

Pain reduction after initial archwire placement in orthodontic patients: A randomized clinical trial

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Introduction: The aim of this study was to compare the efficacy of ibuprofen, viscoelastic bite wafers, and chewing gum in reducing orthodontic pain. **Methods:** This randomized clinical trial included 50 girls between the ages of 13 and 18 years classified into 5 groups of 10 each: placebo, ibuprofen (400 mg), chewing gum, soft viscoelastic wafer, and hard viscoelastic wafer. The patients in each group received 1 method immediately after placement of the initial archwires and every 8 hours if they experienced pain. Pain perception was recorded by the patients while chewing, biting, fitting front teeth, and fitting posterior teeth at 2 hours, 6 hours, bedtime, 24 hours, 2 days, 3 days, and 7 days after archwire placement, using a visual analog scale. Analysis of variance (ANOVA) and Tukey tests were used for data analysis. **Results:** There were significant differences in pain perception of chewing function between the placebo group and the chewing-gum group at 24 hours and 7 days, and between the placebo group and the hard-viscoelastic group on the day 7 ($P < 0.05$). Also, there were significant differences between the placebo group and the soft-viscoelastic group, and between the placebo group and the hard-viscoelastic group in pain severity when fitting posterior teeth at 6 hours ($P < 0.05$). At other times and with other functions, no significant differences were recorded. **Conclusions:** Both chewing gum and viscoelastic bite wafers are effective for pain reduction in orthodontic patients and can be recommended as suitable substitutes for ibuprofen. (Am J Orthod Dentofacial Orthop 2012;141:169-73)

Pain is a common experience in orthodontic patients, and fear of pain and discomfort is a concern for many. Orthodontic pain arises from ischemia, inflammation, and edema in the compressed periodontal ligament.¹ In an inflamed and ischemic periodontal ligament, mediators such as histamine, bradykinin, prostaglandins, serotonin, and substance P are released.² These mediators irritate the nerve ends of the pain receptors, thus causing pain. Orthodontic pain usually begins at 2 hours after force application and reaches its maximum intensity at bedtime or at 24 hours, and lasts approximately 5 to 7 days.³⁻⁸

Various methods have been suggested for pain control in orthodontic patients, including low-level laser therapy,⁹

transcutaneous electrical nerve stimulation,^{10,11} vibratory stimulation of the periodontal ligament,¹² and nonsteroidal anti-inflammatory drugs (NSAIDs).^{3,13-15} Until now, the use of NSAIDs has been reported as the most successful modality in orthodontic pain reduction; in most studies, this method has been called the gold standard. Briefly, NSAIDs block the formation of arachidonic acid in the prostaglandin production cycle, so the concentration of prostaglandins, which are important pain mediators, will be reduced.¹⁵

However, in recent years, the side effects of NSAIDs such as thrombocytopenia, skin rashes, headaches, and so on, have been considered issues of concern, particularly in young orthodontic patients. Consequently, non-drug methods of pain control such as chewing gum or plastic wafers have been recommended.¹⁶ The mechanism of these methods is to loosen the tightly grouped periodontal ligament fibers around the nerves and blood vessels, restoring the normal vascular and lymphatic circulation of the periodontal ligament, thus preventing or relieving inflammation and edema, and finally relieving pain and discomfort.^{1,17}

This study was designed because of the scarcity of research evaluating the efficacy of nondrug methods in orthodontic pain control. The aim of this study was to compare the efficacy of ibuprofen, chewing gum, and

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viscoelastic bite wafers in pain reduction during the first week after initial archwire placement.

MATERIAL AND METHODS

This was a randomized placebo-controlled clinical trial approved by the research ethic committee of Mashhad University of Medical Sciences in Iran. The study took place at the orthodontic clinic of its dental school. Fifty female orthodontic patients between 13 and 18 years of age, scheduled for fixed orthodontic treatment, participated in this research.

The patients had no systemic diseases and were not receiving analgesic therapy. They had moderate crowding (4–8 mm) according to Little's irregularity index. All patients needed extraction of the 4 first premolars for orthodontic reasons, and the extractions were scheduled to be finished at least 2 weeks before the placement of the orthodontic appliances. The patients and their parents were informed about the details of the study, and informed consent was obtained from each patient.

The subjects were randomly assigned to 1 of 5 parallel groups in a 1:1:1:1:1 ratio according to their clinic entrance number and a random number table. In all groups, the orthodontic appliances, including bands, brackets (0.018-in standard edgewise system) and archwires (0.016-in nickel-titanium) were placed during 1 appointment.

In the placebo group, the patients were asked to take a B₆ vitamin tablet as a placebo immediately after archwire placement and at 8-hour intervals for a week if pain persisted.

In the ibuprofen group, the subjects took a 400-mg ibuprofen tablet immediately after archwire placement and at 8-hour intervals for a week if pain persisted.

The subjects in these 2 groups were blinded about the drug that they took.

In the chewing-gum group, the patients chewed a sugar-free gum (Orbit; The Wrigley Company, Chicago, Ill) for 5 minutes immediately after archwire placement and at 8-hour intervals for 1 week if they experienced pain.

In the soft-viscoelastic and hard-viscoelastic groups, the patients used horseshoe-shaped viscoelastic bite wafers with moderate and low toughness, respectively. These blocks were made of polyvinyl siloxane, and their mechanical properties are shown in Table I. Subjects in these 2 groups chewed or bit down on the bite wafers for 5 minutes at 8-hour intervals for 1 week if pain persisted.

The subjects were asked to complete a visual analog scale questionnaire at 2 hours, 6 hours, and bedtime on the day of archwire placement, and at 24 hours, 2 days, 3 days, and 7 days after the first appointment. The format of the questionnaire was a 10-cm line, and the patients were expected to mark a location on the line

Table I. Mechanical properties of the viscoelastic blocks in this study

	<i>Soft viscoelastic</i>	<i>Hard viscoelastic</i>
Pressure resistance in 10% reduction of thickness (MPa)	3.2	6.1
Pressure resistance in 30% reduction of thickness (MPa)	4.7	7.3
Pressure resistance in 50% reduction of thickness (MPa)	5.8	8.5

corresponding to the amount of pain they experienced, with 0 indicating no pain and 10 indicating unbearable pain. The severity of pain was recorded during 4 oral functions including chewing, biting, fitting back teeth, and fitting front teeth. For fitting the front and back teeth, the patients did not eat anything and were instructed to bring the front teeth edge to edge with light force and to fit the back teeth with light force, and then score their pain in each function. For the biting and chewing functions, the subjects used a slice of a yellow apple; they bit and chewed the slice and scored their experienced pain.

The patients were instructed not to use any additional analgesics. All patients returned their questionnaires, and none had used any analgesics.

After data collection, the normal distribution of variables was confirmed by the Kolmogorov-Smirnov test, and the differences between the groups were analyzed with analysis of variance (ANOVA) and Tukey tests using SPSS software (version 11.5; SPSS, Chicago, Ill). The level of significance for all tests was determined at $P < 0.05$.

RESULTS

ANOVA demonstrated no significant differences in the mean ages among the groups. The descriptive statistics for the 5 groups are shown in Table II. The differences in pain perception are presented individually for each function.

1. Chewing. The 1-way ANOVA showed significant differences in pain at chewing at hour 24 and day 7 after initial archwire placement (Table II). The results of the Tukey test (Table III) showed significant differences between the placebo group and the chewing-gum group at hour 24 ($P = 0.029$) and day 7 ($P = 0.031$), and between the placebo group and the hard-viscoelastic group ($P = 0.025$) on day 7. There was no significant difference in pain levels while chewing between the other groups at any time interval.
2. Biting. Based on ANOVA, there was no significant difference in pain at biting between the groups at any time interval.

Table II. Descriptive information of the 5 study groups and ANOVA results

Function	Group	Pain index values						
		2 h	6 h	At night	24 h	2 d	3 d	7 d
Chewing	Placebo	4.80 ± 3.06	6.45 ± 2.58	6.96 ± 2.13	7.47 ± 2.73	6.64 ± 3.11	5.04 ± 3.07	4.02 ± 2.77
	Ibuprofen	5.10 ± 2.20	4.18 ± 2.47	4.90 ± 2.75	4.45 ± 2.07	4.76 ± 3.42	3.08 ± 2.69	1.93 ± 1.73
	Chewing gum	4.88 ± 3.98	5.70 ± 3.75	6.45 ± 3.42	3.47 ± 3.83	3.80 ± 3.39	3.15 ± 3.75	1.22 ± 2.11
	Soft VE	2.87 ± 2.42	4.40 ± 2.51	5.23 ± 2.78	7.15 ± 2.83	5.32 ± 2.01	3.18 ± 1.84	1.55 ± 1.72
	Hard VE	5.29 ± 2.75	5.25 ± 3.28	4.85 ± 3.24	4.22 ± 2.83	3.34 ± 3.16	2.50 ± 2.90	1.14 ± 1.75
	<i>P</i> value*	0.369	0.422	0.366	0.008 [†]	0.144	0.374	0.018 [†]
Biting	Placebo	5.11 ± 4.19	7.51 ± 2.75	7.92 ± 2.25	8.54 ± 1.99	8.22 ± 2.22	6.59 ± 2.30	5.11 ± 3.14
	Ibuprofen	3.87 ± 2.57	6.19 ± 2.73	5.91 ± 1.75	6.65 ± 2.16	5.80 ± 2.01	4.39 ± 2.38	2.11 ± 2.12
	Chewing gum	5.00 ± 4.18	5.19 ± 3.58	5.90 ± 3.50	6.45 ± 3.57	5.53 ± 3.53	4.78 ± 3.32	2.78 ± 3.06
	Soft VE	4.07 ± 2.71	5.50 ± 2.36	6.40 ± 2.58	7.98 ± 2.66	6.67 ± 2.41	5.25 ± 3.04	3.66 ± 2.73
	Hard VE	5.97 ± 3.36	6.27 ± 3.00	6.78 ± 1.62	6.31 ± 1.80	6.09 ± 2.57	4.96 ± 2.56	3.10 ± 1.82
	<i>P</i> value*	0.664	0.448	0.363	0.191	0.170	0.455	0.136
Fitting front teeth	Placebo	4.45 ± 3.18	6.32 ± 2.95	5.80 ± 2.48	4.27 ± 3.07	4.05 ± 2.64	3.59 ± 2.68	2.68 ± 3.14
	Ibuprofen	2.50 ± 2.53	3.67 ± 2.48	3.88 ± 2.68	4.65 ± 3.03	3.02 ± 2.60	2.77 ± 2.76	1.61 ± 1.71
	Chewing gum	5.67 ± 4.00	5.42 ± 3.37	5.52 ± 3.46	6.05 ± 4.15	4.90 ± 4.09	3.55 ± 3.06	2.45 ± 3.18
	Soft VE	2.91 ± 2.26	5.02 ± 3.54	6.38 ± 2.61	7.28 ± 2.96	5.42 ± 3.58	4.09 ± 2.82	1.90 ± 1.09
	Hard VE	4.15 ± 3.55	4.73 ± 3.09	5.58 ± 2.60	5.36 ± 3.05	4.64 ± 3.59	3.74 ± 3.03	2.80 ± 2.41
	<i>P</i> value*	0.190	0.433	0.363	0.275	0.564	0.909	0.806
Fitting back teeth	Placebo	3.87 ± 3.34	6.00 ± 2.49	5.69 ± 2.33	4.00 ± 2.69	3.25 ± 2.49	2.87 ± 2.89	2.27 ± 3.02
	Ibuprofen	4.05 ± 2.40	3.09 ± 2.10	3.37 ± 2.30	3.43 ± 2.58	2.10 ± 1.91	2.37 ± 1.90	1.45 ± 1.42
	Chewing gum	3.35 ± 3.09	3.10 ± 3.08	3.72 ± 3.04	3.48 ± 3.86	2.85 ± 3.75	2.08 ± 3.02	1.55 ± 2.67
	Soft VE	2.58 ± 2.02	2.40 ± 1.63	3.55 ± 1.77	4.69 ± 3.66	2.95 ± 2.86	1.53 ± 1.80	0.30 ± 0.42
	Hard VE	2.03 ± 2.03	1.93 ± 1.69	2.55 ± 2.09	1.84 ± 2.14	1.84 ± 2.67	1.00 ± 1.92	0.33 ± 0.64
	<i>P</i> value*	0.436	0.006 [†]	0.154	0.333	0.768	0.449	0.124

VE, Viscoelastic.
*ANOVA results; [†]Mean difference was significant at the 0.05 level.

Table III. Tukey test results of chewing function at hour 24 and day 7 and fitting posterior teeth at hour 6 after archwire placement in the 5 groups

Group	<i>n</i>	Tukey HSD					
		Chewing function at hour 24		Chewing function at day 7		Fitting posterior teeth at hour 6	
		Subset for alpha = 0.05		Subset for alpha = 0.05		Subset for alpha = 0.05	
		1	2	1	2	1	2
Chewing gum	10	3.4700		1.2200		3.1000	3.1000
Hard VE	10	4.2200	4.2200	1.1400		1.9300	
Ibuprofen	10	4.4500	4.4500	1.9300	1.9300	3.0900	3.0900
Soft VE	10	7.1500	7.1500	1.5500	1.5500	2.4000	
Placebo	10		7.4700		4.0200		6.0000

Means for groups in homogeneous subsets are displayed.
VE, Viscoelastic.

- Fitting front teeth. The 1-way ANOVA demonstrated no significant differences between the groups in pain at fitting front teeth at any time interval.
- Fitting back teeth. The 1-way ANOVA showed significant differences in pain at fitting back teeth at hour 6 after archwire placement (Table II). The Tukey test showed significant differences between

the placebo group and the soft-viscoelastic group ($P = 0.017$), and between the placebo group and the hard-viscoelastic group ($P = 0.005$).

DISCUSSION

In this study, the effects of viscoelastic bite wafers, an anti-inflammatory drug (ibuprofen), and chewing gum on pain perception after initial archwire placement

were compared with a placebo group. In all groups, the intensity of pain during the 4 major oral functions increased from 2 hours after archwire placement and reached its maximum intensity at night or at 24 hours. This finding agrees with the results of Bernhardt et al,³ Law et al,¹³ Polat et al,¹⁴ Ngan et al,¹⁵ and Wilson et al.¹⁸ Peak pain occurred on biting, a finding similar to most previous studies.^{3,13,15,18} In contrast, Polat et al¹⁴ found that peak pain occurred in most patients while fitting their front teeth.

According to Davidovitch and Shanfield,¹⁹ pain during orthodontic treatment is due to an inflammatory response in the periodontal ligament, and NSAIDs have been called the gold standard for orthodontic pain control.

Furstman and Bernik¹ noted that orthodontic pain is a combination of pressure, ischemia, inflammation, and edema. It is believed that any factor that can temporarily displace the teeth under orthodontic force can resolve the pressure and prevent the formation of ischemic areas, thus releasing pain. Based on this belief, Proffit and Fields¹⁶ recommended chewing gum for pain control in orthodontic patients. However, the effectiveness of chewing gum in pain control for orthodontic patients has not been evaluated in any other study. In addition, the toughness of the chewing gum might be not enough to displace the teeth and resolve the ischemia. Therefore, we designed viscoelastic bite wafers made of polyvinyl siloxane with 2 degrees of toughness (Table I).

The experienced pain in the viscoelastic groups and the ibuprofen group showed no statistical differences in any oral functions and time intervals. When these groups were compared with the placebo group, no significant difference was found between the ibuprofen group and the placebo group in any oral function at any time interval. However, the hard-viscoelastic group showed a significant difference compared with the placebo group in pain at chewing on day 7, and the hard-viscoelastic and the soft-viscoelastic groups had significant differences compared with the placebo group in pain at fitting back teeth at hour 6 after initial archwire placement. Chewing gum was also effective in reducing pain in the chewing function at 24 hours and 7 days compared with the placebo group.

According to Table II, it is obvious that the viscoelastic bite wafers were more effective in pain control when fitting back teeth than fitting front teeth. This can be explained by the fact that the thickness of the bite wafers was the same in the back and front areas, so when the back teeth were in touch with the block, the front teeth generally did not touch it. This explanation also can be true for chewing gum. Since most people chew gum with their back teeth, the chewing gum releases the

pain of the back teeth more effectively than it does for the front teeth (Table II).

Otasevic et al²⁰ compared the effects of masticatory bite wafers and the avoidance of hard food on initial orthodontic pain. They concluded that avoiding hard food in the first week after initial archwire placement was more effective in pain reduction than chewing on masticatory bite wafers. However, the recommendation of hard food avoidance to patients does not seem reasonable. Recently, Murdock et al²¹ compared pain response during the first week after initial archwire placements in patients randomly assigned to 1 of the 2 pain management groups: chewing on a bite wafer as desired or taking NSAIDs. They concluded that the bite wafers were at least as effective as NSAIDs for pain management after orthodontic procedures. However, in our study, the bite wafers were more effective than ibuprofen in orthodontic pain reduction compared with the placebo group.

The limitation of this study was that all participants were girls; we suggest conducting another study of male patients with larger group size.

CONCLUSIONS

Our findings suggest that viscoelastic bite wafers can be good substitutes for NSAIDs in orthodontic pain reduction. Chewing gum can also be recommended for orthodontic patients to reduce pain at chewing function.

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