value</th>
<th>Lower boundary of 95% confidence interval</th>
<th>Upper boundary of 95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No primer compared with bonding with primer</td>
<td>1.412</td>
<td>0.33</td>
<td>0.142</td>
<td>0.892</td>
</tr>
<tr>
<td>Lateral incisor compared with central incisor</td>
<td>1.006</td>
<td>0.21</td>
<td>0.977</td>
<td>0.669</td>
</tr>
<tr>
<td>Canine compared with central incisor</td>
<td>0.532</td>
<td>0.13</td>
<td>0.010</td>
<td>0.329</td>
</tr>
<tr>
<td>1st premolar compared with central incisor</td>
<td>0.469</td>
<td>0.13</td>
<td>0.005</td>
<td>0.277</td>
</tr>
<tr>
<td>2nd premolar compared with central incisor</td>
<td>1.068</td>
<td>0.23</td>
<td>0.758</td>
<td>0.703</td>
</tr>
</tbody>
</table>

Table 6. Cox regression with frailty.

<table>
<thead>
<tr>
<th>Hazard ratio</th>
<th>Standard error</th>
<th>P value</th>
<th>Lower boundary of 95% confidence interval</th>
<th>Upper boundary of 95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No primer compared to bonding with primer</td>
<td>1.467</td>
<td>0.32</td>
<td>0.080</td>
<td>0.955</td>
</tr>
<tr>
<td>Lateral incisor compared with central incisor</td>
<td>1.000</td>
<td>0.21</td>
<td>0.999</td>
<td>0.665</td>
</tr>
<tr>
<td>Canine compared with central incisor</td>
<td>0.531</td>
<td>0.13</td>
<td>0.010</td>
<td>0.329</td>
</tr>
<tr>
<td>1st premolar compared with central incisor</td>
<td>0.465</td>
<td>0.13</td>
<td>0.004</td>
<td>0.274</td>
</tr>
<tr>
<td>2nd premolar compared with central incisor</td>
<td>1.061</td>
<td>0.23</td>
<td>0.780</td>
<td>0.699</td>
</tr>
<tr>
<td>1st molar compared with central incisor</td>
<td>1.841</td>
<td>0.42</td>
<td>0.008</td>
<td>1.176</td>
</tr>
</tbody>
</table>

Table 6. Cox regression with frailty.

<table>
<thead>
<tr>
<th>Hazard ratio</th>
<th>Standard error</th>
<th>P value</th>
<th>Lower boundary of 95% confidence interval</th>
<th>Upper boundary of 95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No primer compared to bonding with primer</td>
<td>1.467</td>
<td>0.32</td>
<td>0.080</td>
<td>0.955</td>
</tr>
<tr>
<td>Lateral incisor compared with central incisor</td>
<td>1.000</td>
<td>0.21</td>
<td>0.999</td>
<td>0.665</td>
</tr>
<tr>
<td>Canine compared with central incisor</td>
<td>0.531</td>
<td>0.13</td>
<td>0.010</td>
<td>0.329</td>
</tr>
<tr>
<td>1st premolar compared with central incisor</td>
<td>0.465</td>
<td>0.13</td>
<td>0.004</td>
<td>0.274</td>
</tr>
<tr>
<td>2nd premolar compared with central incisor</td>
<td>1.061</td>
<td>0.23</td>
<td>0.780</td>
<td>0.699</td>
</tr>
<tr>
<td>1st molar compared with central incisor</td>
<td>1.841</td>
<td>0.42</td>
<td>0.008</td>
<td>1.176</td>
</tr>
</tbody>
</table>

Table 7. Independent samples t-test assuming equal variance.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Standard error mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time per bracket</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With primer</td>
<td>2.070542</td>
<td>0.4319669</td>
<td>0.0548599</td>
</tr>
<tr>
<td>No primer</td>
<td>2.002287</td>
<td>0.4770836</td>
<td>0.0596355</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T-test</th>
<th>df</th>
<th>Sig</th>
<th>Mean difference</th>
<th>Standard error difference</th>
<th>95% lower CI</th>
<th>95% higher CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.841</td>
<td>124</td>
<td>0.402</td>
<td>0.0682552</td>
<td>0.0811593</td>
<td>-0.0923818</td>
<td>0.2288922</td>
</tr>
</tbody>
</table>

When the experimental group is compared to the previously published work of in vivo orthodontic studies, the bond failure rate is greater at 15.8 per cent compared with 3 per cent (15) and 5.62 per cent (16). This may be due to a number of factors, which include:

- The increased filler content within pre-coated brackets inhibited penetration of the resin into the etched enamel.
- The in vivo orthodontic study (16) used chemically cured composite, which may provide superior bond strengths.
- Cross-over effects of brackets were significant, which were not taken into account within the study (15).
- Clinicians performing the bond-ups were more experienced clinicians. This has been shown to influence bracket failure rate (26).
- Lack of randomization within the previous study (15).

- Retrospective nature of the previous study (16) and exclusion of patients without full medical records, which may have decreased the bracket failure rate.
- Inclusion of 1st permanent molars within the study, which have been shown to have a higher bracket failure rate. However, this was adjusted within the study (14.4%), but the bracket failure still remained greater than in the previous literature.

When comparing the two groups within this study, bonding orthodontic brackets without primer was shown to be statistically non-inferior to bonding with primer.

**Distribution of bracket failures**

Previous literature has shown that higher bracket failure rates occur in the posterior region (27–29). With a reported debond rate of 33.7
per cent on 1st molars (30) compared with premolar to premolar debond rate of 5–8 per cent (31). Within this study, the highest bond failure rate was achieved on first permanent molars (24.7%) with the second highest failure rate on the 2nd premolars (16.3%). Higher failure rate in the molar region may be attributable to access problems, increased difficulty in moisture control, and an increased presence of aprismatic enamel.

Within this study, a higher bracket failure rate was achieved in the maxilla (14.9%) compared with the mandible (12.1%). However, this was not statistically significant. Previous work has reported higher bracket failure rates in the mandibular arch (27, 32–34). However, other work has shown a higher failure rate in the maxillary arch (35, 36). There is also other research that demonstrates a similar failure rate in both arches (20, 37, 38).

**Bonding time**

Bracket bonding time was reported per tooth. This approach was used because if the case was non-extraction or extraction, this caused variation in the number of teeth bonded for the patient. Also if a tooth/teeth were excluded from the initial bond-up, these teeth would also need to be included. This study demonstrated a tendency for decreased bond-up time per bracket without primer, but this was not statistically significant (P = 0.402). This was as expected, as without the use of primer, one stage is removed from the bonding process. However, this step only takes a matter of seconds; therefore, in order to be statistically significant a much larger sample size would be required. A more important question would be if this tendency for a decreased bonding up time ’clinically significant’. The mean bond-up time per bracket was 2.07 minutes with primer and 2.00 minutes without primer, and the mean difference was 0.068 minutes (4.1 seconds); therefore, in terms of time saving it is clinically insignificant. If, however, missing the primer stage had led to better moisture control and thereby a lower bracket failure, this time difference would be clinically significant.

**Adhesive Remnant Index**

Within this study, there was a statistically significant difference between the two groups. Bond failures were more likely to occur at the composite–enamel interface when no primer was used. This implies that orthodontic bonding with no primer has lower bond strengths than orthodontic bonding with primer.

Failure with a low ARI may have the potential advantage of saving time by reducing the amount of time required for removal of residual composite.

With regards to bonding with no primer, no in vivo study has analysed the ARI as an outcome measure. The results are different to in vitro studies. In vitro orthodontic studies have suggested that the interface of failure is similar for bonding with and without primer (11, 12, 16). However, as the ARI was a secondary outcome measure in this study, there may not have been a sufficient sample size to achieve a statistically significant result. It also has to be considered that the in vitro studies were performed in ’ideal’ conditions and therefore does not reflect the situation in vivo.

**Limitations**

Due to the study being performed by one operator (SN), the results are only truly attributable to their practice. Also some may argue that even a difference in bracket failure rate of 1% may be clinically significant. A figure of 5% was chosen as this would signify an addition bracket failure per patient. If a figure of 1% was chosen this would have dramatically increased the sample size so that it would not be possible to be carried out by a single clinician. Blinding of the clinician was also lost upon insertion of the fixed appliance, it may have been beneficial for one operator to place the appliance. However, due to the practicalities of treatment, this was not possible e.g. reposition of bracket(s) required.

**Generalization**

The results of this study should be interpreted with caution. As previously stated as only one operator performed the study the results are only truly applicable to their practice. One must also consider that the results are based only on one specific bracket system. The result of this study demonstrate no statistically significant difference when bonding with or without primer, however the 95% CI of the Hazard ratio only just included 1 (0.953–2.254), therefore further research is required before stopping the use of primer for bonding orthodontic brackets can be recommended.

**Future work**

Future research could focus on bonding orthodontic brackets without primer in multi-operator (operators at varying levels of clinical experience) randomized controlled clinical trials, which account for clustering and avoid cross-over effects. Other factors that could also be assessed are bonding with different brackets/adhesives, patient comfort at removal of the fixed appliance, decalcification rates, any possible enamel damage, and the time required to remove the fixed appliance(s) and any residual adhesive.

**Conclusions**

- Bonding APC™II Victory Series™ brackets without Transbond™ XT Primer is non-inferior to bonding when APC™II Victory Series™ brackets with Transbond™ XT Primer over a 12-month period (P = 0.08).
- There is no significant difference in the bonding time per bracket when bonding with or without primer.
- Bond failure of AP™II Victory Series™ brackets is more likely to occur at the composite–enamel interface when bonded without primer compared with those bonded with primer.

**References**


