ORIGINAL ARTICLE

Effects of sealant and self-etching primer on enamel decalcification. Part II: An in-vivo study

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Introduction: A self-etching primer (SEP) saves valuable time by eliminating the many steps required to etch, rinse, and place a sealant before application of the adhesive and placement of the bracket. The purpose of this study was to compare the effects of a conventional etch and sealant (CES) and a SEP on enamel decalcification in vivo. **Methods:** Twenty-five patients who required comprehensive orthodontic treatment were included in this study. Before bonding, enamel surfaces were treated with either a CES (Light Bond, Reliance Orthodontic Products, Itasca, Ill) or a SEP (Transbond Plus, 3M Unitek, Monrovia, Calif) by using a split-arch technique. At the end of the observation period (18-24 months), the O'Leary plaque index was used to determine patients' oral-hygiene compliance, and enamel decalcification around the orthodontic bracket was scored based on the amount and severity of decalcification. Scanning electron microscopy images and x-ray spectrum analysis were performed to examine the etched pattern of the 2 bonding systems. Data were analyzed by using analysis of variance (ANOVA) and the Tukey-Kramer test; the confidence level was set at a significant level of $P = 0.05$. **Results:** Significantly higher decalcification scores were found in the SEP group (27.5%) compared with the CES group (13.9%, $P < 0.001$). No significant differences were found in the decalcification scores for teeth in the maxillary and mandibular arches. Significant differences were found between level of hygiene and decalcification ($P < 0.0001$). Patients with fair or poor hygiene compliance had higher decalcification scores in the SEP group than in the CES group. **Conclusions:** Using a SEP might save chair time and improve cost-effectiveness, but it provides less resistance to enamel decalcification than a CES, especially in patients with poor oral hygiene. (Am J Orthod Dentofacial Orthop 2009;135:206-13)

Fixed orthodontic appliances make it difficult for young patients to maintain adequate oral hygiene during treatment. The tooth surface adjacent to bonded attachments is particularly susceptible to caries. Several studies have found increased plaque around orthodontic appliances.[1,2] Other studies reported increases in *Streptococcus mutans* and Lactobacillus species in the oral cavity after placement of fixed orthodontic appliances.[3] Higher concentrations of these bacteria increase the risk of decalcification.[4] The bacteria in the plaque produce organic acids, which cause dissolution of calcium and phosphate ions from the enamel surface. This results in the formation of white spots or early carious lesions in only 4 weeks.[5-8] If the diffusion of ions away from the tooth surface continues, cavitation of the enamel surface will result.

Several methods have been used to prevent or reduce enamel decalcification during orthodontic treatment, including fluoride application in various forms, enamel sealants, rigorous oral-hygiene regimens, and modified appliance designs. Application of a sealant layer after etching has been shown to prevent enamel decalcification in vitro.[9] The application is usually a 2-step procedure involving etching of the enamel with phosphoric acid and application of a primer or sealant before orthodontic bracketing. A new product, Transbond Plus self-etching primer (SEP) (3M Unitek, Monrovia, Calif), allows etching and priming of enamel in 1 step. The SEP contains a methacrylated phosphoric acid ester. No rinsing is necessary after application, so dissolved calcium forms a complex with the phosphate group and subsequently is incorporated into the resin matrix. The advantage of this product is that it saves chair time.[10,11] Its disadvantage is the omission of the sealant layer that might make the

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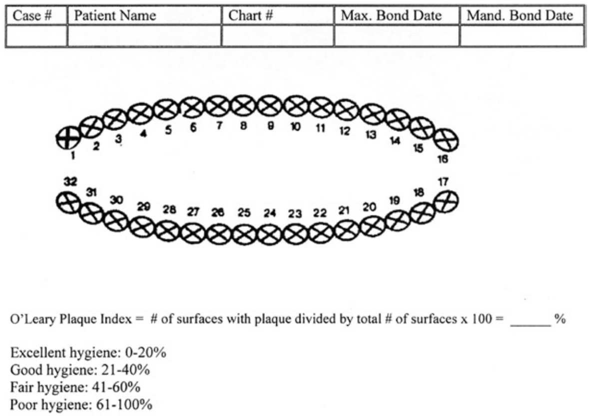


Fig 1. Determination of a patient's oral-hygiene compliance by using the O'Leary plaque index.

etched enamel vulnerable to enamel decalcification. The acidic complex that remains in the resin network when the primer polymerizes also can lower the pH of the enamel surface. The purpose of this study was to determine the effects of a sealant compared with a SEP on enamel decalcification around orthodontic brackets in vivo.

MATERIAL AND METHODS

Twenty-five patients who met the criteria for selection at the Department of Orthodontics, West Virginia University School of Dentistry, were recruited for the study. These criteria included (1) permanent dentition in both arches; (2) no previous orthodontic treatment; (3) comprehensive orthodontic treatment, with fixed appliances, planned to be completed between 18 and 24 months; and (4) no detectable decalcification on the surface of the tooth to be bonded in the maxillary and mandibular dentition. A split-mouth technique was used, allowing each patient to serve as his or her own control. Plaque was scored at pretreatment and throughout the treatment according to the O'Leary plaque index[12] to determine oral-hygiene compliance (Fig 1). An initial plaque index was taken before treatment, 4 plaque scores were taken during treatment, and 1 was taken after treatment. The plaque scores were averaged to determine the patient's final hygiene score. Based on the final hygiene score, a patient was assigned a hygiene grade of excellent (E), good (G), fair (F), or poor (P). E meant 0% to 20% plaque, G meant 21% to 40%, F meant 41% to 60%, and P meant 61% to 100%. All patients received the same oral hygiene instructions after the bonding procedure and during treatment when needed. These instructions included flossing and brushing with fluoridated toothpaste. Two bonding systems were used to prepare the enamel surface for bonding: a conventional etch-sealant system (CES) (Light Bond, Reliance Orthodontic Products, Itasca, Ill) and a SEP system, Transbond Plus (3M Unitek). The patients were randomly assigned to have the CES used on 1 arch and the SEP on the other arch. Twelve patients were bonded with the CES in the maxillary arch and the SEP in the mandibular arch; 13 patients had the SEP in the maxillary arch and the CES in the mandibular arch.

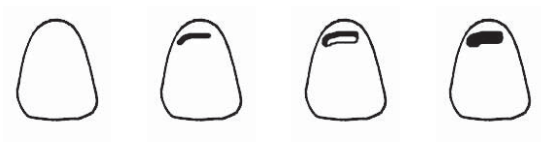
For the CES, the teeth were cleaned with nonfluoride oil-free pumice and etched with 37% o-phosphoric acid for 30 seconds. They were rinsed for 10 seconds and dried thoroughly until the area appeared frosty. A thin coat of primer/sealant (Light Bond light cure sealant resin, Reliance Orthodontic Products) was applied on the etched surface and light-cured for 10 seconds. Resin adhesive (Light Bond composite resin, Reliance Orthodontic Products) was applied, and the bracket was positioned firmly with even pressure on the tooth surface. Excess composite was removed around the bracket base with a scaler before curing with an Ortholux light unit (3M Unitek) for 20 seconds: 10 seconds each on the distal and mesial aspects of each bracket.

For the SEP, the teeth were cleaned with nonfluoride oil-free pumice. Chemicals from different reservoirs were squeezed into and mixed in the dispensing reservoir. The buccal surface of each tooth was etched and primed in 1 stage by rubbing the enamel with a microbrush applicator saturated with SEP for 3 to 5 seconds, followed by drying lightly with oil-free compressed air as recommended by the manufacturer. Composite resin was then applied, and the bracket was positioned firmly on the tooth surface. Excess composite was removed around the bracket base with a sharp dental probe before curing with the same light unit for 20 seconds: 10 seconds on the mesial and 10 seconds on the distal aspects of each bracket.

After orthodontic treatment, decalcification on enamel was scored by one of the authors (M.A.G.). Clinical examinations were performed by using both tactile and visual senses to determine decalcification on enamel. Scoring was done based on the amount and severity of decalcification on the selected teeth (1, no white spots or decalcification; 2, slight white-spot formation or decalcification in 1 area; 3, severe white-spot formation or many areas of decalcification; 4, excessive white-spot formation and cavitation) (Fig 2).

Four extracted third molars were analyzed with a scanning electron microscope (SEM) to compare the surface irregularities of the different surface treatments. For the first tooth, the enamel surface was cleaned with nonfluoride oil-free pumice, rinsed with water, and

Decalcification Score: ______________________________



Score 1 Score 2 Score 3 Score 4

Score 1 = No decalcification
Score 2 = Slight decalcification (one area)
Score 3 = Large area or multiple areas
Score 4 = Cavitation present

Fig 2. Enamel decalcification scoring based on the amount and severity of decalcification.

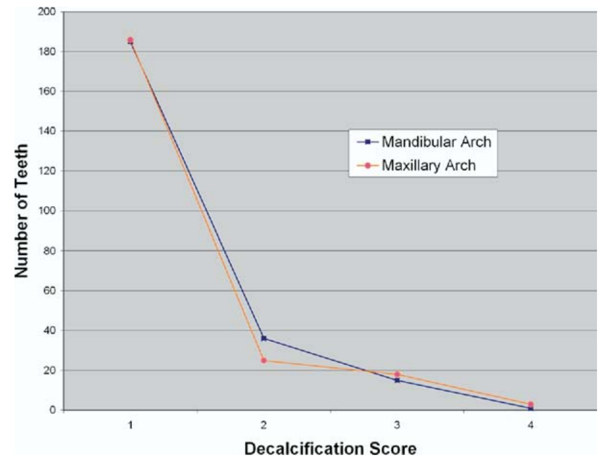


Fig 3. Decalcification score according to location.

allowed to dry for 24 hours. For the second tooth, the surface was cleaned with nonfluoride oil-free pumice, rinsed with water, and etched with 37% phosphoric acid for 30 seconds. The teeth were then rinsed with water and allowed to dry for 24 hours. For the third tooth, the surface was cleaned with nonfluoride oil-free pumice, rinsed with water, and etched with 37% phosphoric acid for 30 seconds. The tooth was then rinsed with water for 10 seconds and air dried, and a thin coat of sealant was applied, and the tooth was light-cured and allowed to dry for 24 hours. For the fourth tooth, the surface was cleaned with nonfluoride oil-free pumice, rinsed with water, and dried. The tooth was etched and primed with SEP according to the manufacturer's instructions, light-cured for 30 seconds, and allowed to dry for 24 hours.

Once the teeth were prepared, each tooth was analyzed with a 1500-times magnification factor by the SEM (model JSM-6400, JEOL, Tokyo, Japan). An x-ray spectrum analysis was performed on the surfaces treated with CES and SEP by using a spectrometer (Princeton Gamma Tech X-ray, Princeton, New Jersey).

Statistical analysis

Significant differences in the frequency of decalcification among the groups were determined with 1-way analysis of variance (ANOVA) and the Tukey-Kramer multiple comparisons test. The level of significance was set at $P \leq 0.05$. Intraexaminer error was determined by using the reliability coefficient.

The method error was determined by rescoring 226 surfaces. This was performed 1 and 2 months after the initial decalcification scoring. The examiner (M.A.G.) was unaware of the location of the bonding agent, and the previous hygiene and decalcification scores for that surface. The surface decalcification scores were then compared with the initial score, and a reliability coefficient was determined for this model. The reliability coefficient was 0.903, indicating no significant intrarater differences ($P < 0.0001$).

RESULTS

A total of 469 teeth were scored for decalcification. We found that 371 (79%) teeth had a score of 1 (no white spot formation), 61 (13%) had a score of 2 (slight white spot formation or decalcification), 33 (7%) had a score of 3 (severe white spot formation or many small areas of decalcification), and 4 (1%) had a score of 4 (cavitation).

A total of 237 teeth were bonded in the mandibular arch and 232 teeth in the maxillary arch. No significant differences were found in the overall decalcification scores between the arches ($P = 0.85$). The mean scores for decalcification in the mandibular and maxillary arches were 1.29 and 1.30, respectively (Fig 3).

Of the 469 teeth in this study, 32.4% had excellent hygiene (E), 40.3% had good hygiene (G), 12.4% had fair hygiene (F), and 14.9% had poor hygiene (P). The ANOVA showed a significant difference between hygiene status and decalcification score ($P < 0.0001$). Multiple comparisons tests showed no significant difference between the E and G groups. Significant differences were found between groups E and F, E and P, G and F, G and P, and F and P. The mean decalcification score of all patients increased as the hygiene level decreased from excellent to poor (Fig 4).

Of the 236 teeth bonded with the SEP, 171 (72.4%) had a score of 1 (no white spots), 41 (17.4%) had a

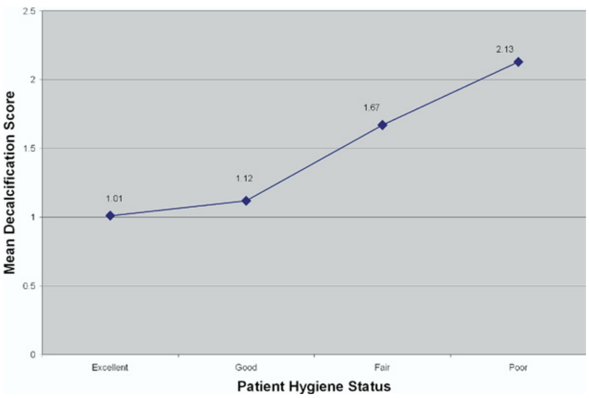


Fig 4. Decalcification score according to hygiene compliance.

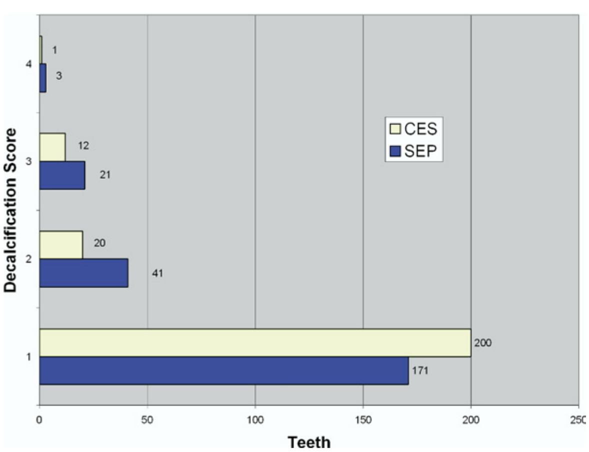


Fig 5. Decalcification score according to bonding agent.

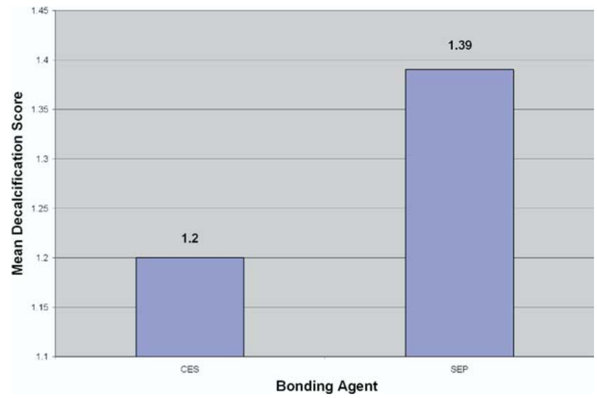


Fig 6. Overall decalcification score according to bonding agent.

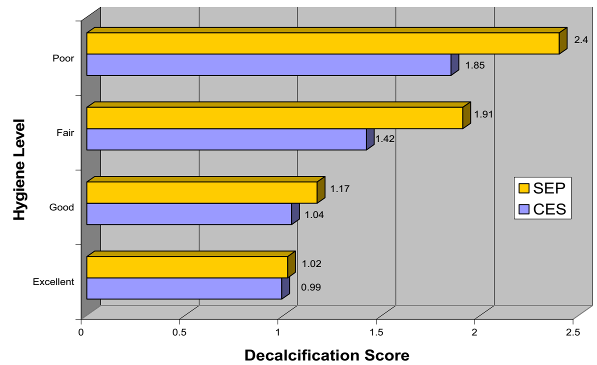


Fig 7. Decalcification score according to agent and hygiene interaction.

score of 2 (slight white spots), 21 (8.9%) had a score of 3 (multiple areas of white spot formation), and 3 (1.3%) had a score of 4 (cavitation). Of the 233 teeth bonded with the CES, 200 (85.6%) had a score of 1, 20 (8.6%) had a score of 2, 12 (5.4%) had a score of 3, and 1 (0.4%) had a score of 4 (Fig 5).

When all teeth with decalcification were grouped together for analysis, we found that the SEP group had 65 decalcified teeth, nearly double the number of affected teeth in the CES group (33 teeth). One-way ANOVA showed a significant difference between the bonding agents ($P = 0.001$). The mean scores of all teeth were 1.39 in the SEP group and 1.20 in the CES group (Fig 6).

When decalcification score, bonding agent (CES or SEP), hygiene level (E, G, F, or P), and location of agent were correlated, ANOVA showed a significant interaction between hygiene level and bonding agent according to the decalcification score ($P < 0.0001$, Fig 7). The differences in decalcification scores between the CES and SEP groups were much greater in the poor-hygiene groups (0.55) than in the excellent-hygiene group (0.03).

Figure 8 shows a representative enamel surface after pumicing (nonfluoride oil-free pumice) with a hand piece and a rubber cup. With the disappearance of the organic (soft) material, the patterned appearance of enamel rods showed that the enamel prisms were still intact, and the cores were not exposed, with visible accentuation of lamellae and pits.

Figure 9 shows a representative enamel surface after treatment with 37% phosphoric acid for 30 seconds. This type of etch pattern corresponded with Silverstone's classification pattern type I.[13] The etch pattern exhibited hollowing of the prism cores with intact peripheral borders, with a honeycomb-like image. The various prism heads had crest-like peripheries, and their jagged contours varied in appearance.

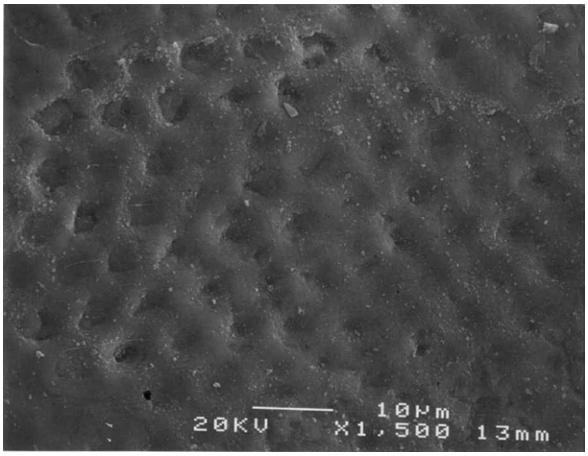


Fig 8. SEM photograph of pumiced enamel surface (1500 times magnification).

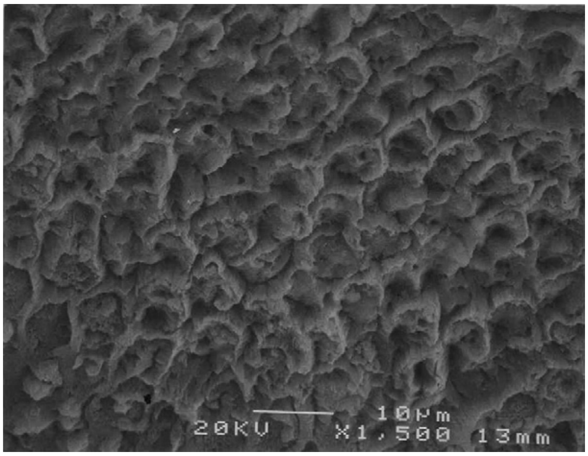


Fig 9. SEM photograph of etched enamel surface (1500 times magnification).

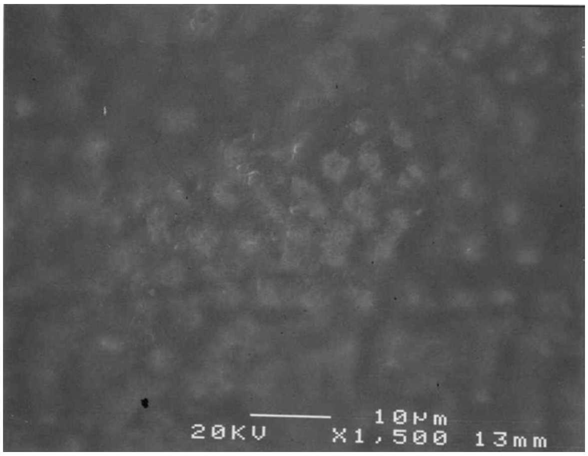


Fig 10. SEM photograph of CES enamel surface (1500 times magnification).

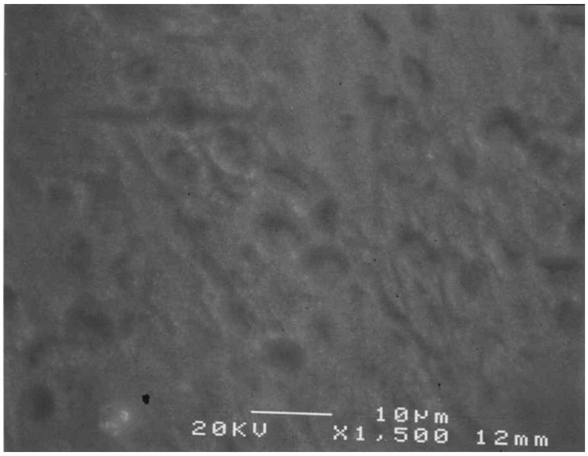


Fig 11. SEM photograph of SEP enamel surface (1500 times magnification).

Figure 10 shows a representative enamel appearance after 37% phosphoric acid treatment and application of a cured sealant layer. The polymerized sealant layer covered the previously exposed enamel rods. The sealant penetrated the enamel prisms, creating sealant tags, which are beneficial for retaining the sealant layer once cured with light. The continuity of the sealant layer filling the cavitations from the etching process, along with nano fillers in the filled sealant, was evident.

Figure 11 is the enamel surface appearance of a SEP after the pumicing shown in Figure 8. The etched and primed enamel lacks the characteristic pattern. The prism cores were dented with irregular crest-like peripheral surfaces. The etched surface appears to be lightly covered by a thin layer of polymerized primer.

Figure 12 is the x-ray spectrum of enamel surfaces treated with SEP or CES. The calcium peaks were identical in both images.

DISCUSSION

In this study, 25 patients with a total of 469 teeth were bonded with either the CES or the SEP. These teeth were followed between 18 and 24 months, and, because of difficulty in oral-hygiene maintenance, 20.9% of all teeth had some decalcification after treatment. When teeth with decalcification were categorized into treatment groups, the SEP group had a significantly higher level of white spot formation (27.5%) than did the CES group (13.9%). This was higher than in previous studies of the significance of white spot formation and lower than in others.[13-15] The study of Geiger et al,[14] which did not include fluoride treatment,

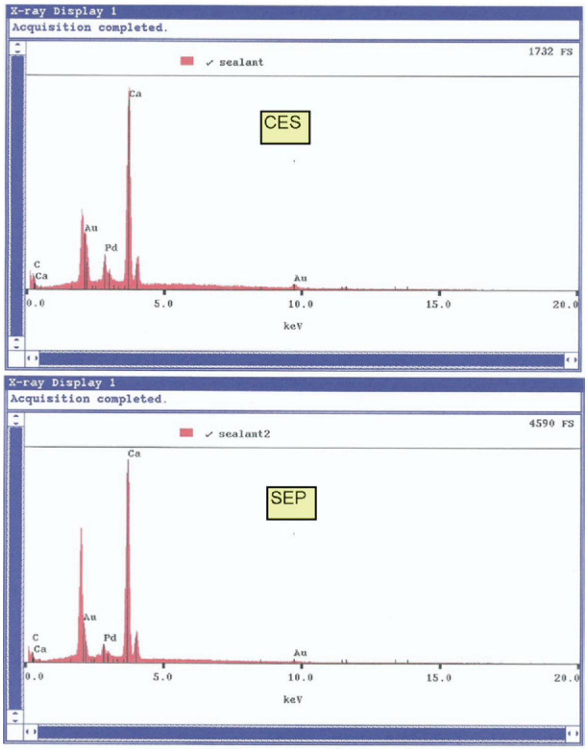


Fig 12. X-ray spectrum showing no change in calcium peak with either CES or SEP, indicating that both procedures do not alter the surface calcium content.

reported that 11.3% had white spot formation; this was similar to our finding in the CES group. Geiger et al[14] found only 7.5% of the teeth had white spots. However, in their study, the protocol included in-office and home fluoride applications with acidulated phosphate gel. Sonis and Snell[16] reported a similar finding of 13% incidence of decalcification in their control group. Differences in decalcification incidence between the SEP and the CES groups could be because the SEP contains only etching and priming agents with no sealant layer. Without rinsing after application, the low pH of 1 in the SEP means a continuous acidic challenge in addition to the absence of a sealant layer. This concurred with the observations by Tay and Pashley[17] that could explain why white spot formation doubled in the SEP group. This observation is substantiated in an in-vitro investigation comparing demineralization between the SEP and the CES. Kao et al[18] reported that a sealant provided resistance to demineralization in 50% of the samples, whereas a SEP provided no resistance to demineralization, and there was 100% incidence of lesion formation. Those authors also found lesions in the sealant group only when there was a break in the sealant layer after 2 minutes of simulated brushing. This agreed with findings of other studies that showed that demineralization occurs with a break in the sealant layer or at the periphery of the sealant material; demineralization slowly advances below the sealant layer.[19,20]

In our study, no significant differences were found between the location of brackets in the 2 arches and the contralateral sides. This agreed with Geiger et al,[14] who found no differences in the incidence of white spot formation between the right and left sides in the maxillary arch. It also agreed with Gaworski et al,[21] who showed no significant difference between the contralateral sides.

We found a significant correlation between the hygiene level and the amount of white spot formation by using a decalcification score. Geiger et al[14] divided their patients according to hygiene status as noncompliers and compliers. A significant association between white spot formation and compliance was found. Their findings agreed with ours about significant differences between paired groups: E and F, E and P, G and F, G and P, and F and P. The decalcification scores of all teeth increased as the hygiene level decreased from excellent to poor.

When considering all groups, decalcification scores, bonding agents, hygiene status, and location of the agent, ANOVA found a significant interaction of hygiene status with bonding agent according to the decalcification score ($P < 0.0001$). Multiple comparisons found no significant difference between bonding agents in the excellent hygiene category. However, as the patients' hygiene compliance decreased and the mean decalcification score increased, significant differences were found between the CES and the SEP groups. When comparing decalcification scores among hygiene levels and the patients with fair and poor hygiene, the mean score of the SEP group in the fair-hygiene group (1.91) was higher than the mean score of the CES group (1.85). This implies that the surface treatment before bonding is irrelevant if hygiene is good or excellent, but the CES should be used if patients have a history of fair or poor hygiene.

An attempt was made to use the SEM to compare the surface characteristics of the etched enamel surfaces. Many studies have shown that etching with 37% phosphoric acid increases the selective solubility of the enamel. The acid exposed the prism structure and roughened the surface, creating deeply penetrating microclefts.[5,22] The etched pattern in the CES group in our study is consistent with the Silverstone's classification pattern 1.[13] However, information concerning the type of etching pattern created by the SEP is limited. Visual detection of the etch pattern with a SEM is difficult because of the polymerizable primer incorporated in the component.

The self-etch effect should be ascribed to monomers to which at least 1 carboxylic or phosphate acid group is grafted.[23] Depending on etching aggressiveness, they can be subdivided into strong and mild self-etch adhesives based on the pH.[17] Van Meerbeek et al[24] showed that, depending on the acidity of the SEP, the strong self-etch adhesives intensively interacted with enamel up to a depth of 5 μm; this is similar to the effect of 37% phosphoric acid. Mild self-etch adhesives penetrate to a maximum of 2 μm and do not have similar effects to 37% phosphoric acid.[24] Figure 12 shows that, when comparing the CES and SEP groups with an x-ray spectrum, there was no change in the calcium peaks on the surface, indicating that neither procedure alters the calcium content or the surface composition significantly.

Strong self-etch adhesives usually have a pH of 1 or below, and a mild self-etch adhesive has a higher pH. The SEP in our study was classified as strong, with a pH of 1.[17] This high acidity results in a deep demineralization effect. At the enamel, the resulting acid-etch pattern resembles phosphoric acid treatment with an etch and rinse approach.[15,22,23] Miller[10] showed that the SEP has a similar effect as phosphoric acid, but without rinsing; the 2 primer chains form a solid primer matrix with calcium upon curing.

When comparing the SEM images of the enamel treated with the CES and the SEP, differences in the surface morphology were found. The SEP-treated surface lacks the distinctive honeycomb appearance; it appears to be lightly etched and porous. The CES image shows the continuity of the sealant layer filling the deep micropores left by the etching process along with the filler in the sealant. The findings in studies by Kao et al[18] and Frazier et al[20] suggested that decalcification occurred only when there was a break in the conventional sealant layer. Kao et al also showed that the entire surface of the SEP group had demineralization, meaning that the entire surface of the SEP is susceptible to acidic challenge by the acid polymer. The manufacturer recommends 3 to 5 seconds of rubbing with light drying but no rinsing, so that the etched surfaces remain unprotected in a continuous acidic environment. The lack of sealant resin in the SEP group could cause further demineralization when the tooth is placed in an artificial acidic environment in vitro or in an acidic oral environment when the patient's hygiene is poor.

CONCLUSIONS

A significantly higher decalcification score (twice the decalcifications) was found when enamel was treated with the SEP when compared with the CES in patients with fair to poor oral hygiene despite a protocol that included in-office and home fluoride applications. No significant difference was found with location of the brackets when comparing the 2 arches or the contralateral sides. Differences in the etched pattern between the SEP and the CES groups were found with the SEM. The enamel surface etched with the SEP lacked the characteristic honeycomb appearance; the etch pattern was shallower and less distinct. Enamel treated with sealant showed a continuous protective layer over the etched surface. These results suggest that a SEP saves chair time but provides less resistance to enamel decalcification than a CES. Clinicians should select the bonding medium carefully for patients with fair or poor oral hygiene.

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