Randomized controlled trial

Orthodontic bonding with and without primer: a randomized controlled trial

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Summary

Objective: To evaluate the incidence of failure of brackets bonded with and without primer.

Design: A single-operator, cross-mouth, randomized controlled trial (RCT).

Setting: The Orthodontic Department at the Postgraduate Dental Education Centre, Örebro, Sweden.

Ethical approval: Ethical approval was granted by the Regional Ethical Review Board, Uppsala, Sweden.

Protocol: The protocol was not published before trial commencement.

Subjects and methods: Fifty consecutive patients requiring bimaxillary orthodontic treatment with fixed appliances and with an equal number of teeth on each side of the dental arch, were included in this RCT. A cross-mouth methodology was applied. In each patient, two diagonal quadrants (i.e. upper right and lower left, or vice versa) were randomly assigned to the primer group (control group) and the contralateral diagonal quadrants to the non-primer group (experimental group). The randomization process was as follows: A computer-manufactured block-randomization list was acquired and stored with a research secretary at the Postgraduate Dental Education Centre. Each time a patient gave consent, the secretary was contacted by e-mail, and information about which quadrants were to be bonded with and without primer was obtained. All incidents of bracket failure and debonding noted in patient records during the 2012–14 observation period were compiled by the other co-author, whom was blinded to the study and did not perform any orthodontic treatment on the study patients.

Main outcome measures: Number of bracket failures over 18 months.

Results: Failure rate without primer was 5.5 per cent and with primer 3.1 per cent; \( P = 0.063, \) odds ratio (OR) 1.89 [95% confidence interval (CI) 0.97–3.68] in the adjusted model. Younger ages (10–13 years), boys, and mandible were significantly associated with higher failure rates. Interaction tests indicated that younger patients had significantly higher failure rates without (12.1 per cent) than with primer (4.1 per cent), \( P < 0.001, \) OR 3.51 (95% CI 1.93–6.38) in the adjusted model. No failure rate differences between study settings were found for older patients (14–18 years).

Limitations: The difference between two groups was powered at 5 per cent. Some clinicians may consider a difference less than 5 per cent clinically significant.

Conclusion: Bonding Victory Series™ brackets with Transbond™ XT with or without Transbond™ MIP primer seems overall to work equally well in a clinical setting, except in younger children where lower failure rate was found in the primer setting.
Introduction
The bonding of brackets to enamel surfaces is the most crucial part of orthodontic treatment because adequate and stable bonding between brackets and enamel is decisive for treatment success. Bracket failure means longer treatment time for the patient and has economic consequences for the orthodontist because it requires increased resources.

Orthodontic bonding has evolved significantly since it was first introduced by Buonocore in the 1950s (1). The use of primer in orthodontic bonding is recommended by manufacturers, and it is postulated that enamel adhesion is ensured by mechanical interlocking between the etched enamel prisms and the polymerized liquid primers (1–3). Nonetheless, there is controversy in the literature regarding the use of primers because differences in the adhesion of orthodontic brackets to enamel with or without previous priming of the enamel surface have not been substantiated. For example, several in vitro studies have found comparable tensile bond strength with or without primer use (4–10), and these results have been confirmed by several in vivo studies assessing the exclusion of primer in orthodontic bonding (11–13). However, one of these studies was a retrospective study (11) with a relatively large risk of bias, one was a non-randomized clinical trial (13) with a risk of selection bias, and just one was randomized clinical trial (RCT) (12), so existing evidence regarding the matter is not substantial. Therefore, further RCTs would be beneficial.

If orthodontic bonding could be accomplished without the use of primer, it might be possible to reduce the risk of occupational exposure to primer and its unpolymerized components. Another advantage of not applying primer is that it saves a step and therefore saves time. This could be crucial when bonding brackets, because the longer it takes to place the brackets, the greater the possibility of moisture contamination that could result in bond failure.

Aims
The primary aim of this RCT was to evaluate the effects of primer on the bracket failure rate in orthodontic patients and thereby assess whether there is a difference in the number of emergency visits during the observation period between the groups. The secondary aim was to evaluate the effects of differences in patient characteristics on bracket failure and whether the effect of primer on bracket failure statistically interacts with gender, age, or bracket localization relative to the jaw.

Hypothesis
The null hypothesis was the following: There is no difference in the bracket failure rate and thereby number of emergency visits when Victory Series™ brackets are bonded with or without Transbond™ MIP Primer over an 18-month period.

Material and methods
Ethical approval
The Regional Ethical Review Board in Uppsala, Sweden, which follows the Helsinki Declaration guidelines, approved the study protocol.

Setting
Fifty consecutive patients participated in this study at the Postgraduate Dental Centre, Department of Orthodontics, Örebro County Council, Sweden.

Sample selection criteria
Inclusion criteria
- Patients requiring conventional bimaxillary fixed appliance therapy.
- An equal number of teeth on each side of the dental arch, with a minimum of four teeth per quadrant, was required.

Exclusion criteria
- Patients with buccal restorations.
- Patients with congenital enamel defects, that is hypomineralization.
- Patients requiring orthognathic surgery.

First and second molars were not included in the statistics because most of the molars were hand-bonded.

Trial design
A cross-mouth design was applied. In each patient, two diagonal quadrants (i.e. upper right and lower left or vice versa) were randomly assigned to the primer group (control group) and the contralateral diagonal quadrants to the non-primer group (experimental group).

The randomization process was as follows: A computer-manufactured block-randomization list was acquired using SPSS software version 17.0 (SPSS, Chicago, Illinois, USA) and stored with a research secretary at the Postgraduate Dental Education Centre. Each time a patient gave his or her consent, the secretary was contacted by e-mail, and the information about which quadrants were to be bonded with and without primer was obtained.

All the brackets in the study were bonded by the same operator using the following sequence. After placing a lip and cheek retractor, the labial enamel surface was professionally cleaned using oil-free pumice and adequate moisture control, using dental cotton rolls in the anterior segment, parotis dental rolls in the lateral segments, and a saliva ejector. The labial surfaces were etched with Ultra-Etch 35 per cent phosphoric acid gel (Ultradent Products, South Jordan, Utah, USA) for 30 seconds and then thoroughly rinsed for approximately 3–4 seconds per tooth. The labial surfaces were then air dried.

In the primer group, a very thin layer of Transbond™ MIP, Moisture Insensitive Primer (3M Unitek, Monrovia, California, USA) was applied to the enamel surface and rubbed in for 5 seconds, blown into the etched prisms using a 3-in-1 syringe, and light-cured for 10 seconds using a Planmeca Lumion (Planmeca Oy, Helsinki, Finland) LED polymerization light. Pre-adjusted metal brackets having either a 0.018” or 0.022” slot (Victory Series™, 3M Unitek) were then bonded using Transbond™ Plus (3M Unitek) and light-cured for 20 seconds. A check for occlusal interference was conducted. The process for the non-primer group was identical, except that primer was not applied.

Immediately after bonding, the patients were instructed about the maintenance of their appliances and about oral hygiene.

The same operator (AK) bonded all brackets on all patients to limit variability. The mechanics used in all cases was sliding mechanics. The patients were then followed for 18 months; all incidents of bracket failure and debonding noted in patient records during the 2012–14 observation period were compiled by the other co-author (HL), and thus were blinded to the operator.

Debonded brackets were rebonded and then removed from future counts.
Blinding
Co-author (HL) did not perform any orthodontic treatment on the study patients and thus was blinded to the study.

Outcome measures
The primary bracket failure rate in the experimental and control settings within a study period of 18 months was the outcome measure.

Sample size calculation
The number of study patients was estimated with respect to the bracket failure rate within 18 months. With 434 brackets per study group, the present study has 80 per cent statistical power to detect a rate difference of 5 per cent (5 and 10 per cent failure rates in the experimental and control groups, respectively) with a 5 per cent two-sided significance level. The present study planned to include 50 patients to allow for some potential drop-outs.

Statistical analysis
Logistic regression for repeated measurements using generalized estimating equations, with an exchangeable correlation structure within patients, was used to evaluate the bracket failure rate difference between the experimental and control settings. The adjusted model also included gender, age (categorized as 10–13 and 14–18 years), and bracket localization (maxilla or mandible). Second, in the adjusted model, interaction tests were used to determine whether failure rate differences between the study settings differed depending on age, gender, or localization. Logistic regression gives odds ratios (OR) with 95% confidence intervals (CIs) as a measure of association and the significance level was set to 5 per cent (two-sided).

Results

Patient flow
One patient (a boy) refused treatment in the lower jaw and therefore was excluded from the study. A total of 49 patients, 29 girls and 20 boys, with a mean age of 14.4 ± 1.8 [standard deviation (SD)] years, completed the trial. All patients were followed for 18 months (range ± 10 days). Figure 1 shows the CONSORT flow chart.

Baseline data
The baseline data and sample demographics are shown in Table 1.
Twenty-eight patients were treated without any extractions, 15 with 4 premolar extractions, and 6 with 2 premolar extractions in the maxilla. In all, 908 teeth were bonded, of which 454 were bonded with primer and 454 without primer. Overall, 39 bond failures occurred by the end of the trial.

The total failure rate in the non-primer setting was 5.5 per cent compared with 3.1 per cent in primer setting; unadjusted OR 1.80 (95% CI 0.98–3.34) and adjusted OR 1.89 (95% CI 0.97–3.68), see Table 2. Boys, younger patients (10–13 years), and mandible were significantly associated with higher failure rates.

Furthermore, the failure rate differences between settings displayed a significant interaction with age (P = 0.040). Among younger patients (aged 10–13 years), the failure rate of brackets bonded without primer (12.1 per cent) was significantly higher than that of brackets bonded with primer (4.1 per cent); OR 3.51 (95% CI 1.93–6.38). Among older patients (14–18 years), the difference in failure rate between the non-primer (2.3 per cent) and primer (2.6 per cent) settings was not significant; OR 0.88 (95% CI 0.28–2.78).

Figure 1. CONSORT flow chart.
The interaction tests with gender \((P = 0.078)\) and with localization \((P = 0.54)\) were not statistically significant.

**Discussion**

Clinical experience has suggested that some patients are more prone to bracket failure than others, possibly due to a multitude of factors, such as diet and tooth anatomy \((12)\). This study was a cross-mouth RCT in which each participant served as his or her own control, as their four quadrants were, diagonally, randomly allocated to each group on enrolment in the study. This design has the benefit of minimizing bias and ensuring that the observed effect is not dependent on specific participants and their oral habits, diets, and anatomical anomalies. Furthermore, the cross-mouth design of the current study ensured the same number of brackets in the two groups regardless of the extraction (2 or 4 premolars) and non-extraction treatments carried out.

**Main findings**

From the present RCT we conclude that the results of bonding brackets with or without Transbond™ MIP primer did not differ significantly in a clinical setting \((5.5 \text{ per cent versus 3.1 per cent}, P = 0.063, \text{ adjusted for all variables})\). The overall bracket failure rate found here is in accordance with that found in earlier published work \((14)\) for the premolar to premolar debond rate, but lower than that found by Nandhra et al. \((12)\), who reported a debond rate of 11.2 per cent with primer and of 15.8 per cent without primer. The primer used by Nandhra et al. \((12)\) was Transbond™ XT, which is more moisture sensitive than is the Transbond™ MIP used here. Transbond™ MIP has been demonstrated to work better in clinical situations even with slight saliva contamination than is Transbond™ XT \((15, 16)\). The choice of primer could be one of the explanatory factors underlying the differences in failure rates between the two studies; differences between the two operators could be another such factor. In addition, cultural and dietary aspects of the participants should be accounted for.

There was an actual difference in failure rate between age groups, genders, and arch distribution in our study: the younger age group \((10–13 \text{ years}; OR 3.54)\) had a failure rate 3.5 times higher than that of the older age group, boys \((OR 5.12)\) had a failure rate 5 times higher than that of girls, and lower arch \((OR 5.15)\) than that of upper arch. This stands in contrast to previous work finding no statistically significant differences between genders \((12)\), but in accordance with other studies regarding the localization of higher bracket failure rate in the mandible \((17–20)\). In the lower arch, the appliance is consistently under the influence of the upper teeth during mastication. This could be an unfavourable factor for appliance retention and a reason for more frequent bond failure in the lower arch.

Significant interaction tests revealed that, when stratified for age, the younger group \((10–13 \text{ years})\) had a significantly higher bracket failure rate without primer \((12.1 \text{ per cent})\) than with primer \((4.1 \text{ per cent})\); moreover, there was a 3.5 times higher risk \((OR 3.5)\) of bracket failure without primer in the younger group. The older group \((14–18 \text{ years})\)
displayed no such difference, the failure rate being 2.3 per cent without primer and 2.6 per cent with primer. The difference between age groups could be because the older patients are more mature; they are therefore somewhat more careful and take better care of their appliances than the younger ones. In normal cases, bonding without primer seems to work as well as bonding with primer, but in cases in which the patient endangers the brackets and exposes them to higher pressure, perhaps by biting on harder food or sweets, brackets bonded without primer appear to detach more easily than do ones bonded with primer.

Some studies find that orthodontic personnel have the highest incidence of hand dermatoses of all sorts of dental personnel (21, 22). Therefore, excluding the use of primer could reduce the risk of occupational exposure to its unpolymerized components. Another advantage of not applying primer is reduction in cost of materials and that it also saves a step and therefore saves time (23). The latter could be crucial in orthodontic bonding because the longer it takes to bond, the greater the possibility of moisture contamination that could result in bond failure.

The results of this RCT suggest that if one chooses to use primer in orthodontic bonding, it might be most beneficial to use it in the younger age group.

Over 90 per cent of the patients in the Department of Orthodontics in Örebro county council, are adolescents. Because the patients were included consecutively, the first 50 patients included in the study happened to just be adolescents. Therefore, no adults were treated within this study.

Generalization

The results of this study should be interpreted with some caution. The results are based on only one specific brackets system. Future RCT without primer and using different operators, different brackets, and different adhesives could better elucidate the actual effect of primer in orthodontic bonding.

Limitations

Some clinicians may consider a smaller difference than 5 per cent to be clinically significant, so the results of this study should be interpreted with some caution. No adults were treated in this study, which could be a limitation.

Conclusions

- Overall, bonding Victory Series™ brackets with versus without Transbond™ MIP primer made no significant difference (5.5 per cent versus 3.1 per cent failure rate) in a clinical setting over an 18-month period (P = 0.063).
- In the younger group (10–13 years), the risk of bracket failure was 3.5 times higher (OR = 3.51) in the non-primer (12.1 per cent) than the primer (4.1 per cent) setting.
- Younger participants (10–13 year) were 3.5 times more likely to experience bracket failure rate than were older participants (P = 0.002).
- Boys appear to be more prone to bracket failure than girls (P < 0.001).
- The failure rate is higher in the mandible than the maxilla (P < 0.001).

References