

A Randomized Clinical Trial to Assess the Efficacy of Reducing the Aligners' Wear Protocol

2024 Research Aid Awards (RAA)

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FollowUp Form

Award Information



In an attempt to make things a little easier for the reviewer who will read this report, please consider these two questions before this is sent for review:

- Is this an example of your very best work, in that it provides sufficient explanation and justification, and is something otherwise worthy of publication? (We do publish the Final Report on our website, so this does need to be complete and polished.)*
- Does this Final Report provide the level of detail, etc. that you would expect, if you were the reviewer?*

Title of Project:*

A Randomized Clinical Trial to Assess the Efficacy of Reducing the Aligners' Wear Protocol

Award Type

Research Aid Award (RAA)

Period of AAOF Support

July 1, 2024 through June 30, 2025

Institution

University of Florida Board of Trustees

Names of principal advisor(s) / mentor(s), co-investigator(s) and consultant(s)

Dr. Sarah Abu Arqub, Dr. Flavio Uribe and Dr. Calogero Dolce

Amount of Funding

\$5,800.00

Abstract

(add specific directions for each type here)

The current focus of Align Technology is to improve the predictability and accuracy of tooth movement for the Invisalign® system. However, due to limitation with the thermoplastic aligner material, a decline in force delivery often results from the added activation to the 3D simulated treatment plan (ClinCheck) on the Invisalign Doctor Platform. Hence, integrating less tooth/aligner movement in the design of the appliance through Invisalign Doctor Platform within the standard of care in the digital treatment set up will help create a more consistent and continuous force and facilitate treatment. This means fabrication of a greater number of aligners for treating the same malocclusion with less amount of activation engineered per aligner, therefore, the duration of wear for each aligner can be reduced to achieve desired outcomes within the same range of treatment duration with standard of care.

This randomized clinical trial aims to assess the effectiveness in increasing the frequency of change per aligner, within the standard of care, on the efficacy of achieving better treatment outcomes. This trial will also monitor the rate of tooth movement via Dental monitoring (DM). This is the latest and most common artificial intelligence intraoral monitoring application, downloaded on the patient's personal smartphone, to track the progress of treatment and movement of teeth within the standard of care. This will provide a comprehensive and accurate evaluation for the amount and rate of tooth movement expected for the reduced wear protocol (3-day change per aligner) compared to the common wear protocol (7-day change per aligner).

Respond to the following questions:

Detailed results and inferences:*

If the work has been published, please attach a pdf of manuscript below by clicking "Upload a file".

OR

Use the text box below to describe in detail the results of your study. The intent is to share the knowledge you have generated with the AAOF and orthodontic community specifically and other who may benefit from your study. Table, Figures, Statistical Analysis, and interpretation of results should also be attached by clicking "Upload a file".

AAOF report.pdf

Overview of Study Goals

This study investigated the clinical effectiveness and tooth movement accuracy of two different clear aligner wear schedules: a 3-day accelerated protocol and the standard 7-day protocol. The objective was to determine whether faster aligner changes compromise treatment efficiency, occlusal outcomes, or movement accuracy, especially during initial alignment stages.

Key Findings

1. Demographics and Study Cohort

A total of 40 patients (20 per group) were included after excluding non-compliant cases.

There were no significant differences in age, gender distribution, or baseline malocclusion severity (Discrepancy Index) between groups.

2. Clinical Efficiency and Treatment Characteristics

3-day wear group required significantly more aligners in the first stage (upper and lower: median = 30.5) compared to the 7-day wear group (median = 14.0); $p < 0.001$.

Refinements were significantly more common in the 3-day group (50%) than in the 7-day group (15%); $p = 0.041$.

Emergency visits and total visits were slightly more frequent in the 3-day group but did not reach statistical significance.

Treatment time for the first series of aligners, lower incisor alignment, and total treatment time was comparable between both groups ($p > 0.3$).

3. Occlusal Improvement: PAR Index

Both groups demonstrated clinically significant reductions in PAR scores from pre-treatment to post-treatment.

3-day group: Mean reduction of 10.4 points

7-day group: Mean reduction of 7.8 points

Differences were not statistically significant ($p = 0.424$), indicating similar occlusal outcomes.

4. Incisor Alignment: Little's Irregularity Index

Both groups showed significant improvement.

However, the 7-day group had significantly lower post-treatment irregularity scores (median = 0.0 mm) than the 3-day group (median = 0.9 mm); $p = 0.035$.

This suggests slightly better precision in anterior alignment with the 7-day protocol.

5. Accuracy of Tooth Movement

Four lower incisors (teeth 31, 32, 41, 42) were analyzed for linear deviations.

Total deviations ranged from 0.4 mm to 0.5 mm in both groups, well within the 0.5 mm ABO clinical significance threshold.

No statistically significant differences were noted for any linear (X, Y, Z axis) measurements, suggesting comparable accuracy across both protocols.

Clinical Implications

The 3-day protocol did not compromise overall treatment duration or movement accuracy, supporting its use in select cases aiming for accelerated outcomes.

However, it was associated with:

Increased number of aligners

Higher rate of refinements

Slightly inferior incisor alignment precision

This suggests that more frequent aligner changes may disrupt biological force continuity, potentially affecting force delivery and efficiency.

Biomechanical Insight

Accelerated wear protocols reduce force application duration per aligner, possibly below the threshold for effective bone remodeling.

Tooth movement depends on reaching a minimum force threshold, not just force continuity.

These findings highlight that force magnitude may be more critical than continuous application in clear aligner therapy, particularly for biologic response activation.

Conclusion

Both wear protocols were clinically effective. However, the 7-day protocol may offer slightly more predictable outcomes with fewer refinements. The 3-day protocol, while appealing for shorter treatment cycles, should be used with caution, especially in cases requiring high precision or complex movements. This study emphasizes the importance of individualized wear schedules based on biomechanics and patient-specific response rather than a one-size-fits-all protocol.

This project was conducted as part of my Master's thesis and represents a significant step in my academic and clinical training. I am currently working with my principal investigator to finalize and publish the findings in a peer-reviewed journal. I am deeply grateful to the American Association of Orthodontists Foundation (AAOF) for their generous support and funding, which made this research possible. Their investment in early-career investigators has played a pivotal role in advancing both my scientific development and contributions to the orthodontic community.

Were the original, specific aims of the proposal realized?*

Yes, the original specific aims of the proposal were successfully realized. The study was designed to compare the clinical outcomes and tooth movement accuracy between 3-day and 7-day clear aligner wear protocols. We were able to collect, analyze, and interpret clinical and digital data to assess treatment efficiency, refinement rates, occlusal improvement (using the PAR and Little's Irregularity indices), and linear deviations between predicted and achieved tooth positions. The results demonstrated that while both protocols are clinically effective, there are important biomechanical and treatment implications associated with accelerated wear. These findings directly address the study's objectives and provide valuable insights for evidence-based aligner therapy.

Were the results published?*

No

Have the results of this proposal been presented?*

Yes

To what extent have you used, or how do you intend to use, AAOF funding to further your career?*

The AAOF funding has had a significant impact on the advancement of my academic and clinical career. It enabled me to design and complete a prospective clinical trial as part of my Master's thesis, focusing on a timely and clinically relevant topic in clear aligner therapy. Through this project, I gained valuable experience in clinical trial design, data collection, digital analysis, and manuscript preparation—skills that are foundational to my development as a clinician-scientist. The findings from this study have already been presented at professional meeting (Spring Synergy at UF) and are currently being prepared for publication in a peer-reviewed journal. The support from AAOF has also strengthened my grant-writing abilities and encouraged my continued pursuit of funded research. Ultimately, this experience has helped position me for a future career in academic orthodontics, with a strong emphasis on evidence-based care and translational research.

Accounting: Were there any leftover funds?

\$600.00

Not Published

Are there plans to publish? If not, why not?*

Yes of course

Presented

Please list titles, author or co-authors of these presentation/s, year and locations:*

We have only completed this study last June , the aim is for it to be presented in IADR, AAO next year and published in AJODO

Was AAOF support acknowledged?

If so, please describe:

Yes , the support of AAO foundation will be acknowledged once this project is presented or published

Internal Review

Reviewer comments

Reviewer Status*

File Attachment Summary

Applicant File Uploads

- AAOF report.pdf

STATISTICAL ANALYSIS

A descriptive analysis was conducted to summarize baseline participant characteristics and outcomes of interest (e.g., treatment times, changes in the PAR index and Little's irregularity index, and movement accuracy) for the 3-day and 7-day wear groups separately.

The two groups were compared for each variable using Wilcoxon rank-sum tests for continuous variables and Fisher's exact tests for categorical variables. None of the baseline participant characteristics showed significant imbalance between the groups; therefore, statistical adjustments were not considered in this study.

All hypothesis tests were two-sided, with p-values evaluated for significance at the 5% level. Statistical analyses were performed using R version 4.4.2.

This clinical trial is currently in progress. As of the latest update, five subjects have not yet completed their treatment, and two participants have not finished their first series of aligners. Consequently, these individuals have been temporarily excluded from some statistical analysis. They will be incorporated into the data set upon completion of their respective treatment phases.

We assumed a mean movement accuracy of 0 mm in the 7-day wear group and a standard deviation of 0.5 mm for both the 3-day and 7-day wear groups. A sample size of 20 subjects per group (40 in total) would provide 85% power at the 5% significance level to detect a mean accuracy difference of 0.5 mm (clinically inaccurate threshold) between the groups, using a Wilcoxon rank-sum test, assuming that both parent distributions follow a normal distribution. This power analysis was performed using G*Power 3.1.9.7.

RESULTS

General Clinical Demographics and Baseline Data

Table 4-1 represents the general clinical characteristics for the included subjects. A total of 45 patients were initially enrolled in the study, evenly distributed between the two groups. After excluding 5 patients due to non-compliance with aligner wear, 40 patients were included in the final analysis: 3-day wear protocol (n = 20) and the 7-day wear protocol (n = 20). The median age of patients in the 3-day wear group was 24.0 years (IQR: 23.0–26.3), while in the 7-day wear group, it was 26.0 years (IQR: 23.8–27.3), with no significant difference between the groups (p = 0.270). The gender distribution was similar, with females comprising 75.0% in the 3-day wear group and 70.0% in the 7-day wear group (p > 0.999). The Discrepancy Index (DI) scores showed no significant difference between groups (p = 0.848).

Patients in the 3-day wear group required significantly more upper (median: 30.5, IQR: 25.0–36.5) and lower aligners (median: 30.5, IQR: 25.0–36.5) in the first stage compared to the 7-day wear group (upper: median 14.0, IQR: 12.0–19.3; lower: median 14.0, IQR: 13.0–19.3) (both p < 0.001). The amount of interproximal reduction (IPR) was not significantly different between groups (p = 0.109). Refinement was required significantly more in the 3-day wear group (50.0%) compared to the 7-day wear group (15.0%) (p = 0.041).

The total number of visits was slightly higher in the 3-day wear group (median: 4.0, IQR: 3.0–5.0) compared to the 7-day wear group (median: 3.0, IQR: 3.0–3.5), but the difference was not statistically significant (p = 0.100). Emergency visits were reported in 31.6% of patients in the 3-day wear group and 10.0% in the 7-day wear group (p = 0.257). Notably, the number of visits specifically for lower incisor alignment was significantly higher in the 3-day wear group (median: 4.0, IQR: 4.0–5.0) compared to the 7-day wear group (median: 3.0, IQR: 3.0–4.0) (p = 0.038).

Regarding treatment duration, the time required for the first series of aligners was not significantly different between groups (p = 0.349), with a median duration of 105.0 days (IQR: 91.0–150.5) in the 3-day wear group and 119.0 days (IQR: 98.0–154.5) in the 7-day wear group. Similarly, the time required for lower incisor alignment (p = 0.703) and the overall treatment duration (p = 0.584) did not show statistically significant differences between the groups. Figure 4-1.

Clinical Outcomes Evaluation

Tables 4-2 and Figure 4-2 present the pre-treatment, post-treatment, and difference in PAR scores between the two groups. The pre-PAR index scores were higher in the 3-day wear group (median: 11.5, IQR: 6.0–14.5) compared to the 7-day wear group (median: 8.0, IQR: 5.8–12.0), but the difference was not statistically significant (p = 0.158). After the first aligner series, both groups showed improvement in PAR scores, with no significant differences (p = 0.415). The Post PAR scores were comparable between groups (p = 0.776). The reduction in PAR scores from pre-treatment to post-treatment was slightly greater in the 3-day wear group (median: 9.0, IQR: 5.0–14.5) compared to

the 7-day wear group (median: 6.0, IQR: 5.0–10.5), but this difference was not statistically significant ($p = 0.424$).

Table 4-3 and Figure 4-3 presents the pre-treatment, post-treatment, and difference in Little’s Irregularity Index scores between the two groups. At baseline, there was no significant difference in initial irregularity between the 3-day wear group (median: 5.1 mm, IQR: 4.5–7.2) and the 7-day wear group (median: 5.0 mm, IQR: 4.3–5.7) ($p = 0.323$). After the first series of aligners, both groups demonstrated substantial improvement; however, the 3-day wear group exhibited slightly higher post-treatment irregularity (median: 0.0 mm, IQR: 0.0–1.7) compared to the 7-day wear group (median: 0.0 mm, IQR: 0.0–0.0), with a statistically significant difference between the groups ($p = 0.035$). The overall reduction in Little’s Irregularity Index from pre-treatment to post-treatment was similar in both groups, with no statistically significant difference ($p = 0.872$).

Deviation and Accuracy of Tooth Movement

Tables 4-4 present the linear deviations in tooth movement between predicted and achieved outcomes for teeth No. 31, 32, 41, and 42 in both the 3-day and 7-day aligner wear groups.

For the overall deviation (DEV) the median deviation was comparable between the two groups for all four teeth, with no statistically significant differences. For Tooth No. 31, the median deviation was 0.4 mm in both groups ($p = 0.729$). For Tooth No. 32, the deviation was slightly higher in the 3-day wear group (0.5 mm) compared to the 7-day wear group (0.4 mm), but this difference was not significant ($p > 0.999$). Similar patterns were observed for Tooth No. 41 ($p = 0.840$) and Tooth No. 42 ($p = 0.751$).

The median deviation in the X-axis (BL) was generally small, with values ranging from -0.2 mm to 0.0 mm across both groups. None of the teeth exhibited significant differences between groups (p -values ranging from 0.146 to 0.954).

Deviation along the Y-axis (OG) showed minor variation, with median values close to 0.0 mm in both groups. Tooth No. 31 had a slightly higher median deviation in the 3-day wear group (0.2 mm) compared to the 7-day wear group (0.0 mm), but the difference was not statistically significant ($p = 0.070$). Similar trends were observed for the other teeth.

Deviation along the Z-axis (MD) remained minimal across both groups, with no significant differences (p -values ranging from 0.414 to 0.815).

Table 4-1. Patient characteristics stratified by group

	N	3-day wear N = 20 ¹	7-day wear N = 20 ¹	p-value ²
Age (y)	40			0.270
Median (IQR)		24.0 (23.0, 26.3)	26.0 (23.8, 27.3)	
Mean (SD)		24.6 (2.7)	25.6 (2.8)	
Gender (F/M)	40			>0.999
F		15 (75.0%)	14 (70.0%)	
M		5 (25.0%)	6 (30.0%)	
DI score	40			0.848
Median (IQR)		4.0 (4.0, 7.3)	5.0 (2.8, 6.8)	
Mean (SD)		5.9 (3.9)	5.8 (4.1)	
No. of Aligners First Stage - Maxilla	40			<0.001

Median (IQR)		30.5 (25.0, 36.5)	14.0 (12.0, 19.3)	
Mean (SD)		32.9 (11.0)	15.6 (4.8)	
No. of Aligners first stage - Mandible	40			<0.001
Median (IQR)		30.5 (25.0, 36.5)	14.0 (13.0, 19.3)	
Mean (SD)		31.9 (9.3)	16.0 (4.4)	
Amount of IPR (mm)	40			0.109
Median (IQR)		1.2 (1.0, 1.5)	1.0 (0.0, 1.2)	
Mean (SD)		1.2 (0.6)	0.8 (0.8)	
Refinement (Y/N)	40			0.041
N		10 (50.0%)	17 (85.0%)	
Y		10 (50.0%)	3 (15.0%)	

Table 4-1. Continued

	N	3-day wear N = 20 ¹	7-day wear N = 20 ¹	p-value ²
No. of Visits-Overall	35			0.100
Median (IQR)		4.0 (3.0, 5.0)	3.0 (3.0, 3.5)	
Mean (SD)		4.2 (1.3)	3.5 (1.1)	
No. of Visits-Emergency	39			0.257
0		13 (68.4%)	18 (90.0%)	
1		3 (15.8%)	2 (10.0%)	
2		2 (10.5%)	0 (0.0%)	
3		1 (5.3%)	0 (0.0%)	
No. of Visits-Lower Incisor Alignment	36			0.038
Median (IQR)		4.0 (4.0, 5.0)	3.0 (3.0, 4.0)	
Mean (SD)		4.3 (0.9)	3.6 (1.2)	
1st Series completion (d)	38			0.349
Median (IQR)		105.0 (91.0, 150.5)	119.0 (98.0, 154.5)	
Mean (SD)		121.9 (43.9)	145.8 (87.8)	
Lower Incisor Alignment (d)	36			0.703
Median (IQR)		126.0 (98.0, 189.0)	140.0 (101.5, 178.0)	
Mean (SD)		143.5 (57.9)	159.2 (88.8)	
Overall Treatment Time (d)	35			0.584
Median (IQR)		171.5 (113.8, 199.5)	140.0 (101.5, 185.5)	
Mean (SD)		164.7 (65.9)	166.9 (98.1)	

¹n (%) ²Wilcoxon rank-sum test; Fisher's exact test

Treatment Time

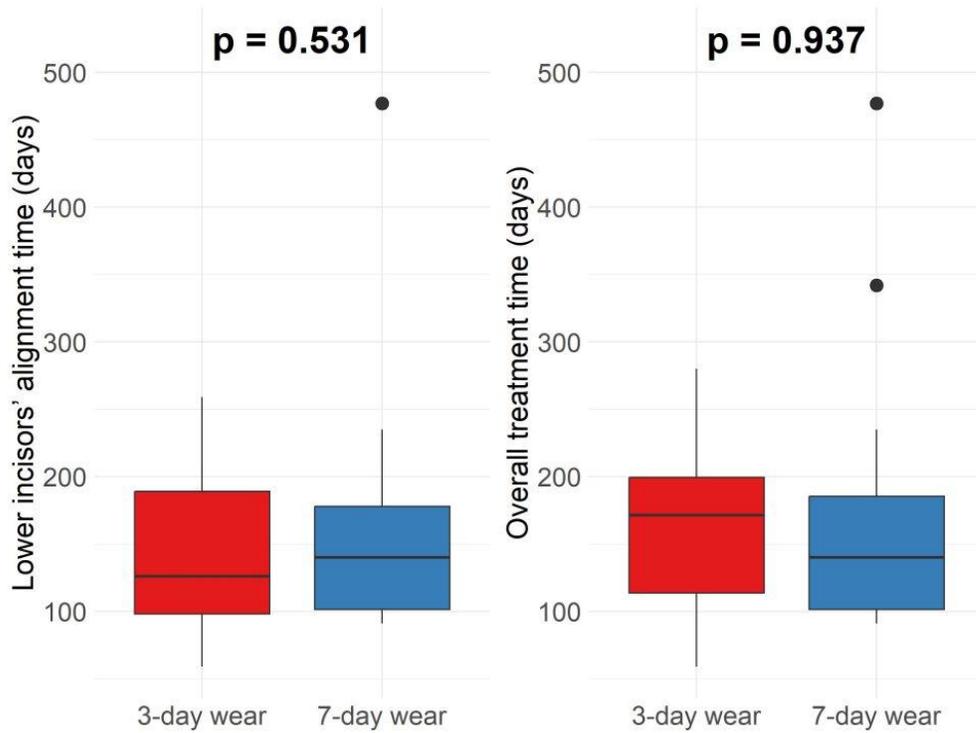


Figure 4-1. Treatment Time Box Plot

Table 4-2. Peer Assessment Rating (PAR) scores

	N	3-day wear N = 20	7-day wear N = 20	p-value ¹
PAR Pre	40			0.158
Median (IQR)		11.5 (6.0, 14.5)	8.0 (5.8, 12.0)	
Mean (SD)		11.8 (6.4)	8.7 (3.5)	
PAR after 1st series	37			0.415
Median (IQR)		1.5 (0.3, 3.5)	1.0 (0.0, 2.0)	
Mean (SD)		2.1 (2.1)	1.5 (1.9)	
PAR Post	35			0.776
Median (IQR)		1.0 (0.0, 2.0)	0.0 (0.0, 2.0)	
Mean (SD)		1.3 (1.7)	0.9 (1.1)	
PAR Pre - 1st series difference	37			0.265
Median (IQR)		9.5 (5.0, 13.5)	6.0 (5.0, 10.0)	
Mean (SD)		9.9 (6.4)	7.2 (3.9)	
PAR Pre – PAR Post difference	35			0.424
Median (IQR)		9.0 (5.0, 14.5)	6.0 (5.0, 10.5)	
Mean (SD)		10.4 (7.2)	7.8 (3.6)	

¹Wilcoxon rank-sum test

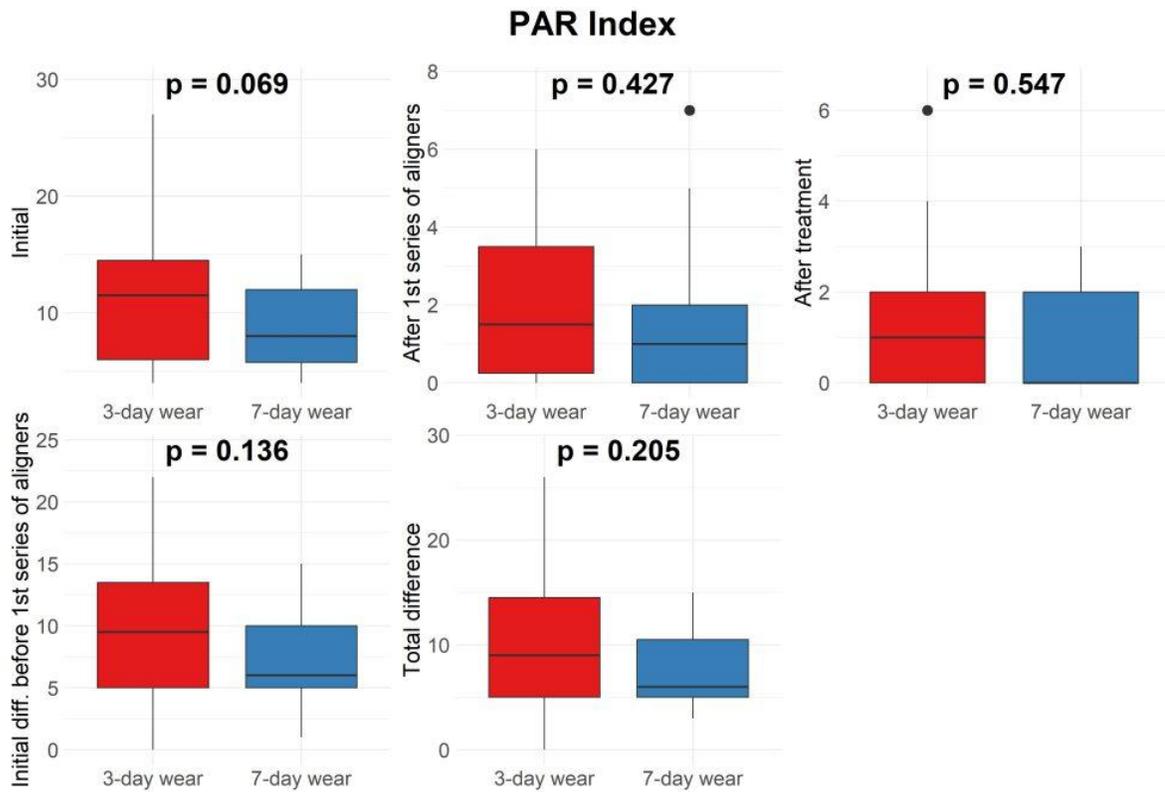


Figure 4-2. PAR Index Box Plot

Table 4-3. Littles Irregularity Index

	N	3-day wear N = 20	7-day wear N = 20	p-value ¹
Irregularity Pre-Treatment (mm)	40			0.323
Median (IQR)		5.1 (4.5, 7.2)	5.0 (4.3, 5.7)	
Mean (SD)		5.9 (1.9)	5.2 (1.3)	
Irregularity after 1 st series (mm)	38			0.035
Median (IQR)		0.0 (0.0, 1.7)	0.0 (0.0, 0.0)	
Mean (SD)		0.9 (1.2)	0.2 (0.7)	
Irregularity Pre-treatment -1 st series difference	38			0.872
Median (IQR)		5.0 (4.0, 6.2)	4.7 (4.0, 5.8)	
Mean (SD)		5.1 (1.8)	5.0 (1.6)	

¹Wilcoxon rank-sum test

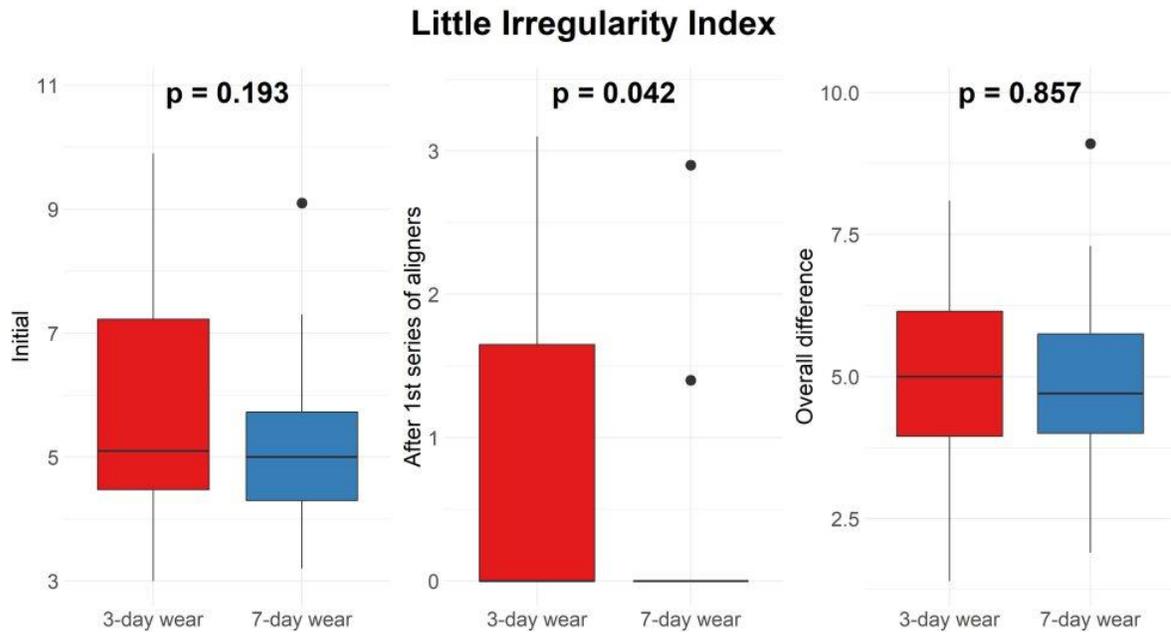


Figure 4-3. Little's Irregularity Index

Table 4-4. Linear deviations between predicted and achieved outcomes

Tooth	Variable	3-Day Wear (n=19)	7-Day Wear (n=19)	p-value ¹
31	DEV (mm)	0.4 (0.3, 0.5)	0.4 (0.2, 0.6)	0.729
31	DEV.BL (mm)	-0.2 (-0.4, 0.0)	-0.1 (-0.1, 0.0)	0.146
31	DEV.OG (mm)	0.2 (0.0, 0.3)	0.0 (-0.2, 0.2)	0.070
31	DEV.MD (mm)	0.0 (-0.1, 0.1)	0.1 (0.0, 0.2)	0.414
32	DEV (mm)	0.5 (0.3, 0.6)	0.4 (0.2, 0.5)	>0.999
32	DEV.BL (mm)	-0.1 (-0.3, 0.2)	-0.1 (-0.2, 0.1)	0.884
32	DEV.OG (mm)	0.0 (-0.1, 0.3)	0.1 (-0.2, 0.3)	0.651
32	DEV.MD (mm)	0.0 (-0.1, 0.2)	0.0 (-0.2, 0.1)	>0.999
41	DEV (mm)	0.4 (0.3, 0.5)	0.4 (0.3, 0.5)	0.840
41	DEV.BL (mm)	-0.1 (-0.4, 0.1)	-0.1 (-0.2, 0.0)	0.726
41	DEV.OG (mm)	0.0 (-0.1, 0.3)	-0.1 (-0.1, 0.3)	0.525
41	DEV.MD (mm)	0.0 (0.0, 0.2)	0.1 (-0.1, 0.2)	0.815
42	DEV (mm)	0.5 (0.3, 0.6)	0.5 (0.3, 0.8)	0.751
42	DEV.BL (mm)	-0.1 (-0.3, 0.0)	-0.2 (-0.3, 0.0)	0.954
42	DEV.OG (mm)	0.0 (-0.1, 0.2)	0.0 (-0.2, 0.3)	0.751
42	DEV.MD (mm)	0.1 (-0.2, 0.2)	0.0 (-0.2, 0.2)	0.729

¹Wilcoxon rank-sum test

Chapter 5 DISCUSSION

Baseline Characteristics

The even distribution of age and gender in this study indicates that the groups were well-matched for this randomized controlled trial⁴⁹. The higher proportion of female participants aligns with existing literature, which suggests that females are more likely to seek orthodontic treatment than males⁵⁰.

The increased number of aligners required in the 3-day wear group resulted from the reduced activation per aligner (0.11 mm/aligner). With each aligner delivering less movement per stage, additional aligners were needed to compensate for the reduced activation and achieve the desired correction. Previous studies have suggested that lower activation per aligner, paired with an increased number of aligners, may help maintain a more consistent force over time, counteracting stress relaxation in thermoplastic materials¹². This illustrated whether the magnitude of force or its consistency plays a more critical role in achieving effective tooth movement with clear aligners.

Accuracy Outcomes

The deviation between predicted and achieved movement was similar, with no statistically significant differences in overall discrepancies.

For all four lower incisors assessed (teeth 31, 32, 41, 42), the total deviation, representing the combined difference across all three linear dimensions (buccal-lingual, occlusal-lingival, and mesial-distal), ranged from 0.4 mm to 0.5 mm in both groups. This places the observed discrepancies at or just below the 0.5 mm threshold considered clinically significant by the American Board of Orthodontics (ABO) Model Grading System⁴⁷. When examining individual movements along the three axes buccal-lingual (X) translation showed small deviations, typically within 0.2 mm for both groups. Occlusal-lingival (Y) translation ranged from 0.0 to 0.2 mm, indicating excellent vertical control. mesial-distal (Z) translation was particularly accurate, with deviations of 0.0 to 0.1 mm, reinforcing that lower anterior alignment was achieved with minimal mesial-distal tipping required.

This is similar to the findings of Al-Nadawi et al. (2021)⁹, who found that linear discrepancies between predicted and achieved outcomes were small and largely clinically insignificant across different wear protocols. Zhao et al. (2023)²⁵ similarly found no significant differences in the accuracy of predicted versus achieved tooth positions when comparing 10-day and 14-day wear schedules, further supporting the idea that shorter wear protocols do not compromise accuracy.

Both Al-Nadawi et al. (2021) and Zhao et al. (2023) highlighted that angular discrepancies (tip, torque, and rotation) were more difficult to control, regardless of wear protocol. Future analysis will incorporate angular variables once the most accurate measurement method is determined. At present, we are collaborating with Geomagic engineers to refine our approach, as initial attempts produced inconsistent and unreliable angular data. Until this issue is resolved, angular analysis remains ongoing.

Clinical Outcomes Between Groups

Despite differences in aligner wear protocols, the overall clinical outcomes were comparable between the 3-day and 7-day wear groups. Both protocols effectively reduced incisor irregularity, though the 7-day wear group exhibited better alignment following the first aligner series as shown by the Littles Irregularity Index⁴⁶. After the first aligner series, the 3-day group had a mean Little's score of 0.9mm, while the 7-day group

achieved a statistically significantly lower score of 0.2mm ($p = 0.035$), indicating better initial alignment in the 7-day group.

The PAR Index was also evaluated to assess overall occlusal improvement. Pre-treatment PAR scores were slightly higher in the 3-day group (11.8 ± 6.4) than in the 7-day group (8.7 ± 3.5), though the difference was not statistically significant ($p = 0.158$). After the first aligner series, both groups showed marked improvement, with mean post-treatment PAR scores of 1.3 ± 1.7 for the 3-day group and 0.9 ± 1.1 for the 7-day group ($p = 0.776$). The reduction in PAR score from baseline to post-treatment represented a mean improvement of 10.4 points for the 3-day and 7.8 points for the 7-day group, both of which exceeded the 30% reduction threshold considered clinically significant.

The reduction in PAR score from pre-treatment to after the first series of aligners offers insight into the effectiveness of each wear protocol in resolving malocclusion. The 3-day group achieved a mean PAR reduction of 9.9 ± 6.4 points, compared to 7.2 ± 3.9 points in the 7-day group, a difference that was not statistically significant ($p = 0.265$).

This finding aligns with the results of Yu et al. (2025), who evaluated occlusal outcomes across different aligner wear schedules (7-day, 10-day, and 14-day). Like this study, Yu et al. (2025) found no significant differences in overall treatment quality across wear schedules after the initial aligner series. This reinforces the concept that shorter wear schedules can be effective for most tooth movements while maintaining efficiency⁴⁰. Also, consistent with the findings of Yu et al. (2025), the 3-day wear group required significantly more refinement on average than the 7-day group. In the present study, the 3-day group required one refinement each in 10 cases (50.0%), compared to 3 cases (15.0%) in the 7-day group ($p = 0.041$).

Despite the need for more refinements in the 3-day group, both protocols were successful in achieving clinically significant occlusal improvement as defined by the PAR Index. These findings support that accelerated wear schedules can produce effective clinical outcomes when paired with refinements to manage any inaccuracies introduced by more frequent aligner changes.

Biomechanical Considerations

A key biomechanical consideration is that reducing activation per aligner and increasing the frequency of aligner changes may alter the force system applied to teeth. A lower force per stage with frequent aligner changes might not allow sufficient time for bone remodeling. OTM is an acute inflammatory response involving bone and periodontal ligament (PDL) remodeling. The applied force triggers a biological response commonly described as frontal aseptic inflammation⁵¹. Moving mineralized tissue through the bone requires both modeling (sculpting) and remodeling (maintenance and turnover)⁵²

On the other hand, tooth movement requires an optimal force range depending on the type of movement. Forces of 35-60 g are typically recommended for tipping and rotation, 70-120 g for bodily translation, 50-100 g for root torque, 15-50 g for extrusion, and 10-20 g for intrusion⁵³⁻⁵⁵. The duration and nature of force application also influence efficiency. Continuous forces, such as those from fixed appliances, yield more predictable movement compared to intermittent forces, as seen in clear aligner therapy^{56,57}. When forces are intermittent, greater magnitudes may be needed to facilitate movement. Excessive forces (>300 g) can also cause adverse effects such as root resorption, pain, and periodontal ligament hyalinization, which may slow down rather than enhance movement⁵⁸.

The forces exerted by thermoplastic aligners depend on activation amount, material composition, thickness, and the thermoforming process.^{59,60} Lombardo et al. have

demonstrated that most tooth movement occurs within the first 24 hours of aligner wear³⁵. The mechanical properties of aligner materials, such as hardness and elastic modulus, strongly correlate with the forces they generate⁶¹. A potential explanation for the reduced efficacy observed in the 3-day wear protocol and the greater need for refinements and emergency appointments is that frequent aligner changes may have interrupted the bone remodeling process, failing to maintain a force threshold required for tooth movement. Tooth morphology and aligner mechanics also influence force transmission. Previous studies have shown that aligner force delivery varies based on tooth size, shape, and arch curvature, with canines experiencing the highest forces⁶²⁻⁶⁵. Since our study focused on lower incisors, the forces applied may have been dissipated when lighter forces were used, reducing their effectiveness.

In summary, the biomechanics of aligner therapy involve multiple variables, including aligner-tooth contact mechanics, material properties, activation levels, and auxiliary components. Literature suggests that increasing activation from 0.2 mm to 0.6 mm enhances force delivery,⁶⁶ and that thicker aligners generate greater force⁶⁷. On the other hand, aligner materials, such as polyurethane-based Exceed 30®, are commonly used due to their mechanical properties, including stress relaxation resistance and elasticity. Since Invisalign aligners are also polyurethane based, reducing activation per aligner may have altered the force delivery characteristics of this material^{68,69}. The above factors should all be taken into consideration when planning tooth movement with aligners.

Force Magnitude vs. Force Continuity

A key question remains: does 0.2 mm activation generate sufficient force to reach the biological threshold for tooth movement, or is force decay over time more critical? Our findings suggest that higher initial force application is more effective than lower, continuous force delivery with increased frequency of aligner changes (3-day wear). Effective tooth movement relies on activating cellular responses within the PDL and alveolar bone, requiring force to reach a threshold level to induce osteoclastic and osteoblastic activity. If the force applied with minimal activation is insufficient, it may not trigger the necessary biological responses, similar to the case observed in the 3-day protocol. Ackerman et al., in their classical study, established that a minimum threshold force ranging from 33 to 548 g/cm² is required to initiate tooth movement and induce resorption. They also found that the extent of resorption is significantly influenced by the duration of the applied force⁷⁰. Therefore, while traditional biomechanics favor continuous force for effective movement, our results suggest that the magnitude of the initial force plays a more critical role than its continuity, especially in clear aligner therapy.

Limitations

A limitation of this study is the reliance on digital superimposition method, which lacks stable anatomic structures. The superimpositions were performed using only clinical crowns and virtual gingiva, meaning all tooth movements were measured relative to the molars, which could introduce minor inaccuracies. Additionally, the presence of attachments, IPR, and variations in technique during these procedures may have influenced the predictability of tooth movement. This study also relied on the clinical decisions of two providers, which may limit external validity. Another limitation is the lack of objective compliance tracking. Although the treating orthodontists could be blinded to initial allocation, blinding was not feasible during treatment itself due to the nature of the treatment flow, including the need to review and approve ClinCheck®

plans. Finally, the study focused on relatively simple cases. Results can vary with more complex cases. This should be considered an initial or pilot study.

CHAPtER 6 CONCLUSION

The clinical outcomes between the two wear protocols were comparable, indicating that both approaches effectively reduced tooth irregularity and malocclusion. However, the 3-day wear protocol posed challenges, particularly in maintaining a consistent force threshold necessary for optimal tooth movement. This study questions the conventional emphasis on continuous force application, suggesting that the magnitude of the initial force is more critical for effective OTM than the duration of force application, provided that the force threshold is met. While continuous force may support sustained movement, achieving a biologically effective force threshold is essential for initiating cellular and tissue remodeling. Future research should focus on determining the precise force required to exceed this threshold and assessing its impact on long-term orthodontic outcomes with clear aligner.

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