# Effect of a hydrophobic tooth coating on gingival health, mutans streptococci, and enamel demineralization in adolescents with fixed orthodontic appliances

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The effect of an anti-adhesive enamel coating on plaque accumulation, gingival health, and enamel demineralization was evaluated in 39 adolescents undergoing treatment with fixed orthodontic appliances using a prospective split-mouth design. Immediately after bracket insertion, the polymer was randomly applied after enamel etching to the buccal surfaces of the teeth in the left or right upper quadrant, leaving the opposite quadrant as an untreated control (218 test and 216 control teeth). Reapplications were carried out every 3rd month during the course of the study. The following data were collected at baseline and at designated follow-ups: visible plaque index, total viable counts and proportion of mutans streptococci in plaque samples, gingival bleeding index, and amount of gingival crevicular fluid. The incidence of enamel demineralization adjacent to the appliances was scored clinically at the termination of the orthodontic treatment. The observation time ranged from 6–24 months, during which the participants used fluoride rinses and toothpaste daily. A slightly impaired gingival health and increased levels of mutans streptococci compared with baseline was disclosed during the treatment. Five subjects showed enamel demineralization on a total of 30 teeth at the time of de-bonding. The results indicated no statistically significant differences between the enamel-coated and untreated teeth with regard to the studied variables at any follow-up. In conclusion, the present findings did not support a clinically beneficial effect of the polymeric tooth coating in a low-caries group of adolescents treated with fixed orthodontic appliances. □ *Dental caries; enamel coating; hydrophobic polymer; orthodontic appliances*

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Orthodontic treatment with fixed appliances may be associated with an extensive plaque accumulation that can jeopardize oral health, and enamel demineralization (white spots) and gingival inflammation are frequently reported side effects (1, 2). Consequently, various preventive measures have been suggested in adjunction to thorough oral hygiene instruction. The most common regimens are without doubt based on the application of fluoride and/or antibacterial agents (3–5). These methods are, however, more or less dependent on either a professional performance or patient compliance. An ideal preventive method is one that can act independently of patient cooperation. An interesting approach to combating the potential oral health problem is to interfere with the early plaque formation and subsequent bacterial accumulation. A hydrophobic enamel-coating polymer with anti-adhesive properties has been developed, and promising data from studies in vitro (6) and in vivo (7) were recently presented. The tooth coating may also act as a barrier that can protect the underlying enamel from the acids produced by plaque during the fermenting process (6). Professional preventive measures are especially suitable for orthodontic patients since they are scheduled for regular follow-ups. Therefore, it was of interest to investigate the possible benefits of this polymer under clinical field conditions. The aim of the present clinical study was to evaluate the effects of a polymeric tooth coating on plaque accumulation and levels of mutans streptococci, gingival health, and enamel caries incidence in adolescents undergoing treatment with fixed orthodontic appliances. The null hypothesis was that these variables would not differ between experimental and control teeth.

## Materials and methods

### *Subjects*

The study group consisted of a convenience sample of 40 healthy adolescents of both sexes (23 girls and 17 boys) that were selected from those referred to the Medical and Dental Health Center, Halmstad, Sweden, for orthodontic treatment with fixed appliances. The inclusion criteria were non-compromised health and at least 10 maxillary brackets, with expected treatment duration of approximately 1 year. The mean age was 14.5 years (range, 12.4–18.8 years), and the participants and their parents consented to participate in the study after verbal and

Table 1. Percentage distribution of gingival bleeding index (GBI, %) at baseline and at designated time intervals in adolescents with fixed orthodontic appliances treated with a polymeric tooth coating and in untreated controls

| | Test | | | Control | | |
|---|---|---|---|---|---|---|
| | 0% | 1%–19% | >20% | 0% | 1%–19% | >20% |
| Baseline | 80 | 13 | 7 | 78 | 15 | 7 |
| 3 months | 75 | 22 | 3 | 81 | 14 | 5 |
| 6 months | 81 | 16 | 3 | 81 | 14 | 5 |
| 9 months | 68 | 16 | 16 | 72 | 18 | 10 |
| 12 months | 67 | 20 | 13 | 67 | 23 | 10 |
| 15 months | 73 | 13 | 14 | 77 | 10 | 13 |

written information. All subjects were living in an area with a low natural fluoride level in the piped drinking water (0.1 ppm) and used fluoridated toothpaste twice daily. One boy gave up the treatment immediately after baseline and was therefore excluded.

### *Study design*

A prospective split-mouth design was used, and the study protocol was approved by the Ethical Committee at Lund University, Lund, Sweden. Baseline registrations and samplings were performed in the upper quadrants before the insertion of the orthodontic appliances. After bracket insertion, the polymer coating was applied randomly to the buccal surfaces of all teeth of the first or second quadrant, leaving the teeth in the opposite quadrant as untreated controls. A total of 218 experimental and 216 control teeth were included in the study. Follow-up registration and samplings were performed at 3-month intervals during the entire treatment period. The incidence of enamel demineralization was scored immediately after de-bonding. Before the insertion of appliances, the participants were thoroughly instructed and trained in oral hygiene procedures, including daily fluoride rinses with a 0.025% sodium fluoride solution.

### *Clinical procedures*

The hydrophobic material used in this study was a novel substantive polymeric tooth coating (3M, St. Paul, Minn., USA), a copolymer of acrylic acid, alkylmethacrylate, and polydimethylsiloxane (8). The coating was applied to the enamel in the test quadrants immediately after the bracket bonding procedure in accordance with the instructions of the manufacturer. After professional tooth cleaning, drying, and etching, adhesive-coated brackets (Victory Twin, APC, 3M Unitek, Monrovia, Calif., USA) were bonded to the enamel with Transbond (3M Unitek) resin. All excessive material was removed before the 40-sec light-curing procedure. The experimental polymer was then applied without further etching in a thin layer on the enamel surface with a small brush, allowing the entire buccal surface to be coated. The hydrophobic coating was left to dry for at least 1 min, and the participants were instructed not to eat or drink for 1 h. Reapplications were carried out every 3rd month during the course of the study after professional cleaning and etching with 10% citric acid for 30 sec. All clinical procedures were carried out by two specially educated dental hygienists.

### *Clinical registration*

*Caries score.* Caries prevalence at baseline (DMFS) was scored clinically in accordance with the WHO-criteria (9). The number of interdental lesions within the enamel was assessed from bitewing radiographs in accordance with Gröndahl et al. (10). In addition, the enamel surfaces of all teeth planned for band and bracket bonding were thoroughly examined by visual inspection before the insertion of the appliances and immediately after removal by one blinded examiner. The incidence and localization of enamel demineralization (white spots) was scored in accordance with Zachrisson & Zachrisson (11).

*Plaque accumulation.* The amount of dental plaque adjacent to the upper band and brackets was scored on the basis of the visible plaque index (12). The presence of dental plaque was made visible by using a discoloring agent, and the frequency in each individual was estimated. Plaque samples were collected and pooled from both the coated and the uncoated teeth and cultivated as described below.

*Gingival health.* The extent of gingival inflammation was assessed by means of the gingival bleeding index (GBI) in accordance with Axelsson & Lindhe (12). The frequency of surfaces with gingivitis for each individual was based on bleeding on probing at six points around each tooth, using a periodontal probe with standardized pressure. In addition, the amount of gingival crevicular fluid (GCF) was measured on the upper canines and second premolars. A paper strip (Periopaper, ProFlow, Amityville, N.Y., USA) was placed into the gingival buccal sulcus for 15 sec after gentle drying with compressed air. The volume of GCF (in microliters) was quantified immediately, using a calibrated Periotrone 8000 (ProFlow).

### *Microbial procedures*

Plaque samples were gently collected and pooled in a standardized manner from the coated and uncoated teeth by the aid of a sterile wooden toothpick. The tips of the

Table 2. Mean volume (μL ± standard deviation (*s*)) of gingival crevicular fluid at baseline and designated times in adolescents with fixed orthodontic appliances after treatment with a polymeric coating (test) and in untreated controls

| | | Test | | Control | | |
|---|---|---|---|---|---|---|
| Time | *n* | Canine, mean ± *s* | Premolar, mean ± *s* | Canine, mean ± *s* | Premolar, mean ± *s* | *P* |
| Baseline | 39 | 0.3 ± 0.1 | 0.4 ± 0.1 | 0.4 ± 0.1 | 0.4 ± 0.1 | NS |
| 3 months | 39 | 0.4 ± 0.1 | 0.6 ± 0.2 | 0.5 ± 0.1 | 0.7 ± 0.2 | NS |
| 6 months | 36 | 0.5 ± 0.2 | 0.5 ± 0.2 | 0.5 ± 0.2 | 0.6 ± 0.2 | NS |
| 9 months | 26 | 0.5 ± 0.2 | 0.5 ± 0.2 | 0.5 ± 0.1 | 0.6 ± 0.2 | NS |
| 12 months | 22 | 0.7 ± 0.2 | 0.6 ± 0.2 | 0.7 ± 0.2 | 0.8 ± 0.3 | NS |
| 15 months | 16 | 0.8 ± 0.3 | 0.8 ± 0.3 | 0.8 ± 0.2 | 0.9 ± 0.3 | NS |

NS = not significant. $P > 0.05$, Student paired *t* test.

toothpicks were cut off into a vial with an RTF transport medium and brought to the laboratory within 6 h. After a 30-sec dispersion, the samples were serially diluted in 10-fold steps in a 0.005 M sodium phosphate buffer with 0.4% KCl (pH 7.1). Aliquots of 25 μL were then placed in duplicate on brain heart infusion (BHI) (Difco, USA) agar with 4% horse blood, to determine total viable counts, and on mitis salivarius bacitracin (MSB) agar for enumeration of mutans streptococci (13). The MSB and BHI agar plates were incubated microaerophilically at 37°C in GasPak (BBL, USA) jars for 48 h and 36 h, respectively. Colony-forming units (CFU) were identified and counted in a stereomicroscope. Mutans streptococci growth was expressed as proportion of total viable counts.

### *Statistical methods*

Data were subjected to the Student paired *t* test or the non-parametric Wilcoxon paired test.

## Results

The mean treatment period with fixed orthodontic appliances was 14.7 months, ranging from 6 to 24 months. Ten subjects had their appliances for more than 18 months, and the average number of polymer applications was 4.8 (range, 2–8). The prevalence of caries at baseline was 2.80 DMFS (standard deviation (*s*), ± 4.44; range, 0–19) and the number of interdental enamel lesions scored from bitewing radiographs was 1.57 (*s*, ± 2.74; range, 0–11).

The level of oral hygiene was found to be fairly stable during the course of the study, and the percentage of sites with visible plaque ranged from 25% to 45% at the designated follow-ups. No statistically significant differences between the coated and uncoated teeth were disclosed at baseline or at any of the follow-ups.

The percentage distribution of the gingival bleeding index is presented in Table 1. A slightly increased number of bleeding sites was registered in both the test and the control quadrants with time, but the quadrants did not differ statistically from each other. The volume of GCF is shown in Table 2. In general, the amount of GCF increased slightly with time, thus reflecting the impaired gingival condition. There were, however, no significant differences between the experimental and control canines or premolars at baseline or at any of the designated follow-ups.

Data on the microbial findings are presented in Table 3. Mutans streptococci were detected in the plaque of 28 children (74%) at baseline, and the proportion of mutans streptococci in relation to the total viable count increased slightly with time in both test and control quadrants. There were no significant differences in total viable counts or the levels of mutans streptococci between experimental and control quadrants.

Five subjects (13%) developed enamel demineralization (white spots) adjacent to the bracket base on a total of 30 teeth during the study period. Fourteen were located in test quadrants, and 16 were located on the control side. Four of the children who developed enamel demineralization showed white spots on smooth surfaces already at baseline.

Table 3. Percentage colony-forming units of mutans streptococci (mean ± standard deviation (*s*)) in relation to total viable counts in plaque samples collected adjacent to fixed orthodontic appliances at baseline and designated times from teeth with a polymeric coating (test) and untreated controls

| Time | *n* | Test, mean ± *s* | Control, mean ± *s* | *P* |
|---|---|---|---|---|
| Baseline | 39 | 3.0 ± 6.1 | 4.9 ± 14.2 | NS |
| 3 months | 39 | 2.5 ± 3.4 | 3.4 ± 6.7 | NS |
| 6 months | 36 | 6.1 ± 13.7 | 6.5 ± 12.0 | NS |
| 9 months | 24 | 3.2 ± 9.5 | 4.1 ± 8.1 | NS |
| 12 months | 22 | 4.1 ± 11.4 | 2.1 ± 3.5 | NS |
| 15 months | 16 | 8.0 ± 16.1 | 4.7 ± 7.6 | NS |

NS = not significant. $P > 0.05$, Wilcoxon paired test.

## Discussion

This study was designed to evaluate whether the use of an

experimental anti-adhesive polymeric tooth coating could be beneficial for children treated with fixed orthodontic appliances when assessed by means of well-established clinical indices of oral health. The novel approach was that the tooth coating was applied already at the insertion of the appliances, which theoretically would enhance the possibility of affecting the developing plaque community. In general, the participants showed low caries prevalence and good gingival conditions at baseline, and before the start of treatment they were thoroughly trained in oral hygiene procedures, and a fluoride-rinse program was introduced. In spite of this, the level of oral hygiene was far from optimal in many subjects during the study period. Nevertheless, it must be emphasized that the findings from this study group might not be representative for a population with a higher level of oral diseases or with an increased caries risk. The fluoride rinses could not be stopped for ethical reasons, but a larger material with higher caries incidence could possibly have increased the power to unveil a positive outcome. On the other hand, Hausen et al. (14) have recently shown that even intensified prevention in high-risk patients has failed to reduce caries increments. The study had only one dropout, a boy who aborted treatment already after 1 month. Furthermore, the treatment plan of two other participants was after 6 months changed to removable appliances. The handling of the coating was rapid and smooth, and it should be noted that no adverse reactions or staining were experienced.

A slight general impairment of the oral health was seen during the course of the study, which was in harmony with several previous observations (for a review, see Ref. 2). Bleeding on probing and the GCF volume increased hand in hand compared with baseline in both the test and control quadrants. In contrast to previous findings (7, 15, 16), we failed to show any beneficial effect of the hydrophobic coating on the plaque accumulation. It should, however, be emphasized that the above-mentioned investigators used a sophisticated digital image technology to monitor plaque growth with a high degree of precision. On the other hand, it can be argued that the index used in the present study is what the clinician is able to register in everyday work. Thus, if a certain plaque-preventive effect occurred after the polymeric coating, it could be too modest to be disclosed by the visible plaque index used.

The volume of GCF is an early and sensitive indicator of gingival health compared with the regular clinical observations such as the bleeding on probing index. The GCF levels increased slightly with time, indicating a mechanical and microbial challenge exerted by the appliances. Our findings can be biased by the fact that the levels of GCF might increase as a result of the tooth movement itself (17), and it can also be influenced by hormonal fluctuations, frequently seen in this age group as puberty gingivitis. However, as the split-mouth design overcomes such confounding factors to a certain extent, our results did not suggest a beneficial effect of the experimental coating on gingival health in this study group.

In accordance with previous findings (18), the proportion of mutans streptococci in plaque increased after the insertion of the brackets, but the experimental teeth did not differ from the control teeth. In the recent study by Resch (7) a definite reduction in cariogenic and total bacterial adherence on the polymer-bonded enamel was seen in subjects with a high risk for caries. The patients participating in our study showed mainly a low caries risk that might explain the diverging findings. Therefore, we compared the experimental and control teeth in those with a caries prevalence above average at baseline (>3 DMFS), but again without any significant differences. It could here be underlined that a plaque reduction per se might not be the ultimate goal of an anti-adhesive strategy. The crucial point for pathogenicity is the composition of the biofilm attaching to the tooth surface, not the amount of plaque. Thus, a plaque composed of increased proportion of commensal (healthy) bacteria as a result of an intervention is likely of true benefit for the patient. Such an effect has been indicated by Resch (7) and needs further elucidation.

The incidence of enamel demineralization adjacent to the bracket base was of expected magnitude in the present material, but we found no evidence of a caries-protective barrier executed by the coating. Previous studies with other enamel sealants during orthodontic treatment have disclosed similar results (19, 20). When taking a closer look at the five subjects who developed new lesions during the present study, no unambiguous risk factor was evident. All were, however, colonized with mutans streptococci already at baseline, and their level of oral hygiene was worse than average. Furthermore, four of the subjects had at least two follow-ups with a gingival bleeding index >20%. As a contrast, it should be mentioned that one subject who developed five new demineralization sites was totally caries-free at the baseline examination, which illustrates the complexity and difficulties involved in caries-risk assessment procedures.

The reason for the non-favorable outcome of the present study is not fully clear. It has been speculated that the polymeric coating material may substantially reduce the free energy of the enamel and repel species in aqueous medium (6), and its anti-adhesive effect has been documented for up to 3 months (16). A prerequisite for this event is of course a complete retention of the material to the enamel. It should be stressed that owing to the transparency of the coating, we were unable to detect and verify whether retention was achieved or to check the duration of the applications.

In conclusion, the present findings failed to show any clinically significant effect of an anti-adhesive polymeric enamel coating used in adjunction to orthodontic appliances in adolescents with low caries activity. Thus, the null hypothesis could not be rejected. The ability of the coating to promote gingival health and protect enamel from demineralization, however, warrants further elucidation in high-risk subjects before the concept is called into question.

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