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Efficacy of Low-Intensity Pulsed Ultrasound for Orthodontic Pain Control: A Randomized Clinical Trial

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A B S T R A C T

Objectives: This study aimed to assess the efficacy of low-intensity pulsed ultrasound (LIPUS) for orthodontic pain control.

Materials and Methods: This spilt-mouth randomized controlled clinical trial was performed on 44 mandibular first molars of 22 orthodontic patients at the Orthodontics Department of Shahid Beheshti Dental University. Elastomeric separators were placed at the mesial and distal of mandibular right and left first molars by separating pliers. Randomly, LIPUS was used at one side for 7 min and the same device with 0-degree intensity was used as sham for the other side on the facial skin. The same procedure was repeated after 24 h. Patients recorded their level of pain at 1, 6, and 24 h, and also on days 2 to 7 after, using a visual analog scale (VAS).

Results: The effect of type of treatment (P=0.019), time of assessment (P<0.000) and the interaction effect of type of treatment and time of assessment (P=0.055) on the pain score were all significant. The mean pain score in the LIPUS group was significantly lower than that in the control group at 24 h (P=0.002), 4 days (P=0.031) and 5 days (P=0.035).

Conclusion: LIPUS can be safely used during orthodontic treatment for pain control since it is safe, non-invasive, low-cost, and easy to use.

Keywords: Orthodontics; Pain; Ultrasonics

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INTRODUCTION

Pain during orthodontic treatment is a major concern for patients and orthodontists [1], and is a major factor in discontinuation of treatment [2,3] and prevention of adequate plaque control [4]. About 70% of the Caucasians and 90% of the Asian population complain of pain during orthodontic treatment [5]. Orthodontic pain is part of an inflammatory reaction due to changes in blood flow following the application of orthodontic forces, causing release of chemical mediators such as substance P, histamine, serotonin, prostaglandin E, leukotrienes, and cytokines, causing hyperalgesia. Pain often continues for the next 2 to 4 days, and then disappears until reactivation of the appliance [4].

There is no standard protocol for orthodontic pain control [6]. Several methods such as transcutaneous electrical nerve stimulation (TENS), soft laser irradiation, vibratory stimulation, plastic bite wafer, chewing gums,

and use of non-steroidal anti-inflammatory drugs (NSAIDs) have been suggested [7-13]. Intraoral use of TENS is effective for pain control; but it prolongs the duration of patient visits [14]. Moreover, pain may develop when the patient is not in the clinic. Thus, TENS does not seem to be well suitable for pain control.

Low level lasers have also shown optimal efficacy for pain control; however, the results in this respect are controversial [7,10]. This may be due to the technical sensitivity of this method.

Most patients cannot tolerate vibration after initiation of orthodontic pain [12]. The results of studies regarding biting on plastic wafers or chewing gums show that although they decrease pain in most patients, in some others, they not only have no significant analgesic effect, but may even aggravate the pain [11,15]. Systemic administration of NSAIDs also has some risks such as toxicity [16] and drug interference, and also has a negative effect on tooth movement [12]. Use of ultrasound as a diagnostic method for therapeutic purposes has been previously reported. Therapeutic ultrasound is extensively used in dentistry for treatment of myofascial pain dysfunction syndrome and temporo-mandibular disorders [17]. Therapeutic ultrasound is often used with 1 and 3 W/cm^2 power [8].

Application of ultrasound in low frequency and power (3 MHz and 0.1 W/cm^2) with 2 ms pulse and 8 ms intervals for 5 min yields the best results for elimination of inflammation and prevents the secretion and production of inflammatory agents by the cells [17]. Pulsed ultrasound products can aid in the reduction of inflammation, enhance the blood flow, reduce edema, increase the pain threshold, relieve pain, and accelerate tissue repair [18] This study aimed to assess the effect of low-intensity pulsed ultrasound (LIPUS) on pain following orthodontic treatment.

MATERIALS AND METHODS

Trial design:

This study was designed as a single-blind split-mouth randomized controlled clinical trial, and each patient in this study received an intervention in mandibular first molar tooth in one side; the contralateral first molar served as the control.

Participants, eligibility criteria, and settings:

A total of 44 mandibular first molars of 22 patients presenting to the Orthodontics Department of Shahid Beheshti School of Dentistry and two private clinics in Tehran were evaluated. The selected patients were 10 females and 12 males in the age range of 19-32 years. Written informed consent was obtained from the patients. The study was approved by the ethics committee of Shahid Behehsti University (IR.SBMU.RIDS.REC.1394.169) and registered at www.irct.ir (IRCT20160626028640N2).

The eligibility criteria were: Absence of periodontal or endodontic problems or active caries, no pain at the onset of study, absence of spacing, presence of tight contacts between the permanent first molar and adjacent teeth, no intake of systemic analgesics, presence of antagonistic tooth, absence of posterior open bite, willingness for participation in the study, and patient expressing pain following placement of orthodontic separators.

The exclusion criteria were detachment of a separator, not filling out the questionnaire, and use of analgesics during the study period.

Interventions:

Elastomeric separators (Ortho Organizer Inc., USA) were placed at the mesial and distal of mandibular right and left first molars using separating pliers by an experienced orthodontist. Randomly, LIPUS (Ultrasound 21 OP; Novin medical engineering, Isfahan, Iran) was used at one side for 7 min, and the same device with 0-degree intensity was used as sham for the other side on the facial skin for 7 min. The output frequency of the device was 1 MHz, its modulation frequency was 100 Htz, and its degree of modulation was 100%. The maximum output power was 3 W/cm^2 in the pulse mode [19]. The same procedure was repeated after 24 h. Patients were requested to record their level of pain at 1, 6, and 24 hours and also at 2 to 7 days after placement of separators using a 0-100 visual analog scale (VAS) for both left and right quadrants of the mandible.

Outcomes (primary and secondary) and changes after trial commencement:

The primary outcome was evaluation of the efficacy of LIPUS for orthodontic pain control.

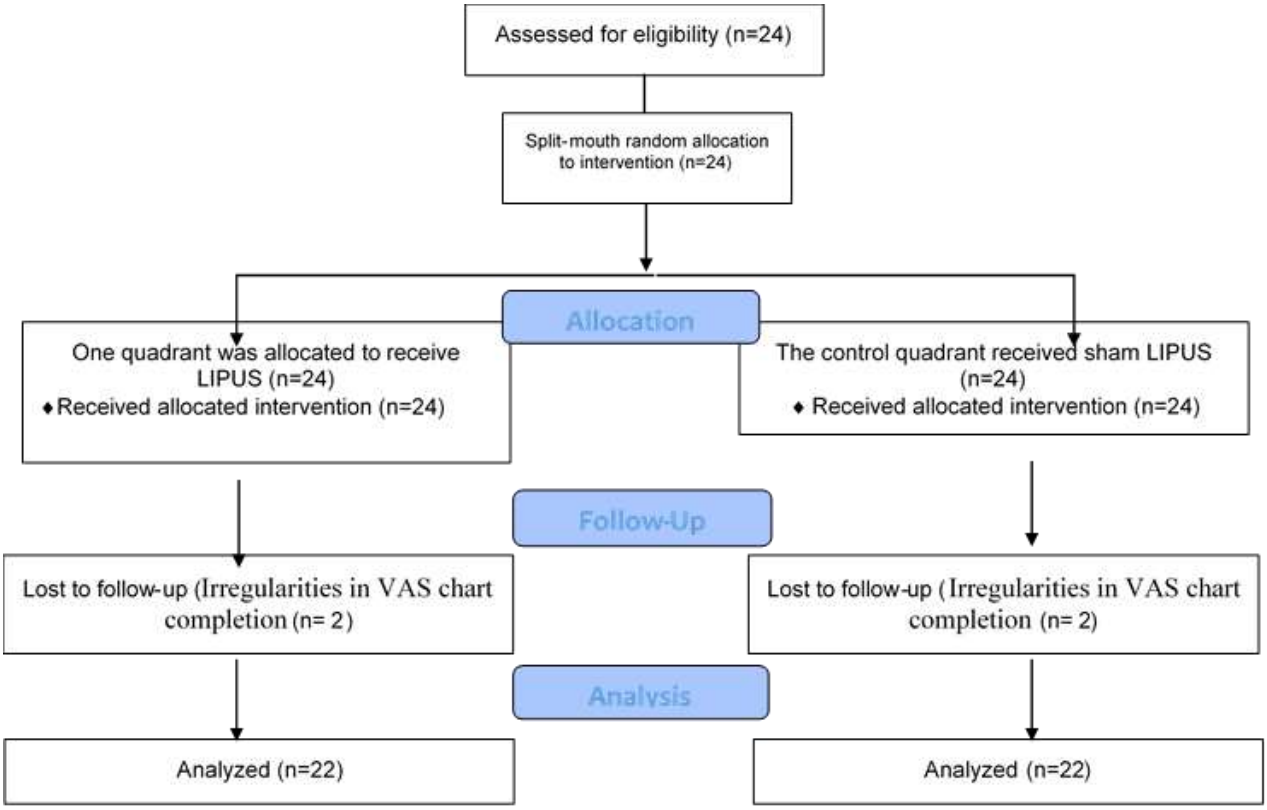

Fig. 1. Study flow diagram

The secondary outcome was to find the day of maximum and minimum pain score. Increased pain was an unpredicted outcome.

Sample size calculation:

The sample size was calculated to be 44 first molars using Minitab software, assuming alpha=0.05, beta=0.2, and mean standard deviation of 14.

Randomization:

In the present split-mouth clinical trial, random allocation of first molars in the right and left sides of the mandible to the experimental and control groups was done by using simple randomization method and a randomization table.

Blinding:

The participants did not know that which one of their mandibular first molars was in the experimental or control group.

Statistical analysis:

Normal distribution of data was assessed using the Kolmogorov-Smirnov test.

Since data were normally distributed (P>0.05), repeated measures ANOVA with two within factors (time of assessment and type of treatment) was applied for general comparison, and Bonferroni test was used to compare the mean pain score between the two groups at each time point. The mean and standard deviation of pain score at different time points in the two groups were reported. Level of statistical significance was set at α=0.05.

RESULTS

A total of 24 patients were assessed to be eligible for participation in this trial. Two patients were excluded from the study due to irregularities in their VAS chart completion (Fig. 1). The mean age of patients was 24.5±12.66 years (range 19 to 32 years). There were 10 females (45.4%) and 12 males (54.5%). In both groups, patients reported the lowest pain score on day seven and the highest level of pain on day two.

Table 1. Mean and standard deviation of pain in the LIPUS and control groups at different time points

Time point	Control N=22	LIPUS (N=22)	Difference	P value
One hour	17.27±13.69	17.27±15.63	0±5.11	1
Six hours	32.95±18.49	30.91±17.50	2.04±7.5	0.215
24 hours	38.40±17.82	31.36±15.28	7.04±9.08	0.002
Day two	42.27±15.01	37.95±15.17	4.31±10.03	0.057
Day three	39.09±15.01	34.09±16.23	5.00±12.14	0.067
Day four	31.36±11.87	26.13±12.14	5.22±10.63	0.031
Day five	25.90±12.21	21.13±12.04	4.77±9.93	0.035
Day six	19.31±11.47	15.45±9.24	3.86±9.11	0.06
Day seven	14.77±10.29	11.13±7.7	3.63±8.33	0.053

Table 1 shows the mean and standard deviation of pain in LIPUS and control groups at different time points. The effect of type of treatment (P=0.019), time of assessment (P<0.001) and the interaction effect of type of treatment and time of assessment (P=0.055) on the pain score were found to be significant by repeated measures ANOVA. Due to the marginally significant interaction effect, it seems that the trend of change in pain score was not completely the same over time between the two groups. Figure 2 shows the trend of change in pain score over time in the two groups. The mean pain score was compared separately between the two groups at each time point (Table 1). The mean pain score in the LIPUS group was significantly lower than that in the control group at 24h (P=0.002), 4 days (P=0.031), and 5 days (P=0.035).

DISCUSSION

Pain due to activation of orthodontic appliances is a common problem in orthodontics, and researchers have long been in search of ways to minimize this pain. Pain due to orthodontic treatment is often local; thus, local pain control measures are often more effective for pain relief [12,20-22].

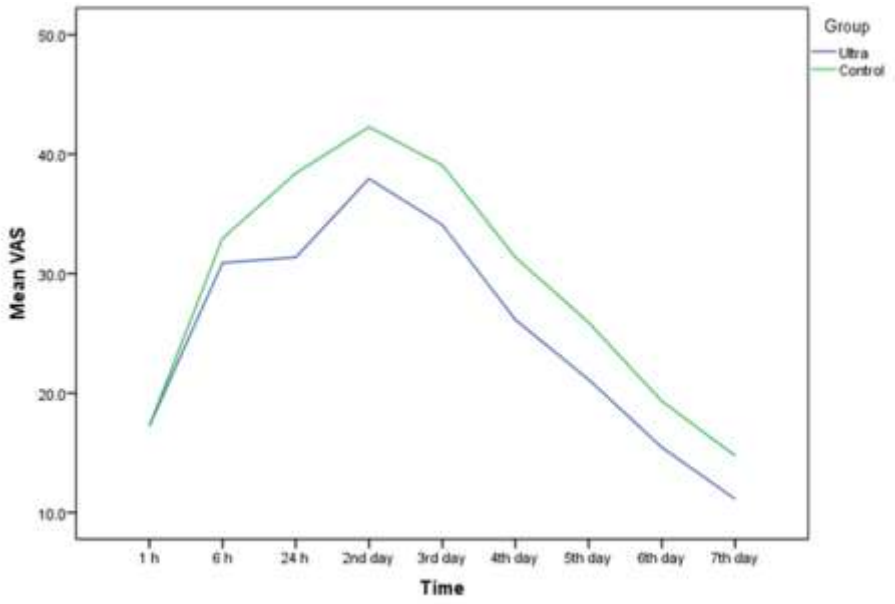

Fig. 2. Trend of change in pain score over time in the two groups

No consensus has been reached on a standard method suitable for local pain control in all orthodontic patients. Thus, this study aimed to assess the efficacy of LIPUS for orthodontic pain control. Orthodontic pain is attributed to the development of ischemic areas in the periodontal ligament that have undergone sterile necrosis and hyalinization.

Hypersensitivity to pressure indicates the presence of inflammation at the apex. Mild pulpitis that usually occurs after the application of orthodontic force also plays a role in pain generation [20]. Ultrasound can enhance the blood flow and circulation of fluids in the body, increase the permeability of the cells and pain threshold, stop the pain cycle, and decrease pain [19,23].

This study had a split-mouth design and one side of the jaw served as the test and the other side as the control group. By doing so, the confounding effect of difference in anatomical force of the jaws was eliminated. Allocation of type of intervention to the side of the jaw was random. Comparison of pain score at the two sides also eliminated the confounding effect of referral pain because referral pain does not cross the midline unless the site is very close to the midline and receive innervation from the other side [1].

Separators often cause significant pain. However, inter-individual differences in pain perception also exist, and some patients report no pain at all. We used elastic separators in this study for the purpose of standardization. Eslamian et al, [10], Patel et al, [24] and Eslamian et al, [9] also used separators to induce pain. VAS was used to assess the intensity of pain, which has been used in many previous studies [9,25].

In the current study, level of pain at 1 h was not significantly different between the two groups, probably because pain and inflammatory mediators often appear after 2-4h. At 6h, the difference between the two groups was not significant either. The greatest difference in pain score was noted at 24 h after the placement of separators following the second dose of LIPUS, which highlighted the efficacy of LIPUS for pain reduction. Both groups experienced maximum pain on day 2 but the pain score was still lower in the LIPUS group (marginally significant difference). On day 3, level of pain was lower in the LIPUS group but not significantly. On days 4 and 5, level of pain in the LIPUS group was significantly lower than that in the control group. The difference in this regard was not significant on day 6, and marginally significant on day 7. The lowest level of pain was noted on day 7 in both groups. The highest mean pain score was noted on day 2 in the control group, and the lowest mean pain score was noted on day 7 in the LIPUS group. Previous studies on the use of LIPUS for orthodontic pain relief are limited. In the study by Eslamian et al, [9] maximum mean pain score in both groups was noted on the second day, and the lowest mean pain score was recorded on day 7. Maximum pain score was at 24 h in the control group, and minimum pain score was noted in both groups on day 7. Esposito et al. [17] used ultrasound with 1 MHz frequency, 120 Htz repetition rate, and 0.75-2 W/cm^2 intensity for 3-5s for treatment of myofascial pain dysfunction syndrome. They concluded that ultrasound is the most successful modality for pain control in such patients. Their results were in line with ours. Majlesi and Unalan [26] used high-intensity ultrasound in continuous mode for treatment of active myofascial trigger points. They concluded that high-intensity technique and static ultrasound are highly effective for treatment of acute trigger points. Grieder et al. [23] evaluated patients with temporomandibular disorders and muscle spasm at the region and reported that ultrasound treatment alone was not effective for elimination of symptoms but it was effective in combination with other therapeutic modalities such as occlusal splint, physiotherapy, heat treatments, and muscle traction exercises. Kropmans et al. [27] reviewed 24 articles on different modalities including ultrasound for temporomandibular disorders and found no significant difference among the modalities in terms of effectiveness. Their study was different from ours since they assessed joint disorders.

Tehranchi et al. [28] evaluated the effect of LIPUS on bone regeneration and pain relief

following orthognathic surgery. They performed LIPUS after mandibular surgery and took digital panoramic radiographs immediately after surgery and 3 weeks later. They reported a significant increase in bone density at the borders and medulla. Also, the pain score was significantly different in the two groups at 3 weeks, and they showed that LIPUS increased bone regeneration and decreased pain after orthognathic surgery; their results were in agreement with ours since our study showed that LIPUS significantly decreased pain after placement of orthodontic separators. Thus, it can be used for pain reduction during orthodontic treatment. The subjective nature of pain was a limitation of this study since patients have different perceptions of pain, and inter-individual differences exist in this respect. However, the split-mouth design of the study overcame this limitation to a great extent. Small sample size was another limitation of this study. Future studies are required to find the perfect settings of ultrasound to obtain the best results. Also, future studies should assess the effect of different doses and durations of LIPUS on pain following other orthodontic procedures and in a larger group of patients.

CONCLUSION

Within the limitations of this study, the results showed that the level of pain was significantly lower in the LIPUS group at 24h, and 4 and 5 days compared with the control group and LIPUS effectively decreased pain following placement of elastic separators.

CONFLICT OF INTEREST STATEMENT

None declared.

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