

Effect of antibacterial monomer-containing adhesive on enamel demineralization around orthodontic brackets: An in-vivo study

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Introduction: The aims of this study were to evaluate the effect of an antibacterial monomer-containing self-etching adhesive in reducing enamel demineralization around orthodontic brackets in vivo and to compare it with the conventional adhesive system quantitatively. **Methods:** Fourteen orthodontic patients were randomly divided into 2 equal groups; they received brackets fitted to all their teeth, bonded with either Clearfil Protect Bond (Kuraray Medical, Okayama, Japan) (experimental group) or Transbond XT (3M Unitek, Monrovia, Calif) (control group). Block randomization to obtain equal numbers in each group was used. After 30 days, all first premolars were extracted with orthodontic indications and longitudinally sectioned. Demineralization was assessed by cross-sectional microhardness. Determinations were made at the bracket edge cementing limits and at occlusal and cervical points 100 and 200 μm away from the edge. In all of these positions, 6 indentations were made at depths of 10 to 90 μm from the enamel surface. Analysis of variance (ANOVA) and the Tukey post-hoc test were used. The statistical significance level was set at $P < 0.05$. **Results:** ANOVA showed statistically significant differences for adhesive type, position, depth, and their interactions ($P < 0.05$). The multiple comparison test showed that the antibacterial monomer-containing adhesive was significantly more efficient than the conventional adhesive system, reducing enamel demineralization in almost all evaluations ($P < 0.05$). **Conclusions:** The results indicated that using antibacterial monomer-containing adhesive for bonding orthodontic brackets successfully inhibited caries in vivo. This cariostatic effect was localized at the area around the brackets and was significant after 30 days. (Am J Orthod Dentofacial Orthop 2011;139:650-6)

Despite the advances in orthodontic materials and treatment mechanics, the placement of fixed appliances is still linked with a high risk of developing white-spot lesions.^{1,2} The prevalence of new decalcifications among orthodontic patients with

fixed appliances is reported to range from 13% to 75%.^{1,2} Previous studies have shown that the rate of demineralization in orthodontic patients was higher than those without orthodontic treatment,³⁻⁵ and teenagers were at higher risk of demineralization than adults.⁵ Placement of fixed orthodontic appliances normally causes an increase in oral colonization by *Streptococcus mutans*, which in turn increases the risk for the development of dental caries.⁶

To inhibit the development of carious lesions in patients with fixed appliances, bacterial plaque around the appliances should be controlled, and a constant level of fluoride should be maintained in the oral cavity.^{7,8} It has been generally accepted that the combined application of fluoride regimens, oral-hygiene instructions, and dietary control can contribute greatly to the inhibition of demineralization during fixed-appliance treatment.⁹ These methods, however, rely on patient compliance. Fluoride-releasing bonding materials showed almost no demineralization-inhibiting effect.⁸ For that reason, it has been suggested that the combined use of antimicrobials and fluoride enhances the cariostatic effect.¹⁰

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The authors report no commercial, proprietary, or financial interest (ownership, stock holdings, equity interests and consultant activities, or patent-licensing situations) in the products or companies described in this article.

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Submitted, April 2009; revised, May 2010; accepted, June 2010.
0889-5406/\$36.00

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doi:10.1016/j.ajodo.2009.06.038

A new antibacterial and fluoride-releasing self-etching adhesive has been developed and introduced in the dental market. Imazato et al¹¹⁻¹⁴ reported the achievement of an antibacterial adhesive system by incorporation of the new monomer 12-methacryloyloxydodecylpyridinium bromide (MDPB) that has strong bactericidal activity against oral bacteria. Based on the results obtained for this experimental material, a new single-bottled 5% MDPB-containing primer was developed, and this 2-step mild self-etching and fluoride-releasing adhesive system with this primer was commercialized as Clearfil Protect Bond (Kuraray Medical, Okayama, Japan).

The bonding ability of antibacterial monomer-containing adhesive systems have evaluated *in vivo*,¹³ and the cytotoxicity,¹² antibacterial effect,¹⁴ and shear bond strength of brackets¹⁵ or lingual retainer adhesives¹⁶ have been demonstrated by *in-vitro* studies. However, no studies have been performed to investigate the efficiency of this material on enamel demineralization around orthodontic brackets.

Therefore, the aims of this study were to evaluate the effect of an antibacterial MDPB-containing adhesive in reducing enamel demineralization around orthodontic brackets *in vivo* and to compare it with conventional adhesive systems quantitatively. In this study, the null hypothesis assumed that the antibacterial monomer-containing adhesive suggested for bracket bonding can significantly reduce the overall amount of demineralization around orthodontic brackets in the mouth.

MATERIAL AND METHODS

This study was approved by the Ethical Committee on Research of Gulhane Military Medical Academy, Ankara, Turkey. Fourteen orthodontic patients, 13 to 17 years of age (mean, 14.30 ± 1.65 years), scheduled to have 4 first premolars extracted for orthodontic reasons, were invited to participate and signed a consent form. This study was organized as a parallel group design with 1 group receiving the experimental material and the other serving as the control. A power analysis was established by G*Power software (version 3.0.10, Franz Faul, Universität Kiel, Kiel, Germany). Based on a 1:1 ratio between groups, a sample size of 14 patients would give more than 80% power to detect significant differences with a 0.40 effect size and at $\alpha = 0.05$ significance level. The patients were divided into 2 groups of 7 each. Block randomization to obtain equal numbers in each group was used. For group standardization, before starting the procedure, all patients' teeth were evaluated clinically and radiographically to determine the baseline carries risk. Eight participants (57%) were boys, and 6 (43%) were girls.

In group 1 (Transbond XT, 3M Unitek, Monrovia, Calif; control), there were 4 boys and 3 girls (mean age, 13.85 ± 1.40 years); in group 2 (Clearfil Protect Bond, antibacterial MDPB-containing adhesive), there were 4 boys and 3 girls (mean age, 14.80 ± 1.85 years).

Salivary flow rate and buffer capacity of the patients were recorded. The criteria for including patients were no active caries lesions, normal salivary flow rate (>1.0 mL/min), and buffer capacity (final pH, 6.7-7.7). All patients received a full-mouth cleaning to remove plaque in preparation for bonding. There were no visible signs of caries, fluorosis, or developmental defects in the teeth used. For evaluating the baseline demineralization values of all selected teeth, a portable battery-powered laser fluorescence device, DIAGNOdent Pen (KaVo, Biberach, Germany), was used,¹⁷ and the 2 groups' scores were low (<13) indicating no demineralization; both were equivalent for caries risk. Orthodontic brackets were bonded with 1 of the following methods.

In group 1 (Transbond XT, control), all teeth were etched for 15 seconds with 37% ortho-phosphoric acid (3M Dental Products, St Paul, Minn), rinsed with water from a 3-in-1 syringe for 15 seconds, and dried with an oil-free source for 15 seconds. Before bracket placement, Transbond XT primer was applied to the etched surfaces in a thin uniform coat. The primer was cured for 10 seconds. Adhesive paste (Transbond XT) was applied to the bracket base, and the bracket was positioned on the facial surface and pressed firmly into place. The excess adhesive was removed from around the bracket with a scaler.

In group 2 (Clearfil Protect Bond), all teeth were etched similar to group 1 for 15 seconds. The self-etching primer containing the antibacterial monomer Clearfil Protect Bond was applied to the etched surfaces for 20 seconds and sprayed with a mild air stream to evaporate the solvent. Then Clearfil Protect Bond was applied, gently air dried, and light cured for 10 seconds. After these steps, a thin layer of the Transbond XT adhesive paste was also applied to the base of the bracket and immediately pressed into the adhesive on the tooth surface.

Stainless steel orthodontic premolar brackets (Dyna-Lok series, 3M Unitek) were bonded by a standard protocol. A light-emitting diode light unit (Elipar Freelight 2, 3M ESPE, St Paul, Minn) was used for curing the specimens for 20 seconds.

For the testing procedure, 28 brackets were cemented for each group (14 maxillary and 14 mandibular first premolars in both groups). After 30 days, the brackets were removed; the teeth were extracted and stored in a refrigerator in flasks containing gauze dampened with 2% formaldehyde, pH 7.0, until the analysis. Demineralization in the enamel around the brackets was

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