

## *Effectiveness of a fluoride-releasing sealant in reducing decalcification during orthodontic treatment*

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Decalcification and caries during orthodontic treatment still remains a problem. A method to protect the susceptible area beneath and adjacent to bonded attachments, independent of patient compliance, would be extremely beneficial. A clinical trial was performed using a dual-cured lightly filled BIS-GMA fluoride-releasing sealant. The barrier effect of this material on white spot formation, gingival irritation, and plaque accumulation during fixed orthodontic therapy was examined. Twenty patients with a total of 225 metal brackets placed on anterior teeth participated in this study. Brackets were placed in both arches in a conventional manner with a chemically cured, unfilled bonding resin; 112 teeth (every other tooth) received the barrier material after bracket placement, while the remaining 113 teeth served as controls. Intraoral photographic slides were taken before and after treatment and were evaluated blindly by 7 observers for white spot formation. Gingival and plaque indexes were recorded initially and consecutively every 6 months. Observation time ranged from 5 to 18 months. The results of this prospective clinical study indicated that there was no significant difference ( $P > .05$ ) between the decalcification rates of the treatment or control groups. Likewise there was no added benefit with respect to plaque accumulation or gingival irritation. (Am J Orthod Dentofacial Orthop 1999;116:629-34)

**P**roper oral hygiene compliance in orthodontic patients has always been difficult to maintain. Millions of patients receive orthodontic treatment each year, and most patients find it difficult to brush properly with appliances in place, even with excellent brushing habits. As a result, plaque readily accumulates around the bracket, and the acidic nature of this material can cause permanent decalcification and caries<sup>1-3</sup> in as little as 1 month.<sup>4-5</sup> Retention of plaque, oral hygiene efficiency, and varied "host susceptibility" of the patient have all been identified as related to white spot prevalence during orthodontic treatment.<sup>6-8</sup> Previous studies have shown that the rate of decalcification after orthodontic therapy varies.<sup>9-16</sup> Table I, modified after Linton,<sup>17</sup> summarizes many of these previous studies.

Fluoride-releasing agents have been shown to protect the enamel from demineralization,<sup>3-9,18</sup> however, orthodontic patients who are treated with fixed appliances are still at increased risk for white spot formation on the labial surface of bonded or banded teeth.<sup>12,15,19</sup> Numerous

attempts have been made to fabricate orthodontic bracket adhesives that release fluoride to help strengthen the enamel surface,<sup>8,9,15,20</sup> but with mixed results. Many bonding adhesives currently in use release fluoride beneath the bracket, but this is often not successful in preventing decalcification in areas adjacent to the bracket.

Pit and fissure resin-based dental sealants used to protect the pits and fissures of posterior teeth have successfully reduced the caries rate on the chewing surfaces of teeth by nearly 50%.<sup>21</sup> These colorless, odorless, and tasteless sealants have been widely accepted by dentists and patients. They have been shown to resist caries development<sup>20,22</sup> and can exist intact in the oral environment for a number of years.<sup>20,22-24</sup> Application of resin sealants on the enamel surface around and beneath the orthodontic bracket has been suggested as a method of preventing demineralization.<sup>20,25</sup> A new product, Resilience M5 Protection Plus (Confidential Products Co, Denver, Colo), claims to address these concerns. This sealant is placed adjacent to the previously bonded bracket to create a fluoride-releasing barrier in the immediate area adjacent to the bracket. If this were as effective as the resin-based dental pit and fissure sealants, it would be an important adjunct during orthodontic therapy. Therefore, the purpose of this prospective study was to investigate the efficacy of this new sealant in preventing decalcification and to evaluate plaque accumulation and gingival irritation associated with its use.

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**Table I.** Review of incidence of white spot lesions per tooth

Reference	Control population		Orthodontic population	
	Sample size	Anterior teeth	Sample size	Anterior teeth
Artun <sup>10</sup>	60	9%	60	44%
Dirks <sup>11</sup>	90	84%		
Gorelick et al <sup>12</sup>	50	3%	121	11.5%
Ingervall <sup>13</sup>	60	13.8%	60	23.5%
Mizrahi <sup>14</sup>	426	7.6%		
Mizrahi <sup>15</sup>	527	5%	269	8.5%
Zacharissou and Zacharissou <sup>16</sup>	50	4.4%	124	12.7%

**Table II.** Overall incidence of decalcification

	Experimental		Control	
	Sample size	% of total	Sample size	% of total
Decalcification	67	60	70	62
No decalcification	45	40	43	38

## MATERIAL AND METHODS

Twenty patients from the orthodontic department at Albert Einstein Medical Center, who required full-fixed appliance therapy, were randomly selected for a prospective study. The average age at the start of treatment was 13 years, 2 months, and ranged from 9 years 3 months to 18 years, 8 months. A total of 234 metal brackets were bonded to maxillary and mandibular incisors and canines with a chemically cured, unfilled, fluoride releasing resin (Rely-a-Bond, Reliance Orthodontic Products, Inc, Itasca, Ill). Teeth with enamel surfaces that were not completely visible at the start of treatment (unerupted or partially erupted) were not included.

A full series of intraoral slides was taken of all patients before the orthodontic appliances were placed, including photographs of all labial surfaces. A Yashica Dental-Eye II camera (Kyocera America, Inc, San Diego, Calif) with a 105 mm/F4 macro lens and a built-in ring flash was used in combination with Kodachrome 64 speed slide film (Kodak Corp, Rochester, NY). Nine intraoral photographs were taken of each patient before appliances were placed and again at the time of appliance removal. Three views were taken at a 1:1 magnification to be used in this study and were taken perpendicular to the labial surface, to provide accurate assessment of possible decalcification.

The patients served as their own controls. With the use of the Universal numbering system (1-32), the teeth were divided into two groups of odd and even numbers. For each patient the odd numbered teeth (ie, maxillary right lateral incisor, maxillary left central incisor, maxillary left canine, mandibular left lateral incisor, mandibular right central incisor, and mandibular right canine [7,

9, 11, 23, 25, and 27]) served as the experimental group with the experimental sealant applied after placement of orthodontic brackets. The even numbered teeth (ie, maxillary right canine, maxillary right central incisor, maxillary left lateral incisor, mandibular left canine, mandibular left central incisor, and mandibular right lateral incisor [6, 8, 10, 22, 24, and 26]) served as a control and brackets were bonded in the traditional manner without sealant application. A total of 12 teeth per patient were included in the study.

Before treatment, ethical approval was sought and granted by the medical center's internal review board, and a written consent was obtained from the subjects (or their guardians) before inclusion in the study. An oral hygiene demonstration was given to each patient, and a note was made as to whether the patient was right-handed or left-handed. Baseline gingival and plaque indexes were recorded before appliance placement, using a previously documented gingival index.<sup>26</sup> After the gingival index was recorded, plaque was disclosed with RED-COTE, (John O. Butler Corp, Chicago, Ill) and the index was then registered for the labial surfaces of each tooth. In this evaluation, a blunt Williams periodontal probe was gently placed into the mesial, labial, and distal gingival sulcus of each tooth to determine gingival irritation. Bleeding from the gingival sulcus elicited by gentle probing is a sensitive, objective indicator of early gingivitis.<sup>27</sup> Scores were assigned as follows, according to the Modified Papillary Bleeding Index<sup>28</sup>:

### Gingival Irritation

0 = no bleeding within 30 seconds

1 = bleeding between 3 and 30 seconds

**Table III.** Decalcification score by tooth type

	Experimental			Control		
	Number of teeth at start of treatment	Number with change noted after treatment	Percentage of decalcification change during treatment	Number of teeth at start of treatment	Number with change noted after treatment	Percentage of decalcification change during treatment
Overall totals	112	67	60	113	70	62
Upper	53	39	74	53	36	68
Lower	59	28	48	60	34	57
Canines	36	25	69	35	21	60
Lateral incisors	37	25	68	39	32	82
Central incisors	39	17	44	39	17	44

2 = bleeding within 2 seconds

3 = bleeding immediately on probe placement

**Plaque Accumulation (modification according to Turesky)<sup>29</sup>**

0 = no recorded plaque

1 = spots of plaque at the cervical margin

2 = thin continuous band of plaque at the cervical margin

3 = gingival one third of tooth surface covered with plaque

4 = two thirds of tooth surface covered with plaque

5 = more than two thirds of tooth surface covered with plaque

The teeth were isolated with cheek retractors, etched for 30 seconds with a 37% phosphoric acid gel, rinsed for 20 seconds, and air dried with compressed air. Fixed orthodontic appliances (Advant-edge, TP Orthodontics, LaPorte, Ind) were used in all patients and were bonded with a fluoride-releasing, chemically cured unfilled resin (Rely-a-Bond, Reliance Orthodontic Products, Inc, Itasca, Ill), according to the manufacturer's directions. The resin was applied to the bracket base, and the bracket was placed onto the tooth. A scaler was used to remove any remaining resin from around the bracket after placement. The experimental group was then etched with the same phosphoric acid gel for 30 seconds, rinsed for 20 seconds, and air dried again. The Protection Plus sealant (PPS) was then applied with a brush circumferentially around the bracket base and light cured with a curing light (3M/Unitek/Ortholux/XT, Dental Division, St Paul, Minn) for 20 seconds. All patients received the same instructions and were seen at 4 to 5 week intervals. At 6-month intervals, the gingival and plaque indexes were recorded. The average observational period was 12.75 months and ranged from 5 to 18 months.

Immediately after the removal of the appliances, photographic slides were taken with the same standardized system established before treatment. All slides taken before and after orthodontic therapy were evaluated for white spot formation. A clinical examination of the state of the entire labial enamel surface was performed (*see following, Reliability of the*

**Table IV.** Percentage of gingival irritation

Tooth	Experimental	Control
Maxillary teeth		
Canine	47	31
Lateral incisor	17	26
Central incisor	26	26
Mandibular teeth		
Canine	32	30
Lateral incisor	55	45
Central incisor	40	35

*Method*). A 3 way score was assigned, (0 = absence, 1 = mild to moderate, or 3 = severe decalcification). Bonded teeth that failed during treatment or were for any other reason rebonded were eliminated. The act of replacing the bracket could affect the incidence of decalcification. Following this criteria, 9 teeth were excluded. This resulted in 112 teeth maintained in the experimental group and 113 in the control group (Tables II and III).

**Reliability of the Method**

Inspection of white spot formation was achieved with projected slides, which imaged the labial surfaces of the bonded teeth.<sup>7,12,19</sup> All slides were randomly projected in an attempt to simulate a blind test and scored by 7 different observers to prevent bias. Each observer scored the entire series (225 before, 225 after for a total of 450 surfaces). Several subjects' slides were repeated to assess consistency and were compared to that observer's original score. The most frequent score of the 7 observers was then used as the overall decalcification score. The decalcification rate was based on the percentage of teeth that a change in clinical appearance of the enamel was noted during treatment. The severity of that change was not recorded.

Rating of white spot formation was found to be a reliable procedure. All the findings of intrajudge reliability were greater than 90%, and were in agreement with earlier studies.<sup>8,30</sup>

**Table V.** Decalcification score as compared to the hand used for brushing

	Experimental			Control		
	Total number of teeth	Number with change after treatment	Percentage with change during treatment	Total number of teeth	Number with change after treatment	Percentage with change during treatment
Left hand used for brushing						
Total	17	10	59	17	11	65
Canine	5	3	60	5	3	60
Lateral	6	3	50	6	4	67
Central	6	4	67	6	4	67
Right hand used for brushing						
Total	95	57	60	96	59	61
Canine	31	22	71	30	21	70
Lateral	31	22	71	33	25	76
Central	33	13	39	33	13	39

**Table VI.** Changes related to hand used for brushing

	Gingival Change			Decalcification Change		
	Number of teeth	Number of teeth with decalcification	Percent worse during treatment	Number of teeth	Number of teeth with gingival change	Percent worse during treatment
Maxillary right lateral incisor	17	15	88%	17	3	17%
Maxillary left lateral incisor	19	16	84%	19	5	26%

Each patient served as their own control, with every other tooth having the sealant placed. The remaining teeth did not receive the sealant application and were evaluated as a control. Adjacent as well as contralateral teeth were then paired and analyzed for decalcification, gingival irritation, and plaque accumulation scores. The changes that occurred during treatment were evaluated with a Wilcoxon signed rank matched pairs test. For the teeth that had the sealant placed, the overall decalcification rate was 60%; the decalcification rate for the control teeth was 62%.

## RESULTS

Data analysis demonstrated the following results:

1. There was no clinically significant advantage for this sealant application in any of the comparisons; the experimental group showed only 2 percentage points less decalcification than the control ( $P > .05$ ) (Table II).
2. There is no significant difference between the overall decalcification rates for both groups ( $P > .05$ ).
3. No significant difference was found between the decalcification rates of maxillary or mandibular teeth, whether the sealant was placed or not ( $P > .05$ ) (Table III).
4. No significant difference was found with regard to overall gingival irritation or plaque accumulation for both groups ( $P > .05$ ) (Table IV).

5. No significant difference was found in gingival irritation or plaque accumulation of maxillary or mandibular teeth, whether the sealant was placed or not ( $P > .05$ ).
6. No significant difference was found between the decalcification rates with respect to which hand the patient used while brushing ( $P > .05$ ) (Tables V and VI).

Apart from whether the sealant was placed or not, data analysis revealed:

1. There was wide variation between maxillary and mandibular decalcification rates. In all cases, the maxillary teeth had higher decalcification rates than the mandibular teeth ( $P < .05$ ) (Table III).
2. Maxillary lateral incisors had a significantly higher rate of decalcification than the other teeth ( $P < .01$ ).
3. Mandibular central incisors had a significantly lower rate of decalcification than the other teeth ( $P < .01$ ).
4. No statistical differences could be demonstrated among the other teeth.

## DISCUSSION

A method to protect the susceptible area beneath and adjacent to bonded attachments, independent of patient compliance, would be extremely beneficial. The results of this study indicated that Resilience M5 Protection Plus did not confer significant protection

against decalcification during orthodontic treatment contrary to the manufacturer's claim. These findings are similar to the results of a study by Banks and Richmond<sup>31</sup> of a sealant used around fixed appliances during orthodontic therapy, as they found it not significantly (13%) affecting the prevalence of decalcification compared with untreated teeth. They also reported a high incidence of decalcification (75%).

Wide variation has been reported in the rate of decalcification. In our study, the overall incidence of decalcification was 61%. 60% of the experimental teeth and 62% of the control teeth were affected. This is encouraging in comparison to the studies by Dirks<sup>11</sup> and Banks and Richmond<sup>31</sup> where the overall incidence was 84% and 75%, respectively, but not as supportive as the prevalence noted by Mitchell<sup>9</sup> and Trimpaneeers.<sup>8</sup> A possible explanation for this difference may be that the decalcification prevalence in our study was based on an ordinal scale to assess overall change during treatment. The teeth in this study were evaluated for decalcification *change* during treatment, meaning some of the teeth included in the study had some degree of decalcification initially. The degree of decalcification change during treatment was determined by the evaluators. Finally, our study evaluated the use of this sealant as a clinical adjunct and was placed in addition to the fluoride-releasing bonding resin. The purpose for this was to evaluate the barrier effect of the material in addition to a fluoride-releasing bonding resin currently used by many practitioners.

Possible explanations for failure of this material to significantly reduce the prevalence of enamel decalcification may be found in its placement and retention qualities. The lightly filled resin was quite viscous and difficult to place with a brush, particularly in the gingival areas. For patients with edematous tissue at the time of placement, it was very difficult to maintain a dry etched surface. The available space between the gingival border of the bracket and the gingival margin is often small, and it is difficult to place a viscous material in that limited space with a brush without contaminating the surface. In addition, the operator must take care to assure that all bracket tie wings and metal bases are clear of any excess sealant resin before curing the material, as they can become blocked out as a result.

It was also very difficult to determine the retention rate of the sealant. It was given a VITA A-2 shade, and matched the teeth very well, but was virtually undetectable once placed. Air drying the teeth did not significantly help detection. The ability of this material to remain intact throughout the length of treatment has not been established. It is possible that if the etched surface were contaminated at any point during place-

ment, the sealant layer could be compromised resulting in failure of the material. An *in vitro* study done by Frazier et al<sup>32</sup> determined that when a sealant was placed around a bracket and then examined microscopically, small isolated areas were seen in the teeth representing "breaks" in the sealant layer. This could quite possibly lead to degradation of the sealant during treatment.

The results of the current study showed that the highest prevalence of decalcification was recorded in the maxillary arch. This difference could be explained by the remineralizing capacity of saliva, demonstrated by Ogaard et al.<sup>33</sup> Their findings suggest a relationship between resistance to white spot formation and the rate of salivary flow. The mandibular dentition might be more susceptible to the influence of saliva because of the anatomic location of the salivary glands and the effect of gravity that may result in a higher degree of saliva contacting the mandibular teeth.

Several authors have studied the distribution of affected teeth. Mizrahi<sup>15</sup> found maxillary incisors and first molars to have the highest prevalence. Geiger et al<sup>7</sup> reported that lesions occurred most frequently in the maxillary anterior and mandibular posterior segments. Gorelick et al<sup>12</sup> found the highest incidence of white spots among the maxillary incisors. The current study supports the findings of others that indicate maxillary anterior teeth are most commonly affected.

## CONCLUSIONS

This prospective clinical investigation was undertaken to evaluate the efficacy of a fluoride-releasing barrier material (Resilience M5 Protection Plus). The results indicate there was no significant difference ( $P > .05$ ) between the treatment group and the control group with respect to decalcification, gingival irritation, and plaque accumulation. Further attention to the delivery method and retention rate of this product is warranted. The goal of developing an ideal product to protect the susceptible area around and beneath orthodontic appliances remains a worthwhile one.

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