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Original Article

A Randomized Trial Measuring Gingival Inflammation and Plaque Levels During Treatment With Clear Aligners Versus Self-Ligating Braces

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ABSTRACT

Background: Orthodontic appliances can interfere with routine oral hygiene and promote plaque retention, leading to gingival inflammation during active treatment. While self-ligating fixed appliances were introduced to reduce plaque accumulation compared with conventional braces, clear aligner therapy has gained popularity due to its removable design and perceived periodontal advantages. Evidence directly comparing the periodontal impact of these two appliance systems under randomized clinical conditions remains limited. Objective: To compare changes in plaque accumulation and gingival inflammation in patients undergoing orthodontic treatment with clear aligners versus self-ligating fixed appliances during the early phase of active treatment. Methods: A parallel-arm randomized controlled trial was conducted over four months in the Islamabad–Rawalpindi region. Sixty orthodontic patients aged 18–30 years were randomly allocated to receive either clear aligners or self-ligating braces. Periodontal status was assessed at baseline, two months, and four months using the Silness and Löe Plaque Index and the Löe and Silness Gingival Index. Data were analyzed using independent t-tests, repeated measures ANOVA, and Pearson correlation analysis, with statistical significance set at $p < 0.05$. Results: Fifty-eight participants completed the study. Both groups showed increases in plaque and gingival index scores over time; however, these increases were significantly greater in the self-ligating brace group. At four months, mean plaque index scores were 1.02 ± 0.26 in the clear aligner group and 1.38 ± 0.31 in the self-ligating group ($p < 0.001$). Mean gingival index scores were 0.94 ± 0.23 and 1.31 ± 0.28, respectively ($p < 0.001$). A strong positive correlation was observed between plaque accumulation and gingival inflammation ($r = 0.68$, $p < 0.001$). Conclusion: Clear aligner therapy was associated with more favorable periodontal outcomes than self-ligating fixed appliances during early orthodontic treatment. Appliance removability appeared to support better plaque control, underscoring the importance of appliance selection and oral hygiene reinforcement in orthodontic care. Keywords: Dental Plaque; Gingivitis; Orthodontic Appliances; Orthodontic Brackets; Periodontal Health; Randomized Controlled Trial; Tooth Movement

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INTRODUCTION

Orthodontic treatment has evolved substantially over recent decades, with increasing emphasis not only on achieving optimal occlusal outcomes but also on preserving oral health throughout the course of therapy (1). Fixed orthodontic appliances have long been associated with challenges in maintaining adequate plaque control due to the presence of brackets, archwires, and auxiliary components that create plaque-retentive niches (2). These mechanical impediments often result in increased plaque accumulation and subsequent gingival inflammation, even among patients with initially satisfactory oral hygiene. As a result, the periodontal consequences of orthodontic treatment have become a growing concern for both clinicians and patients, particularly in the context of prolonged active treatment phases (3).

Self-ligating bracket systems were introduced with the promise of reduced plaque retention and improved periodontal outcomes compared with conventional fixed appliances (4). By eliminating elastomeric ligatures, these systems were thought to facilitate better access for oral hygiene and reduce bacterial adhesion. However, clinical evidence has remained inconsistent, with several investigations reporting only modest or no periodontal advantages when compared with other fixed appliance systems (5). Despite ongoing refinements in bracket design, fixed appliances as a whole continue to present inherent challenges for effective plaque control, especially during the early stages of treatment when patient adaptation is still evolving (6).

In parallel with these developments, clear aligner therapy has emerged as a popular alternative to fixed appliances, driven by increasing patient demand for esthetic, comfortable, and removable orthodontic solutions. Clear aligners offer the theoretical advantage of improved oral hygiene, as they can be removed during toothbrushing and interdental cleaning (7). This removability is frequently cited as a key factor in reducing plaque accumulation and gingival inflammation during treatment (8). Nevertheless, aligners are worn for extended daily durations, and improper hygiene practices or prolonged aligner use without adequate cleaning may negate these potential benefits. Consequently, the true periodontal impact of clear aligner therapy in routine clinical practice remains an area of active investigation (9).

Existing literature comparing periodontal outcomes between clear aligners and fixed appliance systems has yielded mixed results (10). While several studies suggest that aligner-treated patients demonstrate lower plaque indices and reduced gingival inflammation, others report minimal differences once patient compliance and baseline oral hygiene are accounted for. Moreover, many prior studies have been observational in nature, short on methodological rigor, or limited by small sample sizes and heterogeneous assessment tools. Randomized controlled trials directly comparing modern self-ligating braces with clear aligners using standardized periodontal indices remain relatively scarce, particularly in real-world clinical settings where patient behavior and environmental factors play a significant role (6).

The importance of such comparisons extends beyond academic interest. Periodontal health during orthodontic treatment has direct implications for patient comfort, risk of gingival enlargement, development of white spot lesions, and long-term periodontal stability (9). Early inflammatory changes, even if reversible, may influence patient adherence, satisfaction, and overall treatment experience. Understanding how different appliance systems affect gingival health during the initial months of treatment is therefore essential for evidence-based appliance selection and patient counseling (11, 12).

Furthermore, most available data originate from highly controlled or specialized clinical environments, which may not fully reflect everyday orthodontic practice (13). Regional variations in oral hygiene awareness, dietary habits, and access to dental care may further modify periodontal responses during treatment. Generating evidence from routine clinical settings allows for a more realistic appraisal of appliance-related periodontal changes and enhances the external validity of the findings (14).

Against this backdrop, the present randomized controlled trial was designed to address a clinically relevant gap by directly comparing gingival inflammation and plaque accumulation in patients treated with clear aligners and those treated with self-ligating fixed appliances during the active phase of orthodontic therapy. By employing standardized, widely accepted periodontal indices and monitoring changes over a defined treatment period, the study sought to provide a balanced and clinically meaningful assessment of periodontal health outcomes associated with these two commonly used orthodontic systems. The specific objective was to evaluate and compare the progression of plaque levels and gingival inflammation between clear aligner therapy and self-ligating braces during the first four months of active orthodontic treatment.

MATERIAL AND METHODS

The study was conducted as a parallel-arm randomized controlled trial within the field of clinical orthodontics and oral health. It was carried out in the Islamabad–Rawalpindi region, selected because of its dense concentration of tertiary dental care facilities and a patient population with high uptake of contemporary orthodontic appliance systems, allowing direct comparison under routine clinical conditions. The study duration was four months, which was considered sufficient to observe early periodontal changes during active orthodontic treatment while minimizing prolonged behavioral adaptations.

Participants were consecutively recruited from orthodontic outpatient clinics and randomly allocated to receive either clear aligner therapy or self-ligating fixed appliances. A total sample of 60 participants was enrolled, with 30 individuals in each group. This sample size was determined based on prior randomized orthodontic studies comparing periodontal outcomes between aligner and fixed appliance systems, where comparable differences were detected with sample sizes ranging from 40 to 70 participants. The final number was deemed adequate to detect clinically meaningful differences while remaining feasible within the study timeframe.

Eligibility criteria included patients aged 18–30 years requiring non-extraction orthodontic treatment, presenting with good general health, a full complement of permanent teeth excluding third molars, and no evidence of active periodontal disease at baseline. Participants were required to have a baseline plaque index score below 1.5 to ensure comparable periodontal status at enrollment. Exclusion criteria included smoking, pregnancy, systemic conditions affecting periodontal health, recent antibiotic use within the past three months, previous orthodontic treatment, and use of adjunctive oral hygiene devices beyond standard toothbrushing.

Randomization was performed using a computer-generated random sequence, with allocation concealed in sealed opaque envelopes opened at the time of appliance placement. Both groups received standardized oral hygiene instructions at baseline, and no additional professional prophylaxis was provided during the study period. Periodontal assessments were performed at baseline, two months, and four months by a single calibrated examiner blinded to group allocation.

Gingival inflammation was measured using the Löe and Silness Gingival Index, while plaque accumulation was assessed with the Silness and Löe Plaque Index. Measurements were recorded at six sites per tooth for all index teeth using a UNC-15 periodontal probe under standardized lighting conditions. Examiner calibration was confirmed prior to data collection, achieving intra-examiner reliability with a kappa value exceeding 0.85.

Data were analyzed using statistical software after confirming normal distribution through the Shapiro–Wilk test. Descriptive statistics were calculated for all variables. Intergroup comparisons of mean gingival and plaque index scores at each time point were performed using independent sample t-tests, while intragroup changes over time were analyzed using repeated measures ANOVA. Pearson correlation analysis was applied to explore the relationship between plaque accumulation and gingival inflammation. Statistical significance was set at $p < 0.05$, ensuring robust and reproducible interpretation of the findings. An intention-to-treat approach was planned; however, final analysis included participants with complete follow-up data.

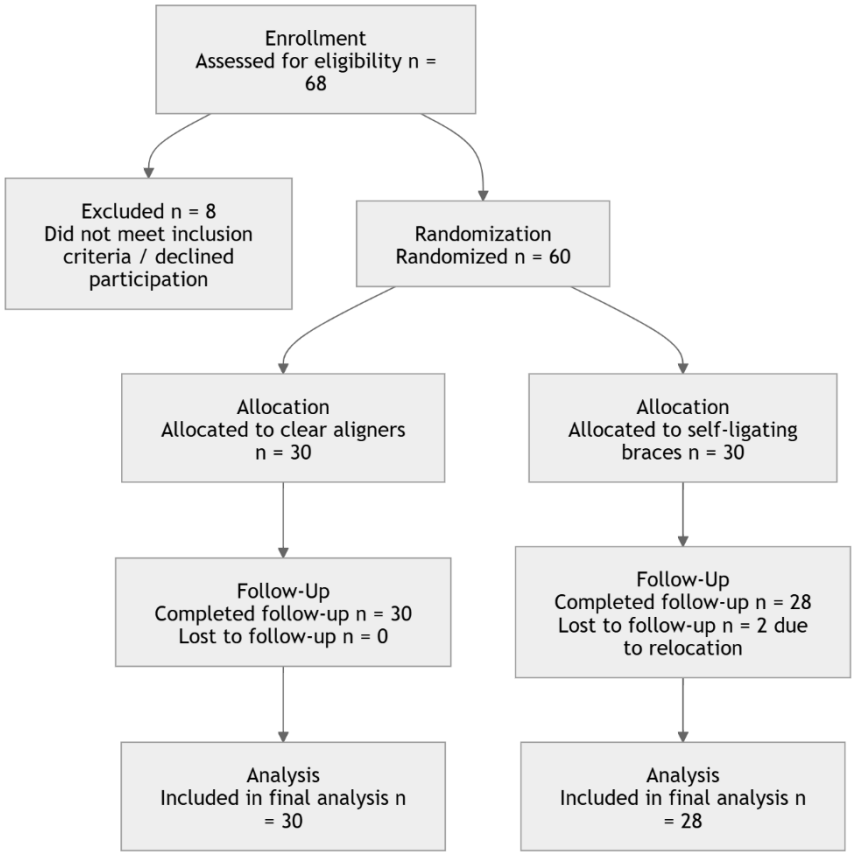

Figure 1 CONSORT Flowchart

RESULTS

Of the 68 patients initially assessed for eligibility, 60 met the inclusion criteria and were enrolled in the trial. All enrolled participants were randomized equally into the clear aligner group (n = 30) and the self-ligating brace group (n = 30). During the four-month follow-up period, two participants from the self-ligating brace group were lost to follow-up due to relocation, resulting in a final analytical sample of 58 participants and an overall response rate of 96.7%. Data from all remaining participants were complete and included in the final analysis.

Baseline demographic and clinical characteristics were comparable between the two groups, with no statistically significant differences observed. The mean age of the total sample was 23.6 ± 3.4 years, with females comprising a slightly higher proportion of participants (56.9%). Oral hygiene status at baseline, as reflected by plaque and gingival index scores, did not differ significantly between groups ($p > 0.05$). The demographic characteristics are summarized in Table 1.

Table 1: Baseline Demographic and Clinical Characteristics of Participants (N = 58)

Variable	Total Sample (N=58)	Clear Aligners (n=30)	Self-Ligating Braces (n=28)
Age (years)	23.6 ± 3.4	23.2 ± 3.1	24.0 ± 3.7
Gender			
- Male	25 (43.1%)	13 (43.3%)	12 (42.9%)
- Female	33 (56.9%)	17 (56.7%)	16 (57.1%)
Baseline Plaque Index	0.82 ± 0.21	0.81 ± 0.20	0.83 ± 0.22
Baseline Gingival Index	0.76 ± 0.19	0.75 ± 0.18	0.77 ± 0.20

At the two-month assessment, both groups demonstrated an increase in plaque accumulation and gingival inflammation; however, the magnitude of change differed significantly. The clear aligner group showed a modest rise in mean plaque index to 0.96 ± 0.24, whereas the self-ligating brace group exhibited a greater increase to 1.24 ± 0.29 ($p = 0.001$). A similar pattern was observed for gingival index scores,

with means of 0.89 ± 0.22 in the aligner group and 1.18 ± 0.27 in the brace group (p = 0.002). By the four-month follow-up, these differences became more pronounced, as presented in Table 2.

Table 2: Plaque Index Scores Over Time (Mean ± SD)

Time Point	Clear Aligners	Self-Ligating Braces	p-value
Baseline	0.81 ± 0.20	0.83 ± 0.22	0.71
2 Months	0.96 ± 0.24	1.24 ± 0.29	0.001
4 Months	1.02 ± 0.26	1.38 ± 0.31	<0.001

Table 3: Gingival Index Scores Over Time (Mean ± SD)

Time Point	Clear Aligners	Self-Ligating Braces	p-value
Baseline	0.75 ± 0.18	0.77 ± 0.20	0.68
2 Months	0.89 ± 0.22	1.18 ± 0.27	0.002
4 Months	0.94 ± 0.23	1.31 ± 0.28	<0.001

Repeated measures ANOVA demonstrated a statistically significant time-by-group interaction for both plaque index and gingival index scores ($p < 0.001$), indicating that periodontal deterioration progressed more rapidly in the self-ligating brace group. Pearson correlation analysis revealed a strong positive correlation between plaque accumulation and gingival inflammation at four months ($r = 0.68$, $p < 0.001$), as detailed in Table 4.

Table 4: Correlation Between Plaque Index and Gingival Index at 4 Months

Variables	r-value	p-value
Plaque Index vs Gingival Index	0.68	<0.001

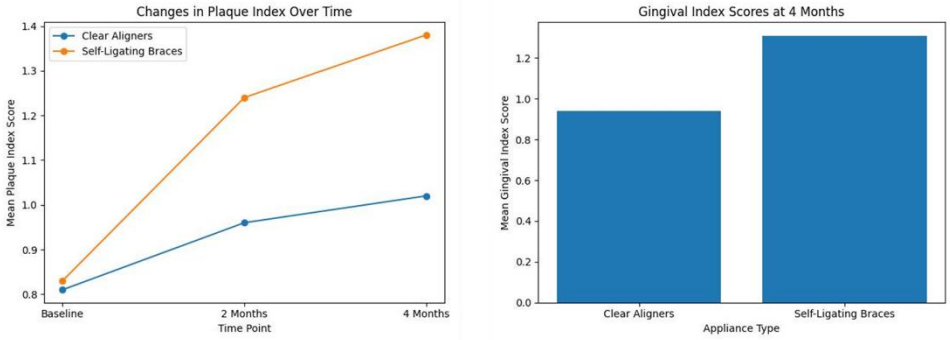

Figure 2 Comparison of plaque index and gingival inflammation between clear aligners and self-ligating braces over time. The line graph shows progressive increases in mean plaque index from baseline to 4 months in both groups, with higher values observed in the self-ligating braces group. The bar chart illustrates greater mean gingival index scores at 4 months among patients treated with self-ligating braces compared to clear aligners.

DISCUSSION

The present randomized controlled trial demonstrated that periodontal health during the early phase of orthodontic treatment differed meaningfully between patients treated with clear aligners and those treated with self-ligating fixed appliances (15). Although both groups exhibited some degree of increase in plaque accumulation and gingival inflammation over time, the magnitude and progression of these changes were consistently greater in the self-ligating brace group (16). These findings suggested that appliance design and removability played an important role in influencing oral hygiene effectiveness and subsequent periodontal response during active orthodontic therapy (17).

The observed increase in plaque and gingival index scores across both treatment modalities aligned with the well-documented tendency for orthodontic appliances to disrupt routine oral hygiene practices, particularly during the initial months of treatment (18). However, the more favorable periodontal profile observed in the clear aligner group supported the premise that removability facilitates improved plaque control (19). The ability to remove aligners during toothbrushing and interdental cleaning likely

reduced plaque retention on tooth surfaces, thereby limiting gingival inflammatory changes (20). In contrast, despite their streamlined design, self-ligating brackets remained fixed to the dentition and continued to create plaque-retentive areas that challenged effective oral hygiene, especially in interbracket and gingival margin regions (21).

Comparison with existing literature revealed general consistency with studies reporting lower plaque accumulation and gingival inflammation among aligner-treated patients compared with those wearing fixed appliances (22). The findings also reinforced previous observations that the absence of elastomeric ligatures alone was insufficient to eliminate the periodontal challenges inherent to fixed orthodontic systems. Some prior investigations had suggested minimal differences between appliance types, attributing periodontal outcomes primarily to patient motivation and oral hygiene instruction (23). While patient-related factors undoubtedly influenced outcomes, the randomized design and comparable baseline characteristics in the present study indicated that appliance-related factors exerted an independent effect on periodontal health.

The strong positive correlation identified between plaque levels and gingival inflammation further emphasized the central role of biofilm accumulation in driving periodontal changes during orthodontic treatment. This relationship underscored the importance of early and sustained plaque control measures, regardless of appliance type. Notably, even the clear aligner group demonstrated gradual increases in plaque and gingival indices over time, highlighting that aligners did not confer complete protection against periodontal deterioration. Prolonged aligner wear, inadequate cleaning of the appliances themselves, and lapses in oral hygiene may have contributed to these changes, suggesting that aligner therapy still requires rigorous patient education and monitoring (10).

From a clinical perspective, the findings carried practical implications for appliance selection and patient counseling. For patients at increased risk of gingival inflammation or with a history of compromised periodontal health, clear aligners may offer a periodontal advantage during the early stages of treatment. However, the results did not imply that self-ligating braces were inherently detrimental; rather, they highlighted the need for enhanced oral hygiene support and closer periodontal monitoring for patients undergoing fixed appliance therapy (7). Individualized risk assessment remained essential, as appliance choice alone could not fully determine periodontal outcomes (24).

The study possessed several strengths that enhanced the credibility of its findings. The randomized controlled design minimized selection bias and allowed for a direct comparison between two commonly used orthodontic systems under similar clinical conditions. Standardized and widely accepted indices were employed to assess periodontal outcomes, and examiner calibration ensured measurement reliability. The prospective follow-up over multiple time points enabled evaluation of temporal changes rather than reliance on single-point assessments (25).

Nevertheless, certain limitations warranted consideration. The relatively short follow-up period restricted conclusions to early periodontal changes and did not capture long-term outcomes or potential adaptive improvements in oral hygiene over time. The modest sample size, while adequate for detecting significant differences, limited the ability to perform subgroup analyses based on factors such as gender or baseline oral hygiene behaviors. Additionally, patient compliance with oral hygiene instructions and aligner wear was not objectively measured, which may have influenced the observed outcomes. The exclusion of patients with pre-existing periodontal disease also limited generalizability to populations with compromised periodontal status (26).

Future research could address these limitations by incorporating longer follow-up durations, larger and more diverse samples, and objective measures of oral hygiene and appliance wear compliance. Comparative studies involving additional appliance systems or adjunctive preventive interventions may further clarify strategies for optimizing periodontal health during orthodontic treatment. Collectively, the present findings contributed to the growing body of evidence supporting the role of appliance design

in periodontal outcomes and emphasized the continued importance of comprehensive oral hygiene management throughout orthodontic care (27).

CONCLUSION

This randomized controlled trial demonstrated that clear aligner therapy was associated with lower plaque accumulation and reduced gingival inflammation compared with self-ligating fixed appliances during the early phase of orthodontic treatment. Although periodontal changes were observed in both groups, the removable nature of aligners appeared to support better oral hygiene maintenance. These findings highlight the importance of appliance selection and reinforced oral hygiene guidance in promoting periodontal health during active orthodontic care.

REFERENCES

1. Di Spirito F, Amato A, Di Palo MP, Cannatà D, Giordano F, D'Ambrosio F, et al. Periodontal management in periodontally healthy orthodontic patients with fixed appliances: an umbrella review of self-care instructions and evidence-based recommendations. 2023;11(2):35.
2. Di Spirito F, D'Ambrosio F, Cannatà D, D'Antò V, Giordano F, Martina S, editors. Impact of clear aligners versus fixed appliances on periodontal status of patients undergoing orthodontic treatment: a systematic review of systematic reviews. Healthcare; 2023: MDPI.
3. Giannini L, Galbiati G, Tartaglia FC, Grecolini ME, Maspero C, Biagi RJDJ. Orthodontic Treatment with Fixed Appliances Versus Aligners: An Experimental Study of Periodontal Aspects. 2025;13(2):70.
4. Samulak R, Suwała M, Górski B, Machoy MJAS. Evaluating clear aligners versus fixed appliances for periodontal patients: A comprehensive narrative review of current evidence. 2024;14(21):9931.
5. Nieoczym K, Rybak ZJAJoP, Orthodontics. Periodontal Care in Orthodontic Patients with Fixed Appliances: An Umbrella Review of Self-Care Protocols and Evidence-Based Guidelines. 2023;3:66-86.
6. Esmaeili S, Shahbazi S, Ziaei H, Younessian F. Evaluating the Impact of Clear Dental Aligners on Dental and Periodontal Conditions, Oral Microbial Patterns, and the Immune System. Oral Immunology: Springer; 2025. p. 605-24.
7. Marya A, Nalabothu P, Arqub SA, editors. Orthodontic management in reduced periodontal support: Evidence mapping of interdisciplinary strategies. Seminars in Orthodontics; 2025: Elsevier.
8. Lanzetti J, Queirolo S, Furini Evans G, Gibello U, Deregibus A, Pera FJDJ. Evaluation of the Impact of Probiotic Supplementation on Gingival Inflammation in Subjects Undergoing Orthodontic Treatment with Fixed Appliances or Clear Aligners: A Randomized, Single-Blind Pilot Study. 2025;13(11):526.
9. Luchian I, Surlari Z, Goriuc A, Ioanid N, Zetu I, Butnaru O, et al. The influence of orthodontic treatment on periodontal health between challenge and synergy: A narrative review. 2024;12(4):112.
10. Zhong W, Zhou C, Yin Y, Feng G, Zhao Z, Pan Y, et al. Expert consensus on orthodontic treatment of patients with periodontal disease. 2025;17(1):27.
11. Naveed N, Sabapathy K. Biological Response of Self-Ligation Bracket Systems. 2024.
12. Cretel M. White spot lesions in orthodontics: comparison of the impact of fixed orthodontics appliances versus aligners. 2025.
13. Peterson BW, Tjakkes GH, Renkema AM, Manton DJ, Ren YJP. The oral microbiota and periodontal health in orthodontic patients. 2024.
14. Al-Mutairi MA, Al-Salamah L, Nouri LA, Al-Marshedy BS, Al-Harbi NH, Al-Harabi EA, et al. Microbial changes in the periodontal environment due to orthodontic appliances: a review. 2024;16(7):e64396.
15. Llera-Romero AS, Adobes-Martín M, Iranzo-Cortés JE, Garcovich DJKJoO. Periodontal health status, oral microbiome, white-spot lesions and oral health related to quality of life-clear aligners versus fixed appliances: A systematic review, meta-analysis and meta-regression. 2023;53(6):374-92.
16. Coronel-Zubiate F-T, Luján-Valencia S-A, Meza-Málaga J-M, Aguirre-Ipenza R, Echevarria-Goche A, Luján-Urviola E, et al. Effect of conventional and self-ligating brackets on periodontal health. Systematic review and meta-analysis. 2024;16(3):e358.
17. Yen E-TJAoODS. Influence of Fixed and Removable Appliances on the Periodontal Health of Orthodontic Patients. 2025;2.
18. Baneshi MJP-G. Effectiveness of clear orthodontic aligners in correcting malocclusion-systematic review. 2023.

19. Hendiani I, Prasetyo BC, Evangelina IA, Rizqita PAJJoID, Research M. The Effects of Using Conventional and Self-Ligating Brackets on Oral Hygiene and Periodontal Health Status: A Rapid Review. 2023;16(1):384-93.
20. Inchingolo F, Inchingolo AM, Latini G, Ferrante L, Trilli I, Del Vecchio G, et al. Oxidative stress and Natural products in Orthodontic Treatment: a systematic review. 2023;16(1):113.
21. Rădeanu AC, Surpăţeanu M, Munteanu CM, Liliac IM, Popescu AD, Andrei EC, et al. Periodontal changes induced by fixed orthodontic therapy. 2024;97(3):370.
22. Bona C, Camacho-Alonso F, Vaca A, Llorente-Alonso MJAJoP, Orthodontics. Oral Biofilm Control in Patients Using Orthodontic Aligners: Evidence from a Systematic Review. 2025;5(1-2025):33-42.
23. Kadhom ZM, Al-Chalabi HJKJoM. The Impact of Orthodontic Therapy on the Periodontal Health and Oral Microbiome. 2024;17(2):2703-8.
24. Danan CE. Discomfort and pain perception in orthodontic patients with aligners versus fixed Orthodontics. 2025.
25. D'Antò V, De Simone V, Caruso S, Bucci P, Valletta R, Rongo R, et al. Effects of clear aligners treatment in growing patients: a systematic review. 2025;5:1512838.
26. Hussain U, Campobasso A, Noman M, Alam S, Mujeeb R, Shehzad S, et al. Influence of elastomeric and steel ligatures on periodontal health during fixed appliance orthodontic treatment: a systematic review and meta-analysis. 2024;25(1):24.
27. Kim JE, Kim S, Kim DHJIJoDH. Comparison of oral health status, oral hygiene management behaviours and satisfaction of patients with fixed orthodontic appliance and clear aligner: A quasi-experimental design. 2024;22(4):939-48.