

Assessing Pain and Cooperation Levels of Orthodontic Patients Treated with Medium and Heavy Intermaxillary Elastics: a Randomized Clinical Trial

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Abstract

Introduction and Objective: The main objective of the current study was to assess the pain intensity and cooperation level of the patients when using intermaxillary elastics (Class II, Class III, and Box elastic with heavy and medium forces). **Methods and Materials:** 134 patients were randomly assigned into two groups of medium and heavy elastics. The study included measuring the pain and cooperation with heavy and medium forced elastics. The cooperation level was assessed using the questionnaire for cooperation. The severity of the pain was recorded using the visual analog scale (VAS) on the first day (at three intervals of two hours, six hours after receiving elastic and at the end of the night) and one, four and fourteen days after receiving the elastics. **Results:** From 67 patients in each group, 55 patients of the medium group and 57 patients of the heavy group completed the questionnaires. Assessing the effects of the type of elastics, i.e. medium or heavy, on the mean pain intensity at each time interval, showed that while the clinical pain intensity in the group of medium-forced elastic is lower than the other group, this difference is not statistically significant (except on the 4th day, $p=0.018$). Assessing the level of cooperation, showed that there is no significant difference between the two groups of patients. **Conclusion:** The pain intensity was lower in the medium group; but, the difference was not statistically significant. Comparing the pain level among various types of elastics, i.e. Class III, Class II, and the Box elastic, does not reveal a significant difference (except for the 4th and 14th days). The cooperation level was similar in both groups.

Keywords: inter-maxillary elastic, orthodontics treatment, pain, cooperation, heavy force, medium force

INTRODUCTION

Pain can be defined as a mental response to environmental stimuli. It should be noted that individual factors such as age, gender, and pain threshold, as well as the intensity of the applied stimulus and cultural differences, are influential in perceived pain intensity^{1, 2}. It can be said that almost all dentistry procedures are in some way accompanied by a level of pain and discomfort, rendering pain a major concern in modern dentistry^{3, 4}.

Orthodontic treatment is no exception; in various studies, 90 to 95 percent of patients undergoing orthodontic treatment have reported some level of pain³⁻⁵. Pain during orthodontic treatment may be due to transient pulpitis, compression of the periodontal ligament, and mechanical trauma of the soft tissue⁶, and it usually reaches its peak during the first 24 hours, gradually decreasing within seven days^{4, 7}. In modern orthodontics, intermaxillary elastics have a special place and are widely used; however, their use is commonly accompanied by pain and discomfort. For instance, in a study carried out by Tuncer et al., the patients had the highest level of pain six hours after using elastics; while two days later, the patients reported the lowest level of pain⁷.

An acceptable level of cooperation from the patients seems necessary for achieving the desired outcome in using these elastics^{7, 8}. This issue is so significant that the level of patient cooperation is considered the most important factor in the development and success of this type of treatment⁹. Nevertheless, assessing patients' attitudes towards such treatments shows that pain may discourage the patients from continuing the treatment, and it may reduce their level of

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collaboration, so it is the most important factor in discontinuing treatment^{3,9}. Previous research shows that 8 to 30 percent of patients are not willing to continue the treatment because of the pain and discomfort caused by various types of orthodontic treatments¹⁰⁻¹². The cooperation level of patients is a complex factor that can't be fully predicted before the orthodontic treatment¹³. Various factors such as pain, interfering with eating, the benefits of the elastic application, social factors, interfering with sports activities, elastics loss or tearing and forgetting to use it, have been reported as influential on the cooperation of patients treated with Class II and III elastics⁸.

In a study by Egolf *et al.*, the authors showed that, regardless of the type and size of the elastics, pain intensity, interference with daily activities, and personality traits were the main factors influencing the cooperation of patients in using intermaxillary elastics¹⁴. In another study, Panda *et al.* showed that the highest intensity of pain was reported by the patients in the T-loop activation group, followed by patients being treated with intermaxillary elastics (regardless of the type and size of the elastics)¹⁵. However, patients are expected to have different levels of pain and cooperation based on the differences in force between the two types of heavy and medium elastics. The main objective of the current study is to assess the pain intensity and cooperation level of patients when using intermaxillary elastics (Class II, Class III, and Elastic box with heavy and medium sizes). It seems that the orthodontist's awareness of the patient's level of pain and discomfort due to the use of elastics and informing the patient about this issue along with prescribing analgesic drugs based on the expected pain level can help increase the level of cooperation from the patient and his/her motivation to continue the treatment.

MATERIALS AND METHODS

This randomized clinical trial was carried out from October 2017 to September 2018 in the Department of Orthodontics of the Faculty of Dentistry of Tabriz, as well as three private clinics in Tabriz City on 134 patients with the fixed orthodontic treatment scheme who were going to receive intermaxillary elastics including medium and heavy-sized Class II and Class III intermaxillary elastics and elastic boxes. Considering a difference of 20% as the significant clinical difference threshold, and by setting $\alpha = 0.05$ and *power* = 80%, and using the *MedCalc* software (version 14.8.1), the required sample size was estimated to be 106. In order to increase the validity of the results, we considered a 50 percent increase in the sample size. Therefore, 158 participants (78 subjects in each group) were selected through simple random sampling. The participants were entered into the study after obtaining their informed consent.

Inclusion Criteria

The criteria for including the participants in the study included having consent for participating in the study as well

as having an education level of at least primary school in order to be able to fill out the questionnaires.

Exclusion Criteria

The following patients were excluded from the study: patients suffering from systemic or mental illnesses, patients with an addiction to alcohol or any other psychoactive substance, patients with a history of using intermaxillary elastics, and the presence of any causes of pain other than the elastics during the evaluation period that may affect the patient's pain and collaboration levels such as tooth decay, pulp waste, change of archwires or use of any space-closure mechanics.

Patients were randomly divided into two groups using the *RandList* software application, i.e. a heavy-forced elastic group (which exerts a relatively heavy force of about 184 grams), and a medium-forced elastic group (with exerts a moderate force of about 128 grams)¹⁶.

The elastics were connected from the canine teeth to the first molars (according to the type of malocclusion) and the elastic size (1.8, 3.16, and 1.4) was selected based on the "third experimental law" (optimal force application by the elastics in their tensile state of 300% of their diameter)¹⁷. Patients were advised to use the elastics full time except when eating and brushing their teeth, and they were also advised to replace their elastic each night. During the evaluation period, painful orthodontic mechanics such as the replacement of the archwire of the elastic, activating loops, inserting separators, and tooth extraction were avoided. Patients were evaluated based on two aspects: 1) assessment of pain intensity when using elastics; and 2) assessment of patient collaboration for using the elastics.

The severity of the patients' pain was recorded using the visual analog scale (VAS) on the same day (at three intervals of two hours and six hours after receiving elastic and at the end of the night), and one, four, and fourteen days after receiving the elastics⁷. In order to perform the assessment, a checklist was provided to the patient when prescribing the elastics, and he/she was asked to rate the intensity of his or her pain from 0 to 10 according to the figure shown in the checklist. The necessary explanations about the checklist and the method of rating the pain were given to the patients. Taking painkillers was optional for the patients; however, they were asked to take notes on the checklist when taking the medication including its type, the time of taking the drug, and the dose.

In order to measure the level of cooperation of the patients, a 23-item questionnaire developed by the researcher based on the Likert spectrum was utilized. In order to assess the content validity of the questionnaire, it was given to three orthodontic experts and they were asked to make the necessary changes. The questionnaire was given to the patient at the next session and he/she was asked to complete it in the clinic. It should be noted that each patient completed the questionnaire only once throughout the study. In order to evaluate the reliability of the

questionnaire, the test-retest method and Spearman's Correlation test were used. There was a positive statistical correlation between the result of each of the questions and the result obtained by asking the question again (P Value = 0.001, *correlation coefficient* = 1). This study was approved by the Committee of Medical Ethics of Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.106) and registered at the Iranian Center for Registering Clinical Trials with the registration number of IRCT20150628022951N5.

Statistical Analyses

The data obtained from the study were analyzed using descriptive statistical methods (frequency, percentage, mean, and standard deviation). Moreover, the Friedman test was used for comparing pain levels at different time intervals for each of the groups in the study. The Wilcoxon signed-rank

test was used for pairwise comparison of pain levels of two different times in each of the heavy and medium-forced groups. The Mann-Whitney U and Kruskal-Wallis tests were used for independent groups, and the chi-square test was used for analyzing the descriptive data. The software application used for performing the analyses was SPSS 18. A p value of less than 0.05 was considered statistically significant.

RESULTS

Among the 134 patients participating in the study, 112 patients (92 females and 20 males) with an average age of 23 years were present until the end of the study (Figure 1). 48 patients were treated with Class II elastics, 36 patients were treated with Class III elastics, and 28 patients were treated with the elastic box. Table 1 depicts the demographic information of the participating patients.

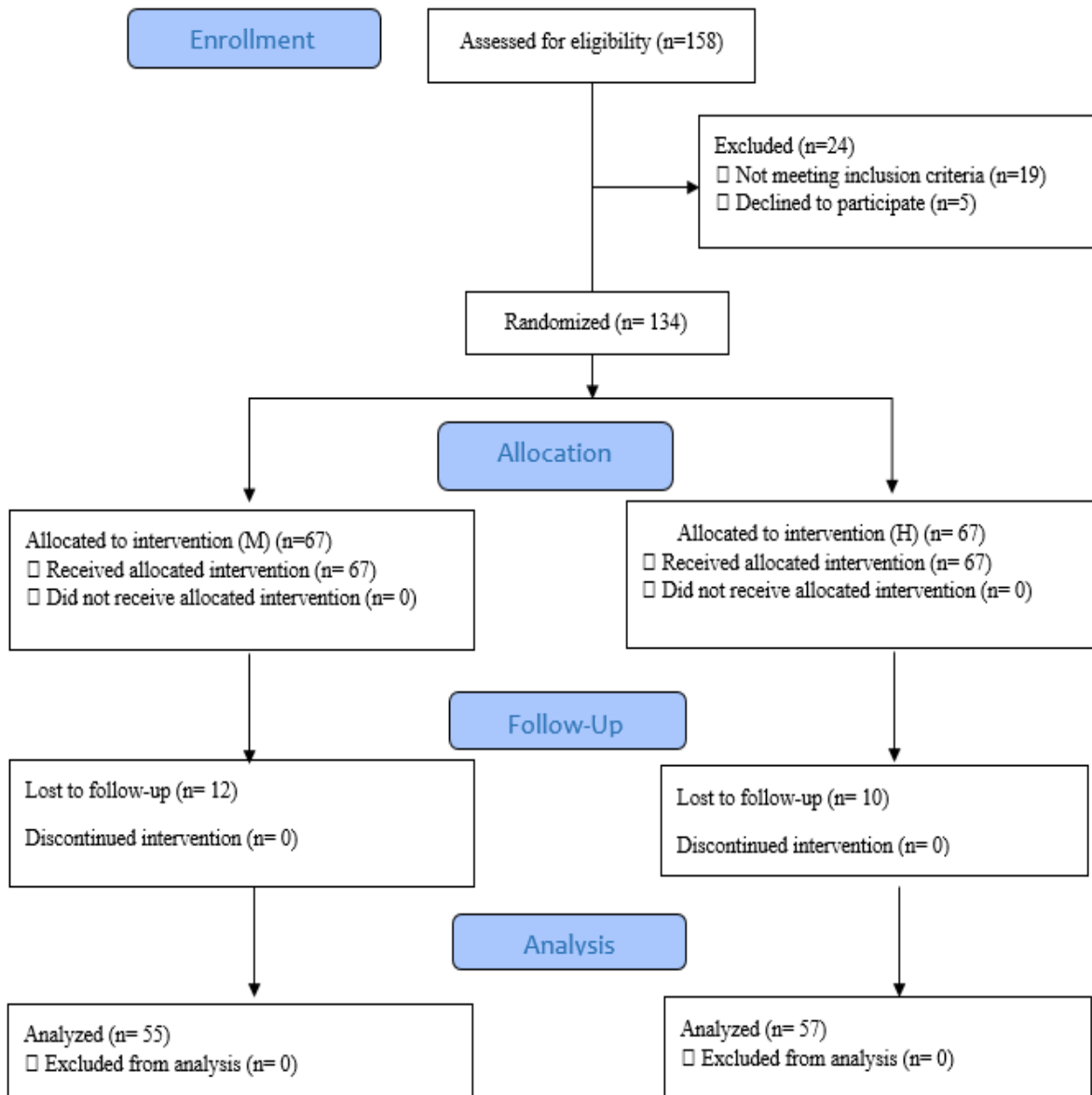


Figure 1: The CONSORT Flow Diagram for Patients in the Study

Table 1: Demographic Data of Patients Participating in the Study.

	Heavy elastics group	Moderate elastics group	Total
Female	51 (77.4%)	41 (22.6%)	92 (82.1%)
Man	8 (13.6%)	12 (22.6%)	20 (17.9%)
right side	5 (10.5%)	8 (14.5%)	13 (12.5%)
Left side	3 (5.2%)	7 (12.7%)	10 (8.9%)
Both sides	51 (84.3%)	37 (72.8%)	88 (78.6%)
Standard deviation ± mean age	22 ± 6.270	24 ± 8.234	23 ± 7.252

A pain scale based on the VAS criterion was used to evaluate the patients' level of pain. Patients were asked to record the severity of pain on the same day (at three intervals of two hours and six hours after receiving the elastic and at the end of the night) and on the second day, the fourth day, and two weeks after receiving the elastics using VAS. Taking painkillers was optional for the patients in the study; however, they were asked to write down the type of the medication, the time of taking it, and its dose on the checklist. According to the results of the chi-square test, there was no statistically significant difference among the study groups with regards to taking painkillers. Moreover, 83.92 percent of the patients did not take painkillers during any of the intervals in the study.

Table 2 presents the average pain intensity of the patients based on VAS in two groups and at different times. As shown in this table, the pain intensity of patients reached its highest level in the first six hours, gradually decreasing until the fourteenth day. The Mann-Whitney U test was used to study the effects of the type of elastics, i.e. medium or heavy, on the mean pain intensity at each time interval for the independent groups. The results of this test showed that during all the selected intervals, while the clinical pain intensity in the group receiving the medium-forced elastic was lower than the other group, and this difference was not statistically significant (except on the fourth day) (Table 2).

Table 2: Pain Intensity at Different Time Intervals of the Study (mean ± SD).

Study groups	Standard deviation ± Mean pain intensity of patients						P value
	2 hours later	6 hours later	End of the night	First day	4 th day	14 th day	
Medium elastic	2.96 ± 2.9	3.10 ± 4.16	2.83 ± 3.50	2.82 ± 3.98	2.12 ± 1.75	1.53 ± 0.86	0.000
Heavy elastic	3.10 ± 3.86	3.54 ± 2.73	2.93 ± 4.03	3.32 ± 2.86	2.24 ± 2.58	1.88 ± 1.41	0.000
Total	3.03 ± 3.44	2.94 ± 3.87	2.88 ± 3.78	2.84 ± 3.67	2.21 ± 2.19	1.74 ± 1.15	
** P value	0.09	0.310	0.354	0.103	0.018	0.063	
	*Friedman test			**Mann-Whitney U test			

In order to compare the patients' pain level at the six-time intervals of the study in the medium and heavy groups, the Friedman test was used. The results of the test showed that there was a statistically significant difference between different time intervals in each of the groups ($p < 0.0001$). Moreover, a decreasing trend in the pain level was observed from six hours after the start of the elastic treatment up to two weeks later. In order to perform a pairwise comparison

between the various time intervals considered in the study with regards to the mean pain intensity of patients, the Wilcoxon signed-rank test was used to measure the mean pain intensity. Based on the results of this test, there was a significant difference between pain decrease on the second and fourth days as well as on the fourth day and after two weeks in the heavy and medium elastic groups ($p < 0.001$). Moreover, in the medium elastic group, from two to six hours

after receiving the elastic, a significant increase in pain was observed ($p < 0.001$) (Figure 2).

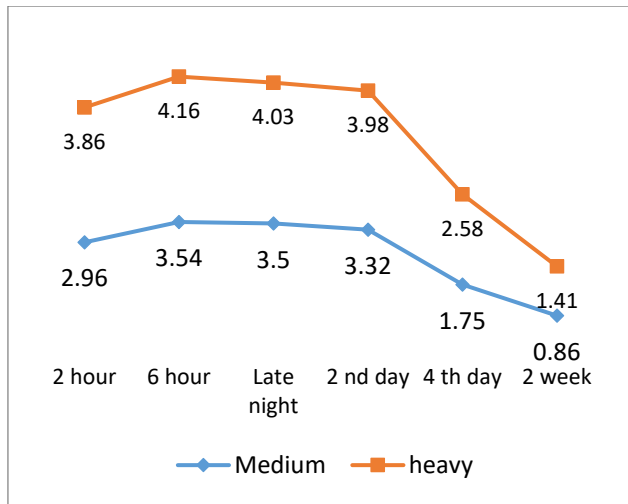


Figure 2: The Relationship between Pain Level in Various Time Intervals for Heavy and Medium Elastics

In order to measure the level of pain for Class III elastics, Class II elastics and elastic box groups in various time

intervals selected for the study, the Kruskal-Wallis analysis was used. No significant difference was observed in pain severity for any of the above-mentioned elastics groups except for the 4th day and the 2nd week. In order to measure the difference between groups, we performed a pairwise comparison between the elastics on the fourth day and two weeks later using the Mann-Whitney U analysis. There was no difference between Class III and Class II elastics ($p = 0.711$ and $p = 0.153$, respectively). However, there was a significant difference between elastic boxes and Class III elastics in both time intervals ($p = 0.022$ and $p = 0.008$, respectively). The comparison between elastic boxes and Class II elastics on the fourth day showed a significant difference ($p = 0.022$); however, there was no significant difference two weeks later ($p = 0.082$).

Table 3: Pain Intensity of Patients at Various Time Intervals Based on Type of Elastics (Class III, Class II, and Elastic Box).

Study groups	Standard deviation ± mean pain intensity of patients					
	Two hours later	Six hours later	At the end of the night	First day	Fourth day	Fourteenth day
Elastic Box	4.29 ± 2.89	4.14 ± 2.78	4.50 ± 2.90	4.11 ± 2.48	3.29 ± 2.599 ^{a†}	2.00 ± 2.12 ^a
Class II Elastic	3.23 ± 3.01	3.59 ± 2.68	3.35 ± 2.53	3.29 ± 2.89	1.90 ± 1.93 ^b	1.04 ± 1.58 ^{ab}
Class III Elastic	3.17 ± 3.12	4.19 ± 3.37	3.92 ± 2.22	3.94 ± 3.02	1.81 ± 2.02 ^b	0.69 ± 1.43 ^b
<i>p value</i>	0.255	0.566	0.246	0.456	0.035	0.022

* *Kruskal – Wallis*

† Same letters indicate statistically non-significant differences at $p < 0.05$ level according to Mann-Whitney U analysis.

Table 4: Frequency and Percentage of Participants’ Responses to the Items in the Cooperation Questionnaire.

Question	The group under study	I completely agree	I agree	No idea	I disagree	I completely disagree	P-value
Medium Elastic	Frequency	0	3	4	18	28	0.487
	Percentage	0.0%	5.7%	7.5%	34%	52.8%	
Heavy elastic	Frequency	1	3	8	15	29	
	Percentage	1/7%	5.1%	13.6%	25.4%	49.2%	

improving the configuration of my teeth.	Medium elastic	Frequency	0	3	1	32	0.763	
		Percentage	0%	5.7%	1.9%	60.4%		32.1%
	Medium elastic	Frequency	0	2	2	12	40	0.244
		Percentage	0%	3.4%	3.4%	20.3%	67.8%	
	Heavy Elastic	Frequency	3	10	10	12	18	0.765
		Percentage	5.7%	18.9%	18.9%	22.6%	34.0%	
	Medium elastic	Frequency	7	14	6	7	22	0.394
		Percentage	11.9%	23.7%	10.2%	11.9%	37.3%	
	Heavy Elastic	Frequency	2	5	7	22	17	0.171
		Percentage	3.8%	9.4%	13.2%	41.5%	32.1%	
	Medium elastic	Frequency	0	6	10	18	22	0.765
		Percentage	0.0%	10.2%	16.9%	30.5%	37.3%	
	Heavy Elastic	Frequency	4	13	9	15	12	0.394
		Percentage	7.5%	24.5%	17.0%	28.3%	22.6%	
	Medium elastic	Frequency	6	11	5	10	24	0.171
		Percentage	10.2%	18.6%	8.5%	16.9%	40.7%	
	Heavy Elastic	Frequency	17	15	16	2	3	0.171
		Percentage	32.1%	28.3%	30.2%	3.8%	5.7%	
Heavy Elastic	Frequency	20	22	11	2	0	0.171	
	Percentage	33.9%	37.3%	18.6%	3.4%	0.0%		

Table 4: Frequency and Percentage of Participants' Responses to the Items in the Cooperation Questionnaire-Continued

Question	The group under study		I completely agree	I agree	No idea	I disagree	I completely disagree	P-value
The elastics are easily torn while talking or doing other activities.	Medium elastic	Frequency	0	10	6	13	24	0.663
		Percentage	0.0%	18.9%	11.3%	24.5%	45.3%	
	Elastic Heavy	Frequency	2	7	4	18	25	
		Percentage	3.4%	11.9%	6.8%	30.5%	42.4%	
I get a headache when using elastics.	Medium elastic	Frequency	1	13	7	13	19th	0.199
		Percentage	1.9%	24.5%	13.2%	24.5%	35.8	
	Heavy elastic	Frequency	1	10	3	19th	23	
		Percentage	1.7%	16.9%	5.1%	32.2%	39%	

Removing the elastics and putting them back are difficult.	Medium elastic	Frequency	3	7	5	23	15	0.708
		Percentage	5.7%	13.2%	9.4%	43.4%	28.3%	
	Heavy elastic	Frequency	1	7	4	16	28	
		Percentage	1.7%	11.9%	6.8%	27.1%	47.5%	
Using elastics awakens me while sleeping.	Medium elastic	Frequency	0	5	12	34	2	0.361
		Percentage	0%	9.4%	22.6%	64.2%	3.8%	
	Heavy elastic	Frequency	0	2	17	33	4	
		Percentage	0%	3.4%	28.8%	55.9%	6.8%	
Sometimes I intentionally delay the use of the elastics to feel more comfortable.	Medium elastic	Frequency	0	17	9	12	15	0.273
		Percentage	0%	32.1%	17%	22.6%	28.3%	
	Heavy elastic	Frequency	2	14	5	17	18	
		Percentage	3.4%	23.7%	8.5%	28.8%	30.5%	
I use the elastics at school and at work.	Medium elastic	Frequency	23	20	4	4	2	0.997
		Percentage	43.4%	37.7%	7.5%	7.5%	3.8%	
	Heavy elastic	Frequency	29	19th	6	1	1	
		Percentage	49.2%	32.2%	10.2%	1.7%	1.7%	

Table 4: Frequency and Percentage of Participants' Responses to the Items in the Cooperation Questionnaire-Continued

Question	The group under study		I completely agree	I agree	No idea	I disagree	I completely disagree	P-value
Every time the elastics need replacing, I do it.	Medium Elastic	Frequency	26	23	3	1	0	0.523
		Percentage	49.1%	43.4%	5.7%	1.9%	0%	
	Heavy Elastic	Frequency	29	23	3	1	0	
		Percentage	49.2%	39%	5.1%	1.7%	0%	
I use elastics everywhere I need.	Medium elastic	Frequency	19	24	3	5	2	0.957
		Percentage	35.8%	45.3%	5.7%	9.4%	3.8%	
	Heavy Elastic	Frequency	24	21	6	3	2	
		Percentage	40.7%	35.6%	10.2%	5.1%	3.4%	
Since using elastics, I feel pain and discomfort in my jaw.	Medium elastic	Frequency	3	18	7	12	13	0.167
		Percentage	5.7%	34%	13.2%	22.6%	24.5%	

If the elastics are finished sooner than the next appointment, I will go to the clinic sooner to get new elastics	Heavy Elastic	Frequency	3	18	7	12	13	0.61
		Percentage	5.1%	30.5	11.9	25.4%	22%	
	Medium elastic	Frequency	16	24	11	1	1	
		Percentage	30.2%	45.3%	20.8%	1.9%	1.9%	
I think using elastics is effective in accelerating orthodontic treatment.	Heavy Elastic	Frequency	14	30	6	4	2	0.530
		Percentage	23.7%	50.8%	10.2%	6.8%	3.4%	
	Medium elastic	Frequency	18	25	8	2	0	
		Percentage	34.0%	47.2%	15.1%	3.8%	0.0%	
I'm happy to participate in my own treatment by using elastics.	Heavy elastic	Frequency	18	23	12	2	1	0.145
		Percentage	30.5%	39.0%	20.3%	3.4%	1.7%	
	Medium elastic	Frequency	22	21	9	1	0	
		Percentage	41.5%	39.6%	17.0%	1.9%	0%	
	Heavy elastic	Frequency	22	24	7	3	0	
		Percentage	37.3%	40.7%	11.9%	5.1%	0%	

Table 4: Frequency and Percentage of Participants' Responses to the Items in the Cooperation Questionnaire-Continued

Question	The group under study		I completely agree	I agree	No idea	I disagree	I completely disagree	P-value	
The presence of the elastic in my mouth feels uncomfortable and causes nausea.	Medium elastic	Frequency	3	4	10	15	21	0.162	
		Percentage	5.7%	7.5%	18.9%	28.3%	39.6%		
	Heavy elastic	Frequency	0	4	5	16	31		
		Percentage	0.0%	6.8%	8.5%	27.1%	52.5%		
Using the elastics restricts the movement of my jaw.	Medium elastic	Frequency	10	20	11	5	7	0.506	
		Percentage	18.9%	37.7%	20.8%	9.4%	13.2%		
	Heavy elastic	Frequency	10	25	4	9	7		
		Percentage	16.9%	42.4%	6.8%	15.3%	11.9%		
		Frequency	40	9	3	1	0		0.248

I use elastics exactly where the orthodontist advised.	Medium elastic	Percentage	5.7%	1.9%	75.5%	17.0%	0%	
	Heavy elastic	Frequency	40	14	2	0	0	
		Percentage	67.8%	23.7%	3.4%	0.0%	0.0%	
I use my elastics all day and night, except when eating and brushing my teeth.	Medium elastic	Frequency	29	15	3	6	0	.0248
		Percentage	54.7%	28.3%	5.7%	11.3%	0.0%	
	Heavy elastic	Frequency	30	22	2	2	0	
		Percentage	50.8%	37.3%	3.4%	3.4%	0%	
My child uses the elastics based on the prescription.	Medium elastic	Frequency	38	15	0	0	0	
		Percentage	71.7%	28.3%	0%	0%	0%	
	Heavy elastic	Frequency	42	14	0	0	0	
		Percentage	71.2%	23.7%	0%	0%	0%	

In the second session of prescribing elastics for the patients, the cooperation questionnaire was given to them and they were asked to answer the questions during the same session. Table 3 shows the frequency and percentage of the different responses of the participants to the items in the cooperation questionnaire. Since the response pattern for none of the items in the cooperation questionnaire had a normal distribution, the participants' answers were analyzed in three groups, i.e. 'I completely agree', 'I completely disagree', and 'no idea'. The chi-square test was used to compare the level of cooperation of patients in the two groups. The results of this test show that there is no significant difference between the responses of the two groups of patients, i.e. heavy and medium-forced elastics, to the items in the questionnaire.

The majority of patients in the heavy (about 71%) and medium (60%) groups believed that elastics had a positive effect on improving the configuration of their teeth. No significant clinical difference was observed between the two groups. Moreover, 87 percent of the patients in the medium group and 74 percent of the patients in the heavy group stated that they did not need others to remind them about the use of elastics. Furthermore, 73% and 72% of individuals in the heavy and medium groups, respectively, acknowledged that wearing and removing elastics wasn't difficult and they do not need the help of others for doing so. For 32% of the patients in the medium group and 29% of the patients in the heavy group, others seeing their orthodontic elastics in their mouth was annoying; however, most of the patients (about 81% of the patients in both groups) wore elastics at work or at school. Most patients in both groups claimed that they changed and wore elastics at any time or place needed. While the majority of the patients in both groups believed that using

the elastics did not cause sleep disorders, interference with their concentration, or developing headaches and nausea. 57 percent of the patients in the medium group and 69 percent of the patients in the heavy group reported that the presence of the elastics limited their jaw movements. In addition, 81 percent of the patients in the medium group and 78 percent in the heavy group were satisfied with the fact that they cooperated with their own treatment. Finally, in response to the last question of the collaboration questionnaire which relates to the parents and companions of the patients, all parents stated that the patients had a complete cooperation level. Nevertheless, 11 percent of the patients in the medium elastics group and 3 percent of the patients in the heavy elastic group said that they didn't have full cooperation. Based on the chi-square test, there was no significant difference with regards to patient cooperation between the Class II elastics, Class III elastics, and elastic box groups.

DISCUSSION

Intermaxillary elastics are considered an important part of the orthodontic treatment mechanics. At this stage of treatment, the level of cooperation from some patients is reduced due to the pain and discomfort caused by the elastics⁷. The pain experienced during orthodontic treatment can be due to pressure, ischemia, hyperalgesia, and prostaglandins release^{18, 19}.

However, some studies argue that with the progress of treatment, patients may adapt to continuous pain. This adaptation is created either because the stimuli are stopped or because the stimuli are no longer the focus of the patient. The orthodontist is required to explain to the patients how long it

takes for them to adapt to the pain. Failure to establish an effective relationship with the patient and to transfer necessary information to him or her may cause the patient to stop cooperating, which results in treatment failure^{1, 2, 20}.

In the current study which was carried out in order to compare the pain and cooperation levels of patients being treated by medium and heavy intermaxillary elastics, the results showed that the pain intensity in both groups reaches its peak during the first six hours. However, because of the lower level of force exerted by the medium-forced elastics, this group of patients experienced lower immediate pain compared to the heavy elastics group of patients. The pain level reduced gradually until the 14th day when it reached its minimum. When comparing the two groups from a clinical point of view, the pain intensity of the medium elastics group was lower. This difference was not statistically significant, except for the fourth day when a significant difference was observed between the medium elastics and the heavy elastics group. The mean reported pain intensity for both groups was low and based on the VAS, this mean was 2.7 for the medium elastics group and 3.4 for the heavy elastics group. The patients in both groups used the same amount of painkillers. Taking painkillers was used as a qualitative measure for measuring the pain level. We observed that only during the first day of using elastics and only 16 percent of the patients took painkillers, which is in line with the findings of the quantitative evaluations. Our findings are important since the orthodontist must inform the patient about the mild pain and discomfort during the first day of prescribing the elastics and he or she must consider the necessary measures to prevent the development of pain. The important clinical implication of our findings is that in contrast to the expectations; there is no concern about pain and discomfort for prescribing heavy and medium elastics, and it is most likely that the main criterion for prescribing elastics will be the biomechanical conditions. In the current study, the pain reported by the patients increased after two hours of putting in the elastics, reaching its maximum level six hours after putting them in, and continued until the end of the night and the next day. From the fourth day onwards, the pain intensity of the patients started decreasing, reaching its minimum on the 14th day. There was no significant difference between Class II and Class III elastics in any of the selected time intervals. However, those receiving elastic boxes experienced a higher level of pain on the fourth day and after two weeks, which was statistically significant. The main reason for this finding is most likely the higher movement limitation of elastic boxes, which results in a more pronounced feeling of discomfort as time passes. The findings obtained in the current study are in line with the findings of Tuncer *et al*; however, the sample size of this study was smaller and they didn't report any differences between the types of elastics.

In a study in 2011, Tuncer *et al.* measured and compared the intensity of the pain reported by 60 patients receiving archwires and 19 patients receiving intermaxillary elastics based on VAS when chewing and biting (anterior and

posterior teeth). Their results show that using intermaxillary elastics causes a pain similar to using the archwires, except for the fact that the duration of the pain created when using elastics is shorter. The patients' pain starts increasing two hours after putting the elastics in and reaches its peak six hours later and at the end of the first night, continuing to the next day. Two days after using the elastics, the patients experienced the least amount of pain. During the study, the patients in the elastic group didn't take any painkillers⁷.

Panda *et al.* (2015) divided 100 orthodontic patients into five categories, i.e. the separator group, the banding group, the initial *NiTi* group, the T-loop group, and the intermaxillary elastics group, and compared them based on the time of peak pain, the peak intensity of pain, the need for painkillers, and the effects on everyday activities. They concluded that the patients in the separator and the initial *NiTi* groups took the highest amount of painkillers. The most significant interference with everyday activities was reported by the patients in the intermaxillary elastics group and the initial *NiTi* group; however, the difference wasn't statistically significant. The highest level of pain intensity was reported by the patients in the T-loop activation group, followed by patients receiving the intermaxillary elastics. In line with the results of the current study, in this study, the peak pain intensity of the patients in the intermaxillary elastics group was at six hours after putting in the elastics. However, in contrast to the current study, this study didn't specify the type and size of the elastics used¹⁵.

In order to reduce the pain caused by using intermaxillary elastics, using bite blocks^{20, 21}, lasers²², and transcutaneous electric nerve stimulation²³ are some of the methods proposed in various studies. However, taking painkillers is still considered the simplest and most effective treatment method²⁴. In the current study, 84 percent of the patients didn't need painkillers.

Since based on the pain scale, the level of pain in both groups doesn't show a significant difference and the pain decreases in the form of a similar function of time for both groups, we expect a similar level of cooperation from the patients in both groups. In the current study, the cooperation level of patients was similar for both groups and it was at a desirable level. Among the patients who entered the study, 83 percent submitted the questionnaire, which can be an important point for the level of cooperation in their treatments. Since the level of cooperation is measured based on asking the patients and his or her parents, the results can suffer from a level of error similar to any survey-based study. Therefore, there is a need for methods for evaluating cooperation with elastics treatment which are independent of the patient and his or her parents.

In the current study, the majority of the patients reported that they didn't need others to remind or help them to use the elastics and removing and putting in the elastics wasn't a difficult task for them, which is in line with the findings of

the study by Veeroo *et al.*⁸. In their study, the 'if-then plan' was used as a reminding plan. While it is reported that using the 'if-then plan' can increase the level of cooperation, there was no statistically significant difference with the control group.

About half of the patients (56 percent) claimed that the presence of the elastics resulted in limitations in jaw movements. While the elastics aren't torn when speaking, they are still a source of discomfort. This may lead to joint disorders, so when prescribing elastics for patients suffering from joint disorders or those who develop joint disorders during the course of the treatment, we should err on the side of caution.

In our study, the majority of the patients (77.7 percent) believed that using elastics accelerates the treatment and improved the configuration of the teeth, and they were feeling satisfied with cooperating with and participating in their own treatment. This is in line with the 83 percent cooperation and indicates the effects of cognitive awareness on cooperation.

Our findings were in line with the findings of Siddegowda and Rani, who reports that the duration of using the facemask reported by the parents was two times that of the real usage by the patient²⁵. In the current study, the cooperation level reported by the parents was 100 percent, while the level of cooperation reported by the patient was 86 percent, confirming the results of the two previous studies.

Based on the current study, it can be concluded that headache, difficulty in putting elastics in, forgetting to use the elastics, discomfort during sleep, and lack of concentration even at school or at work are not important factors for lack of cooperation. In fact, factors such as others seeing the elastics in the mouth, pain, limitations of jaw movements, and most importantly, incentives for treatment are more important and they must be considered. It is recommended that future studies focus on methods of increasing cooperation so that we can improve patient cooperation as an important part of orthodontic treatment. In a study by Nanda and Kierl, the relationship between parents and the patient is reported as a determining factor for cooperation. This study claims that by improving the relationship between the orthodontist and the patient, we can improve the cooperation of an unwilling patient²⁶. Therefore, improving the relationship with the patient and in general, using behavioral reinforcement methods can be used as a cost-effective yet valuable method for increasing cooperation.

CONCLUSIONS

The pain intensity of the patients in both groups reaches its peak within the first six hours, decreasing gradually until the 14th day when it reaches its minimum. When comparing the two groups from a clinical point of view, the pain intensity of the patients in the medium-forced elastics group was lower, this difference wasn't statistically significant, and the patients in both groups used similar doses of painkillers.

Comparing the pain level among various types of elastics, i.e. Class III elastics, Class II elastics, and the elastic box doesn't show a significant difference, except for the 4th and 14th days when the pain level of patients in the elastic box group was higher than the other two groups. Moreover, the cooperation level of patients in both groups of elastics, i.e. medium and heavy elastics, was similar and at an acceptable level. There was no significant difference with regards to patient cooperation among Class III elastics, Class II elastics, and the elastic box groups.

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