Original Article

Influence of personalized replacement protocol and low-level laser therapy combined with vibration on tooth movement rate and tooth movement accuracy in clear aligner treatment: a randomized clinical trial

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ABSTRACT

Objectives: To evaluate the influence of personalized aligner replacement, with or without physical methods of acceleration using low-frequency vibration combined with a low-level laser, on the tooth movement rate and accuracy of clear aligners.

Materials and Methods: Forty participants were randomly allocated to three groups. Fourteen participants used the standard replacement protocol in Group A, Group B included 14 participants using a personalized replacement protocol, and 12 participants in Group C followed the personalized replacement protocol and used a physical device that combined low-frequency vibration and low-level laser. Aligner replacement cycles of the first 12 steps were recorded, and GOM inspect suite software 2022 (GOM; Braunschweig, Germany) was used to evaluate maxillary molar movement accuracy using digital models collected before treatment and at the end of the 12th step.

Results: No significant difference was found in the accuracy of maxillary molar movement between Groups A and B, but the tooth movement rate in Group B was significantly greater. The accuracy of maxillary molar movement was similar in Groups B and C, and the tooth movement rate in Group C was significantly increased.

Conclusions: The personalized replacement protocol decreased the number of aligner replacement cycles without impacting the accuracy of tooth movement. With personalized replacement, a physical method of acceleration combining low-level laser and low-frequency vibration significantly accelerated orthodontic tooth movement and had little influence on the accuracy of tooth movement. (*Angle Orthod*. 2025;00:000–000.)

KEY WORDS: Clear aligner; LLLT; Low-frequency vibration; Personalized replacement protocol; Accelerating orthodontic tooth movement

INTRODUCTION

Orthodontic treatment usually lasts between 2 and 3 years.[1] Orthodontic patients generally experience prolonged treatment, which may cause various potential complications.[2] A common goal of orthodontists and patients is to reduce the duration of orthodontic clinical treatment.

Physical methods of acceleration are commonly used for accelerating orthodontic tooth movement (OTM), which is acceptable because of its advantages of non-invasiveness, comfort, and portability.[3,4] Low-frequency vibration (LFV) has been used for fracture healing and bone reinforcement in osteoporosis, and it has been used to accelerate OTM by promoting periodontal cell proliferation and differentiation.[4,5] Although the results from the in vitro and animal studies were positive, the conclusions of some clinical studies about LFV were controversial. One study that used LFV in clear aligner patients reported no evidence of accelerating OTM.[6] Another study showed that the tooth movement accuracy of a 7-day aligner replacement protocol combined with LFV was similar to a 14-day protocol.[4]

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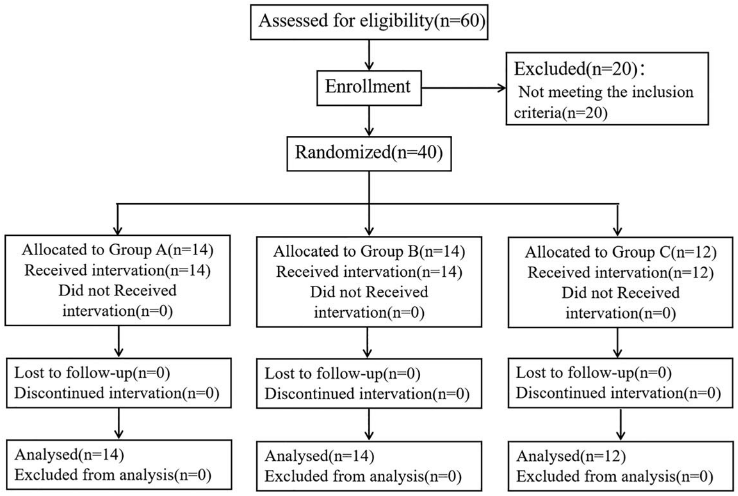

Figure 1. CONSORT flow chart.

Low-level laser therapy (LLLT) exposes tissue to light in the red to near-infrared range (600–1000 nm) with a low-energy laser or light-emitting diodes. When a low-level laser is applied, cytochromophores in mitochondria absorb energy and produce adenosine triphosphate (ATP), which promotes cellular proliferation and cellular activity by increasing transcription and protein synthesis.[7] Research indicated that applying lasers within the 720–860 nm spectrum can increase the rate of space closure in patients with fixed appliances.[8,9] A study also found that LLLT shortened clear aligner treatment duration.[3] In addition, most LLLT was performed chairside and the two physical methods of acceleration (LFV and LLLT) were applied separately.

Clear aligners are a common choice for orthodontic therapy and have been used for more complex cases with further development of clear aligner techniques.[10] The tooth movement distance between each step is constant, and the aligner replacement cycle is used to evaluate the orthodontic tooth movement rate.[4] Typically, this cycle is set at 14 days, and a study reported that the tooth movement accuracy between a 7-day protocol and 14-day protocol was similar mid-treatment.[11] Therefore, the 14-day protocol might unnecessarily extend treatment duration, and personalized replacement may be better for decreasing the duration and evaluating the effects of LLLT and vibration. Patients were required to change aligners once they felt loose in a previous study,[12] but this method lacked quantification and tooth movement accuracy was not evaluated.

Therefore, the aim of this study was to separately evaluate the influence of aligner personalized replacement and physical methods of acceleration: low-frequency vibration combined with low-level laser, the tooth movement rate, and accuracy.

MATERIALS AND METHODS

Trial Design

This study was a prospective, three-arm, parallel, randomized clinical trial, which was ethically approved by the Stomatological Hospital of Xi'an Jiaotong University Medical ethics committee (2022-XJKQIEC-028-002).

Sample

Sixty participants were invited and assessed for eligibility at the Department of Orthodontics at the Stomatological Hospital of Xi'an Jiaotong University, Xi'an, Shaanxi, China. Each participant was treated with Angelalign (EA Medical Instruments, Shanghai, China) by an experienced orthodontist who was certified in clear aligner treatment.

The participants met the following inclusion criteria: (1) nonextraction plan treated with clear aligners; (2) age ranging from 19–45 years; (3) complete dentition or, at most, one missing anterior tooth per quadrant (excluding third molars); (4) absence or previous extraction of maxillary third molars; (5) no tooth or root shape anomalies; (6) permanent dentition and no supernumerary teeth; and (7) mild to moderate crowding or minor space per arch. The following exclusion criteria were used: (1) extraction plan; (2) systemic pathology; (3) ongoing pharmacological treatment that may influence orthodontic movement (eg, prostaglandin inhibitors or bisphosphonates); (4) active periodontal disease; and (5) detachment or refinement during observation.[4] A total of 40 participants were recruited for this study and all participants provided written informed consent (Figure 1, Table 1).

A power analysis using the aligner replacement cycle as the primary outcome was performed as previously reported.[12] Using an alpha of 0.05 and 90% power, a total sample size of 27 was required, which was

Table 1. Descriptive Statistics of the Sample

	Group A		Group B		Group C	
	Mean, n	SD, %	Mean, n	SD, %	Mean, n	SD, %
Age	24.79	9.82	28.07	6.42	27.83	6.42
Sex						
Male	5	35.7%	4	28.6%	3	25%
Female	9	64.3%	10	71.4%	9	75%
Malocclusion						
Class I	4	28.6%	1	7.1%	3	25%
Class II	7	50%	12	85.7%	7	58.3%
Class III	3	21.4%	1	7.1%	2	16.6%
Maxillary crowding/mm	0.11	2.71	1.54	2.58	0.89	3.33
Mandibular crowding/mm	1.29	1.33	2.18	1.81	2.35	2.59
SNA/°	81.81	4.87	80.69	3.76	80.48	3.92
SNB/°	79.01	5.64	76.49	3.65	76.88	2.81
ANB/°	2.80	2.99	4.25	1.71	3.59	2.54
GoGn-SN/°	25.84	9.24	31.94	6.60	29.03	7.97
Wits/mm	0.52	4.38	0.057	2.10	0.72	4.10

increased to 30 to consider a possible dropout rate of 10%.

Randomization

An external statistician randomized the sample. Randomization was based on a random number table and the sequence in which participants started treatment. The participants were allocated to three groups.

Blinding

The treating orthodontist and clinical operators who performed the setup were blinded to the group allocation. The data collectors and outcome assessors were also blinded.

Intervention

The clear aligner treatment included two types (single-aligner versions: one aligner in each step and a 14-day replacement cycle; double-aligner versions: involving a soft and a hard aligner of the same shape per step, participants were instructed to wear the soft aligner for 7 days followed by the hard aligner for 3 days).

Most studies using fixed appliances observed participants for the first 3 months.[7] Most participants in the current study were designed to have maxillary molar distalization (11 of 14 in Groups A and B, and 12 of 12 in Group C). The first 12 steps of treatment lasted more than 3 months, and maxillary molar distalization was almost complete. Therefore, the first 12 steps were regarded as the observation period for the current study.

The numeric rating scale (NRS) is a reliable and valid tool for measuring subjective experiences.[13] The present study designed the scale for aligner personalized replacement based on the sensation of tightness. The NRS of tightness used a five-point scale ranging from 1 (no tightness) to 5 (tightness once wearing a new aligner). The scale was presented as an electronic questionnaire (www.wjx.cn) and sent daily to participants by a single operator. Participants were instructed to complete the scale every day and replace aligners based on the results of the scale. A "5" indicated the start of wearing a new aligner, and a replacement was due when the rating fell to "1."

An orthodontic accelerating device (Beshone Intelligent Technology, Suzhou, China) was used in this study as the physical intervention. This portable physical device simultaneously produces a low-level laser and low-frequency vibration (LLLT: wavelength $=$ 850 nm and intensity $\leq$ 30 mW/cm^2; LFV: vibration frequency $\geq$ 110 Hz and horizontal vibrational acceleration $\leq$ 1.2 Grms). Participants in Group C used the device for 5 minutes every day without aligners and while biting on the working side.

The following intervention protocols were compared in the study.

1. Group A (8 of the single-aligner versions + 6 of the double-aligner versions): aligner treatment with a standard replacement protocol.
2. Group B (8 of the single-aligner version + 6 of the double-aligner version): aligner treatment with a personalized replacement protocol.
3. Group C (8 of the single-aligner version + 4 of the double-aligner version): aligner treatment with personalized replacement + 5 minutes per day of LLLT combined with vibration.

Tooth Movement Rate

The replacement cycles of Groups B and C were recorded based on the collection of the electronic NRS.

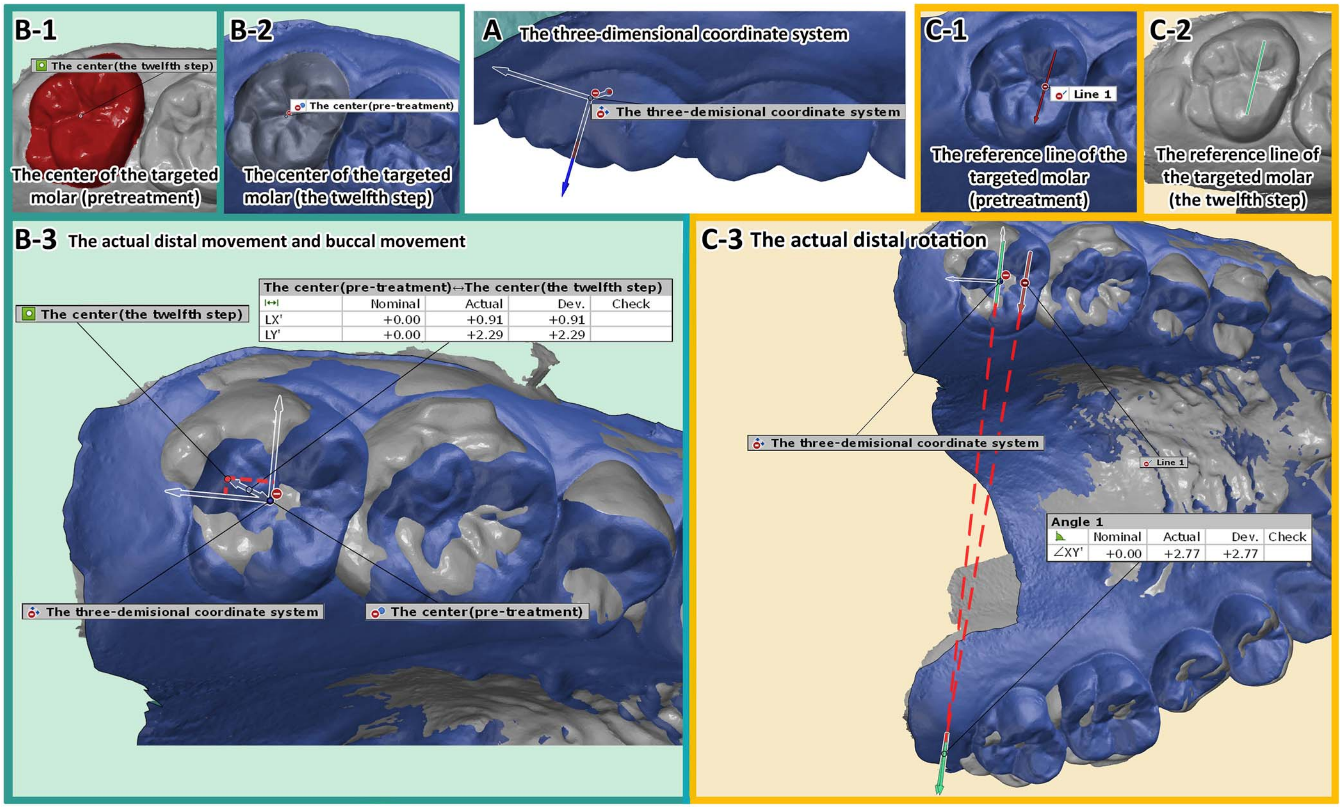

Figure 2. Measurement of maxillary molar linear and angular movements.

The tooth movement distance for each step was 0.2 mm in the single-aligner version and 0.3 mm in the double-aligner version. The tooth movement rate was evaluated using the following equation:

$$\text{Toothmovementrate}(\text{mm/d}) = \text{toothmovingdistance}(\text{mm})/\text{alignerreplacementcycle}(\text{day})$$

Digital Setup Analysis

An additional tendency for maxillary molar intrusion, distal tip, and buccal torque appeared during maxillary molar distalization in a previous study[10] and no reproducible structure was found in the mandible. Therefore, maxillary molar mesial-distal movement, buccolingual movement and mesial-distal rotation were used to evaluate tooth movement accuracy.

The digital models were acquired before treatment and after completing the 12th step. The models were captured using an iTero Element 2 (Align Technology, San Jose, Calif) intraoral scanner, exported from orthoCAD software (Align Technology) as STL files, and imported into GOM inspect suite software 2022 (GOM; Braunschweig, Germany) for measurement.

First, pre-alignment was used to superimpose the initial- and final-stage models. Then, final digital model superimposition was completed with the local best fit function after selecting the palatal rugae area. The actual mesial-distal and buccolingual linear movements were measured as reported in a previous study.[10] The mesial-distal rotation was measured after selecting the markers (the mesiobuccal and mesiolingual cusps) and connected to a reference line. The angle was created by the two lines and projected to the X-Y plane of the targeted teeth (Figure 2).

The predicted movement was obtained from the virtual tooth movement table and the tooth movement accuracy was evaluated using the following equation.[14]

$$A_{percentage} = 100\% - \frac{M_{predicted} - M_{achieved}}{M_{predicted}} \times 100\%$$

Statistical Analysis

SPSS software (version 22; IBM Corp., Armonk, NY) was used for statistical analysis. The Shapiro–Wilk test was used to evaluate normality of the data. Differences in baseline data were compared using independent-samples *t*-tests, rank-sum tests and chi-square tests.

Single-sample, independent-sample rank-sum test and independent-sample rank-sum tests were used to evaluate intergroup differences. Stepwise regression was used in the multivariable linear regression model to investigate the relationships between the rate and

Table 2. Descriptive Statistics of Tooth Movement Rate and Aligner Replacement Cycle in Each Group

	Tooth Movement Rate (mm/d)			Aligner Replacement Cycle (days/step)		
	Group A	Group B	Group C	Group A	Group B	Group C
Single-aligner version	0.014	0.019 ± 0.0032	0.029 ± 0.0083	14	10.96 ± 0.88	7.17 ± 1.41
Double-aligner version	0.030	0.031 ± 0.0043	0.035 ± 0.0082	10	9.89 ± 1.32	9.15 ± 2.39
Total	0.021	0.024 ± 0.0071	0.031 ± 0.0086	/	/	/

accuracy of tooth movement and associated factors ($P < .05$).

Reproducibility of the measurements was evaluated by the intraclass correlation coefficient (ICC). The same examiner and another examiner remeasured 20% of the models after 2 weeks.[10] The intrarater reliability value was 0.974 ($P < .001$), and the interrater reliability was 0.991 ($P < .001$).

RESULTS

Baseline data across groups showed no significant differences (Table 1). The tooth movement rate and aligner replacement cycle are reported in Table 2, and significant differences were found in the intergroup comparisons ($P < .05$) (Figure 3). Group A (B $= -0.003$, $P < .05$), Group C (B $= 0.009$, $P < .001$), and aligner version (B $= 0.013$, $P < .001$) showed significant regression relationships with tooth movement rate (Table 3).

Predicted linear and angular movements of <0.1 mm and $<1.0°$ were excluded from analysis to reduce measurement and design errors in tooth movement direction.[15] Tooth movement accuracy did not significantly differ in the intergroup comparisons (Table 4). The second molar (B $= 0.148$, $P < .05$) and age (B $= 0.014$, $P < .01$) exhibited a significant regression relationship with distal rotation, and a significant relationship was found between GOGN-SN (B $= 0.009$, $P < .05$) and molar distal movement (Table 5).

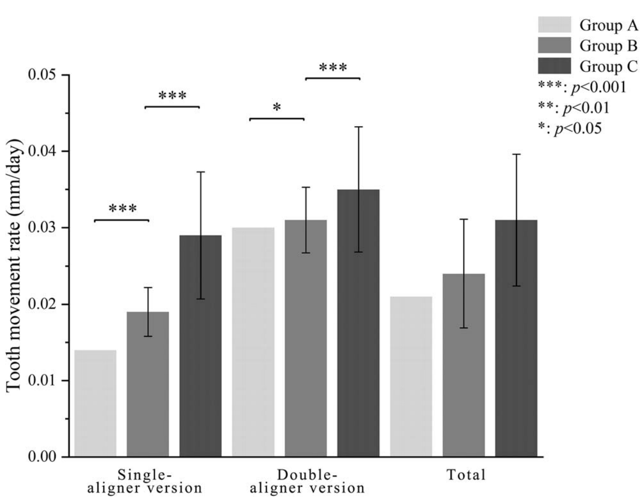

Figure 3. Rate of tooth movement in the different groups.

DISCUSSION

In this randomized clinical trial, all three groups had similar baseline data. Tooth movement rate and accuracy were used to investigate the personalized replacement and LLLT combined with vibration in accelerating tooth movement. This study found that personalized replacement and the LLLT with vibration shortened treatment time without affecting tooth movement accuracy.

In the present study, the accuracies of molar distal and buccal movements were 60%–85%, and distal rotation was approximately 60% in the standard replacement protocol. These findings were in agreement with previous studies that showed incomplete molar movement.[15,16] Poor strength of the aligner material may have reduced linear movement expression, and the cylindrical shape of molars likely influenced mesiodistal rotation accuracy. Special attachments and overcorrection in virtual design may improve outcomes.

Studies showed that a 7-day protocol might lower the accuracy of molar angular movement compared to a 14-day protocol, while having little impact on linear movement.[11,17] Achieving angular movement with clear aligners can be more difficult and there may be an optimal replacement cycle between 7 and 14 days for maintaining tooth movement accuracy. With the protocol of replacing the aligner immediately after loosening, it was

Table 3. Relationships Between Tooth Movement Rate and Associated Factors in the Multivariable Linear Regression Model[a]

	Tooth Movement Rate (mm/d)		
	B	95% CI	*P*
Group			
Group A	−0.003	−0.006, 0.000	.037
Group C	0.009	0.006, 0.012	.001
Group B	Reference		
Aligner version			
Double-aligner	0.013	0.011, 0.016	.001
Single-aligner	Reference		
Sex			
Female	0.001	−0.002, 0.004	.458
Male	Reference		
Age	−0.00004	−0.0002, 0.0001	.624
GoGn-SN	0.00003	−0.0001, 0.0002	.713

[a] B indicates regression coefficient; CI, confidence interval.

Table 4. Tooth Movement Accuracy in Different Groups[a,b]

Tooth Movement Accuracy	Group A Mean	Group A SD	Group B Mean	Group B SD	Group C Mean	Group C SD	*P* A-B	*P* B-C
Maxillary first molar								
Buccal movement	0.701	0.469	0.887	0.711	0.539	0.397	.412[a]	.068[b]
Distal movement	0.549	0.388	0.537	0.254	0.620	0.351	.907[a]	.768[b]
Distal rotation	0.505	0.304	0.475	0.298	0.498	0.251	.558[b]	.816[a]
Maxillary second molar								
Buccal movement	0.845	0.561	0.544	0.336	0.815	0.548	.071[b]	.095[a]
Distal movement	0.632	0.438	0.610	0.305	0.601	0.393	.852[a]	.661[b]
Distal rotation	0.659	0.423	0.568	0.373	0.645	0.301	.530[a]	.508[a]

[a] Independent-samples *t*-test; [b] Independent-samples rank-sum test.
[b] A-B: Group A vs Group B; B-C: Group B vs Group C.

shown that the average replacement cycle of the aligner was about 10 days,[12] and it took an average of 719 days to finish 81.5 sets of aligners.[3] The current study demonstrated that a personalized replacement protocol resulted in a moderate decrease in the aligner replacement cycle without compromising the efficiency of tooth movement. The aligner replacement cycle for the single-aligner version was 10.96 days, in agreement with findings from prior research.[12] The replacement cycle for the double-aligner was reduced to 9.89 days. Aligners were crafted from a 3D-printed model derived from digital design, allowing for some discrepancy between the predicted and actual tooth positions. As the aligner was worn and adapted, it generated orthodontic forces that prompted tooth movement. This process continued until the aligner and tooth positions aligned closely enough to reduce the force to a point where further movement ceased, reaching a state of equilibrium. Slight aligner deformations meant that the teeth did not always fully match the designed position. With personalized replacement, the aligner was replaced timely once equilibrium was achieved, shortening treatment duration without affecting accuracy.

A previous study indicated that vibration did not enhance molar movement accuracy on either a 14- or 7-day protocol.[4] Similarly, in this study, using LLLT and vibration did not increase tooth movement accuracy under a personalized replacement protocol ($P > .05$), which was typically between 50% and 80%, and in agreement with earlier findings.[4] In studies in which aligners were replaced after looseness, Kaur[12] reported that LLLT reduced the replacement cycle from 10.81 to 6.02 days. Additionally, LLLT decreased the treatment duration from 767 to 377 days,[18] and vibration reduced treatment duration by 352.07 days.[19] These outcomes are consistent with the current findings that, after applying LLLT and vibration, the replacement cycle for the single-

Table 5. Relationships Between Tooth Movement Accuracy of Maxillary Molar and Associated Factors in the Multivariable Linear Regression Model[a]

Maxillary First Molar	Buccal Movement B	Buccal Movement 95% CI	Distal Movement B	Distal Movement 95% CI	Distal Rotation B	Distal Rotation 95% CI
Group						
Group A	−0.078	−0.375, 0.220	0.006	−0.1.71, 0.182	−0.050	−0.237, 0.136
Group C	−0.151	−0.416, 0.115	0.097	−0.065, 0.259	0.047	−0.119, 0.213
Group B	Reference		Reference		Reference	
Aligner version						
Double-aligner	−0.033	−0.267, 0.200	−0.014	−0.143, 0.114	0.139	−0.007, 0.284
Single-aligner	Reference		Reference		Reference	
Maxillary molar						
Second molar	0.020	−0.203, 0.242	0.040	−0.84, 0.164	0.148*	0.013, 0.283
First molar	Reference		Reference		Reference	
Sex						
Female	−0.180	−0.445, 0.084	0.138	−0.014, 0.290	0.089	−0.063, 0.240
Male	Reference		Reference		Reference	
Attachment						
Y	−0.152	−0.383, 0.079	0.002	−0.126, 0.130	0.082	−0.059, 0.222
N	Reference		Reference		Reference	
Age	−0.012	−0.028, 0.004	0.000	−0.009, 0.009	0.014**	0.004, 0.023
GoGn-SN	−0.001	−0.016, 0.014	0.009*	0.002, 0.017	−0.005	−0.014, 0.005

* $P < .05$; ** $P < .01$.
[a] B indicates regression coefficient; CI, confidence interval.

aligner version was shortened from 10.96 to 7.17 days and, for the double-aligner version, from 9.89 to 9.15 days. LLLT and vibration reduced the aligner replacement cycle to approximately 1 week. With the assistance of LLLT and vibration, teeth achieved adequate movement in a shorter timeframe, and tooth movement accuracy did not decline due to the shortened replacement cycle. The unachieved tooth movement may be attributed to the mechanical characteristics of aligners. A well-designed overcorrection strategy, in conjunction with LLLT and vibration, can facilitate tooth movement toward the desired position while also reducing overall treatment duration.

This study found that the double-aligner version accelerated tooth movement without affecting accuracy, potentially due to using two aligners per step and a soft-to-hard replacement strategy. This strategy might prevent aligner fatigue, and the teeth initially tipping followed by bodily movement. Older patients, second molars, and those with high angles had better accuracy, possibly due to better aligner fit, compliance, and bone density.

Limitations

Even if the sample size of this study was calculated statistically, a greater number of participants would have provided more generalizable results, and a larger sample size is necessary in future studies.

Most clear aligner patients in this study underwent maxillary molar distalization. Although molar distalization is difficult and the feasibility of personalized replacement protocols and LLLT combined vibration therapy was shown, more challenging cases, such as extraction cases, should be studied in the future. In addition, some subjects were not designed to undergo maxillary molar distalization, potentially affecting sample coherence. Future studies should standardize treatment design.

This study evaluated the effects of LLLT combined with vibration. Future research should separately examine each intervention with personalized replacement. Both types of aligners were included to reflect real clinical practice and evaluate the type of aligner as a secondary focus. Although a multivariable linear regression model was used for analysis, this may have slightly affected the results. Subsequent investigations should more strictly control for aligner versions.

The first 12 steps of clear aligner therapy were evaluated and no detachment or refinement occurred during the observation period. The risk of detachment increases as the course of treatment progresses and longer observations are necessary.

Due to the absence of reproducible structures in the mandibular model, only the accuracy of maxillary molar movement was investigated. Future research should explore methods for assessing mandibular tooth movement efficiently and accurately.

CONCLUSIONS

- The personalized replacement protocol decreased the number of aligner replacement cycles without impacting the accuracy of tooth movement.
- With personalized replacement, physical methods of acceleration combining LLLT and vibration significantly accelerated orthodontic tooth movement and had little influence on the accuracy of tooth movement.

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