INPLASY

Comparative Impact of Clear Aligners and Fixed Appliances on Quality of Life, Periodontal Health and Pain: A systematic Review and Meta-analysis

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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.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 March 2025 and was last updated on 23 March 2025.

INTRODUCTION

Review question / Objective To compare the impact of clear aligners and fixed appliances on quality of life, periodontal health, and pain perception in orthodontic patients.

Rationale Clear aligners have gained popularity due to their aesthetic appeal and potential benefits in periodontal health, pain management, and quality of life. This systematic review and meta-analysis aim to consolidate evidence comparing these factors between clear aligners and fixed appliances.

Condition being studied Orthodontic treatment outcomes, specifically quality of life, periodontal health (plaque index, gingival index, probing depth), and pain perception in patients treated with clear aligners or fixed appliances.

METHODS

Search strategy A systematic search across PubMed, Embase, Scopus, Web of Science, Cochrane Library, and ScienceDirect, including randomized controlled trials (RCTs) and observational studies using PRISMA guidelines. Boolean operators and predefined search terms were applied.

Participant or population Patients of all ages undergoing orthodontic treatment with either clear aligners or fixed appliances across all age groups and genders. Excluded: severe periodontal disease, craniofacial anomalies, or orthognathic surgery patients.

Intervention Orthodontic treatment with clear aligners, including commercially available systems such as Invisalign.

Comparator Fixed orthodontic appliances, including conventional metal braces, self-ligating brackets, and ceramic braces.

Study designs to be included Randomized controlled trials (RCTs), observational cohort, and case-control studies. Excluded: reviews, case reports, expert opinions.Mixed-methods, quantitative, and qualitative original research. Excluded reviews, editorials, and non-peer-reviewed studies.

Eligibility criteria Studies comparing clear aligners and fixed appliances that measure at least one of the primary outcomes. Exclusion of studies on patients with severe periodontal disease, craniofacial anomalies, or undergoing orthognathic surgery.

Information sources PubMed, Cochrane Library, Scopus, Web of Science, and Embase databases. Additional sources include reference lists of eligible studies.

Main outcome(s) Primary: Quality of life (OHIP-14), periodontal indices (plaque, gingival, probing depth), pain intensity (VAS/NRS).

Additional outcome(s) Treatment duration, Patient-reported discomfort, Oral hygiene adherence, microbial composition, speech impact, analgesic use, and relapse rates.

Data management Data extraction via piloted Excel sheets; EndNote for deduplication. Analyzed using Comprehensive Meta-Analysis (CMA) software.

Quality assessment / Risk of bias analysis Assessed via Cochrane tools for RCTs and ROBINS-I for observational studies. Evaluated domains like randomization, missing data, and publication bias (Egger's test, funnel plots).

Strategy of data synthesis A meta-analysis will be conducted using Comprehensive Meta-Analysis software version 3.7. Random-effects models will be applied for outcomes with significant heterogeneity ($I^2 > 75\%$), while fixed-effect models will be used for low heterogeneity. Mean difference (MD) and standardized mean difference (SMD) will be used for continuous outcomes. Heterogeneity will be assessed using the I^2 statistic, and publication bias will be evaluated with funnel plots and Egger's test.

Subgroup analysis By treatment duration (short-term: ≤1 month; long-term: ≥12 months) and study type (RCTs vs. observational).

Sensitivity analysis Conducted to assess the impact of excluding studies with a high risk of bias on overall findings.
Assessed robustness using the trim-and-fill method to impute missing studies and fail-safe N to estimate publication bias impact. Re-ran analyses excluding high-risk-of-bias studies to evaluate effect stability.

Language restriction Only articles in English.

Country(ies) involved Saudi Arabia.

Other relevant information Compliance with PRISMA guidelines. Data synthesis will involve both qualitative and quantitative methods.

Keywords Clear aligners, Invisalign, fixed appliances, braces, orthodontic treatment, QOL.

Dissemination plans Publication in peer-reviewed orthodontic/dental journals, presentation at conferences, and dissemination via academic platforms.

Contributions of each author

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