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Comparison Between Two Clear Aligner Activation Increments and Conventional Orthodontic Fixed Appliance in Treatment of Lower Incisors Crowding: A Randomized Clinical Trial

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Abstract:
Background*: The aim of this clinical study was to compare the 0.25 mm and 0.35 mm clear aligner activation increments with conventional fixed appliance in the treatment of lower incisors crowding, specifically concerning the rate of tooth movement, treatment duration, and pain levels.*
Patients and Methods*: Twenty-one non-extraction adults (18–40 years) with lower anterior crowding (Little's Irregularity Index (LII) ≤6 mm) were enrolled and randomly allocated to Aligner I (0.25 mm activation increment per aligner, Aligner II (0.35 mm/step), and fixed appliances (0.018" Roth brackets with sequential nickel-titanium-to-stainless steel archwires). The allocation ratio was 1:1:1, with 7 participants per group. Aligners were replaced biweekly; brackets were adjusted monthly. LII was measured from intraoral digital scans at baseline, biweekly in the aligner groups, and monthly in the fixed group. Pain was assessed via a 10-cm Visual Analogue Scale (VAS) every two weeks in all groups until crowding resolution. Non-parametric tests (Kruskal–Wallis, Mann–Whitney U, Friedman with Dunn's correction) were employed for intergroup and intragroup comparisons (α = 0.05).*
Results*: All groups achieved significant LII reductions over their respective active treatment periods. At week 12, significant intergroup differences emerged. The Control group showed the lowest median LII (0.00 mm), followed by Aligner II (0.43 mm), while Aligner I showed the highest median LII (0.85 mm); pairwise differences were reported as statistically significant. Treatment duration was shortest for fixed appliances (median = 10 weeks), followed by Aligner II (12 weeks) and Aligner I (16 weeks). Pairwise comparisons showed that Aligner I required significantly more weeks than both Aligner II and the Control group, and the Control group required significantly fewer weeks than both aligner groups. Pain scores were comparable initially; however, at week 8, both aligner groups reported significantly higher VAS scores than the Control group, and at week 10, Aligner I had the highest pain scores, followed by Aligner II, while the Control group had the lowest scores, with pairwise differences reported as statistically significant.*
Conclusion: *All modalities effectively resolve mild-to-moderate crowding. The 0.35 mm activation demonstrated greater efficiency than the 0.25 mm protocol but did not surpass fixed appliances in overall time efficiency. Pain profiles are stage-dependent, challenging the assumption of universal appliance-based comfort superiority.*
Key Word*: Fixed orthodontic appliances; Clear aligners; Crowding; Pain level; Tooth movement; Little's Irregularity Index*

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I. Introduction

Lower incisors crowding is considered one of the most common malocclusion in orthodontic practice, often leading to functional impairment, challenges in oral hygiene maintenance, and negative psychosocial effects. (1) Mild-to-moderate crowding, typically defined by a tooth-arch length discrepancy of a few millimeters, is associated with an increased risk of plaque accumulation, gingival inflammation, and early periodontal changes, as well as potential impacts on patient self-confidence. (2)

Conventional fixed orthodontic appliances have traditionally been considered the gold standard treatment option for correcting lower incisors crowding, as they enable continuous force application with precise three-dimensional control, facilitating predictable tooth movement even in more challenging cases. (3)

Nevertheless, unesthetic appearance, associated discomfort, dietary limitations, and difficulties with oral hygiene maintenance often reduce patient acceptance, particularly among adults and aesthetically concerned younger individuals. (4)

Since their introduction by Align Technology as an aesthetic alternative to conventional fixed appliances, clear aligners have transformed orthodontic practice. This approach relies on orthodontic movement generated by a planned discrepancy between the current tooth position and the aligner shape, which corresponds to the intended final alignment. To achieve the desired outcome, patients are required to wear a sequential set of aligners for 22 hours per day, with each appliance inducing small, progressive tooth movements.(5) Initially, aligners were indicated mainly for minor dental corrections and mild malocclusions. Over time, however, enhancements in material properties and SmartFeatures have expanded their biomechanical capacity, broadening their clinical indications. (6)

Several studies indicate that clear aligners can provide clinically acceptable results in mild to moderate crowding, offering possible benefits in terms of periodontal health, comfort, and patient-reported quality of life relative to fixed appliances. (1,7–9) Nevertheless, concerns remain about their effectiveness in managing complex tooth movements, including root torque, extrusion, and pronounced rotations, which maintains the relevance of fixed appliances in more challenging clinical situations. (10)

Despite the widespread availability of aligner systems and strong marketing efforts, much of the current evidence is based on retrospective studies, non-randomized comparisons, or industry-associated data, which limits the ability to draw firm conclusions about their comparative effectiveness in routine clinical practice. (1,4,7) Several studies have focused on treatment duration and efficiency, but their designs vary considerably regarding inclusion criteria, crowding severity, and outcome measures, which restrict their applicability to well-defined patient subgroups. (1,7) From a patient-centered perspective, there is also a need to assess not only alignment quality and treatment time, but also pain, satisfaction, and early complications such as enamel decalcification, factors that directly affect compliance, perceived value, and long-term acceptance of the treatment approach. (10,11)

Given these knowledge gaps, there is a clear need for high-quality clinical trials to evaluate the comparative effectiveness of different aligner activation increments, particularly regarding the rate of tooth movement, overall treatment duration, and associated patient discomfort. Accordingly, the aim of this clinical trial was to compare the effectiveness of 0.25 mm versus 0.35 mm clear aligner activation increments with conventional fixed appliances in the treatment of lower incisor crowding, with specific reference to the rate of tooth movement, total treatment time, and pain levels experienced during active treatment.

II. Patients and Methods

This study was designed as a three-arm, parallel-group, randomized clinical trial with a 1:1:1 allocation ratio. The study protocol was reviewed and granted ethical approval by the Research Ethics Committee of the Faculty of Dentistry, Ain Shams University (approval no. FDASU-Rec-im012257).

Participants were recruited from the outpatient clinic of the Orthodontics Department, Faculty of Dentistry, Ain Shams University. Eligibility was determined according to predefined criteria, including an age range of 18–40 years, a non-extraction treatment plan, a LII of ≤ 6 mm, the presence of permanent dentition from first molar to first molar, and the absence of supernumerary teeth or tooth-shape anomalies. Exclusion criteria comprised a history of prior orthodontic treatment, systemic pathologies, ongoing use of medications known to influence tooth movement (e.g., prostaglandin inhibitors, bisphosphonates), active periodontal disease, or belonging to vulnerable populations. All clinical procedures were performed at the outpatient clinic of the Orthodontics Department, Faculty of Dentistry, Ain Shams University.

A total of 21 patients were enrolled and equally distributed into three groups (n = 7 per group). Sample size was determined by a priori using G*Power software (version 3.1.9.7), with an alpha level of 0.05, a beta of 0.2 (80% power), and an effect size (f) of 0.480, derived from the findings of **Hennessy et al. (2016)**.(12) Simple randomization was employed for group allocation. A colleague not involved in the clinical trial generated the allocation sequence using Microsoft Excel (Office 365, Microsoft Corp., Redmond, WA, USA). Each patient was assigned a sequential number corresponding to their presentation order, and group assignment was determined by matching this number to the pre-generated sequence. Allocation concealment was ensured by sequentially numbered, opaque, sealed envelopes prepared by an independent person. The investigator who screened and enrolled participants was unaware of the upcoming group assignment until after the participant had been formally enrolled and baseline records had been completed. Because clear aligners and fixed appliances are visibly different, blinding of participants and the clinical operator was not possible. The outcome assessor

who measured LII on the intraoral digital scans was blinded to group allocation, and the statistical analyst analyzed data using [coded group labels.

The three groups consisted of Aligner I, treated with aligners incorporating 0.25 mm activation increment per aligner; Aligner II, treated with aligners incorporating 0.35 mm activation increment per aligner; and Control Group, treated with conventional fixed appliance therapy.

Comprehensive written informed consent was obtained from all participants after a full explanation of the procedures and study objectives. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram detailing participant enrollment, allocation, follow-up, and the final analytical sample is presented in **Figure (1)**. Preoperatively, a comprehensive medical and dental history was recorded, followed by a thorough extraoral and intraoral clinical examination to confirm eligibility, with all findings documented using the department's standardized evaluation chart. Baseline orthodontic records were obtained for all patients prior to treatment and included extraoral and intraoral photographs captured using a 20.3‑megapixel digital camera (Canon PowerShot SX540 HS), intraoral digital scans of each arch and the occlusion using an intraoral scanner (Trios 3®, 3 Shape, Copenhagen, Denmark), standardized lateral cephalometric radiographs for skeletal and soft tissue analysis, and panoramic radiographs to evaluate alveolar bone, identify pathologies, and rule out impactions or supernumerary teeth.

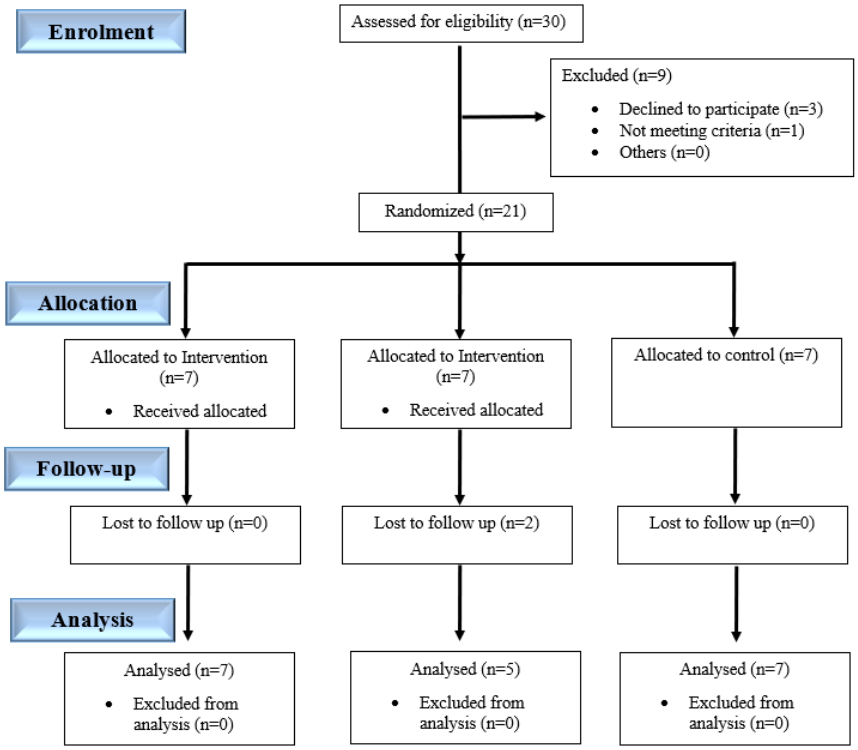


Figure 1: CONSORT 2010 flow diagram of participant enrollment, allocation, follow-up, and analysis.

For the Aligner I and II groups, aligner therapy workflow commenced with software procedures. The intraoral scan datasets were imported into 3Shape software (3Shape Ortho System, 3Shape A/S, Copenhagen, Denmark), and the models were spatially oriented using three reference points (central fossae of the maxillary right and left first molars and the contact point between the central incisors).

Model bases were created 4–5 mm apical to the gingival margins, and individual tooth segmentation was performed by identifying mesial and distal contact points, refining tooth splines, and adjusting axial orientation. The diagnostic setup involved adjusting the occlusal plane to reproduce any clinical canting, selecting and refining the arch form, and performing a three-dimensional tooth setup to achieve ideal alignment per American Board of Orthodontics criteria, with no overcorrection. Incremental staging steps were then generated, with extrusive and intrusive movements set at 0.15 mm per step and rotational, tipping, and torquing movements at 1 degree per step, while the planar translation increments constituted the group-specific variable: 0.25 mm per step for Group A and 0.35 mm per step for Group B. Each staging step was meticulously inspected for interproximal or occlusal interferences exceeding 0.2 mm, which were iteratively resolved within the

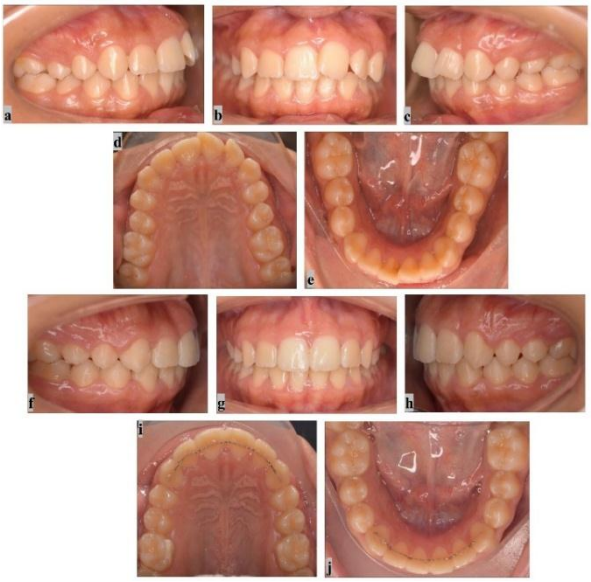
software. Attachments were inserted according to biomechanical needs: vertical attachments for tip or rotation ≥ 5 degrees, and horizontal attachments for extrusion ≥ 0.5 mm, positioned centrally and as incisally or occlusally as possible without interfering with occlusion; standard dimensions were 3.5 × 1.5 × 0.8 mm, with adjustments made based on tooth morphology or occlusal interferences. The finalized digital models were labeled with the patient's name and exported as STL files for fabrication.

For laboratory procedures, STL files were sent to a digital lab where models were printed using Formlabs Grey resin (Formlabs, Somerville, MA, USA) on a 3D printer (Form 2, Formlabs Inc., Somerville, MA, USA). Samples were washed in a Form Wash tank (Formlabs, Somerville, MA, USA) for 20 minutes and subsequently post-cured in a Form Cure tank (Formlabs, Somerville, MA, USA). Aligners were thermoformed from 0.8 mm Erkodur-AL material (Erkodent Erich Kopp GmbH, Germany) using a MiniSTAR S® machine (Scheu-Dental GmbH, Iserlohn, Germany) and were subsequently trimmed in a straight line, terminating 2 mm apical to the gingival margins.

Clinically, one week prior to bonding, patients received dental prophylaxis. After isolation with cheek retractors, cotton rolls, and suction, the enamel surfaces were etched with 37% phosphoric acid for 15 seconds, rinsed, and dried to a frosty appearance. A thin layer of Transbond XT primer (3M Unitek, Monrovia, Calif) was applied and light-cured. The attachment template was then seated, and flowable composite (Nexcomp Flow, Meta Blomea, Korea) was injected into the attachment recesses and light-cured through the template. The template was removed, and excess composite was finished using a carbide bur. Interproximal reduction was performed using metallic abrasive strips as prescribed, with the gained space measured using IPR gauges, and the treated surfaces were subsequently polished. The first aligner was seated using chewies, and patients were instructed to wear the aligners for 22 hours daily, except during meals and hot or staining beverages, and to clean them with a soft toothbrush. Patients were followed up every two weeks to monitor progress, compliance, and adverse events, with biweekly intraoral scans obtained to track LII changes. Pain was assessed using a Visual Analogue Scale, compliance was reinforced, and progression to the subsequent aligner occurred every two weeks.

For patients allocated to the Control group, conventional fixed appliance therapy was initiated. One week after polishing, the teeth were isolated and etched with 37% phosphoric acid for 30 seconds. After rinsing and drying, Transbond XT primer was applied, and stainless steel brackets with a Roth prescription and 0.018-inch slot size, along with bondable molar tubes, were bonded using Transbond XT composite. Each bracket was firmly seated, excess adhesive was removed, and the adhesive was light-cured for 20 seconds per tooth. Leveling and aligning were performed using a standardized, progressive sequence of nickel-titanium archwires, advancing to rectangular stainless-steel wires. Patients were seen monthly for intraoral scans to measure LII, and pain was assessed every two weeks via VAS, with archwire changes every 4 weeks based on clinical response; oral hygiene was reinforced, and any appliance complications were addressed.

The primary outcome was the rate of orthodontic tooth movement, quantified by measuring LII at baseline (T1) and at each follow-up using 3Shape 3D Viewer software (3Shape Ortho System, 3Shape A/S, Copenhagen, Denmark). The time in weeks required to achieve complete alignment, defined as an LII score of zero at the final scan (T3), was recorded for all groups. Pain level was assessed as a secondary outcome using a 10-cm Visual Analogue Scale, with scores ranging from 0 (no pain) to 10 (maximum pain); an Arabic version was administered to ensure accuracy. In all groups, pain was evaluated every two weeks until crowding resolution was achieved. All collected data were transcribed into a Microsoft Excel spreadsheet, and each patient was assigned a numerical code for identification.
Representative intraoral photographs documenting the clinical outcomes are shown in



Figures (2–4) for the three treatment groups.

Figure 2: Intraoral photographs of a representative patient treated with Aligner I (0.25 mm/step planar translation). Pretreatment views: (a) lateral right, (b) frontal, (c) lateral left, (d) upper occlusal, and (e) lower occlusal, showing anterior crowding. Posttreatment views: (f) lateral right, (g) frontal, (h) lateral left, (i) upper occlusal, and (j) lower occlusal following active therapy, demonstrating complete alignment, normalized overjet and overbite, stable arch form with proper interdigitation, and improved occlusal contacts in both arches.

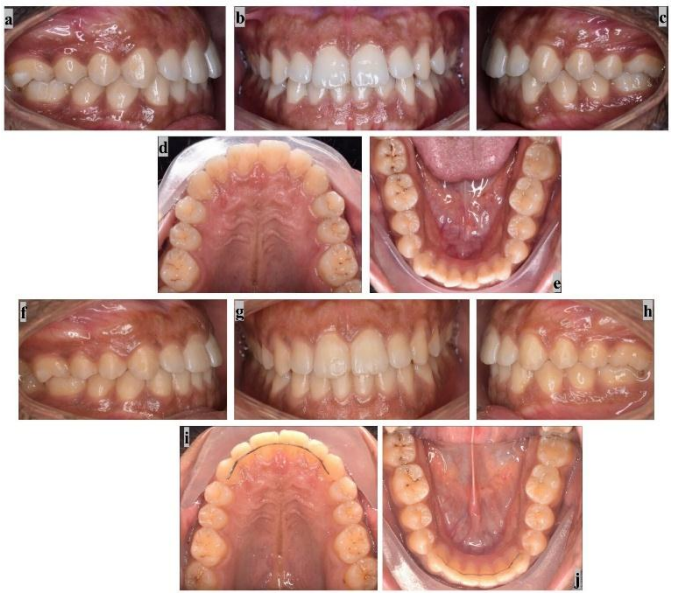


Figure 3: Intraoral photographs of a representative patient treated with Aligner II (0.35 mm/step planar translation). Pretreatment views: (a) lateral right, (b) frontal, (c) lateral left, (d) upper occlusal, and (e) lower occlusal, displaying crowding. Posttreatment views: (f) lateral right, (g) frontal, (h) lateral left, (i) upper occlusal, and (j) lower occlusal after therapy, revealing complete resolution of crowding with harmonious occlusal interdigitation.

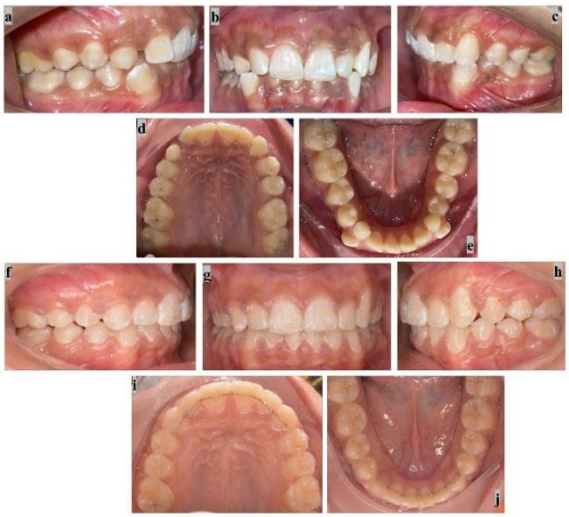


Figure 4: Intraoral photographs of a representative patient treated with fixed appliances (0.018" Roth brackets). Pretreatment views: (a) lateral right, (b) frontal, (c) lateral left, (d) upper occlusal, and (e) lower occlusal, showing crowding. Posttreatment views: (f) lateral right, (g) frontal, (h) lateral left, (i) upper occlusal, and (j) lower occlusal after therapy, demonstrating well-aligned dental arches.

Statistical analysis

The normality of the numerical data was assessed through visual inspection of the distribution and confirmed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Since all variables exhibited non-normal distributions, non-parametric statistical methods were employed throughout the analysis. Data were summarized as median, range, mean, and standard deviation (SD). Intergroup comparisons among the three study groups were performed using the Kruskal–Wallis test, followed by the Mann–Whitney U test for pairwise comparisons between two groups. To evaluate longitudinal changes within each group over time, Friedman test was applied. In cases where Kruskal–Wallis or Friedman tests yielded statistically significant results, post-hoc pairwise comparisons were conducted using Dunn's test. The threshold for statistical significance was set at $P \leq 0.05$. All statistical analyses were carried out using IBM SPSS Statistics for Windows (Version 23.0, Armonk, NY: IBM Corp).(13)

III. Result

A total of 19 participants were enrolled: 7 in the Aligner I group, 5 in the Aligner II group, and 7 in the Control group. In the Aligner I group, two participants dropped out. Therefore, five participants in the Aligner I group completed the study. No participants dropped out from the Aligner II or Control groups.

Baseline characteristics

Baseline characteristics of the three groups are presented in **Table (1).**

Table 1: Descriptive statistics for base line characteristics in the three groups.

Base line characteristics	Aligner I	Aligner II	Control
Gender [n, (%)]			
Male	3 (42.9%)	2 (40%)	2 (28.6%)
Female	4 (57.1%)	3 (60%)	5 (71.4%)
Age [Mean, SD]	21 (2.7)	20.8 (3.1)	22 (3.3)
Number of aligners [Median, Range]	8 (5-10)	6 (5-8)	-

Little's Irregularity Index (mm)

a. Comparison between the three groups

LII was compared among all three groups at baseline, week 4, week 8, and week 12. At weeks 2, 6, and 10, LII was compared only between the Aligner I and Aligner II groups because the Control group had no data at those time points.

At baseline and at weeks 2, 4, 6, 8, and 10, there was no statistically significant difference between the compared groups (P = 0.201, 0.465, 0.484, 0.223, 0.238, and 0.164, respectively). At week 12, there was a

statistically significant difference among the three groups (P = 0.020, effect size = 0.156) **(Table 2 and Figure 5).**

Pairwise comparisons at week 12 revealed that the Control group had the lowest median LII (0.00 mm), followed by the Aligner II group (0.43 mm), while the Aligner I group had the highest median LII (0.85 mm); all pairwise differences were statistically significant. At weeks 14 and 16, LII was compared only between the Aligner I and Aligner II groups, and there was no statistically significant difference (P = 0.733 and P = 0.429, respectively). At weeks 18 and 20, the Aligner I group had two remaining cases while the other groups had no cases, so no statistical comparison could be made **(Table 2 and Figure 5).**

b. Changes within each group

Friedman's test showed a statistically significant change in Little's Irregularity Index (LII) over time in all three groups: Aligner I group (P = 0.029), Aligner II group (P = 0.035), and Control group (P = 0.007).
In the Aligner I group, LII decreased significantly from onset to week 2, followed by no statistically significant change from week 2 to week 4. Statistically significant decreases were observed from week 4 to week 6, week 6 to week 8, and week 8 to week 10. No statistically significant change occurred from week 10 to week 12. LII then decreased significantly from week 12 to week 14, followed by no statistically significant change from week 14 to week 16. Statistically significant decreases were also observed from week 16 to week 18 and from week 18 to week 20 **(Table 2 and Figure 5).**

In Aligner II group, LII decreased significantly from onset to week 2 and from week 2 to week 4, week 4 to week 6, week 6 to week 8, and week 8 to week 10. No statistically significant change occurred from week 10 to week 12. Statistically significant decreases were then observed from week 12 to week 14 and from week 14 to week 16. In Control group, LII decreased significantly from onset to week 4, from week 4 to week 8, and from week 8 to week 12 **(Table 2 and Figure 5).**

Table 2: Descriptive statistics and results of Kruskal-Wallis test for comparison between Little's Irregularity Index (mm) in the three groups, Mann-Whitney U test for comparison between two groups and Friedman's test for changes within each group.

Time	Aligner I					Aligner II					Control					*P*-value	*Effect size*
	Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD		
Onset	4.61 ^{D}	3.57	6.03	4.66	0.94	3.97 ^{D}	3.23	5.45	4.11	0.86	5.36 ^{D}	3.27	6.38	5.21	1.06	0.201	0.191
Week 2	3.21 ^{E}	2.54	5.34	3.67	1.06	3.03 ^{E}	2.43	4.78	3.3	0.92	-	-	-	-	-	0.465	0.432
Week 4	2.78 ^{E}	2.07	4.74	3.07	0.99	2.32 ^{F}	1.32	3.95	2.44	1.03	3.21 ^{E}	1.39	4.27	3.04	0.95	0.484	0.081
Week 6	2.04 ^{F}	1.57	4.03	2.5	0.89	1.87 ^{G}	0.75	3.05	1.74	0.91	-	-	-	-	-	0.223	0.751
Week 8	1.69 ^{G}	0.78	3.51	1.89	0.95	0.93 ^{H}	0.38	2.32	1.09	0.76	1.37 ^{F}	0	2.48	1.03	1.02	0.238	0.183
Week 10	1.03 ^{H}	0	2.93	1.28	0.97	0.46 ^{I}	0	1.65	0.59	0.69	-	-	-	-	-	0.164	0.869
Week 12	0.85 ^{AH}	0.2	2.14	1.05	0.75	0.43 ^{BI}	0	0.97	0.47	0.49	0 ^{CG}	0	0	0	0	0.020*	0.156
Week 14	0.37 ^{I}	0	1.76	0.59	0.69	0.24 ^{J}	0	0.47	0.24	0.33	-	-	-	-	-	0.733	0.237
Week 16	0.27 ^{I}	0	0.89	0.36	0.44	0 ^{K}	0	0	0	-	-	-	-	-	-	0.429	0.667
Week 18	0.35 ^{J}	0.23	0.46	0.35	0.16	-	-	-	-	-	-	-	-	-	-	Not computed	
Week 20	0 ^{K}	0	0	0	0	-	-	-	-	-	-	-	-	-	-	Not computed	
P-value	0.029*					0.035*					0.007*						
Effect size (w)	1					1					1						

**: Significant at P ≤ 0.05, Effect size: Eta squared (for three-group comparisons) and (d) for two-group comparisons, A,B,C superscripts in the same row indicate statistically significant difference between groups, D through K superscripts in the same column indicate statistically significant change within group*

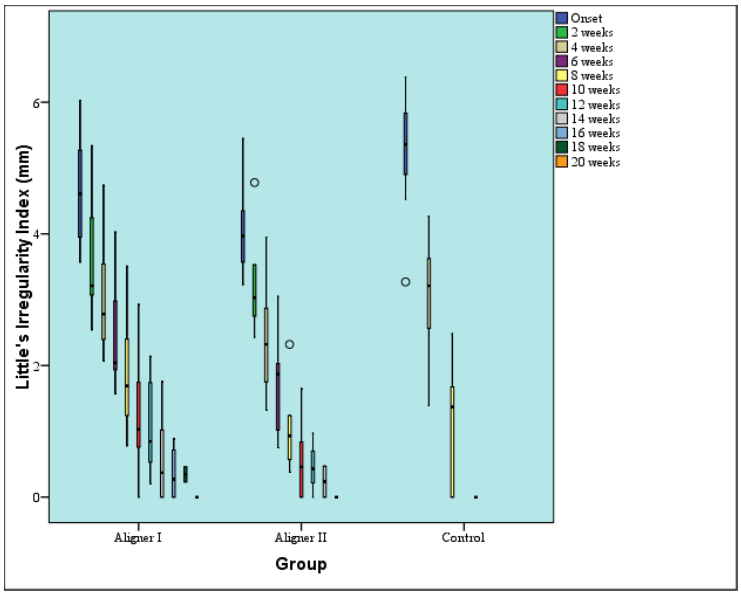


Figure 5: Box plot representing median and range values for Little's Irregularity Index scores in the three groups (Circles represent outliers)

Pain (VAS scores)

a. Comparison between the three groups

After 2, 4, and 6 weeks, there was no statistically significant difference between the groups (P = 0.230, 0.081, and 0.066, respectively). After 8 weeks, there was a statistically significant difference between the groups (P = 0.004, effect size = 0.707). Pairwise comparisons revealed that there was no statistically significant difference between Aligner I and Aligner II groups; both showed statistically significantly higher pain scores than the Control group. After 10 weeks, there was a statistically significant difference between the groups (P = 0.010, effect size = 0.673) **(Table 3 and Figure 6).**

Pairwise comparisons revealed that Aligner I group had the highest pain scores, followed by Aligner II group, while Control group had the lowest scores. All pairwise differences were reported as statistically significant. After 12 weeks, there was no statistically significant difference between the groups (P = 0.124). At weeks 14 and 16, pain was compared between Aligner I and Aligner II groups only, and there was no statistically significant difference between the groups (P = 0.721 and P = 0.343, respectively). After 18 and 20 weeks, the Aligner I group had two remaining cases while the other groups had no cases, so no statistical comparison could be made **(Table 3 and Figure 6).**

b. Changes within each group

There was a statistically significant change in pain scores by time in the three groups (P = 0.002, P = 0.001, and P < 0.001, respectively). In the Aligner I group, there was a statistically significant decrease in pain scores after four weeks and from four to six weeks. This was followed by a non-statistically significant change from six to eight and eight to ten weeks. From 10 to 12, 12 to 14, and 14 to 16 weeks, there was a statistically significant decrease in pain scores **(Table 3 and Figure 6).**

This was followed by a non-statistically significant change from 16 to 18 weeks. From 18 to 20 weeks, there was a statistically significant decrease in pain scores. In the Aligner II group, there was a statistically significant decrease in pain scores after four weeks and from four to six, six to eight, eight to ten, and ten to twelve weeks. This was followed by a non-statistically significant change from 12 to 14 weeks. From 14 to 16 weeks, there was a statistically significant decrease in pain scores **(Table 3 and Figure 6).**

In the Control group, there was a statistically significant decrease in pain scores after four weeks and from four to six, six to eight, and eight to ten weeks. From 10 to 12 weeks, there was no statistically significant change in pain scores **(Table 3 and Figure 6).**

Table 3: Descriptive statistics and results of Kruskal-Wallis test for comparison between pain (VAS scores) in the three groups, Mann-Whitney U test for comparison between two groups and Friedman's test for the changes within each group.

Time	Aligner I					Aligner II					Control					*P*-value	*Effect size*
	Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD		
Week 2	8 ^{D}	6	9	7.71	1.11	8 ^{D}	7	9	8	0.71	7 ^{D}	5	9	6.86	1.35	0.230	0.18
Week 4	6 ^{E}	4	7	5.71	0.95	7 ^{E}	6	7	6.6	0.55	5 ^{E}	3	7	5.29	1.25	0.081	0.241
Week 6	5 ^{F}	3	5	4.43	0.98	5 ^{F}	4	5	4.8	0.45	3 ^{F}	2	5	3.29	1.25	0.066	0.330
Week 8	4 ^{AF}	3	5	4.14	0.9	4 ^{AG}	3	4	3.6	0.55	1 ^{BG}	0	3	1.17	1.17	0.004*	0.707
Week 10	4 ^{AF}	1	4	3.14	1.21	3 ^{BH}	2	3	2.6	0.55	0 ^{CH}	0	1	0.25	0.5	0.010*	0.673
Week 12	3 ^{G}	0	3	2.14	1.21	2 ^{I}	1	3	2	1	0 ^{H}	0	0	0	0	0.124	0.405
Week 14	2 ^{H}	0	3	1.67	1.03	1.5 ^{I}	1	2	1.5	0.71	-	-	-	-	-	0.721	1.071
Week 16	1 ^{I}	0	2	1	1	0 ^{J}	0	0	0	-	-	-	-	-	-	0.343	0.768
Week 18	1 ^{I}	1	1	1	0	-	-	-	-	-	-	-	-	-	-	Not computed	
Week 20	0 ^{J}	0	0	0	0	-	-	-	-	-	-	-	-	-	-	Not computed	
P-value			0.002*					0.001*					<0.001*				
Effect size (w)			0.99					1					1				

**: Significant at P ≤ 0.05, Effect size: Eta squared (for three-group comparisons) and (d) for two-group comparisons, A,B,C superscripts in the same row indicate statistically significant difference between groups, D through J superscripts in the same column indicate statistically significant change within group*

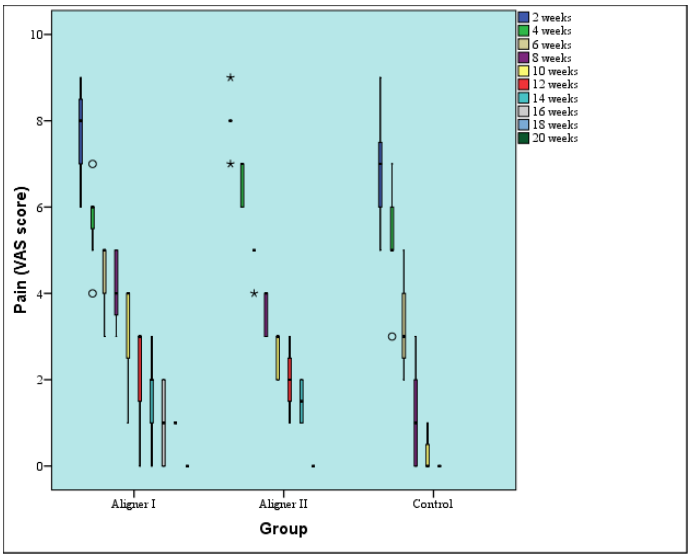


Figure 6: Box plot representing median and range values for pain scores in the three groups (Circles and stars represent outliers)

Number of weeks

There was a statistically significant difference between the groups (P = 0.010, effect size = 0.511). Pairwise comparisons revealed that Aligner I group required the highest number of weeks (median = 16; range 10–20), followed by Aligner II group (median = 12; range 10–16), while the Control group required the lowest number of weeks (median = 10; range 6–12). All pairwise differences were statistically significant **(Table 4 and Figure 7).**

Table 4: Descriptive statistics and results of Kruskal-Wallis test for comparison between number of weeks in the three groups.

Aligner I					Aligner II					Control					*P*-value	*Effect size (Eta Squared)*
Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD	Median	Min.	Max.	Mean	SD		
16 [A]	10	20	15.7	3.5	12 [B]	10	16	12.4	2.6	10 [C]	6	12	9.4	2.2	0.010*	0.511

**: Significant at P ≤ 0.05, Different superscripts in the same row indicate statistically significant difference between groups*

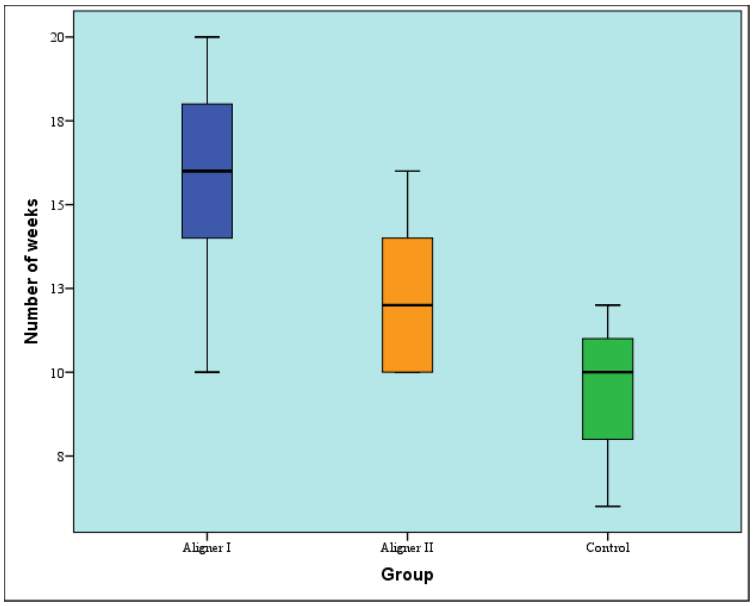


Figure 7: Box plot representing median and range values for number of weeks in the three groups

IV. Discussion

The present study evaluated the efficiency of two clear aligner activation protocols (0.25 mm and 0.35 mm per step) compared with conventional fixed appliances in treatment of mild-to-moderate lower anterior crowding. The rate of tooth movement was the primary outcome and was assessed using the LII until the LII value reached zero, with treatment duration and pain as secondary outcomes.

Regarding LII, no significant differences were observed among the three groups during the initial treatment phase up to 10 weeks. This finding aligns with a previous study by **Mario et al. (2024)** in which LII in the upper and lower jaw did not significantly differ among the treatment groups. (14) The absence of early differences may be attributed to the initial alignment phase in which all appliances exert comparable forces on the dentition, regardless of the mechanotherapy employed.

Within-group patterns differed among the three modalities. In the Aligner I group, a biphasic pattern was observed: a significant reduction after two weeks, followed by a plateau from two to four weeks, then significant reductions from four to ten weeks, another plateau from ten to twelve weeks, a significant reduction from twelve to fourteen weeks, a plateau from fourteen to sixteen weeks, and further significant reductions from sixteen to twenty weeks. This "stuttering" pattern may reflect the sequential tooth movements programmed into the aligner system, in which certain teeth are moved in specific sequences rather than simultaneously.

The Aligner II group demonstrated a more consistent pattern, with statistically significant decreases at nearly every evaluation interval from baseline through 10 weeks, followed by additional significant reductions at 12–14 and 14–16 weeks. This more consistent improvement may indicate more efficient force delivery with the 0.35 mm activation protocol compared with the 0.25 mm protocol.

In the Control group, significant reductions occurred at more extended intervals (after four weeks, from four to eight weeks, and from eight to twelve weeks), yet this group still achieved complete alignment in the shortest median time. This is consistent with fixed appliance mechanics, in which continuous archwire forces engage multiple teeth simultaneously.

At the 12-week time point, a statistically significant intergroup difference emerged (P = 0.020). The Control group had the lowest median LII (0.00 mm), followed by Aligner II group (0.43 mm), while Aligner I group had the highest median LII (0.85 mm). All pairwise differences were reported as statistically significant. This indicates that, in this non-extraction lower incisor crowding sample, fixed appliances achieved complete alignment earlier than either aligner protocol. Among the aligner groups, the 0.35 mm activation increment was more efficient than the 0.25 mm increment, but it did not surpass fixed appliance therapy.

From 14 to 16 weeks, no statistically significant differences were observed between the two aligner groups, suggesting convergence as the remaining aligner cases also approached alignment. After 18 and 20 weeks, only two Aligner I cases remained, precluding formal statistical comparison; this observation requires further investigation with larger samples.

Regarding treatment duration, there was a statistically significant difference among the groups (P = 0.010). Fixed appliances were the most time-efficient overall, with a median of 10 weeks (range 6–12), followed by Aligner II group (median 12 weeks; range 10–16) and Aligner I group (median 16 weeks; range 10–20). Pairwise comparisons confirmed that Aligner I group required significantly more weeks than both Aligner II and the Control groups, and the Control group required significantly fewer weeks than both aligner groups. Among aligner groups, the 0.35 mm protocol was significantly faster than the 0.25 mm protocol, which may relate to the larger per-step activation producing more effective movement per aligner while remaining clinically tolerable. The 0.25 mm protocol still achieved complete resolution within a clinically acceptable timeframe, indicating that both activation protocols are clinically effective.

These findings align with biomechanical principles. **Lombardo et al. (2017)** reported that lower canine rotation was the least predictable movement (54.2%), while mesiodistal tipping of lower premolars was among the most predictable (96.7%). (15) The more consistent improvement in Aligner II group may reflect more favorable force distribution. **Elshazly et al. (2022)** described uneven force transmission with aligners, (16) which may explain the "stuttering" pattern observed in Aligner I group. **Li et al. (2016)** demonstrated that force attenuation follows a biphasic pattern—rapid relaxation in the first 8 hours, slower decay from 8 hours to 4–5 days, and a plateau thereafter—emphasizing that the initial days after aligner change are critical. (17) In the present study, Aligner I group showed multiple non-significant intervals (weeks 2–4, 10–12, 14–16), whereas Aligner II group showed only one non-significant interval (weeks 10–12). This suggests that the 0.35 mm protocol provided more stable force delivery throughout the wear period. **Dongyu et al. (2013)** reported that residual stresses in thermoplastic materials decrease over time and are accelerated by immersion in a 37°C water bath, (18) suggesting that the intra-oral environment may further accelerate force decay beyond laboratory observations.

The present data do not support the claim that clear aligners achieve more efficient anterior alignment than fixed appliances during the intermediate treatment phase. Previous research has shown that fixed orthodontic treatment can be more efficient than clear aligners, particularly in extraction cases. However, the present study included only non-extraction cases, which may explain some discrepancies with earlier findings. The more efficient movement observed with Aligner II group compared with Aligner I group supports the concept that a larger activation increment within the tested range can improve aligner efficiency. This is consistent with **Li et al. (2016),** who found that greater activation affects force generation and decay patterns. (17) **Barbagallo et al. (2008)** reported initial orthodontic forces of 5.12 N for 0.5 mm activation, (19) while **Proffit et al. (2018)** suggested that optimal force for bodily movement is 0.75–1.25 N, (20) indicating that aligner forces may exceed optimal levels initially and then decay into the therapeutic range. Aligner II group may have maintained forces within a more effective range for a greater proportion of the treatment period than Aligner I group.

A review by **Martínez-Lozano et al. (2024)** emphasized that micro-staging is central to creating space and distributing anchorage but stressed that comparative staging studies remain scarce. (21) Therefore, while the present trial supports the concept that a 0.35 mm activation step accelerates lower incisor alignment compared with 0.25 mm, it does not establish 0.35 mm as the definitive universal optimal increment.

Regarding pain, no statistically significant differences were observed among the three groups at weeks 2, 4, and 6. These findings are consistent with meta-analyses by **Li et al. (2023)** and **Cardoso et al. (2020)**, which demonstrated that while clear aligners may confer a transient advantage in pain reduction during the first few days, these differences are not sustained beyond the first week. (22,23) **Gao et al. (2021)** also showed that although fixed appliances typically elicit a more pronounced pain peak during the initial 24–48 hours, pain levels across appliance modalities tend to converge shortly thereafter. (24) At week 2, median pain scores ranged from 7 to 8 out of 10 across groups, consistent with **Fujiyama et al. (2014),** who reported comparable discomfort during the initial phase of both aligner and fixed appliance therapy. (25)

A notable finding was the emergence of statistically significant differences at weeks 8 and 10 ($P = 0.004$ and $P = 0.010$, respectively), with both aligner groups reporting significantly higher pain scores than the Control group. This appears to contradict the general conclusion of **Cardoso et al. (2020)** that patients treated with Invisalign experienced lower pain during the initial days. (23) However, the review acknowledged that appliance type may influence discomfort due to differences in force application, noting that removable appliances generate intermittent forces that permit tissue reorganization between compressive episodes. At week 8, both aligner groups had higher pain than the Control group. This may reflect the continuous force application inherent in aligner therapy, as patients changed to new aligners every two weeks, potentially experiencing recurrent discomfort. In contrast, the fixed appliance group had typically progressed to more flexible archwires by this time, potentially reducing active discomfort.

Several factors may account for this discrepancy. First, **Cardoso et al. (2020)** noted that advantages of clear aligner therapy are typically observed in patients with mild-to-moderate malocclusions. (23) The present study may have included patients with greater treatment complexity. The review further acknowledged that Invisalign cases often present lower irregularity indices, suggesting that patient selection may have influenced pain outcomes in prior investigations. As **Shalish et al. (2012)** hypothesized, differences in malocclusion severity between groups may represent a significant bias in result interpretation. (26)

Second, biomechanical differences between treatment modalities may contribute to divergent pain profiles. Fixed appliances deliver continuous forces with monthly adjustments, whereas aligners are replaced every two weeks, potentially generating repeated cycles of discomfort. **Cardoso et al. (2020)** suggested that aligner patients may experience lower pain per activation but over a more prolonged duration. (23) The elevated pain scores at weeks 8 and 10 in the present study may reflect cumulative effects of successive aligner changes, indicating that temporal pain patterns differ in ways not fully captured by short-term investigations.

Both aligner groups experienced similar initial pain at week 2 (median 8 on VAS for both), but Aligner I group maintained significantly higher pain levels longer, showing significantly higher pain scores than Aligner II group at week 10 (median 4 vs 3, $P = 0.010$). This may be explained by differences in treatment duration and number of aligner changes, as the 0.25 mm protocol required more aligners and more weeks, potentially leading to more cumulative discomfort. Alternatively, force distribution and staging differences may have contributed. **Fujiyama et al. (2014)** reported that pain levels with aligner treatment were lower than with fixed appliances, but significant pain was still experienced during the first few days of each aligner change. (25) The present study extends this understanding by demonstrating that activation protocol significantly influences the pain profile. The fact that Aligner II group achieved faster tooth movement with lower pain at week 10 than Aligner I group suggests that the 0.35 mm protocol may provide a more favorable balance between efficiency and discomfort.

The significant decrease in pain scores over time within each group is consistent with orthodontic pain being primarily an initial treatment phenomenon. **Miller et al. (2007)** similarly reported that fixed appliance subjects took more pain medication during days 2 and 3, (27) suggesting that the initial phase is most intense for conventional appliances. However, the present data reveal that even within aligner groups, pain follows a decreasing pattern with periods of significant reduction interspersed with stability. This may reflect patient adaptation to the recurring stimulus of new aligner insertion, as well as progressive reduction in required tooth movement magnitude as treatment progresses.

At weeks 18 and 20, pain was reported exclusively in the Aligner I group, while no cases were documented in the other groups. Although statistical comparison was precluded, this observation is clinically noteworthy and may suggest that certain aligner systems present unique challenges during later stages of treatment. Whether this reflects differences in appliance design, force delivery, or specific tooth movements remains uncertain.

Therefore, these results highlight that the pain experience during orthodontic treatment is highly dynamic and stage-dependent, rather than determined solely by appliance type. While clear aligners may offer a more comfortable start, this benefit does not persist, and at certain timepoints, aligner therapy may even be associated with greater discomfort than fixed appliances.

Regarding treatment duration, the present findings contrast with earlier reports indicating no substantial difference between appliance types; for instance, one study found that nickel–titanium wires and clear aligners were equally effective in reducing lower crowding. (28,29) Conversely, some studies have shown that clear aligners completed treatment faster than fixed appliances, possibly due to differences in malocclusion severity between samples. (30–32) **Borda et al. (2020)** reported that clear aligner treatment achieved results approximately six months earlier than fixed appliances for mild malocclusions. (33) In the current study, Aligner II group achieved complete crowding resolution in a median of 12 weeks, while Aligner I group required 16 weeks, suggesting that the activation increment significantly influences treatment duration. However, the Control group achieved complete resolution in a median of 10 weeks, significantly shorter than both aligner groups.

The finding that fixed appliances were fastest may appear to contradict the common perception that clear aligners offer faster treatment. However, the fixed appliance group benefited from continuous force application and simultaneous engagement of all teeth with full-sized archwires. Additionally, as noted by **Borda et al. (2020),** sequencing of mechanics in fixed appliance therapy allows for concurrent correction of multiple aspects of malocclusion. (33) The broader literature does not definitively answer whether aligners or fixed appliances are faster. In mild-to-moderate crowding, a 2024 systematic review found no significant overall difference in treatment duration between clear aligners and fixed appliances, but the evidence quality was low. (1) Older comparative reviews suggested shorter duration with aligners in some settings, (28) whereas extraction-based and more complex cases often favor fixed appliances for shorter treatment times and better occlusal control. (34) This trial therefore fits one important scenario: for non-extraction lower incisor crowding, fixed appliances still appear most time-efficient, while increasing aligner activation from 0.25 to 0.35 mm recovers some of that gap.

It is important to note that all cases in the present study were non-extraction. For extraction cases, studies have shown that clear aligners require 44% more time compared with fixed appliances. (35) This differs from previous studies (36,37) and may be attributed to differences in treatment planning protocols, such as the G6 Align protocol, which retracts canines first and increases the number of aligners required. (38) The non-extraction nature of the present sample may have contributed to the observed differences in treatment duration.

The present study offers a novel and valuable baseline reference for future research. Its strengths include a prospective randomized controlled design that inherently minimizes bias, well-defined eligibility criteria targeting a clinically relevant subgroup, and standardized treatment protocols. Internal validity is further reinforced by the comprehensive evaluation of both clinical and patient-reported outcomes, the application of objective indices (e.g., LII), the use of calibrated examiners, and a priori sample size calculation.

However, several limitations of this study should be acknowledged. The small sample size, particularly in the Aligner I group during the later stages of treatment, limited the statistical power. Additionally, the study did not evaluate outcomes such as root resorption or periodontal health. Future research with larger sample sizes, longer follow-up periods, and comprehensive outcome measures would provide valuable insights into the comparative effectiveness of different clear aligner systems. Furthermore, investigating the biomechanical factors underlying the different temporal patterns of tooth movement observed between the aligner systems would contribute to the optimization of clear aligner therapy.

V. Conclusion

Within the limitations of this study, the following can be concluded:

• All three modalities effectively reduce mild-to-moderate lower anterior crowding over their respective active treatment periods.

• Fixed appliances were the most time-efficient overall for non-extraction lower incisor crowding, achieving the shortest median treatment duration and the lowest LII at week 12.

• Among the aligner groups, the 0.35 mm activation increment was more efficient than the 0.25 mm increment, but it did not surpass fixed appliance therapy in overall time-efficiency.

• Pain and alignment are highly stage-dependent, confirming that the treatment experience is dynamic rather than determined solely by appliance type. Aligner therapy was not universally more comfortable; at weeks 8 and 10, aligner groups reported higher pain scores than fixed appliances.

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