

# EFFECT OF ORTHODONTIC TREATMENT ON ORAL HEALTH-RELATED QUALITY OF LIFE AND PSYCHOSOCIAL OUTCOMES IN PATIENTS WITH MALOCCLUSION: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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## Keywords

Malocclusion; orthodontic treatment; clear aligners; fixed appliances; OHRQoL; OHIP-14; self-esteem; psychosocial outcomes; meta-analysis.

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## Abstract

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### Background:

Malocclusion can impair appearance, oral function, social confidence, and oral health related quality of life (OHRQoL). Although orthodontic treatment can lead to short-term discomfort, it can also enhance psychosocial well-being.

### Objectives:

To assess the impact of orthodontic treatment on OHRQoL and self-esteem-related psychosocial outcomes in patients with malocclusion, a pooled analysis comparing clear aligners and fixed appliances was performed, where possible.

### Methods:

This systematic review and meta-analysis followed PRISMA 2020 guidelines. Randomized clinical trials reporting OHRQoL, self-esteem, anxiety, discomfort, emotional well-being, or social well-being of patients undergoing orthodontic treatment for malocclusion were eligible. Nonrandomized studies, reviews, meta-analyses, and trials that did not provide extractable psychosocial or OHRQoL data were excluded. The RoB 2-style approach was used to assess the risk of bias. For similar OHIP-14 outcomes, mean differences (MDs) with 95% confidence intervals (CIs) were pooled, whereas for the heterogeneous trials, a narrative synthesis was performed. Publication bias was not evaluated as there were fewer than 10 studies for each pooled outcome.

### Results:

**Adonis Abu Kariem**

167 records were identified, 17 of them were full-text assessed, and 12 randomized clinical trials were included. Four trials of four clear aligners (or orthodontic aligners) versus fixed appliances supported the OHIP-14 meta-analysis. Clear aligners showed lower OHIP-14 scores than fixed appliances at 7–10 days (MD = -8.16; 95% CI, -13.30 to -3.02;  $I^2 = 81.9\%$ ), 1 month (MD = -6.41; 95% CI, -7.91 to -4.90;  $I^2 = 0\%$ ), 6 months (MD = -3.62; 95% CI, -5.49 to -1.74;  $I^2 = 29.9\%$ ), and 12 months (MD = -3.85; 95% CI, -5.72 to -1.98;  $I^2 = 0\%$ ). Scale data were not extractable to pool direct self-esteem outcomes.

**Conclusion:**

Clear aligners could be more beneficial in terms of OHRQoL, particularly in early orthodontic treatment. There is still limited evidence due to a few pooled trials and heterogeneity of interventions and follow-up periods. Standardized OHRQoL and self-esteem measures should be used in future RCTs.

**Introduction:**

Malocclusion is not just a dental alignment issue, it can also impact appearance, oral function, social interaction and psychological well-being. For children, adolescents and adults, visible occlusal irregularities can have an impact on self-image, social confidence, the way they smile and their perceived attractiveness, which can all impact on oral health related quality of life (OHRQoL) [8,13,25,26]. Past literature indicates that people with more severe malocclusion are more likely to experience more functional, emotional and social consequences than normal or mild occlusal variation [17,22,24]. These effects are particularly relevant during childhood and adolescence, when there is a strong association between peer acceptance, facial appearance and self-esteem and psychosocial development [1,2,14].

OHRQoL is an important patient-reported outcome in orthodontics because it is a reflection of the patient's experience of oral symptoms, functional limitations, discomfort, and emotional and social well-being [31]. The traditional measures of orthodontic results are clinical occlusal correction and dental measurements; however, these outcomes may not fully reflect the impact of orthodontic treatment in daily life. For this reason, instruments for assessing the overall impact of malocclusion or orthodontic treatment, such as the OHIP, including OHIP-14, and child-specific quality-of-life instruments have become more popular in assessing the impact of malocclusion and/or orthodontic treatment

[7,15,16,31]. There is some evidence that over time orthodontic treatment can improve OHRQoL, but that patients can suffer from discomfort, pain, impaired speech and limited eating, anxiety and social inconvenience during the initial stages of wearing orthodontic appliances [10,18,23,32].

Association of malocclusion, orthodontic treatment and psychosocial outcome is still complicated. Some studies have indicated that orthodontics could enhance their self-esteem and quality of life, especially if they are worried about the appearance of their teeth or if they need oral rehabilitation [11,20]. But, sometimes psychological outcomes are not measured directly. For many orthodontic trials, the psychosocial effects are measured via OHRQoL domains (psychological discomfort, emotional well-being and social well-being), but not by using self-esteem scales [1,2,13]. This poses a significant constraint to the literature because although the clinical discussion of self-esteem-related outcomes is common, quantitative synthesis is not always possible, as they are not necessarily measured in the same way.

The OHRQoL may also be influenced by the different orthodontic treatment modalities. Fixed appliances are still quite common and there are some patients that prefer a clear aligner or some modified aligner system due to the appearance, removability, and apparent comfort of the appliance [3,4,9,18,32]. Randomized clinical trials have shown a difference between OHRQoL with

clear aligners or orthodontic aligners versus fixed appliances, particularly when used in early treatment, when pain, discomfort, difficulty eating and social embarrassment may be more evident [4,9,18,32]. Other RCTs have researched self-ligating brackets, lingual appliances, rapid palatal expansion, anterior crossbite, open bite, functional appliances, and modified aligner appliances; but the parameters of population, types of intervention, comparator, scales of outcomes, and follow-up period differ among the studies [3,5,10,21,27,28,29,30].

There are several systematic reviews evaluating malocclusion, orthodontic treatment, and OHRQoL, but many of these involved observational studies, age range, variety of instruments used for outcome measurement, and the types of overall orthodontic treatment [6,7,14,17,19,22,23,24]. These reviews are relevant but a synthesis with a specific focus on RCTs to evaluate the impact of orthodontic treatment on OHRQoL and psychosocial outcomes related to self-esteem is needed. Importance of this kind of review is that the results from randomized trials give stronger evidence of effects of treatments than do the results of observational studies, but pooling is appropriate only when studies are sufficiently akin with regard to intervention, comparator intervention, outcome measure, and follow-up period.

Thus, the objective of this systematic review and meta-analysis was to review the effect of orthodontic treatments on OHRQoL and psychosocial outcomes related to self-esteem of maloccluded patients in RCTs. For those outcomes where data were comparable, quantitative synthesis was conducted for clear aligners/orthodontic aligners versus fixed appliances, using OHIP-14 outcomes. Trials which had substantial differences in type of intervention, comparator, population, outcome instrument, and/or reporting format were synthesized narratively.

## Methods:

The systematic review and meta-analysis were performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses

(PRISMA) 2020 guidelines. The aim of the review was to assess the evidence from randomized clinical trials regarding the impact of orthodontic treatment for malocclusion on oral health-related QOL and self-esteem-related psychosocial outcomes. The review protocol was not registered. A systematic search of the literature was conducted in PubMed/MEDLINE, Scopus, Web of Science, Cochrane CENTRAL, and Embase. Key words included malocclusion, orthodontic care, clear aligners, fixed appliances, OHIP-14, self-esteem, anxiety, discomfort, psychosocial impact, and randomized clinical trials. Boolean operators were used to combine search terms. Additionally, lists of eligible studies and associated reviews were scanned manually for further potentially eligible trials. The studies considered for inclusion were those available until March 31, 2026.

Randomized clinical trials were included if they involved patients with malocclusion treated with orthodontic therapy, compared orthodontic therapy modalities, appliances, and/or orthodontic therapy with a control group (when applicable), and evaluated Oral Health Related Quality of Life, self-esteem, anxiety, discomfort, emotional well-being, social well-being, or related psychosocial factors. Validated questionnaires (OHIP-14, CPQ, COHIP, OHRQoL-UK or other patient reported questionnaires) assessing the outcome were deemed eligible. Systematic reviews, meta-analytic studies, narrative reviews, observational studies, case-control studies, cross sectional studies, retrospective studies, case reports, conference abstracts and nonrandomized comparative studies were excluded. Randomized orthodontic trials were also omitted when OHRQoL, self-esteem, and/or psychological outcome data were not extractable.

All identified records were screened based on the set eligibility criteria. Duplicate removal was followed by abstract and title screening to remove studies that did not appear relevant. The full-text articles were then excluded if they did not meet the inclusion criteria, and the exclusion criteria at full text stage were documented. A PRISMA 2020 flow diagram was used to summarize the final study-selection process.

Using a structured extraction form, data were extracted. Data extracted comprised the authors, year of publication, country, study design, sample size, participant characteristics, type of malocclusion, intervention, comparator, treatment duration, follow-up time points, OHRQoL (or psychosocial outcomes) and adverse or discomfort outcomes. In quantitative synthesis, data of mean and standard deviation extracted from the literature were given preference. When studies reported results for more than one follow-up period, results for each individual follow-up period were collected.

The main outcome was oral health-related quality of life. The most comparable outcome instrument from the clear-aligner or orthodontic-aligner versus fixed-appliance trials was OHIP-14, which was used for the main quantitative analysis. The OHIP-14 scores were lower, suggesting a better OHRQoL. Other psychosocial or quality of life outcomes were also included as secondary outcomes (self-esteem, anxiety, pain, discomfort, emotional well-being, social well-being). It was intended to include direct self-esteem findings in the synthesis, but there was no dedicated self-esteem scale data available in the randomized trials included. Thus the findings related to self-esteem were analyzed in the psychosocial and emotional dimensions of OHRQoL instruments when available.

For randomized trials, the risk of bias was evaluated using a domain-based approach similar to the RoB 2 tool. The risk of bias due to the randomization process, deviation from intended interventions, missing outcome data, outcome measurement, and selective reporting was assessed. Each study was evaluated based on the information found in the full text and risk of bias results were narratively summarized and displayed in tables.

Studies that were comparable in intervention, comparator, outcome instrument and follow-up period were only included in meta-analysis. Since the principal similar data was OHIP-14 scores for clear aligners or orthodontic aligners and fixed appliances, pooled analyses were completed at

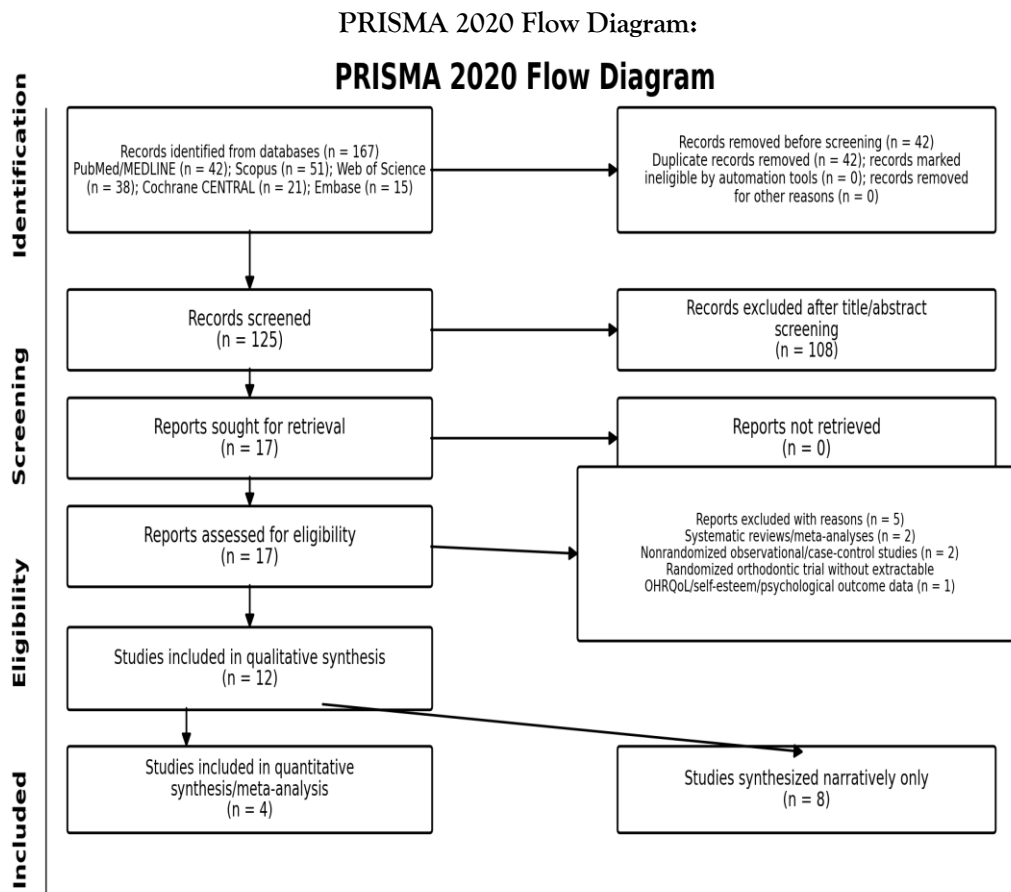
each time period (7-10 days, 1 month, 6 months, and 12 months). Continuous OHIP-14 outcomes were assessed by calculating mean differences at the 95% confidence interval (CI). Since lower OHIP-14 scores indicate better OHRQoL, negative mean differences were favored for clear and orthodontic aligners.  $I^2$  statistic was used to assess statistical heterogeneity. Trials that had any of the following differences in intervention(s), comparator, population, outcome scale, follow-up period, or reporting format were not pooled and were synthesized narratively.

Funnel plots or statistical tests for publication bias were not performed for any of the pooled outcomes as there were fewer than 10 studies for each outcome. In such situations, the interpretation of funnel plot is unreliable and may be misleading, so no funnel plot was created.

## Results:

A total of 167 records were identified through database searching. After removal of 42 duplicates, 125 records were screened by title and abstract. Of these, 108 records were excluded, and 17 full-text articles were assessed for eligibility. Five articles were excluded with reasons: two were systematic reviews or meta-analyses, two were nonrandomized observational or case-control studies, and one randomized orthodontic trial did not provide extractable OHRQoL, self-esteem, or psychological outcome data. Finally, 12 randomized clinical trials were included in the qualitative synthesis, of which 4 contributed data to the quantitative meta-analysis and 8 were synthesized narratively.

Four trials directly compared clear aligner or orthodontic aligner treatment with conventional fixed appliances and reported extractable OHIP-14 mean and standard deviation data at one or more follow-up points. These studies formed the main quantitative meta-analysis. The remaining eight RCTs were synthesized narratively because their interventions, comparators, age groups, outcome instruments, or reporting formats were not sufficiently comparable for direct pooling with the clear-aligner versus fixed-appliance analysis



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**Characteristics of Included Randomized Trials:**

The included RCTs evaluated a wide range of orthodontic approaches, including rapid palatal expansion, self-ligating and conventional brackets, clear aligners, lingual and labial fixed appliances, low-friction bracket systems, modified aligner

appliances with Ni-Ti springs, open-bite treatment with spurs, Class II functional appliances, and early anterior crossbite correction. OHRQoL was measured using OHIP-14, OHIP-16[M], CPQ8-10, CEQ, COHIP, MIQ, or OHRQoLUK instruments.

**Table 1. Characteristics of the 12 included randomized clinical trials.**

| Study              | Population/condition  | Intervention vs comparator                   | Analyzed sample | Outcome/time points   | Use in synthesis             |
|--------------------|---|--|-----------------|---|------------------------------|
| Pithon et al. [30] | Brazil; children aged 8-10 years with transverse maxillary deficiency and bilateral posterior crossbite | Rapid palatal expansion vs untreated control | 40 / 40         | CPQ8-10 at baseline, during RPE, end of activation, and 1 month after appliance removal | Narrative/model-based ratios |
| Othman et al. [28] | Malaysia; patients requiring fixed  | Conventional brackets vs active/passive      | 20 / 20 / 20    | OHIP-16[M] after bonding and activations  | Narrative/exploratory only   |

|                                |  |   |                    |   |  |
|--------------------------------|--|---|--------------------|---|--|
|                                | orthodontic treatment  | selfligating brackets   |                    |   |  |
| Alfawal et al. [4]             | Syria; adults with mild to moderate non-extraction malocclusion/crowding | Clear aligners vs fixed appliances                                | 22 / 22            | OHIP-14 at 1 week, 1 month, 3 months, 6 months, post-treatment      | Main pooled OHIP-14 analysis               |
| Jaber et al. [18]              | Syria; adults with severe crowding requiring extraction                  | Clear aligners vs fixed appliances                                | 18 / 18            | OHIP-14 at 1 week, 2 weeks, 1 month, 6 months, 12 months            | Main pooled OHIP-14 analysis               |
| Kara-Boulad et al. [21]        | Syria; class I malocclusion with moderate crowding                       | Lingual vs labial fixed appliances                                | 19 / 19            | OHIP-14 from baseline to end of treatment                           | Narrative; different intervention contrast |
| Curto et al. [10]              | Spain; patients receiving fixed orthodontic appliances                   | Conventional vs low-friction bracket/slot protocols               | 120 total          | OHIP-14 and pain during first month                                 | Narrative; different intervention contrast |
| Alhafi et al. [3]              | Syria; mild crowding treated without extraction                          | Modified aligner appliance with Ni-Ti springs vs fixed appliances | 18 / 18            | OHIP-14 and OHRQoL-UK at 2 weeks, 1 month, 2 months, post-treatment | Narrative/effect estimates only            |
| Aliaga-Del Castillo et al. [5] | Brazil; children aged 7-11 years with anterior open bite                 | Spurs plus posterior build-ups vs spurs only                      | 24 / 25            | CPQ8-10 and adaptation/discomfort outcomes                          | Narrative/model-based pediatric synthesis  |
| Tunca et al. [32]              | Turkey; mild or moderate malocclusion                                    | Conventional fixed appliances vs Invisalign/clear aligners        | 30 / 30            | OHIP-14, OHRQoL-UK, anxiety, pain at days 1, 10, and 20             | Main pooled early OHIP-14 analysis         |
| Borsato et al. [9]             | Brazil; Angle Class I malocclusion, age 13-35 years                      | Orthodontic aligners vs fixed appliances                          | 19 / 19 analyzed   | OHIP-14 at 1, 6, and 12 months                                      | Main pooled OHIP-14 analysis               |
| Pacha et al. [29]              | United Kingdom; adolescents aged 10-14 years with Class II malocclusion  | Hanks Herbst vs Twin-block functional appliances                  | 40 / 40 randomized | CEQ, COHIP, MIQ, and appliance-experience questionnaires            | Narrative; different appliance comparison  |
| Miamoto et al. [27]            | Brazil; children aged 8-10 years with                                    | Removable appliance with digital                                  | 15 / 15            | CPQ8-10 at baseline and 12 months                                   | Narrative; medians/modes, not mean/SD pool |

|                    |        |                                       |  |  |  |
|--------------------|--------|---------------------------------------|--|--|--|
| anterior crossbite | dental | springs vs resin-reinforced bite pads |  |  |  |
|--------------------|--------|---------------------------------------|--|--|--|

Abbreviations: CEQ, Childhood Experience Questionnaire; COHIP, Child Oral Health Impact Profile; CPQ8-10, Child Perceptions Questionnaire 8-10; FA, fixed appliance; MIQ, Malocclusion Impact Questionnaire; OHIP, Oral Health Impact Profile; OHRQoL, oral health-related quality of life; RPE, rapid palatal expansion.

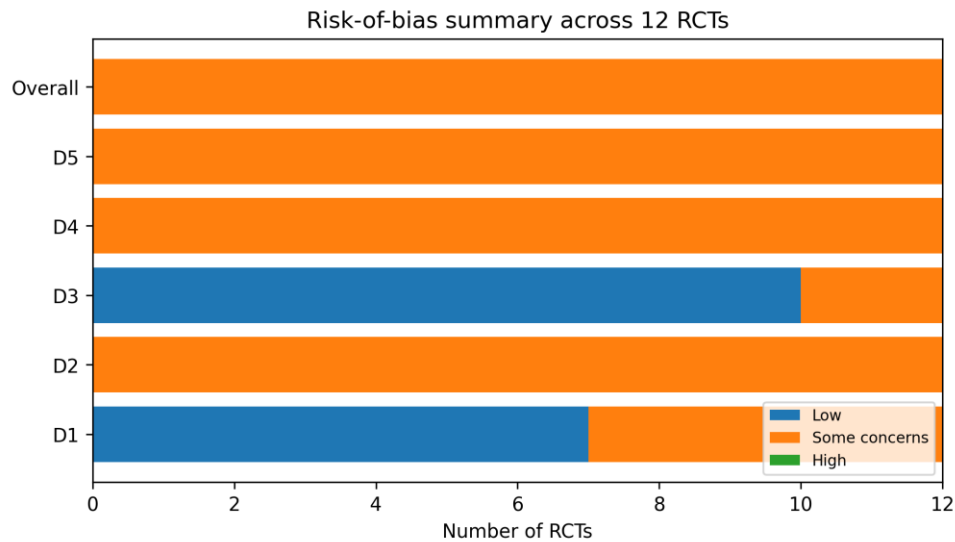
**Risk-of-bias assessment:**

Using a RoB 2-style domain assessment, most trials were judged as having some concerns overall. The main reasons were the impossibility of blinding participants and clinicians to appliance type, reliance on patient-reported outcomes, incomplete clarity around allocation concealment or selective reporting in some trials, and small sample sizes. Missing outcome data were generally limited, but some trials had endpoint-specific losses or incomplete questionnaire data.

**Table 2. RoB 2-style risk-of-bias judgments for included randomized trials.**

| Study                             | D1 randomization | D2 deviations | D3 missing data | D4 outcome measurement | D5 reported result | Overall       |
|-----------------------------------|------------------|---------------|-----------------|------------------------|--------------------|---------------|
| Pithon et al. (2022)              | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Othman et al. (2014)              | Some concerns    | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Alfawal et al. (2022)             | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Jaber et al. (2022)               | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Kara-Boulad et al. (2022)         | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Curto et al. (2020)               | Some concerns    | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Alhafi et al. (2024)              | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Aliaga-Del Castillo et al. (2024) | Low              | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Tunca et al. (2024)               | Some concerns    | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |
| Borsato et al. (2025)             | Some concerns    | Some concerns | Some concerns   | Some concerns          | Some concerns      | Some concerns |
| Pacha et al. (2023)               | Low              | Some concerns | Some concerns   | Some concerns          | Some concerns      | Some concerns |
| Miamoto et al. (2018)             | Some concerns    | Some concerns | Low             | Some concerns          | Some concerns      | Some concerns |

Figure 2. Risk-of-bias summary across included randomized trials.



D1: randomization process; D2: deviations from intended interventions; D3: missing outcome data; D4: measurement of the outcome; D5: selection of the reported result.

**Primary quantitative synthesis: clear aligners or orthodontic aligners versus fixed appliances**

The main meta-analysis was restricted to trials comparing clear aligners or orthodontic aligners with fixed appliances and reporting OHIP-14 total scores as mean and standard deviation. Lower OHIP-14 scores indicate better OHRQoL. Therefore, negative mean differences favour aligners. Random-effects inverse-variance models were used because clinical differences between trials were expected.

At the early 7-10-day follow-up, three RCTs were pooled. Clear aligners were associated with lower OHIP-14 scores compared with fixed appliances, with a pooled MD of -8.16 points (95% CI, -13.30

to -3.02). Heterogeneity was substantial ( $I^2 = 81.9\%$ ), mainly because Tunca et al. showed a smaller difference at day 10 than the two 1-week trials.

At 1 month, three RCTs were pooled. Clear aligner/orthodontic aligner treatment showed significantly lower OHIP-14 scores than fixed appliances, with a pooled MD of -6.41 points (95% CI, -7.91 to -4.90;  $I^2 = 0.0\%$ ). This finding was consistent across studies.

At 6 months, three RCTs were pooled. The pooled MD remained in favour of aligners at -3.62 points (95% CI, -5.49 to -1.74), with low-to-moderate heterogeneity ( $I^2 = 29.9\%$ ).

At 12 months, two RCTs contributed data. The pooled MD was -3.85 points (95% CI, -5.72 to -1.98;  $I^2 = 0.0\%$ ), again favouring aligners. This longer-term estimate should be interpreted cautiously because only two studies contributed data.

Table 3. Pooled meta-analysis results for OHIP-14 total scores:

| Comparison/outcome        | Studies | Participants | Effect measure    | Pooled effect (95% CI) | $I^2$ | Heterogeneity p | Interpretation   |
|---------------------------|---------|--------------|-------------------|------------------------|-------|-----------------|------------------|
| Clear aligner/orthodontic | 3       | 140          | MD, OHIP-14 total | -8.16 (-13.30          | 81.9% | 0.004           | Favours aligners |

|   |   |     |                   |                        |        |       |                  |
|---|---|-----|-------------------|------------------------|--------|-------|------------------|
| aligner vs fixed appliance, 7-10 days                           |   |     |                   | to - 3.02)             |        |       |                  |
| Clear aligner/orthodontic aligner vs fixed appliance, 1 month   | 3 | 118 | MD, OHIP-14 total | -6.41 (-7.91 to -4.90) | 0.0%   | 0.520 | Favours aligners |
| Clear aligner/orthodontic aligner vs fixed appliance, 6 months  | 3 | 118 | MD, OHIP-14 total | -3.62 (-5.49 to -1.74) | 29.9 % | 0.240 | Favours aligners |
| Clear aligner/orthodontic aligner vs fixed appliance, 12 months | 2 | 74  | MD, OHIP-14 total | -3.85 (-5.72 to -1.98) | 0.0%   | 0.767 | Favours aligners |

Negative MD values favour aligners. OHIP-14 scores range from 0 to 56, with higher scores indicating worse oral health-related quality of life.

Table 4. Study-level OHIP-14 data used in the main meta-analysis.

| Time point | Study                 | Exact assessment | Aligner n | Aligner mean (SD) | Fixed n | Fixed mean (SD) | MD (95% CI)              |
|------------|-----------------------|------------------|-----------|-------------------|---------|-----------------|--------------------------|
| 7-10 days  | Alfawal et al. (2022) | 1 week           | 22        | 14.14 (3.66)      | 22      | 25.18 (4.15)    | -11.04 (-13.35 to -8.73) |
| 7-10 days  | Jaber et al. (2022)   | 1 week           | 18        | 12.94 (7.54)      | 18      | 22.88 (9.60)    | -9.94 (-15.58 to -4.30)  |
| 7-10 days  | Tunca et al. (2024)   | 10 days          | 30        | 13.10 (7.91)      | 30      | 16.50 (7.45)    | -3.40 (-7.29 to 0.49)    |
| 1 month    | Alfawal et al. (2022) | 1 month          | 22        | 9.59 (2.70)       | 22      | 15.59 (2.91)    | -6.00 (-7.66 to -4.34)   |
| 1 month    | Jaber et al. (2022)   | 1 month          | 18        | 5.82 (3.96)       | 18      | 14.12 (9.07)    | -8.30 (-12.87 to -3.73)  |
| 1 month    | Borsato et al. (2025) | 1 month          | 19        | 6.47 (6.66)       | 19      | 14.79 (11.01)   | -8.32 (-14.11 to -2.53)  |
| 6 months   | Alfawal et al. (2022) | 6 months         | 22        | 5.27 (2.62)       | 22      | 8.59 (2.59)     | -3.32 (-4.86 to -1.78)   |
| 6 months   | Jaber et al. (2022)   | 6 months         | 18        | 4.12 (3.18)       | 18      | 10.12 (6.84)    | -6.00 (-9.48 to -2.52)   |

|           |                       |           |    |             |    |             |                        |
|-----------|-----------------------|-----------|----|-------------|----|-------------|------------------------|
| 6 months  | Borsato et al. (2025) | 6 months  | 19 | 5.16 (5.32) | 19 | 6.84 (6.93) | -1.68 (-5.61 to 2.25)  |
| 12 months | Jaber et al. (2022)   | 12 months | 18 | 2.88 (2.57) | 18 | 6.88 (3.81) | -4.00 (-6.12 to -1.88) |
| 12 months | Borsato et al. (2025) | 12 months | 19 | 4.89 (5.58) | 19 | 8.21 (6.86) | -3.32 (-7.30 to 0.66)  |

Figure 3. Forest plot for clear aligner/orthodontic aligner versus fixed appliance treatment at 7-10 days. Negative values favor aligners.

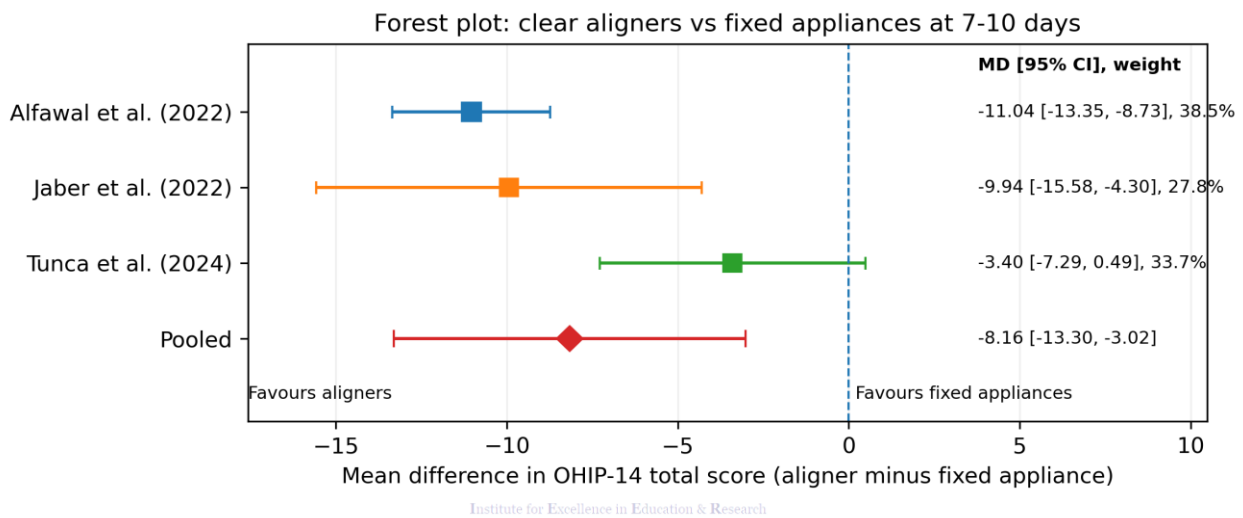


Figure 4. Forest plot for clear aligner/orthodontic aligner versus fixed appliance treatment at 1 month. Negative values favour aligners.

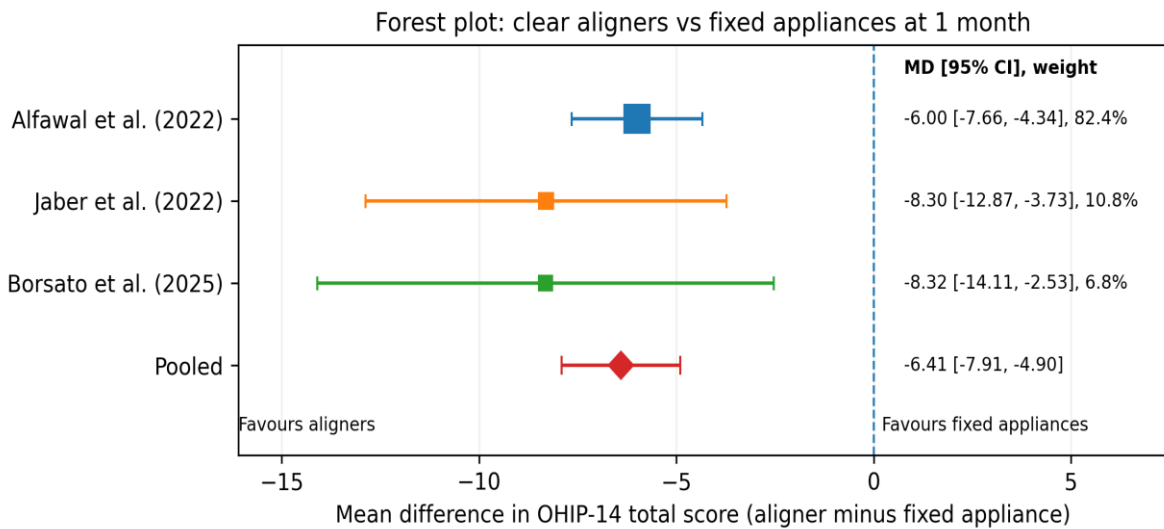


Figure 5. Forest plot for clear aligner/orthodontic aligner versus fixed appliance treatment at 6 months. Negative values favor aligners.

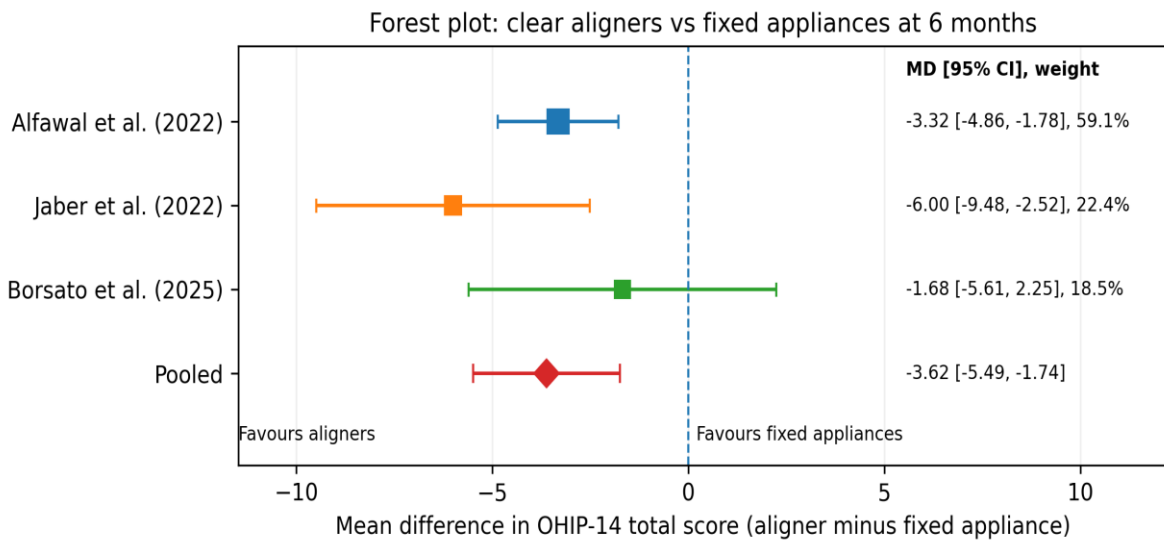
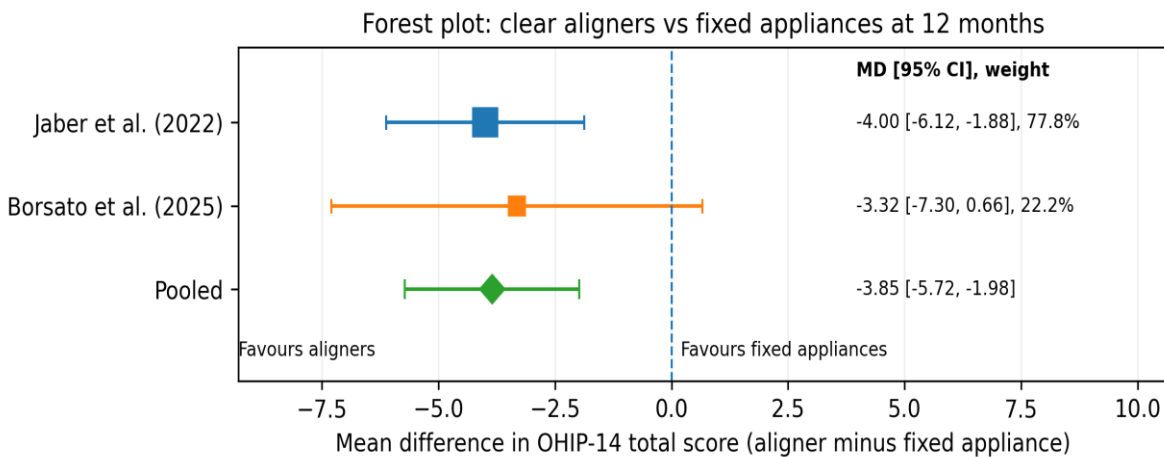


Figure 6. Forest plot for clear aligner/orthodontic aligner versus fixed appliance treatment at 12 months. Negative values favor aligners.



**Trials not pooled in the primary meta-analysis:**  
 Eight RCTs were not included in the primary OHIP-14 pooled analysis because they evaluated different orthodontic interventions, pediatric interceptive protocols, functional appliances, or

outcome scales that were not directly comparable with the clear-aligner versus fixed-appliance OHIP-14 data. These trials were retained in the systematic review and are summarized below.

Table 5. Key findings from randomized trials not directly pooled in the primary meta-analysis.

| Study              | Comparison               | Outcome         | Extracted result                                   | Interpretation   |
|--------------------|--------------------------|-----------------|--|--|
| Pithon et al. [30] | RPE vs untreated control | CPQ8-10 overall | Overall OHRQoL ratio 1.17 at T1 and T2; 0.28 at T3 | Temporary worsening during activation, followed by improvement after appliance removal |

|                                |   |                    |  |   |
|--------------------------------|---|--------------------|--|---|
| Othman et al. [28]             | Self-ligating vs conventional brackets                  | OHIP-16[M]         | Immediate bonding MD approximately -3.75 (95% CI -9.42 to 1.92)  | No clear overall difference between bracket systems   |
| Kara-Boulad et al. [21]        | Lingual vs labial fixed appliances                      | OHIP-14            | 1-week MD 2.17 (95% CI 1.44 to 2.90)   | Greater early OHRQoL burden with lingual appliances   |
| Curto et al. [10]              | Low-friction vs conventional brackets                   | OHIP-14 at 1 month | MD -3.00 (95% CI -4.46 to -1.54)   | Lower OHRQoL burden with low-friction brackets  |
| Alhafi et al. [3]              | Modified aligner appliance vs fixed appliances          | OHIP-14 overall    | 2-week MD 2.77 (95% CI -0.80 to 6.36)  | No statistically clear overall difference; functional limitation favored fixed appliances, psychological disability favored modified aligner at later time points |
| Aliaga-Del Castillo et al. [5] | Spurs plus build-ups vs spurs only                      | CPQ8-10 overall    | Group effect ratio 0.99 (95% CI 0.64 to 1.52)  | No clear between-group OHRQoL difference  |
| Pacha et al. [29]              | Hanks Herbst vs Twin-block                              | CEQ, COHIP, MIQ    | CEQ b 2.8 (95% CI -0.3 to 5.8); COHIP b 0.3 (95% CI -4.4 to 5.0); MIQ b -0.1 (95% CI -3.9 to 3.6)      | Overall OHRQoL questionnaire scores did not differ clearly; selected MIQ/OEQ items suggested greater embarrassment and negative perceptions with Twin-block       |
| Miamoto et al. [12]            | Removable appliance vs bite pads for anterior crossbite | CPQ8-10            | Group 1 overall median improved from 35 to 12; Group 2 from 7 to 8; ANCOVA treatment protocol p = 0.39 | Not pooled because results were medians/modes and baseline CPQ8-10 differed between groups  |

**Psychological outcomes and self-esteem:**

Direct self-esteem outcomes were not available for quantitative pooling. None of the included RCTs provided extractable data from a dedicated self-esteem scale such as the Rosenberg Self-Esteem

Scale. Psychological and self-esteem-related effects were instead captured indirectly through OHRQoL domains, including psychological discomfort, psychological disability, emotional well-being, social well-being, confidence-related

MIQ items, and embarrassment-related appliance-experience items.

Across the clear-aligner trials, the early improvement in OHRQoL was driven mainly by lower pain, fewer functional limitations, and lower psychological burden in the aligner groups. In the functional-appliance RCT, overall questionnaire scores did not differ clearly between Hanks Herbst and Twin-block appliances, but selected MIQ and appliance-experience items suggested more negative self-perception, embarrassment, and appliance-related concerns among Twin-block users. In pediatric interceptive studies, changes in emotional and social domains were reported, but different scales and reporting formats prevented quantitative pooling.

#### **Adverse effects, follow-up completeness, and publication bias:**

Follow-up completeness was generally acceptable across trials, although some studies reported incomplete endpoint questionnaire data or losses to follow-up. The most common patient-reported negative effects were temporary pain, discomfort, functional limitation, speech or eating difficulty, and appliance-related embarrassment. No serious harms directly attributable to the OHRQoL outcomes were consistently reported across the included trials.

A funnel plot was not generated and publication-bias tests were not performed. This was methodologically appropriate because each pooled time-point analysis included fewer than 10 studies. With such a small number of studies, funnel-plot asymmetry and statistical small-study-effect tests would be unreliable and potentially misleading.

#### **Overall summary of results:**

Overall, the randomized evidence suggests that orthodontic treatment can temporarily worsen OHRQoL during the early active-treatment phase, especially after appliance insertion or activation. In the main pooled comparison, clear aligners or orthodontic aligners were associated with better OHIP-14 scores than fixed appliances at 7-10 days, 1 month, 6 months, and 12 months. The most robust pooled estimate was observed at 1 month because three RCTs contributed consistent OHIP-

14 data with no observed heterogeneity. Evidence for direct self-esteem improvement remains insufficient because self-esteem was not measured with a dedicated extractable scale in the included RCTs. Therefore, the self-esteem-related interpretation should remain limited to psychosocial and emotional OHRQoL domains rather than a direct self-esteem meta-analysis.

#### **Discussion:**

This systematic review and meta-analysis provided a summary of the randomized clinical trial evidence for the effect of orthodontic treatment on oral health-related quality of life (OHRQoL) and self-esteem-related psychosocial outcomes in patients with malocclusion. A total of 12 trials were identified that used a randomized design. Trials comparing clear-aligner or orthodontic-aligner with fixed-appliance were quantitatively pooled due to similar OHIP-14 outcomes at similar follow-up time points [4,9,18,32]. The remaining were synthetically narrated as they included different orthodontic treatment modalities, subjects, controls, instruments, or follow-up periods [3,5,10,21,27-30].

Results of the pooled data indicated that the clear aligners had lower OHIP-14 scores at 7-10 days, 1 month, 6 months, and 12 months compared to fixed appliances. These findings may suggest that aligner-based treatment may have a less detrimental impact on daily life, especially in the initial treatment phase, than fixed appliances in view of the lower OHIP-14 scores. This finding is clinically important because during the first stages of orthodontic treatment, patients often experience pain and discomfort, have trouble eating, struggle to speak and are socially inconvenienced [10,18,32]. The direction of the effect is also in line with the results of previous reviews; the type of appliance used during the treatment could affect the level of pain and OHRQoL during orthodontic treatment [7,23]. Heterogeneity was low to moderate at 1 month and 6 months and heterogeneity was the lowest at these two time points. There was no statistical heterogeneity at 1 month, indicating that across the included trials, there was a consistent advantage for the aligners. Heterogeneity was low

at 6 months, and this justified the pooled estimate. The 7-10-day analysis, on the other hand, indicated high heterogeneity that could be related to the baseline level of malocclusion, the type of appliances, the methods used for treatment, the adaptation of patients, the perception of pain, and the time of evaluation of the outcomes [4,18,32]. Based on this, the early-treatment result, in favor of the aligners, should be interpreted with caution. The apparent OHRQoL benefit of aligners may be due to their removability, cosmetic appearance and decreased interference with eating, brushing, and social confidence. Fixed appliances can lead to more initial soft tissue discomfort, limited diet, problems with oral care, and embarrassment in social situations. But these results should not be confused with proof that aligners are best for every orthodontic patient. The selection of the appliance should always be based on the type of malocclusion, complexity of the case, required tooth movement, patient cooperation, price, and the doctor's clinical opinion.

The narrative synthesis also indicated that other orthodontic modalities had an impact on OHRQoL and psychosocial outcomes, but could not be statistically pooled. The studies assessing self-ligating brackets, lingual appliances, rapid palatal expansion, anterior crossbite correction, open bite treatment, functional appliances, and modified aligner appliances varied with respect to their study design, outcome tools, and clinical context [3,5,10,21,27-30]. The importance of these studies is that they demonstrate that patient reported outcome is dependent on the type of appliance and indication for treatment. But there would have been significant clinical and methodological variability if they had been used in clear-aligner versus fixed-appliance trials.

The major drawback of the evidence that is available is that there is a lack of actual data on self-esteem. While there was a general association between malocclusion and orthodontic treatment to self-image, confidence, and psychosocial well-being, the dedicated self-esteem scale outcomes were not consistently reported in the included RCTs. Rather, psychosocial impacts were typically assessed by using aspects of OHRQoL including psychological discomfort, emotional well-being

and social well-being. This is in line with previous works that have demonstrated that self-esteem is of interest in orthodontic patients, but not always assessed with standardized and extractable instruments [1,2,11,20]. Thus, any assertions concerning self-esteem need to be kept to a minimum and guarded.

The results confirm the relevance of incorporating PROs in orthodontic studies. Traditional measures of orthodontic success include occlusal correction, alignment, overjet, overbite and efficiency of the treatment. But these clinical measures are not comprehensive of the patient's experience of the treatment. OHRQoL instruments are a source of valuable data in terms of pain, function, appearance, emotions and social interaction [31]. This is significant as malocclusion can be a negative influence on quality of life [8,13,16,25,26] and treatment may have a negative impact on quality of life initially and then a positive impact overtime.

### Limitations:

There are limitations of this review. First, of the 12 RCTs included, only four (clearly or orthodontic-aligner versus fixed-appliance) provided data for the primary OHIP-14 meta-analysis at one or more time points [4,9,18,32]. Thus, the results of the pooling should be viewed with caution. Secondly, there was a lack of broad pooling due to the varying age of patients treated, malocclusion type, treatment modality, comparator, outcome instrument and follow-up duration. Third, there was significant heterogeneity in the 7-10-day analysis which suggests some differences in patient experience in the first week and the methods used. Fourth, publication bias could not be evaluated as the number of studies less than 10 per pooled outcome were not sufficient to interpret funnel plots.

A further restriction was that there was no possibility of meta-analysis of direct self-esteem outcomes. The objective for the review was to evaluate the self-esteem related psychosocial outcome, but the randomized trial evidence primarily reported on domains of OHRQoL, and not self-esteem specific scale data. Furthermore, there were fewer than adequate reports of

allocation concealment, blinding, missing data and outcome assessment methods in some trials, which could impact the confidence in the evidence.

### Future work implications:

In future randomized clinical trials, the use of standardized patient-reported outcome measures in addition to clinical orthodontic outcomes should be considered. Trials should always provide full mean and SD data of OHIP-14 or other validated OHRQoL instruments at similar time points. Self-esteem and psychosocial well-being instruments should also be included and dedicated to this purpose, as to enable direct quantitative synthesis of psychological outcomes. The patient groups should be better defined in future studies, based on the type of malocclusion, such as mild-to-moderate crowding, severe crowding, Class II malocclusion, anterior open bite, anterior cross bite and transverse maxillary deficiency. Further investigation of this topic is also warranted to assess the long-term OHRQoL outcomes of the two types of orthodontic appliances 6 or more years following treatment to verify if OHRQoL differences are maintained, reduced or eliminated after the adaptation period. An improved certainty of evidence would come from better reporting of randomization, allocation concealment, blinding (where applicable), missing data, adverse effects and protocol registration.

### Conclusion:

The results of this systematic review and meta-analysis indicate that clear aligners or orthodontic aligners might have an association with better OHRQoL than fixed appliances with lower OHIP-14 score at 7-10 days, 1 month, 6 months and 12 months. There is limited evidence, however, because of the small number of pooled trials, high level of heterogeneity across trials at the earliest follow-up, and variation in interventions and outcome measures. Other orthodontic treatments had relevant impacts on OHRQoL and psychosocial aspects, but were not pooled due to clinical and methodological differences. Regarding direct self-esteem outcomes, data could

not be meta-analyzed due to the lack of dedicated self-esteem scale data. When designing future randomized trials, more consistent OHRQoL and self-esteem instruments should be used to more clearly elucidate the psychosocial impact of orthodontic treatment for malocclusion.

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