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Assessment of the Alignment Acceleration of the Lower Incisors Using a Single Aligner Appliance Modified with Nickel-Titanium Coils: A Randomized Controlled Clinical Trial in Adults.

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Abstract

OBJECTIVE: The aim of this study was to investigate the effects of a single aligner appliance modified with nickel-titanium coils in accelerating the alignment of crowded lower incisors.

MATERIALS AND METHODS: 36 patients with mild crowding of their lower incisors were randomly divided into two groups: one group received a modified aligner appliance with nickel-titanium coils (Experimental group), while the other group received traditional orthodontic brackets (Control group). The degree of irregularity in the alignment of the incisors was measured every 2 weeks using Little's irregularity index, and this was done at different time points throughout the study: before treatment (T0), after 2 weeks (T1), after 4 weeks (T2), after 6 weeks (T3), after 8 weeks (T4).

RESULTS: A total of 87 patients with anterior mild crowding in the lower dental arch were initially assessed for eligibility. Out of these, 64 patients met the inclusion criteria. Eventually, 36 participants were assigned to receive the treatment. Accordingly, the data from 36 patients were analyzed statistically. There was no significant difference when comparing the two groups at T0, T1, T3, and T4. However, the difference was significant at T2 ($p = 0.037$). The differences were statistically significant at all time periods within each group ($P < 0.001$).

CONCLUSION: The use of a modified aligner appliance with nickel-titanium coils effectively treats lower incisors crowding, but it does not accelerate the alignment process compared to the traditional fixed orthodontic appliance.

KEYWORDS: Aligners; Teeth alignment; Dental crowding; Acceleration

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Introduction

The rising focus on appearance in society has resulted in a greater desire among adults to resolve minor dental problems like mild crowding [1-3]. However, instead of choosing conventional braces orthodontic appliances due to the non-aesthetic metallic appearance of wires and brackets, they are increasingly inclined towards reconstructive procedures that may have the potential to harm dental tissues [1, 4-6]. As a result, there is a growing preference for invisible orthodontic methods, particularly among adults [7]. Consequently, numerous

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methods and substances have been created in the field of clinical practice to alleviate these constraints, such as porcelain brackets, orthodontic techniques that are placed on the inner surface of the teeth, and clear aligners [8], but these options tend to be quite costly [9]. The Spring aligner appliance, also known as the spring retainer, was introduced by Barrer in 1974 as a removable device for aligning the incisors. It has been used for more than 25 years [10]. However, its activation was limited and it was only used to correct simple issues after orthodontic treatment and for retention [11]. In 2001, Don Inman modified the traditional spring retainer and created the Inman Aligner, a removable appliance that served multiple orthodontic purposes [4]. This new appliance relied on superelastic open coil springs to apply light and constant forces on both the front and back surfaces of the anterior teeth [11]. After reviewing the medical literature, we found that no clinical studies had been conducted that evaluated the acceleration of mandibular incisor alignment using any type of aligner appliance in the treatment of mild crowding in adult patients. Based on this reasoning, the aim of this research was to assess the efficiency of a single aligner appliance modified with nickel-titanium springs, by comparing it with a traditional fixed orthodontic appliance in treating mild crowding of the lower incisors in adults.

Material and Methods

Study Design

The study design was a randomized, single-blinded clinical trial with two groups and an equal allocation ratio. The study received approval from the university institutional review board and the Ethical Review Committee of Damascus University (Approval Number: 3166). The trial was also registered in the ClinicalTrials.gov database with the identifier NCT04988373.

Sample Size Estimation

Minitab® program (Version 20.1; Minitab, LLC, State College, Pa) was used to determine the sample size for the study. They considered the average movement of teeth per day with traditional fixed orthodontic appliances and aimed for 80% power at a significance level of 5%. Based on previous data, it was determined that a minimum of 17 patients was needed in each group (Figure 1). To account for potential dropouts, the number of patients was increased to 18 per group.

Patient selection, recruitment

The study included a total of 36 patients, consisting of 29 females and 7 males. These patients were selected from individuals who sought treatment at the Department of Orthodontics, Faculty of Dentistry, Damascus University in Syria between January 2021 and April 2021.

Inclusion criteria

- Adults' patients between the ages of 16 - 28 years.
- Mild crowding (1-4 mm) in the frontal area of their lower dental arch according to Little's irregularity index (LII).
- Class I malocclusion.
- Should be no extracted or congenitally missing teeth, except for third molars.

Exclusion criteria

- Previous orthodontic treatment.
- Severe skeletal discrepancy.
- Severe protrusion of both upper and lower teeth.
- Any systemic diseases that could affect tooth movement.
- Poor oral hygiene.

Randomization and Blinding

The participants were divided into both groups using a 1:1 allocation ratio, utilizing the simple computer random method through the Minitab® program (Version 20.1; Minitab, LLC, State College, Pa). Blinding of the examiner and the patient was not possible, but blinding could be implemented during the analysis of the findings to prevent bias in detection.

Interventions

The patients underwent a clinical examination, and impressions were

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Power and Sample Size

2-Sample t Test
Testing mean 1 = mean 2 (versus ≠)
Calculating power for mean 1 = mean 2 + difference
α = 0.05 Assumed standard deviation = 0.022

Results

Difference	Sample Size	Target Power	Actual Power
0.0224	17	0.8	0.820790

The sample size is for each group.

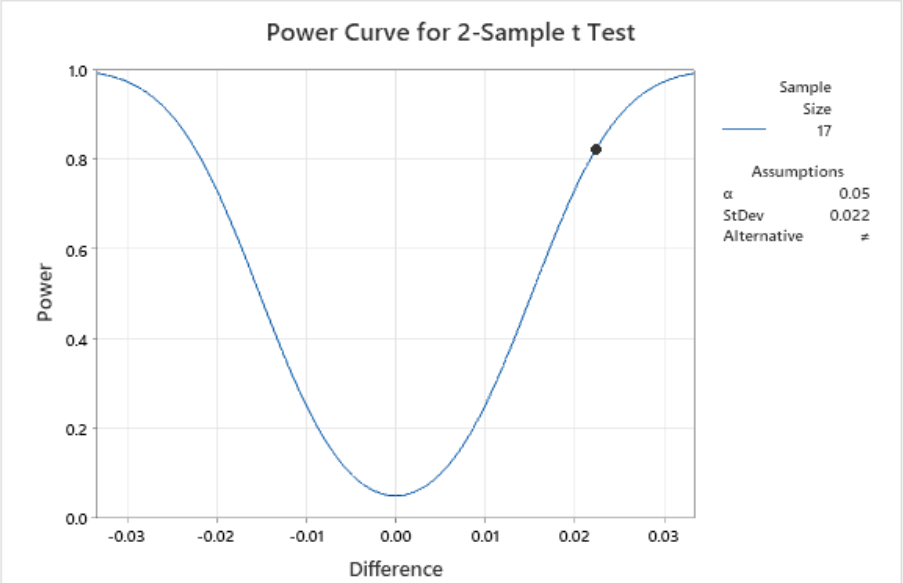

Figure 1. *Sample size estimation.*

made to create study models. Additionally, digital lateral cephalometric and panoramic x-rays were requested.

In the single aligner appliance modified with nickel-titanium coils group (Experimental group), 18 patients were treated A setup was created using the orthodontic panel of BlueSkyPlan® software to align the anterior teeth. The setup was then used to create a modified digital model, which was printed using a resin 3D printer. The bands were placed and the single aligner appliance was fabricated on this model. Before placing the aligner appliance, interproximal reduction (IPR) was performed manually using an abrasive strip, which varied depending on the case planning. The amount of IPR was determined using an IPR Gauge (Ortho Technology Inc, West Columbia, USA). The molars were then fitted with bands and cemented using GIC (Ivoclar Vivadent, Enderby, UK). The aligner appliance was subsequently placed. The force applied during the procedure was measured using an intraoral orthodontic force gauge (DTC Medical Apparatus CO, Hangzhou, China) and adjusted to a maximum of 80 grams per side, based on the specific needs of each case (Figure 2).

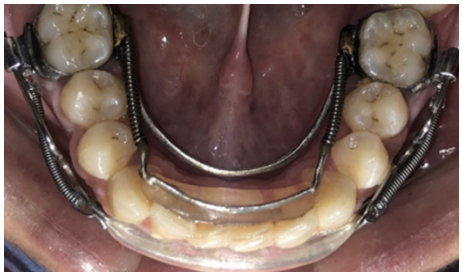

Figure 2. *The applied appliance in the experimental group.*

In the conventional orthodontic appliance (control group), 18 patients were treated using a traditional edgewise with the MBT prescription, 0.022-inch slot (Master Series, American Orthodontics, Sheboygan, USA). The archwire sequence used in this group was as follows: 0.012-inch nickel-titanium (NiTi), 0.014-inch NiTi, 0.016-inch NiTi, 0.016 × 0.022-inch NiTi, 0.016 × 0.022-inch stainless steel (SS), and 0.017 × 0.025-inch SS. Interproximal reduction (IPR) was performed in the same manner as described in the experimental group.

The visual confirmation of the completion of alignment for both groups was done using Little's Irregularity Index (LII) [12], which

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indicated an equality of zero (Figure 3).

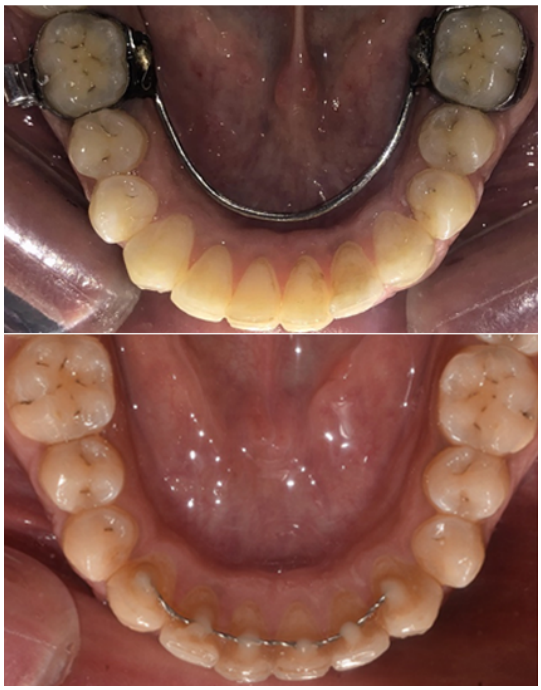

Figure 3. *End of the lower incisor alignment stage.*

Outcome Measures

Little's Irregularity Index (LII) was the measure used to assess the outcome in this study. The LII was measured on study models at multiple time points: before treatment (T0), after 2 weeks of treatment (T1), after 4 weeks (T2), after 6 weeks (T3), and after 8 weeks (T4). The measurements were conducted using a digital caliper (Insize, Insize Co, China) with a precision of 0.1 mm. The methodology for measuring LII followed Little's guidelines [12].

Statistical analysis

The statistical analysis of the search results was conducted using SPSS software (version 26.0, IBM Corp, Armonk, NY). The Shapiro-Wilk test was used to assess the normality of the data distribution, and it indicated that the distribution was normal. Therefore, parametric tests were employed. The independent t-Test was utilized to identify significant differences in the mean values of the Little Irregularity Index between the two groups at each time point. Additionally, the paired t-test was used to detect significant differences within each group. The statistical significance level was set at 0.05 with a 95% confidence interval.

Results

CONSORT guideline shows the flowchart of the patients throughout the trial (Figure 4). A total of 36 patients (7 males, 29 females) were included in the study and divided into two groups of 18 participants. There were no dropouts or withdrawals during any stage of the trial.

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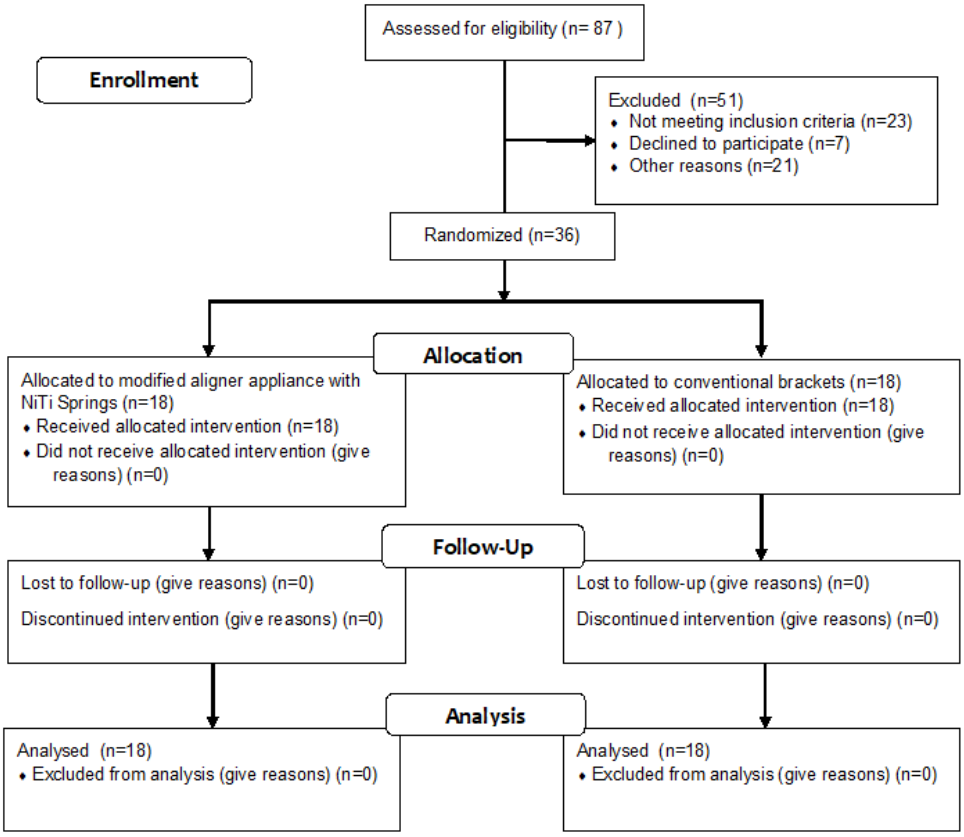

Figure 4. *CONSORT flow diagram*

The enrollment of participants in this study included a total of 36 patients, as shown in Table 1 which presents the basic characteristics of the sample. Table 2 provides the descriptive statistics for the variables that were evaluated in the study.

The findings regarding changes in LII at different time points are presented in Table 3. There were no significant differences between the two groups at T0, T1, T3, and T4 (P = 0.994, P=0.095, P=0.060, P=0.191, respectively). However, a significant difference was found at T2 (P=0.037).

Table 4 shows that there are statistically significant differences in the mean values of LII between the five studied time periods within each group (P<0.001).

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Table 1: Basic sample characteristics

Group	Mean Age ±SD	Min. Age	Max. Age	P value*	Gender n (%)	P value†
Experimental	22.56 ± 3.50	18	28	0.130	Male 3 (16.7)	0.674
					Female 15 (83.3)	
Control	20.89 ± 2.90	17	28		Male 4 (22.2)	
					Female 14 (77. 8)	
Total	21.72 ± 3.28	17	28		Male 7 (19.4)	
					Female 29 (80.6)	

*: employing independent t-test, Min: minimum, Max: maximum, †: employing chi-square test

Table 2: Descriptive statistics of Little's irregularity index values (mm) in the two groups.

Variable	Group	Mean	SD	Min	Max	Q1	Median	Q3
LIIT0	Experimental	3.10	0.68	2	4	2.32	3.38	3.58
	Control	3.09	0.68	2	4	2.5	3.08	3.77
LIIT1	Experimental	1.88	0.56	1	2.70	1.27	2	2.24
	Control	2.23	0.66	1.23	3.33	1.65	2.15	2.78
LIIT2	Experimental	1.01	0.51	0.22	1.90	0.58	1.06	1.41
	Control	1.40	0.54	0.67	1.70	0.91	1.30	1.91
LIIT3	Experimental	0.37	0.33	0	1	0	0.35	0.68
	Control	0.63	0.46	0	1.45	0.19	0.60	1
LIIT4	Experimental	0.10	0.17	0	0.56	0	0	0.21
	Control	0.18	0.19	0	0.57	0	0.19	0.36

LIIT0: Little's irregularity index before treatment; LIIT1: after 2 weeks of treatment; LIIT2: after 4 weeks; LIIT3: after 6 weeks; LIIT4: after 8 weeks; SD: Standard Deviation; Min: minimum; Max: maximum, Q1: first quartile; Q3: third quartile.

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Table 3: The results of the observed LII changes between two groups (in mm)†.

Little's Irregularity Index	Group	Mean (SD)	Mean Difference	95% CI of the difference		P-value
				Lower Bound	Upper Bound	
Before treatment	Experimental	3.10 (0.68)	0.001	-0.46	0.46	0.994
	Control	3.09 (0.68)				
At 2 weeks	Experimental	1.88 (0.56)	-0.35	-0.77	0.06	0.095
	Control	2.23 (0.66)				
At 4 weeks	Experimental	1.01 (0.51)	-0.38	-0.74	-0.02	0.037*
	Control	1.40 (0.54)				
At 6 weeks	Experimental	0.37 (0.33)	-0.26	-0.53	0.01	0.060
	Control	0.63 (0.46)				
At 8 weeks	Experimental	0.10 (0.17)	-0.08	-0.20	0.04	0.191
	Control	0.18 (0.19)				

†: Independent t-test, *: significant at P<0.05; SD: Standard Deviation.

Table 4: The results of the observed LII changes within each group †.

Group	Time period	Mean Difference	t	P-value
Experimental	LIIT0- LIIT1	1.21	25.51	<0.001**
	LIIT1- LIIT2	0.86	17.99	<0.001**
	LIIT2- LIIT3	0.64	11.37	<0.001**
	LIIT3- LIIT4	0.27	5.54	<0.001**
	LIIT0- LIIT4	2.99	21.60	<0.001**
Control	LIIT0- LIIT1	0.86	24.61	<0.001**
	LIIT1- LIIT2	0.83	21.84	<0.001**
	LIIT2- LIIT3	0.76	24.04	<0.001**
	LIIT3- LIIT4	0.45	6.84	<0.001**
	LIIT0- LIIT4	2.91	23.25	<0.001**

†: Paired t-test, *: significant at P<0.05,**: significant at P<0.001; LIIT0: Little's irregularity index before treatment; LIIT1: after 2 weeks of treatment; LIIT2: after 4 weeks; LIIT3: after 6 weeks; LIIT4: after 8 weeks; SD: Standard Deviation.

Discussion

As far as we know, this research is the initial randomized controlled trial to assess the acceleration impact of using a modified single aligner appliance with nickel-titanium springs to align mildly crowded lower incisors.

This study is a well-controlled clinical trial with a parallel-group design, and a simple computerized randomization method was used to allocate participants to the two groups to avoid bias in patient selection. It was not possible to blind the researcher and patients during the evaluation period due to the researcher's involvement in the application and periodic monitoring of the orthodontic appliances. However, the researcher was blinded during the plaster cast study phase and measurements were performed by another academic physician who had no connection to the research in

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order to avoid bias in the investigation.

In order to prevent the oversight of important changes, the assessment was performed every two weeks throughout the duration of the treatment to accurately monitor progress. To avoid discrepancies in metabolic rate across various age groups, participants between the ages of 16 and 28 were chosen for the study. The experimental group had an average age of 22.56 ±3.50 years, while the control group had an average age of 20.89 ±2.90 years [13]. The majority of participants in this study were women, aligning with previous studies that women are more likely to seek orthodontic treatment as adults [14, 15].

Digital dental scanning was relied upon to obtain a digital model as it is an accurate and proven effective method [16, 17]. Additionally, the device was manufactured based on a 3D printed resin model, which studies have shown to provide clinically acceptable results [17, 18]. The NiTi springs were activated using a force of 80 g on both sides because each tooth requires a force between 35 and 60 g to create a tipping motion [19]. Specifically, a force of 40 g was applied to each incisor, resulting in a total force of 160 g (80 g on each side). In order to ensure accurate results, a fixed type of appliance was utilized in this research, which eliminates the reliance on patient compliance. It has been established in previous studies that achieving optimal treatment outcomes with removable appliances is contingent upon patient compliance [20, 21].

The researchers used LII as a method to measure the progress in alignment because it is a reliable and widely accepted way to accurately measure the difference in length of the front arch. This method has been proven to be consistent and trustworthy in previous studies [22].

The study results showed that the average values of Little's index were lower in the experimental treatment group compared to the control group. This can be explained by the difference in the application of force between the two appliances, as the point of force application in the traditional fixed orthodontic appliance is towards the buccal side from the center of resistance [23], while it is towards the lingual side in the application of the aligner appliance. This means that it is closer to the center of resistance of the anterior teeth, which may affect the speed of alignment of the lower incisors as in the lingual orthodontic technique [24]. However, this slight difference is not clinically or statistically significant at all evaluation times except at T2 (P=0.037). This can also be attributed to the magnitude of force applied at the beginning of treatment, as the forces applied in the aligner appliance are calibrated and consistent, while these forces were random and unmeasurable in the control group [25]. Therefore, the forces in the aligner appliance gradually dissipate as the treatment progresses and crowding is resolved, which explains the absence of differences in subsequent stages. No study has evaluated the alignment of anterior teeth using any type of spring appliance, and the difference in this current study from other studies limits the possibility of comparison with them [11].

The findings showed a significant difference in the value of the LII between the five time periods studied within both groups (P<0.001). This means that the value of this index decreased significantly as the lower anterior teeth were aligned in both groups. This difference was not due to any problem in the progress of treatment in any of the studied time periods.

The application of the single aligner appliance modified with nickel-titanium coils within the lower anterior dental arch was the main limitation of the current study.

Conclusion

The clinical use of a modified aligner appliance with nickel-titanium coils effectively resolves lower incisors crowding, but it does not accelerate the alignment process compared to the conventional fixed orthodontic appliance.

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