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Research Article

The Evaluation of the Pain-Relief Effect of Mechanical Vibration in Conventional Fixed and Clear Aligner Treatments

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Abstract

Background: The aim of this study was to investigate the effects of vibration on pain caused by fixed orthodontic and aligner treatments.

Materials and Methods: 80 patients with 3-6-mm maxillary dental crowding and a non-extraction treatment plan were included in the study. The patients were allocated randomly into four groups, with ten females and ten males in each. The groups were titled: (1) Fixed Control Group (FCG), (2) Fixed Vibration Group (FVG), (3) Aligner Control Group (ACG), and (4) Aligner Vibration Group (AVG). In the FCG and FVG groups, treatment was initiated in the maxillary arch with a 0.018 × 0.025-inch pre-adjusted edgewise appliance and a 0.014-inch round nickel-titanium archwire. In the ACG and AVG groups, treatment was started in the maxillary dental arch with polyurethane aligners. In the FVG and AVG groups, vibration was applied three times with 20 minutes per season: immediately, 24 hours, and 48 hours after the initiation of the treatment. Pain scores were measured by the visual analog scale during the first seven days of treatments.

Results: The pain score of the FVG at the sixth hour was statistically significantly lower than the pain score of the FCG. No statistically significant differences were detected at the remaining time points of the fixed treatment groups, nor at any time point between the aligner groups.

Conclusions: Mechanical vibration was not found to have a clinically significant pain-relief effect on the pain that occurred in fixed orthodontic treatment, nor in aligner treatment.

Keywords: Aligner Treatment; Fixed Orthodontic Treatment; Pain; Vibration

Introduction

Patients are often concerned about sensations of pain and discomfort prior to fixed orthodontic treatment. In the first seven days of fixed treatment, 80%-95% of orthodontic patients report feeling these sensations [1-3]. Even if they decrease significantly with time, many patients avoid undergoing orthodontic treatment due to this concern. Pain can deteriorate patients' compliance and oral hygiene during their treatment, and can cause them to miss appointments [4]. Rarely, pain and discomfort even cause patients to discontinue their treatment [5].

With the introduction of Invisalign aligners (Align Technology, Santa Clara, Calif) in 1997, clear aligners have gained popularity in the market and are preferred by patients who are concerned with esthetics. Pain occurs in clear aligners just as in fixed orthodontic treatment; however, the amount of pain is controversial in the literature. It was reported that adults treated with aligners experienced less pain than subjects treated with fixed appliances during the first week of treatment [6]. In a study that compared labial, lingual, and aligner techniques, it was shown that pain was greater in patients treated with aligners than with fixed labial braces [7]. Fujiyama., *et al*. stated that aligners may cause less pain compared to fixed therapy during the initial stages of treatment [8]. However, variables that would affect the perception of pain, such as gender and pain threshold, were not considered in any of these studies.

To date, nonsteroidal anti-inflammatory drugs (NSAIDs), chewing gum, plastic wafer, transcutaneous electrical nerve stimulation, vibrational devices, and low-level lasers have been assessed as methods of alleviating orthodontic pain [9]. Although the most effective of these methods is NSAIDs, non-pharmacological methods have become prominent in recent years. This is due to some drugs preventing orthodontic tooth movement and causing systemic health problems, such as allergies, bleeding disorders, gastric and duodenal ulceration, renal insufficiency, asthma, congestive heart problems, hypertension, and atherosclerosis [10]. The theory that

vibratory stimulation-a method renowned for alleviating musculoskeletal pain-might relieve orthodontic pain, was first introduced by Marie*., et al*. [11,12]. However, there is no current consensus on the usefulness of the method for alleviating orthodontic pain. Although there are studies reporting that it is successful, there are also studies showing that it does not work [11,13,14].

The objective of this study was to evaluate the pain-relief efficiency of vibrational stimulation in fixed orthodontic and clear aligner treatments.

Materials and Methods

Patients who applied for orthodontic treatment were subjected to inclusion and exclusion criteria, and subjects who met the standards were included in the study. The inclusion criteria were as follows: 1-) 3-6 mm maxillary dental crowding, 2-) Nonextraction fixed treatment modality, 3-) Being in the age range of 14-19, 4-) Healthy teeth and gum, 5-) Permanent dentition. The exclusion criteria were as follows: 1-) Chronic usage of analgesic drugs, 2-) Unerupted tooth, 3-) Using transpalatal arch, miniscrew, or headgear as a component of treatment, 4-) Medical history.

A total of 80 patients were selected and they were allocated randomly into four groups, including 20 patients (ten females and ten males) in each group: aligner control group (ACG), aligner vibration group (AVG), fixed control group (FCG), and fixed vibration group (FVG). Randomization was carried out with red and blue raffle boxes, which were separate for male and female participants.

In FCG and FVG, treatments were started on the maxillary dental arch with a 0.018 × 0.025-inch pre-adjusted edgewise appliance (Mini Master, American Orthodontics, Sheboygan, Wisconsin). As an initial archwire, 0.014-inch round nickel-titanium archwire (TP Orthodontics, Inc. La Porte, Indiana) was engaged with elastomeric ties. Appliances such as miniscrew, transpalatal arch, headgear, and molar band were not used due to their potential to be a source of pain. The patients were given oral hygiene instructions and were advised to avoid taking analgesic medication.

In ACG and AVG, treatments were started on the maxillary dental arch with polyurethane aligners manufactured after taking polyvinyl siloxane impressions. Subjects were instructed to wear their aligners for a minimum of 20 hours per day. Treatments on the mandibular arch were not started as in fixed treatment groups. The patients were given oral hygiene instructions and were advised to avoid taking analgesic medication.

For the intervention groups (FVG and AVG), vibrational stimulation was applied three times: immediately, 24 hours, and 48 hours after the start of the treatments. Each season was 20 minutes, and the total application duration per patient was 60 minutes. The vibration device was operated with parameters of 111 Hz and 0.06 N. Applications were done under supervision in the clinic.

For the control groups (FCG and ACG), no additional application aside from the routine treatments was carried out.

The subjects' perceptions of pain were measured with the Visual Analog Scale (VAS) at 6-time points: 2nd hour, 6th hour, 1st day, 2nd day, 3rd day, and 7th day of their treatments. Patients were instructed on how they should mark the 10-cm VAS forms; zero and ten indicated no pain and intolerable pain, respectively. Prior to measurements, subjects were asked to tap their teeth ten times and apply pressure by the thumb.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Science (SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.). The Kolmogorov-Smirnov test and histogram graphics were utilized in evaluating the distribution of the data. Mann-Whitney U and repeated measures ANOVA tests were used for the statistical analysis. Statistical significance was established for *p*-values less than 0.05.

Results

Pain values of FCG and FVG were compared for all time points. A statistically significant difference was determined at the 6th hour (p = 0.032). At this time point, the pain value of FVG was statistically significantly lower than FCG (Table 1). There were no significant differences at the other time points. When the changes in the values measured from the 2nd hour to the 7th day were compared, no significant difference was found between the two groups (p = 0.397), i.e., the general course of the pain was similar in both groups (Figure 1).

	FCG	FVG	p[1]
	Mean (cm) ± Standard Deviation	Mean (cm) ± Standard Deviation	
2nd hour	1.74 ± 2.39	1.24 ± 1.31	0.891
6th hour	3.98 ± 3.03	2.10 ± 2.13	0.032*
1st day	5.19 ± 2.09	3.91 ± 2.93	0.098
2nd day	4.28 ± 2.26	3.09 ± 2.53	0.132
3rd day	3.41 ± 2.27	2.80 ± 2.39	0.316
7th day	1.28 ± 1.78	0.91 ± 1.31	0.296

Table 1: Comparison of the FCG and FVG groups in terms of VAS scores.

[1]Mann-Whitney U Test.*Significant at p < 0.05.

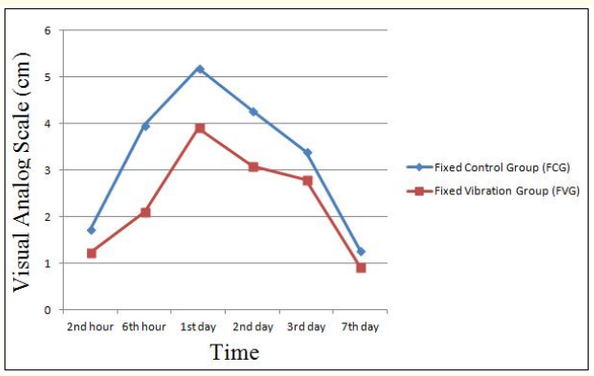

Figure 1: The general course of pain in fixed treatment groups.

Pain values of ACG and AVG were compared for all time points. There were no significant differences between the groups at any time point (Table 2). When the changes in the values measured from the 2nd hour to the 7th day were compared, there was no significant difference between the two groups (p = 0.061). The general progression of the pain was similar in both groups (Figure 2).

	ACG	AVG	p[1]
	Mean (cm) ± Standard Deviation	Mean (cm) ± Standard Deviation	
2nd hour	0.59 ± 0.99	0.35 ± 0.86	0.204
6th hour	1.51 ± 1.43	1.57 ± 1.66	0.869
1st day	2.50 ± 2.08	1.43 ± 1.10	0.088
2nd day	1.96 ± 1.68	1.23 ± 1.34	0.068
3rd day	1.50 ± 1.16	1.15 ± 1.51	0.168
7th day	0.60 ± 0.79	0.95 ± 1.61	0.859

Table 2: Comparison of the ACG and AVG groups in terms of VAS scores.

[1]Mann-Whitney U Test, *Significant at p < 0.05.

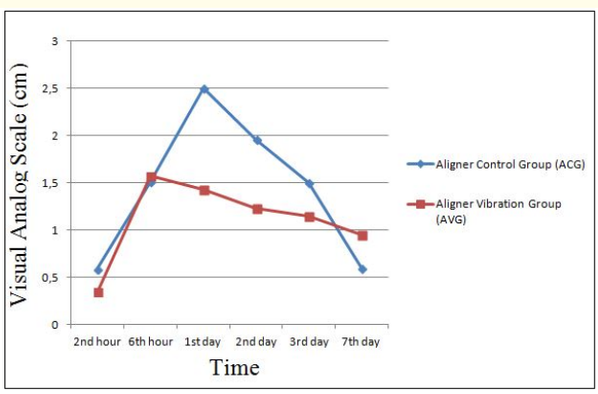

Figure 2: The general course of pain in aligner treatment groups.

The differences between the pain values of FCG and FVG and that of ACG and AVG were compared. The difference between the pain values of FCG and FVG was statistically higher at the 6th hour compared to that of ACG and AVG. No significant differences were found at the other time points (Table 3).

	FCG-FVG	ACG-AVG	p[1]
	Mean (cm) ± Standard Deviation	Mean (cm) ± Standard Deviation	
2nd hour	0.50 ± 2.55	0.24 ± 1.41	0.956
6th hour	1.87 ± 3.23	-0.06 ± 1.82	0.013*
1st day	1.27 ± 3.37	1.07 ± 2.26	0.892
2nd day	1.19 ± 3.65	0.74 ± 2.02	0.464
3rd day	0.61 ± 3.49	0.35 ± 1.75	0.914
7th day	0.36 ± 2.43	-0.35 ± 1.60	0.485

Table 3: Comparison of the differences between the FCG and FVG groups' VAS scores and the differences between the ACG and AVG groups' VAS scores.

[1]Mann-Whitney U Test, *Significant at p < 0.05

Discussion

Pain is a subjective phenomenon, and it is extremely hard to document objectively. It is also significantly affected by many individual variations, such as age, gender, applied force amount, and cultural differences [9]. Therefore, the method of forming the groups and the reliability of the results can be a subject of contradiction in pain studies. In this study, particular attention was paid to the forming method of the groups, and individual variable differences among the groups were tried to be minimized. An equal number of female and male participants were included in the groups, and gender equality was ensured among the groups. In addition, 3-6 mm maxillary crowding was determined as an inclusion criterion, so the amount of force to be applied during the treatment was also tried to be equalized among the groups. VAS was preferred as the measurement method because VAS provides (1) the freedom to choose the exact intensity of pain and (2) a maximum opportunity for pain expression in an individual style [9]. Besides, it has been utilized widely in orthodontic pain studies [1,2,10].

In this study, it was detected that vibration had a statistically significant effect on the pain that occurred at the 6th hour in the fixed orthodontic treatment groups. At other time points, there was no such effect of vibration on pain (Table 1). In both groups, the pain detected at the 2nd hour reached its highest point on the 1st day and then gradually decreased. There was no statistically significant difference between the two groups in the general course of pain (p = 0.397).

The results in the literature are not consistent with each other regarding the pain-relief effect of vibration in fixed orthodontic

treatment. Lobre., *et al*. investigated pain control in orthodontics using a micropulse vibration device [15]. They have concluded that the micropulse vibration device significantly lowered the pain scores for overall and biting pain. Marie., *et al*. suggested vibration as a pain relief method in fixed orthodontic treatment [11]. However, Taha., *et al*. found no statistically significant differences in pain perceptions between the vibration and control groups [16]. Woodhouse et al. stated that vibrational force did not reduce pain experience during initial alignment with fixed orthodontic appliances [17]. Similarly, Miles., *et al*. demonstrated that there appears to be no clinical advantage in using the vibrational appliance for the alleviation of pain during initial alignment [13].

We think that this contradiction in the literature is due to the methodological differences of the studies and the fact that the individual variations of the participants were not considered while creating the groups. In a review article, Bakdach., *et al*. stated that it is difficult to answer the question of whether vibration alleviates orthodontic pain or not with existing literature. They related this situation to multiple shortcomings of the research articles [18]. Similarly, Jing et al. stated that the effect of vibration on pain intensity is inconclusive, and high-quality clinical trials are needed before warranting recommendations to clinical applications [19]. In some of the studies in the literature, even the most basic criteria such as the amount of crowding and gender distribution were not taken into account when forming the groups [15-17]. These shortcomings negatively affect the reliability of the study results and prevent the clarification of the topic. We think that our study provides reliable data for the literature by eliminating the deficiencies of other studies.

In the aligner groups, a pain-relieving effect of vibration was not detected at any time point (Table 2). Moreover, the mean scores in the vibration group (AVG) were higher than the control group (ACG) at the 6th hour and the 7th day. Although we could not detect a significant statistical difference in fixed treatment groups except the sixth hour, at least, the scores in the vibration group (FVG) were lower than the control group (FCG) at all time points. Unfortunately, there are not enough publications in the literature that examine the effect of vibration in aligner therapy. To our knowledge, just one study is available in the literature [20]. In that study, Katchooi et al. found that vibration had no significant effect on the reduction of orthodontic pain when used with aligner therapy. Similarly, it has been revealed in this study that vibration has no relieving effect on pain occurring during aligner treatment.

The idea that vibration can be used in accelerating orthodontic treatment and relieving pain has become the subject of many studies in recent years [15,16,20,21]. Vibration devices with high costs (The AcceleDent device, OrthoAccel Technologies, Inc. Houston, Texas) were also offered with various promises for sale in the market. Even though nearly 20 years have passed since the date it was first introduced in orthodontics [11], it is still unclear whether vibration can help in accelerating tooth movement and relieving pain. We think that this ambiguous situation is due to the following reason: Vibration has a positive effect on both acceleration of tooth movement and pain, but this is not large enough to make a clinical difference. This effect still encourages researchers to study this issue. Unfortunately, since this effect is rather weak, they cannot present strong evidence that this method works.

In our study, VAS, which is one of the subjective methods, was used as the pain measurement technique. This situation can be expressed as a limitation of the study. In fact, we had to use this technique because today there is still no method to measure pain objectively. Various biochemical substances, such as substance P and interleukins, could be analyzed in the gingival crevicular fluid and the outcomes could be strengthened. However, we did not want to use this method because there is no consensus in the literature that there is a relationship between orthodontic pain and these substances [22-24]. In addition, the content of the gingival crevicular fluid is affected by mechanical irritation. When the aligner is placed in the mouth, it contacts the palatal gingiva. Due to mechanical irritation caused by the contact, the content of the gingival crevicular fluid could change, and we could have misleading results. Therefore, this method was not preferred.

Conclusions

The outcomes of the study can be summarized as follows:

- When the data of the fixed treatment groups were examined, the average VAS scores of the vibration group were lower than that of the control group at all time points. However, a statistical difference was detected only at the 6th hour.
- In the aligner groups, the mean VAS scores at the 6th hour and on the 7th day were higher in the vibration group (AVG) as compared to the control group (ACG). However, no statistically significant difference was detected at any time point.
- Clinically significant pain-relief effect of vibration has not been detected in either fixed orthodontic treatment or alignment therapy.

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