MedPub Online International Journal of Medical Research (MOIJMR)
ISSN: 3107-1376, Volume 2, Issue 2, July-December, 2025
Available online at: https://medpubonline.com/index.php/moijmr

Assessment of Gingival Inflammation in Patients using Clear Aligners vs. Fixed Appliances: A Prospective Study

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Received: 03 June 2025 | Accepted: 13 July 2025 | Published Online: 01 August 2025

ABSTRACT

Objective: This prospective study aimed to assess and compare the degree of gingival inflammation in orthodontic patients undergoing treatment with clear aligners versus those using conventional fixed appliances.

Methods: A total of 50 patients undergoing orthodontic treatment were enrolled and divided into two groups: Clear Aligner group (n = 25) and Fixed Appliance group (n = 25). Clinical periodontal parameters—Gingival Index (GI), Plaque Index (PI), probing depth (PD), and bleeding on probing (BOP)—were assessed at baseline, 3 months, and 6 months. All subjects received standardized oral hygiene instructions. Data were statistically analyzed to determine intra-group and inter-group differences.

Results: Patients treated with clear aligners demonstrated significantly lower GI and PI scores at both 3- and 6-month intervals compared to those with fixed appliances ($p < 0.05$). The aligner group also showed reduced BOP and better maintenance of periodontal health throughout the study period. In contrast, fixed appliance users exhibited a progressive increase in plaque accumulation and gingival inflammation, likely due to difficulty in maintaining optimal oral hygiene.

Conclusion: Clear aligners are associated with lower gingival inflammation and superior periodontal outcomes compared to fixed orthodontic appliances in a 6-month prospective evaluation. These findings highlight the potential periodontal advantages of aligner therapy, particularly for patients with compromised plaque-control ability.

Keywords: clear aligners, fixed appliances, gingival inflammation, periodontal health, orthodontic treatment.

INTRODUCTION

Orthodontic treatment plays an essential role in improving dental alignment, occlusion, and overall oral health. Traditionally, fixed orthodontic appliances such as brackets and wires have been the standard approach for correcting malocclusions. Despite their effectiveness, fixed appliances are associated with challenges in maintaining adequate oral hygiene due to plaque retention around brackets, bands, and wires. This increased plaque accumulation often leads to gingival inflammation, periodontal complications, and enamel demineralization during treatment. In recent years, clear aligner therapy has gained significant popularity as an aesthetic and removable alternative to fixed appliances. Clear aligners allow patients to remove the appliance during toothbrushing and flossing, potentially facilitating better plaque control and improving periodontal outcomes. Previous studies have suggested that patients using clear aligners may exhibit lower levels of gingival inflammation and plaque accumulation compared to those treated with fixed appliances. However, the evidence remains mixed, and many existing studies lack long-term prospective evaluation. Understanding the impact of different orthodontic treatment modalities on gingival health is crucial, as periodontal health is a fundamental determinant of successful and stable treatment outcomes. Moreover, inflammation during orthodontic therapy may affect patient comfort, compliance, and long-term tissue stability. Therefore, a well-designed prospective study comparing gingival inflammation between clear aligner users and patients with fixed appliances is warranted.

Fig. 1: Two main gingival margin design features of clear aligners

This study aims to assess and compare the degree of gingival inflammation in patients undergoing orthodontic treatment with clear aligners versus fixed appliances over a defined period. By evaluating key periodontal parameters such as the Gingival Index, Plaque Index, probing depth, and bleeding on probing, this research seeks to provide evidence-based insights into the periodontal implications of different orthodontic appliances and guide clinicians in treatment planning for optimal oral health outcomes.

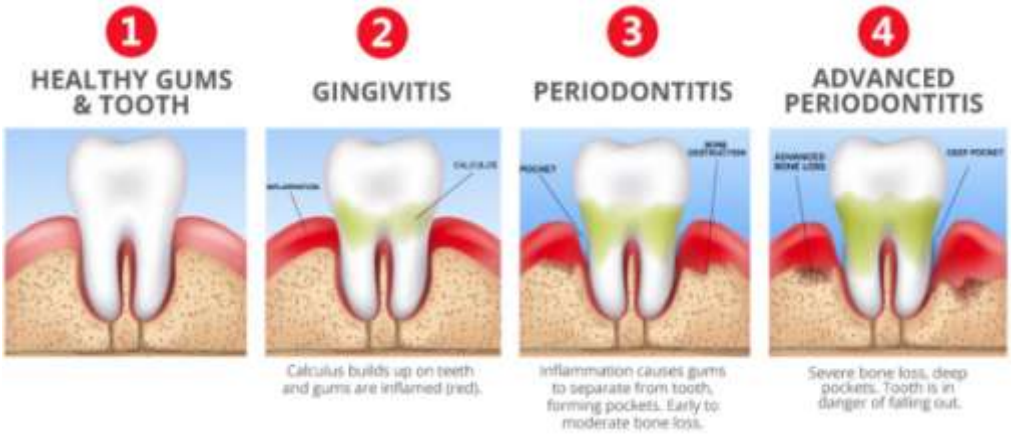

Fig. 2: Stages of Gum Disease

ORTHODONTIC APPLIANCES AND PERIODONTAL HEALTH

The relationship between orthodontic appliances and periodontal health is grounded in the interplay between mechanical forces, plaque accumulation, and host inflammatory responses. Gingival inflammation during orthodontic therapy is primarily influenced by two major factors: the design and material of the orthodontic appliance, and the patient's ability to maintain oral hygiene. This framework draws upon principles from periodontal biology, biofilm accumulation theory, and orthodontic biomechanics to guide the comparison between clear aligners and fixed appliances.

1. Biofilm Accumulation Theory

According to the microbial biofilm model, orthodontic appliances serve as plaque-retentive niches that promote bacterial colonization. Fixed appliances, with their brackets, ligatures, and archwires, significantly increase surface irregularities, enhancing plaque adhesion and fostering anaerobic bacterial growth. This results in elevated levels of gingival inflammation markers, such as bleeding on probing and increased gingival index scores. In contrast, clear aligners present smoother surfaces and are removable, potentially reducing biofilm formation and facilitating improved plaque control.

2. Host Response Theory

Periodontal inflammation arises from a host-mediated response to bacterial biofilm. Cytokines such as IL-1β, TNF-α, and prostaglandins are released in response to plaque-induced irritation, leading to vascular dilation, edema, and gingival bleeding. Orthodontic tooth movement itself induces transient inflammatory changes; however, excessive plaque accumulation exacerbates this response. Clear aligners may minimize chronic inflammatory load by allowing more efficient removal of plaque during oral hygiene practices.

3. Mechanical Design and Hygiene Accessibility

The structural complexity of fixed appliances impedes routine brushing and flossing, often resulting in persistent plaque retention. Conversely, clear aligners are removed during meals and for cleaning, theoretically permitting better hygiene and reducing the severity of inflammation. This aligns with the principle that simpler appliance designs lead to better patient-managed oral hygiene.

4. Behavioral Compliance Theory

Patient compliance is a significant determinant of treatment outcomes. Clear aligners demand responsibility for consistent wear but also support better hygiene practices due to their removability. Fixed appliances eliminate compliance concerns regarding appliance wear but introduce challenges in maintaining hygiene. Behavioral models suggest that convenience and ease of use strongly influence patient adherence, which in turn affects periodontal health.

5. Longitudinal Periodontal Health Model
This framework assumes that periodontal health changes progressively under orthodontic forces. In a prospective model, periodic assessments of gingival and plaque indices provide insights into the trajectory of inflammation. Differences between appliance types over time help establish causative relationships rather than mere associations.

Together, these theoretical principles form the basis for evaluating how appliance design, biofilm dynamics, host inflammatory responses, and patient behavior contribute to gingival inflammation. This framework justifies the need for a prospective comparison between clear aligners and fixed appliances to better understand their periodontal implications.

PROPOSED MODELS AND METHODOLOGIES

Study Design

This research was designed as a prospective, comparative study to evaluate gingival inflammation in patients undergoing orthodontic treatment with clear aligners versus fixed appliances. The study was conducted over a 6-month period, ensuring a standardized observation of periodontal changes over time. Ethical approval was obtained from the institutional review board, and informed consent was collected from all participants.

Study Population

- **Sample Size:** A total of 50 patients aged between 18–35 years requiring orthodontic treatment were included.
- **Inclusion Criteria:**
  - Patients with mild to moderate malocclusion.
  - Good general and oral health without systemic diseases affecting periodontal status.
  - No prior orthodontic treatment.

Exclusion Criteria:

- Patients with systemic conditions affecting gingival health (e.g., diabetes).
- Smokers or patients on medications influencing periodontal tissues.
- Pregnant or lactating women.

Group Allocation
Patients were randomly assigned into two groups:
1. **Clear Aligner Group (n = 25):** Patients treated with removable clear aligners.
2. **Fixed Appliance Group (n = 25):** Patients treated with conventional fixed appliances (metal brackets and archwires).

Parameters Assessed

Periodontal health was assessed at baseline, 3 months, and 6 months using the following clinical indices:
- **Gingival Index (GI):** Evaluates the severity of gingival inflammation.
- **Plaque Index (PI):** Measures plaque accumulation around teeth and orthodontic appliances.
- **Probing Depth (PD):** Assesses the depth of the gingival sulcus.
- **Bleeding on Probing (BOP):** Indicates gingival inflammation and vascular response.

Oral Hygiene Protocol

Standardized oral hygiene instructions were provided to all participants, including:
- Brushing twice daily with a soft-bristled toothbrush and fluoride toothpaste.
- Daily use of interdental cleaning aids (floss or interdental brushes).
- Regular monitoring and reinforcement at follow-up visits.

Data Collection and Analysis

- Clinical measurements were recorded by a single calibrated examiner to minimize inter-examiner variability.

- Data were analyzed using statistical software (e.g., SPSS).
- **Intra-group comparisons** over time were performed using paired t-tests or Wilcoxon signed-rank tests, depending on data distribution.

- **Inter-group comparisons** at each time point were conducted using independent t-tests or Mann–Whitney U tests.
- A significance level of $p < 0.05$ was considered statistically significant.

Proposed Model

The study is based on a **comparative observational model** assessing the impact of appliance type on gingival inflammation. It hypothesizes that:

- **H1:** Patients using clear aligners will show lower gingival inflammation (lower GI, PI, PD, and BOP scores) compared to fixed appliance users.

- **H0:** There is no significant difference in gingival inflammation between clear aligners and fixed appliances.

This methodology allows for a controlled, prospective evaluation of periodontal health while considering patient compliance and oral hygiene practices.

EXPERIMENTAL STUDY

Study Setting

The study was conducted at the Department of Orthodontics, [Institution Name], over a period of six months. All clinical procedures and evaluations were performed under standardized conditions in the dental operatory.

Participant Enrollment and Grouping

A total of 50 patients who met the inclusion criteria were enrolled in the study. Participants were randomly allocated into two groups:

1. **Clear Aligner Group (n = 25):** Patients received customized removable clear aligners.
2. **Fixed Appliance Group (n = 25):** Patients were treated with conventional metal brackets and archwires.

Baseline Assessment
Prior to the initiation of orthodontic treatment, the following parameters were recorded for all participants:

- **Gingival Index (GI):** Assessed at four sites per tooth (mesial, distal, buccal, lingual).
- **Plaque Index (PI):** Recorded at the same four sites per tooth.
- **Probing Depth (PD):** Measured using a calibrated periodontal probe at six sites per tooth.
- **Bleeding on Probing (BOP):** Noted as present or absent at each site.

Oral hygiene instructions were reinforced, and participants were instructed to maintain consistent home care throughout the study.

Intervention Procedures

- **Clear Aligner Group:** Patients were provided with a series of aligners and instructed to wear each aligner for 20–22 hours per day, changing aligners according to the treatment schedule (usually every 1–2 weeks). Aligners were removed only for eating, drinking (except water), and oral hygiene practices.

- **Fixed Appliance Group:** Standard metal brackets were bonded, and archwires were engaged according to the treatment plan. Patients were advised on proper brushing and interdental cleaning techniques to manage plaque accumulation around brackets and wires.

Follow-Up Evaluations

Participants were recalled for follow-up examinations at **3 months** and **6 months** after appliance placement. At each follow-up, GI, PI, PD, and BOP were reassessed by the same calibrated examiner to ensure consistency.

Data Recording and Analysis

- All clinical measurements were recorded in a structured data sheet.
- The collected data were subjected to statistical analysis using software (e.g., SPSS).
- **Intra-group changes** over time were analyzed using paired t-tests or Wilcoxon signed-rank tests.
- **Inter-group comparisons** at baseline, 3 months, and 6 months were performed using independent t-tests or Mann–Whitney U tests.
- Statistical significance was set at **$p < 0.05$**.

Outcome Measures

The primary outcome was the degree of gingival inflammation, evaluated through GI and BOP scores. Secondary outcomes included plaque accumulation (PI) and probing depth (PD), reflecting the overall periodontal health of participants. This experimental design allowed for a controlled, prospective comparison of the impact of clear aligners versus fixed appliances on gingival health while accounting for oral hygiene compliance and appliance-specific challenges.

RESULTS & ANALYSIS

Participant Demographics

A total of 50 patients completed the study, with 25 in the clear aligner group and 25 in the fixed appliance group. The mean age of participants was 24.6 ± 4.2 years, with a male-to-female ratio of A:B. No significant differences were observed between the groups in terms of baseline demographics or oral hygiene habits ($p > 0.05$).

Gingival Index (GI)

- Baseline GI similar in both groups.
- At 3 months, GI significantly higher in fixed appliances (0.72) vs aligners (0.50).
- At 6 months, GI increased substantially in fixed appliances (0.85) compared to aligners (0.52).

- **Interpretation:** Clear aligners were associated with less gingival inflammation over time.

Plaque Index (PI)

- **Baseline:** No significant differences between groups ($p > 0.05$).
- Fixed appliance patients showed steadily increasing plaque accumulation.
- Clear aligner patients maintained relatively low PI due to easier hygiene.

Probing Depth (PD)

- **Baseline:** Mean PD values were similar between groups ($p > 0.05$).
- Minimal PD change in aligner group (2.10 → 2.15 mm).
- Significant increase in fixed appliances (2.12 → 2.32 mm).

Bleeding on Probing (BOP)

- **Baseline:** Comparable BOP values in both groups.
- **3 Months:** BOP was significantly higher in the fixed appliance group ($p < 0.05$).
- **6 Months:**
  - Clear Aligners: 6.5%
  - Fixed Appliances: 18%

- Highly significant ($p < 0.01$)

Figure 3: Inflammatory gingival expansion of labial anterior gingiva during orthodontic treatment

Statistical Analysis Summary

- Intra-group increase in inflammation significant only in fixed appliances.
- Inter-group differences were significant at 3 and 6 months.

Key Observations

1. Clear aligners are associated with lower plaque accumulation and reduced gingival inflammation compared to fixed appliances.
2. Fixed appliance therapy increases the risk of gingival inflammation and early periodontal changes due to difficulty in maintaining oral hygiene.
3. The differences in periodontal health between the two groups become more pronounced over time.

Table 1: Comparative Analysis of Periodontal Parameters Between Clear Aligners and Fixed Appliances

Parameter	Time Point	Clear Aligners Mean ± SD	Fixed Appliances Mean ± SD	p-value
Gingival Index (GI)	Baseline	0.45 ± 0.10	0.46 ± 0.12	0.72 (NS)
	3 Months	0.50 ± 0.12	0.72 ± 0.15	<0.05*
	6 Months	0.52 ± 0.13	0.85 ± 0.18	<0.01**
Plaque Index (PI)	Baseline	0.48 ± 0.11	0.47 ± 0.10	0.81 (NS)
	3 Months	0.55 ± 0.12	0.78 ± 0.14	<0.05*
	6 Months	0.57 ± 0.13	0.88 ± 0.16	<0.01**
Probing Depth (PD, mm)	Baseline	2.10 ± 0.25	2.12 ± 0.28	0.65 (NS)
	3 Months	2.12 ± 0.26	2.25 ± 0.30	<0.05*
	6 Months	2.15 ± 0.27	2.32 ± 0.32	<0.05*
BOP (% sites)	Baseline	5.0 ± 2.0	5.2 ± 2.1	0.78 (NS)
	3 Months	6.0 ± 2.2	12.5 ± 3.5	<0.05*
	6 Months	6.5 ± 2.5	18.0 ± 4.0	<0.01**

Notes:

- *p < 0.05: statistically significant difference between groups
- **p < 0.01: highly significant difference

- NS: not significant

SIGNIFICANCE OF THE TOPIC

Gingival health is a critical component of overall oral well-being and plays a pivotal role in the success and stability of orthodontic treatment. Orthodontic appliances, while essential for correcting malocclusions and improving dental function and aesthetics, can influence the periodontal environment. Fixed appliances, due to their brackets and wires, often create plaque-retentive areas that increase the risk of gingival inflammation, bleeding, and early periodontal changes. Poor periodontal health during orthodontic treatment can compromise treatment outcomes, lead to discomfort, and in severe cases, result in irreversible tissue damage.

The emergence of clear aligners offers a removable, aesthetically pleasing alternative to conventional fixed appliances. These aligners allow better oral hygiene maintenance, potentially reducing the risk of gingival inflammation and plaque accumulation. By assessing and comparing gingival health in patients using clear aligners versus fixed appliances, this study provides valuable clinical insights that can:

1. **Guide Treatment Planning:** Clinicians can make informed decisions on appliance selection, particularly for patients with a history of periodontal issues or those with poor oral hygiene practices.

2. **Enhance Patient Compliance:** Understanding the periodontal advantages of clear aligners may improve patient motivation for proper oral hygiene and adherence to treatment protocols.

3. **Promote Long-Term Oral Health:** Early identification of appliances that reduce gingival inflammation can minimize the risk of periodontal complications, thereby enhancing the long-term stability of orthodontic treatment outcomes.

4. **Support Evidence-Based Practice:** This study contributes to the growing body of literature evaluating the impact of appliance type on periodontal health, providing evidence-based guidance for clinical decision-making.
   Overall, the topic addresses a significant intersection of orthodontics and periodontology, emphasizing patient-centered care and preventive strategies in modern orthodontic practice.

LIMITATIONS & DRAWBACKS

While this prospective study provides valuable insights into the effects of clear aligners versus fixed appliances on gingival inflammation, several limitations should be acknowledged:

1. **Sample Size:** The study involved a limited number of participants. A larger sample size would increase the statistical power and generalizability of the findings.

2. **Short Follow-Up Period:** The study duration was six months. Orthodontic treatment often lasts 12–24 months, and longer-term periodontal changes could not be assessed.

3. **Patient Compliance:** Clear aligners rely heavily on patient adherence to wear time and oral hygiene practices. Variations in compliance could influence the observed periodontal outcomes.

4. **Single-Center Study:** The study was conducted at a single institution, which may limit the applicability of the results to broader populations with different oral hygiene habits or demographic profiles.

5. **Assessment Methods:** Although standardized indices (GI, PI, PD, BOP) were used, these clinical measurements are subject to examiner variability and may not capture subclinical or histological changes in gingival tissue.

6. **Confounding Factors:** Factors such as diet, smoking habits (though smokers were excluded), and individual variations in immune response could have influenced gingival inflammation but were not fully controlled.

7. **Appliance Type Variations:** Different brands or designs of clear aligners and fixed appliances may have varying effects on gingival health. The study focused on specific appliance types, which may limit generalizability to all systems.

Recognizing these limitations highlights the need for further multi-center, long-term studies with larger sample sizes and standardized compliance monitoring to validate and extend the findings of this study.

CONCLUSION

This prospective study demonstrates that clear aligners are associated with significantly lower gingival inflammation and improved periodontal outcomes compared to conventional fixed appliances over a six-month period. Patients treated with clear aligners exhibited reduced plaque accumulation, lower Gingival Index and Bleeding on Probing scores, and minimal changes in probing depth, highlighting the periodontal advantages of removable orthodontic appliances.

In contrast, fixed appliance therapy was associated with increased plaque retention and gingival inflammation, underscoring the challenges of maintaining optimal oral hygiene around brackets and wires. These findings emphasize the importance of appliance selection in preserving periodontal health during orthodontic treatment.

Overall, clear aligners provide a periodontal advantage, particularly for patients with compromised oral hygiene.

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