

COMPARISON BETWEEN CHEWING GUM AND IBUPROFEN FOR ORTHODONTIC PAIN CONTROL AFTER INITIAL ARCHWIRE PLACEMENT: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Aim: This randomized controlled trial (RCT) aimed to compare the effectiveness of chewing (SFG) versus taking ibuprofen (IBP) in reducing pain levels after the placement of fixed orthodontic appliances in patients undergoing orthodontic treatment.

Materials and methods: Patients were randomly assigned to two groups: chewing gum (CG) and IBP. Pain levels were measured using a visual analog scale (VAS) at 10 different intervals following the placement of the initial archwire. Statistical analyses were performed using Mann-Whitney test and independent t-test to determine any significant differences between the two groups.

Results: Although pain scores were lower in the IBP group than in the CG group at several time points, there were no statistically significant differences between the two groups. All patients completed the study with no lost to follow-up nor treatment discontinuation.

Conclusion: Our findings suggest that both CG and taking IBP have comparable effectiveness in reducing pain levels after the placement of fixed orthodontic appliances. The use of SFG as a low-cost and easily accessible alternative to analgesic medications may be considered for patients who experience pain during orthodontic treatment.

KEYWORDS: Chewing gum, Ibuprofen, Visual analogue scale, Pain control, Initial archwires.

INTRODUCTION

One of the most regular drawbacks of orthodontic treatment either with fixed or removable appliances is feeling pain during moving the teeth.⁽¹⁾ Pain has been known to affect 70 to 95 percent of children

receiving treatment, and the strength and length of the pain varies among patients, often starting 2 to 3 hours after appliance fitting^(2,3) and continuing up to 7 days, with the most intense pain occurring at 2 days.⁽⁴⁾

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Pain is a subjective reaction that varies greatly depending on various aspects, including the patient's emotional condition, age, gender, pain tolerance, and orthodontic force intensity.⁽⁵⁾ The pain associated with orthodontic treatment has been recognized as a key obstacle to treatment compliance and the primary cause for treatment termination.⁽⁶⁾

Orthodontic pain is caused by changes in the compressed periodontal ligaments (PDL), such as ischemia, inflammation, and edema, which occur when orthodontic force is applied to teeth.⁽⁷⁾ Controlling pain during treatment is necessary to improve compliance over the course of treatment.

Different ways were used to reduce the pain during treatment such as using drugs as non-steroidal anti-inflammatory drugs (NSAIDs) that interfere with the metabolism of the prostaglandins⁽⁸⁾ but it was found that chronic use of NSAIDs can result in side effects as gastrointestinal disorders and reducing the tooth movement rate due to inhibiting prostaglandin synthesis especially in younger individuals.^(9,10)

Regarding the side effects of the NSAIDs, other non-drugs based methods were advocated to control the pain as low-level laser therapy⁽¹¹⁾, electric nerve stimulation⁽¹²⁾ and chewing gum⁽¹³⁾ (CG). These methods reduce pain by loosening the tightly packed fibers around the nerves and blood vessels in the periodontal ligament thus restoring normal blood and lymph circulations, as a result of this, inflammation and edema are either prevented or undergo resolution and eventually reduces pain.^(14,15)

This study was conducted to evaluate the effectiveness of CG as compared to ibuprofen (IBP) as a method in reducing orthodontic pain in the 1st week after applying orthodontic force.

MATERIALS AND METHODS

Subjects

This study was designed as a two-arm RCT and approved by the ethics committee of Faculty

of Medicine, Assiut University, Assiut, Egypt (No. 17300677). The sample in this trial was the same as in a previous study.⁽¹⁶⁾ Informed consent was obtained from each patient after a detailed explanation of the study steps and procedures. To ensure the privacy of data each patient was given a unique ID and only investigators had the right to view patients' files.

The inclusion criteria were as follows: patient should be between 13 and 17 years of age, scheduled for fixed orthodontic appliances placement, and medically free with no history of systemic disease nor previous orthodontic treatment. On the other hand, patients with cleft lip and palate, syndromes, mental problems, gingival inflammation, or periodontitis; patients with a history of IBP hypersensitivity or chronic users of analgesics; pregnant women; smokers; patients who cannot take phenylalanine contained in synthetic sugars; and temporomandibular disorders (TMD) in whom chewing gum can increase TMD symptoms were excluded.

Study groups, sample size calculation, randomization, and blinding

From the original sample consisted of 50 patients according to sample size calculation done in a previous study,⁽¹⁶⁾ 46 patients were randomly assigned to CG or IBP groups with a mean age of 15.48 ± 1.20 and 15.56 ± 1.17 , respectively. In the previous study,⁽¹⁶⁾ two patients lost to follow up and one patient was excluded due to taking analgesics. In this study, one patient declined to participate. The randomization was done using a specific formula in spreadsheet (Microsoft Excel, Microsoft Office 2016, Microsoft, Redmond, Wash) developed to obtain a 1:1 allocation ratio. The allocation was concealed using consecutively numbered opaque sealed envelopes opened only after patient agreement and consent for participation. Although blinding the operator and patients was not possible because of the nature of the study, the data were manipulated and statistically analyzed by a blinded analyst.

Methods

Orthodontic treatment for patients included in this study was provided by the two authors. A straight wire edgewise fixed orthodontic MBT appliances with 0.022 × 0.028-inch bracket slots (DB Orthodontics, Silsden, Keighley, UK) and 0.014-inch nickel-titanium (NiTi) initial archwires (3M Unitek, Monrovia, California, USA) were fitted on the maxillary arches of all patients in one appointment. For standardization, the archwires were completely engaged in the brackets by elastomeric ligatures (3M Unitek, Monrovia, California, USA). If teeth extraction was indicated as a part of the treatment plan, the extraction was performed at least two weeks prior to the placement of orthodontic appliances.

Patients in the CG group were instructed to chew (SFG) (Trident, Kent Gıda Maddeleri Sanayii ve Ticaret Anonim Şirketi, Cumhuriyet Mah. 2253. Sok. No:11 41400 Gebze, Kocaeli, Turkey) for 10 minutes immediately after fixed appliance placement and then at eight-hours intervals for one week. Regarding the IBP group, the patients were asked to take IBP (400-mg tablets; Kahira Pharmaceuticals & Chemical Industries Co., Shoubra, Cairo, Egypt) immediately after placement of the appliance and at eight-hours intervals. Patients were instructed neither to take any analgesics in the CG group nor any additional analgesics in the IBP group; otherwise, they had to document the frequency, dosage, and the type of analgesics used.

Data collection

The patients' pain level was measured using a visual analog scale (VAS) at 10 intervals: 2 hours, 6 hours, bedtime, 24 hours, 2 days, 3 days, 4 days, 5 days, 6 days, and 7 days following initial archwire placement. From day 2 to 7, the patients were requested to record their pain scores at a fixed time during the day (9:00 PM). The VAS used in this study was a 10-cm horizontal line that uses 0–10 integers to define the level of pain with both ends defined as the extreme limits of the scale; 0 indicates

no pain while 10 indicates worst pain possible. The patients were instructed to respond to the VAS by writing the score which corresponds to their pain sensation and to return the scale after the one-week duration of the study.

Statistical analysis

After data collection and extraction, Statistical Package for the Social Sciences software (SPSS, Windows version 26, SPSS Inc., Chicago, Illinois, USA) was used to perform all statistical analyses. As Shapiro-Wilk test confirmed the non-normal distribution of pain scores, Mann–Whitney test was used to accept or reject the null hypothesis with significance level set at a *P* value less than 0.05. To check for difference between the two groups in age and gender variables, we used independent t-test and Chi-square test, respectively.

RESULTS

Regarding the baseline characteristics, there was no statistically significant difference between the CG and IBP groups in age and gender variables (Table 1). The flow of the patients though the study is shown in Figure 1. All randomized patient completed the study with neither lost to follow up nor treatment discontinuation. All patients returned the VAS and none of the patients was excluded due to disobedient of instructions.

TABLE (1) Age and gender of the included patients.

	Chewing gum (CG) (n = 23)	Ibuprofen (IBP) (n = 23)	<i>P</i> value
Age (years)			
Range	13.0 – 17.0	13.0 – 17.0	
Mean ± SD	15.48 ± 1.20	15.56 ± 1.17	0.814
Gender			
Male	12 (52.2%)	12 (52.2%)	1.000
Female	11 (47.8%)	11 (47.8%)	

SD= standard deviation.

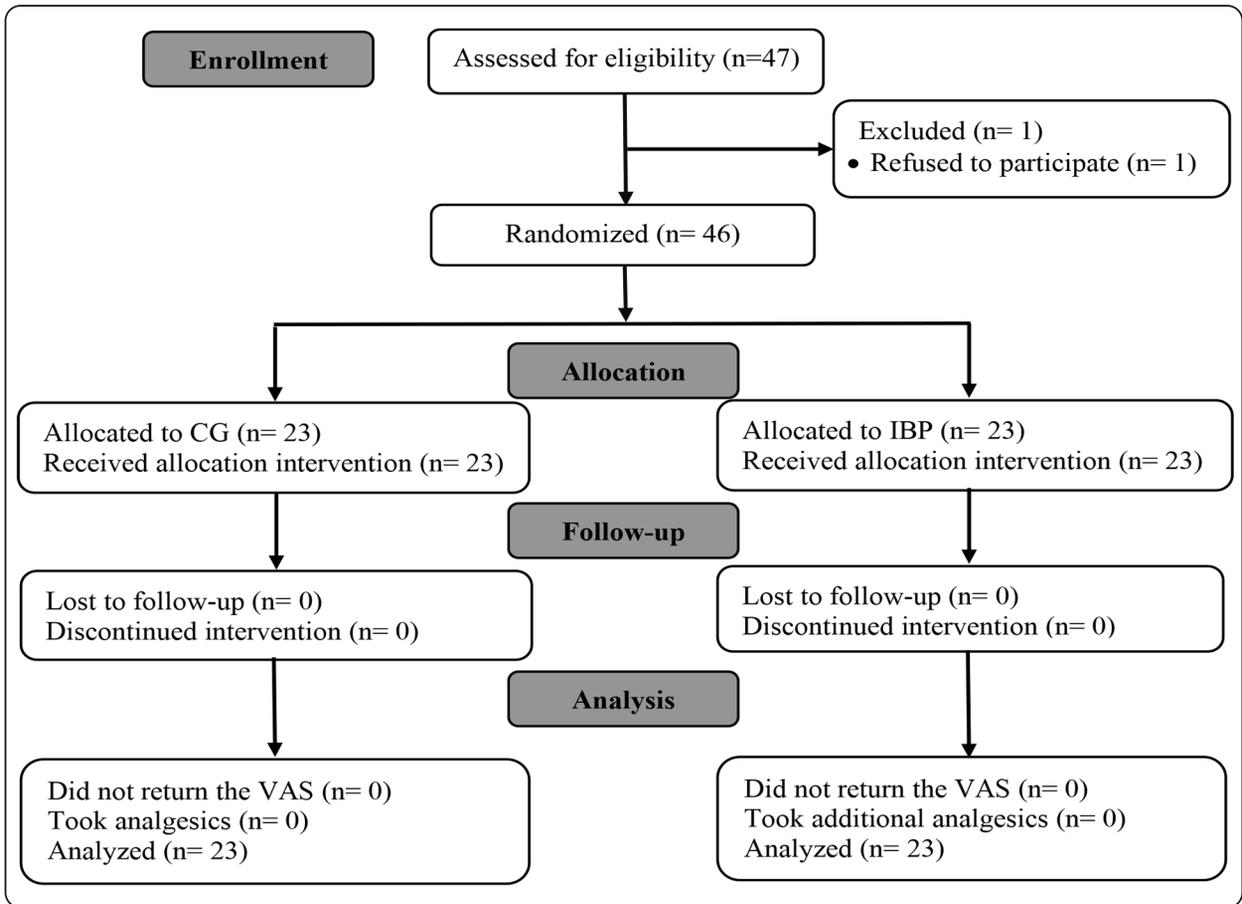


Fig. (1) Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the patients through the trial

Although IBP showed lower pain scores as compared to CG at 6 hours, bedtime, 24 hours, 2 days, 3 days, 6 days, and 7 days; the results of this RCT showed no statistically significant differences between the two interventions at all-time intervals (Table 2). Over the one-week period of the study, the trend of the pain intensity was ascending from 2 hours and reached its culmination at 24 hours interval with mean pain scores of 5.09 ± 0.85 and 4.83 ± 0.72 for CG and IBP, respectively. Afterwards, the pain scores adopted a descending direction until reached its bottom values at 7 days point (Table 2).

DISCUSSION

The effectiveness of CG and IBP for pain alleviation after initial orthodontic archwire placement was examined in the current study, since chewing SFG is an inexpensive, non-invasive alternative to other pain control techniques used in fixed orthodontic treatment.

The use of NSAIDs such as IBP is a common practice in managing pain after orthodontic treatment. However, concerns have been raised about the potential adverse effects of NSAIDs on gastric mucosa, renal function, bleeding, and rate of tooth movement. In contrast, chewing SFG has been

TABLE (2) Pain scores at different time points in the two groups.

Time	Chewing gum (CG) (n= 23)	Ibuprofen (IBP) (n= 23)	P value*
	Mean \pm SD Median (min, max)	Mean \pm SD Median (min, max)	
2 hours	3.26 \pm 0.92 3 (1, 5)	3.57 \pm 1.16 4 (1, 5)	0.324
6 hours	3.96 \pm 0.71 4 (3, 5)	3.52 \pm 0.79 4 (2, 5)	0.069
At night	4.61 \pm 0.84 5 (3, 6)	4.30 \pm 0.56 4 (3, 5)	0.151
24 hours	5.09 \pm 0.85 5 (3, 6)	4.83 \pm 0.72 5 (4, 6)	0.137
Day-2	4.17 \pm 0.72 4 (3, 5)	4.00 \pm 0.80 4 (2, 6)	0.377
Day-3	3.48 \pm 0.99 3 (2, 5)	3.09 \pm 0.67 3 (2, 4)	0.213
Day-4	2.43 \pm 0.51 2 (2, 3)	2.83 \pm 0.89 3 (1, 4)	0.053
Day-5	1.78 \pm 0.52 2 (1, 3)	2.17 \pm 0.78 2 (1, 4)	0.064
Day-6	1.61 \pm 0.84 2 (0, 3)	1.22 \pm 0.60 1 (0, 2)	0.078
Day-7	1.09 \pm 0.79 1 (0, 2)	0.78 \pm 0.60 1 (0, 2)	0.161

*Significance at $P \leq .05$.

shown to have a beneficial effect on oral health, including increasing salivary flow, reducing caries, and improving oral hygiene. The present study provides evidence that chewing SFG may also have a role in managing pain after orthodontic treatment.

The results showed that there were no statistically significant differences in pain scores between the two interventions at any time intervals, although pain scores were generally lower in the IBP group. These findings suggest that chewing SFG may be an effective alternative to IBP in managing pain after orthodontic treatment.

These results are the same as Delavarian et al, study in which they compared both CG and IBP to alleviate the pain after initial orthodontic wire placement, and they concluded that both interventions were effective in reducing the initial pain and there was no statistical difference.⁽¹³⁾

The results were also consistent with a recent systematic review carried out by Jabr et al, in which they included nine RCTs and concluded that CG can be a good alternative to using drugs during orthodontic treatment.⁽¹⁷⁾

Our results were not consistent with Mando et al systematic review, in which they evaluated the efficacy of CG in reducing pain intensity in patients undergoing orthodontic treatment and included sixteen RCTs in the final analysis, and the meta-analysis showed that CG significantly reduced pain intensity compared to analgesics and placebo. However, in their study they were measuring only pain at the peak level, after 24 hours of initial wire placement.⁽¹⁸⁾

Another study that was not consistent with our results showed that CG had more significant pain

alleviation than IBP. In this study conducted by Santos et al, they found that, at rest and during biting, the CG group reported less pain than the IBP group. The group that chewed gum during bite reported less pain than the acetaminophen and control groups.⁽¹⁹⁾

It is important to note that the pain scores in both groups peaked at 24 hours after appliance placement and gradually decreased over the one-week study period. This is consistent with previous studies that have shown that post-treatment pain is generally highest in the first 24 to 48 hours and then gradually subsides. It is possible that the natural course of post-treatment pain may have masked any potential differences between the two interventions.^(5,15)

The present study has some limitations that should be taken into consideration. First, the sample size was relatively small and may not be representative of the general population. Second, the study only assessed pain as an outcome measure and did not evaluate other factors such as medication side effects, patient satisfaction, and treatment adherence.

CONCLUSION

The present study suggests that chewing SFG may be an effective alternative to IBP in managing pain after orthodontic treatment.

Future studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and to evaluate other potential benefits and drawbacks of CG as a pain management strategy in orthodontic patients.

REFERENCES

1. Ertan Erdiñç AM, Diñçer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod.* 2004;26(1):79-85.
2. Kvam E, Gjerdet NR, Bondevik O. Traumatic ulcers and pain during orthodontic treatment. *Community Dent Oral Epidemiol.* 1987;15(2):104-107.
3. Firestone AR, Scheurer PA, Bürgin WB. Patients' anticipation of pain and pain-related side effects, and their perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod.* 1999;21(4):387-396.
4. Campos MJdS, Fraga MR, Raposo NRB, Ferreira AP, Vitral RWF. Assessment of pain experience in adults and children after bracket bonding and initial archwire insertion. *Dent Press J Orthod.* 2013;18:32-37.
5. Al Shayea EI. Comparative assessment between ibuprofen, chewing gum, and bite wafers in pain control following first archwire placement in orthodontic patients. *J Contemp Dent Pract.* 2020;21(4):416-420.
6. Patel V. Non-completion of active orthodontic treatment. *Br J Orthod.* 1992;19(1):47-54.
7. Gameiro GH, Schultz C, Trein MP, Mundstock KS, Weidlich P, Goularte JF. Association among pain, masticatory performance, and proinflammatory cytokines in crevicular fluid during orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 2015;148(6):967-973.
8. Ngan P, Wilson S, Shanfeld J, Amini H. The effect of ibuprofen on the level of discomfort inpatients undergoing orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1994;106(1):88-95.
9. Ecklund CR, Ross MC. Over-the-counter medication use in preschool children. *J Pediatr Health Care.* 2001;15(4):168-172.
10. Thomas J, Straus WL, Bloom BS. Over-the-counter nonsteroidal anti-inflammatory drugs and risk of gastrointestinal symptoms. *Am J Gastroenterol.* Sep 2002; 97(9):2215-2219.
11. Bayani S, Rostami S, Ahrari F, Saeedipouya I. A randomized clinical trial comparing the efficacy of bite wafer and low level laser therapy in reducing pain following initial arch wire placement. *Laser Ther.* 2016;25(2):121-129.
12. Roth PM, Thrash WJ. Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement. *Am J Orthod Dentofacial Orthop.* 1986;90(2):132-138.
13. Delavarian M, Imani MM, Delavarian F, Bayani S. Comparison of chewing gum and ibuprofen in alleviating orthodontic pain: A single centre, randomised clinical trial. *Aust Orthod J.* 2020;36(1):38-44.
14. White L. Pain and cooperation in orthodontic treatment. *J Clin Orthod.* 1984;18(8):572-575.

15. Farzanegan F, Zebarjad SM, Alizadeh S, Ahrari F. Pain reduction after initial archwire placement in orthodontic patients: a randomized clinical trial. *Am J Orthod Dentofacial Orthop.* 2012;141(2):169-173.
16. Abdul-Aziz AI. Does green tea (*Camellia Sinesis*) mouthwash reduce pain after placement of orthodontic separators? A randomized controlled trial. *Egypt Orthod J.* 2021;60(1):32-40.
17. Jabr L, Altuhafy M, Barmak AB, Rossouw PE, Michelogiannakis D. Comparative assessment of chewing sugar-free gum and conventional analgesic drugs in alleviating self-reported pain associated with fixed orthodontic appliances: A systematic review and meta-analysis. *J Orthod.* 2022:14653125221144059.
18. Mando M, Talaat S, Bourauel C. The efficacy of chewing gum in the reduction of orthodontic pain at its peak intensity: a systematic review and meta-analysis. *Angle Orthod.* 2023.
19. Da Silva Santos DJ CJJ. Chewing gum as a non pharmacological alternative for orthodontic pain relief: a randomized clinical trial using an intention-to-treat analysis. *Korean J Orthod.* 2021;51:346-354.