



## **Comparative evaluation of effects of fluoride releasing composite on enamel demineralization in orthodontic patients - A systematic review**

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### **ABSTRACT**

**Introduction:** Demineralization around orthodontic appliances is a common problem. Suboptimal oral hygiene, long intervals between appointments, and potentially poor patient cooperation with using fluoride dentifrices and mouth rinses are the factors which necessitate incorporation of a compliance-free means of preventing tooth decay. The hypothesis of this systematic review is that the fluoride releasing composites play a significant role in the inhibition of enamel demineralization around orthodontic brackets.

**Materials and methods:** The electronic databases were systematically searched to obtain the articles related to enamel demineralization and fluoride releasing composites around orthodontic brackets in orthodontic patients from the year 2005. The reviewers assessed the risk of bias of individual studies with the Cochrane risk of bias tool, excluding RCTs with a high risk of bias in any domain.

**Results:** 8 articles assessing the enamel demineralization and white spot lesions were included in this systematic review. Severity of enamel demineralization after the use of fluoride releasing composites was assessed. It was found that all the types of fluoride releasing composites produce significant results in reducing the severity of demineralization surrounding an orthodontic appliance and orthodontic brackets.

**Conclusion:** The changes in enamel surface demineralisation and white spot lesions around orthodontic brackets on the tooth surface have been thoroughly documented in the past. Though it was found difficult to maintain oral hygiene in areas around the orthodontic brackets, however numerous studies have revealed that enamel demineralization and white spot lesions can be reduced after using fluoride releasing composites if proper protocol is followed.

**Keywords:** enamel demineralisation, fluoride releasing composites, orthodontic brackets.

### **INTRODUCTION**

Due to its ability to precisely plan tooth movements in all three planes, fixed appliance orthodontic therapy has become a fundamental component of modern orthodontics. However, fixed appliances have also been linked to negative consequences on the teeth and the structures around them, such as demineralization of the teeth, clinical attachment loss, root resorption, and subgingival microbial alterations.<sup>[1]</sup> White spot lesions (WSLs), which are tooth demineralizations surrounding the orthodontic brackets, can negatively affect the aesthetic results of orthodontic treatment and even develop into carious lesions.<sup>[2]</sup>

Long-term use of a fixed orthodontic appliance promotes the development of dental plaque, making oral hygiene exceedingly challenging and limits the ability of saliva to self-clean,

thereby fostering the initiation of caries. <sup>[3,4]</sup> A connecting area that is ideal for a rise in bacterial populations are adhesives around orthodontic attachments. <sup>[4]</sup> According to reports, the bacterial makeup of plaque changed quickly after orthodontic appliances were applied, and the proportion of acidogenic bacteria such *Streptococcus mutans* and *Lactobacillus* increased significantly. When there are fermentable carbohydrates present, these bacteria lower the pH of the plaque. When the pH of the oral environment is lower than the remineralization threshold level, decalcification takes place. <sup>[3]</sup> The need for a prophylactic approach to lower the frequency of peri-bracket demineralization is thus suggested. The flawless smile and better aesthetics that orthodontic treatment promises are the main drivers for patients to seek treatment, however these demineralized zones of enamel frequently compromise otherwise outstanding treatment outcomes. The extensive study being done to try to get rid of these demineralized/white spot lesions, is a sign of how serious the problem is.

Fluoride was first used in dentistry more than 70 years ago, and today it is acknowledged as the main cause of the sharp reduction in caries prevalence that has been seen globally. <sup>[5,6]</sup> It was discovered in the 1980s that fluoride mostly prevents caries through its topical impact. Fluoride has been shown to limit the growth of carious lesions and promote the remineralization of white spot lesions. The results of earlier trials have demonstrated the efficacy of fluoride regimens, including dentifrice, gel, rinse, and varnish on reduction of caries incidence. <sup>[7,8]</sup> These procedures only partially succeed in preventing demineralization since they depend on patient compliance. There have been numerous developments in the provision of topical fluoride reservoirs to address these problems. Examples of these include addition of fluoride to composite materials, bonding cements, and specific fluoride-releasing brackets and modules. <sup>[11]</sup> Bonding adhesives stand out among them as a fluoride reservoir due to their close proximity to enamel surface. Hence, the ability to release fluoride can be seen as a favorable quality in an orthodontic bonding agent. In an effort to prevent demineralization, researchers have sought to turn the bonding resin into a reservoir for fluoride. <sup>[12-17]</sup> Fluoride should not, however, hinder the bonding composite's ability to perform its principal duty of offering enough shear bond strength as established in clinical practice. <sup>[18,19]</sup> Although fluoride-releasing orthodontic adhesives are commercially available but they are still quite new. Thus, it is important to assess both their ability to reduce demineralization and whether or not their bond strength is enough for clinical requirements.

## **MATERIAL AND METHOD PROTOCOL**

This systematic review is written and conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA Statement) checklist recommendations and was registered on PROSPERO (International prospective register of systematic reviews) (protocol number PROSPERO CRD42023409424)

## **ELIGIBILITY CRITERIA**

Establishment of eligibility criteria preceded the literature search. The controlled vocabulary Medical subject Headings (MESH) terms and free keywords for search strategy based on the aforesaid PI(E)COS question were applied. Selection criteria were based on PRISMA

## **INCLUSION CRITERIA**

- Enamel demineralisation and fluoride releasing composites related articles were considered.

- Randomized controlled trial study articles were collected which were published from year 1983 to 2022.
- All articles that were in English language were included.

### **EXCLUSION CRITERIA**

- Case reports, case series, uncontrolled studies, review articles, opinion articles, studies on animal teeth were considered “Non-eligible” for present systematic review.
- Articles, in which fluoride releasing materials other than fluoride releasing composites was used to assess enamel demineralisation.
- All articles published before 1983 and after year 2022.
- Articles that were not in English language were excluded.

### **SEARCH STRATEGY**

The studies to be included in present systematic review were searched by two independent reviewers and in case of any discrepancy, a third examiner intervened to resolve the difference in opinion. The following combinations of title, abstract, Medical Subject Heading Terms (MeSH) and keywords were used to search through the above-mentioned databases (fluoride releasing composite OR fluoride) AND (white spot lesions) And (caries OR Cavities OR demineralization) AND (orthodontics).(Table1,2and3)

**Table 1- Primary and Secondary keywords**

<b>Primary keywords</b>	<b>Secondary keywords</b>
Enamel demineralisation	White spot lesions
Fluoride releasing composite	Fluoride
Orthodontic brackets	Orthodontics

**Table 2: Distribution of the journals in which the articles are published**

<b>Sr no</b>	<b>Name of journal</b>	<b>Number of articles</b>
01	Journal of Dental Research	01
02	Americanjournaloforthodonticsanddentofacial Orthopaedics	05
03	EuropeanJournalofOrthodontics	02

**Table3-Electronic Search approach for Each Database**

<b>Keywords</b>	<b>No of articles searched</b>	<b>No of articles selected</b>	<b>Reason for exclusion</b>
Enamel demineralisation	702	2	Case reports, observational studies
Fluoride releasing composite and enamel demineralisation	28	4	Case reports, unclear result
Fluoride releasing composite and white spot lesions	3	2	Clinical trial, split mouth study

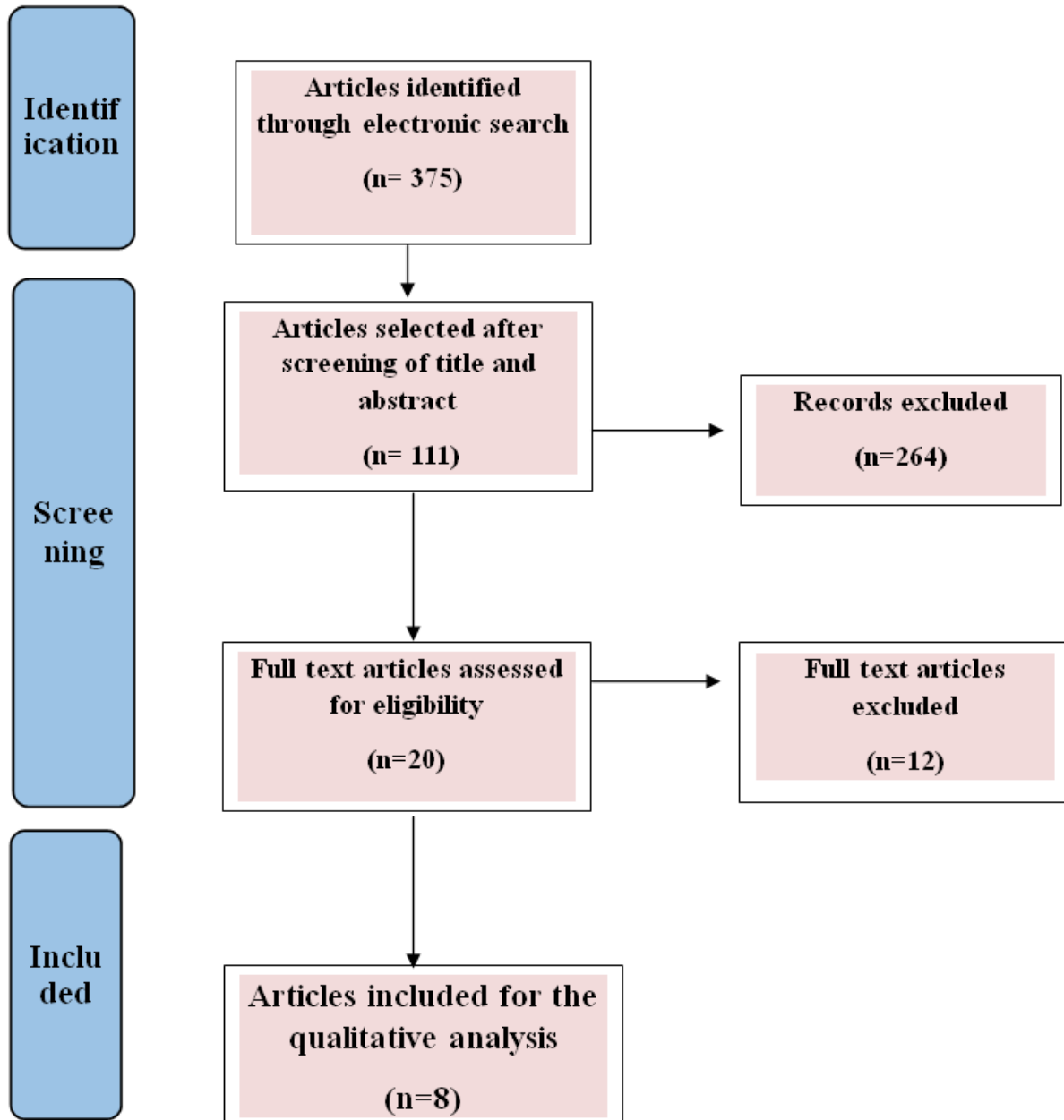
### **STUDY SELECTION AND IDENTIFICATION**

The articles evaluating the enamel demineralisation and occurrence of white spot lesions in patients undergoing orthodontic treatment were first selected from the database by reading titles and abstracts. The duplicate records were identified and removed.

## SCREENING

Two independent reviewers screened the identified publications based upon inclusion and exclusion criteria.

### Prisma Flow diagram of systematic review



## DATA COLLECTION PROCESS

After a thorough electronic and manual search using the above-mentioned search strategy, studies obtained through duplicate searches were eliminated and the title and abstract of plausible eligible studies were noted. Furthermore, studies which do not fulfil the eligibility criteria were eliminated. In the next phase, full text detailed reading of the narrowed down

studies was carried out, and studies that do not fulfil the systematic review criteria were excluded. The formal screening and data extraction were performed independently by two individual review team members. Any disagreement between them over the eligibility of particular studies was resolved through discussion with a third reviewer.

### **RISK OF BIAS ASSESSMENT IN INDIVIDUAL STUDIES**

Bias refers to the tendency of a measurement process to over or underestimate the value of a population parameter. For experimental studies, bias may arise from the errors in assessment of the outcome due to human element. It may occur on the part of participants who may subjectively report positive or negative feelings after acknowledgement of the treatment.

Observer bias may arise on the part of the investigator while measuring the outcome if he is acquainted with the treatment allocation of the participant. Bias in evaluation may occur if the investigator purposefully reports favourable results of the study.

Assessment of bias is predominantly concerned with the issues that are likely affect the ability to draw reliable conclusions from the study. Hence, it forms an integral part of qualitative analysis of the evidence in a systematic review.

□ All the eligible studies were subjected to a qualitative assessment, performed for every eligible study independently using risk of bias (quality) assessment. The Revised Cochrane Risk-of-Bias tool for Randomized trials, Version 2.0 (RoB 2) was used to perform the quality assessment of eligible studies.

□ ROB 2 tool provides a framework for considering the risk of bias in the findings of any type of randomized trial. It assesses each trial intricately under five major domains whose name clearly describes the causes of bias addressed by that particular domain. The assessment is performed at an individual study level.

□ Bias arising due to randomization process

□ Bias due to deviations from intended interventions

□ Bias arising due to missing outcome data

□ Bias in measurement of the outcome

□ Bias in selection of the reported result

A template constructed according to the design of the randomized trial was used to address the above mentioned domains. Response of two individual reviewers were recorded. Free textboxes were utilized to provide information to support the response. Risk of bias judgement was assigned for each domain. Optional judgements provided in the tool was utilized to ascertain the direction of the bias for each domain.

Finally, an overall risk of bias was determined for each study considering individual risk of bias judgement for each domain and an overall risk of bias judgement and direction of the bias was concomitantly determined. (Annexure)

Disagreements between the review authors over the risk of bias in particular studies were resolved by discussion, with the involvement of a third review author, wherever necessary.

### **RISK OF BIAS**

Cochrane risk of Bias assessment was done.

Risk of bias was evaluated for each question. For each question-based entry the judgment was: “Yes, for low risk of bias” and a point were allocated (\*), and “No, for high risk of bias” and a point was not allocated. The questions evaluated in each study were based on the following criteria from the Newcastle Ottawa scale: representativeness of the sample (evaluated by the methods of generation of samples, allocation concealment and sample calculation); sample size, non-respondents, ascertainment of the exposure, the subjects in different outcome groups are comparable, assessment of the outcome, statistical test. The representativeness criteria were evaluated through the sampling methods. The presence of a

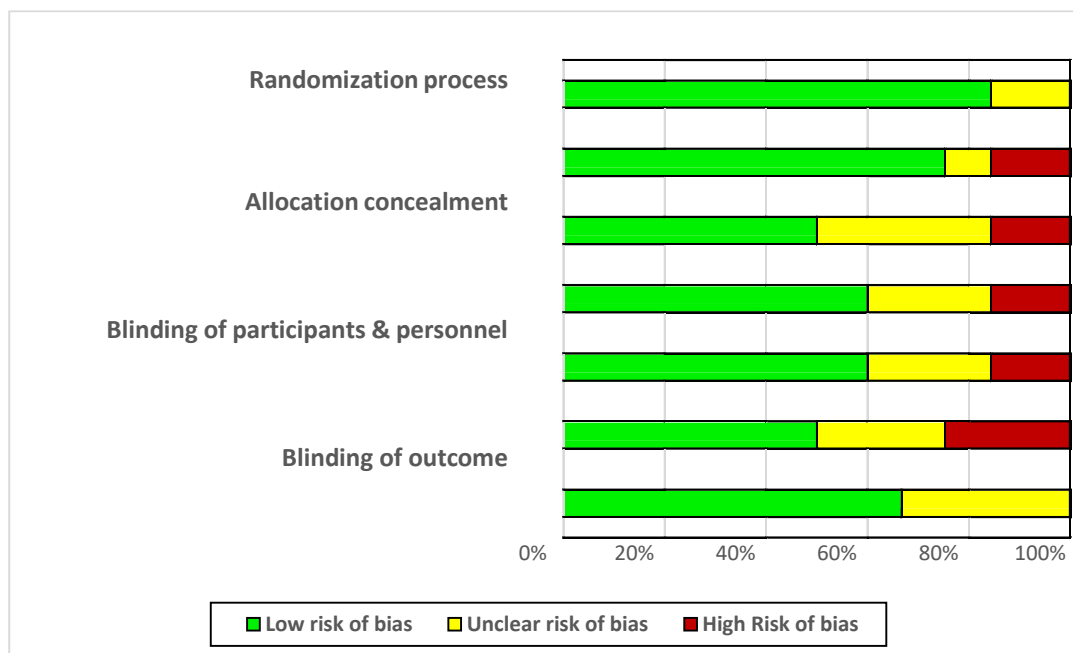
random component in the sequence generation was judged as low risk of bias. Allocation concealment was also used as a criterion for assessing representativeness. Thus, any method that precluded participants and researchers from foreseeing assignment was judged as low risk of bias.

The evaluation was done on answering the questions, answers were yes towards the low risk bias. Evaluations were done and after estimation were found to be low risk articles.(Table 6 and 7)

**Table6-Individual risk of Bias**

Studies(year)	Randomization process	Allocation concealment	Blinding of participants & personnel	Blinding of outcome	Incomplete outcome data	Selective reporting	Other Bias
Chanetal1990	+	-	?	?	+	+	?
BjornOgaardetal 1992	?	?	?	?	-	?	?
Basdraetal 1996	+	-	?	+	-	+	+
Cohenetal2003	+	+	+	-	?	-	?
Vilchisetal2006	+	+	+	+	+	?	+
Paschosetal 2009	?	+	?	?	+	+	?
Pseineretal 2010	+	+	+	+	+	-	+
EserTufekcietal 2014	+	+	-	+	+	-	+
GopinathSwarnaetal 2016	+	+	+	+	?	+	+
Pellizzarietal 2017	+	-	+	+	?	+	+
Alabdullahetal 2017	+	+	+	+	+	+	+
Althagafietal 2022	+	+	-	-	+	?	+

**Table7-Overall risk of bias**



## RESULTS OF INDIVIDUAL STUDIES

**Mohannad M Alabdullah et al 2017** The percentage of the teeth showing the effects of demineralization and WSL formation, increased from 6.3% to 15% for the control group after three and twelve months, respectively, and from 3% to 16.3% for the study group, after three to twelve months, respectively.

**E.K. Basdra et al (1996)** The results of this in vitro study show that certain fluoride-releasing orthodontic bonding systems may provide an additional degree of safety against caries susceptibility in patients with fixed appliances for a limited period.

**Bjernaard et al (1992)** A fluoride-releasing adhesive reduced lesion development significantly adjacent to brackets compared with a nonfluoride adhesive.

**Scogall Vilchis et al (2007)** The shear bond strength of the fluoride releasing composites was lesser than that of the conventional composite but well within the clinically acceptable range.

**Nebras Mohammed Althagafi et al (2021)** Statistically significant differences found among the tested variables ( $P < 0.05$ ). Group P showed the highest mean SBS values regardless of the type of adhesive used, and the difference was statistically significant ( $P < 0.05$ ). The application of the fluoride gel showed no statistically significant improvement in SBS values. The failure mode distribution among the test groups indicated that failures at the adhesive–bracket interface were predominant in group C compared with the other study groups.

**Gopinath Swapna et al (2016)** The mean depth of enamel demineralization and standard deviation was compared between subgroups A and C and B and C and the p value obtained was 0.02 in each group, suggestive of a considerably lesser degree of demineralization in fluoride releasing composites compared to conventional composite.

## DISCUSSION

The current systematic review summarizes evidence from randomized trials on preventive measures against WSL development during orthodontic treatment with fixed appliances. The purpose of our review was to evaluate the more clinically relevant outcome of WSL development which in fact has an impact on the final aesthetic outcome and on the integrity of dental structure. The need for a prophylactic approach to lower the frequency of peri-bracket demineralization is thus suggested. Fluoride has been shown to limit the growth of carious lesions and promote the remineralization of white spot lesions. In an effort to prevent

demineralization, researchers have sought to turn the bonding resin into a reservoir for fluoride. [12-17] Although fluoride-releasing orthodontic adhesives are commercially available but they are still quite new. In the fight against fluoride plays a crucial role against demineralization and dental caries, due to the increased resistance of fluoridated hydroxyapatite to acidic environments compared to initially formed hydroxyapatite.

The fluoride-release measurements for both materials indicate continuous fluoride release up to day 60 and at day 90, no fluoride was measurable within the sensitivity of the electrode. We observed a dramatic decrease in the fluoride release for the first 48 hours, which continued up to day 60. Most fluoride-releasing bonding materials studied show the same sharp decline the first few days, 16'2°23 whereas very low fluoride quantities can be detected up to 2 or 3 months. According to **E.K. Basdra et al (1996)**.

## **CONCLUSION**

From the assessment of studies in this systematic review, it can be concluded that there is sufficient evidence to support the effect of fluoride releasing composites for prevention and management of enamel demineralisation. Fluoride releasing composites helps to reduce the enamel demineralisation around orthodontic brackets and hence it is more efficient than any other conventional composite in the management of white spot lesion without reducing shear bond strength.

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