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Comparison of the periodontal status of orthodontic aligner treatment against traditional orthodontic treatment: A Comprehensive Systematic review and Meta-Analysis study

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### **ADMINISTRATIVE INFORMATION**

Support - King Khalid University.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420090

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 February 2024 and was last updated on 21 February 2024.

#### INTRODUCTION

Review question / Objective The objective of this present study was to identify studies in the field of orthodontic treatment and systematically review the studies with a meta-analysis aimed at examining whether clear aligners are more effective in improving periodontal health status compared with traditional fixed appliances in patients receiving orthodontic treatment.

Condition being studied This study compares the periodontal health of patients treated with aligners with those who received traditional fixed appliances.

#### **METHODS**

**Search strategy** In order to ensure relevant studies were included in the research, an electronic search was conducted for the systematic review

with meta-analysis. Different combinations of key words were formulated according to the PICO guidelines using the two booleans (OR and AND) and used to search for articles through various databases such as Web of Science (WOS), PubMed, Cochrane Library, Science Direct, and Google Scholar.

Participant or population The number of patients with no gender or age restriction receiving orthodontic therapy, including orthodontic aligner treatment and traditional orthodontic treatment.

**Intervention** This includes orthodontic aligner treatment reported.

**Comparator** The comparison of patients undergoing orthodontic treatment with any type of traditional orthodontic like fixed appliance, bracket and band, self-ligating and Fixed buccal Traditional vs Digital splints.

**Study designs to be included** Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PICOS) criteria.

Eligibility criteria Studies published in English.

**Information sources** Include a randomized controlled trial (RCT), prospective study, or cohort study that compares different parameters of the patients undergoing orthodontic treatments with any type of aligner treatment and traditional orthodontic treatment.

Main outcome(s) Patients with aligner treatment have a better periodontal health status than patients with traditional fixed appliance treatment based on the periodontal clinical parameters plaque index, gingivitis indexes.

Data management A predefined Excel sheet was adopted and used for the data collection, and relevant data were extracted from the final included studies into formulated sheets. The data extracted includes the following: author first name, study design (clinical trials, prospective, and cohort studies), Year of publication: Population size, patient age (mean and standard deviation), gender (male and female), type of aligner orthodontic therapy (intervention) and type of traditional orthodontic treatment (comparison), and outcomes measures such as gingivitis indexes (GI), plaque index (PI), probing depth (PD), sulcus bleeding index (SBI), and papillary bleeding index (PBI).

Quality assessment / Risk of bias analysis The quality of the final included studies for the systematic review and meta-analysis on the comparison of the periodontal status of orthodontic aligner treatment vs. traditional orthodontic treatment was assessed by the authors. (ROBINS-1) tool [15] for methodological quality of systematic review composed of 7 different domains was adopted to assess the quality of the included studies under the non-randomized controlled trial, which include retrospective, cohort, and prospective studies for interventions. While the randomized controlled studies were assessed using the ROB tool for quality assessment with five domains.

The peer reviewers independently evaluated the overall quality of the included studies using the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) approach, as stated in [16]. The articles were assessed using twelve specific questions (Appendix 1), with a score rating ranging from 0 to 2 for each topic, yielding an overall score of 24. The assessment

revealed that a score of 0–12 suggested a high risk of bias, 13–18 suggested a moderate risk of bias, and 19–24 showed a low risk of prejudice.

Strategy of data synthesis The numerical data extracted from the included studies were subjected to descriptive statistics such as number, mean, and standard deviation, and charts were also used to visualize some variables, including the study's characteristics such as age, population size, and country. In cases where two or more studies reported the same outcome indices, a random-effects meta-analysis with a standardized mean difference (SMD) was adopted to measure the effect size. The results were presented using a forest plot, which displayed the overall SMD for each study. Heterogeneity among the studies was evaluated using I2 statistic. In cases where I2 is less than 25%, it is considered low heterogeneity, and where I2 is greater than 25% but less than or equal to 50%, it is denoted as moderate heterogeneity, while I2 ≥ 75% and above is considered high heterogeneity.

A 95% confidence level and a 5% significance level were utilized for decision-making. The null hypothesis of no significant difference among the two groups of aligner and traditional orthodontic treatments examined would be rejected if the calculated p-value is less than the significance level.

To evaluate publication bias, a funnel plot was used. And when included studies end up in the funnel, the funnel plot is symmetric, which means that the studies show no evidence of publication bias. The statistical analysis was conducted using RevMan version 5.4 (The Cochrane Collaboration, Copenhagen, Denmark).

**Subgroup analysis** The data was compiled from a variety of articles:

- Author(s), year of publication, country, study design.
- Total number of patients/datasets.
- Training/validation datasets.

Sensitivity analysis Not applicable.

Language restriction Only articles in English.

Country(ies) involved Saudi Arabia.

**Keywords** Aligner therapy, periodontal health, periodontal index in orthodontic patients.

**Dissemination plans** All the data and the article will be share after the publication.

### Contributions of each author

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