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Original Article

## Comparative assessment between chewing gum, bite wafers, and ibuprofen in pain control following separators placement among orthodontic patients

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## ABSTRACT

**Objective:** This study aimed to evaluate the efficiency of chewing gum and using bite wafers in reducing pain after the placement of separators in orthodontic patients and to compare that efficiency with ibuprofen use. Additionally, this study evaluated the effect of non-pharmacological pain control methods on the frequency of separators falling out.**Methods:** The study sample comprised 105 female patients between 15 and 35 years of age. The patients were randomly selected and classified into three groups (35 each). Each group was given either ibuprofen, viscoelastic bite wafers, or chewing gum immediately after the placement of separators and every 8 h for 1 week, as needed. The patients were asked to record their pain perception using a visual analog scale following separator placement at 2 h, 6 h, bedtime, 24 h, and at 2, 3, and 7 days. Analysis of variance testing was used for the data analysis.**Results:** Among the three studied groups, there were no significant differences in pain perception at any time point. The patients experienced significantly higher pain scores at bedtime and 24 h after separator placement. In addition, there were statistically significant findings in pain perception at different time points within each pain relief method ( $p = 0.000$ ,  $p < 0.05$ ).**Conclusion:** The use of chewing gum and bite wafers in alleviating orthodontic pain was beneficial and comparable to ibuprofen use following the placement of separators before orthodontic treatment among orthodontic patients.

## 1. Introduction

Pain—an unpleasant subjective feeling—is a major worry for clinicians and patients. Furthermore, pain has been ranked as an important factor for determining treatment acceptance, considered a restriction in patient compliance, and the major reason for the discontinuation of orthodontic treatment (Chow and Cioffi, 2018). This is especially true after separator placement, which causes tooth separation and can thus have an undesirable influence on patients' daily activities (Chow and Cioffi, 2018; Shenoy et al., 2013). Several factors, such as age, gender, amount of orthodontic force, and pain threshold, have been found to affect orthodontic pain (Sandhu and Leckie, 2016; Shenoy et al., 2013). During orthodontic treatment, pain commonly arises from a combination of different abnormalities in the compressed periodontal ligaments (PDL), including ischemic necrosis, inflammation, and edema (de Almeida et al., 2016; Higashi et al., 2017). Orthodontic pain usually initiates within a few hours after separator placement and persists for

5–7 days (Burstone, 2017; Sandhu et al., 2016). In general, children tend to report pain less often than adults, although the former report their pain as having greater intensity (Campos et al., 2013). In addition, it has been found that females report having greater pain than males (Sandhu and Sandhu, 2013).

Orthodontic pain control is an important issue in enhancing patient compliance and cooperation during the course of treatment. Therefore, various pharmacological and non-pharmacological methods have been recommended for controlling orthodontic pain, such as nonsteroidal anti-inflammatory drugs (NSAIDs) (Patel et al., 2011; Shetty et al., 2013), low-level laser therapy (LLLT), low-intensity pulsed ultrasonography (Alhanbali et al., 2024a; Almallah et al., 2020; Owayda et al., 2022), transcutaneous electrical nerve stimulation (Kasat et al., 2014), anesthetic gels (Kwong et al., 2011), medicated wax (Eslamian et al., 2013), vibratory stimulation of the PDL (Aljudaibi and Duane, 2018), bite wafers, and chewing gum. It has been suggested that non-pharmacological alternatives, such as bite wafers and chewing gum,

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for pain control help overcome the side effects of NSAIDs, such as stomach problems, liver toxicity, thrombocytopenia, allergic reactions, hypertension, and renal insufficiency (Del Vecchio et al., 2017; Farzanegan et al., 2012). The effect of bite wafers and chewing gum on orthodontic pain control stems from temporarily displacing the teeth and loosening the tightly grouped PDL fibers enough to allow blood to flow through compressed areas, which prevents inflammation and edema and relieves pain and discomfort (Farzanegan et al., 2012; Ireland et al., 2017). Therefore, this study aimed to evaluate the efficiency of chewing gum and using bite wafers in reducing pain after the placement of separators in orthodontic patients and to compare that efficiency with ibuprofen use. This study also evaluated the effect of non-pharmacological pain control methods on the frequency of separators falling out.

**2. Materials and methods**

After obtaining patients’ informed consent and institutional ethical board approval [E-22-7436], a randomized clinical study was conducted at the Department of Orthodontics, College of Dentistry, King Saud University, Riyadh, Saudi Arabia. The sample comprised 105 female patients scheduled for separator placement for molar bands before receiving fixed orthodontic appliances.

**2.1. Inclusion criteria**

- Aged 15–35 years
- Medically fit
- No temporomandibular disorders
- Mild dental crowding according to Little’s Irregularity Index (Little, 1975)

**2.2. Exclusion criteria**

- A history of ibuprofen hypersensitivity
- Receiving any analgesic therapy
- Systemic periodontal disease
- Previous orthodontic therapy
- Pregnant

**2.3. Data collection**

The anonymity of the study participants was ensured, and data were kept protected to ensure information confidentiality. The patients were randomly placed into three groups (35 each) using the random number table method. The patients in each group received one of the following treatments immediately after separator placement at the mesial and distal of the maxillary first molars, and every 8 h for 1 week, as necessary: ibuprofen (400 mg, oral tablets), hard viscoelastic bite wafers (Dentakit Company), or sugar-free chewing gum (Trident White Spearmint Sugar-Free Gum, Mondelez International Group, East Hanover, USA). In the bite wafer and chewing gum groups, the patients were instructed to chew for only 5 min immediately after separator placement and at 8-h intervals (as needed) for 1 week. In addition, they were informed that they could take 400 mg of ibuprofen as a backup medication if the first two methods proved ineffective. They were instructed to document the frequency and dosage if any ibuprofen was taken. The patients used a visual analog scale (VAS) and recorded their pain perception while biting, chewing, and fitting anterior and posterior teeth immediately after separator placement at 2 h, 6 h, bedtime, 24 h, and 2, 3, and 7 days following separator placement. All patients were asked to rate their pain intensity by marking a calibrated 10-cm line, with both ends defined as the extreme limits of the parameter to be measured (Streiner et al., 2015). Furthermore, all participants were asked to report any separators falling out while using non-pharmacological methods to the orthodontists at their next

appointment.

**2.4. Statistical analysis**

The normal distribution of variables was analyzed using the Shapiro–Wilk test. The sample size was calculated after performing the G\*Power software analysis.

Age and VAS scores are presented as mean ± standard deviation (SD). To analyze the significance of the mean decrease in VAS scores between the three groups, one-way analysis of variance (ANOVA) and Tukey tests were applied. In addition, a repeated measurement was used within each method to analyze the time points’ effects. Data were analyzed using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA), with the level of significance determined at  $P \leq 0.05$ .

**3. Results**

A total of 15 patients were excluded from the present study either for failure to return the given VAS with their pain perception or because they had taken additional medication (chewing gum and wafer groups). Hence, A total of 90 patients (30 patients in each group) participated in the study. Descriptive statistics with mean values and SDs reporting the individuals’ age, pain perception values at different time points, and incidences of separators falling out among the three groups are presented in Table 1. At each follow-up point, the bite wafer and chewing gum groups showed no significant differences and had similar decreases in the mean pain score for each follow-up compared to the ibuprofen group (Table 1).

Fig. 1 illustrates the mean pain perception values at each time point for the three groups. It shows that the pain score was at its highest level at bedtime and/or at 24 h among the different groups. No clinical or statistical differences were found between the groups ( $p = 0.57$ ,  $p < 0.05$ ). However, when repeated measurement was used, the pain

**Table 1**

Descriptive statistics with mean values and standard deviations reporting the individuals’ age, pain perception values at different time points, separators falling out incidence among the three groups and analysis of variance (ANOVA) results.

	Pain Relief Methods	Mean	Std. Deviation	P-Value*
Age	Ibuprofen	24.65	6.12	–
	Wafer	21.75	7.38	
	Chewing gum	25.90	6.99	
2 Hours	Ibuprofen	3.95	1.65	0.78
	Wafer	3.64	1.43	
	Chewing gum	3.67	1.51	
6 Hours	Ibuprofen	4.40	1.63	0.75
	Wafer	4.37	1.24	
	Chewing gum	4.22	1.80	
Bed Time	Ibuprofen	5.10	1.63	0.69
	Wafer	4.97	1.10	
	Chewing gum	4.86	1.21	
24 Hours	Ibuprofen	5.09	1.71	0.19
	Wafer	4.44	1.20	
	Chewing gum	4.22	1.90	
2 Days	Ibuprofen	3.39	1.20	0.34
	Wafer	2.59	1.35	
	Chewing gum	2.87	1.89	
3 Days	Ibuprofen	1.88	1.15	0.49
	Wafer	1.76	1.28	
	Chewing gum	2.10	1.64	
7 Days	Ibuprofen	1.09	1.20	0.79
	Wafer	0.98	0.98	
	Chewing gum	1.07	1.14	
separators falling out	Ibuprofen	0.00	0.00	0.56
	Wafer	0.00	0.00	
	Chewing gum	0.002	0.22	

\*One-way repeated measurement analysis of variance (ANOVA) at the 0.05 level.

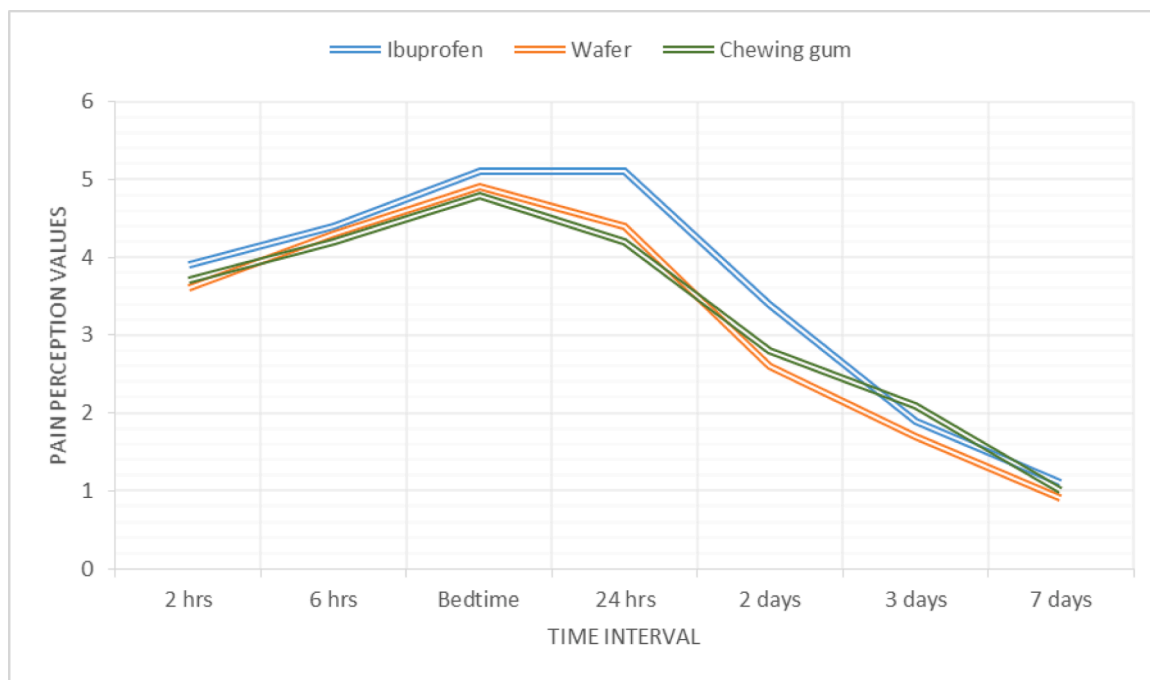


Fig. 1. The pain perception mean values at each time point in the three groups showed that the pain scores were slightly higher with maximum intensity at bedtime and/or at 24 h among different groups.

perception finding at different time points using each pain relief method (ibuprofen, wafers, and chewing gum) was statistically significant ( $p = 0.000$ ,  $p < 0.05$ ) (Tables 2 and 3). ANOVA results confirmed that no statistically significant differences in separators falling out were observed between the groups ( $p = 0.56$ ,  $p < 0.05$ ), even though one subject from the chewing gum group reported an incident of separators falling out at the next routine visit (Table 1).

#### 4. Discussion

This randomized clinical study was designed to evaluate the efficiency of chewing gum and using bite wafers in reducing pain after the placement of separators in orthodontic patients and to compare it with ibuprofen use. Since some differences in pain experiences between genders have been reported, only female patients were included in the present study to exclude any gender-dependent variability in the sample (Sandhu and Sandhu, 2013). No statistically significant difference was found in pain perception at any time point among the three groups. This finding aligns with several studies on the effect of sugar-free chewing gum and plastic wafers as non-pharmacological methods for orthodontic pain control following the placement of orthodontic separators and/or appliances (Abdul-Aziz, 2021; Alshayea, 2020; Azeem et al., 2018; Bayani et al., 2016; Farzanegan et al., 2012; Santos and Jr, 2021).

Alhanbali et al.'s systematic review in 2024 assessed evidence of the effectiveness of pharmacological and nonpharmacological methods in

Table 2 Mean pain perception findings at different time points and their overlap with highest intensity at bedtime and/or at 24 h among different groups.

Time points	Mean	Std. Deviation
2 Hours	3.55	1.64
6 Hours	3.76	1.68
Bed Time	4.87	1.21
24 Hours	4.48	1.75
2 Days	2.77	1.61
3 Days	2.08	1.45
7 Days	0.94	0.95

Table 3 Repeated measurement results showing no statistical differences between pain relief methods (ibuprofen, wafers, and chewing gum) while the pain perception findings at different time points within each pain relief method was statistically significant.

Variables		Means ± SD	Sig. *
Time points	Mean increase from baseline to bedtime	1.30 ± 1.28	.000
	Mean decrease from bedtime to 7 days	4.08 ± 1.22	
Pain relief methods	Ibuprofen	Mean increase from baseline to bedtime	1.4 ± 1.52
		Mean decrease from bedtime to 7 days	4.20 ± 1.30
	Wafer	Mean increase from baseline to bedtime	1.4 ± 1.20
		Mean decrease from bedtime to 7 days	4.16 ± 1.25
	Chewing Gum	Mean increase from baseline to bedtime	1.2 ± 1.28
		Mean decrease from bedtime to 7 days	3.87 ± 1.09

\*Sig – approximate significance, where P-value at 0.05 level.

pain reduction induced by orthodontic separators. They found that the application of LLLT decreased pain on the day of separator placement. Although LLLT effectively reduced pain, the evidence was weak to moderate. In addition, no comparison was achieved between LLLT and the use of bite wafers and chewing gum due to a lack of thorough research on this topic, which provided the stimulus for this paper (Alhanbali et al., 2024b).

The results of the present study show that in all groups, the pain score increased to maximum intensity at bedtime and 24 h after separator placement, indicating that the overall difference in pain perception between the three methods was not statistically significant. Conversely, between time points within each pain control method, it was statistically significant. This pain trend was similar to the findings reported in several studies (Azeem et al., 2018; Farzanegan et al., 2012). The pain

score peaking at bedtime and 24 h after separator placement can be attributed to the combination of different abnormalities in the compressed PDL, such as ischemia, inflammation, and edema (Farzanegan et al., 2012).

Furthermore, this study evaluated the effects of non-pharmacological pain control methods on the frequency of separators falling out. Even though the orthodontists instructed their patients to avoid using chewing gum to prevent the separators from falling out and the gum from otherwise sticking to the separators, the patients in the chewing gum groups were instructed to chew for not more than 5 min every 8 h (as needed) for 1 week to avoid the risk of the separators falling out. If the separators fell out, the patient was instructed to contact the clinic immediately to replace the lost separator. This study showed that neither bite wafers nor chewing gum use had a significant impact on the number of separators falling out compared to patients using ibuprofen only. To the best of our knowledge, no previous research has investigated such a comparison. However, several clinical trials (Alshayea, 2020; Benson et al., 2012; Ireland et al., 2016) have shown that chewing gum use has no significant effect on the number of appliance breakages. The single incidence of a separator falling out could be attributed to other reasons, such as hard brushing or intentional removal of the separator. The limitations of the present study were its small sample size and gender being limited to females only. Therefore, further studies with a larger sample size are needed, along with those including male patients to study the gender effect. Additionally, further comparisons between different pharmacological and nonpharmacological methods in decreasing the pain induced by orthodontic separators are needed.

## 5. Conclusion

The use of bite wafers and sugar-free chewing gum significantly decreased the initial pain resulting from orthodontic separators. The results showed that bite wafers and chewing gum were as effective as ibuprofen in reducing pain at all time points among Saudi orthodontic patients. Therefore, the use of bite wafers and chewing gum can be recommended as a non-pharmacological alternative to reduce the need for systemic analgesics, such as ibuprofen. In addition, no significant differences in the incidence of separators falling out were found between the studied groups.

## Ethical statement

The work has been approved by the Institutional Review Board (IRB), King Saud University [E-22-7436] in which it was performed and that subjects gave informed consent to the work.

## CRedit authorship contribution statement

**Eman Alshayea:** Conceptualization, Investigation, Methodology, Project administration, Resources, Validation, Writing – original draft. **Aljazi Aldweesh:** Conceptualization, Methodology, Resources, Visualization. **Hana Albalbeesi:** Data curation, Formal analysis, Methodology, Writing – review & editing. **Mohammad Aldosari:** Formal analysis, Investigation, Supervision, Writing – review & editing.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sdentj.2024.04.010>.

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