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Comparison of pain perception caused by aligner and conventional fixed orthodontic treatments

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ABSTRACT

Objectives: The aim of this study was to compare the pain perceived in fixed orthodontic and aligner treatments during the first seven days of treatment.
Materials and Methods: Forty patients who had 3–6 mm maxillary dental crowding and a non-extraction treatment plan were included in this study. The subjects were randomly divided into two groups: the fixed orthodontic group and the aligner group, with ten females and ten males in each. In the fixed orthodontic group, treatment was started with 0.014-inch round nickel-titanium archwire, and a 0.018×0.025-inch preadjusted edgewise appliance was used. In the aligner group, treatment was started with a polyurethane aligner. Throughout the study, teeth in the upper jaw were treated in both groups. The pain scores of the subjects were measured with the visual analog scale at the second and sixth hours and on the first, second, third, and seventh days of treatment.
Results: The pain scores of the fixed orthodontic group were significantly higher than those of the aligner group at the sixth hour, on the first, second, and third day. The differences at the second hour and on the seventh day were not statistically significant.
Conclusions: According to the study outcomes, less pain was felt during the aligner treatment compared to the fixed orthodontic treatment. However, it should be considered that the force activation interval is shorter in the aligner treatment, and the cumulative pain score may be higher.

1. Introduction

The visibility of appliances is one of the major concerns reported by orthodontic patients.[1] Even though the desire for orthodontic treatment has increased, many patients are still not willing to be treated because of the appliances' appearance. However, advances in orthodontics have made it possible to treat patients with less visible appliances. Products such as ceramic brackets, coated esthetic archwires, lingual fixed systems, and aligners have been designed to meet this demand.

The popularity of aligners has been increasing since their introduction to clinical use in the early 2000s.[2] Patients have shown a growing interest in these appliances due to their advantages such as esthetics, comfort, and hygiene. Females, especially 20–30 years of age, prefer aligners over the labial and lingual appliances due to aesthetic and functional reasons.[3,4] Aligners are significantly more comfortable compared to the lingual fixed appliances that have similar esthetic advantages. In a recent study that investigated patients' adjustability to the three treatment options (labial, lingual, and aligner), it was shown that lingual appliances caused more pain, higher analgesic consumption, the greatest oral dysfunction, and the longest and most difficult recovery.[5]

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Polyethylene Terephthalate Glycol (PETG), Polycarbonate (PC), and Thermoplastic Polyurethane (TPU) are the materials frequently used in the production of aligners.[6] These materials have different physical properties. PETG, a non-crystalline amorphous co-polymer of Polyethylene Terephthalate (PET), exhibits high fatigue resistance, dimensional stability, and solvent resistance. PC has high mechanical strength, low water absorption, and transparency.[7] TPU exhibits good physical properties such as chemical resistance, abrasion resistance, adhesion properties, and ease of processing. There are aligner brands produced from different types of materials in the market such as Invisalign, Duran, Biolon, Zendura, Erkodur, Kombiplast, Imprelon, ClearCorrect, Erkoflex 95, Erkoloc pro, etc.[6]

Pain and discomfort are often the primary complaints experienced and reported by patients during orthodontic treatment. Studies have revealed that between 80% and 95% of patients experience pain during the treatment process.[8–10] Furthermore, it has been reported that pain is the most disliked aspect of orthodontic treatment and ranked fourth among the major fears and apprehensions, prior to treatment.[1] Pain reduces patient cooperation, causing a deterioration in oral hygiene, as well as missed appointments.[11] Its influence on daily life is one of the main reasons for discontinued orthodontic treatments.[12] There are many studies to elucidate the pain pattern triggered by labial fixed systems.[10–13] According to these studies, pain starts at the second hour of treatment, it reaches its peak level between the 24th and 36th hour and then gradually decreases and disappears within 5 – 7 days.[10]

There are previous studies evaluating and comparing the pain levels that occurred with the use of aligners and fixed appliances in the literature.[5,14–20] The results of these studies are partially controversial. Some of these studies reported that aligners caused less pain and discomfort during treatment.[14–17] However, there are also studies reporting relatively high levels of pain in the aligner group, or at least no difference between the groups in the first days after insertion.[5,20]

The aim of this study was to evaluate and compare the aligner and fixed labial appliances in terms of pain that occurred during the first seven days of treatment. While designing the study, the limitations of previous studies were taken into consideration.

2. Materials and Methods

This study was approved by the Clinical Research Ethics Committee of the ————————. Patients who applied to the department of orthodontics and met the inclusion and exclusion criteria (Table 1) were selected for the study. Informed consent forms were signed by the patients and their parents, if they agreed to participate, they were included in the study.

Based on the previously reported effect size for pain, power analysis showed that 16 patients were necessary per group for an alpha of 0.05 and a power of 95%.[16] A total of 40 patients (20 females, 20 males) were included in the study. In line with the country's health policies, the treatment fees of a significant portion of orthodontic patients under the age of 18 are covered by the public insurance institution. Therefore, there was no remarkable difference for the patients in terms of cost in both treatment modalities. Patients who insisted on one of the treatments were not included in the study. They were randomly allocated into the aligner (20 subjects) and fixed appliance (20 subjects) groups in such a way that the groups would have equal gender distribution (10 females, 10 males). Randomization was carried out with red and blue raffle boxes, which were separate for male and female participants. Male subjects used a blue raffle box and female subjects used a red raffle box, so the groups were equal in terms of sex (Figure 1).

In the fixed appliance group, treatment was started with a 0.018 × 0.025-inch Roth prescription appliance (Mini Master, American Orthodontics, Sheboygan, Wisconsin). The appliance was placed on the maxillary dental arch from the left first molar to the right first molar. A 0.014-inch round nickel-titanium archwire (ODP Inc.; Vista, CA) was engaged with the aid of elastomeric ties and cut at the end of the first molar bondable tube without performing cinch back. Applications such as a molar band, a transpalatal arch, headgear, and mini screws that could be a source of pain and affect the study results were avoided. The patients were given oral hygiene training and were asked to stay away from painkillers if they felt any pain.

In the aligner group, polyvinyl siloxane impressions of the lower and upper dental arches, cephalometric radiographs and intra- and extra-oral photographs were obtained at the initial appointment. Diagnostic materials were sent to the manufacturer, and removable thermoplastic polyurethane aligners were fabricated. Only the upper teeth were included in the study, and the treatment of the lower teeth was not processed during the study period. The planning of the aligner treatment process was carried out in cooperation with the manufacturer, in line with the instructions of the orthodontist. It was planned to achieve 0.5 mm tooth movement with each aligner in the leveling phase and change the aligner every two weeks. All composite attachments belonging to the upper arch were placed at the aligner delivery appointment. The upper aligners were given to the patients and they were instructed to wear them for 22 hours per day, removing them only at mealtimes and for oral hygiene.

For both groups, the pain experienced in the first seven days of the treatment was measured by using a 10-cm visual analogue scale (VAS). Patients were instructed on how to record their pain by using a VAS diary containing six forms for six different times: the second hour, the sixth hour, the

twenty-fourth hour, the second day, the third day and the seventh day. They were requested to tap their teeth ten times by using jaw movements and applying pressure with the thumb before each measurement. Subsequently, they were asked to mark 10-cm VAS form which indicates that 0 represents no pain and 10 represents intolerable pain.

2.1. Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.). The distribution of the data was evaluated by using The Kolmogorov–Smirnov test and histogram graphics. Mann-Whitney U and Repeated Measures ANOVA tests were used for the statistical analysis. The p-values less than 0.05 were accepted as statistically significant.

Table 1: Inclusion and exclusion criteria

Inclusion Criteria
3-6 mm maxillary dental crowding
Nonextraction fixed treatment modality
Being in the age range of 14-19
Healthy teeth and gum
Permanent dentition
Exclusion criteria
Chronic usage of analgesic drugs
Unerupted tooth
Using transpalatal arch, miniscrew, or headgear as a component of treatment
Medical history

Table 2: Comparison of the fixed treatment andaliner groups in terms of VAS scores

	Fixed Treatment Group	**Aligner Group**	**p**[1]
	Mean (cm)±Standard Deviation	**Mean (cm)±Standard Deviation**	
2nd hour	1.74±2.39	0.59±0.99	0.050
6th hour	3.98±3.03	1.51±1.43	0.005*
1st day	5.19±2.09	2.50±2.08	0.000*
2nd day	4.28±2.26	1.96±1.68	0.001*
3rd day	3.41±2.27	1.50±1.16	0.003*
7th day	1.28±1.78	0.60±0.79	0.108

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

3. Results

The pain scores of the fixed treatment group and the aligner group were compared across all time points. Statistically significant differences were determined at the time points of the sixth hour, the first day, the second day, and the third day. For all of these times, the pain scores of the aligner group were statistically lower. There was no significant difference between the groups at the second hour and on the seventh day (Table 2).

The highest pain levels were found at the 24th hour in both groups. When the changes in the scores measured from the second hour to the seventh day between the fixed treatment and aligner groups were compared, no significant difference was found. The general course of pain was similar in both groups. The pain detected at the second hour increased and reached the highest level at the 24th hour, then gradually decreased and descended to quite low levels towards the seventh day (Figure 2).

4. Discussion

In recent years, the demand for aligner therapy has increased exponentially due to patients' aesthetic concerns, and this situation has opened up a new area that needs to be examined in orthodontic literature. Companies manufacturing in this field are trying to increase the popularity of aligner treatment with various claims, for example, that they are providing a faster and more comfortable treatment process. However, these claims do not have sufficient evidence because there are few studies in the literature, and the results of the existing publications are inconsistent with each other.[5,14–20] We think that there are two main reasons for this contradiction. The first one is that the studies are methodologically different from each other when considering factors such as patient selection criteria, measurement methodology and treatment materials. In a systematic review that investigated the pain level between aligners and fixed appliances, this issue was criticized, and it was stated that there was a high level of heterogeneity in the design of the studies.[21]

The second one is that the individual variations of the participants were not considered while forming the groups in these studies. Pain is a subjective phenomenon and is greatly influenced by individual variations such as age, gender, the amount of dental crowding, the pain threshold, the emotional status of the participant, cultural differences and previous experiences of pain.[13,22,23] There is a positive correlation between the amount of applied force caused by dental crowding and the amount of pain experienced.[24] For instance, Fujiyama et al. compared the pain levels in cases treated with aligner and fixed edgewise appliance therapy.[15] They did not take into account the amount of dental crowding in designing the groups, and they simply said that they did not include complex or surgery cases in the study. However, sometimes the patient with excessive dental crowding can be a simple case or vice versa. Similarly, gender was not considered in some of these studies.[15,16,18] In the White et al.'s study, while there were 11 males and 12 females in the aligner group, the fixed appliance group consisted of 6 males and 12 females.[16] However, it has been found that females report more discomfort/pain than males

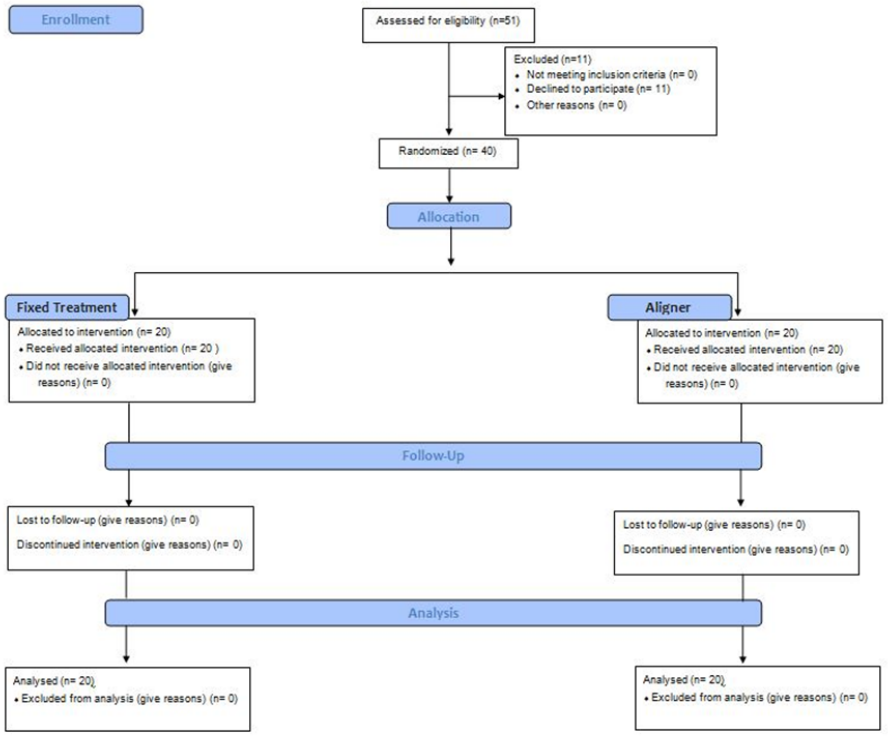

Fig. 1: CONSORT Flow diagram of the study

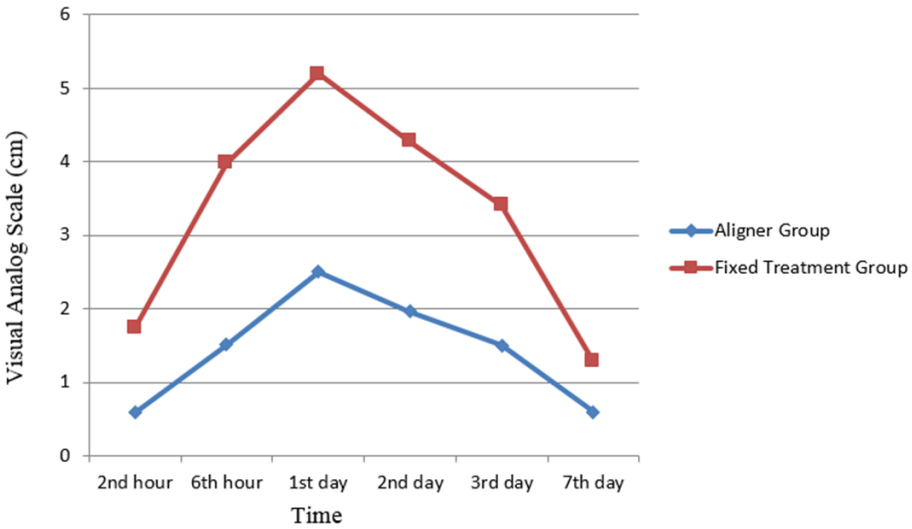

Fig. 2: General pain courses of the groups

during fixed orthodontic treatment.[10]

In this study, the researchers endeavored that the groups were created equal in terms of individual variations, as much as possible. Subjects in a limited age range were included in the study. A 3 – 6 mm maxillary dental crowding and a non-extraction treatment modality were assigned as the inclusion criteria. It was ensured that the groups consisted of an equal number of females and males (10 females, 10 males).

In this study, it was found that there were statistically significant differences between the groups' VAS scores at the sixth hour, on the first day, the second day and the third day. At all these time points, the pain was higher in the fixed treatment group. In the literature, there are publications reporting similar results to ours.[14–16,18,19] Miller et al. reported that patients treated with aligner treatment perceived less pain and experienced fewer negative impacts on their lives during the first week of treatment than did those treated with fixed appliances.[14] Similarly, White et al. stated that patients treated with traditional fixed appliances reported greater discomfort and consumed more analgesics than patients treated with aligners.[16] There are also studies presenting different outcomes.[5,20] Casteluci et al. compared the pain intensity in patients treated with aligners and conventional fixed appliances. They concluded that patients treated with aligners and conventional fixed appliances did not differ significantly concerning the perception of pain.[20] Shalish et al. evaluated the three orthodontic appliances (labial, lingual, and aligner), and they found that the aligner patients complained of relatively high levels of pain in the first days after insertion, compared to the buccal appliance.[5]

We think that the reason for the detection of more pain in the fixed treatment group in the studies is somewhat related to the period of the studies. In fixed orthodontic treatments, appointment intervals are generally between 5 – 8 weeks on average. The clinician engages the archwire into the bracket slot in a way that the effect will last for 5 – 8 weeks and the archwire applies that amount of force. Sometimes at the next appointment, the archwire is not even activated since the archwire is still working. With the aligner treatment, the aligners are changed every two weeks and force activation is performed at shorter intervals. Thus, less force is activated with each aligner change in the aligner treatment, compared to each archwire insertion. There is one point that needs to be highlighted. Since the most intense pain occurs in the first seven days, many previous studies similar to this one, examined only the first week of the treatment and compared this period with the aligner system.[14,17–19] However, three or four aligners are changed during the aligner treatment within a fixed treatment session and the force activation is renewed after each aligner change. Therefore, the cumulative pain experienced during aligner treatment may be more than the pain experienced with fixed orthodontic treatment. Consequently, studies should not be limited to the first seven days, and long-term studies should also be carried out. Unlike other studies, Casteluci et al. compared the pain perceptions caused by conventional fixed and aligner treatments over a period of six months.[20] The cumulative effect was not evaluated in this study either. Nevertheless, they found that there was no significant difference between the groups.

There were no statistically significant differences between the groups at the second hour and on the seventh day. Pain scores at these points were already quite low for both groups. Therefore, a report of no difference is an expected outcome. In both groups, the highest pain was detected at the 24th hour. This finding is consistent with the previous publications in the literature. Many studies on both fixed orthodontic and aligner treatments have reported that pain reaches its highest levels between the 24th and 48th hour.[14,18,25]

5. Conclusions

In this study, the pain perceptions occurring in the first seven days of conventional fixed and aligner treatments were evaluated. The outcomes can be summarized as follows:

1. The pain perceptions at the sixth hour, on the first day, the second day and the third day were statistically higher in the fixed treatment group. At the second hour and on the seventh day, there were no significant differences between the groups.
2. The highest pain level was detected at the 24th hour in both groups.
3. When interpreting the study results, it should be considered that the force activation interval is shorter in the aligner treatment, and the cumulative pain score may be higher.

6. Conflict of Interest

None.

7. Source of Funding

None.

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