Pain intensity and control with fixed orthodontic appliance therapy (A clinical comparative study on Iraqi sample)

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ABSTRACT

Background: The purpose of this prospective, randomized clinical trial was to investigate the level and intensity of patients` pain and discomfort, and to compare between the use of Bite Wafer and Paracetamol in reducing pain and discomfort associated with initial orthodontic tooth movement in both adolescents and adults.

Sample: 110 subjects with two age groups, 52 adolescents with age range from 12 to less than 18 years and 58 adults with age range 18-24 years, successfully completing the study. For each subject fixed orthodontic appliance (Roth 0.022) was bonded and round 0.014 NiTi arch wire was ligated with elastic ligature. The subjects in the Bite Wafer group were instructed to chew on it whenever they feel pain for the next 7 days, and document the time and effectiveness of it in the questionnaire. The Paracetamol group subjects instructed to use Paracetamol 500mg to relive pain and record times and effectiveness of its use in questionnaire.

Results: The peak of pain was occurred in the first day and declined gradually till totally disappeared at the sixth day after initial arch wire placement. A marked reduction of pain intensity was noticed in both adolescents and adults groups, using Bite Wafer, from the first to the sixth day which is much higher than Paracetamol group especially in adolescents. No gender differences (P>0.05) was noticed in this study.

Conclusion: Although both Bite Wafer and Paracetamol reduced pain gradually, Bite Wafer reduced pain more obviously and safely in comparison to Paracetamol especially in adolescents.

Key words: pain, Wafer, orthodontic. (J Bagh Coll Dentistry 2012;24(3):122-128).

INTRODUCTION

Fear of pain is a key element in deterring patients from seeking orthodontic treatment[1]. Orthodontic therapy was reported to be painful for 90% of patients, with some 30% contemplating terminating their treatment early because of discomfort[2]. Pain and discomfort after appliance adjustment had been shown to be higher than after dental extraction[3].

Patients in orthodontic treatment often describe the discomfort as pressure, tension, ache, or soreness of the teeth[4]. The pain intensity usually increases gradually from 2 hours after application of orthodontic force to a peak at 24 hours, with pain resolution by the seventh day[5-7].

Pain-free orthodontics is not often considered, and often the orthodontist ignores the patient's discomfort[8]. However, it is increasingly less acceptable for the patients to suffer from pain or discomfort[9].

In 2007 Proffit et al., identified an immediate and delayed pain response; the immediate pain related to the initial compression of the periodontal ligament immediately after placement of the archwire. Whereas, the delayed response started a few hours later, was termed hyperalgesia of the periodontal ligament. Orthodontic treatment provides the type of chronic periodontal insult that encourages a continual and increased production of prostoglandins[10], which have been shown to cause hyperalgesia, an increased sensitivity to noxious agents such as histamine, bradykinin, serotonin, acetylcholine, and substance P. There are indication that perceptios of pain are due to changes in blood flow in the periodontal ligament and are correlated with the presence of substances as prostaglandins and substance P[11].

Pain management: the most frequently recommended treatments for pain are over-the-counter analgesics (OTC), often a nonsteroidal anti-inflammatory drug (NSAID) that works by inhibiting prostaglandin synthesis. Previous studies assessing the efficacy of analgesics for pain management have focused on medications administered immediately before[12,13] or before and immediately after the orthodontic procedures[14,15]. All of these studies reported that analgesics were effective for pain management.

The overuse and potential side effects of OTC analgesics have been raised as a concern, particularly for children[16,17], because of these concerns, non-analgesic pain management approaches such as chewing gum or chewing on a plastic wafer have been recommended to loosen the tightly grouped fibers around the nerves and blood vessels, restoring normal vascular and lymphatic circulation, thus preventing or relieving inflammation and edema[10]. Although several studies have indicated that the rhythmic chewing of either Aspergum (Insight Pharmaceuticals, Langhorne, Pa)[18], a gum containing aspirin, or a bite wafer (BW)[19] reduced the pain and discomfort after archwire placement. No comparison of the effectiveness of either of these non-pharmacologic approaches and OTC medications has been researched in Iraq.

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This study aimed to investigate the level and intensity of patients` pain and discomfort following insertion of fixed orthodontic appliance and to compare the effectiveness of Bite Wafer as a non-pharmacologic approach for pain management of orthodontic treatment, with Paracetamol analgesics during the first week after initial archwire placement.

MATERIALS AND METHODS

This study started with 160 patients; 12-24 years old divided into two age groups, ***group A*** 12 to less than18 years old and ***group B*** 18 up to 24 years old. Within both A and B groups, patients are randomly allocated into 1 of 2 groups: the Bite Wafer group and the Paracetamol analgesic medication group. They are scheduled to begin the orthodontic treatment (banding and bonding of at least 10 teeth and archwire placement in at least single arch) [20]. Readjusted edgewise (Roth prescription) brackets would be used with 0.022-in slot; and 0.014-in Nickel Titanium archwire was used as the first archwire with all the teeth engaged with ligature elastics.

The pain management instructions were given to each group as follow:

***Bite Wafer** group*: instruct them to use a Bite Wafer (Fig 1) as a measure to relive pain or discomfort and never use any medication to control pain. Ask them to chew on the Wafer, under supervision, for 10–12 minutes within an hour after placement of archwire, also tell them to document how many times the Wafer had been used, and its effectiveness for discomfort relief at the end of each day for seven days[21].Additional Wafers are given to the patients to chew them as much as they want whenever they feel discomfort or pain.

**** Paracetamol** group*: for this group 500 mg paracetamol tablet, are given and ask them to take it whenever they need to relive pain or discomfort. They also asked to document the number of tablets that required for pain relief [22].

Before placement of the appliance, a preoperative Visual Analog Scale (VAS) score was taken to exclude any pre-existing painful condition. Immediately after placement of a fixed appliance, the patient completes the VAS questionnaires at the clinic. The VAS (Fig.2) consisted of an unmarked horizontal line with a descriptive terminology, e.g. not hurting, no discomfort, no pain, hurting a whole lot, very uncomfortable, severe pain, and pictorially, with a happy face and sad face. The VAS was translated to simple Arabic words to simplify the scoring for the patients. Each patient was asked to put a mark on the line that best corresponded to the level of pain he/she felt at that moment. If there is no pain, the patient would mark the end of the line by happy face. If there is some pain, the patient would mark the line somewhere in the middle, depending on the severity.

The patients were asked to complete the questionnaire to rate their pain and its intensity at 7 times after archwire placement: the bed time of the same day, bed time of the 2^{nd}, 3^{rd}, 4^{th}, 5^{th},6^{th} and 7^{th} days later. At the end of the week, the patient should return the questionnaire for analysis. The data will be collected for drawing a curve of pain intensity and amount of pain reduction or increment for each group.

Statistical analyses: Data were collected and analyzed using SPSS software version 19 for windows XP Chicago, USA. The following statistics were used:

Descriptive statistics include sample distribution within each age group for both genders, with means, medians, standard deviations, and *P* values using nonparametric Mann-Whitney U test to compare between genders, two age groups and two different methods of pain control.

In statistical evaluation, the following levels of significance are used:

$P > 0.05$	NS	Non-significant
$0.05 \geq P > 0.01$	*	Significant
$0.01 \geq P$	**	Highly significant

RESULTS

The study started with 160 subjects, 80 adults and 80 adolescents, 28 persons were dropped from adolescents group and 22 from adults group resulting in 110 subjects, 52 adolescents and 58 adults successfully completing the survey, including both genders.

Descriptive statistics including number of participants (N), means, medians and standard deviations of pain intensity, according to VAS, after pain management in both Bite Wafer and Paracetamol groups for both adolescents and adults groups through the whole study period are shown in Tables 1,2 and 3. Moreover, the sixth and seventh days showed zero findings for all variables that cannot be encountered statistically.

The Mann-Whitney U test showed no significant differences ($P>0.05$) between males and females at any variable; therefore, the findings were evaluated with no gender discrimination, and the data for males and females were combined for analyses (Table 1).

The peak of pain was occurred in the first day and little bit higher in adolescents than in adults and declined gradually till totally disappeared at the sixth day after initial arch wire placement, (Figures 3-6).

In comparison of age groups, in Bite Wafer group a highly significant difference (P<0.01) was found only in the first day and a non significant difference (p>0.05) in all other days, which means both age groups got approximately the same benefit from Bite Wafer in pain reduction, whereas in group using Paracetamol, a highly significant difference (P<0.01) was found between adolescents and adults in all five days, which means pain reduction is significantly higher in adults using Paracetamol than in adolescents (Table 2).

In comparison of pain management regimens, Bite Wafer and Paracetamol groups, Mann-Whitney U test showed a highly significant difference (P<0.01) which mean more pain reduction in Bite Wafer group than in Paracetamol group (Table 3).

In comparison of pain intensity before and after pain management procedure, a marked reduction of pain intensity was noticed in both adolescents and adults, using Bite Wafer, from the first to the sixth day (Figure 3 and 4), whereas, in group using Paracetamol, adolescents showed a fluctuant pain intensity level which become little bit increased in the first, second and fourth days and little bit decreased in the third, fifth and sixth days. On the other hand, adults in Paracetamol group showed more similar pattern to Bite Wafer group in gradual pain reduction than adolescents from the first to the sixth day of study (Figure 5 and 6).

DISCUSSION

Since the data in this study were collected by questionnaires, a firm instruction to the participants and/or parents has been given and even training how to use the Bite Wafer has been done in the first visit to reduce the subjectivity as much as possible. Also the questionnaire was translated to simple Arabic words to simplify the selection of the most appropriate score in the visual analog scale (VAS).

Although there is evidence to suggest higher levels of pain reported by females[10], this study showed no statistically significant difference between males and females (P>0.05) in all records and this come in accordance with several other studies [6,15,21].

Pain intensity for both Bite Wafer and Paracetamol groups in both adolescents and adults followed a similar pattern, pain peaked in the first day and decreased over the rest of the week and this come in coincidence with findings of other previous studies [6,21], which demonstrated a gradual declination of pain levels during the week after placement of orthodontic appliances.

Bite Wafer reduced the pain to a minimal level in both adolescents and adults through the recording period (Figures 3 and 4), the pain reported by Paracetamol group was slightly higher than Bite Wafer group in adults, whereas in adolescents it was much higher and sometimes pain intensity increased, this could be explained by the frequency of analgesic intake, as shown in Figure 7 and 8, the adults used the Bite Wafer more frequently than analgesic resulting in more pain reduction in Bite Wafer group than in Paracetamol group (Figure 4 and 6), also the adolescents used the Bite Wafer more than analgesic that's why pain reduced markedly with Bite Wafer (Figures 3 and 5) whereas pain sometime increased in Paracetamol group especially in adolescents this is because less analgesic intake was noticed by adolescents in comparison to adults (Figure 8) which could be related to the afraid of the side effects of drugs, since some drugs may cause gastric or duodenal ulceration, bleeding disorders, asthma, renal insufficiency and drug allergy, that make persons afraid of freely use analgesics.

In contrast, the effect of Bite Wafer in pain relief comes from the acceleration of blood flow into and around the periodontal membrane, which in turn reduces the edema caused by the trauma of orthodontic forces, this agree with findings of many studies[10,15] and disagree with others in which more pain was reported with Bite Wafer[22].

As a conclusion, It seems reasonable for orthodontists to offer Bite Wafers to patients as another possible way to alleviate the pain and discomfort during the leveling and alignment steps of orthodontic treatment with fixed appliances and further studies were suggested to investigate its effect on the orthodontic tooth movement.

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Figure 1: Bite Wafer

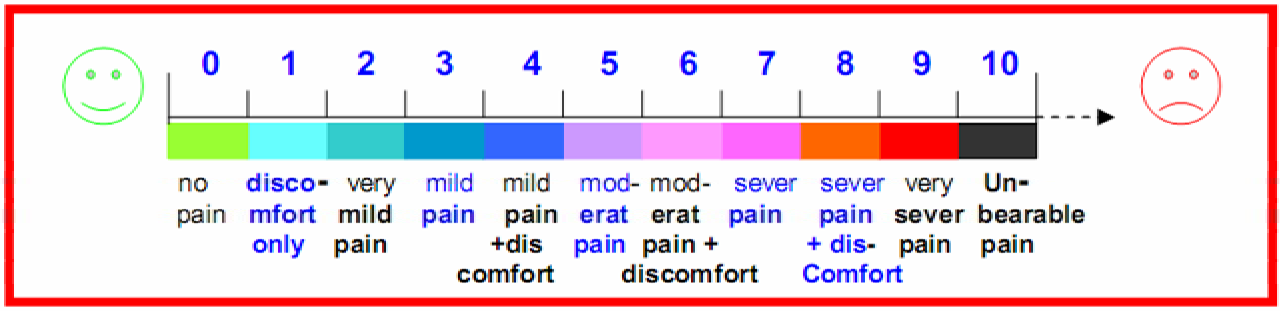

Figure 2: Visual Analog Scale (VAS)

Table 1: Gender difference in pain intensity (VAS) after pain management regimes in seven days

	Adolescent using Bite Wafer							
	Males (N=13)			Females (N=14)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p value
1st	1.5	1.0	0.9	1.0	1.0	0.7	61.5	0.243
2nd	0.8	1.0	0.7	0.6	1.0	0.5	76.5	0.687
3rd	0.6	1.0	0.7	0.4	0.0	0.5	69.0	0.448
4th	0.4	0.0	0.5	0.1	0.0	0.3	58.5	0.186
5th	0.0	0.0	0.0	0.0	0.0	0.0	84.5	1.000
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		
	Adult using Bite Wafer							
	Males (N=13)			Females (N=15)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p value
1st	0.8	1.0	0.7	0.5	0.0	0.6	84.0	0.377
2nd	0.6	1.0	0.6	0.5	0.0	0.7	85.5	0.400
3rd	0.6	1.0	0.5	0.5	1.0	0.5	101.0	0.880
4th	0.1	0.0	0.3	0.2	0.0	0.4	91.5	0.561
5th	0.0	0.0	0.0	0.0	0.0	0.0	105.0	1.000
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		
	Adolescent using Paracetamol							
	Males (N=13)			Females (12)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p value
1st	6.4	7.0	2.4	7.4	7.0	1.8	78.0	0.387
2nd	6.5	7.0	2.7	6.2	6.0	1.0	67.5	0.170
3rd	2.2	2.0	2.0	2.4	2.0	0.9	87.5	0.650
4th	2.8	2.0	0.9	2.4	3.0	1.3	83.5	0.525
5th	0.5	0.0	0.8	1.0	1.0	0.8	59.0	0.080
6th	0.2	0.0	0.4	0.2	0.0	0.4		
7th	0.0	0.0	0.0	0.0	0.0	0.0		
	Adult using Paracetamol							
	Males (N=15)			Females (N=15)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p value
1st	2.6	1.5	2.3	1.7	2.0	0.8	87.0	0.905
2nd	1.9	1.5	1.5	1.7	2.0	0.7	82.0	0.719
3rd	1.0	1.0	0.9	1.1	1.0	0.7	66.5	0.256
4th	1.4	1.0	0.8	1.3	1.0	0.6	79.0	0.614
5th	0.2	0.0	0.4	0.3	0.0	0.5	73.5	0.427
6th	0.0	0.0	0.0	0.1	0.0	0.4		
7th	0.0	0.0	0.0	0.0	0.0	0.0		

P>0.05 = No significant difference

Table 2: Age difference in pain intensity (VAS) after pain management regimes in seven days

Bite Wafer								
	Adolescent (N=27)			Adult (N=28)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	P value
1st	1.2	1.0	0.8	0.7	1.0	0.7	232.0	0.008
2nd	0.7	1.0	0.6	0.6	0.0	0.7	325.0	0.330
3rd	0.5	0.0	0.6	0.6	1.0	0.5	351.0	0.616
4th	0.2	0.0	0.4	0.1	0.0	0.4	342.0	0.377
5th	0.0	0.0	0.0	0.0	0.0	0.0	377.0	1.000
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		
Paracetamol								
	Adolescent (25)			Adult (N=30)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	P value
1st	6.9	7.0	2.1	2.2	2.0	1.8	23.0	0.000
2nd	6.3	6.5	2.0	1.8	2.0	1.2	48.0	0.000
3rd	2.3	2.0	1.5	1.1	1.0	0.8	162.0	0.000
4th	2.6	2.5	1.1	1.4	1.0	0.7	124.0	0.000
5th	0.7	0.5	0.8	0.2	0.0	0.4	213.0	0.002
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		

P>0.05 = No significant difference

Table 3: Management regimes difference of pain intensity (VAS) for both age groups in seven days

Adolescent								
	Bite wafer (N=27)			Paracetamol (N=25)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p level
1st	1.2	1.0	0.8	7.3	7.0	1.7	0.0	0.000
2nd	0.7	1.0	0.6	5.7	6.0	2.2	30.0	0.000
3rd	0.5	0.0	0.6	1.7	2.0	1.0	86.5	0.000
4th	0.2	0.0	0.4	2.5	3.0	1.1	22.0	0.000
5th	0.0	0.0	0.0	0.9	1.0	0.7	78.0	0.000
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		
Adult								
	Bite wafer (N=28)			Paracetamol (N=30)			Mann-Whitney U test	
Time (day)	Mean	Median	SD	Mean	Median	SD	Mann-Whitney U	p level
1st	0.7	1.0	0.7	1.8	2.0	0.8	80.0	0.000
2nd	0.6	0.0	0.7	1.9	2.0	0.9	66.5	0.000
3rd	0.6	1.0	0.5	1.2	1.0	0.9	154.0	0.008
4th	0.1	0.0	0.4	1.4	1.0	0.6	34.5	0.000
5th	0.0	0.0	0.0	0.3	0.0	0.5	188.5	0.006
6th	0.0	0.0	0.0	0.0	0.0	0.0		
7th	0.0	0.0	0.0	0.0	0.0	0.0		

P>0.05 = No significant difference

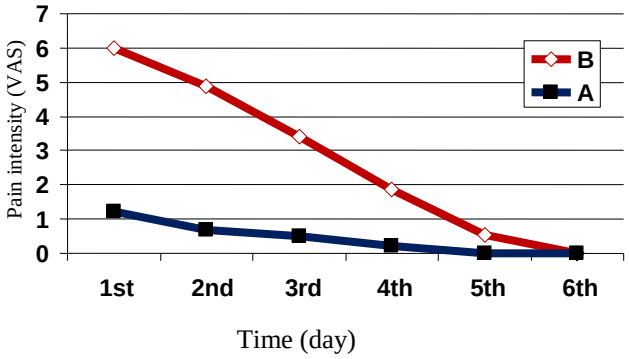

Figure 3: Pain intensity before(B) and after(A) using *Bite Wafer* in adolescents

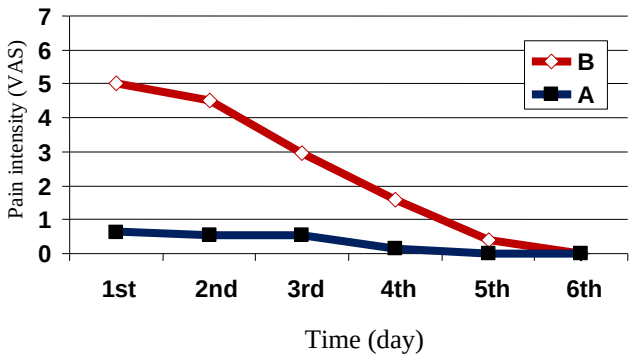

Figure 4: Pain intensity before(B) and after(A) using *Bite Wafer* in adults

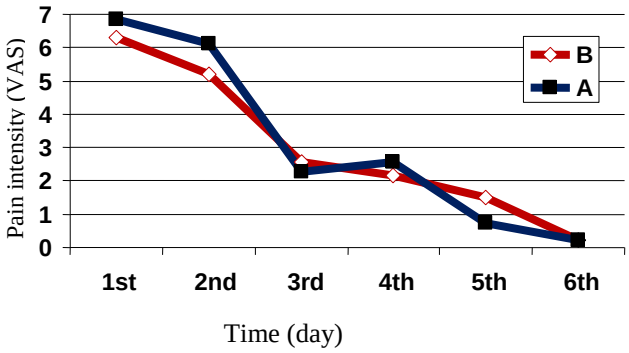

Figure 5: Pain intensity before(B) and after(A) using *paracetamol* in adolescents

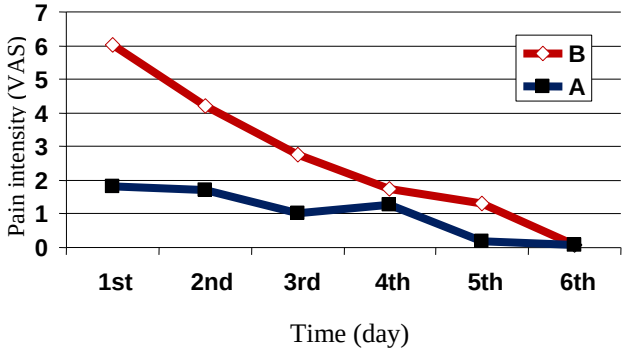

Figure 6: Pain intensity before(B) and after(A) using *paracetamol* in adults

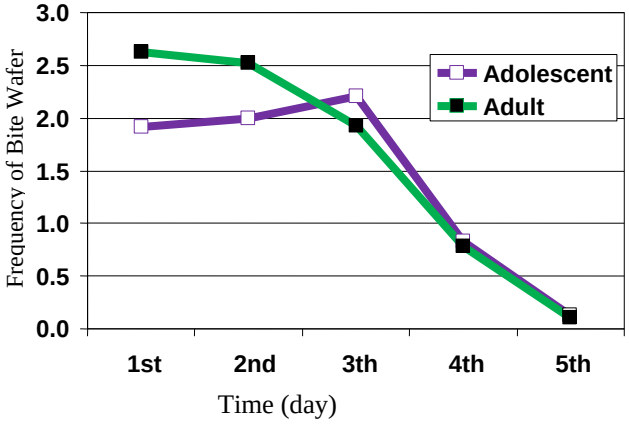

Figure 7: Frequency of using *Bite Wafer* by adolescents and adults

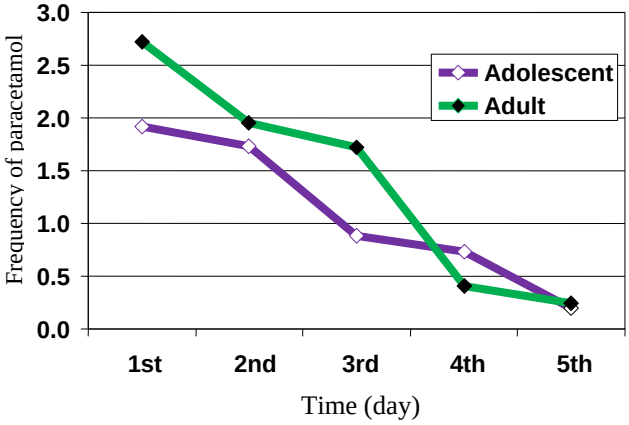

Figure 8: Frequency of using *paracetamol* by adolescents and adults