Optimizing Aligner Wear Time and Change Frequency: A Single-Blind, Randomized Control Trial

2021 Grants

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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*

Optimizing Aligner Wear Time and Change Frequency: A Single-Blind, Randomized Control Trial

Award Type

Biomedical Research Award (BRA)

Period of AAOF Support

July 1, 2021 through June 30, 2023

Institution

Harvard College

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

Desiree Hsiou, Benjamin Smith, Sunnie Kuna, Mohamed Masoud

Amount of Funding

$3,220.00

Abstract

(add specific directions for each type here)

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 .pdf
INTRODUCTION AND LITERATURE REVIEW
The rising popularity of clear aligners among adults, who prefer them over conventional fixed appliances for their esthetics, has been well-documented. Studies show that adults are willing to pay more for aligners, which not only offer cosmetic benefits but also result in less discomfort and pain compared to fixed appliances. Additionally, patients report greater satisfaction with eating and chewing when using aligners. Despite their effectiveness, clear aligners often fail to produce the exact tooth movements simulated by treatment software, leading to a need for refinement trays. This discrepancy is attributed to incomplete seating of the aligners, premature switching to the next set of aligners, or insufficient daily wear time. These issues can result in additional financial and time commitments for both patients and providers.
DentalMonitoring (DM) has emerged as a leading AI-based solution for remotely monitoring orthodontic treatment. DM offers benefits such as improved patient compliance, early detection of issues, and reduced emergency visits. It has been shown to increase the frequency of patient evaluations while reducing the number of appointments and chair time.
This study will explore variations in aligner change frequencies as determined by DM and will compare the effects of wearing aligners for 22 hours a day (Standard Aligner Protocol) versus 12 hours a day (Part-Time Aligner Protocol).
Specific objectives or hypotheses
The primary aim of this study was to evaluate whether scanning every 4 days with DM leads to more personalized progress through a series of 10 Invisalign treatment aligners, as opposed to systematic aligner changes every 7, 10, or 14 days. Our null hypothesis was that patients monitored with DM will progress through Invisalign aligners at the same pace as with a clinician's standardized aligner change frequency of 7, 10, or 14 days.
Another aim of this study was to determine the effect of full-time (22-hour a day) versus half-time (12-hour a day) wear on treatment duration. Our null hypothesis was that full-time aligner wear will result in the same amount of time needed to complete 10 trays as half-time wear.

METHODS
This study was a single center, two-arm parallel-group randomized, controlled, single-blind clinical trial with a 1:1allocation ratio approved by the Institutional Review Board of XXXXX (IRB19-0644) and conducted following patients at the XXXXX Orthodontics Clinics. No changes were made to the study methodology upon commencement of the trial.
Participants, eligibility criteria, and settings
Patients were selected according to the following inclusion criteria: aged 18-65 years old, healthy periodontal condition, currently undergoing Invisalign treatment with at least 10 trays remaining, owns a smartphone that can download and store the DM application, and capable of mastering the use of the DM application and performing intraoral scans. Exclusion criteria included the following: active antibiotic use, active caries or periodontal disease, history of medications or systemic diseases that could affect bone remodeling, active smoking, temporomandibular disease, temporary anchorage devices, and ClinCheck (Align Technology) plans in which the provider dictates the number of treatment trays. Patient enrollment was not limited by specific types of tooth movement or stage of treatment.Interventions
Participants were randomly assigned to 1 and the 2 treatment groups based on daily wear time.
1. Group 1: 22-hour tray wear time
2 Group 2: 12-hour tray wear time

Patients received a $25 Starbucks gift card for enrolling in the study and a Propel electric toothbrush for completing the 10-tray series. Subjects downloaded the DentalMonitoring application onto their smartphones and were added to the DentalMonitoring website under a pseudonym; the only personal data that was used on the website was a working personal email address that was required for activation of the app. Study investigators also documented patients' ages and races. Patients signed two informed consent forms: the XXXXX Institutional Review Board (XXXXX IRB) Informed Consent and the informed consent provided by the DentalMonitoring application. Patients were informed of which group they were assigned to and instructed to follow the designated wear time protocol. Patients in all groups were instructed to use Chewies for 5-10 minutes every day. All patients were instructed to follow aligner change instructions from DentalMonitoring for 10 trays.

The first scan was completed chairside at the initial enrollment appointment to ensure that the patient knew how to take scans using the Cheek Retractor Tube (DM) and ScanBox (DM) and submit scans on the DentalMonitoring app. Scans were taken of both the teeth alone and the teeth with the trays in. Patients submitted scans every 4 days, and the DM software analyzed the scans and sent a notification to the doctor on the website indicating "Satisfactory Aligner Tracking," "Slight Unseat," or "Noticeable Unseat." In the former case, patients received a "GO" and progressed to the next set of aligners. In the latter two cases, patients received a "NO-GO" and stayed on the current tray for 3 more days (7 days total) before scanning again. If the patient continued to receive "NO-GO's," the patients stayed on the same tray and rescanned every 3 days (10 days total, 13 days total, and so on) until they received a "GO." XXXXX also reviewed DM scans and decisions and were able to answer questions from the patient through the website and app. The DentalMonitoring workflow is demonstrated in Figure 1.

Fig 1. DentalMonitoring Workflow

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcomes were the total treatment time and the average time per tray. Total treatment time was measured as the number of days between a "GO" on tray 1 to a "GO" on tray 10. Since this is actually a treatment duration of 9 trays rather than 10, the average time per tray was calculated as the total treatment time divided by 9. No changes to the measured outcomes were made after trial commencement.

Sample size calculation

An a priori power analysis was completed to determine the number of subjects per group using the following variables: mean of 10 days per aligner tray change, standard deviation of 3 days per aligner change, effect size of 3 days per aligner change, power of 0.9, and significance level of 0.05. The mean estimate of 10 days per aligner tray change was selected because 10 days is the median of the standard protocols of 7, 10, and 14 days. The standard deviation estimate of 3 days per aligner change was selected because one standard deviation from 10 days in either direction approximates the other two standard protocols. Similarly, the effect size estimate of 3 days per aligner change was selected because 3 days fewer than the mean estimate of 10 days would result in an aligner change frequency of 7 days per tray.

Statistical analysis

All statistical analyses were performed with statistical programming software R (version 4.2.2; R Core Team 2022). The data in each group were tested for normality using the Shapiro-Wilk test, after which it was determined that nonparametric tests should be used. The data were right-skewed due to an unexpectedly high portion of the patients progressing at the maximum speed of 4 days per aligner change. We did not have reason to suspect that the data would be non-normally distributed when the a priori sample size calculation was completed, so the sample size calculation was done assuming normality while the final statistical analysis was done using nonparametric tests. One-sample Wilcoxon rank sum tests were used to compare each group with the standardized clinician protocol of 7-14 days per tray. Intergroup comparison was performed using two-sample Wilcoxon rank sum tests. A significance level of 0.05 was used.

RESULTS

Of the 120 Invisalign patients in the university orthodontic clinics who were assessed for eligibility from November 2020 to April 2023, 80 met the selection criteria. A total of 76 patients agreed to participate and were randomized using the Random function in Excel (Microsoft Office 2019, Seattle, WA) with a 1:1 allocation ratio into two groups. Altogether, 48 patients completed the study, calculating to an attrition rate of 37% .

Baseline data

Table I shows the baseline demographics and outcomes summary for each group. The groups were similar in age, sex, and race composition.

Table I. Patient Characteristics
The total treatment time as well as the average number of days per aligner change are summarized for each group in Table I. The results of the one-sample Wilcoxon tests and the standardized clinician protocols are summarized in Table II. The average number of days per aligner change for Groups are all significantly lower ($p < 0.01$) than 7, 10, or 14 days. Note that since the total treatment time is a treatment duration of 9 trays rather than 10, total treatment times for standardized clinician protocols of 7, 10, and 14 days would be 63, 90, and 126 days, respectively. The total treatment durations for Groups 1-4 are all significantly lower ($p < 0.01$) than 63, 90, or 126 days.
Full-time group had significantly faster ($p = 0.0007$) aligner changes than half-time group.
CONCLUSIONS
-Clear aligner protocols should be individualized for each patient and each set of aligners.
-Patients scanning every 4 days with DM progressed through Invisalign aligners more quickly than a clinician's standardized aligner change frequency of 7, 10, or 14 days.
-Full-time aligner wear resulted in less time needed to complete 10 trays compared to half-time wear.
-DM can serve as a valuable treatment adjunct, improving the efficiency and individualization of clear aligner therapy, by supplementing, not supplanting, in-person appointments

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

Yes, the original specific aims of the proposal were successfully realized. The study aimed to evaluate the ability of DentalMonitoring (DM) to personalize patient treatment schedules and determine the effects of full-time versus half-time wear on treatment duration.

The study was conducted with clear aligner patients randomized into four groups based on their aligner wear time. The results showed that all groups progressed through aligners more efficiently than the standard protocols. Additionally, full-time wear groups showed significantly greater efficiency compared to half-time wear groups.

This indicates that the study not only met its initial goals but also provided valuable insights into the efficiency and individualization of clear aligner therapy. The findings support the use of DM as an effective tool to enhance treatment efficiency and tailor treatment plans for individual patients.

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?*

I am deeply grateful for the AAOF funding, which has been instrumental in advancing my career in orthodontics. With this support, I have been able to contribute to research that pushes the boundaries of our understanding and application of orthodontic treatments. Specifically, I have used the funding to further my work in AI applications and their use in our specialty, which has not only broadened my knowledge but also allowed me to contribute to the collective body of research in our field.

Looking ahead, I intend to leverage the insights and skills gained through AAOF-supported projects to continue my research and clinical practice with a strong focus on innovation. My goal is to translate research findings into improved patient outcomes, and to mentor future professionals in the field, inspiring them to pursue excellence in orthodontics.

AAOF funding has been, and will continue to be, a pivotal resource in my journey to become a leader in orthodontic research and practice, enabling me to contribute meaningfully to our field and to the patients we serve.

Comment: *The AAOF PARC commends you on your completed project and encourages you to continue toward publication. We are excited for promising scholars like you who will help expand our knowledge base of academic orthodontics and excellence.*

Accounting: Were there any leftover funds?

$0.00

Not Published

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

Yes, absolutely. There are plans to publish the findings. Given the results and contributions of the study to the field of orthodontics, particularly in the use of DentalMonitoring for personalized treatment schedules, we believe that sharing these insights with the broader academic and professional community is essential.

Presented

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

1. AI Driven Remote Monitoring Applications in Combination with Clear Aligner Therapy/ Negin Katebi/ 2024/ AAO annual meeting- New Orleans
2. Individualizing Aligner Change Schedule: A Single-Blind, Randomized Controlled Trial/ Grace Huang DMD, Zhu Shen MS, Stephanie Yang, Sunnie Kuna DMD, MMSc, Benjamin Smith DMD, MMSc, ScM, Desiree Hsiou

DDS, PharmD, MMSc, Mohamed Masoud BDS, DMSc, Negin Katebi DDS, DMSc/ 2024/ Poster presentation during the AAO annual meeting- New Orleans
3. Individualizing Aligner Change Schedule: A Single-Blind, Randomized Controlled Trial/ Grace Huang DMD, Zhu Shen MS, Stephanie Yang, Sunnie Kuna DMD, MMSc, Benjamin Smith DMD, MMSc, ScM, Desiree Hsiou DDS, PharmD, MMSc, Mohamed Masoud BDS, DMSc, Negin Katebi DDS, DMSc/ April 2024/ Research Day Poster presentation at Harvard School of Dental Medicine/ Boston, MA

Was AAOF support acknowledged?

If so, please describe:

Yes, of course. The AAOF support was acknowledged. The manuscript includes a formal acknowledgment section where the support provided by the American Association of Orthodontists Foundation (AAOF) is explicitly recognized. This acknowledgment highlights the financial assistance or resources provided by AAOF that contributed to the research and development of the study. Moreover, the AAOF was acknowledged both during the actual presentation at the AAO annual meeting and was included in both posters for poster presentations.

Internal Review

Reviewer Comments

Reviewer Status*

Approved

File Attachment Summary

Applicant File Uploads

- AAOF .pdf

ABSTRACT

Introduction: Presently, patients' aligner change frequency and wear time are primarily determined by the clinician's judgment rather than by literature comparing distinct protocols. The aim of this study is to evaluate DentalMonitoring (DM) (Dental Mind, Paris, France)'s ability to personalize patients' treatment schedules.

Methods: Clear aligner patients at the XXXXX Orthodontics Clinics were randomized into 2 groups: Group 1 (full-time wear), Group 2 (half-time wear). All groups submitted intraoral scans to DM every 4 days and followed DM's aligner change instructions for 10 trays. Treatment durations of each group were compared with standard protocols of 7-14 days/tray and between groups by a statistician blinded to the group descriptions.

Results: Of the 76 patients enrolled, 48 patients (24 per group) completed the study. All groups progressed through aligners more efficiently (4.315-5.370 days/tray) than standard protocols of 7-14 days/tray ($p<0.01$). Full-time groups (4.407 days/tray) progressed through aligners more efficiently ($p=0.0007$) than half-time groups (5.310 days/tray).

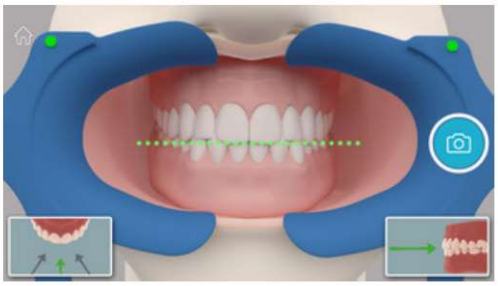
Conclusions: Clear aligner protocols should be individualized for each patient and each set of aligners. Patients scanning every 4 days with DM progressed through aligners more quickly than a standardized change frequency of 7-14 days/tray. Treatment efficiency was improved with increased daily wear time. DentalMonitoring can serve as a valuable treatment adjunct, improving the efficiency and individualization of clear aligner therapy, by supplementing, not supplanting, in-person appointments.

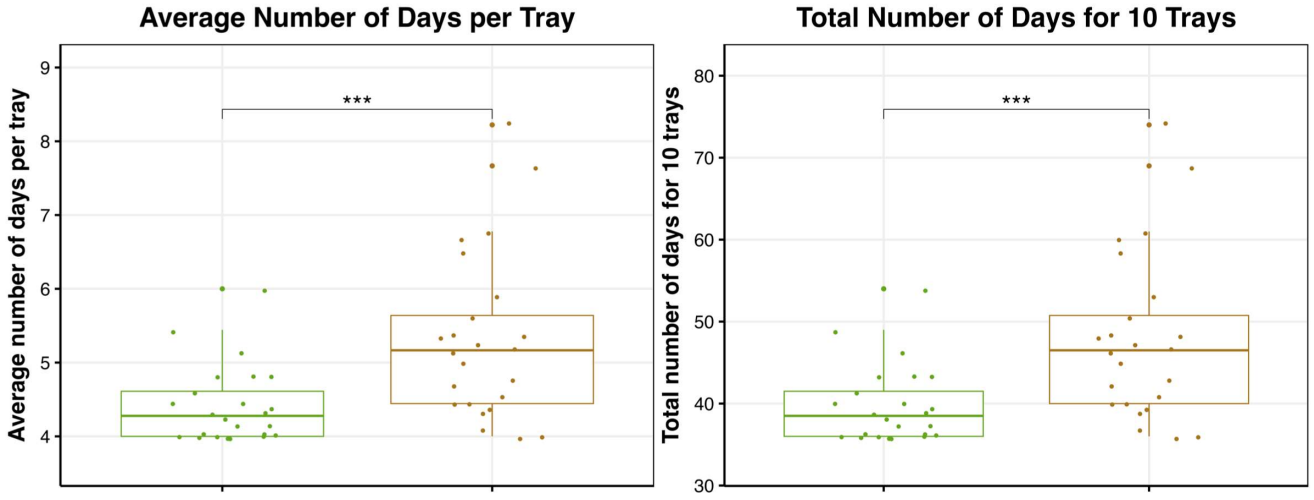
Registration: This randomized clinical trial was registered and reported at

ClinicalTrials.gov (NCT04260633).

Protocol: The protocol was not published before trial commencement.

Funding: This study was funded by an AAO Foundation Biomedical Research Award.

	
a. Patient will take an intraoral photo and video of their teeth with and without the aligners with the Cheek Retractor Tube and DentalMonitoring ScanBox on the DentalMonitoring application on their phone.	b. DentalMonitoring technicians and orthodontists will analyze the photos and videos.
	
c. DentalMonitoring technology will analyze if the trays are seated or unseated.	d. DentalMonitoring will notify the doctor portal about tray seating and the patient about whether to move on to the next tray.


Average Number of Days per Tray
Average number of days per tray
9
8
7
6
5
4
***
Total Number of Days for 10 Trays
Total number of days for 10 trays
80
70
60
50
40
30
***

	Group 1 (n = 24)	Group 2 (n = 12)
Characteristic		
Sex, No. (%)		
Male	10 (41.67)	8 (25.00)
Female	14 (58.33)	16 (75.00)
Age, median (IQR)	34.00 (27.00-41.25)	33.50 (30.75-44.25)
Race, No. (%)		
African American	1 (8.33)	1 (8.33)
Asian	5 (41.67)	8 (41.67)
Hispanic	1 (8.33)	2 (16.67)
Indian	2 (16.67)	2 (16.67)
Middle Eastern	2 (16.67)	1 (8.33)
White	13 (50.00)	10 (41.67)
Outcome		
Total number of days for 10 trays, mean (SD)	40.50 (5.81)	48.33 (11.83)
Average number of days per tray, mean (SD)	4.50 (0.65)	5.37 (1.31)

	Standardized Clinician Protocols					
	7 days per tray		10 days per tray		14 days per tray	
	Test Statistics	p value	Test Statistics	p value	Test Statistics	p value
Group 1						
Average number of days per tray	0.00	0.0000 ****	0.00	0.0000 ****	0.00	0.0000 ****
Group 2						
Average number of days per tray	10.00	0.0001 ****	0.00	0.0000 ****	0.00	0.0000 ****
Pooled Group 1 and 2						
Average number of days per tray	11.00	0.0000 ****	0.00	0.0000 ****	0.00	0.0000 ****

	Standardized Clinician Protocols					
	7 days per tray		10 days per tray		14 days per tray	
	Test Statistics	p value	Test Statistics	p value	Test Statistics	p value
Group 1						
Total number of days for 10 trays	0.00	0.0000 ****	0.00	0.0000 ****	0.00	0.0000 ****
Group 2						
Total number of days for 10 trays	10.00	0.0001 ****	0.00	0.0000 ****	0.00	0.0000 ****
Pooled Group 1 and 2						
Total number of days for 10 trays	11.00	0.0000 ****	0.00	0.0000 ****	0.00	0.0000 ****

1. Due to deviation from normality of the outcomes and limited sample size per group, one-sample Wilcoxon rank sum tests are performed to compare the two outcomes: the average number of days and the total number of days for 10 trays between four groups and the standardized clinician protocol of 7-14 days per tray. The one-sample Wilcoxon rank sum test is a non-parametric alternative to one-sample t-test, and is used to determine whether the median of the sample is equal to a known standard value.

2. In the analysis, we conduct a two-sided Wilcoxon rank sum test without applying a continuity correction. Since there are multiple tied ranks within the groups, we resort to using a normal approximation to calculate the p-values.

3. A p-value below 0.05 is marked with one star (*), below 0.01 with two stars (**), below 0.001 with three stars (***), and below 0.0001 with four stars (****).

		Outcomes			
		Average number of days per tray		Total number of days for 10 trays	
Contrast Groups		Test Statistics	p value	Test Statistics	p value
Group 1	Group 2	124.5	0.0007 ***	124.5	0.0007 ***