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The Effect of Lavender Inhalation on the Pain Perception of Orthodontic Separator Placement: An Open-Label Randomized Controlled Trial

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Abstract

Lavandula angustifolia Mill. (lavender) is known for its antibacterial, muscle relaxant, antispasmodic, sedative, and anesthetic effects, and is also proposed to be used as an analgesic agent. Despite several studies on the analgesic activity of lavender, this is the first experiment in patients with orthodontic pain. This "2-arm parallel" study aims to evaluate the effect of lavender oil inhalation on reducing pain after elastomeric separator placement as a part of orthodontic treatment. Patients who needed elastic separator placement in mesial and distal of first permanent molars of all quadrants prior to their first-ever fixed orthodontic treatment, with the age range of 20 to 24, were randomly assigned to one of the two study groups: lavender oil and sesame oil. Participants had to breathe in their medication for 2 minutes just before separator insertion, as well as 4, 8, 12, 24, 36, and 48 h afterward. A visual analog scale (VAS) was used to measure the level of pain during three oral situations, including rest, fitting posterior teeth, and chewing at the following periods: just before separator placement (T0), immediately after insertion (T1), 3 h post-insertion (T2), 12 h post-(T3), 24 insertion h post-insertion (T4), and 48 h after separator placement (T5). The current study indicated the effectiveness of lavender oil inhalation in reducing pain perception while chewing 48 h after elastic separator placement. The pain level in lavender inhalation was lower from 12 h to 48 h after separator insertion, although not considerable, indicating the probability of its effectiveness on delayed responses to orthodontic pain.

Keywords: Lavandula; Orthodontic pain; Medicinal plants; Pain management

Introduction

Recent researches are focused on the concerns of orthodontic treatment, some exacerbating the side effects of the process, and some enhancing the backward pace to relapse after treatment. Factors affecting the acceleration of tooth movement [1,2], the quality of bone formation, which affects the retention period and the amount of relapse, [3,4] the type of appliances [5,6], and so forth. One other critical concern is pain and discomfort as one of the most common complaints among the patients who undergo orthodontic treatments. The amount and experience of pain perception vary among individuals [7]. Some factors such as anxiety and a negative experience of previous dental treatments might increase the chance of pain perception. Reaction to pain perception seems to vary with the individuals' incentive, gender, and personality [8,9]. According to earlier studies, approximately 10% of orthodontic patients give up therapy due to the experience of pain in the first stages. Additionally,

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hearing about the probability of pain during orthodontic treatment might prevent orthodontic patients from attending even if it was urgent [8].

Molars generally have a very tight interproximal contact point; therefore, elastic separators are used in the early stages of the therapy to create the space. We need a sufficient separation to have a good orthodontic band adaptation [10,11]. Among different separating devices for banding molars, such as brass wire, separating tape, rubber separator, separation springs, and latex plastics, the most popular ones are elastomeric separators due to their simplicity and effectiveness [12,13].

The reason for orthodontic pain is inflammation, ischemia, and edema in the compressed periodontal ligament. Subsequently, mediators like histamine, bradykinin, prostaglandins, serotonin, and substance P are released. These mediators stimulate the nerve endings, which results in pain perception. There are various approaches to manage orthodontic pain and reduce the discomfort of this treatment. Apart from the efficiency of these methods, some are as follows: using systemic analgesics, chewing on a hard subject like a gum or plastic wafer at the beginning of the activation, Low-Level Laser Therapy (LLLT), Transcutaneous Electrical Nerve Stimulation (TENS), and Vibratory Stimulation [13-21].

TENS is an effective non-pharmacologic method of controlling post-adjustment tooth pain [19]. Although the efficiency of these methods is controversy, Tortomano et al. indicated the patients who received LLLT had lower mean scores for oral pain and intensity of pain on the most painful day. Also, their pain ended sooner [17]. Moreover, more studies should be conducted to confirm the effectiveness of these strategies. Systemic analgesics can have some systematic effects like decelerating the tooth movement rate. Also, taking medications needs the compliance of patients [20]. The other methods could achieve a reduction in pain and have no drawbacks. The effectiveness of these methods varies. However, more research on their efficacy is suggested. [17,22].

Recently, herbal extracts have attracted attention due to their biocompatibility and no systematic side effects [23-25]. *Lavandula angustifolia* Mill. (lavender) is from the Lamiaceae family, and in addition to its antibacterial, antifungal, antiflatulent, muscle relaxant, antispasmodic, sedative, and anesthetic effects, it is proposed to be used as an analgesic agent [23,26-28]. It is reported that lavender compounds can have implicit or explicit anti-inflammatory or antinociceptive effects [29].

According to the experiments by Arslan et al., the inhalation of the lavender oil could result in less anxiety and pain in the 6-12-year-old children after the tooth extraction [30]. In addition, Martinez et al. reviewed articles on the medicinal herb effects on dental pain. Among all the medicinal herbs used in aromatherapy, lavender oil is one of the safe essential oils. It is "generally recognized as safe " (GRAS) by the U.S. Food and Drug Administration [26,29]. Nevertheless, Silva et al. concluded that lavender essential oil has some toxic effects in doses up to 1.5 g/kg. However, a 0.6 g/kg dose appears well-tolerated orally [29]. Lavender is commonly consumed in foods. It is possibly safe when taken as medicine. Side effects might include constipation, diarrhea, and headache. When applied to the skin, lavender can sometimes cause skin irritation. It has been used safely as aromatherapy for up to 12 weeks [26, 29].

This study aims to determine the effectiveness of inhaling lavender oil due to its analgesic effect on the pain perception from elastomeric separator placement as a part of orthodontic treatment.

Methods

Trial design

This was a parallel-group, randomized, triple-blind, placebo-controlled clinical trial with a 1:1 allocation ratio, conducted in Shiraz, Iran.

Participants

Thirty-two patients aged 20 to 24 entered the study according to the inclusion criteria: needing elastic separator placement in both maxillary and mandibular arch before fixed orthodontic treatment, starting orthodontic treatment for the first time, being informed, and signing the written informed consent. This narrow range is due to the fact that the pain pattern varies among different age groups. Non-including criteria were recent use of medications such as antibiotics, analgesics, anti-inflammatory, and chronic systemic disease, and not signing the written informed consent. The exclusion criteria were using analgesics, missing the next session, early loss of separators, uncooperative patient, unwilling to continue the study. Participants who met these criteria and signed the written consent form were enrolled in the study. No changes to methods after trial commencement occurred.

The study took place at the Orthodontic Clinic of Dental School at Shiraz University of Medical Sciences, Iran, from February 2020 to June 2021. This study was confirmed by the Ethics Committee of Shiraz University of Medical Sciences (code: IR.SUMS.DENTAl.REC.1399.068). Also, the investigation was registered in the Iranian Registry of Clinical Trials as IRCT20111130008257N3.

Interventions

At the very moment of initiating treatment, patients were given a visual analog scale (VAS) booklet con-

sisting of eighteen VAS prints. The VAS scale was a 10-cm line from zero, demonstrating no pain, to 10, indicating a patient's worst pain.

The same clinician inserted all the separators in the mesial and distal of the first molars of all quadrants.

Medication, either lavender essential oil (Tabibdaru, Iran) or sesame oil (Tabibdaru, Iran), was given in a white bottle, and the investigator, the patients, and the statistician were all blind. Participants had to drip five drops of their medication (lavender oil or sesame oil) on a sterilized gauze and breathe in for 2 minutes just before separator (Dentaurum, Germany) insertion, as well as 4, 8, 12, 24, 36, and 48 h afterward. Then, they had to record their perception of pain in the booklet. VAS was used to measure the level of pain at the following periods: just before separator placement (T0), immediately after insertion (T1), 3 h post-insertion (T2), 12 h post-insertion (T3), 24 h post-insertion (T4), and 48 h after separator placement (T5). In order not to forget the intervals, the alarm was set.

Sesame oil is used as a placebo. Based on previous studies, sesame has no effect and is the best material for a placebo [31].

Lavender oil was extracted by hydrodistillation from L. angustifolia aerial parts and was pure, natural and without any artificial or hazardous components or any kind of adulteration.

We instructed patients to circle the amount of pain during three oral situations, including rest, fitting posterior teeth, and chewing, and hand the questionnaire back in the coming session (a week later). In the rest position, teeth were not in contact. When fitting posterior teeth, the patient should bring the teeth together with a gentle force and not eat anything during the procedure. For chewing function, the participant should bite a yellow apple.

There were no outcome changes after trial commencement.

Sample size calculations

The sample size calculation was based on detecting a significant decrease in the pain perception of elastic separator between the two trial arms (at least two numbers difference in VAS score, with α=0.05, β=0.2, and power of 80%) [21,31].

Randomization

To allocate subjects into two groups of lavender oil and sesame oil inhalation, the statistician accomplished permuted block randomization by random allocation software 2.0 with a block length of 9 with an equal distribution between two groups. The practice manager received the randomization and carried out the process.

Statistical Methods

After data gathering, the normal distribution of the data was determined by the Kolmogorov-Smirnov normality test, and an independent sample T-test evaluated differences between the mean pain score of the two groups by SPSS software (version 22.0). Repeated measure ANOVA and paired T-test were conducted to determine the difference in the pain scores at each time interval. The level of significance for all tests was determined at $p < 0.05$.

Results

In this study, 36 patients (12 males and 24 females) who required fixed orthodontic treatment were randomized in a 1:1 ratio to either lavender or sesame oil. One lost the elastic separators earlier, and three of them used NSAIDs; therefore, the total number of 32 patients (9 males and 23 females) entered this study (Figure 1).

The difference between the two study groups in terms of age was not significant (P = 0.594); the mean age of the control group was 22.85 ± 1.21 years old, and the mean age of the case group was 22.56 ± 1.55 (T-test). Also, the two groups had no significant difference regarding gender (P =0.999).

The trend of pain perception in both groups was the same. In general, the pain was felt and increased gradually after separator placement and reached its peak in T4(24 h) and stayed the same in T5(48 h); however, the severity of pain in the rest position diminished after T4(24 h). (Figures 2,3,4)

Patients in the lavender group underwent less pain and claimed lower VAS scores in 12 h, 24 h, and 48 h post-administration at all positions; nevertheless, no statistically significant difference was detected. The only exception was 48 h after separator insertion while chewing; the control group suffered significantly more (P = 0.034). The control group declared a mean VAS score of 5.38±2.75; while the other reported 3.31 ± 2.24. Table 1 outlines the two groups' descriptive information and repeated measure ANOVA results.

There was a significant difference in pain perception scores during different times in each position (P < 0.001) (Table 1).

In the control group, the results of the paired sample T-test showed significant difference between T0 and T3(P < 0.001), T0 and T4(P < 0.001), T0 and T5(P < 0.001), in rest position and between T0 and T2 (P = 0.001), T0 and T3(P <0.001), T0 and T4(P <0.001), T0 and T5(P <0.001), T1 and T4 (P = 0.002), T2 and T4 (P = 0.001) while fitting posterior teeth. And in chewing function significant differences were between T0 and T1 (P <0.001), T0 and T2 (P <0.001), T0 and T3(P <0.001), T0 and T4(P <0.001), T0 and T5(P <0.001), T1 and T3 (P = 0.002), T1 and T4 (P = 0.001), T2 and T3 (P <0.001), T2 and T4 (P <0.001), T2 and T5 (P = 0.001).

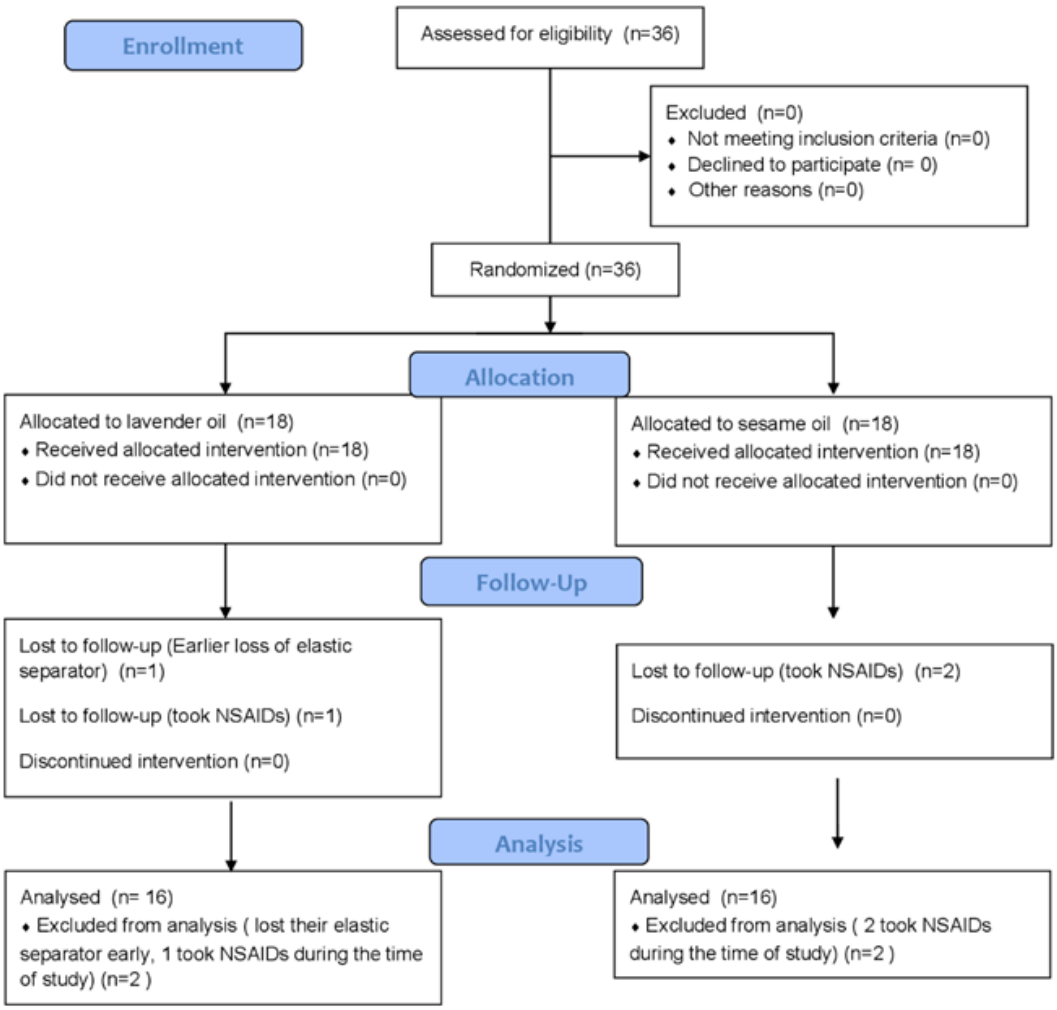

Figure 1. CONSORT flow diagram

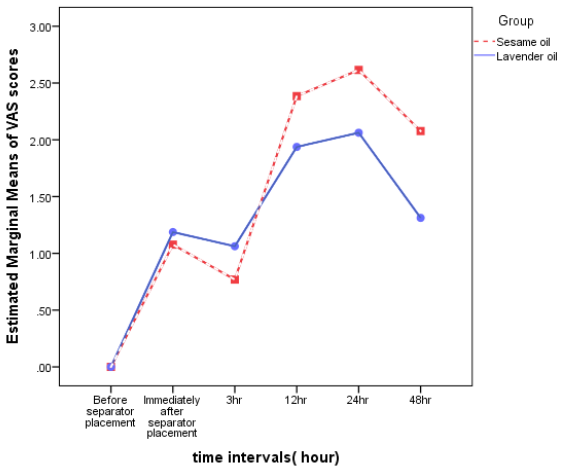

Figure 2. The estimated marginal means of pain score at rest position throughout intervals for the two groups

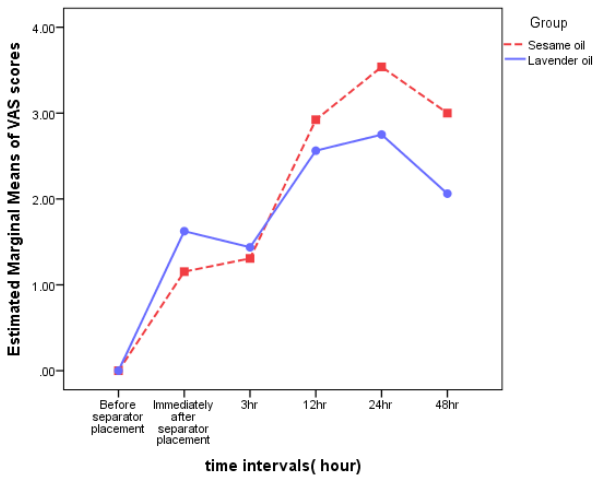

Figure 3. The estimated marginal means of pain score while fitting posterior teeth throughout intervals for the two groups

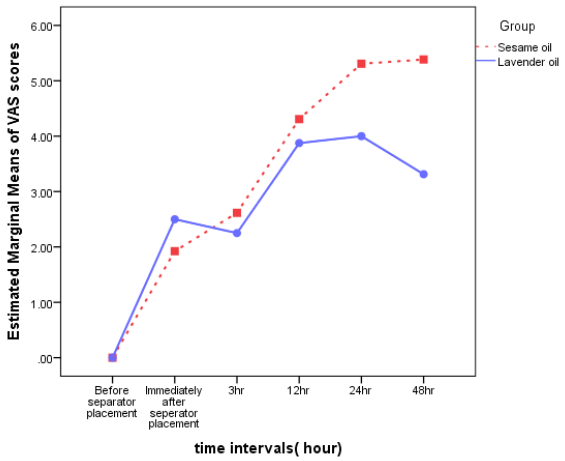

Figure 4. The estimated marginal means of pain score during chewing throughout intervals for the two groups

In the intervention group, the results of the paired sample T-test showed a significant difference between T0 and T4(P <0.001). While fitting posterior teeth, significant differences were between T0 and T1(P =0.001), T0 and T2(P = 0.001), T0 and T3(P < 0.001), T0 and T4(P < 0.001), T0 and T5(P <0.001), and in chewing function were between T0 and T1 (P = 0.002), T0 and T2 (P = 0.003), T0 and T3(P <0.001), T0 and T4(P < 0.001), T0 and T5(P < 0.001).

In both groups, the amount of pain perceived after separator insertion was significantly more in chewing function than in the rest and posterior teeth position (Table 1).

Chewing was the most painful experience among the three studies' parameters (Table 1).

No harm and allergic reaction were observed in both groups.

Table 1. Descriptive information and repeated measurement results of two treatment groups

		Pain index values						
Function	group	T0	T1	T2	T3	T4	T5	P value
Rest	Sesame oil	0	1.07± 1.32	0.77±1.01	2.38± 1.56	2.61± 1.45	2.07± 1.32	<0.001
	Lavender oil	0	1.18± 1.68	1.06±1.53	1.93± 2.17	2.06± 1.73	1.31± 1.49	<0.001
	P value	-	.848	.558	.539	.366	.161	<0.001
Fitting posterior teeth	Sesame oil	0	1.54± 1.41	1.30±1.031	2.92± 1.66	3.54± 1.51	3.00± 1.68	<0.001
	Lavender oil	0	1.62± 2.19	1.43±2.03	2.56± 2.39	2.75± 2.24	2.06± 1.73	<0.001
	P value	-	.508	.836	.649	.287	.154	<0.001
Chewing	Sesame oil	0	1.92± 1.38	2.61±1.04	4.30± 1.70	5.31± 2.25	5.38± 2.75	<0.001
	Lavender oil	0	2.50± 2.42	2.25±2.24	3.87± 2.70	4±2.88	3.31± 2.24	<0.001
	P value	-	.452	.592	.621	.192	.034*	-

The values in the table mean ± standard deviation. P values are based on the independent sample T-test. T0 (before separator placement), T1 (immediately after separator placement), T2 (3 h), T3 (12 h), T4 (24 h), and T5 (48 h).
*Mean difference was significant at the 0.05 level.

Discussion

In this study, we investigated the efficacy of lavender oil on the pain resulting from an orthodontic separator insertion. Although in both groups, the pain perception gradually increased after separator placement and reached its peak in 24 h, those who inhaled lavender oil declared lower VAS scores. Our results revealed that treatment with lavender essential oil effectively reduced the chewing pain induced by elastomeric separator placement 48 h post-administration (P =0.034).

The pain was evaluated and compared using VAS. VAS is widely recognized as reliable, valid, and easy to measure acute and chronic pain. The VAS has previously been used to record pain severity caused by orthodontic separators in child and adolescent studies [32]. Also, the patients could conveniently grasp the definition and answer the questions.

Systemic analgesics might have some adverse effects like decelerating the tooth movement rate. Also, taking medications needs patients' compliance, so the effectiveness of these methods varies [22]. Eslamian et al. explored the relieving property of naproxen patches on orthodontic pain. Zarif et al. also compared the efficacy of acetaminophen, meloxicam, and ibuprofen on separator pain [33]. On the other hand, we used lavender oil and sesame oil due to their safety.

Lavender is available in most areas. It has already been used to treat some gastrointestinal, nervous, and rheumatic disorders and reduce pain during delivery [34,35].

According to the studies, linalool and linalyl acetate are the two of the major components of lavender essential oil [29,31,36]. Some reports show that lavender increases blood flow. Linalyl acetate and linalool in the essential oil stimulate the parasympathetic system, resulting in a lower heart rate, blood pressure, and respiratory rate; therefore, they act as sedatives and narcotics [27].

Arslan et al. and Ghaderi et al. declared the efficacy of lavender oil inhalation on dental anxiety and pain in children [30,37]. Also, Vaziri et al. concluded that lavender inhalation in the early hours of postpartum could lessen the mother's pain and fatigue and improve their mood [31]. Similarly, in the current study, the trend of pain perception in both groups was like each other, with the difference that lavender could decrease the pain more than the control group. The efficacy of lavender might be related to its anxiolytic and antinociceptive potential [27].

In Ghaderi et al. study, children received restorative treatment with lavender aromatherapy in the intervention session and without aroma in the control session [37]. In Arslan et al. study, the lavender group inhaled 100% lavender oil for 3 min before the interventions, tooth extraction, and the control group received no prior application [30]. Also, Vaziri et al. gave 5 drops of lavender oil in each three doses during the first 24 h after delivery. The intervention with lavender oil was repeated 6 h after the first intervention and at bedtime [31]. In present study, patients inhaled 5 drops of the oil 4, 8, 12, 24, 36, and 48 h after the insertion of separator.

Zarif Najafi et al. [21], Mirhashemi et al. [38], and Almelh et al. [22] evaluated the severity of pain in patients who underwent separator insertion. Mirhashemi et al. investigation lasted for 5 days [38]. Almelh et al. asked the subjects to report their findings on a Verbal Scale and a VAS every second minute for a period of 10 min [22]. Moreover, Zarif Najafi et al. study lasted for 48 h [21]. Due to the results of the previous studies that demonstrated the most pain perceived in the first 48 h, the current study recorded the pain perception in 48 h [21,39].

The pain typically begins within 2 h, gets to its maximum at 24 h, and then decreases within seven days after applying the force [8,40-42]. Our results indicated that the pain increased gradually after separator placement and reached its peak in 24 h, which was predictable. This result agrees with the previous studies [21,43,44].

Moreover, the pain subsided 48 h after separator placement, except in the chewing position in the sesame oil group, which increased slightly. This decrease could be related to flushing the inflammatory mediators out caused by increased blood flow induced by lavender inhalation [27]. This tendency toward a reduction in the average pain severity was in concurrence with Artes Ribas et al. [45] and Almallah et al. [46]. They used LLT to examine pain experiences related to orthodontic treatment. However, Farzanegan et al. [47] reported a slight increase using 400 mg ibuprofen in pain levels between 24 h and 48 h when chewing.

Those patients who inhaled lavender oil declared less VAS scores compared to the control group 12h, 24h, and 48h post-administration. Although not statistically significant, except in 48 h while chewing, the pain perception was significantly less in patients who inhaled lavender oil ($P = 0.034$).

As we know, orthodontic forces lead to both immediate and delayed responses from the teeth and alveolar bone structures. Burstone et al. attributed the initial response to ischemia and PDL compression [48]. Delayed responses begin several hours later and largely are imputed to hyperalgesia of the PDL. This hyperalgesia has been related to prostaglandins (PGEs). Released prostaglandins can raise the sensitivity of the pain receptors to noxious agents, such as bradykinin, serotonin, acetylcholine, substance P, and histamine. This condition continues with neurogenic inflammation, osteoblastic and osteoclastic activity, periodontal vasodilation, and pain [48,49].

It is believed that Protein kinase C mediates various intracellular signal transduction pathways, including phospholipase A2-dependent arachidonic acid, which transforms into PGEs. On the other hand, numerous protein kinases C are activated by the mediators created due to the activation of receptors coupled to a G protein. Silva et al.'s findings propose that the process engaged with the anti-inflammatory impact of Lavender might be identified with a G protein-coupled receptor or potentially impedance in the arrangement of intracellular second messenger phospholipase C/ino-

sitol phosphate [29].

As seen in table 1, similar to Zarif Najafi et al. [21] and Farzanegan et al. [47], the most painful experience occurred during chewing. It is comprehensible since orthodontic pain is caused by compression, inflammation, and edema in the periodontal ligament, which is compressed more during function.

Eventually, it should be noted that cultural background, past traumatic experience, and psychological factors might influence the amount of recorded pain perception.

The result of the current study might be generalized; however, it might be limited to different age groups since the pattern of pain differs concerning age. More studies on the molecular process of the anti-inflammatory effect of lavender are suggested for future.

Conclusion

The current study indicated the effectiveness of lavender oil inhalation in reducing pain perception while chewing 48 h after elastic separator placement. The pain level in lavender inhalation was lower in 12 h, 24 h, and 48 h post-administration; although not statistically significant, it seems that it affects delayed responses to orthodontic pain.

Conflict of Interests

None.

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