



Review Article

Evaluation of white spot lesion (WSL) and periodontal (PDL) health between patients treated with clear aligners and conventional fixed orthodontic brackets: A systematic review

Souradip Swarnakar¹, Sumita Mishra^{2*}, Smruti Bhusan Nanda²

¹SOA University, Bhubaneswar, Odisha, India

²Siksha 'O' Anusandhan, Bhubaneswar, Odisha, India



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ABSTRACT

Aim: The primary objective of this systematic review is to evaluate and compare the incidence of white spot lesions between clear aligner and fixed Orthodontic therapy.

Materials and Methods: Randomized clinical trials of parallel, block randomisation, computer based and stratified randomisation and split-mouth design, involving patients undergoing Orthodontic treatment are considered. Studies had to compare the WSLs and periodontal health between CA and FA groups were searched in the electronic databases PubMed and Cochrane Library. A summary of the overall strength of evidence available was assessed using the Grades of Recommendations Assessment.

Data Collection: A total of 51 records were found, from which only 4 articles met the inclusion criteria and were subjected to analysis.

Results: Majority of the studies included in this review have positively correlated a potential decrease in WSLs and better periodontal health with the use of clear aligners. However, most of the studies lack a long-term duration and follow up.

Conclusion: More clinical trials in this area are welcome in order to have a better conclusion in terms of which appliance therapy would provide optimal dental and periodontal health during and after Orthodontic therapy.

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1. Introduction

Orthodontic treatment helps to establish a balance between functional harmony, structural balance and an improved aesthetics.¹ White spot lesions around Orthodontic attachments are an unsightly, and one of the common side effects of Orthodontic treatment.² The complex design of Fixed Orthodontic appliances (FAs) makes it difficult to perform proper oral hygiene, which causes accumulation of bacterial bio films on the dental surface especially around the brackets.³ A rapid increase in the volume

of dental plaque, higher levels of acidogenic bacteria such as *Streptococcus mutans* and various *Lactobacilli*, and a persistent low pH for a longer period leads to the demineralization of dental enamel. Moreover, this can also lead to deterioration of the periodontal status if patient does not maintain a good oral hygiene.^{4,5} Consequently, patients with fixed appliances should follow a very rigid oral hygiene protocol to prevent these side effects. Unlike fixed Orthodontic appliances, removable appliances like clear thermoplastic aligners (Was) can be taken out and thus enable patients to practice oral hygiene procedures under ideal conditions.⁶ They have the potential of not hindering oral hygiene, as patients do not encounter any of

* Corresponding author.

E-mail address: sumita.mitali@gmail.com (S. Mishra).

the obstructions caused by brackets, bands, or arch wires. The increased popularity and use of Clear Aligners has raised the question if Clear Aligners are effective and to evaluate their proficiency. Although the general assumption is that these appliances are hygienic by design,^{6,7} this hypothesis still requires high-quality evidence to define the pros and cons of Clear Aligners. Information regarding enamel decalcification (WSLs) and periodontal status in patients undergoing Clear Aligner therapy has not been widely disseminated and is generally lacking in the literature.⁸ To unfold this enigma, a thorough strategic analysis of literature was planned to map the evidence for the evaluation of White Spot Lesions and Periodontal health status between Clear Aligners and Fixed Orthodontic therapy.^{9–22}

The primary objective of this systematic review is to evaluate and compare the incidence of white spot lesions between clear aligner and fixed Orthodontic therapy. The secondary objective is to evaluate and compare the periodontal health status between clear aligner and fixed Orthodontic therapy.

2. Materials and Methods

2.1. Types of studies

Randomized controlled trials

2.2. Types of participants

Study participants receiving Orthodontic Treatment aged between 10 and 51 years.

2.3. Types of interventions

Experimental interventions –Experimental group treated with clear aligners to evaluate WSL and periodontal health.

Comparison (control) intervention- Control group treated with conventional Orthodontic brackets.

2.4. Types of outcome measures

2.4.1. Primary outcomes

To evaluate and compare the incidence of white spot lesions between clear aligner and fixed Orthodontic therapy.

2.4.2. Secondary outcomes

To evaluate and compare the periodontal health status between clear aligner and fixed Orthodontic therapy.

2.5. Search methods for identification of studies

2.5.1. Electronic searches

Systematic searches were made in the following databases for randomised controlled trials and controlled clinical trials. There was no language, publication year or publication status restrictions. The searches were re-run just

before the final analyses and further studies were retrieved for inclusion. The databases are:

1. Pub Med/ MEDLINE
2. Scopus
3. Cochrane

2.6. Search strategy

Fixed Orthodontic OR Orthodontic appliances OR Orthodontic OR conventional appliances OR orthodon* AND Clear Aligner OR Invisalign OR ALIGNER AND Periodontal health OR Periodontal Status OR Gingival Health OR Gingival Status OR Periodontal Perio* OR Gingivae* OR white spot lesion OR WSL OR enamel demineralisation OR sub surface demineralisation.

2.7. Data collection and analysis

2.7.1. Selection of studies

Following the electronic search, review authors independently screened the titles and abstracts (if available) to exclude all articles clearly not meeting the inclusion criteria.

The search was designed to be sensitive and include controlled clinical trials; these were filtered out early in the selection process if they were not randomised. Of all the remaining articles, full texts were obtained and assessed independently and only articles fully meeting the inclusion criteria were considered. Detailed reasons were stated for all excluded studies. This process is summarised in Figure 1.

2.8. Data extraction and management

Data extraction will be done on an excel sheet with proper grouping under the headings:

Gender, Age, follow up period, Type of intervention, along with outcome parameters such as PI score, GI Score and Periodontal bleeding index, probing depth, BOP, Papillary bleeding index for periodontal health and quantitative light induced fluorescence (QLF) images for white spot lesion.

Two reviewers independently assessed titles and abstracts of all identified reports. Full texts were retrieved for any study with insufficient information in the title and abstract to allow a clear decision on inclusion. Any disagreements regarding suitability for inclusion between the two reviewers were resolved by discussion and a third reviewer was consulted if a consensus was not reached. Full texts of studies selected for inclusion is obtained for data extraction and management as evident in Table 1.

2.9. Assessment of risk of bias in included studies

Risk of Bias assessment will be assessed according to Cochrane Hand Book criteria for risk assessment for

Table 1: Demographic characteristics

Sl No.	Author, Year and country	Study Design	Age Range	Outcome Assessed	No. of patients	Gender distribution	Test Procedure	Control Procedure	Follow-up
1.	Rainer-Reginald Miethke et al. 2005, Germany	CT NR	18yr-51yr	modified Gingival Index, modified Plaque Index, modified Papillary Bleeding Index, and sulcus probing depth	60	43F, 17M	Aligner	Conventional fixed Orthodontic treatment	6weeks, 12 weeks
2.	Ziad Albhaisi et al. 2020, Jordan	RCT using coin toss	17yr-24yr	mean amount of fluorescence loss (DF). Number of newly developed lesions, deepest point in the lesion (DFMax), lesion area (pixels), and plaque surface area (DR30)	113	39F, 10M	Aligner	Conventional fixed Orthodontic treatment	3 months, 6 months
3.	Aditya Chhibber et al. 2017, Australia	RCT computer based	10yr-18yr	plaque index, gingival index, periodontal bleeding index	55	24F, 16M	Aligner	Conventional fixed Orthodontic treatment	1 months, 3 months
4.	Gian Marco Abbate, 2015, Germany	RCT, using sealed envelopes	13yr-19yr	plaque index, White spot lesion	60	NA	Aligner	Conventional fixed Orthodontic treatment	3months, 6months, 12 months

RCT-Randomized controlled trial, NA-Not available, F-Female, M-Male, yr-Year

Randomised clinical trials. The studies will be graded to have low, moderate and high risk based on the information provided in the included studies regarding randomization, allocation concealment, blinding of participants, personnel and assessors, attrition bias or selective reporting. In case of missing information, the authors of the respective studies may be contacted to provide adequate information, if not, will be marked unclear. These assessments are reported in the Characteristics of included studies table and also graphically.

2.10. Measures of treatment effect

For continuous outcomes (e.g., PI, GI, BI), mean differences (change score) along with 95% confidence intervals (CIs) were used to summarise data for each treatment group.

2.11. Dealing with missing data

In case of missing data, we contacted the corresponding author of the article through e-mail to obtain complete data.

In case of no response, the same e-mail was sent to co-authors for a maximum of three times. If no answer was obtained, the study was excluded from the analysis.

2.12. Data synthesis

Data from studies are subjected to qualitative and quantitative analysis. Quantitative analysis outcome measures which are continuous will be expressed as mean and standard deviation and those which dichotomous will be expressed as relative risk.

2.13. Subgroup analysis and investigation of heterogeneity

In addition to the different protocols if sufficient studies are identified, subgroup analyses will be carried out to investigate:

1. Gender
2. Age

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aditya et al	+	+	+	+	+	+	+
Gian et al	+	+	+	+	+	+	+
Rainer et al	?	+	?	+	?	?	+
Ziad et al	+	+	+	+	+	+	+

Figure 1: Study flow diagram

3. Results

3.1. Results of the search

The electronic search retrieved 51 records, after discarding 6 duplicates by review authors, 45 titles were screened, and 34 records were excluded. The full text was obtained for 11 potentially eligible articles and of these, 7 were excluded with reasons. Finally, with agreement among the review authors 4 studies were included in this systematic review.

3.2. Included studies

3.2.1. Design

Of the 4 studies that were included, 3 are randomized clinical trial and 1 is concomitant trial.

1 had computer-based randomisation with a total of 55 participants, 1 had randomisation using coin toss with a total of 113 participants, 1 had randomisation by sealed envelope with a total number of participants 45, 1 had not mentioned the method of randomisation with a total number of 60 participants.

3.2.2. Participants

The age range of the participants of 4 included studies was between 10 and 51 years.

Out of four, one study had the age range of 18 to 51 years with mean age of 31.5.

Another one age limit is 17 to 24 with an average of 21.25. Third one was from 10 to 18 and the 4th one did not mention the age limit, took an average of 15.6. All 4 studies included both men and women, but with different proportions.

3.2.3. Interventions

The general comparison was between a group using clear aligners (experimental group), and a group that has undergone conventional fixed therapy (comparison group)

3.2.4. Excluded studies

We excluded 11 studies from the review, for the reasons mentioned in Table 2.

Table 2: Excluded studies

Sl. no.	Study	Reason of Exclusion
1.	Tufekcia, Dixonb, Gunsolleyc and Lindauer (2011) ⁵	Intervention on non-Orthodontic patients
2.	Lucchese and Gherlone (2012) ²	Non-randomization
3.	Azeem M and Hamid WU (2017) ⁸	Intervention on non-Orthodontic patients
4.	Buschang et al (2018) ²³	Non-randomization
5.	Karad et al (2019) ²⁴	Compared verbal care to chair side demonstration
6.	Miethke and Vogt (2005) ²⁵	Non-randomization
7.	Karkhanechi et al (2013) ²⁰	Compared verbal care to chair side demonstration

3.3. Outcomes

3.3.1. Primary outcomes

1. Change in Plaque Index (PI) was reported in 2 studies

- Change in Gingival Index (GI) was reported in 1 study.
- Change in Bleeding Index (BI) was reported 2 studies.
- Change in White Spot Lesions (WSLs) was reported in 1 study.
- Change in amount of fluorescence loss (DF) was reported in only 1 study.

5. Changes in number of newly developed lesions, was reported in only 1 study.

3.4. Risk of bias in included studies

The risk of bias in included studies is summarized in.

3.5. Allocation

3.5.1. Random sequence generation

The randomisation was performed correctly in most of the studies: The methods used were computer-based randomisation, randomisation using coin toss, randomisation by sealed envelope. The randomisation method was not described in one article, which was an unclear risk of bias.

3.6. Allocation concealment

Out of the 4 studies, 2 studies have low risk bias where they have used sealed envelopes and web based randomization, one is unpredictable where they used coin toss. And another one did not mention the method of randomization.

3.7. Blinding

The blinding was done in most of the studies. However, it was not reported in one study, which was at unclear risk of bias.

3.8. Incomplete outcome data

The completeness of outcome data was adequate in all but one study in which the number of subjects that finished the study was not clear.

3.9. Selective reporting

Four studies properly reported data for all patients but one study failed to report which was at unclear risk of bias.

4. Discussion

Orthodontic therapy apart from its benefits also has potential risks and limitations in terms of tissue damage. Dentally, the teeth may undergo decalcification that appears as WSLs on the enamel surface and root resorption. Gingival and periodontal inflammation is also common soft-tissue side effects that usually lead to gingival overgrowth and bone loss especially when the patient has very poor oral hygiene. Thus, oral hygiene maintenance has to be very meticulous for patients with braces otherwise the plaque accumulation and retention can happen faster than those without braces which in turn increases the risk of side effects.⁸ The main strength of this review was the inclusion of only comparative studies comparing the incidence of WSLs between the two treatment modalities. It is because of these criteria

that only a limited number of studies were identified to be eligible in this review. The other salient feature of this review was its extensive unconstrained search of the published and unpublished literature. The current clinical evidence is still insufficient to prove a substantive clinical result. Four studies consisted of two Randomized controlled trials,^{26,27} one Retrospective Cohort Study²³ and 1 narrative review.²⁴ Three studies^{23,24,27} reported higher incidence of WSLs in FA therapy when compared with CA, whereas Alshatti et al.²⁶ reported no difference in the incidence and the severity of WSLs among clear aligners, self-ligating brackets and conventional brackets. This might be attributed to the different diagnostic methods used in the studies for the detection and quantification of WSLs. While Albhaisi et al.²⁷ used Quantitative light-induced fluorescence, Buschang et al.²³ and Alshatti et al.²⁶ used the Visual evaluation of pre- and post-treatment digital photographs as the diagnostic method.

The three important parameters that should be observed while evaluating white spot lesions are incidence (the number of newly formed lesions), size or surface area of the lesions, and depth of the lesions. The first RCT to compare the incidence of WSL among aligners and traditional braces was done by Alshatti et al.²⁶ including 60 participants. They reported no significant difference in the incidence of WSL between the types of appliances.

They found that for Group 1 (CA), 2 (Self ligating brackets) and 3 (FA), the percentage of patients who change from lesion-free at the beginning of the treatment (T0) to having lesion(s) after 18 months of treatment (T1) were 41.18%, 63.64%, and 52.94% respectively, with $p=0.56$, rendering the finding statistically insignificant. Also, when they considered the entire sample size, the incidence of WSL, regardless of the appliance type, was about 39%.

Moreover, difference in the WSL Surface Area (SA) were calculated by subtracting the Surface Area at T0 from size at T2 (i.e., $SA\ Difference = SizeT2 - SizeT0$). The change in the SA was found to be statistically insignificant between the three groups. Contrary to the above findings, Buschang et al.²³ reported a significantly less incidence of WSL in CA (1.2%) compared with FA (25.7%). According to Buschang et al.²³ the low incidence of WSLs in patients with removable aligners can be attributed to the shorter treatment duration and better hygiene. This study also showed that 94.3% of the aligner patients were able to maintain or even improve their OH during treatment, compared to 84.8% of the traditional patients. However, further investigation is needed to evaluate the effect of size, shape, and location of the attachments on enamel decalcification because one could anticipate that attachments with angular sharp edges might cause more food entrapment than smooth circular ones. Although the SA of WSLs was found to be more in CA group, a greater amount of demineralization i.e., depth of the lesion, was

seen in the FA group with a significantly more mineral loss of 1.2% than 0.4% in CA group. This finding was consistent with the significantly increased amount of plaque that was present in FA group and agrees with almost all the studies that illustrated their association.²⁸ This was because fixed appliances had rough surfaces proven to be the perfect sites for plaque accumulation. This scoping review also included a narrative review where Karad et al²⁴ stated that patient education, motivation and compliance in maintaining oral hygiene plays a major role in the low incidence of newly developed WSLs with clear-aligner therapy. Overall, the present scoping review suggested that patients treated with aligners showed less incidence and risk of developing WSLs than patients treated with traditional braces. It is an undeniable fact that patient education and motivation on oral hygiene practice are essential components for the prevention of WSLs.

Investigators in the included studies used 6 clinical indices to assess periodontal health: Plaque Index (PI), Gingival Index (GI), Probing Depth (PD), Papillary Bleeding Index (PBI), Sulcus Bleeding Index (SBI) and Bleeding on Probing (BOP). Generally, periodontal health indexes can be classified into 3 main categories: oral hygiene indexes, gingivitis indexes, and periodontal disease indexes. The OHI-S and the Turesky modification of the Quigley and Hein Index, which clinicians often use for a basic periodontal health evaluation, could be recommended for oral hygiene evaluation in patients undergoing Orthodontic treatment.

In clinical practice, the use of a graded bleeding index is more likely to help identify sites at risk of developing further destructive activity and, hence, deserve a relatively higher recommendation. The results of few studies^{20,29–40} states that clear aligners allowed relatively better periodontal health conditions than fixed appliances. On the contrary some studies^{25,28,41,42} exhibited that the periodontal condition in the two treatment modalities was nearly identical. The CA group showed better levels in all 6 indices recorded, which could be explained by the ease of access and better oral hygiene. The BOP showed no difference in any of the groups, which might be explained by patient compliance of hygienic instructions. Srinath et al⁴⁰ also reported a decreased GI, PD and BOP with the CA treatment at 6 months and 1 year in contrast to FA treatment. According to Levriani et al,³² along with a significant worsening of all the periodontal parameters, higher level of bacteria concentration in patients treated with FA, as assessed by RT-PCR, further supported the findings. Reduction in the total bacterial count and *S. mutans* count in the CA group was observed by Agarwal S,³³ Chhibber A²⁹ and Jones MS.³⁹ This may be attributed to the direct impact of fixed appliances on dental plaque accumulation. However, they found no significant correlations between periodontal health

parameters and bacterial / *S. Mutans* counts. Hence, both CA and FA influence the oral microbiome and can lead to micro-environmental changes that favour colonization with periodontal pathogens. However, the supportive therapy provided by the professional dental hygienist determined a dramatic improvement in the periodontal health of both groups of patients, independently from the kind of appliance.

These results suggest that when appropriate oral hygiene instruction and motivation were offered to the patients, the type of Orthodontic treatment had no effect on periodontal health. Furthermore, these findings were in accordance with the prospective randomized control trial by Chhibber et al.²⁸ that pointed out no evidence of differences in oral hygiene levels among CA, SLB, and conventional FA after 18 months of active Orthodontic treatment.

The three meta-analyses^{34–36} included in the study underlined that clear aligners should be used in patients with high risk of gingival inflammation, but the level of evidence was low. This was due to the inclusion of studies other than RCTs, like prospective cohort studies which made the risk of bias inevitable; hence more high-quality studies are required to corroborate these results. Lu et al³⁴ stated that CA are more conducive to the maintenance of periodontal health. These findings align with the meta-analysis conducted by Jiang et al.⁴³ Prajapati and Esfandiarib³⁶ reported that patient satisfaction and oral hygiene compliance were reported to be higher in CA group.

These findings also align with the systematic review conducted by Erotokritou N³⁷ who stated that the possible explanations for better periodontal health in CA therapy could be the factors that CA patients can clean the appliance outside the oral cavity and remove the appliance during brushing and flossing which was a critical point to maintaining optimal oral hygiene for the patient. Also, another possible reason was that aligners cover the majority of crown thus partially preventing dental plaque from accumulating on the surface and also the transition of supragingival dental plaque to subgingival tissues that cause destruction of the periodontal tissues. Overall, the present scoping review suggested that patients treated with aligners showed better periodontal parameters and health status than patients treated with fixed Orthodontic appliances.

5. Limitation

Despite the sound methodology of the present review, this review had some limitations. One such limitation was the inclusion of only English literature for the review. In the included RCTs, random assignment of patients into different treatment groups was difficult to perform due to the nature of the study. This became one of the limitations of the included RCTs. The general quality of the available RCTs was not high because it was easy to distinguish fixed appliances from clear aligners. Blinding of personnel and

participants was also impossible in practice.

Investigators in most of the included studies did not describe clearly whether the outcome assessments were blinded. The high heterogeneity of the included studies in this review also questions the reliability of the results. There is a need for more robust studies to validate the results of periodontal health outcomes and incidence of white spot lesions during Orthodontic treatment.

Studies tracking long-term effect on the development of white spot lesions in clear aligner therapy, periodontal health, patient satisfaction and economic effectiveness are necessary. Future study designs should include studies with appropriate randomization, blinding of treatment groups, masking of outcome assessments, rigid eligibility criteria, sensitive and reproducible diagnostic criteria and quality assessment of included studies to reduce bias.

6. Conclusion

Majority of the studies included in this review have positively correlated a potential decrease in WSLs and better periodontal health with the use of clear aligners. However, most of the studies lack a long-term duration and follow up. Thus, interpretation towards clinical practice should be made with caution. More clinical trials in this area are welcome in order to have a better conclusion in terms of which appliance therapy would provide optimal dental and periodontal health during and after Orthodontic therapy. Regardless of the type of appliance used, a periodic reinforcement by the Orthodontist to maintain oral hygiene has been found to be beneficial. The motivation received acts as a trigger, allowing for better oral hygiene practice, and as a result leads to prevention of periodontal problems as well as WSLs. However, if the patient fails to maintain oral hygiene during the course of Orthodontic treatment, the type of appliance used will have little influence on the end result.

7. Source of Funding

None.

8. Conflict of Interest

None.

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Author biography

Souradip Swarnakar, Post Graduate Trainee

Sumita Mishra, Professor  <https://orcid.org/0000-0001-9856-1321>

Smruti Bhusan Nanda, Professor and Head

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