

Research Proposal

Use of a “flash-free” adhesive resin for orthodontic bracket bonding: a clinical study of bonding time, bond survival, and adhesive remnant cleanup

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Background:

The time required for bracket bonding and cleanup of remnant adhesive from the enamel surface after bracket debonding are important determinants of the duration of the two longest appointments during orthodontic treatment. The development of “flash-free” adhesives resin for orthodontic bracket bonding, which is due on the market in the near future, now promises a decrease in chair time for both patient and orthodontist. However, questions remain regarding the bonding time and bond survival of orthodontic brackets bonded using these adhesives, and the time required for adhesive remnant cleanup. These factors will be critical in determining the acceptance of these new “flash-free” adhesive resins in the orthodontic community.

Purpose:

The purpose of this study is to compare (1) bonding time, (2) bond survival, (3) amount of adhesive remaining on the tooth surface after bracket debonding, and (4) time required for adhesive remnant cleanup between a new “flash-free” and a conventional adhesive resin for orthodontic bracket bonding.

Methods:

Thirty consecutive patients presenting for comprehensive orthodontic treatment with fixed appliances at the University of Minnesota, who are willing to participate, will be included in the initial study. Selection criteria will include full permanent dentition through the first molars, teeth with sound, non-carious buccal enamel and no pretreatment with chemical agents such as hydrogen peroxide, and no previous orthodontic treatment with fixed appliances. The patients will have their maxillary incisors, canines, and premolars bonded with ceramic orthodontic brackets pre-coated with a “flash-free” adhesive resin (Clarity Advanced Brackets “flash-free”, 3M Unitek Monrovia, CA, USA) on one side and a conventional adhesive resin (Clarity Advanced Brackets APC II, 3M Unitek) on the other side. The side allocation and order of bonding will be randomized for each patient.

A total of ten calibrated clinicians will perform the clinical procedures together with their dental assistants.

Bonding time

The patient's teeth will be polished using a fluoride-free prophylaxis paste (Topex Prep&Polish, Sultan Healthcare, Hackensack, NJ, USA) on a rubber cup attached to a low speed handpiece, etched with 35% phosphoric acid (Temrex, Freeport, NY, USA) for 30 seconds, rinsed with water, air-dried, and primed using a conventional primer (Transbond Light Cure Adhesive Primer, 3M Unitek) following the manufacturer's instructions. The teeth will then be bonded according to the predetermined protocol with the "flash-free" product on one side (group 1) and the conventional (APC II) product on the other side (group 2) using a direct bonding technique. Excessive adhesive in group 2 will be removed with a sharp scaler. The adhesive will be light cured for 20 seconds (5 seconds on each side of the bracket) with a light-emitting diode polymerization device (Ortholux LED, 3M Unitek). The distance between the exit window and the adhesive surface will be maintained at less than 5 mm in order to obtain adequate polymerization. The time taken to bond each side will be timed to the nearest second using a digital stopwatch.

Bond survival

Possible bond failure will be recorded at standardized intervals of four weeks. In case of a bond failure, the patients will be asked about a possible explanation for the bond failure. Bond failure as a consequence of habits and trauma will be excluded from the evaluation.

Adhesive remnant cleanup

After completion of orthodontic treatment, the brackets will be debonded following the manufacturer's instructions. The order of debonding will be randomized for each patient. Once the brackets are debonded, the adhesive remnant index (ARI; Årtun and Bergland, 1984) will be scored under $\times 10$ magnification using an optical microscope (MVX10, Olympus, Tokyo, Japan).

Remaining adhesive will be removed from the tooth surfaces using a tungsten carbide finishing bur (H 283-21-012, Brasseler, Savannah, GA, USA) in a low speed handpiece until the enamel has regained its natural gloss (David *et al.*, 2002). Satisfactory removal of the remnant adhesive will be verified by visual inspection under a dental operating light. The time taken to clean up the residual adhesive in each quadrant will be timed to the nearest second using a digital stopwatch.

Statistical analysis

Descriptive statistics will be applied to the data to obtain mean values and standard deviations, and the data will be tested for normality (Kolmogorov-Smirnov test). Differences between the groups will be tested for statistical significance using a Student's *t*-test if the data are normally distributed and a Mann-Whitney U test if the data are non-normally distributed. Bracket survival times will be compared using a Cox's *F* test. A Cochran-Armitage test will be used to determine if there is an association between group membership and ARI. For all tests, *P*-values of less than 0.05 will be considered statistically significant.

Approval:

Approval to conduct this study will be obtained from the Institutional Review Board at the University of Minnesota. Informed consent will be obtained from all participating patients. In case of minors, consent will be obtained from a parent or guardian; assent will be obtained from the minor.

Anticipated outcomes:

Following completion of this study it is expected that significant information will be gained regarding the following:

1. The time required for direct bracket bonding with a “flash-free” orthodontic adhesive resin compared to a conventional adhesive resin together with a possible decrease in chair time when using a “flash-free” product.
2. Bond survival of brackets bonded with a “flash-free” orthodontic adhesive resin compared to a conventional adhesive resin.
3. The amount of adhesive remaining on the tooth surface after bracket debonding using the above products.
4. The time required for adhesive remnant cleanup using the above products and possible decrease in chair time when using a “flash-free” product.
5. An independent assessment of the clinical performance, suitable for peer-reviewed publication, of a new “flash-free” orthodontic adhesive resin.

References:

Årtun J, Bergland S (1984). Clinical trials with crystal growth conditioning as an alternative to acid-etch enamel pretreatment. *Am J Orthod* 85:333–340.

David VA, Staley RN, Bigelow HF, Jakobsen JR (2002). Remnant amount and cleanup for 3 adhesives after debracketing. *Am J Orthod Dentofacial Orthop* 121:291–296.