

Changing clear aligners every 10 days or 14 days ? A randomised controlled trial

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Objectives: To compare 10-day and 14-day change regimens to achieve orthodontic tooth movement (OTM) in patients wearing clear aligners and to determine their subsequent pain perception.

Material and methods: A total of 175 clear aligner patients were assessed for eligibility. Seventy-two patients were randomly assigned to a 10-day group ($N = 36$) and a 14-day group ($N = 36$) and were instructed to change the appliances every 10 or 14 days, respectively. OTM efficacy and OTM variation between the actual and predicted OTM digital models measured by shell-to-shell deviation, as well as pain perception determined by a visual analog scale (VAS), were assessed at T0 (baseline, before the placement of the aligners), T1 (stage 8, after completion of aligners #8), and T2 (stage 16, after completion of aligners #16).

Results: The 10-day and 14-day groups showed similar OTM efficacy at both T1 and T2 for all types of tooth movements ($p > 0.09$ for all) and similar OTM shell-to-shell deviation at T1 ($p = 0.06$) and T2 ($p = 0.22$). The two groups also had similar VAS scores of pain perception throughout the study ($p > 0.05$ for all).

Conclusion: The 10-day and 14-day groups showed similar tooth movement and pain perception, suggesting that the clear aligners may be changed every 10 days without a significant compromise in the clinical efficacy of OTM and patient comfort.

Trial registration: ChiCTR, ChiCTR-IOR-15007532. Registered 17 November 2015, <https://www.chictr.org.cn/showproj.aspx?proj=12500>

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Introduction

In comparison with traditional fixed appliances, clear aligner treatment has become increasingly popular due to its advantages related to aesthetics and comfort.¹⁻³ Patients are usually instructed to wear each clear aligner at least 22 hours a day for 7 to 14 days. With this routine wearing protocol, an average tooth movement of 0.25 mm, 2° of rotation and 1° of root torque per tooth is possible via each appliance.⁴ Several clinical studies and systematic reviews have demonstrated that a clear aligner system has its strengths and weaknesses, and the programmed orthodontic tooth movement sometimes may not be fully achieved.⁵⁻⁸

To enhance the clinical efficacy and patient experience of clear aligner treatment, Align Technology (San Jose, California, USA) has introduced several modifications involving optimised attachments, bite ramps, power ridges, SmartForce, SmartTrack material, and SmartStage technology.⁴ A recent study by Haouili et al. reported a marked improvement in the overall accuracy of clear aligners for all tooth movement, but the efficiency of tooth movement using aligners remained relatively the same.⁸ Nevertheless, patients usually desire treatment of shorter duration and with less discomfort.^{9,10} Therefore, clinicians and patients have increased the change frequency of clear aligners, for example, from 14 days to every 10 days.^{8,11} However, the clinical evidence for this shortened wear protocol is

absent. A systematic review in 2019 suggested that clear aligners have the advantage of treating segmented movement of teeth but are less effective in producing adequate occlusal contacts, controlling tooth torque and increasing transverse width than fixed appliance therapy.¹² An additional systematic review reported that clear aligners may produce clinically acceptable outcomes that could be comparable to fixed appliance therapy for the buccolingual inclination of upper and lower incisors in mild to moderate malocclusions.⁷

It is still unclear whether a 10-day or a 14-day change regimen produces the same OTM efficacy and patient comfort. Most previous studies focused on the conventional 14-day change regimen,^{13–17} although some also involved a relatively more frequent change (i.e., 1 week).^{18–20} Unfortunately, clear aligner wear did not follow a common clinical protocol in these studies because the focus was on an intervention for accelerating tooth movement (e.g., AcceleDent vibration and periodontally accelerated osteogenic orthodontics). However, several studies used a 14-day change regimen but also presented data at other time points, for example, a prospective

trial using a 14-day change regimen showed that most of the OTM was achieved in the first week and material fatigue did not impact the later rate or amount of OTM.^{21,22} These findings indirectly indicated that the clinically ‘tried’ 10-day change regimen might produce similar OTM efficacy as the routine 14-day change period.

Therefore, the aim of the present study was to compare a 10-day and 14-day change regimen to determine OTM efficacy and pain perception in patients wearing clear aligners. The null hypothesis was that the 10-day and 14-day change regimens would produce similar OTM outcomes.

Materials and methods

Study design

The study was designed as a prospective, randomised, two-arm parallel-group, controlled trial, with a 1:1 allocation (Figure 1). Permission was approved by the Ethics Committee of West China Hospital

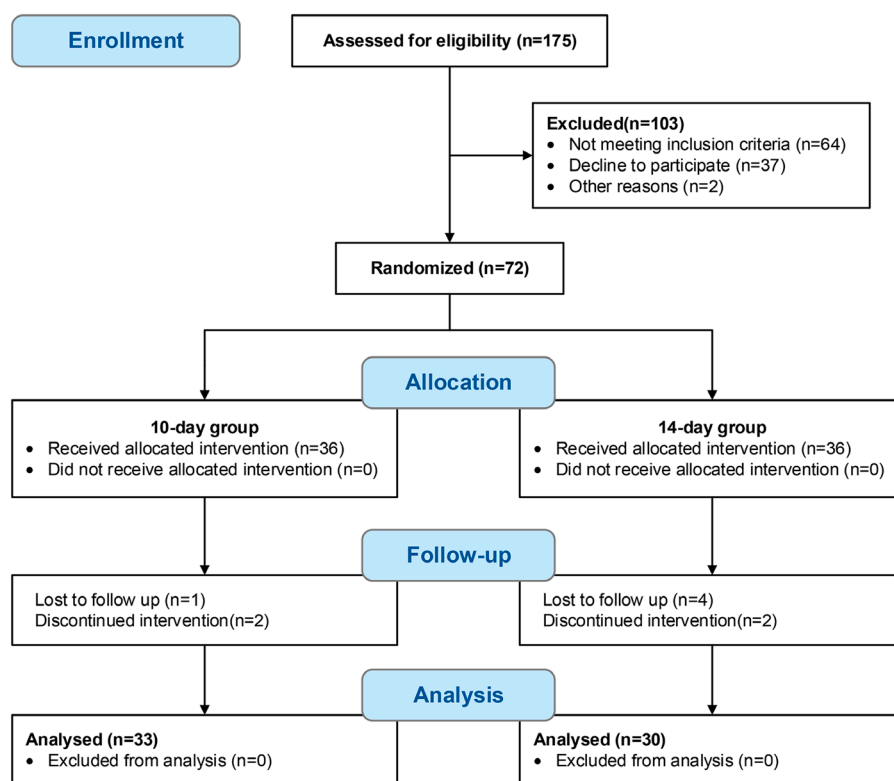


Figure 1. CONSORT flow chart showing subjects flow during the trial.

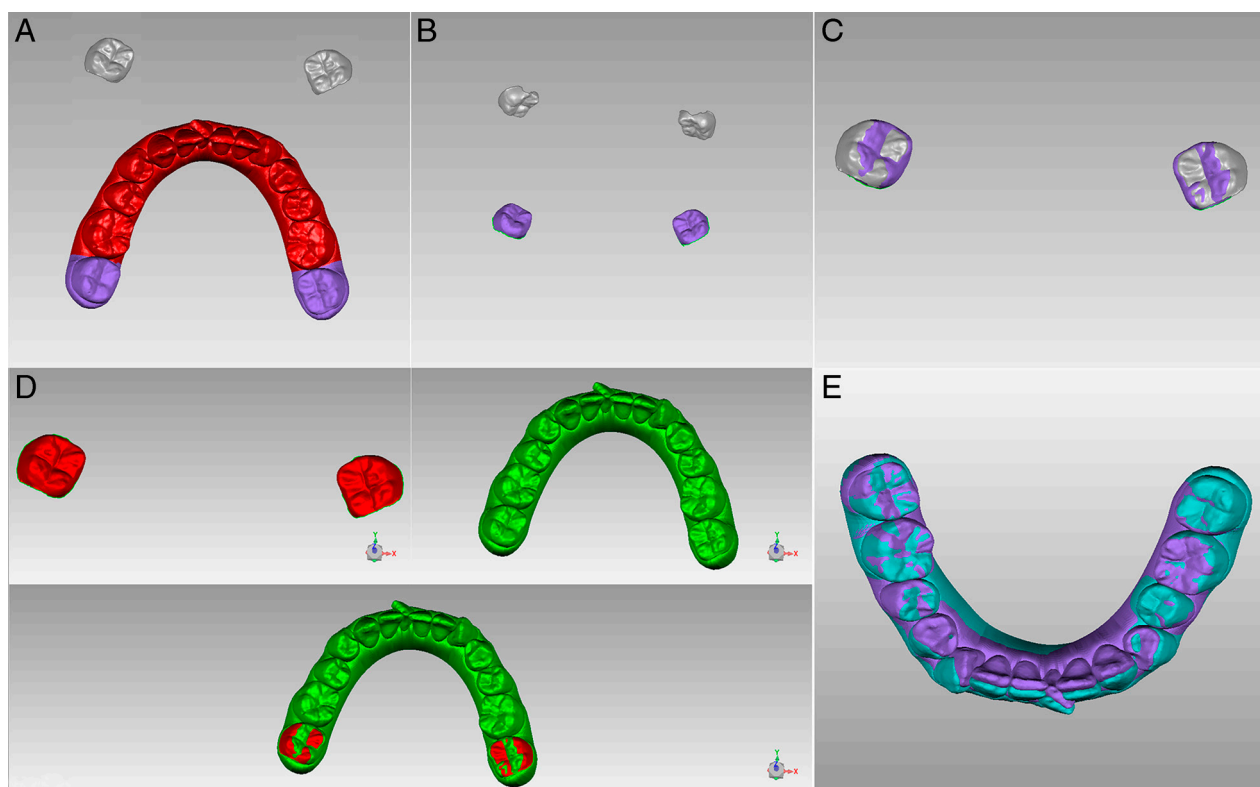


Figure 2. Superimposition of the initial models and progress models based on the stable structure method (unmoved teeth in the ClinCheck) using the GEOMAGIC studio software. (a) Teeth designed not to be moved in ClinCheck were respectively separated from initial models and progress models (grey and purple coloured the second molars); (b) and (c) Registration of the unmoved teeth (second molars); (d) and (e) Final superimposition using the unmoved teeth (second molars) as reference.

of Stomatology, Sichuan University (WCHSIRB-ST-2015-095). The study was registered at the Chinese ClinicalTrials.gov (ChiCTR-IOR-15007532) and the methodology was not changed after the trial commenced.

Participants and settings

A total of 175 adult patients who sought clear aligner treatment at the West China Hospital of Stomatology from November 2016 to July 2018 were assessed for eligibility (Figure 1). Seventy-two patients were recruited. The sample size calculation was based on the previously published literature;^{5,13} a clinically significant difference of 20% in OTM efficiency was considered; an OTM efficacy of 59% with a SD of 20% was used; the power was set at 80% and at a 95% confidence interval ($\alpha=0.05$). A minimum sample of 66 participants ($N=33$ per group) was required. A total of 72 participants ($N=36$ each) were assigned to allow for potential dropout. All of

the eligible participants were informed of the study design and submitted their written informed consent.

The inclusion criteria identified: (1) patients who required clear aligners in both arches; (2) were in the permanent dentition without congenitally missing teeth except for the third molars; (3) a willingness to participate in the trial; (4) requiring clinically significant OTM (torque $>5^\circ$, derotation $>5^\circ$, molar distalisation or mesialisation >1.5 mm, incisor retraction >1 mm, intrusion or extrusion >1 mm, posterior expansion >1 mm);⁵ (5) treatment would involve more than 16 sets of clear aligners, and with at least one tooth not moved in the ClinCheck plan during the first phase of 16 aligner sets, because the predicted and achieved OTM were superimposed using a stable tooth/teeth based on a past protocol.^{21,23} The exclusion criteria omitted patients who: (1) wore an auxiliary device, such as temporary anchorage devices, elastics, and extraoral headgears; (2) had severe periodontal disease; (3) a systemic disease, syndrome, or cleft lip and/or palate.

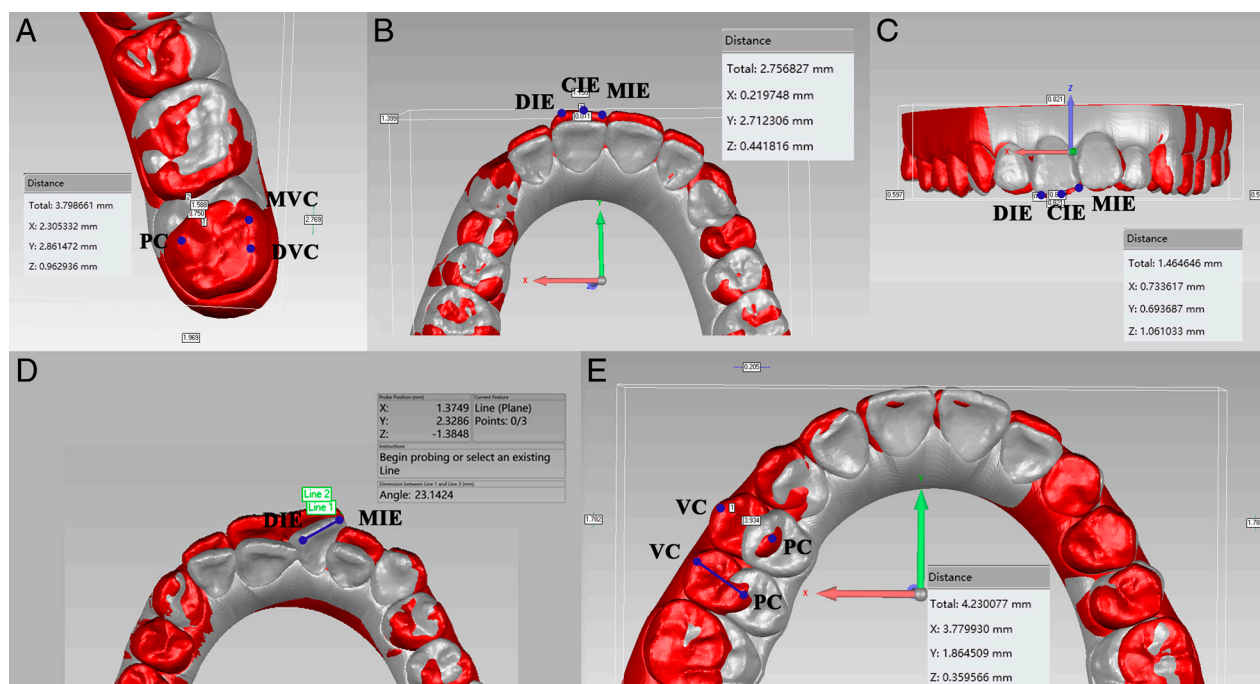


Figure 3. Measurement of OTM. (a) Molar distalization was measured at points of each cusp tip of molars; (b) Points of incisor edges were used to measure anterior retraction; (c) Measurement of anterior intrusion; (d) Lines of incisor edges were used to measure angle of anterior rotation; (e) Measurement of posterior expansion. CIE: central incisal edge; DIE: distal incisal edge; DVC: distal vestibular cusp tip; MVC: mesial vestibular cusp tip; MIE: mesial incisal edge; PC: palatal cusp tip; VC: vestibular cusp tip.

Randomisation and allocation concealment

The participants were randomly assigned into two groups (10-day vs 14-day) using computer-generated randomisation numbers and sequences. Allocation concealment was achieved using sequentially numbered opaque, sealed envelopes. The investigators (RZ, HL) and the statistician were all blinded.

Interventions

The 10-day group ($N = 36$) changed their clear aligners every 10 days; the 14-day group ($N = 36$) changed their clear aligners every 14 days. All of the participants were instructed to wear each aligner for at least 22 hr a day and bit 'chewies' for five minutes after inserting each new clear aligner. For monitoring patient compliance, patients were asked to record their daily wear time for each aligner on a smartphone app (Orthodontic Home, Souya Zhuhai Network Technology, China). The trial period included stage 1 (aligner #1) to stage 16 (aligner #16) of the aligner treatment (i.e., 160 days for the 10-day group and 224 days for the 14-day group).

Each participant was examined at three time points. T0: before the initial insertion of the clear aligners;

T1: after completion of aligner #8 (stage 8); T2: after completion of aligner #16 (stage 16). Stage 8 and stage 16 were selected as the observation time points based on the previous literature.¹⁶ According to the American Board of Orthodontics (ABO) model grading system described by Grunheid et al.²⁴ and relevant studies,^{25–27} differences larger than 0.5 mm for linear measurements and 2° for angular measurements were considered clinically relevant. Therefore, clinical significance was set for linear movements at >0.5 mm and angular movements at $>2^\circ$.

Assessment of orthodontic tooth movement (OTM)

Two methods were used to assess the OTM: (1) The stable structure method (Figures 2 and 3) using unmoved teeth in the ClinCheck plan to superimpose the initial models and check the progress models. Using this method, it was possible to measure and calculate the level of OTM and OTM efficacy for different types of tooth movement. (2) The shell-to-shell deviation method (whole surface best fit method, Figure 4): The shell-to-shell deviation is the 3D euclidean distances between the superior

surface points of the actual scanned OTM models and the predicted OTM digital models and evaluated by means of a color-mapping analysis. Using this method, the OTM deviation was analysed between the actual and predicted dentitions.

Intraoral digital scans were taken (iTero Element; Align Technology Inc., Santa Clara, CA, USA) to assess the actual OTM at each time point (i.e., T0, T1, and T2). The models were labelled as 'initial' (T0) and 'actual' (T1 and T2). The corresponding predicted OTM at each time point was provided by Align Technology after communication, and the models were labelled as 'predicted'. The initial, actual, and predicted models were exported as .STL files and imported into the GEOMAGIC Studio version 2013 (Raindrop Geomagic, NC, USA). All of the digital models were anonymised, and the soft tissues and bonded attachments were digitally removed to ensure that the evaluation was solely based on the tooth surface features.¹⁵

Based on the previous literature,^{5,13} the OTM (in millimeters) was measured by a blinded dental investigator (HL) on the superimposed 3D models at T1 and T2 (Figure 2); the OTM efficacy (%) was calculated as the percentage of the actual OTM distance divided by the predicted OTM distance. The molar distalisation/mesialisation was measured

at the three points using each cusp tip of the molars (parallel to the occlusal plane), and the mean was calculated. The anterior retraction was measured using three points at the incisal edges parallel to the occlusal plane. The intrusion/extrusion of anterior/posterior teeth was measured at three points at the incisal edges perpendicular to the occlusal plane. The rotation of anterior/premolar teeth was measured by the angle between the lines parallel to the occlusal plane that connected the two points on the incisal edges or by labelling the lingual and labial cusp tips of the premolars. The posterior expansion was measured at three points (the labial and lingual cusp tips and central fossae) of the posterior teeth, parallel to the occlusal plane (Figure 3).

Shell-to-shell deviation between the actual and predicted OTM digital models at T1 and T2 was analysed using the GEOMAGIC Studio software (Figure 4). The actual and predicted models were superimposed on analogous teeth using a whole-surface, best-fit algorithm to compute the shell-to-shell deviation between tooth positions. Data from the deviation analysis were obtained to analyse the OTM difference between the actual and predicted dentitions (Figure 5).

The intra-observer reliability of the measurements was calculated. Thirty digital models were randomly

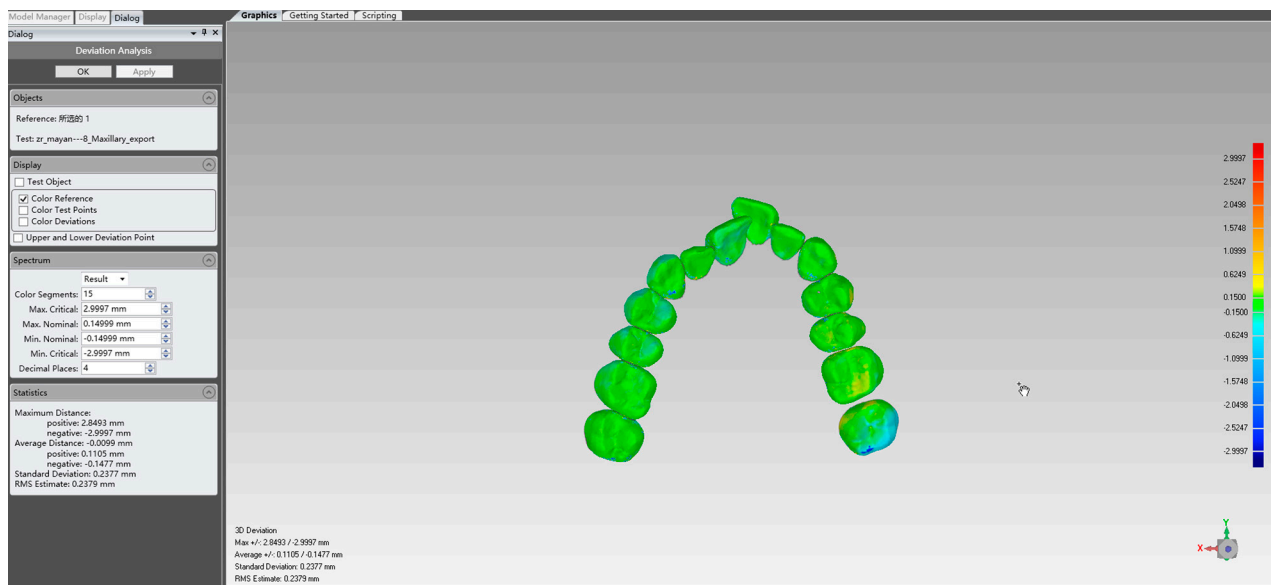


Figure 4. Shell-to-shell deviation of OTM by using a whole surface best fit algorithm and colour-mapping methods in the GEOMAGIC studio software. Green represents no deviation; red represents a large and positive deviation; blue represents a small and negative deviation. The bigger the deviation is the more OTM stray from the ClinCheck.

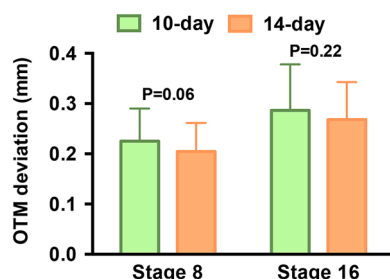


Figure 5. Shell-to-shell deviation of OTM (mean $\pm$ standard error) at Stage 8 (T1) and Stage 16 (T2) of the Invisalign treatment. There was no statistically significant difference between the 10-day group and 14-day group.

selected from each group to repeat the measurements after 30 days. Dahlberg's formula was applied to assess the method error for all of the measurements.²⁸ The intra-observer reliability was excellent (intra-class correlation coefficient = 0.90).

Assessment of pain

Pain perception was assessed using a visual analog scale (VAS)^{29,30} involving a 10-cm straight line ranging from 0 (no pain at all) on the left to 10 (worst pain possible) on the right.³¹ A mark was required on the long line, matching the pain perception experienced by each patient. A higher score indicated more severe pain. Patients were asked to record their pain perception on days 1, 2, 3, and 7 after placement of each new aligner from stage 1 to stage 16.

Statistical analysis

An intention-to-treat analysis was conducted using a mixed-models approach in SPSS 19.0 (IBM, Chicago, Illinois, USA). After confirming the normal distribution of data by the Kolmogorov-Smirnov test, OTM data were compared using a two-sided Student's *t* test. The VAS data were analysed using two-way ANOVA with repeated measures. A *p*-value of <0.05 was considered statistically significant.

Results

Participants

Table I presents the baseline characteristics of the participants. The participant's baseline values, including age, gender, and clinical characteristics (malocclusion, extraction, initial incisor irregularity, and VAS), were all similar (*p* > 0.05 for all). The patient's daily wear time of the clear aligners was

22.38 $\pm$ 0.61 hours, with no adverse events noted during the trial.

A total of 175 aligner patients were assessed for eligibility. Sixty-four patients did not meet the inclusion and exclusion criteria, 37 declined to participate and two were excluded for other reasons (studying overseas); therefore 72 subjects were involved in the study (Figure 1). During the first 16-stage follow-up, nine patients (six in the 14-day change group and three in the 10-day change group) were excluded due to a reduced wear time for each aligner, i.e., <22 hr (one subject), non-compliance with instructed aligner change regimen (three subjects), or a lack of time to complete the collection of the required intraoral digital scans (five subjects). The dropout rate was 12.5%, which was acceptable compared with dropout rates of 5% to 21% previously reported.^{18,32–34}

Orthodontic tooth movement (OTM)

The 10-day and 14-day groups showed a similar OTM efficacy for all types of tooth movements at

Table I. Baseline characteristics of participants included in the final analysis.

	10-day group (N = 33)	14-day group (N = 30)
Gender (N, %)		
Male	8 (24.24%)	6 (20.00%)
Female	25 (75.76%)	24 (80.00%)
Age (N, %)		
≤45	32 (96.97%)	28 (93.33%)
>45	1 (3.03%)	2 (6.67%)
Malocclusion (N, %)		
Class I	14 (42.42%)	11 (36.67%)
Class II	15 (45.45%)	13 (43.33%)
Class III	4 (12.12%)	6 (20.00%)
Initial incisor irregularity (mean $\pm$ standard deviation)	6.38 $\pm$ 2.44	6.53 $\pm$ 2.08
Visual analog scale (VAS) score (mean $\pm$ standard deviation)	0.06 $\pm$ 0.18	0.08 $\pm$ 0.26

Table II. Comparison of orthodontic tooth movement (OTM) efficacy between 10-day and 14-day groups at stage 8 (T1) of the Invisalign treatment.

OTM	10-day group					14-day group					P-value
	N	Predicted OTM	Actual OTM	Mean OTM efficacy	SD	N	Predicted OTM	Actual OTM	Mean OTM efficacy	SD	
Anterior intrusion	76	1.78 mm	1.34 mm	75.15%	13.20%	81	1.72 mm	1.26 mm	73.42%	13.92%	0.43
Anterior extrusion	17	1.69 mm	1.29 mm	76.63%	9.29%	14	1.78 mm	1.45 mm	81.26%	10.14%	0.19
Anterior proclination	69	7.44°	6.17°	82.90%	9.84%	63	6.81°	5.75°	84.46%	9.63%	0.36
Anterior retraction	23	1.85 mm	1.48 mm	80.10%	7.81%	16	1.84 mm	1.53 mm	83.46%	8.32%	0.21
Anterior derotation	29	8.31°	6.36°	76.55%	13.44%	22	7.76°	5.66°	72.94%	10.91%	0.31
Posterior expansion	22	1.62 mm	1.25 mm	77.58%	12.25%	18	1.57 mm	1.23 mm	78.50%	10.92%	0.81
Premolar derotation	11	6.74°	5.65°	83.78%	11.92%	9	7.32°	6.02°	82.20%	9.08%	0.75
Molar distal tipping	27	1.62 mm	1.3 mm	80.49%	9.59%	23	1.64 mm	1.27 mm	77.73%	12.93%	0.39
Posterior mesial tipping	8	1.52 mm	1.19 mm	78.88%	12.64%	12	1.79 mm	1.37 mm	76.71%	15.80%	0.75
Posterior intrusion	17	1.18 mm	0.95 mm	80.87%	7.26%	22	1.14 mm	0.93 mm	81.34%	7.48%	0.85

The OTM efficacy was calculated as the percentage of the actual OTM distance divided by the predicted OTM distance, N: numbers of teeth measured for each type OTM; Predicted OTM: the distance of predicted OTM in Clincheck plan measured form initial STL model and predicted STL model; Actual OTM: The distance of actual OTM measured form initial STL model and actual STL model; Mean OTM efficacy: the mean value of OTM efficacy; SD: standard deviation of OTM efficacy.

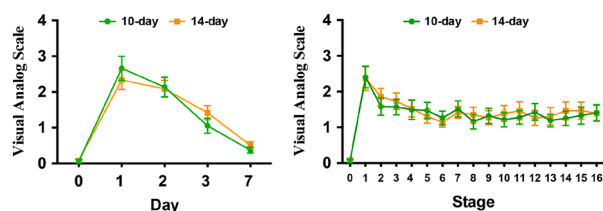


Figure 6. Pain perception (VAS score, mean $\pm$ standard error) of the 10-day and 14-day groups was similar throughout the study.

both T1 (stage 8) and T2 (stage 16) of the aligner treatment ($p > 0.09$ for all) (Tables II).

At T1 (Stage 8), OTM efficacy of the 10-day group ranged from $75.15\% \pm 13.20\%$ (anterior intrusion) to $83.78\% \pm 11.92\%$ (premolar derotation); OTM efficacy of the 14-day group ranged from $72.94\% \pm 10.91\%$ (anterior derotation) to $84.46\% \pm 9.63\%$ (anterior proclination). At T2 (Stage 16), OTM efficacy of the 10-day group ranged from $65.66\% \pm 16.46\%$ (anterior intrusion) to $79.58\% \pm 11.75\%$ (anterior retraction); OTM efficacy of the 14-day group ranged from $69.09\% \pm 12.22\%$ (anterior intrusion) to $78.23\% \pm 12.87\%$ (anterior proclination).

OTM shell-to-shell superimposition deviation (Figure 5) of the 10-day (0.23 ± 0.06 mm) and 14-day (0.20 ± 0.05 mm) groups was not statistically significant at T1 (95% CI: -0.04 – 0.001 ; $p = 0.06$). At T2, the OTM shell-to-shell superimposition deviation was also similar between the 10-day (0.29 ± 0.09 mm) and 14-day (0.27 ± 0.07 mm) groups (95% CI: -0.02 – 0.04 ; $p = 0.22$).

Pain perception

The 10-day and 14-day groups showed similar VAS scores of pain perception throughout the study ($p > 0.05$) (Figure 6).

Pain perception was maximum on day 1 after the initial placement of the aligners for both groups (2.66 ± 1.93 for the 10-day group and 2.33 ± 1.47 for the 14-day group); and decreased steadily thereafter to the baseline level after a week (0.37 ± 0.49 for the 10-day group and 0.51 ± 0.55 for the 14-day group). The pain perception was highest at stage 1 (aligner #1) during the entire course of aligner treatment; decreased and fluctuated in the subsequent treatment stages (Figure 6).

Discussion

During clear aligner treatment, clinicians usually instruct patients to change clear aligners every 10 to 14 days, mainly based on the clinical experience. The evidence-based optimum wear protocol and change frequency are still lacking in the literature. To the best of current knowledge, the present study is the first to directly compare a 10-day and 14-day change regimen for OTM and pain perception during clear aligner treatment. The 10-day and 14-day groups in the current study demonstrated similar OTM efficacy and pain perception, suggesting that the clear aligners may be changed every 10 days without a significant compromise in the clinical efficacy of OTM and patient comfort.

In 2016, Align Technology announced a treatment modification, claiming that patients could change aligners from every two weeks to every one week based on their internal data derived from 200 patients.^{35,36} However, these data were not published and, to date, there is still no robust clinical evidence supporting this guideline. Indeed, some clinicians and patients explored changing aligners every 10 days⁸ while some studies tried even shorter intervals, from 3 to 7 days.^{19,20,37} However, these studies mainly focused on the interventions for OTM acceleration (*e.g.*, vibration and periodontally accelerated osteogenic orthodontics) instead of the change frequency of clear aligners. In addition, the studies usually designed a single tooth movement or a specific type of tooth movement, with limited clinical relevance to the aligner's change regimen.^{21,22}

3D digital model and superimposition and shell-to-shell deviation analysis, which were used in the current study to assess the OTM, has shown acceptable accuracy^{16,38,39} and reproducibility compared with the traditional method using plaster models.^{40,41} Other methods for assessing OTM have also been reported, such as the Peer Assessment Rating Index, completion rates for the initial set of aligners, and the incisor irregularity measurements, with limited accuracy.^{40–44}

It has been suggested that patients wearing clear aligners experience less pain compared with the wear of traditional fixed appliances;^{30,32} however, aligners still cause discomfort or pain to varying degrees. In the present study, pain perception was similar between the 10-day and 14-day groups while the first day after placing new aligners was the most

Table III. Comparison of orthodontic tooth movement (OTM) efficacy between 10-day and 14-day groups at stage 16 (T2) of the Invisalign treatment.

OTM	N	10-day group				14-day group				P-value
		Predicted OTM	Actual OTM	Mean OTM efficacy	SD	N	Predicted OTM	Actual OTM	Mean OTM efficacy	
Anterior intrusion	100	2.09 mm	1.37 mm	65.66%	16.46%	93	1.93 mm	1.33 mm	69.09%	0.09
Anterior extrusion	29	2.13 mm	1.41	66.15%	11.00%	26	2.06 mm	1.45 mm	70.25%	0.15
Anterior proclination	72	11.95°	9.01°	75.40%	12.02%	66	11.42°	8.93°	78.23%	0.18
Anterior retraction	51	2.14 mm	1.7 mm	79.58%	11.75%	43	2.12 mm	1.63 mm	76.92%	0.28
Anterior derotation	41	9.52°	6.74°	70.80%	14.36%	35	9.14°	6.37°	69.73%	0.75
Posterior expansion	29	1.84 mm	1.39 mm	75.63%	11.74%	38	1.97 mm	1.52 mm	77.00%	0.66
Premolar derotation	16	7.57°	5.65°	74.66%	17.20%	19	8.54°	6.53°	76.46%	0.75
Molar distal tipping	51	2.27 mm	1.76 mm	77.71%	11.74%	48	2.06 mm	1.57 mm	76.19%	0.51
Posterior mesial tipping	12	1.83 mm	1.21 mm	65.72%	12.57%	17	1.91 mm	1.35 mm	70.92%	0.32
Posterior intrusion	24	1.42 mm	1.04 mm	73.22%	9.67%	34	1.47 mm	1.12 mm	76.01%	0.30

The OTM efficacy was calculated as the percentage of the actual OTM distance divided by the predicted OTM distance, N: numbers of teeth measured for each type OTM; Predicted OTM: the distance of predicted OTM in Clincheck plan measured form initial STL model and predicted STL model; Actual OTM: The distance of actual OTM measured form initial STL model and actual STL model; Mean OTM efficacy: the mean value of OTM efficacy; SD: standard deviation of OTM efficacy.

painful period which, thereafter, decreased to the baseline level after about a week. This is consistent with previous studies.^{29,30} The pain perception during stage 1 of aligner treatment was higher than that during the subsequent stages, suggesting that clinicians could consider designing less OTM in stage 1 to enhance patient experience and adaptation with aligner treatment, minimising a potential compromise in patient co-operation with wearing clear aligners as a result of pain or discomfort.

Additional factors can affect the clinical efficacy of aligner treatment, particularly a patient's compliance. Patient compliance in the current study was relatively good, and exhibited an average wear time of 22.38 ± 0.61 hr/day. According to the literature, poor patient compliance in wearing clear aligners decreased the orthodontic force delivery and may cause compromised tooth movement efficacy.⁴⁵ In the current trial, all of the patients were adults, with relatively better comprehension and co-operation with clinical instructions than children. The patients were asked to record their daily aligner wear time using a smartphone 'app', which provided ample assistance and supervision to comply with aligner wear requirements.^{46–48} In addition, factors, related to the fit of aligners, are also crucial for the clinical efficacy of treatment. In the current study, all of the clear aligners fitted the teeth tightly, and each patient was asked to bite 'chewies' for 5 min after appliance insertion.

There were several limitations to the present study. The observation time was relatively short and involved only 16 stages of clear aligner treatment (160 days and 224 days for the 10-day and 14-day groups, respectively) which meant that the types of OTM measured were limited. As the observation period was the first 16 stages of aligner treatment, some types of OTM had not yet started. The superimposition of the 3D digital models was registered using a theoretically designed 'unmoved' tooth in the ClinCheck plan due to the unavailability of standard anatomic structures in the system; therefore, the OTM measured in the study was relative to these 'stable' teeth, which, in practice, might have experienced some intangible movements. Future studies could consider combining the 3D digital models with an implant-based superimposition,^{49,50} the cranial-based superimposition on cone-beam computed tomography,^{51,52} a novel equilibrium of forces moments (EFM), and minimisation of bone remodelling volume (MRV) approach⁵³ for more accurate measurements of OTM.

Conclusion

The 10-day and 14-day aligner groups showed similar tooth movement and pain perception, suggesting that clear aligners may be changed every 10 days without a significant compromise in clinical OTM efficacy and patient comfort.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Declarations

Ethical approval and consent to participate: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for the study was granted by the XX Hospital (WCHSIRB-ST-2015-095). This study was registered at the Chinese ClinicalTrials.gov (ChiCTR-IOR-15007532).

Informed consent was obtained from all individual participants included in the study.

Consent for publication: Written informed consent for publication was obtained from all participants.

Availability of supporting data: The data sets supporting the results of this article are included within the article and its additional files.

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Authors' contributions

Rui Zhao: Conceptualization, Methodology, Software, Writing-Original draft preparation, Project administration. Li Mei: Data curation, Investigation, Writing - Review & Editing. Hu Long: Software, Investigation, Validation, Resources. Fan Jian: Resources, Formal analysis. Wenli Lai: Conceptualization, Supervision, Funding acquisition.

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