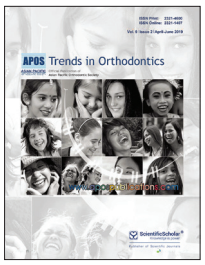
ScientificScholar®
Knowledge is power
Publisher of Scientific Journals

www.apospublications.com

APOS Trends in Orthodontics



Original Article

Evaluation of gingival health and pain level in orthodontics treatment with clear aligners: A systematic review and meta-analysis

Bayan M. Abusafia[1], Abdelrahman M. A. Mohamed[2], Maher Al-Balaa[1], Qiao Yi Qiang[2], Yousef S. Abbas[3], Yan Yang[1]

[1]Department of Orthodontics, Wuhan University, Wuhan, [2]Department of Orthodontics, Stomatology Hospital, Zhengzhou University, Zhengzhou, China, [3]Faculty of Dentistry, Fayoum University, Fayoum, Egypt.

***Corresponding author:**
Yan Yang,
Department of Orthodontics,
Wuhan University, Wuhan,
China.

yangyan209@whu.edu.cn

Received: 27 September 2022
Accepted: 23 January 2023
EPub Ahead of Print: 20 March 2023
Published: 27 September 2023

DOI
10.25259/APOS_177_2022

Quick Response Code:

ABSTRACT

Objectives: The aim of the study was to assess the proficiency of clear aligners (CAs), and to evaluate all aspects of this orthodontic procedure including bleeding on probing (BOP), plaque index (PI), gingival index (GI), and probing pocket depth (PD), which all are clinical parameters of gingival inflammation in addition to the pain score.

Material and Methods: We performed an electronic search in the different databases such as Cochrane CENTRAL for eligible studies, SCOPUS, PubMed, and Web of Science. The quality of the involved trials has been measured according to Cochrane's risk of bias tool. The following outcomes have been assumed: BOP, PI, GI, probing PD, and pain score. The homogeneous and heterogeneous data have been evaluated using random-effects model and fixed-effects model, consistently.

Results: Ten clinical trials have been included in the study. The pooled analysis that The CAs has been associated with a significant decrease in the pain score (standardized mean difference = 0.74 [0.46, 1.02]), (P = 0.0001). No significant variations between post-treatment and pre-treatment group were found regarding plaque index (mean difference [MD] = −0.11 [−0.45, 0.22]), (P = 0.5), BOP (MD = 0.20 [−0.01, 0.41]), (P = 0.06), GI (MD = 0.17 [−0.06, 0.40]), (P = 0.15), and BOP (MD = 0.01 [−0.16, 0.17]), (P = 0.94).

Conclusion: Patients treated by CAs showed a noticeable decrease in pain scores. On contrary, there was not any difference between the pre-treatment data and post-treatment data regarding other indices.

Keywords: Orthodontic treatment, Aligner, Pain

INTRODUCTION

In recent years, there are great technological advancements in dentistry and orthodontic mechanotherapy. In addition, there is rising in the number of adults and young asking for orthodontic treatment.[1] Because there is a demand for more comfortable, esthetic, and less complicated procedures. Clear aligner (CA) had been developed as a reliable alternative to the traditional fixed appliance (FA) in orthodontic treatment.[2,3]

Dentists have initially used CA in the management of minor irregularities in tooth position since the first CA was introduced in 1999 by Joffe *et al.*[4] Nowadays, patients seeking orthodontic treatment prefer CAs over other procedures.[5] The previous studies reported that CA is associated

with better oral hygiene, less pain, more esthetic, fewer appointments, and more comfortable than the standard FA.[6,7] Furthermore, published studies showed that Invisalign® aligners are associated with better gingival indices, periodontal health, shorter treatment duration, and less white spot lesions than FA.[8,9] In contrast, Årtun *et al*.[10] reported similar results between both CA and FA concerning periodontal indexes.

Although CA has many advantages compared to other appliances, only a few trials focused on the safety, adverse events, and implications of oral health of CA.[11-13] Published studies reported that Invisalign® aligners are expensive and cannot treat some types of malocclusions.[14,15]

The clinical data regarding the overall effectiveness and safety of CAs are not sufficient enough to provide a high level of evidence and few published clinical trials adequately evaluated the patients after treatment.[5] Therefore, we aim in our meta-analysis to assess the proficiency of CAs, and to evaluate all aspects of this orthodontic procedure including bleeding on probing (BOP), plaque index (PI), gingival index (GI), and probing pocket depth (PD), which all are clinical parameters of gingival inflammation in addition to the pain score. This has been done by comparing the two phases pre- and post-treatment indices of patients attributed to CA orthodontic treatment.

MATERIALS AND METHODS

In this study, the authors worked in light of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).[16]

Search strategy

The authors performed systematic database research using the following strategy: "clear aligners" OR Invisalign® aligners OR "removable aligners" until January 2022.

Study selection

The first step of the screening was importing the studies from the different databases to the Excel software[17] using the EndNote X8.0.1 version.[18] Then, we conducted title and abstract screening of the studies in the Excel sheet. Finally, the authors screened the research's full text from the previous step.

Eligibility criteria

The study selection criteria were as follows:

- Study design: The authors at first excluded other designs, and they involved only randomized and clinical trials (RCTs).
- Participants: All patients seeking orthodontic treatment with no restrictions regarding age or gender.
- Intervention: Treatment with CAs.
- Comparator: The pre-treatment data of patients.
- Outcomes: Gingival and PI, BOP and probing PD, which all are clinical parameters of gingival inflammation in addition to the pain score.

Data extraction

We searched Scopus; the authors utilized the included studies independently to extract information. They extracted the demographic data of patients, data of the primary and secondary outcomes such as BOP, PI, GI, PD, and the pain score, and finally the data required for the assessment of effectiveness.

Data collection

We collected three categories of data from each included study: The first category is the baseline and demographic characteristics of the included participants, such as the author, year, country, sample size, age, gender, and follow-up period. The second category included the outcomes of analysis, mainly: PI, BOP, GI, probing depth, and pain score. The third category was data of quality assessment. The process of data collection was done using Microsoft Excel.[17]

Risk of bias assessment

We followed The Grading of Recommendations Assessment, Development, and Evaluation Guidelines in assessing the quality of this study. We assessed the risk of bias in included trials using Cochrane's risk of bias tool.[19] The tool assesses proper randomization of patients, allocation concealment, and adequate blinding through seven domains. Each domain is put to either a "low," "unclear," or "high" risk of bias.

Statistical analysis

The authors analyzed dichotomous and continuous data using mean difference (MD) and odds ratio, consistently. The confidence interval was 95% in all cases. Using Review Manager Software, all data analysis was performed.[18] The heterogeneous data were examined under a model of random effects, while homogeneous data were examined using a model of fixed effects. The Chi-square tests and I^2 index were utilized to assess the heterogeneity.[20] Any values for I^2 >50% or $P < 0.1$ or were considered heterogeneous. We tried Cochrane's leave-one-out method to resolve the heterogeneous outcomes.[20]

RESULTS

Included studies summary

The outcomes of the electronic search of the different databases are defined in the PRISMA flow chart [Figure 1]. Ten studies were included in the study.[6,9,21-28] We analyzed 255 patients who were treated using the Invisalign aligner.

The average age of the patients in our study was 26.8 years. A summary of the included studies, the demographic data of patients, gender, country, and follow-up duration are described in detail in [Table 1].

Risk of bias assessment

According to Cochrane's tool, the results of quality assessment for RCTs produced a low risk of bias. As for the randomization domain, five studies[21-25] were categorized as low risk, three studies[6,9,28] were labeled as high risk, and two other types of research [27,28] did not report sufficient data. According to allocation concealment, four studies[21,22,24,28] were at low risk and three studies [23,25,26] were at low risk and three studies[24,26,27] were at high risk. The authors excluded the remaining studies because they did not contain sufficient details. All the studies were blinded to the participants and personnel except four studies[6,23,26,27] were not blinded and two studies[22,26] did not report enough data. Five studies[21-24,28] were blinded to outcome assessors. [Figure 2] shows a summary of the included trials' risk of bias. [Table 2] shows a detailed risk of bias assessment.

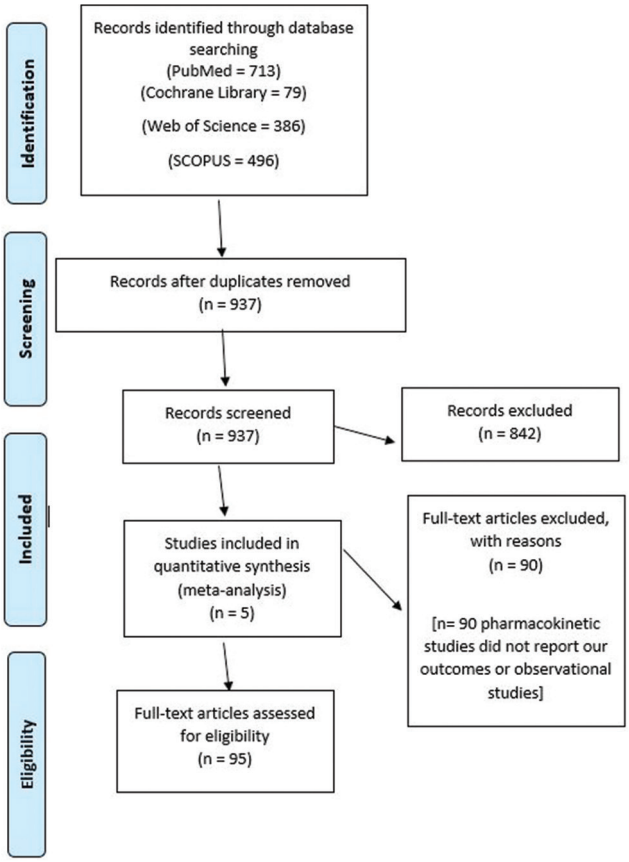


Figure 1: A PRISMA flow diagram of our literature search. PRISMA: Preferred reporting items for systematic reviews and meta-analyses.

Analysis of outcomes

PI

Five studies[9,22-24,26] reported the PI outcome. The combined analysis showed no difference between the pre-treatment data and post-treatment data (MD = −0.11 [−0.45, 0.22]), (P = 0.5). We conducted a subgroup analysis based on the follow-up duration. Three studies[9,24,26] followed up the patients for 6 months. The MD showed no significant difference (MD = 0.14 [−0.01, 0.29]), (P = 0.07). Pooled analysis was homogeneous (P = 0.45); I^2 = 0%. One study[23] followed up the patients for 3 months. One study[22] followed up the patients for 9 months [Figure 3].

BOP

BOP was stated by three researches.[9,22,27] They showed similar indices after treatment compared with pre-treatment data (MD = 0.20 [−0.01, 0.41]), (P = 0.06). The overall analysis was homogeneous (P = 0.23); I^2 = 32% [Figure 4].

GI

A total of 77 patients were analyzed from three studies.[9,22,26] The change in the values between the pre-treatment data and post-treatment was not significant (MD = 0.17

Table 1: A detailed summary of the included participants and their demographic data.

Study ID	Country	Follow up	Sample size (*n*)	Age (years)	Male (*n*)	Female (*n*)
Shalish *et al*., 2012	Israel	2 weeks	21	(18–60) range	5	16
Miethke *et al*., 2005	Germany	6 months	30	(18–51) range	NR	NR
Madariaga *et al*., 2020	Italy	3 months	20	34.7±12.5	5	15
Katchooi *et al*., 2017	Canada	3 weeks	13	31.46±11.2	6	7
Karkhanechi *et al*., 2013	USA	6 months	20	28±6.86	8	12
Fujiyama *et al*., 2014	USA	2 months	38	26.64±5.69	10	28
Chhibber *et al*., 2018	Australia	9 months	27	16.56±3.99	20	7
Almasoud, 2018	Saudi Arabia	1 week	32	28.47±8.17	10	22
Abbate *et al*., 2015	Italy	6 months	22	(10–18) range	NR	NR
Albhaisi *et al*., 2020	Jordan	3 months	23	21.25±3	6	17

NR: Not reported

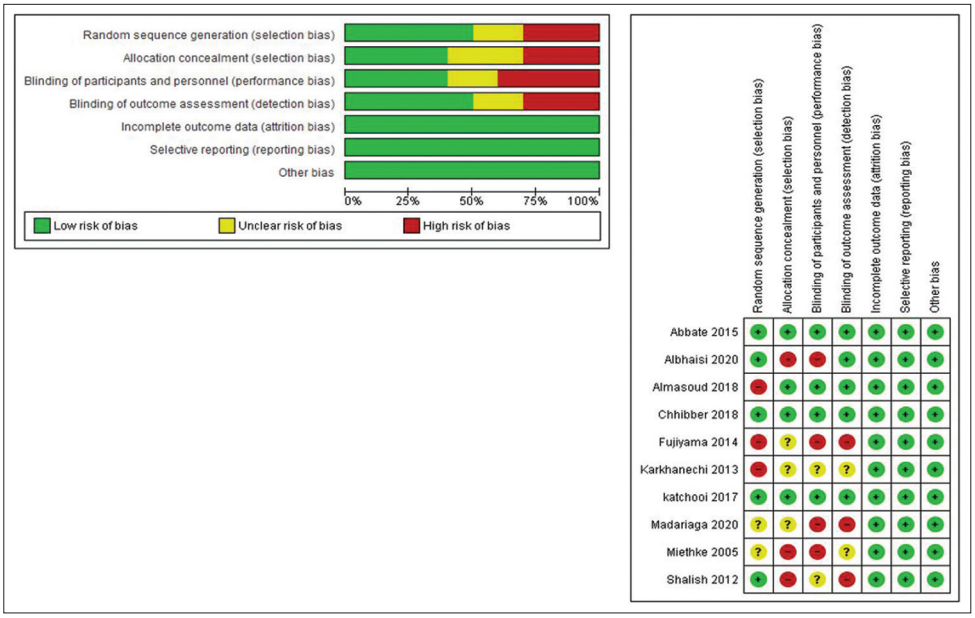


Figure 2: Risk of bias assessment.

Table 2: A detailed risk of bias assessment.

Study	Randomization	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Attrition bias	Selective reporting	Other bias
Shalish *et al.*, 2012	Low	High	Unclear	High	Low	Low	Low
Miethke *et al.*, 2005	Unclear	High	High	Unclear	Low	Low	Low
Madariaga *et al.*, 2020	Unclear	Unclear	High	High	Low	Low	Low
Katchooi *et al.*, 2017	Low	Low	Low	Low	Low	Low	Low
Karkhanechi *et al.*, 2013	High	Unclear	Unclear	Unclear	Low	Low	Low
Fujiyama *et al.*, 2014	High	Unclear	High	High	Low	Low	Low
Chhibber *et al.*, 2018	Low	Low	Low	Low	Low	Low	Low
Almasoud, 2018	High	Low	Low	Low	Low	Low	Low
Abbate *et al.*, 2015	Low	Low	Low	Low	Low	Low	Low
Albhaisi *et al.*, 2020	Low	High	High	Low	Low	Low	Low

[−0.06, 0.40]), (P = 0.15). The analysis was heterogeneous (P = 0.09); I^2 = 58% [Figure 5a]. We solved the heterogeneity by the exclusion of Chhibber *et al.*[22] The GI was higher after treatment than before it (MD = 0.28 [0.13, 0.44]), (P = 0.0003). Pooled analysis was homogeneous (P = 0.7); I^2 = 0% [Figure 5b].

Probing depth

Four studies[9,24,26,27] reported the probing depth outcome. The combined estimate displayed no variation between both groups (MD = 0.01 [−0.16, 0.17]), (P = 0.94). The analysis was heterogeneous (P = 0.009); I^2 = 74% [Figure 6a]. The authors resolved the heterogeneity by excluding Madariaga *et al.*[27] (P = 0.37); I^2 = 0% and the overall estimation after resolving heterogeneity did not differ from the heterogeneous analysis (MD = − 0.07 [−0.19, 0.05]), (P = 0.25) [Figure 6b].

Pain score

Pain score was reported by four studies.[6,21,25,28] The treatment was associated with lower score than before the treatment which means a lower level of pain (standardized mean difference = 0.74 [0.46, 1.02]), (P = 0.0001). The analysis for the studies collection was homogeneous (P = 0.25); I^2 = 26% [Figure 7].

DISCUSSION

Throughout our meta-analysis, the authors have analyzed 255 cases for patients who were treated using the CAs. The analysis of 10 included studies yielded no difference in the pre-treatment data and post-treatment data concerning BOP, PI, GI, probing PD, and the pain score. On the contrary, the post-treatment group was related with a weighty decrease in pain scores.

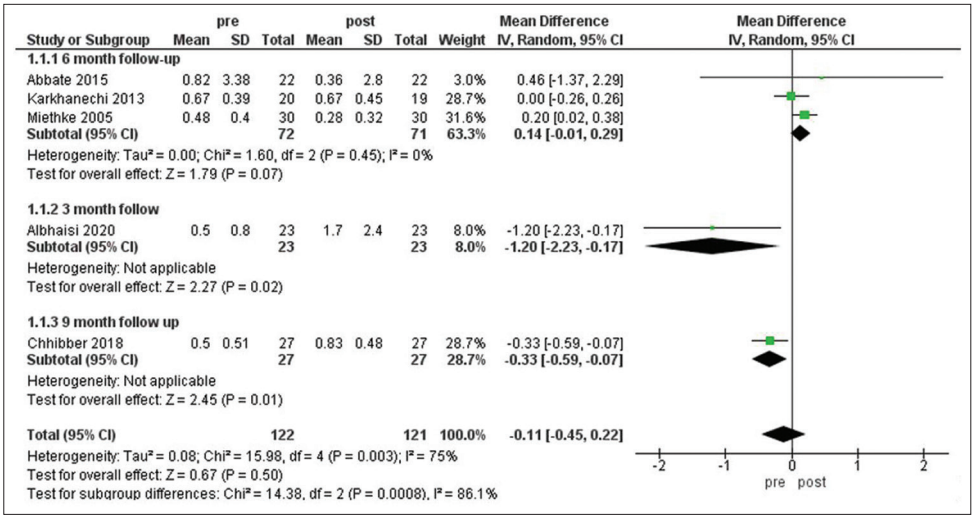


Figure 3: Plaque index outcome.

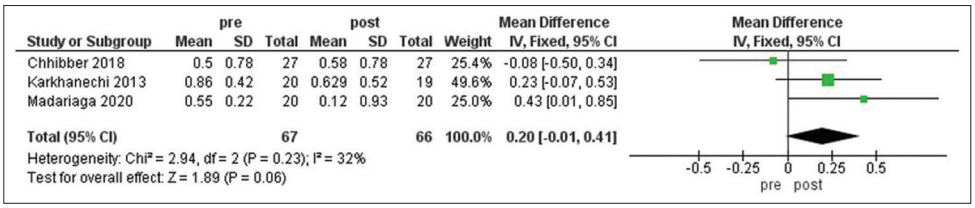


Figure 4: Bleeding on probing outcome.

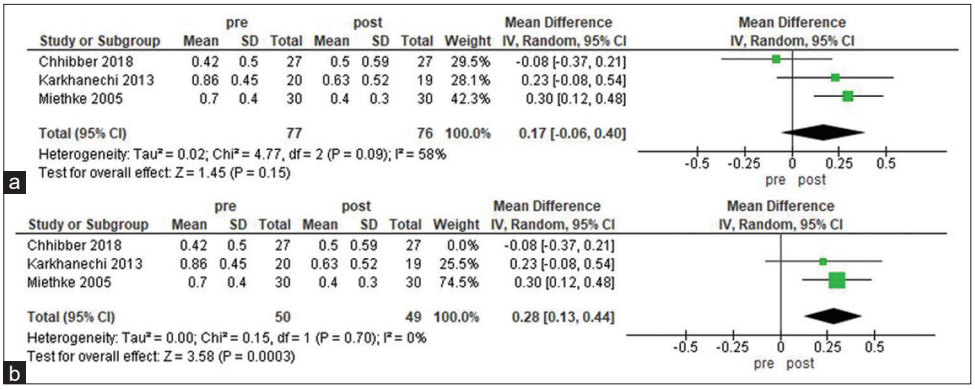


Figure 5: (a and b) The Gingival index outcome.

In 2017, Zheng *et al.*[5] experimented a meta-analysis to assess the effectiveness of CAs. They found that aligner therapy was associated with significant improvement related to treatment and chair time depending on many cross-sectional studies. Nevertheless, there is inadequate evidence in terms of the treatment stability and efficacy of CAs compared with conventional therapy. This analysis faced major limitations, which were the small number of included patients and the lack of randomized controlled trials. Funnel plots and Begg's rank correlation test were excluded from the study; they included only four studies which in turn may lead to some publication bias. Despite the several advantages of CAs compared to other appliances, only a few trials focused on implications of oral health, adverse events, and safety of CA.[11-13] Besides, some published evidence showed that CA is an expensive procedure and cannot treat some types of malocclusions.[14,15]

In 2021, Oikonomou *et al.*[29] tested a meta-analysis to assess the difference between oral hygiene parameters in patients undertaking orthodontic treatment by CAs in comparison to multibrackets FAs. They found that aligner therapy was accompanied by good oral hygiene parameters than FAs in short-term therapy. Several studies compare the different intervention procedures in the field of oral hygiene. The

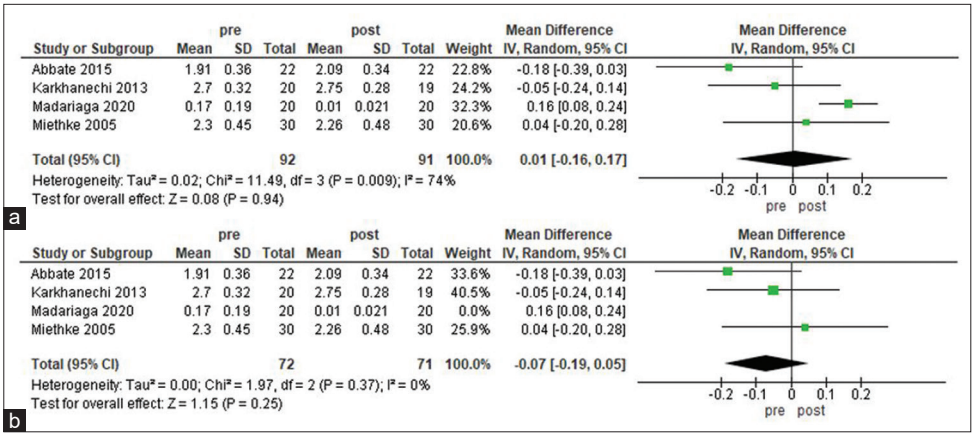


Figure 6: (a and b) The probing depth outcome.

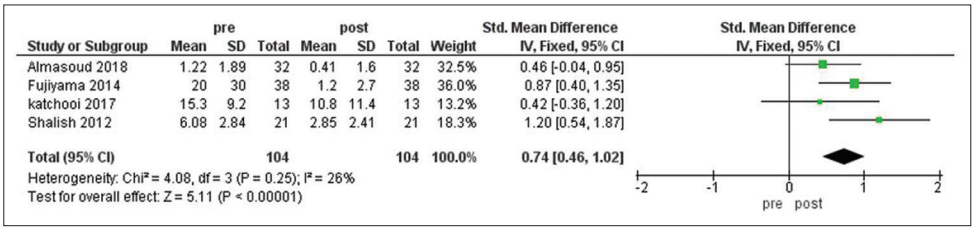


Figure 7: The pain score outcome.

current evidence showed a great scarcity as it was based on a few reports up to 2015.[30] The published studies were still heterogeneous and not of high quality with a great focus on periodontal health.[32] Jiang *et al.*[31] showed the superiority of CAs in terms of periodontal health based on the plaque and gingival indices. However, the evidence quality was not high enough due to the heterogeneity of the results and the risk of bias. A study by Fujiyama *et al.*[6] compared the difference of pain score using the visual analog scale between Invisalign and multibrackets FAs. They found that Invisalign resulted in less pain score in comparison with the edgewise appliance during the adjustment stage. Besides, at the last stage of treatment, the CAs group observed less pain. Furthermore, the cause of agony in the Invisalign cases was tray distortion. Therefore, tray distortion should be checked wisely during the use of CAs.

Almasoud[28] compared the pain perception between the Invisalign and the multibrackets FAs group. During the 1st week, they found that the pain perception was much lower in the Invisalign group in comparison with FAs.

Abbate *et al.*[24] aimed to study the periodontal and microbiological changes that occurred during 12 months of orthodontic treatment with removable aligners or multi brackets appliances. They concluded that oral hygiene was an important factor in reserve periodontal health during the period of orthodontic treatment. Albhaisi *et al.*[23] performed an RCT to examine the appearance of white spot lesions in patients treated by CAs. They demonstrated that CAs were associated with larger and shallower white spots while FA was associated with smaller and deeper ones. Besides the accumulation of plaque was more in the FA in comparison to CAs.

Limitations

The major limitation facing us was the heterogeneous data in few outcomes. However, we managed to solve the heterogeneity by the leave-one out study. Besides, like all systematic reviews, some research may have been missed; however, the authors performed a wide-scope strategy to search electronic databases and conducted a manual search, to limit this bias.

CONCLUSION

In this meta-analysis, the authors found that patients treated by CAs proved a noticeable decrease in pain scores. On contrary, there was not any difference between the pre-and post-treatment data regarding other indices.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

None.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: A systematic review. Angle Orthod 2015;85:881-9.
2. Tamer I, Öztas E, Marsan G. Orthodontic treatment with clear aligners and the scientific reality behind their marketing: A literature review. Turk J Orthod 2019;32:241-6.
3. Vaid NR. Lets talk ALIGNers! APOS Trends Orthod 2016;6:177-8.
4. Joffe L. Invisalign®: Early experiences. J Orthod 2003;30:348-52.
5. Zheng M, Liu R, Ni Z, Yu Z. Efficiency, effectiveness and treatment stability of clear aligners: A systematic review and meta-analysis. Orthod Craniofac Res 2017;20:127-33.
6. Fujiyama K, Honjo T, Suzuki M, Matsuoka S, Deguchi T. Analysis of pain level in cases treated with Invisalign aligner: Comparison with fixed edgewise appliance therapy. Prog Orthod 2014;15:64.
7. Miller KB, McGorray SP, Womack R, Quintero JC, Perelmuter M, Gibson J, *et al*. A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. Am J Orthod Dentofacial Orthop 2007;131:302.e1-9.
8. Buschang PH, Shaw SG, Ross M, Crosby D, Campbell PM. Comparative time efficiency of aligner therapy and conventional edgewise braces. Angle Orthod 2014;84:391-6.
9. Karkhanechi M, Chow D, Sipkin J, Sherman D, Boylan RJ, Norman RG, *et al*. Periodontal status of adult patients treated with fixed buccal appliances and removable aligners over one year of active orthodontic therapy. Angle Orthod 2013;83:146-51.
10. Årtun J, Spadafora AT, Shapiro PA, McNeill RW, Chapko MK. Hygiene status associated with different types of bonded, orthodontic canine-to-canine retainers: A clinical trial. J Clin Periodontol 1987;14:89-94.
11. Krieger E, Drechsler T, Schmidtmann I, Jacobs C, Haag S, Wehrbein H. Apical root resorption during orthodontic treatment with aligners? A retrospective radiometric study. Head Face Med 2013;9:21.
12. Kravitz ND, Kusnoto B, BeGole E, Obrez A, Agran B. How well does Invisalign work? A prospective clinical study evaluating the efficacy of tooth movement with Invisalign. Am J Orthod Dentofacial Orthop 2009;135:27-35.
13. Simon M, Keilig L, Schwarze J, Jung BA, Bourauel C. Treatment outcome and efficacy of an aligner technique--regarding incisor torque, premolar derotation and molar distalization. BMC Oral Health 2014;14:68.
14. Prescott TM, Miller R. Interview with align technology executives. Am J Orthod Dentofacial Orthop 2002;122:19A-20.
15. Bearn D. Orthodontics and dentofacial orthopedics. J Orthod 2002;29:154.
16. Moher D, Liberati A, Tetzlaff J, Altman DG, Antes G, Atkins D, *et al*. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. Rev Espanola Nutr Humana Diet 2014;18:172-81.
17. Katz A. Microsoft Excel 2010. Illinois: Style DeKalb IL; 2010.
18. Hujar P, Lebowitz F. Endnote. Aperture 2021;242:164.
19. Munder T, Barth J. Cochrane's risk of bias tool in the context of psychotherapy outcome research. Psychother Res 2018;28:347-55.
20. Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, *et al*. Cochrane Handbook for Systematic Reviews of Interventions. United States: Wiley; 2019.
21. Katchooi M, Cohanim B, Tai S, Bayirli B, Spiekerman C, Huang G. Effect of supplemental vibration on orthodontic treatment with aligners: A randomized trial. Am J Orthod Dentofacial Orthop 2018;153:336-46.
22. Chhibber A, Agarwal S, Yadav S, Kuo CL, Upadhyay M. Which orthodontic appliance is best for oral hygiene? A randomized clinical trial. Am J Orthod Dentofacial Orthop 2018;153:175-83.
23. Albhaisi Z, Al-Khateeb SN, Abu Alhaija ES. Enamel demineralization during clear aligner orthodontic treatment compared with fixed appliance therapy, evaluated with quantitative light-induced fluorescence: A randomized clinical trial. Am J Orthod Dentofacial Orthop 2020;157:594-601.
24. Abbate GM, Caria MP, Montanari P, Mannu C, Orrù G, Caprioglio A, *et al*. Periodontal health in teenagers treated with removable aligners and fixed orthodontic appliances. J Orofac Orthop 2015;76:240-50.
25. Shalish M, Cooper-Kazaz R, Ivgi I, Canetti L, Tsur B, Bachar E, *et al*. Adult patients' adjustability to orthodontic appliances. Part I: A comparison between Labial, Lingual, and Invisalign™. Eur J Orthod 2012;34:724-30.
26. Miethke RR, Vogt S. A comparison of the periodontal health of patients during treatment with the Invisalign® system and with fixed orthodontic appliances. J Orofac Orthop 2005;66:219-29.
27. Madariaga AC, Bucci R, Rongo R, Simeon V, D'Antò V, Valletta R. Impact of fixed orthodontic appliance and clear aligners on the periodontal health: A prospective clinical study. Dent J (Basel) 2020;8:4.
28. Almasoud NN. Pain perception among patients treated with passive self-ligating fixed appliances and invisalign® aligners during the first week of orthodontic treatment. Korean J Orthod 2018;48:326-32.
29. Oikonomou E, Foros P, Tagkli A, Rahiotis C, Eliades T, Koletsi D. Impact of aligners and fixed appliances on oral health during orthodontic treatment: A systematic review and meta-analysis. Oral Health Prev Dent 2021;19:659-72.
30. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Periodontal health during clear aligners treatment: A systematic review. Eur J Orthod 2015;37:539-43.
31. Jiang Q, Li J, Mei L, Du J, Levrini L, Abbate GM, *et al*. Periodontal health during orthodontic treatment with clear aligners and fixed appliances: A meta-analysis. J Am Dent Assoc 2018;149:712-20.e12.
32. Eliades T, Papageorgiou SN, Ireland AJ. The use of attachments in aligner treatment: Analyzing the "innovation" of expanding the use of acid etching-mediated bonding of composites to enamel and its consequences. Am J Orthod Dentofacial Orthop 2020;158:166-74.

How to cite this article: Abusafia BM, Mohamed AM, Al-Balaa M, Qiang QY, Abbas YS, Yang Y. Evaluation of gingival health and pain level in orthodontics treatment with clear aligners: A systematic review and meta-analysis. APOS Trends Orthod 2023;13:246-52.