Evaluation of bracket failure rate in orthodontic patients bonded with and without primer

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KEYWORDS
Bracket failure; Orthodontic adhesive; Orthodontic primer

Abstract
Introduction: Primers are considered widely essential for bonding orthodontic brackets. However, their role in minimizing bracket failure rates has been frequently questioned.
Objective: To investigate the difference in the bracket failure rate in direct bonding with and without the use of orthodontic primer.
Setting and design: A prospective, single blinded clinical study at a private clinical practice in Ras Al Khaimah, United Arab Emirates.
Methods and material: 38 class I bimaxillary protrusion patients requiring all first premolar extraction treatment were assigned to primer and non primer group (19/group) and bonded in a standardized manner. They were followed up from strap up till the end of treatment and bracket failure rate during the entire treatment was recorded, assessed and compared.
Statistical analysis: Statistical significance between the two groups was checked using Fischer’s exact test (P less than .05 was considered significant).
Result: Debonding in non primer group was more than in primer group but not statistically or clinically significant.
Conclusion: The bonding of brackets without using orthodontic primer is possible; however, further research is advocated.

1. Introduction

Conventional orthodontic bonding is usually a tri-step procedure involving etching, priming and bonding.1 Bonding without the use of primer has been a subject of much interest to the orthodontist. Primer is usually an unfilled resin whose primary function is to improve the effectiveness of the final bond. Secondly, they are also claimed to protect the enamel from the consequent demineralization by the acid-etching and to reduce marginal leakage.

However, the use of primer adds a step in the bonding procedure which entails increased chair time, risk of moisture contamination and an increased procedural cost.

To date, six in vitro and three in vivo orthodontic studies have been published investigating bonding with and without the use of an intermediary liquid resin (primer/unfilled resin).
Bracket failure rate in orthodontic patients bonded with and without primer

The in vitro studies\(^2\text{–}^7\) have shown to a variable extent the possibility of achieving satisfactory bonding without using primer in orthodontics.

While the importance of in vitro studies cannot be underrated, it is also essential to consider clinical studies. Whilst these cannot control all variables to the extent of the laboratory-based studies, they may better reflect a more realistic clinical situation.

Bazargani et al. (1991)\(^8\) compared the failure rate of bonded lingual retainers with and without the use of primer. The study found a higher failure rate in the no primer group (27%) compared to the group with primer (4%). This was statistically significant and deemed clinically significant by the authors, who recommended bonding lingual retainers with primer.

However, this may not truly apply to bonding of orthodontic brackets as low viscosity resin used for retainer bonding generally has a lower shear bond strength than “normal” composite used for orthodontic bonding which may have affected the failure rate. Also, the surface area used for bonding retainers is generally less than for bonding of brackets. Therefore, previous studies observing bracket failure rates are more appropriate when analysing bonding brackets without primer.

A retrospective controlled study was carried out by Tang et al. (2000)\(^9\) comparing a chemically cured adhesive with and without the use of primer on bracket failure rates. The first bracket failure incidence was retrieved from patient records (with only the first failure counted for each bracket). The overall bracket failure rate was similar in both groups (5.62% without primer and 6.22% with primer), and it was concluded that the fixed appliances bonded without primer worked equally well; and did not reveal any clinician or material factors which may influence bracket failure rates.

Banks and Richmond (1994)\(^10\) analysed the risk of enamel decalcification as a primary outcome with or without use of sealants. Bracket failure rate was measured as the secondary outcome and was found to be similar in both groups (4% when primer is used and 3% without primer).

The drawbacks of these studies were their lack of randomization in sample allocation; 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.

In a routine bonding procedure the bracket with composite at its base is placed on the tooth surface and gently pressed. This pressure helps to closely adapt the bracket on to the tooth surface and remove any excess composite as flash. The logic that this pressure application can also cause the high viscosity resin to flow into the microporosities on the tooth surface had there been no primer, and still provide adequate retention to the brackets, forms the backbone of this study, which was designed, with an aim to investigate the difference in the bracket failure rate when bonded with and without the use of an orthodontic primer.

2. Materials and method

This was a prospective clinical study carried out with all the cases started and followed up by the same clinician. The inclusions were selected from the patients who reported to the private clinical practice at the Al Reef Dental and Orthodontic Centre, Ras Al Khaimah, United Arab Emirates for orthodontic treatment from November 2011 to April 2014. An informed consent for orthodontic treatment was taken from all the patients/parents in case of minor.

2.1. Inclusion criteria

(i) Age, sex, diet and dentition: 14–25 years mixed diet male and female patients with full complement of erupted permanent teeth present from first molar to first molar in both arches.

(ii) Malocclusion: Non surgical class1 bimaxillary dentoalveolar protrusion cases which required conventional orthodontic treatment only were included with overbite and overjet between 1 and 4 mm; crowding <4 mm in either of the arches where treatment plan involved all four first premolars extraction.

(iii) No deleterious habits; good oral hygiene.

(iv) Absence of any buccal surface caries.

(v) The enamel surface being judged to be relatively free of developmental and morphologic defects known to interfere with bond strength.

2.2. Exclusion criteria

All cases other than aforementioned were excluded.

2.3. Sampling procedure

Sample sized calculation was done using sample size calculator (considering the population to be large) (http://www.survey-system.com/sscale.htm).\(^11\) The sample size needed was 385 with bond strength.

The sample size needed was 385 with bond strength.

Since every patient had 20 teeth bonded, it accounted for 19.25 individuals (385/20) which was rounded off to the nearest whole number 19 per group. Difference between the two groups would be considered significant if the P value obtained after statistical test would be less than .05.

The patients were blinded about their inclusion in the NP (Non Primer) or the P (Primer) group. This was done to avoid any additional care the patient in the study group may take to minimize bracket debonding by information acquisition through the general dentist/any other orthodontist or through internet. Since their was only one orthodontist treating the patients and following them up in he was not blinded to the group allocation of the subjects.

All subjects were alternatively assigned to primer and non primer group and were then followed up for the entire treatment duration, being, from the time of strap-up (first strap up November 2011) to the time of debonding (last debonding April 2014).

In case siblings were started for the treatment with a similar treatment plan an exception to the above was made, and they were included in the same group to maintain blinding of skipping one step during the procedure.

In case of dropouts, subjects were added to the trailing group and the study continued till a 19-subjects/group finishes
their treatment. This was primarily done to retain adequate power of the study by maintaining sample size so that the result obtained is scientifically meaningful.

A total of 44 individuals were included in this study. However, 4 from the primer group and 1 from the non-primer group dropped out of the study for various reasons. The last inclusion in the non-primer group was excluded from the study statistics as the case was still under treatment at the time of drafting this study which was deemed complete when required number of cases per group (19 subjects/group) got debonded. The dropouts were also excluded from the statistical analysis since the data pertaining to their debondings could not be completed. Statistical analysis was performed using 19 individuals per group.

Ethical clearance from the medical research section of ministry of health Ras Al Khaimah was obtained for the above research.

It was decided that the study would be terminated in case 50% brackets failed in at least three patients during the first three review appointments, which were scheduled between 30 and 45 days as this would be detrimental to the overall treatment of the patient and would be highly unacceptable clinically. In case, the trial had to be terminated due to high failure rate in the test group no additional cost was to be borne by the patients in case a re-strap up was required and the retainers were to be given free of charge as complementary on moral grounds.

2.4. Bonding procedure

0.022 in. metal Gemini MBT versatile +™ (3M Unitek, Monrovia, California, USA) brackets were directly bonded to the tooth surface after scaling and polishing with a non fluoride pumice paste, etching with 37% phosphoric acid gel for 30 s followed by rinsing and drying using a three way syringe. A standards isolation procedure was followed to prevent moisture contamination using cotton rolls and saliva ejector. Bracket bonding was done using Transbond XT™ (3M Unitek, Monrovia, California) Orthodontic adhesive paste in both the primer (P) and the primer free (NP) groups besides, the additional use of Transbond adhesive primer in the primer (P) group. Composite curing in both the groups was done for 30 s using visible light curing unit (Beyond™ Cordless LED Curing light, Stafford, Texas). Besides, an additional of 5 s of curing was done after primer application on every tooth in the primer (P) group.

Both the arches were bonded from molar to molar in all the patients at the same appointment and the first aligning NiTi was engaged. Care was taken to avoid any occlusal interferences especially in the lower premolar region which may increase the chance of debonding. Space closure was done using custom fabricated 0.019·0.025 in. stainless steel arch wire using active tie-backs with activation scheduled between 30 and 45 days. Finishing and detailing was done using 0.012/0.014 Australian stainless steel™ (A.J. Wilcock, Whittlesea, Victoria, Australia) with up-righting bends and settling elastics when needed. Debonding rates were recorded between the two groups during levelling and aligning, space closure and finishing and detailing. If any bracket de bonded more than once, only the first time debonding was included for statistical analysis to eliminate the effect of clustering (Tables 1 and 2).

Rebonding in both the groups used the procedure standard for the group allocated using new brackets of the same prescription and make.

2.5. Statistics

Inter group comparison between the two groups was made using Fischer’s exact test (Table 3) using Graph pad software™ (Graph Pad Software, Incorporation, La Jolla, California, USA).

Fédération Dentaire Internationale (FDI) notation was used in this study for tooth numbering.

3. Result

19 individuals per group were compared for the number of debondings which amounted to the assessment of 385 teeth per group (20 brackets bonded per individual). 24 brackets failed in the primer group and 25 in the non primer group of which 22 in the former and 24 in the latter were first time failures and hence counted for the calculations. The bond failure rate in the primer and non primer group was 5.79% and 6.32% respectively. The statistical difference in bond failure rate between the two group was statistically not significant ($P = 0.879$).

Most of the debondings occurred during the initial levelling and aligning stage of the treatment, being, 15 in primer and 16 in non primer group respectively which accounted for greater than 50% of total debondings in the entire treatment.

Most of the debondings occurred in the molar–premolar region, being, 8 and 7 buccal tubes; 6 and 9 premolar brackets, in the primer and non primer group.

The primer group had equal distribution of debondings, being, 12 each in maxilla and mandible. However, in the non primer group the number of debondings in mandible was more than maxilla, being, 14 and 11 respectively (Fig. 1)(Tables 1–3).

4. Discussion

This study was designed as a prospective clinical trial aiming to attain a high level of power with suitable sample size to get result which is scientifically strong.12–15

The participants were alternately 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. However, it dramatically increases the sample size required for the statistical calculation to have significant power.16,17

It was mathematically calculated that to get a study with 80% power mandatorily 19 cases should be finished per group which was achieved by continued inclusions in the study till desired number of cases got finished.

Within any clinical study attrition bias is often encountered in form of drop out of participants during the course of study. Excluding these patients from the data analysis often creates misleading results as often the most severely affected participants’ data are excluded from the analysis.16 However, to address this issue of drop outs the deadline of this study was not predefined and inclusion in the study continued till the desired number of subjects got debonded. This method,
however, had a distinct disadvantage of increasing the duration of the study and its associated cost. The study was continued only till the time of achieving treatment completion of 19 individuals per group and no more considering mainly the economic issues and the ethical bindings in running such a study in a private clinical practice.

One method of potentially reducing the sample size would have been to use previous research as a historic control group, however as there are inter operator variations, variations in

### Table 1  Group wise subject demographic: primer group.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age/Sex</th>
<th>Number of debonding</th>
<th>Levelling and aligning</th>
<th>Space closure</th>
<th>Finishing and detailing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>17.3/M</td>
<td>1 (26)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1 (35)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15.1/F</td>
<td>1 (15)</td>
<td>1 (46)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>19.1/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>14.1/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>22/F</td>
<td>4 (33, 43, 45, 46)</td>
<td>3 (15, 16, 45)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>14/M</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>18.11/M</td>
<td>0</td>
<td>0</td>
<td>1 (12)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>14.7/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>19/F</td>
<td>1 (16)</td>
<td>1 (26)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>20/M</td>
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<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>11</td>
<td>21.3/M</td>
<td>2 (34, 41)</td>
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<td>0</td>
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</tr>
<tr>
<td>12</td>
<td>25/M</td>
<td>3 (21, 22, 23)</td>
<td>1 (23)</td>
<td>0</td>
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</tr>
<tr>
<td>13</td>
<td>22.7/F</td>
<td>0</td>
<td>0</td>
<td>1 (33)</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>19.8/M</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>15</td>
<td>23.9/M</td>
<td>1 (26)</td>
<td>0</td>
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<tr>
<td>16</td>
<td>18.1/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>19.7/M</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>18</td>
<td>18.11/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>24/M</td>
<td>1 (36)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Total debondings: 24
Total debondings counted:<sup>b</sup> 22

<sup>a</sup> Number in parenthesis: tooth number.
<sup>b</sup> Total debondings counted: total number of debondings occurring for the first time.

### Table 2  Non primer group.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age/Sex</th>
<th>Number of debonding</th>
<th>Levelling and aligning</th>
<th>Space closure</th>
<th>Finishing and detailing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15.6/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18.3/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>19.11/F</td>
<td>2 (35, 36)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>24/M</td>
<td>1 (15)</td>
<td>1 (25)</td>
<td>1 (31)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>22.1/F</td>
<td>1 (23)</td>
<td>1 (21)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>17.6/F</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>7</td>
<td>16.8/M</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>20.1/M</td>
<td>3 (35, 43, 45)</td>
<td>0</td>
<td>1 (36)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>14/M</td>
<td>0</td>
<td>2 (34, 11)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>18.8/M</td>
<td>1 (36)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>21.7/M</td>
<td>2 (26, 35)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
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<td>20.2/M</td>
<td>1 (21)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>14.3/F</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>14</td>
<td>14.8/F</td>
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<td>0</td>
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<tr>
<td>15</td>
<td>18.6/M</td>
<td>4 (15, 26, 35, 41)</td>
<td>1 (36)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>15.9/F</td>
<td>0</td>
<td>1 (12)</td>
<td>1 (12)</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>15.4/F</td>
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<td>0</td>
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</tr>
<tr>
<td>18</td>
<td>16/F</td>
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<td>0</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>21.9/M</td>
<td>1 (36)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Total debondings: 25
Total debondings counted:<sup>b</sup> 24

<sup>a</sup> Number in parenthesis: tooth number.
<sup>b</sup> Total debondings counted: total number of debondings occurring for the first time.
force present on teeth when NiTi is engaged. Surgical cases would invariably be higher due to occlusal interferences or lary protrusion cases since debonding rate in crowding cases was limited to mainly class I bimaxillary protrusion. All other malocclusions were avoided for this study.

In an effort to minimize the risk of bias in this study, both the patient and/or the patients’ parents were blinded from their study group enrolment. Besides, the siblings were bonded using the same technique. Subjects allocation was done to ensure that the treatment allocation could not be predicted in advance, as predication of allocation had been reported to be associated with biased treatment effects. In an effort to minimize the risk of bias in this study, both the patient and/or the patients’ parents were blinded from their study group enrolment. Besides, the siblings were bonded using the same technique. Subjects allocation was done to ensure that the treatment allocation could not be predicted in advance, as predication of allocation had been reported to be associated with biased treatment effects.

Another potential form of bias could have been if the investigator had a subconscious preconceived notion as to requirement of primer, as this may have affected the clinical record. If the investigator had a subconscious preconceived notion as to requirement of primer, as this may have affected the clinical record. The only person who was not blinded to the group allocation was the investigator. In an ideal situation one person should perform the bonding procedure and one person who was blinded to the intervention would perform the orthodontic treatment. The sample size was limited to bare minimum which was considered too risky to be included in an experimental methodology which is still under investigation.

Fisher’s test was chosen for statistical analysis as it is considered to be the best choice to compute a $P$ value from a contingency table and give the exact $P$ value, while the chi-square test only calculates an approximate $P$ value and is not accurate, with or without the Yates’ correction. The bond failure rates achieved in this study were 5.8% with primer and 6.3% without primer respectively (overall 6.1%) including 1st permanent molars. In comparison to previously published work the control group (with primer) achieved a bracket failure rate of 5.8% which is similar to the higher range of the established literature when regular orthodontic composites were used. When the experimental group is compared to the previously published work of *in vivo* orthodontic studies the bond failure rate is greater at 6.3% compared to 5.62% and 3%. This may be due to a number of factors, being, retrospective nature of previous study and exclusion of patients without full medical records, which may have decreased the bracket failure rate; lack of randomization and cross-over effects of brackets were significant, which was not taken into account within the Banks and Richmond (1994) study and the greater experience of clinicians performing the bond-ups which had been shown to influence bracket failure rate.

When comparing the two groups within this study there was no statistically significant difference between the two groups. However, there was a tendency for a higher bracket failure rate without primer. The author would acknowledge the following limitations of his study which are potential areas of further research. This study was a single blinded, unicentric trial which should have ideally been a double blinded and multicentric. The sample size was limited to bare minimum which was needed to get statistically relevant result. A large sample size decreases the margin of error and hence increases the power of study besides, reflecting a broader picture. However, considering the cost involved in running such a trial in a private clinical setting the sample size was kept to the minimum to obtain a respectable statistical power.

Only single malocclusion group was considered in this study, being those of class I bimaxillary protrusion where tensile forces generated are minimal. A better study design would have been to include different malocclusion group especially crowding cases where high amount of tensile forces are generated and must be borne by the bracket without debonding. No effort was made to age match and sex match the subjects in this study. It is a common clinical observation that the adults are more careful than children in taking care of their braces than adolescents and females are more careful than males.

The result of the study may reflect its success in the author’s practice. However, the result of this study must be taken with

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<table>
<thead>
<tr>
<th>Group</th>
<th>Inclusions</th>
<th>Sex (M/F)</th>
<th>Mean (age)</th>
<th>SD</th>
<th>Bond failure %</th>
<th>$P$ value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primer</td>
<td>19</td>
<td>10/09</td>
<td>19.26</td>
<td>3.34</td>
<td>5.79 (22/380)</td>
<td>0.879</td>
</tr>
<tr>
<td>Non primer</td>
<td>19</td>
<td>09/10</td>
<td>18.17</td>
<td>2.94</td>
<td>6.32 (24/380)</td>
<td></td>
</tr>
</tbody>
</table>

* $P$ value less than .05 was considered significant.

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![Flow diagram of the study.](image-url)
caution and considered universally applicable if bonding without primer is demonstrated to produce similar results across multicentric trials involving different malocclusion groups.

5. Conclusion

This study did not find any significant difference in debonding rate between the primer and non-primer group and it was concluded that bonding with or without primer is equally successful clinically as far as bracket failure rate is concerned.

Conflict of interest

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.sjdr.2014.08.001.

References