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Prevalence of white spot lesions during clear aligner therapy: a systematic review

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Objectives: To determine if an association exists between the prevalence of white spot lesions (WSLs) and orthodontic treatment using clear aligners.
Methods: Electronic databases were searched with no restrictions on year. Article selection criteria included human clear aligner studies conducted during the permanent dentition and with a full description of the applied technique and oral hygiene status.
Results: The search strategy resulted in a total of 4177 articles. After title and abstract screening, 156 relevant articles were identified from which five remained after the application of the exclusion criteria. The articles were mostly classified as having a low risk of bias.
Conclusions: Clear aligner therapy induces a lower development rate of new WSLs than orthodontic treatment by fixed appliances. In patients who have poor oral hygiene and/or existing WSLs, clear aligner treatment could be recommended.
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Introduction

The history of orthodontics is replete with descriptions of novel treatment possibilities.[1] Although clear aligners were first introduced by Kesling[2] in 1946 to detail teeth following fixed appliance therapy, they were used until 1998 to obtain only minor tooth movements and to correct minor relapse after orthodontic treatment.[3] Due to the recent increase in the number of adults seeking orthodontic care, the demand for appliances that are more aesthetic and comfortable compared to traditional fixed appliances, has increased.[4] After the introduction of the Invisalign® appliance in 1998 by Align Technology, Inc.,[4,5] clear aligners have quickly become a preferred orthodontic appliance for patients with aesthetic concerns.[5] Due to improved material and computer design, the range of tooth movement achieved by clear aligners has been greatly expanded.[6] Numerous successful cases supporting that clear aligner therapy can treat almost any orthodontic condition ranging from mild to severe malocclusions have been reported.[6,7]

White spot lesions (WSLs) are defined as occasional white or ashy grey lesions of a small surface area limited to tooth enamel.[8] The difference in the refractive index between healthy enamel and demineralised area results in a lesion of milky-white opaque appearance that is readily distinguishable from the surrounding healthy enamel.[9] Although the main aetiological factor for the WSL is excess plaque build-up, many contributing factors associated with the calcium, phosphate, bicarbonate, and fluoride levels in saliva, diet, and genetics have been implicated.[10] Patients with poor oral hygiene, chronic

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diseases, and physical and mental disabilities are more susceptible to developing WSLs.[11]

WSLs may also occur during orthodontic treatment using fixed appliances in cases in which adequate oral hygiene is not achieved nor maintained.[12] During treatment, significant changes occur in the number and composition of the oral microflora, facilitating the formation of the WSLs.[13] In addition to the increase in cariogenic bacterial species (streptococcus mutans and lactobacilli), the number of oral yeasts, especially the potential cariogenic fungus, candida albicans, also increases.[13] It has been shown that the risk of developing WSL increases if the duration of orthodontic treatment exceeds 36 months, if there are changes in oral hygiene during treatment and, if pre-existing WSLs are present.[14] Clinically, WSLs are formed two weeks after plaque build-up, while re-mineralisation has been shown to occur during the first six months after the removal of appliances.[8,15] That WSLs are still present six months after the end of orthodontic treatment will likely not show any further improvement and result in aesthetic concerns for affected patients.[15,16]

Since one of the main goals of orthodontics is to achieve an aesthetic smile, dental micro-aesthetics associated with tooth colour, texture, and enamel translucency, have recently become a consideration for orthodontists and patients.[17] It is important to determine the prevalence of WSLs after treatment by clear aligners, which have been increasingly used for aesthetic purposes. This issue has also attracted the attention of researchers and contradictory studies have been reported, especially comparing the effects of clear aligners and fixed orthodontic treatment on the formation of white spot lesions.[14,18] Therefore, the present systematic review aims to extract, summarise, and critically evaluate available information from published studies regarding the incidence and prevalence of WSLs, in addition to determining the risk of developing WSLs following clear aligner use.

Table I. Computerized search terms on the electronic sources.

Database	Search strategy
Web of Knowledge, PubMed, PubMed Central, Medline	("Clear Aligner" Or "Aligner" Or "Invisalign" Or "Clear Appliances" Or "Clear Plaque Therapy" OR "Removable Thermoplastic Aligners") And ("Demineralization" OR "White Spot Lesion" OR "Decalcification" OR "Tooth Demineralization" OR "Early Caries Lesions")
Google Scholar	Clear Aligner + White Spot Lesion
	İnvisalign + White Spot Lesion
	Clear Aligner + Demineralization
	İnvisalign + Demineralization

Material and methods

In January 2022, a systematic literature search was conducted to identify all peer-reviewed articles potentially relevant to the question of the present review paper. In the given databases, the search strategy shown in Table I was implemented, to obtain a list of possible articles to be included in the review. Inclusion and exclusion criteria are presented in Table II.

Results

Five relevant studies were identified in total. Three studies[18–20] were categorised as randomised controlled trials (RCTs), while two[14,21] were identified as controlled clinical trials (CCTs). The PRISMA Flow Chart shows the process for article selection (Figure 1).

Table II. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Prospective and retrospective original studies on human subjects with permanent dentition	Case reports
Studies on orthodontic treatment with clear aligners	Reviews
Studies that included clear descriptions of materials and applied technique	Abstracts
Studies with adequate statistical analysis	Author debates
	Summary articles
	Studies in vitro
	Studies with surgical orthodontic techniques

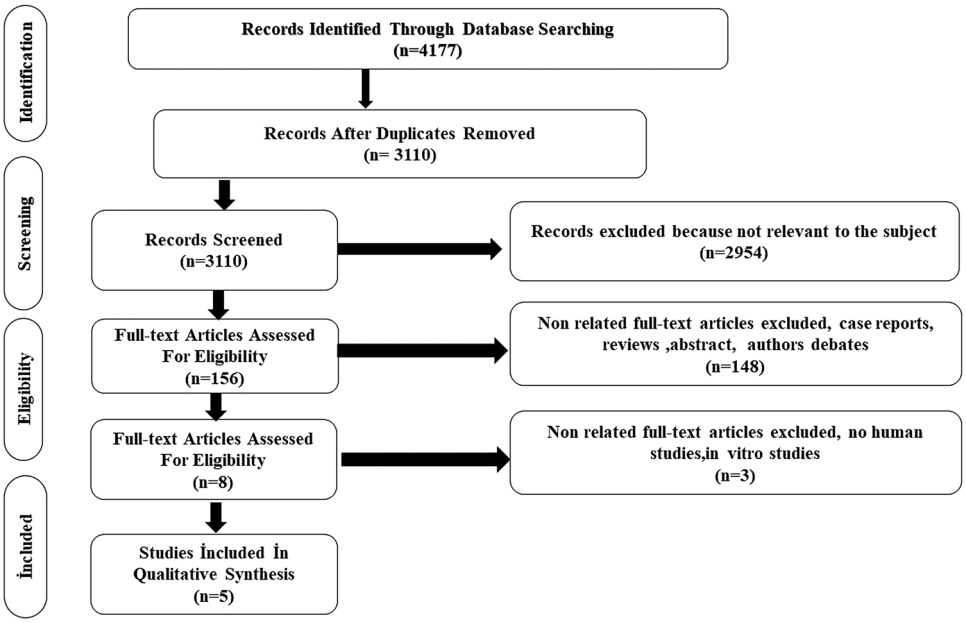


Figure 1. The PRISMA Flow Chart shows the process for article selection.

The sample size varied between 25 and 450 patients in individual studies. The clear aligners utilised in two studies[19,20] were Invisalign appliances. The remaining three studies did not specify the brand of clear aligner used. Table III shows the characteristics of the included studies, and indicates age, gender, setting, and interventions.

Quality analysis

The Downs and Black[22] checklist was applied for a quality assessment of the selected articles (Table IV). Despite the purpose, method, main findings, intervention methods, and statistical methods of all selected and reported studies, several biases were identified, including a lack of computation of sample size and blinding.

Risk of bias in the studies

Only one study was assessed as having a low risk of bias, while the other studies were at a high or unclear risk of bias. It was found that random sequence generation was sufficient in three studies,[18,19,21] whereas it was insufficient in two studies.[14,20] In all included studies, low risks of reporting bias were detected. The risk of bias summary is provided in Table V.

Discussion

Different evaluation methods for WSLs were applied in the studies. Azeem and Hamid et al.[21] and Albhaisi et al.[18] used quantitative light-induced fluorescence (QLF) to evaluate WSLs, while Buschang et al.[14] and Alshatti et al.[19] utilised digital photographs. Tuncay et al.,[20] however, did not mention the method used for WSL evaluation.

The assessment of the WSL formation on clear aligner patients was conducted at different time intervals. While Azeem and Hamid[21] evaluated the before and after treatment records of 25 orthodontic patients, Albhaisi et al.[18] evaluated 23 patients at the beginning of treatment and after the third month. Buschang et al.[14] evaluated 244 patients before and after treatment while Alshatti et al.[19] evaluated 24 orthodontic patients at the beginning of treatment and 18 months after treatment. Tuncay et al.[20] evaluated 62 patients at the beginning of treatment, at 3-monthly intervals and at the end of treatment (or after 24 months). The daily wear time of the aligners was reported to be at least 21 hours by Tuncay et al.,[20] while it was not specified in the other studies. Since the methods, results and time intervals of the WSL assessment varied between the studies, a meta-analysis could not be performed and therefore a systematic review was conducted.

Table III. Characteristics of included studies.

Authors	Journal	Methods	Participants	Age	Inclusion criteria	Exclusion criteria	Setting	Interventions	Outcomes
Azeem and Hamid (2017)[21]	*Journal of World Federation Orthodontist*	CCT	25 Randomized (12 Male, 13 Female)	Mean age, 16.17 ± 1.76 years	1. Comprehensive clear aligner treatment of upper and lower arches 2. Age 14–18 years at the start of aligner therapy 3. No previous orthodontic therapy 4. No hypodontia.	1. Patients with any systemic disease, clefts, general dental problems, taking daily fluoride supplements or on ongoing medications for a chronic disease 2. Patients with WSL, hypoplastic or fluorotic enamel	Not reported	Tooth groups used in the current study Group 1: *n*=4 (22–12) Maxillary incisors: 22, 21, 11, 12 Group 2: *n*=20 (15–45) Maxillary and mandibular incisors, canines, first and second premolars: 11–15, 21–25, 31–35, 41–45 Group 3: *n*=24 (16–46) Maxillary and mandibular incisors, canines, first and second premolars, and first molars ** Definition by World Dental Federation numbering system	1.The overall incidence of new WSLs 2.Tooth related WSL formation in tooth groups All measurements were made before and at the end of the treatment.

Albhaisi et al. (2020)[18]	*American Journal of Orthodontics and Dentofacial Orthopedics*	RCT	49 Randomized (39 female,10 male) Group 1: *n*=19 Group 2: *n*=23 * In total, 42 of the 49 participants recruited completed the study	21.25 ± 3 years Group 1: 21.2 years. Group 2: 21.3 years.	1. Healthy patients of both sexes between the ages of 17–24 2. ClassI malocclusion with mild-to-moderate crowding (≤5 mm) 3. Nonextraction treatment plan 4. Optimum oral hygien	1.Patients with poor oral hygiene, defective enamel, extensive restorations, and salivary glands diseases	Orthodontic clinic at Jordan University of Science and Technology	The patients were divided into two groups by drawing lots. Group 1: Treated with clear aligner Group 2: Fixed orthodontic treatment *Quantitative light-induced fluorescence (QLF) images were taken before treatment (T0) and 3 months later (T1). The QLF images were then analyzed to assess the research outcomes.	1. Plaque measurements 2. Changes in white spot lesion parameters 3. Preexisting white spot lesions vs newly developed ones All measures before treatment and 3 months after the start of treatment

Table III. Characteristics of included studies.

Authors	Journal	Methods	Participants	Age	Inclusion criteria	Exclusion criteria	Setting	Interventions	Outcomes
Buschang et al. (2019)[14]	Angle Orthodontist	CCT	450 Randomized Group 1: *n*=244 Group 2: *n*=206 *Gender not reported	Group 1: 30.4 years. Group 2: 29.2 years	1. Patients in late mixed or permanent dentition with only high-quality digital photographs of pre- and post-treatment 2.All malocclusion, provided that the gingival one-third of the anterior teeth is visible in the photographs	Not reported	Private practice and at the Department of Orthodontics, Texas A&M University College of Dentistry	Patients were chosen consecutively, starting with the most recently completed cases. Group 1: Treated with clear aligner Group 2: Fixed orthodontic treatment Initial and final intraoral photographs were retrieved from the Dolphin Imaging System, placed side by side on a computer monitor, enlarged, and evaluated in a darkened room.	1. Oral Hygiene Status 2. The incidence of WSLs All measurements were made before and at the end of the treatment.

Alshatti (2017)[19]	Master of Dental Science at the University of Connecticut, 2017	RCT	59 Randomized Group 1: n=24 Group 2: n=16 Group 3: n=19 *Gender not reported	Group 1: 21.44 years Group 2: 14.83 years Group 3: 14.47 years	1.Nonextraction treatment plan. 2.There should be less than 8mm of anterior crowding. 3. Patients should have all permanent teeth present, except third molars. 4. Demonstrable ability to maintain adequate oral hygiene. 5. Show optimum dental health without immediate need for restorations.	1.Skeletal anterior-posterior discrepancies between the maxilla and mandible (ANB ≥ 5°). 2. Centric relation (CR)- Centric occlusion (CO) discrepancies of greater than 3 mm. 3. Anterior or posterior open bites. 4. Patients who are pregnant, diabetic or using mouth rinses or interacting medications, including antibiotic therapy. 5. Presence of impacted teeth. 6. Presence of pre-treatment white spot lesions. 7. Presence of active periodontal disease as evidenced by attachment loss.	Division of Orthodontics, Department of Craniofacial Sciences, University of Connecticut Health Center.	Randomization sequence was generated by using a PC based software "Random Allocation Software". Group 1: Patients receiving treatment with clear semi-elastic polyurethane aligners. Group 2: Patients receiving treatment with self-ligating brackets. Group 3: Patients receiving treatment with conventional pre-adjusted edge wise brackets.	1: Measuring the incidence of WSLs 2.Measuring the severity (surface area) of wsls 3.Measuring the correlation between gingival, plaque and bleeding ındices and white spot lesions All measurements were pre-treatment and (T0) 18 months after treatment initiation. (T2) done

Table III. Characteristics of included studies.

Authors	Journal	Methods	Participants	Age	Inclusion criteria	Exclusion criteria	Setting	Interventions	Outcomes
Tuncay et al. (2013)[20]	Journal of Clinical Orthodontist	RCT	62 Randomized *Gender not reported	Participants were under 18 years old	1.Patients with class I or mild class II occlusion	1. Active caries 2. Periodontal disease 3. Patients unsuitable for aligner	Michigan, New Jersey, Oklahoma, and Pennsylvania	62 patients were treated by clinicians. It was recommended to use at least 21 hours a day. Of the 62 patients who began the study, 42 completed treatment.	1. Gingival-index measurements 2. Decalcification index 3. Patient Satisfaction All measurements were collected in the first 24 months

Table IV. Quality assessment of the studies based on checklist of Downs and Black.

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Azeem and Hamid (2017)[21]	1	1	1	1	1	1	1	1	0	1	0	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	1
Albhaisi et al. (2020)[18]	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	1	1
Buschang et al. (2019)[14]	1	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0
Alshatti (2017)[19]	1	1	1	1	1	1	1	1	0	1	0	0	0	0	1	0	1	1	1	1	1	0	1	0	0	0	1
Tuncay et al. (2013)[20]	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0

Reporting: 1, yes: 0, no. Questions: 1. Is the hypothesis/aim/objective of the study clearly described? 2. Are the main outcomes to be measured clearly described in the introduction or methods section? 3. Are the characteristics of the patients/samples in the study clearly described? 4. Are the interventions of interest clearly described? 5. Are the distributions of principal confounders in each group of subjects to be compared clearly described ? (2, yes; 1, partially; 0, no) 6. Are the main findings of the study clearly described? 7. Does the study provide estimates of the random variability in the data for the main outcomes? 8. Have all important adverse events that may be a consequence of the intervention been reported? 9. Have the characteristics of patients lost to follow-up been described? 10. Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001? (external validity: 1, yes; 0, no and unable to determine) 11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? 12. Were the subjects who were prepared to participate representative of the entire population from which they were recruited? 13. Were the staff, places, and facilities where the patients were treated representative of the treatment the majority of patients received? (Internal validity/bias: 1, yes; 0, no and unable to determine) 14. Was an attempt made to blind the subjects to the intervention they received? 15. Was an attempt made to blind those measuring the main outcomes of the intervention? 16. If any of the results of the study were based on "data dredging," was this made clear? 17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time between the intervention and outcome the same for subjects and controls? 18. Were the statistical tests used to assess the main outcomes appropriate? 19. Was compliance with the intervention reliable? 20. Were the main outcome measures used accurate (valid and reliable)? (Internal validity/confounding (selection bias): 1, Yes; 0, no and unable to determine) 21. Were the patients in different intervention groups (trials and cohort studies) or were the subjects and controls (case-control studies) recruited from the same population? 22. Were study subjects in different intervention groups (trials and cohort studies) or were the subjects and controls (case-control studies) recruited over the same period? 23. Were study subjects randomized to intervention groups? 24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? 25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? 26. Were losses of patients to follow-up considered? Power: 27. Did the study have sufficient power to detect a clinically important effect where the probability for a difference due to chance was less than 5%? Sample sizes have been calculated to detect a difference of x % and y %.

Table V. Risk of bias summary.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Azeem and Hamid (2017)	+	+	+	+	+	+
Albhaisi et al. (2020)	+	+	–	+	+	+
Buschang et al. (2019)	–	–	?	+	+	+
Alshatti (2017)	+	+	+	?	+	+
Tuncay et al. (2013)	–	+	–	+	+	+

High Risk: - Unclear Risk:? Low risk: +

Incidence of new WSLs

In all evaluated studies, the incidence of new WSLs increased according to the number of patients and the number of affected teeth after clear aligner treatment. The percentage of patients who developed new white spot lesions after clear aligner therapy varied between the articles and ranged between 1.2%[14] and 41.18%.[19] Alshatti et al.[19] reported that the number of patients who developed WSLs after clear aligner treatment (41.18%) was lower than those who underwent fixed orthodontic treatment via self-ligating brackets (63.64%) and conventional pre-adjusted edgewise brackets (52.94%). Albhaisi et al.[18] identified the development of 6.21 new WSLs per patient in clear aligner cases, while 8.25 new WSLs per patient were detected in those treated using fixed appliances. Azeem and Hamid[21] indicated that the overall incidence of new WSLs was 2.85% for all assessed teeth and 28% of the patients were affected by at least one new WSL during clear aligner therapy. Buschang et al.[14] reported that 1.2% of the clear aligner patients developed WSLs, while this rate was 26% in traditionally-treated patients.

Azeem and Hamid.[21] and Buschang et al.[14] reported that the incidence of new WSLs increased with increasing duration of treatment, although age and gender had no effect. Azeem and Hamid et al.[21] showed that treatment duration increased the incidence of WSL formation involving the maxillary incisors and Buschang et al.[14] reported that patients who underwent treatment for more than two years were 1.6 times more likely to develop WSLs than patients treated for a lesser period.

The incidence of WSLs after fixed orthodontic treatment varied between 2% and 96%, but it is known that the diagnostic method used to detect WSLs has an impact on this percentage.[22] Heymann et al.[23] indicated that studies using QLF reported a higher prevalence of WSLs in comparison with studies that used only visual inspection. Buschang et al.[14] used digital photography and found that approximately 1.2% of the aligner patients developed WSLs. However, Alshatti et al.[19] evaluated WSLs via digital photography and showed that 41.18% of the patients developed WSLs. Furthermore, Azeem and Hamid et al.[21] reported that 28% of the patient sample were affected by at least one new WSL during clear aligner treatment despite the use of QLF. This also indicated that the prevalence of WSLs after clear aligner treatment was also related to the method of assessment. Being a treatment method directly related to patient co-operation, the new WSL development in clear aligner patients may be affected by patient-related conditions such as wear time, eating habits, and oral hygiene procedures. Eating and tooth brushing habits of patients are also factors that cannot be fully controlled in studies conducted on those receiving fixed appliance treatment. However, in studies evaluating clear aligner patients, measures should be taken to determine the wear time of the

appliances, since it may differ between patients, unlike in fixed orthodontic treatment.

Treatment duration

Azeem and Hamid[21] found that 28% of the patient sample was affected by at least one new WSL over an average study period of 18.11 ± 5.12 months, while Alshatti et al.[19] determined that 41.18% of patients developed WSLs over a period of 18 months. Buschang et al.[14] reported that 1.2% of the clear aligner patients developed WSLs after a treatment period of 1.5 ± 0.9 years. More controlled studies are required to analyse the effect of the treatment period on the development rate of new WSLs associated with clear aligner therapy.

Other factors

Buschang et al.[14] reported that, the patients who underwent fixed orthodontic treatment developed lesions on 18.9% of their maxillary and on 15.3% of their mandibular teeth, while clear aligner patients developed WSLs on 0.8% of their maxillary and 0.4% of their mandibular teeth, showing that more WSLs developed in the maxillary teeth in both groups.

Conclusions

In the present study, several issues related to the development of new WSLs after orthodontic treatment were evaluated and included treatment duration, dental anatomy, the jaw in which the teeth were located, age, gender, the institution providing treatment, oral hygiene education and treatment methods. More clarifying studies are recommended.

Although reported clear aligner treatment showed a lower rate of new WSL development compared to fixed orthodontic treatment, a lower prevalence of WSL may have been found in evaluated studies as well as systematic reviews due to the risk of bias and heterogeneity. In patients presenting with poor oral hygiene or existing WSLs, treatment using a clear aligner may be recommended to reduce further incidence of WSL. However, many factors such as the location and size of added attachments, the cleanliness of the aligner, and the duration of use, need further evaluation.

Conflict of Interest

The authors declare that there is no conflict of interest.

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