

Clinical Comparison of Ibuprofen Drug Effect and Low Power Laser Diode on Orthodontic Separator Implementation Pain

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Abstract: *Objective:* Placing orthodontic separators is one of the common tasks in orthodontics. It can cause low to moderate pain, because of the pressure of the periodontal ligament and the release of prostaglandins. The purpose of this study was to compare the analgesic effects of Ibuprofen® 400mg (Gelophen, Zahravi Pharmaceutical Co, Tabriz, Iran) and LLLT on pain after the placement of orthodontics separator.

Material and Methods: In this randomized clinical trial study, 61 orthodontics patients were randomly divided into two groups: group one LLLT (31 patients) and group two Ibuprofen drug (30 patients). The age of the patients was 13 to 25 years old. After obtaining informed consent from the patients, Maxillary first molars were selected to place separators in mesial and distal contacts.

Results: After receiving the questionnaires, 11 patients (6 patients from the laser group and 5 patients from drug group) due to the taking of another medication during the study period, were set aside. Data from 50 of them were analyzed. Using the Chi-square test, no difference was seen between two groups base on the amount of pain experienced, time to start pain and other causes of pain. Only in the drug group initiation of pain was observed later than the laser group.

Conclusion: As there was no difference in pain experienced between the two groups according to cost and time, it is not preferable to use low-power laser compared to medicine. The drug seems to be more effective.

Keywords: Pain, Orthodontics, Anti-inflammatory agents, Low-Level Laser Therapy.

INTRODUCTION

To correct malocclusion in early stages of orthodontic therapy, patients suffer degrees of pain is a usual clinical symptom in orthodontic patients, and it is an unpleasant feeling caused by some tissue changes [1]. Pain during orthodontic treatment is the most common reason for not continuing treatment, and It has been described as the worst part of treatment [2]. Pain mechanism in orthodontic therapies is a result of pushing forces that results in ischemia, inflammation, and oedema in periodontal tissues [3]. Changes in blood circulation in teeth results in the release of inflammatory mediators like prostaglandins [1]. Orthodontic patients have reported different degrees of pain and discomfort in some stages of therapy, including putting separator. Bergius *et al.* [4] have put a

difference between two kinds of pain during orthodontic treatment, mentioned that a sort of pain is constant, and the other one shows itself during chewing. On the first day after activating orthodontic forces, about 82% of patients have reported pain while chewing, and 24% have reported constant pain, a part of patients have mentioned that constant pain has decreased by passing time that on the seventh day it has stopped. In comparison, around 30% of them have mentioned that pain during chewing has remained. Studies have shown 8-30% of patients have stopped therapy because of pain [5].

Even though there are tremendous advances in orthodontic technology, the pain problem is not fully solved yet [5]. Pain control during orthodontic therapy is important for orthodontists and patients.

Elastomeric separators are used to prepare space for orthodontic bands which can result in significant

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pain [5]. Sometimes pain resulting from putting separator is even more than the pain of extraction a tooth [6]. Negan [7] has reported that 4 to 24 hours after placing separator; patients have experienced significant discomfort.

It may be needed in patients experiencing high degrees of pain to use medical or nonmedical treatments to reduce pain [8]. Among several usual medications, non-steroidal anti-inflammatories (NSAIDs) are especially effective [9]. It has been proven that patients who use ibuprofen one hour before doing orthodontic therapy have experienced less pain because it prevents the release of prostaglandins and delays inflammatory responses and as a result reduces the pain [10].

Some studies have shown that low-level laser therapy (LLLTT) may be effective in reducing pain [5, 11]. It is believed that laser therapy can result in the reduction of the inflammatory procedure and neural signals and an increase in blood pressure of under radiation area and these events result in a reduction in pain [5].

LLLTT can prevent inflammation and accelerate the healing of bones and increase the movement of teeth. LLLTT is a nonaggressive treatment, and there are no reports on its side effects. Also, it is clinically more advantageous than medication. But there is still no documented evidence proving that LLLTT can reduce orthodontic pain [5].

In a systematic review and meta-analysis published in 2017 to investigate the effect of LLLTT on orthodontic pain relief, it was found that LLLTT is effective in reducing spontaneous pain and chewing after orthodontic forces. However, because of the low quality of studies, the interpretation of the results should be made with caution [12].

Shi *et al.* [5] concluded that pain decrease in 6 hours and 1 to 3 days after laser therapy, while in the first 2 hours and days 4 and 5 no pain was seen [5]. Also, clinical results show a decrease in pain depends on the kind, wavelength, energy, duration, and frequency of the laser. The best characteristic of laser found in the studies is 2 J/cm² energy, 100 MW power, 20s duration, and 810 nm wavelength.

LLLTT is better than medications clinically, but still, there is little evidence proving the effectiveness of LLLTT. The goal of this controlled clinical trial (CCTs) is

conducting a comparison between the efficacy of LLLTT and ibuprofen and recognizing which one is more effective in pain reduction after putting separator.

MATERIAL AND METHODS

This study was a randomized clinical trial. This study initiated in April 2017 in the orthodontic department, dental school, Hamadan University of Medical Sciences. The trial was approved with Ethical Committee (IR.UMSHA.REC.1395.150) and registered on IRCT (Iranian Registry of Clinical Trials) with a number of IRCT2016061316582N2.

Inclusion criteria were as follows: Patients between 13 to 25 years old from both sexes of women and men. Minimum weight of drug group should be 40 kg, Patients should have healthy molars and fully vegetated and have no record of RCT therapy, have no decay or treatment used for first molars should not be questionable, the first molar of maxilla on both sides should have proximal contact, and no periodontal disease should be observed which is based on some indexes like visible plaques, bleeding in gum, bleeding while probing, depth of probe and clinical attachment loss.

Exclusion Criteria were as Follows

Records of systemic diseases and pregnancy, records of former orthodontic therapy, use of antibiotics, and patients with histories of reaction to Ibuprofen.

At first, the procedure was explained to the patients, and informed consent was taken from them, after that the patients were divided randomly into two groups of drugs and laser. Kind of separator (Ortho organizers) was the same for all of them.

In the laser group, the separator was located between contacts of the molar tooth. Immediately after locating the separator, the laser radiated to 3 spots of the apex, mesial and distal from the laser with a wavelength of 94 nm, duration of 40 secs, the radiation dose of 8 j/cm² and power of 200 MW.

Regarding previous studies which have shown a single dose of medication is effective in pain control, Ibuprofen 400 mg was given to the drug group one hour before putting the separator [9].

After putting the separators, Modified McGill questionnaire was given to both groups of patients, and

they were asked to record their level of pain. The McGill Pain Questionnaire was developed by Malzak in 1975, which was first used to evaluate and investigate pain in various types. The modified McGill Pain Questionnaire is the shorter form of its original version and has widely used regarding its reliability, validity, and consistency based on many studies [13-16].

The questionnaire consisted of questions concerning the trigger of pain, location, description, duration, medication, beginning, and intensity.

The randomization method in this study was coin tossing. The blindness of the research director or care providers was not possible; however, the outcome analyzer and participants were blind, because in the laser group we used light and placebo (Ibuprofen capsule without medication) and in the drug group, we used Ibuprofen and light without activation.

In this study, statistical analysis software SPSS (SPSS IBM, Chicago, IL, USA) was employed. An independent t-test used to compare a quantitative variable between two separate groups. A chi-square independence test carried out to investigate the relationship between qualitative variables. In this study,

differences between groups with P-value < 0.05 were considered significant.

RESULT

In this study, 61 patients (21 males and 40 females) were enrolled. Eleven patients (6 patients from the laser group and 5 patients from drug group) due to the taking of another medication during the study period, were set aside. Finally, 50 patients (25 patients in the laser group and 25 patients in the drug group) were analyzed. The consort diagram is shown in Figure 1. In each group, there were 6 men and 19 women, and hence no statistical association between sex and groups was made. The mean (± standard deviation) of age in drug and laser groups were 17.96 (±5.87) and 18.64 (± 3.59), respectively.

In the first question, which was about the most important factor causing pain in the patients, 92% of the understudy population mentioned chewing.

In the second question, which was about the area of feeling pain, 52% of both groups reported posterior teeth as the area of pain.

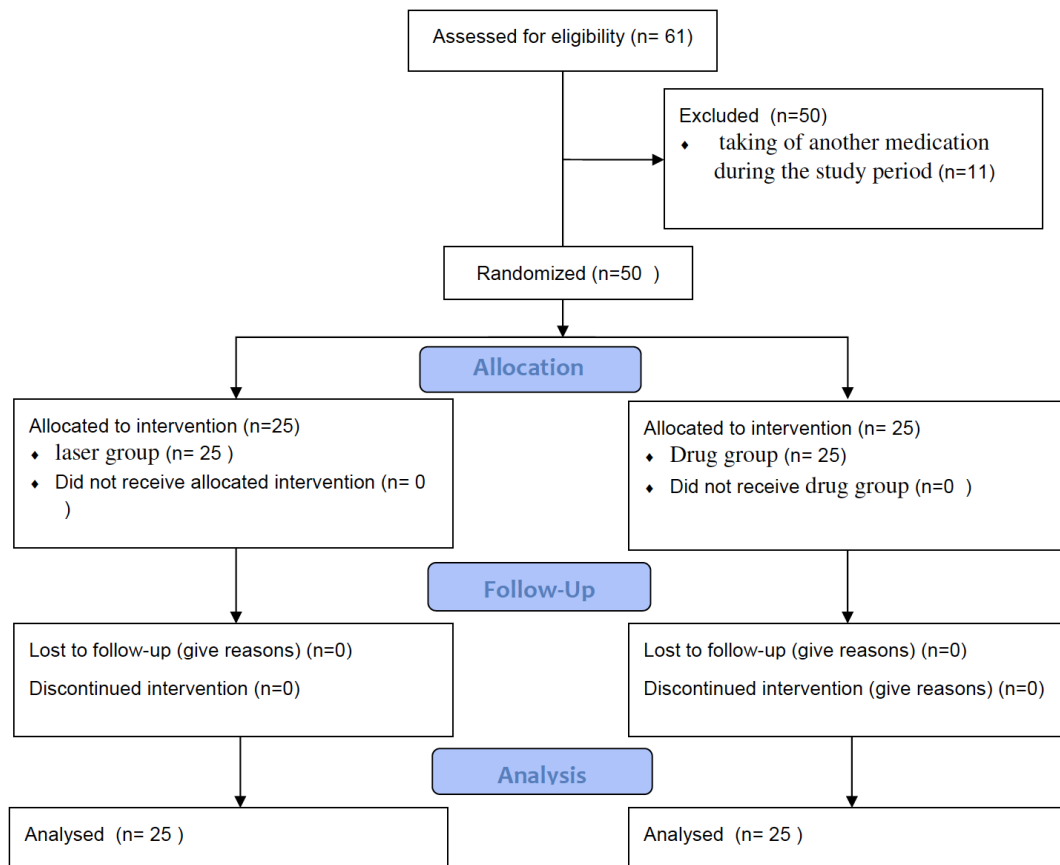


Figure 1: The CONSORT flow diagram.

Table 1: Evaluation of Time to Start the Pain in Drug and Laser Groups using Chi-Square and Fisher's Exact Test

| variable | drug | laser | total | p. value | df |
|--------------------------------------|-----------|-----------|----------|----------|----|
| directly after putting the separator | 5 (20%) | 5 (20%) | 10 (20%) | | |
| 6 hours later | 3 (12%) | 10 (40%) | 13 (26%) | | |
| 12 hours later | 9 (36%) | 2 (8%) | 11 (22%) | 0.028 | 4 |
| 24 hours later | 4 (16%) | 7 (28%) | 11 (22%) | | |
| 2 days later | 4 (16%) | 1 (4%) | 5 (10%) | | |
| total | 25 (100%) | 25 (100%) | 50(100%) | | |

For the highest degree of pain felt (Question 3), which is a descriptive statistic, the mean score is 4.24 ± 2.115 .

In the fourth question about describing the pain, 56% of the population described it as a forcing pain.

Question 5 has asked about the starting time of the pain, and in the 50 individual population of the study, 26% mentioned that the pain had started 6 hours after putting the separator.

In question number 6, it has asked about the length of the pain, and the most obtained per cent from the understudy group was 34% which was for 4 days' duration.

In part about question 7, it was asked if the level of pain was reduced by passing the time or not. From the 50 individual population under study, 86% (43 individuals) mentioned that they had experienced pain reduction.

And at last in question number 8, which is about the use of pain killer medications, any patient who has used pain killers while putting the separator would be omitted from the study.

From the 61 individuals of the study, five individuals from the drug group and six individuals from the laser group announced that they had taken other medication during the study, and they were omitted from the study. From the 50 remained people, none of them had taken medication, and their answers to the questionnaires were assessed.

In the comparison conducted between the highest degree of pain felt (question 3) and age of the two groups according to the independent Chi-square test (Fishers) no relation where observed and the two groups showed no difference in this regard.

Study of the relation of groups with other variables:

In the question related to the most important factor causing pain (question 1), the pain feeling area (question 2), on describing the pain (question 4), duration of pain (question 6) and pain reduction during the time (question 7) There was no significant relationship between the two groups.

As it can be seen in Table 1, About the starting time of the pain (question 5), a significant relation was seen between the two groups, in such a way that individuals who had taken drug 1 hour before putting the separator, had delayed pain starting time. (df= 4, Chi-Square=10.842, p-value= 0.028).

DISCUSSION

The results of this trial showed a significant difference between the two groups based on Time to start the pain. While examining other features of pain, no significant difference was observed as in the drug group initiation of pain was observed later than the laser group.

Pain feeling is related to some physical and psychological factors including age, sex, stress, patients' emotional state, cultural differences and previous experiences of pain [17]. The present study might have been affected by these individual variations. In malocclusion correction during orthodontic therapy, especially in the early stages, patients experience degrees of pain [1]. This effect can be counteracted using the split-mouth method. Although the split-mouth process can reduce bias; however, according to the design of our study, this type of design is not possible due to the systemic effect of the drug.

Previous researches have studied the effect of medication or laser solely, and just in one study comparison between the effect of these two methods was assessed in 28 persons who were lower than the

population of our study [6, 18-20]. In general, most of the studies include a smaller statistical society.

In our study, comparing the effects of NSAID and LLLT, both NSAID and LLLT were shown to be equally effective in reducing pain.

NSAIDs can reduce pain and postpone it. Studies have proven that patients who take ibuprofen 1 hour before orthodontic therapy have experienced less pain because it prevents the release of prostaglandins and delays the inflammatory response and as a result reduces the pain [9, 10, 21]. As studies imply, NSAIDs have been used as a pain killer for orthodontic pains for a long time, in our study Ibuprofen 400 mg was given to the medication group one hour before putting the separator [20].

Previous studies have suggested the relieving effect of LLLT by using a single dose and several doses of laser [18, 22]. But further investigation of the single dose is discussed in several studies, and many of them suggested that the single-dose has had an important effect on pain reduction in comparison with the control group [3, 12, 19].

Eslamian *et al.* [18], Artés-Ribas *et al.* [19] and Almallah *et al.* [11] and conducted a study to achieve the effective level of low power laser on the pain experienced after putting the separator. The results of these studies showed significant pain reduction compared with the placebo group.

Shi *et al.* [5] a meta-analysis conducted on the effect of low power laser on the pain caused by separator concluded that low power laser could reduce the pain caused by separator and is effective in this case. The results of our study showed that laser-like medication is effective in reducing pain.

As mentioned above, the results of the studies of Eslamian *et al.* [18], Bernhardt *et al.* [21], Almallah *et al.* [11], Shi *et al.* [5], Artés-Ribas *et al.* [19] and Minor *et al.* [9] are in the coordination with the aim of the current study and their final result has led to pain reduction. Furquim *et al.* [23] and Abtahi *et al.* [24] have conducted separate studies, and they didn't observe the positive effect in reducing pain caused by putting separator, using low power laser. Their results are not in coordination with our result.

Consequently, this inconsistency between the investigations might be due to the differences in the properties of the laser used.

In a study by Oshagh *et al.* [20] Who discussed the comparison between the painkilling effect of ibuprofen and low power laser on the reduction of the pain caused by putting orthodontic separator Similar to the present study, final results show that no difference was observed between the relieving effect of laser and medication. This study differs from the present research in the laser wavelength (820 nm). Whereas in the present study, 940nm wavelength was used.

In the present study, unequal numbers of women and men patients and lack of control group could make no difference between the two groups.

CONCLUSION

Based on the study result, no difference was observed on the effects of diode low power laser 940nm, and Ibuprofen 400mg on reducing the pain after putting separator, except in the drug group delayed pain occurs later comparing with the laser group. Regarding the fact that laser therapy is more expensive and less available, using NSAID is more efficient in patients who are predicted to have less tolerance for the pain.

CONFLICTS OF INTEREST STATEMENT

There are no conflicts of interest.

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None.

APPENDIX A

Modified McGill Pain Questionnaire (MPQ) with Visual Analogue Scale (VAS) [25]

Patient name: Age:

Please answer the following question

What was the pain trigger?

1. no pain
2. chewing
3. biting
4. cold food or liquid
5. hot food or liquid
6. at rest

7. physical activity

Where did you perceive pain?

1. frontal teeth
2. posterior teeth
3. all teeth
4. upper teeth
5. lower teeth
6. head

Describe the pain:

1. discomfort
2. pressure
3. tingling
4. dull
5. sharp
6. pulsating
7. headache

On the scale from 0 to 10 (0 – no pain; 10 – the severest pain

you have ever experienced) please mark the pain you perceived

after archwire insertion:

0 1 2 3 4 5 6 7 8 9 10

When did the pain start?

1. Immediately after insertion of archwire
2. 6 hours later
3. 12 hours later
4. Two days later
5. More than two days later

Duration of pain:

1. 1 day
2. 2 days
3. 3 days
4. 4 days
5. Longer

Has the intensity of pain decreased over time? Yes No

Have you taken pain medication Yes No

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