COMPARATIVE EFFECTS OF FIXED ORTHODONTIC APPLIANCES AND CLEAR ALIGNERS ON PERIODONTAL HEALTH IN ADULTS: A PROSPECTIVE OBSERVATIONAL STUDY

Study Protocol with Statistical Analysis Plan

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Scientific Background

Orthodontic appliances may influence periodontal health by modifying plaque accumulation and oral hygiene conditions. Fixed orthodontic appliances may create plaque-retentive areas around brackets and archwires, whereas removable clear aligners may facilitate access to tooth surfaces during oral hygiene procedures.

Previous studies have reported differences between fixed orthodontic appliances and clear aligners in plaque accumulation, gingival inflammation, bleeding on probing, and probing pocket depth. However, variation in baseline periodontal status and oral hygiene protocols may affect these findings.

The present study will therefore compare early periodontal changes and patient-reported outcomes in adults receiving fixed orthodontic appliances or clear aligners following standardized non-surgical periodontal treatment and oral hygiene instruction.

Study Aim

The primary aim is to compare periodontal changes associated with fixed orthodontic appliances and clear aligners during the first three months of orthodontic treatment.

Secondary aims include comparison of oral health-related quality of life, gingival symptoms, and perceived oral hygiene difficulty between the two groups.

Study Design

This study will be conducted as a prospective observational cohort study at Altınbaş University Dental Hospital.

A total of 30 systemically healthy adults will be included. Participants will be evaluated in two groups according to the orthodontic treatment modality they receive:

Clear Aligner Group: 15 participants receiving clear aligner therapy.

Fixed Orthodontic Appliance Group: 15 participants receiving fixed orthodontic appliances.

Participants will not be assigned to treatment groups by the research protocol; treatment modality will be determined as part of routine orthodontic care.

Before orthodontic appliance placement, all participants will undergo standardized non-surgical periodontal treatment and receive oral hygiene instructions.

Eligibility Criteria

Participants will be adults aged 18 years or older who are systemically healthy, periodontally healthy or diagnosed with gingivitis, have probing pocket depths of 3 mm or less without clinical attachment loss or reduced periodontium, require non-extraction orthodontic treatment, and have less than 5 mm of crowding in both arches.

Pregnant or breastfeeding individuals, current tobacco users, individuals with systemic diseases that may influence periodontal status, individuals who received initial periodontal therapy within the preceding six months, and individuals with previous orthodontic treatment will be excluded.

Study Assessments

Clinical assessments will be performed at:

T0: Baseline, before non-surgical periodontal treatment.
T1: Following periodontal treatment and before orthodontic treatment initiation.
T2: Three months after orthodontic treatment initiation.

The following periodontal parameters will be assessed at T0, T1, and T2:

Full Mouth Plaque Score (FMPS): percentage of tooth surfaces exhibiting visible plaque, ranging from 0% to 100%.

Bleeding on Probing (BoP): percentage of sites exhibiting bleeding within 30 seconds following probing.

Gingival Index (GI): assessed on a 0–3 scale according to Löe and Silness criteria.

Probing Pocket Depth (PPD): measured in millimeters at six sites per tooth using a UNC-15 periodontal probe.

Clinical Attachment Level (CAL): measured in millimeters from the cementoenamel junction to the base of the periodontal sulcus or pocket.

Patient-Reported Outcomes

Oral health-related quality of life will be assessed using the Oral Health Impact Profile-14 (OHIP-14) at T0 and T2. Total scores range from 0 to 56, with higher scores indicating poorer oral health-related quality of life.

At T2, an 8-item Visual Analog Scale (VAS) ranging from 0 to 10 will be used to assess gingival symptoms, toothbrushing and interdental cleaning difficulty, and satisfaction with gingival health.

Statistical Analysis Plan

Statistical analyses will be performed using IBM SPSS Statistics version 27.

Descriptive statistics will include number, percentage, mean, standard deviation, median, minimum, and maximum values, as appropriate.

Normality of continuous variables will be assessed before inferential analyses. Between-group comparisons will be performed using appropriate parametric tests when assumptions are satisfied and the Mann-Whitney U test when they are not.

Longitudinal changes within groups across T0, T1, and T2 will be evaluated using repeated-measures analyses when parametric assumptions are satisfied and the Friedman test when they are not. Appropriate paired tests will be used for post-hoc comparisons. Comparisons involving two repeated measurements will be performed using paired-samples tests or Wilcoxon signed-rank tests, as appropriate.

Categorical variables will be analyzed using Pearson's chi-square test or Fisher's exact test when required. Bonferroni adjustment will be applied where appropriate for multiple comparisons.

Statistical significance will be set at $p < 0.05$.

Ethical Considerations

The study was approved by the Istinye University Human Research Ethics Committee under approval number 2025-239.

Written informed consent will be obtained from all participants before study-related assessments. Participant confidentiality and privacy will be maintained throughout the study.