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Effect of changing the activation frequency of the arch wires on the pain perception in moderate crowding cases: A randomized controlled clinical trial

Dental Sciences

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Abstract

Purpose: The aim of this study is to compare the pain perception of two different frequencies of archwire activation.

Methodology: 19 patients were divided into 2 groups. In the intervention group the archwire was changed every 6 weeks while in the control group the archwire was changed every 4 weeks. Discomfort score data sheets were delivered to the patients after the orthodontic visit. The patient recorded the discomfort score after 4 hours, 24 hours, 3 days and 7 days.1 score means minimum discomfort while a 7 score means maximum discomfort.

Results: The difference in the discomfort score between both groups was statistically insignificant. **Conclusion:** The discomfort scores between both activation frequency rates showed no significant difference and the pain decreased gradually throughout time in both groups. Trial number registration: ClinicalTrials.gov with an identifier number.

Keywords: Class I crowding, leveling and alignment, discomfort score, archwire sequence

Introduction

Leveling and alignment of teeth is the initial stage of any orthodontic treatment. In this phase, wires are inserted into the bracket slots to align the teeth, starting with the more flexible archwires to allow for the full engagement of the bracket slot. As the teeth become more aligned, the cross-section of the archwires can be increased thus increasing their rigidity ^[1].

Based on a thorough systematic search, it was recommended that archwires should be changed every 4 weeks ^[2-4]. It is worthy to note that the archwires sometimes don't express their full force thus they were re-ligated. Nevertheless, other studies have tested the change of the wire every 6 weeks [5-7].

Patient discomfort arising from the force of the aligning archwires is a factor that should be considered during treatment. The goal must be decreasing the patient's discomfort as much as possible. Studies were done to assess the patient discomfort toward the orthodontic treatment ^[8, 9]. One study compared different archwire sequences and their effect on patient discomfort ^[10]. However, no study compared the effect of increasing the duration of the archwire and its outcome on patient discomfort.

The primary aim of this study was to measure the pain perception in patients having moderate class I crowding with two different archwire activation rates.

Materials and Methods

Study design

This randomized controlled trial is a parallel-group two-armed trial which was conducted following the guidelines of the (CONSORT) [11]. The study protocol was approved by the research ethics committee and was registered at ClinicalTrials.gov with an identifier number.

Patient selection and setting

The study was conducted in the outpatient clinic of the Orthodontic Department, Inclusion criteria: Age from 16 to 24 years old, cervical maturation index stage 6, upper moderate crowding (4-8 mm), no extractions are required, full permanent dentition except for the third molars, good oral hygiene, no systemic diseases, no previous extractions except for the wisdoms and no dental anomalies. Written informed consent was provided prior to enrollment in the study.

Sample size calculation

The sample size calculation was based on the study conducted by Maria de Castro^[3]. Considering dropouts, a sample size of 20 patients was considered appropriate.

Randomization, allocation concealment, and blinding

The randomization was performed with a 1:1 ratio of allocation, the sequence was computer generated. The randomization numbers produced from the sequence generation were sealed in opaque envelope. At the time of intervention, each participant was allowed to choose an envelope from the sealed box. To ensure no bias, (H.O) was contacted, who was not part of the study, to allocate the participants according to the envelope number. Considering the nature of the intervention, patients and investigators could not be blinded during the study. The assessor (neither the main operators nor the supervisors) carried out the discomfort scores measurements blindly.

Interventions

The patients were randomly allocated to one of the two treatment groups: Group 1 (changing the archwire every 6 weeks) and group 2 (changing the archwire every 4 weeks). 0.022×0.028 slot Roth prescription brackets (master series, American orthodontics, USA) were bonded to the maxillary arch. The archwire sequences for both groups were 0.014 Nickel-titanium alloy (NiTi), 0.016, NiTi, 0.018, NiTi and 0.016 x 0.022, NiTi respectively. The wires were engaged in the brackets using Figure 8 ligation of the O-ties, this ligation was used to ensure that the archwire was secured inside the bracket slot (Fig. 1 & 2).

After insertion of the archwire, the patients were instructed to fill a seven-point Likert scale at 4 hours, 24 hours, 3 days and 7 days. The patients were given the discomfort data sheets (Fig. 3) and these sheets were delivered at the next appointment with the scores. 1 score means minimum discomfort, while a 7 score means maximum discomfort.

Statistical analysis was performed with SPSS 20[®], Graph Pad Prism[®] and Microsoft Excel 2016. All quantitative data were explored for normality by using Shapiro Wilk Normality test and presented as means and standard deviation (SD) values.

Tests used

- Shapiro Wilk Normality test for data exploration.
- Mann-Whitney test to compare between 2 groups of nonparametric data (Difference). A P-Value of less than 5% was considered statistically significant.

Results

Total of 35 patients were assessed for eligibility; 15 patients were excluded (10 didn't meet the inclusion criteria while the other 5 declined to participate). 20 patients were randomized equally in both groups. One patient from the intervention group was lost to follow up thus a total of 19 patients completed the trial. A consort diagram showing the flow of

the patients through the study is shown in (Fig.4). The demographic and initial data of both groups are shown in (Table 1).

Mean discomfort scores at different time intervals for each group are shown in Table 2, figure ^[5]. For example, the score at 4 hours for the intervention group indicates the mean discomfort experienced for the whole archwire sequence at 4 hour (0.014, Nickel-titanium alloy (NiTi), 0.016, NiTi, 0.018, NiTi and 0.016 x 0.022, NiTi) and the same is applied at 24 hours, 3 days and 7 days.

Discussion

The patient discomfort scores were measured every 4 hours, 24 hours, 3 days, and 7 days after the insertion of each archwire as instructed by ^[12]. The discomfort scores were done using a Likert scale where 1 meant minimum discomfort and 7 meant severe discomfort. The patients received the data sheets and were instructed to return them filled at the next appointment as done by (Mandall *et al.*, 2006) ^[10].

In this study, there was a rise in the discomfort levels at 4 hours and 24 hours and the scores decreased gradually at 3 days and 7 days. This result was corresponding to the studies conducted by ^[13].

In this study in hand, the difference between the discomfort score between the intervention and control groups was found to be insignificant (P-Value > 0.05). Likewise, Scott *et al.* (2008) measured the discomfort score when using different bracket systems (conventional and self-ligating brackets) and there was no significant difference between both groups, and the discomfort score decreased over time.

Furthermore, there were other studies that measured discomfort rates during leveling and alignment as ^[15] who used a visual analog scale from zero to 10 to express the discomfort levels and it was found that the severity of pain decreases gradually through time.

Conclusion

The discomfort scores between both activation frequency rates showed no significant difference and the pain decreased gradually throughout time in both groups.

List of figures

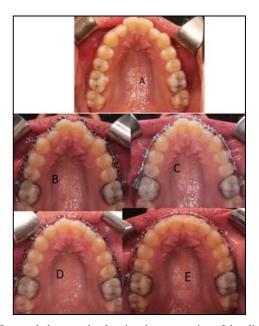


Fig 1: Intraoral photographs showing the progression of the alignment with each month in the intervention group (A = Pretreatment, B = 0.014, NiTi, C = 0.016, NiTi, D = 0.018, NiTi and E = 0.016 x 0.022, NiTi)

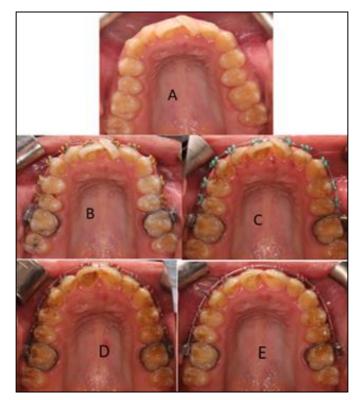


Fig 2: Intraoral photographs showing the progression of the alignment with each month in the control group (A = Pretreatment, B = 0.014, NiTi, C = 0.016, NiTi, D = 0.018, NiTi and E = 0.016 x 0.022, NiTi).

Name of the patient								اسم المريض
1- Determine the Disco	omfort so	:ore aft	er 4 ho	urs fror	n the vi	isit.	من الزيارة	حدد مدی شعور که بالاًم بعد 4 سامات
minimum discomfort آلم طفيف					5			severe discomfort الم حاد
2- Determine the Discomfort score after 24 hours from the visit. مند مدى شعورڭ بالألم بعد 24 ساعة من الزيارة								
minimum discomfort الم طنيف					5			severe discomfort الم حاد
3- Determine the Discomfort score after 3 days from the visit. حدد مدی شعوریاء بالالم بعد 3 أبنام من الزیاری								
minimum discomfort البرطنوف					5			severe discomfort الم حاد
4- Determine the Discomfort score after 7 days from the visit. حدد مدی شعوراک بالالم بعد 7 آیام من الزیاری:								
	1	2	3	3	1 5	ō	67	
minimum discomfort	0						0 0	severe discomfort
ألم طنيف	0							الم حاد

Fig 3: A questionnaire on the discomfort score at 4H, 24H, 3 days and 7 days

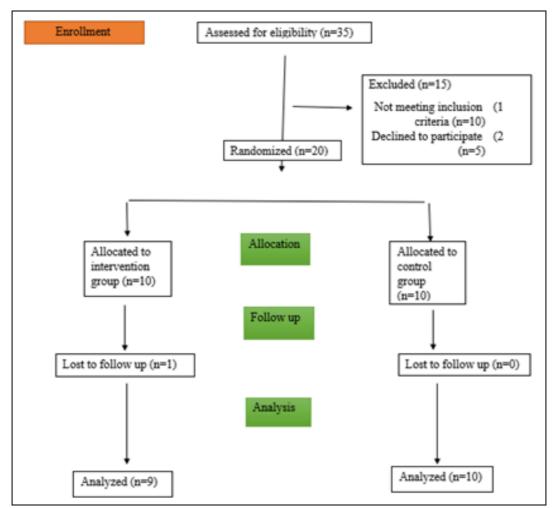


Fig 4: A CONSORT diagram showing diagram showing the flow of the patients through the study

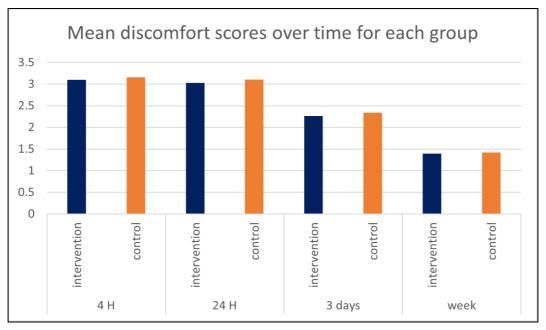


Fig 5: Mean discomfort scores over time for each group

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