

# The effect of sealant on prevention of enamel demineralization in patients with fixed orthodontic appliances: A systematic review

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## ABSTRACT

**Introduction:** One of the common problems of patients undergoing orthodontic treatment with fixed appliances is the development of enamel demineralization. The objective of this review is to evaluate the effectiveness of sealants in preventing the occurrence of enamel demineralization in patients with fixed orthodontic appliances during treatment.

**Methods:** A complex search was performed in Medline (1969 to May 2013), and by hand in individual articles, in order to identify any relevant study based upon various combinations of key words. The included studies are Randomized Controlled Trials (RCTs), or otherwise prospective clinical trials, with patients (teeth) of any age undergoing fixed orthodontic treatment and with a control group or at least two intervention groups. In the absence of the above, any prospective cohort with more than ten patients was evaluated. To assess the internal validity of the eligible studies, the Cochrane Risk of Bias Tool for Randomized Clinical Trials was applied.

**Results:** The searches originally identified 237 titles and abstracts, 6 fulfilled the inclusion criteria of the review. From these studies, 4 were randomized clinical trials and 2 prospective clinical trials. The results were contradictory, with half of the studies showing significant reductions in the incidence of enamel decalcification for the sealed teeth compared with the control group while the remaining half did not show any important differences.

**Discussion:** Based on the findings from the present systematic review, it was impossible to make any reliable recommendations on the usage of sealants during orthodontic treatment for the prevention of WSL development. Nevertheless, their use in general seems to be beneficial for caries prevention, depending on the type of material, the method of its application and the caries risk status of the patient.

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## INTRODUCTION

One of the commonest problems of patients undergoing orthodontic treatment with fixed appliances is the development of enamel demineralization. In the study of Gorelick et al. (1982) <sup>1</sup> 50% of the patients undergoing orthodontic treatment with fixed appliances developed white spot lesions compared to 25% of the non-orthodontic patients. These initial lesions can be visible as soon as the fourth week after the placement of the fixed orthodontic appliances, <sup>2,4</sup> and may be detectible even 5 years after treatment. <sup>5</sup> Studies have shown that their incidence can be present in 25% of patients under orthodontic treatment despite the application of preventive measures for this group. <sup>6,7</sup>

Brackets and bands create areas on the tooth surfaces, which favor the increase of plaque and food accumulation due to the restrictive access for self-cleaning. <sup>8</sup> Their placement causes significant quantitative and qualitative changes in the oral biofilm such as decrease in pH and increase of *Streptococcus mutans* and *Lactobacilli*. <sup>9</sup> Consequently, patients being in treatment with fixed appliances and bands are at an increased risk for developing dental caries. The earliest sign of the caries process is enamel demineralization with an opaque white surface. These initial lesions (White Spot Lesion-WSL) are most often seen at the facial surfaces of the maxillary incisors, mandibular canines and first premolars at the cervical and middle third of the tooth surface. <sup>1,10</sup>

They often have a "U" shape since they develop around the borders of the brackets where the remaining cement favors the accumulation of plaque.

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Prevention of white spot lesions is imperative in order to avoid cavitation, which would require restorative intervention. Fluoride use is the most documented and widespread method of prevention of enamel demineralization. Several vehicles of fluoride administration in orthodontic patients have been reported by researchers such as topical fluoride application and use of fluoride releasing bonding materials. Chadwick et al. (2005)<sup>11</sup> report that an evidence-based recommendation for the treatment of WSL is impossible. A more recent systematic review by the Cochrane group concluded that regular rinsing with a 0.05% sodium fluoride mouthrinse is effective at reducing the severity of WSL in people undergoing orthodontic treatment, but there was no strong evidence.<sup>12</sup>

The ideal preventive measure should not depend on patient cooperation, and should be easily applied in the clinical setting and protect the tooth surface during orthodontic treatment.

Attempts have been made to use orthodontic adhesive that releases fluoride beneath the bracket, but with contradictory results. A systematic review by Rogers et al. (2010)<sup>13</sup> showed that recommendations about the use of fluoride-containing orthodontic adhesives during treatment could not be made. In addition, the use of glass-ionomer cement could be preferred over composite resin as a preventive method of WSL development but with weak evidence. The idea of using sealants as a method for WSL prevention has been studied extensively on the occlusal surfaces with positive results.<sup>14</sup> Their application around and/or beneath orthodontic brackets has been also proposed as a caries preventive method in orthodontic patients. In this regard the use of resin filled sealants showed better retention and increased resistance to mechanical abrasion.<sup>15,16</sup> The fact that most of the studies in this area have been carried out in vitro, coupled with the knowledge that the volume of this information is increasing as new materials enter the market, make a systematic review of the topic imperative.

The objective of this review is to evaluate the effectiveness of sealants in preventing the occurrence of enamel demineralization in patients with fixed orthodontic appliances during treatment and if possible to make recommendations for their use during fixed orthodontic treatment.

## MATERIALS AND METHODS

The electronic search was conducted by one investigator (SG) in Medline (1969 to May 2013). Hand searching of the reference lists of the retrieved for full text assessment articles were also carried out. A complex search was performed to identify any relevant study, based upon various combinations of key words as follows: ((*prevention*) OR (*caries prevention*) OR (*sealant*) OR (*pit and fissure sealant*)) AND ((*demineralization*) OR (*enamel demineralization*) OR (*decalcification*) OR (*enamel decalcification*) OR (*white spot lesion*)) AND ((*orthodontic*) OR (*orthodontic treatment*) OR (*orthodontic therapy*) OR (*fixed orthodontic appliances*) OR (*brackets*)). Eligibility assessment for study inclusion was conducted independently and in a standardized manner.

Titles and abstracts were examined first followed by full text evaluation of any potential article for inclusion.

### *Inclusion/Exclusion criteria of individual studies*

The following inclusion criteria were applied:

1. Study Design: Randomized Controlled Trials (RCTs), or otherwise prospective clinical trials with a control group or at least two intervention groups. In the absence of the above, any prospective cohort with more than ten patients was evaluated
2. Participants: Patients (teeth) of any age undergoing orthodontic treatment with fixed appliances

### *Data collection process*

Data extraction from the included studies was transcribed onto specially designed data abstraction forms. To reduce selection bias and avoid double counting if more than one report of the same study/or follow up study was retrieved, only the report containing the maximum relevant data was considered. Information was obtained from each included study on the following domains: (a) sample size, (b) age of the participants, (c) number of dropouts, (d) type of intervention/s, (e) observation period, (f) index and parameter measured (g) study outcomes, and (h) study authors' conclusions regarding primary endpoint.

### *Risk of bias in individual studies*

To assess the internal validity of the eligible studies, the Cochrane Risk of Bias Tool for Randomized Clinical Trials was applied.<sup>17</sup> The risk of bias of the included studies was assessed for the following domains: (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and/ or personnel involved in the study, (4) blinding of assessors, (5) incomplete outcome data reporting, (6) selective reporting of outcomes, (7) other sources of bias.

The risk of bias in the prospective clinical trials was evaluated based on a modification of the first two domains of the Cochrane Risk of Bias tool due to lack of randomization in those studies and to the minimization of the baseline differences between the recruited groups (selection bias). An overall assessment of the risk of bias was made for each included study (high, unclear, low). Trials with at least one item designated to be at high risk of bias were regarded as having an overall high risk of bias.

In cases where no data was given concerning participant drop out, the attrition bias was characterized as unclear. The same was applied for the performance bias while the detection bias was scored as high if the authors did not clearly mention the blindness of the assessors. Regarding the sample selection, the random sequence generation was considered unclear if the authors did not provide any additional information about the method of the sample randomization process.

When study participants were allocated to groups, allocation concealment was scored as low only in cases where this was carried out by a third party, thereby ensuring that the method was concealed. Otherwise it was characterized as high.

## RESULTS

Electronic and hand searches identified 237 titles and abstracts, of which 226 were excluded at the first stage. From the remaining 11 articles 6 fulfilled the inclusion criteria of the review. From these studies, 4 were randomized clinical trials and 2 prospective clinical trials. Due to the different methodologies, a meta-analysis could not be undertaken. Descriptions of the main characteristics as well as evaluation of the risk for bias of the included studies are presented in tables 1, 2 and 3 respectively.

Only one study<sup>18</sup> followed the parallel design while the single parameter common to all other included studies was a split mouth technique.<sup>15,19-22</sup>

Sealant was applied on etched tooth surfaces, which were then light cured and this was followed by resin adhesive and bracket placement. Most of the researchers mentioned that the sealant was applied to the entire labial surface of the enamel. Benham et al. (2009)<sup>19</sup> specified that they placed sealant from the gingival surface of the bracket to the free gingival margin before bracket placement while Wenderoth et al. (1999)<sup>15</sup> did the same circumferentially around the bracket base but after its placement (Table 1).

Enamel decalcification was clinically evaluated in all studies<sup>15,18,20-22</sup> except one where DIAGNOdent (KaVo, Germany) was used as a supplementary diagnostic method.<sup>19</sup> The WSL assessment was based on visual examination and imaging analysis (photos) in 4 studies,<sup>15,18-19,22</sup> while the clinical examination consisted of only visual inspection in the remaining two.<sup>20,21</sup> In half of the studies, the index used for the WSL registration was the one suggested by Gorelick et al. (1982)<sup>1</sup> which ranges from scores 1 to 4 (from no white spot to cavitation stage).<sup>18,19,21</sup> The authors of the three remaining studies used their own scoring system based on lesion severity and/or size.<sup>15,20,22</sup> Of these researchers, Wenderoth et al. (1999)<sup>15</sup> examined the reliability of their method and this was greater than 90% and in agreement with earlier studies.<sup>23,24</sup> Additional parameters such as plaque assessment and gingival condition were registered in two out of six studies.<sup>15,20</sup>

Information about the removal of the adhesive and sealants, which is an important factor implicated in the WSL registration, are provided in three out of six studies. Benham et al. (2009)<sup>19</sup> used a 30-fluted bur, Heining et al. (2008)<sup>18</sup> carbide finishing burs and DiaGloss (Axis, USA) polishers while the use of a carbide friction grip debonding bur at slow speed was mentioned by O'Reilly et al. (2013)<sup>21</sup> as a means of removal.

The observation period was approximately 12-18 months in two studies,<sup>15,22</sup> while two of the remaining studies assessed enamel decalcification over a longer period of time (a mean duration of 2 years)<sup>20,21</sup> and one carried out the evaluation within 3 months after debonding.<sup>18</sup>

The majority of the researchers based the assessment of decalcification on the number of teeth.<sup>15,19-22</sup> Only Heining et al. (2008)<sup>18</sup> reported the results per tooth surfaces for each group of study subjects participating in the study.

### *Risk of Bias in Included Studies*

Overall, all studies included were deemed to be at high risk of bias (Table 2 and 3). In particular, only three of the included RCTs reported information about the method of generation of random allocation sequence. From these, two studies were at low risk of bias since they used a random number generator<sup>19</sup> and a computer algorithm.<sup>21</sup> The last study also adequately described allocation concealment<sup>21</sup> and it was characterized as low (Table 2). No analysis of the risk of bias for random sequence generation and allocation concealment was conducted for the two prospective studies in which the study participants/teeth were matched according to baseline characteristics.<sup>18-22</sup> (Table 3)

Blinding of outcome assessors to reduce detection bias was reported as low only in two studies<sup>20,22</sup> while no clear information was mentioned in the others. The same applied for the performance bias that was characterized as unclear in all included studies.

Four of the studies were judged to be at low risk of attrition bias as the reported withdrawals were less than 10 percent and the reasons given were unlikely to be associated with the assigned intervention<sup>15,19,21,22</sup> while no clear information were given in the studies by Heining et al. (2008)<sup>18</sup> and Ghiz et al. (2009).<sup>20</sup> One out of six studies presented a major protocol deviation and it was characterized as having a high risk of detection bias.<sup>21</sup> According to this, the final clinical examination of the patients in one practice was based only on photos while the examination in the remaining dental practices used visual examination. High risk of "other biases" was suspected in all of the studies mainly due to inappropriate handling of the correlated data on a tooth level rather than at a patient level (Table 2 and 3).

### *Main results*

The results were contradictory with half of the studies showing significant reductions in the incidence of enamel decalcification for the sealed teeth compared with the control group<sup>18-20</sup> while the remaining half did not show any important differences. In the study by Benham et al. (2009),<sup>19</sup> the teeth without sealants showed 3.8 times more the number of WSL than were found in the sealed teeth. When the enamel decalcification was registered per jaw, the sealed maxillary laterals and canines showed significantly less WSL than the non-sealed teeth ( $p < 0.001$ ). Regarding the mandible, this was the case only for the canines ( $p < 0.005$ ). These results were supported by both visual examination and DIAGNOdent measurements. On the contrary, no significant differences were reported in the sealed compared to the non sealed teeth between the arches by Ghiz et al. (2009).<sup>20</sup>

Table 1. Characteristics of the included studies

Study	Sample Size	Age / Dentition	Dropouts	Interventions	Observation Period	Parameters/index	Outcome
Wenderoth CJ et al. 1999 <sup>15</sup>	n=234 teeth	9 yrs, 3 mths - 18 yrs, 8 mths	n=9 teeth	Group 1: Protection Plus sealant Group 2: no sealant	5-18 months	Enamel decalcification 0 = absence 1 = mild 2 = moderate 3 = severe	Teeth from group 1 showed only 2 percentage points less decalcification than group 2 (p>0.05)
Heinig N., Hartmann A. 2008 <sup>18</sup>	n=78 patients (43 male, 35 female)	11.6-39.5 yrs		Group 1: no sealant Group 2: Light Bond™ Reliance sealant	Within 3 months after debonding	A combined index system	Significantly reduced level of severity and depth of enamel demineralisation in teeth from group 2 (p=0.013 and 0.080, respectively)
Benham AW et al. 2009 <sup>19</sup>	n=618 teeth (360 maxillary teeth and 258 mandibular teeth) n=60 adolescents (30 male, 30 female)	11-16 yrs	n=45 teeth (9 maxillary and 36 mandibular)	Group 1: no sealant Group 2: Ultraseal XT Plus clear	15-18 months	Øgaard's modification of the scoring systems proposed by Gorelick	Six lesions were identified on the teeth from group 2 and 22 lesions on the teeth in group 1
Ghiz MA et al. 2009 <sup>20</sup>	n=25 patients n=469 teeth	-	-	Group 1: Light Bond™ Reliance Sealant Group 2: no sealant	18-24 months	O'Leary plaque index	Significantly higher decalcification scores were found in the group 1 compared with group 2 (13.9%, p<0.001) Patients with fair or poor hygiene compliance had higher decalcification scores in group 1 than group 2
Leizer C et al. 2010 <sup>22</sup>	n=18 patients n=177 teeth	10-40 yrs	n=4 patients	Group 1: Pro Seal Group 2: no sealant	12-18 months	Decalcification 3-point scale: 0 no decalcification 1 slight decalcification 2 significant decalcification	Decalcification worsened in 60 of 87 teeth (69%) treated with Pro Seal versus 65 of 90 teeth (72%) in group 2
O'Reilly MT et al. 2013 <sup>21</sup>	n=62 (male and female) n=371 teeth	10.1-25.4 yrs	n=3 patients	Group 1: sealant BisCover LV Group 2: no sealant	497-1,176 days	Gorelick index for the 6 teeth	Slightly lower incidence of white spot lesions on the teeth in group 1 (rate, 13.5%; 95% confidence interval [CI], 8.6-18.4) compared with the teeth from group 2 (rate, 17.7%; 95% CI, 12.4-23.7) White spot lesion severity was nearly the same for all teeth

Table 2. Risk of bias and level of evidence of the included randomized clinical studies

Study	Random Sequence Generation	Allocation Concealment	Blinding of personnel (performance bias)	Blinding of Outcome assessment (detection bias)	Incomplete Outcome Data (attrition bias)	Selective Reporting (reporting bias)	Other Bias
Benham AW et al. 2009 <sup>19</sup>	Low	High	Unclear	High	Low	High	High
Ghiz MA et al. 2009 <sup>20</sup>	Unclear	High	Unclear	Low	Unclear	Low	High
O'Reilly MT et al. 2013 <sup>21</sup>	Low	Low	Unclear	High	Low	Low	High
Wenderoth CJ et al. 1999 <sup>15</sup>	High	High	Unclear	High	Low	Low	High

Table 3. Risk of bias and level of evidence of the included prospective clinical studies

Study	Random Sequence Generation	Allocation Concealment	Blinding of personnel (performance bias)	Blinding of Outcome assessment (detection bias)	Incomplete Outcome Data (attrition bias)	Selective Reporting (reporting bias)	Other Bias
Heinig N., Hartmann A. 2008 <sup>18</sup>	-	-	Unclear	High	Unclear	Low	High
Leizer C et al. 2010 <sup>22</sup>	-	-	Unclear	Low	Low	Low	High

\* Prospective clinical trials: matched according to baseline characteristics

Nevertheless these authors found more decalcifications in the group with the non sealed teeth compared with the sealed ones (27.5% vs. 13.9%,  $p < 0.001$ , respectively). In the same study, the level of oral hygiene was significantly associated with the incidence of WSL and WSL was commoner in children with poor oral hygiene. Significant reductions in the level of severity ( $p = 0.013$ ) and depth ( $p = 0.080$ ) of the WSL in the sealed tooth surfaces versus the control tooth surfaces were also reported in the study by Heining et al. (2008).<sup>18</sup> The same authors also investigated the influence of the sealant on bracket loss and this was found to be reduced by half in the sealed tooth surfaces. The incidence of WSL was slightly but significantly lower in the sealed vs. the control teeth while no differences were seen in the severity of the lesions between them.<sup>21</sup> On the contrary in the study by Leizer et al. (2010)<sup>22</sup>, the difference in the percentage of teeth with WSL between the sealed versus the non sealed teeth was neither statistically significant nor clinically important (69% vs. 72%,  $p = 0.90$ , respectively). No significant differences between the WSL incidence between treated and control teeth was also reported by Wenderoth et al. (1999).<sup>15</sup>

## DISCUSSION

The present systematic review would not permit a meta-analysis as there is a lack of homogenous data, together with several differences in methodology, and all the included studies were characterized as having high bias. Therefore, only a qualitative synthesis was attempted.

Split mouth was the technique of choice for all studies except one, allowing the patients to act as their own controls. When a fluoride releasing sealant is used, the crossover effect to the control side via saliva must be considered.<sup>25</sup> This would reduce the power of the experiment to find a significant difference, and indeed this could have been the case in half of the included studies that used a fluoride releasing sealant.<sup>15,18,22</sup>

The diagnosis of WSL was made after clinical examination and/or evaluation of photographs in all of the studies. However both methods have flaws. Clinical examination requires well-trained and calibrated examiners and blinding is crucial and cannot truly be achieved when the operator is also the assessor. Indeed 4 out of the 6 included studies did not provide any information about the parameter of blinding.<sup>15,18,19,21</sup> Secondly, a well organized and detailed protocol for the standardization of the taking and analysis of the photographs is necessary. They should be taken with consistency in both lighting and technique while reflections should be avoided. In one study a supplementary means of caries diagnosis such as DIAGNOdent was used.<sup>19</sup>

Although DIAGNOdent has been found to be reliable for confirming the clinically visible WSL, this is not the case for the non-visible lesions. Based on the literature, this device is more appropriately used to assess the severity, progression and depth of the decalcification and its accuracy in the diagnosis of WSL in orthodontic patients needs further investigation.<sup>19</sup> The index by Gorelick (1982) was used by

half of the researchers in the studies included in our review for the registration of WSL.<sup>18,19,21</sup>

This index provides information about the presence or absence of WSL and its extent but not about the specific areas of the tooth being decalcified, nor its severity. The three remaining studies used different indices for the assessment of WSL,<sup>15,20,22</sup> while only one study examined the size as well as the severity of WSL.<sup>18</sup> The intervention period in all studies was at least 12-18 months, which is the average duration of an orthodontic treatment. This duration parameter is important since some sealants might have an initial preventive effect that may not last as a result of mechanical abrasion or material deterioration.<sup>22</sup> Therefore, the study duration should resemble the real duration of an orthodontic treatment in order to detect any wash out of the caries preventive effect of the sealant.

The sealants used in the present review have been also described in previous studies. They were all light-cured while half of them were filled resins<sup>15,19,22</sup> and the remaining half unfilled.<sup>18,20-21</sup>

The filled group of sealants has lower potential to wear and higher abrasion resistance than the second unfilled group. For the unfilled group of sealants, plaque attaches easily, resulting in increased risk for WSL lesion development.<sup>26</sup> The idea of using sealants for the bonding of bracket is not new. As Heinig et al. (2008)<sup>18</sup> have stated, a small gap of approximately 10µm results around the bracket between the bonding resin and enamel due to the shrinkage of resin during polymerization. Consequently, plaque and food accumulation is facilitated which in turn enhances WSL development. This fact plus the increased risk of the development of demineralization in the gingival quarter of a clinical crown resulted in some clinicians applying sealant on the entire labial tooth surface as a means of caries prevention. This was the case in most of the included studies.<sup>18,20-22</sup> The opponents of the enamel sealing technique argue that covering the entire labial tooth surface with sealant reinforces plaque accumulation on the resin surface and impedes remineralisation. We have to bear in mind that the application of sealant is done carefully and no material flows into the sulcus, therefore gingival inflammation is minimal.<sup>18</sup>

The breaks sometimes found in the sealant layers of sealed teeth with demineralization are due to surface contamination, incomplete application, and placement of the bracket before the placement of the sealant, making access more difficult for both application and light curing.<sup>27</sup>

Another benefit of using sealants in orthodontic treatment is the lower incidence of bracket loss. The reduced incidence reported by Heinig et al. (2008)<sup>18</sup> has been also found in other studies. The literature has shown that the bond strengths achieved with various enamel sealants are at least equal to conventional bonding techniques regardless of whether the sealant was placed on the entire surface or just partially around.<sup>18</sup> Nevertheless we have to bear in mind that various parameters are involved in bracket adhesion such as bracket and product type, degree of wetting of the tooth surface, enamel porosity and morphology.<sup>18</sup>

The clinical evidence is indisputable that fluoride is effective in the prevention of WSL development generally, but with regard to orthodontic patients specifically the evidence is limited. Based on a recent systematic review and until further high quality trials are conducted, the best practice for the prevention of WSL in patients with fixed appliances is the use of fluoridated toothpaste combined with once per day rinsing with 0.05% NaF mouthwash.<sup>28</sup> However, the variability of patient compliance is an issue, which has resulted in researchers investigating other supplementary means of WSL prevention such as the use of fluoride releasing orthodontic adhesives. The latest systematic review on this subject concluded that the use of fluoride releasing glass-ionomer cement is more effective in preventing WSL during orthodontic treatment than a conventional composite resin, albeit with weak evidence.<sup>13</sup> Due to the limitations of successful bonding with fluoride releasing glass ionomer cement, the technique cannot be recommended clinically. The majority of the studies included in the present review showed a significant reduction of WSL development in the sealed vs. control teeth.<sup>18-21</sup> Wenderoth et al. (1999)<sup>15</sup> considered the difficulties of placement of the enamel sealants after bracket placement was the main responsible factor for the failure of its caries preventive effect. The authors advised that the clinician should be careful when placing the quite viscous sealant they used (Protective Plus Sealant) after the bracket placement and that the etched tooth surface must remain

dry and that the tie-wings as well as the base of brackets are clear of any excess of the sealant before curing the material. However, Leizer et al. (2010)<sup>22</sup> did not find any important preventive effect of WSL by using sealant. According to the authors, comparison of their results with those from other studies can be difficult due to variations in dietary habits, oral hygiene, saliva, types of brackets as well as type of sealant and application technique.

Based on the findings from the present systematic review, it was impossible to make any current recommendations on the usage of sealants during orthodontic treatment for the prevention of WSL development. Nevertheless their use overall seems to be beneficial for caries prevention depending on the type of material, the method of its application and the caries risk status of the patient. Standard tools for the diagnosis of the WSL and protocols for the handling of debonding are necessary for future clinical trials while different materials need to be investigated.

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