TREATMENT OF PAIN FOLLOWING INITIAL ARCH WIRE PLACEMENT

Sean Murdock, DDS

A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the School of Dentistry (Orthodontics).

Chapel Hill
2008

Approved by

Advisor: Ceib Phillips, PhD, MPH
Reader: Garland Hershey, DDS, MS
Reader: William Maixner, DDS, PhD

ABSTRACT

SEAN MURDOCK: Treatment of Pain Following Initial Arch Wire Placement
(Under the direction of Dr. Ceib Phillips)

Pain is a major apprehension of patients prior to orthodontic treatment. No study has compared a non-pharmacological option and an over the counter analgesic medication (OTC) for pain management. A parallel two group stratified block randomized clinical trial was designed to assess the pain response of adolescents during the first week following initial arch wire placement. Subjects were randomly assigned to one of two pain management groups: bite wafer (BW) or over the counter analgesics (OTC). Pain levels were reported using a numerical rating scale (NRS) and the Gracely Box scale at 8 different time points over a 7 day period. The pattern of current pain level over time was similar for the two groups (P=0.88) and the overall current pain level was not statistically different for the two groups (P=0.36). The use of a bite wafer was not inferior to the use of OTC medications for pain management.

TABLE OF CONTENTS

Page

LIST OF TABLES

Table Page

LIST OF FIGURES

Figure Page

LIST OF ABBREVIATIONS

Description	Abbreviation
Bite Wafer	BW
Non-Steroidal Anti-inflammatory Drug	NSAID
Numerical Rating Scale	NRS
Over The Counter medication	OTC
Visual Analogue Scale	VAS

SECTION I

LITERATURE REVIEW

Pain and Orthodontic Therapy

Pain and orthodontic therapy tend to go hand in hand. Many patients often ask the question “Is it going to hurt?”, and the overwhelming answer is “Yes”. Not surprisingly, pain is a major fear and cause of apprehension for patients prior to orthodontic treatment (1). Because of that fact, it should be of great concern not only for the patient, but also the clinician (2).

Pain is a subjective response to stimuli that is quite variable depending on the individual, and is dependent upon many things such as, but not limited to, age, gender, cultural differences, and previous experiences. Pain also includes sensations evoked by and reactions to noxious stimuli (3). Patients in orthodontic treatment often describe the pain or discomfort as a feeling of pressure, tension, ache, and soreness of the teeth (4). The pain cycle begins as soon as the appliances are placed as they begin to exert forces on the dentition and periodontuim. The pain intensity usually increases gradually from 2 hours after application of orthodontic force to a peak level at 24 hours, and resolution of the pain by the seventh day (5-8).

The pain that patients undergo has long been thought a part of treatment that just can’t be avoided. In order to better serve our patients, we as clinicians have to find the best

way possible to alter the experience of our patients in order to help them better cope with this negative aspect of treatment.

So what causes orthodontic pain? Simply put; the movement of teeth whether from placement of separators, arch wire placement and activation, elastic wear, or head gear application. In order to move teeth orthodontic force must be applied, and when those forces are applied to the teeth, it is transmitted to the bone and surrounding periodontal ligament. If this force lasts for more than a few seconds, a pain response is elicited (9). Since orthodontic force is applied over a long duration of time, pain is inevitable. The source of pain is probably the creation of ischemic areas that undergo sterile necrosis within the periodontal ligament (10). Algogens such as histamine, bradykinin, prostaglandins, serotonin, and substance P are released after periodontal ligament compression and activate the inflammatory process (11). Because these chemical mediators are the cause of the pain, the best way to control the pain is to either stop the production of these noxious chemicals or reduce there production.

Pain Management

Different methods and protocols have been developed to control pain. Methods such as application of low level laser therapy to periodontal tissues (12), transcutaneous electrical nerve stimulation (13), and vibratory stimulation of the periodontal ligament (14) have been tried, and pain control to some degree has been achieved. To date the most preferred method of pain control has been the administration of NSAIDs (non-steroidal anti-inflammatory drugs) which work by inhibiting prostaglandin synthesis and has become the standard of care for orthodontic pain management. NSAIDs given preoperatively have been shown to be effective in many studies (11). For those patients unable to take NSAIDs, the use of

acetaminophen, ibuprofen, aspirin, and naproxen sodium could be an alternative. All of these drugs have been studied and found to be effective to varying degrees (4,15).

But what about those parents and patients who do not want to take medication for pain and want an alternative? Also the fact that analgesics often are prostaglandin inhibitors raises the interesting possibility that the medication used by many to control pain after orthodontic appointments could interfere with tooth movement (9). So what about a non-pharmacological approach for pain?

Proffit recommended chewing something such as gum or a plastic wafer during the first 8 hours after an orthodontic appliance has been activated (9). Chewing something hard after appliance adjustment has been recommended as a means of loosening the tightly grouped fibers around the nerves and blood vessels, and restoring normal vascular and lymphatic circulation, thus preventing or relieving the inflammation and edema (16). In a study conducted by White, 63% of participants said that they had experienced less discomfort when they chewed two pieces of Aspergum for 20 to 30 min immediately following arch wire changes (17). In a study by Hwang, patients were given a bite wafer to chew for 10-12 minutes within an hour after an orthodontic adjustment, or when ever they felt discomfort. Of patients who used the wafers, 55.4% found the wafers to be effective in reducing pain, 69.4% reported that the bite wafer was effective when used within an hour following treatment, and 86.4% found them to be effective during subsequent periods of discomfort (10). Based on these studies, it has been shown that the rhythmic process of chewing can help reduce post operative pain.

Pain Assessment Measures

Pain is inherently a subjective feeling and so its measurement/evaluation relies solely on patient self report. This is mainly assessed through patient interview or a questionnaire that asks the patient to define their pain experience. This can be done by describing some of its qualities such as its intensity, or unpleasantness. Pain studies in the literature primarily use either a visual analog scale (VAS) (7), numerical rating scale (NRS) (18) or a verbal descriptive scale (19). The VAS consists of an unmarked 100mm long horizontal line that is weighted at both ends with the 2 extremes of pain (i.e. “no pain” and “worst pain imagined”). The patient marks on the line in relation to the two extremes that which best describes their pain. The distance from the left margin is then measured and scored.

The NRS can consist of a 6 or 11 point scale (0-5 or 0-10) that is anchored on either end point by extremes of “no pain” and “worst pain imagined” and can be administered either verbally or graphically. NRS have been shown to give valid and reliable information for clinical use, shows good sensitivity, and provides data that can be statistically analyzed using parametric analyses (20).

Verbal pain descriptors, such as the verbal descriptive scale, provide a valid scaling method which discriminates between the sensory intensity and affect, or unpleasantness, of pain (21). They generally consist of two lists made up of 13 words each. The patient chooses one word from each list that best describes the sensory intensity and unpleasantness of the pain. Each word is given a numerical score by the patient, which is accomplished by the patient ranking the 13 words in each list in order of perceived intensity (least to greatest). The numerical score is assigned to each word from 1-13 corresponding to the rank order for

that individual. The relative magnitudes of the words within a dimension are reliably quantified by these ranking procedures (21).

Relevance

In the last decade, several studies have focused on the effectiveness of a masticatory bite wafer for pain management and the effectiveness of one drug versus another in controlling orthodontic pain. To date, no study has compared the non-pharmacological approach of using masticatory bite wafers for pain management, and the standard of care over the counter (OTC) pharmacological approach. The purpose of this study is to compare the pain response following orthodontic initial arch wire placement and aims to specifically 1) compare the pain intensity between the two treatment groups; 2) compare the sensory and afferent quality of pain between the two treatment groups; and 3) determine the percentage of non-pharmacological (bite wafer) patients who require rescue medicine (any OTC medicine that they choose to take for management of pain).

From this study, we will assess the effectiveness of the two different approaches, and establish a preferred method for treatment of orthodontic pain following initial arch wire placement.

REFERENCES

1. O'Connor PJ. Patients' perceptions before, during, and after orthodontic treatment. J Clin Orthod. 2000 Oct;34(10):591-2.

2. Asham AA. Readers' forum: orthodontic pain. Am J Orthod Dentofacial Orthop. 2004 Mar;125(3):18A.

3. Krishnan V. Orthodontic pain: from causes to management--a review. Eur J Orthod. 2007 Apr;29(2):170-9.

4. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. Am J Orthod Dentofacial Orthop. 1989 Jul;96(1):47-53.

5. Erdinc AM, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. Eur J Orthod. 2004 Feb;26(1):79-85.

6. Jones M, Chan C. The pain and discomfort experienced during orthodontic treatment: a randomized controlled clinical trial of two initial aligning arch wires. Am J Orthod Dentofacial Orthop. 1992 Oct;102(4):373-81.

7. Bernhardt MK, Southard KA, Batterson KD, Logan HL, Baker KA, Jakobsen JR. The effect of preemptive and/or postoperative ibuprofen therapy for orthodontic pain. Am J Orthod Dentofacial Orthop. 2001 Jul;120(1):20-7.

8. Fernandes LM, Ogaard B, Skoglund L. Pain and discomfort experienced after placement of a conventional or a superelastic NiTi aligning archwire. A randomized clinical trial. J Orofac Orthop. 1998;59(6):331-9.

9. Proffit WR, Fields HW. Contemporary Orthodontics. 3rd ed. Rudolph P, editor. St. Louis: Mosby; 2000.

10. Hwang JY, Tee CH, Huang AT, Taft L. Effectiveness of thera-bite wafers in reducing pain. J Clin Orthod. 1994 May;28(5):291-2.

11. Polat O, Karaman AI, Durmus E. Effects of preoperative ibuprofen and naproxen sodium on orthodontic pain. Angle Orthod. 2005 Sep;75(5):791-6.

12. Lim HM, Lew KK, Tay DK. A clinical investigation of the efficacy of low level laser therapy in reducing orthodontic postadjustment pain. Am J Orthod Dentofacial Orthop. 1995 Dec;108(6):614-22.

13. Roth PM, Thrash WJ. Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement. Am J Orthod Dentofacial Orthop. 1986 Aug;90(2):132-8.

14. Marie SS, Powers M, Sheridan JJ. Vibratory stimulation as a method of reducing pain after orthodontic appliance adjustment. J Clin Orthod. 2003 Apr;37(4):205,8; quiz 203-4.

15. Steen Law SL, Southard KA, Law AS, Logan HL, Jakobsen JR. An evaluation of preoperative ibuprofen for treatment of pain associated with orthodontic separator placement. Am J Orthod Dentofacial Orthop. 2000 Dec;118(6):629-35.

16. Furstman L, Bernick S. Clinical considerations of the periodontium. Am J Orthod. 1972 Feb;61(2):138-55.

17. White LW. Pain and cooperation in orthodontic treatment. J Clin Orthod. 1984 Aug;18(8):572-5.

18. Farrar JT, Young JP,Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain. 2001 Nov;94(2):149-58.

19. Gracely RH, McGrath P, Dubner R. Validity and sensitivity of ratio scales of sensory and affective verbal pain descriptors: manipulation of affect by diazepam. Pain. 1978 Jun;5(1):19-29.

20. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs. 2005 Aug;14(7):798-804.

21. Gracely RH, McGrath F, Dubner R. Ratio scales of sensory and affective verbal pain descriptors. Pain. 1978 Jun;5(1):5-18.

SECTION II

MANUSCRIPT

INTRODUCTION

Pain is one of the major fears and apprehensions of patients prior to orthodontic treatment (1). Patients often describe the discomfort as a feeling of pressure, tension, ache, or soreness of the teeth (2). The pain cycle begins as soon as appliances are placed and forces are exerted on the dentition and periodontuim. The pain intensity usually increases gradually from 2 hours after application of orthodontic force to a peak level at 24 hours, with resolution of the pain by the seventh day (5-8).

Currently the most frequently recommended treatment for pain is the use of over the counter analgesics (OTC), most notably, non-steroidal anti-inflammatory drugs (NSAIDs), which work by inhibiting prostaglandin synthesis. Previous studies assessing the efficacy of analgesics for pain management following orthodontic procedures have focused on medication administered immediately before (17,9) or before and immediately after (18,20) the procedure. All of these studies have reported that analgesics are effective for pain management following orthodontic procedures.

The over-use of medications, including OTC analgesics, and potential side effects have been raised as a concern particularly for children (24,25). Non-analgesic pain management approaches such as chewing gum or chewing on a plaster wafer have been recommended (6) as a means of loosening the tightly grouped fibers around the nerves and

blood vessels, restoring normal vascular and lymphatic circulation, thus preventing or relieving the inflammation and edema (16). Several studies have indicated that the rhythmic process of chewing either Aspergum (7) or chewing on a bite wafer (8) reduced the pain and discomfort following arch wire placement but no study has compared either of these non-pharmacological approaches to the use of the standard of care OTC medication.

The purpose of this study was to compare the pain response during the first week following initial arch wire placement of patients randomly assigned to one of two pain management groups: bite wafer or OTC analgesics.

MATERIALS AND METHODS

Sampling Method

Consecutive adolescent patients, 8 to18 years of age, accepted for treatment in the graduate orthodontic clinic at the University of North Carolina between August 2006 and November 2007 who met the inclusion/exclusion criteria (Figure 1) were invited to participate. The study was approved by the Biomedical Institutional Review Board. Patients who successfully completed the study received $20 for their participation.

Figure 1 Subject inclusion/ exclusion criteria

Inclusion Criteria

1. Healthy adolescents (8-18) being treated at UNC Chapel Hill School of Dentistry Graduate Orthodontic Clinic.
2. Minimum weight of 88 lbs (***FDA-approved OTC pediatric dosage labeling guidelines***)
3. Full Band and Bond in at least 1 arch
4. Informed consent obtained from parent or guardian

Exclusion Criteria

1. Patient taking pain meds for chronic pain
2. Medical condition that precludes the use of OTC pain meds
3. asthma
4. Meds taken 3-4 days before the start of treatment
5. Allergies to common OTC meds
6. Oral surgery procedures in previous 4 weeks

** No subject was excluded on the basis of sex or ethnicity **

Study Design

The study was designed as a stratified block randomized two group parallel clinical trial. Subjects were randomly assigned to either an over the counter analgesic medication (OTC) group or a bite wafer (BW) group. Assignments were made using a computer generated random assignment strategy that balanced groups with respect to sex (block size of 4). The assignments were placed in sealed envelopes and were opened sequentially within strata.

Masking of subjects was not possible due to the nature of the treatments. The specific pain management instructions (Figure 2) given to each group were reviewed with the patient and parent prior to and immediately after the initial arch wire placement. Patients in the OTC group were instructed not to take pre-procedure medication since the bite wafer could not be used preoperatively.

Figure 2 Pain management instructions given to each group (patient and parent) immediately prior to and after the arch wire placement.

Bite wafer group: Chew or bite on wafer for 10-12 minutes within an hour after adjustment. Chew on wafer as much as you want whenever you feel discomfort **OTC medicine group:** Take any OTC medicine of your choosing, and take as needed for pain, following directions of manufacturer

Sample Size Calculation

Data by Polat et al (9) were used to calculate the estimated sample size required for a non-inferiority comparison of the two treatment groups. A non-inferiority comparison was chosen because, from a clinical standpoint, there was no expectation that using a bite wafer would provide better pain control than an analgesic. Twenty five subjects per group, using an unpaired t-test approach with a one-sided level of significance of 0.05, were estimated to provide approximately 80% power to detect an effect size difference of 0.70.

Data Collection

Subjects were asked to rate their pain and the quality of their pain at eight time points following arch wire placement: at 2 and 6 hours, at bedtime on the day of the appointment, 24 hours after the appointment, and at bedtime two days, three, five, and seven days after bonding. Subjects were given instructions on completion of the questionnaires before leaving the clinic and were given a binder containing all of the questionnaires along with a self-addressed-stamped envelope for return at the end of the protocol period.

Current pain level and pain during four functions (biting on front teeth, back teeth, chewing, and tapping teeth together three times) were assessed at each time point using numerical rating scores (NRS) from no pain “0” to as bad as you can imagine “10”. Respondents also completed the Gracely Box Afferent (Intensity) and Sensory (Unpleasantness) scales (12) at each time point. Because the Gracely scales have not been

used extensively with adolescents, each subject was asked to rank each group of words from the least "1" to the most intense / unpleasant "13" prior to the arch wire placement. The subject's ranking of the words was used as the post arch wire placement numerical response to quantify the quality of the pain rather than the published adult rankings (19).

At bedtime each day, the subject was asked to rate the average pain during the day and the % of time during the day that pain was experienced (0=no time to 10 = all day). The OTC treatment group was asked to document what pain medication had been used, the number of tablets, and the dose of each tablet. To assess the effectiveness of treatment, patients were asked how happy they were with their discomfort relief at the end of the week (0= not happy to 10= very happy). The bite wafer treatment group was asked to document how many times the wafer had been used, the total number of minutes used, and how effective it was for discomfort relief at the end of the week. If a subject in the bite wafer group required rescue medication, (s)he was asked to document what pain medication was used, number of tablets, and dose of each tablet. Subjects were encouraged not to take rescue medication and were asked to call the principal investigator if medication was taken.

Statistical Analysis

A general linear mixed model (SAS Proc Mixed) with heterogeneous compound symmetry covariance matrix was fitted separately for each outcome variable (current pain, pain during function, affective pain, sensory pain) to compare the bite wafer and OTC groups. The covariance structure was selected based on Akaike's Information Criterion and the Bayesian Information Criterion, the most commonly used criteria for choosing among competing covariance structures. The model controlled for the effect of gender, a design variable, and time. The interaction between group and time was also included to assess

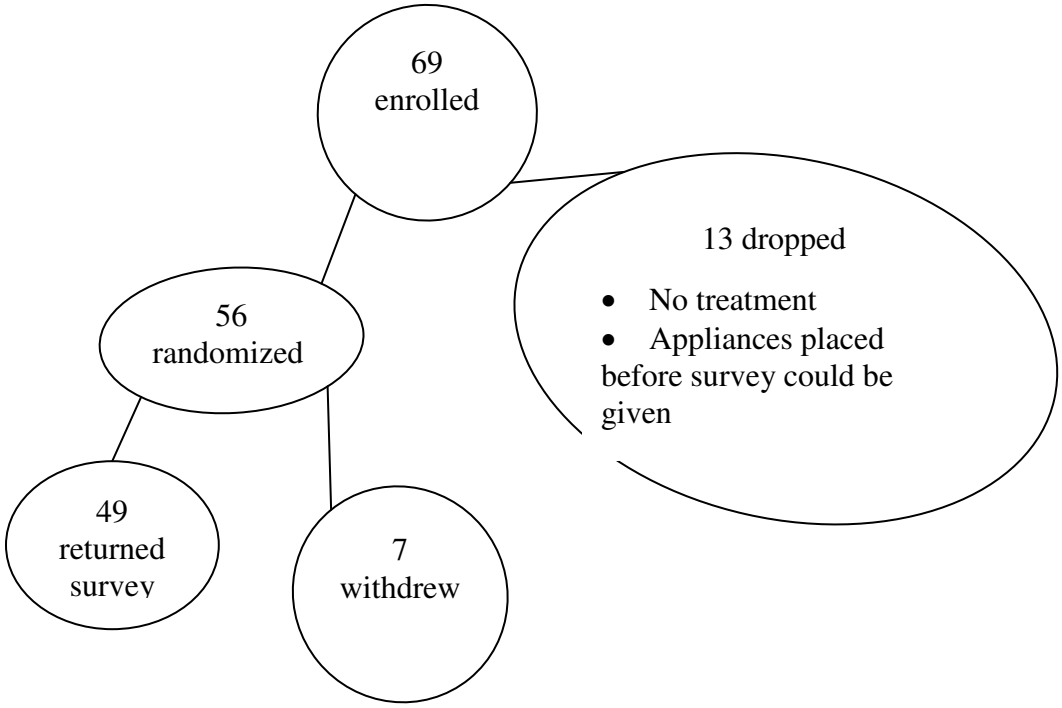
whether a differential pattern occurred over time in the two groups. The estimates and standard errors from the mixed models were used to test the hypothesis that the bite wafer group, on average, was not inferior with respect to pain management to the OTC group. Level of significance was set at $p < 0.05$ for all analyses.

RESULTS

Sample

Sixty-nine adolescent subjects were enrolled. Of the 56 subjects who were randomized, (Fig 3) 87.5% successfully completed the survey. Fifty-seven percent of the subjects who withdrew were female, and the average age was 13. Two subjects had been assigned to the bite wafer group and 5 to the OTC group.

Figure 3 The enrollment and retention of participants



Sixty-nine percent of the participants were Caucasian, 16% African American, 4% Hispanic, and 12% other. The average age (Table 1) at enrollment for the 24 subjects randomized to the bite wafer (BW) group was not significantly different from that of the 25 subjects randomized to the over the counter (OTC) medication group (unpaired t-test; P= 0.90). The percentage of females in the two groups was similar (chi-square test; P= 0.88).

Table 1 Descriptive statistics for the demographic characteristics of the two treatment groups

Age

Group	% Females	Mean	SD	Min	Max
BW	54	13.6	2.0	11.0	17.8
OTC	52	13.7	1.7	10.1	16.7

Patients in the OTC group used a variety of medications. 40 % used an NSAID, 50% a non-NSAID, and 10% percocet. These patients took an average of 1.5 tablets a day, and recorded more use during the first two days: 2.5 (s=1.5) and 2.7 (s=2.3) tablets respectively.

The bite wafer was used an average of 3 times a day, with more use the first two days (4.7 (s=6.4) and 3.9 (s=5.5) times respectively) after arch wire placement. Patients used the bite wafer from 0 to 20 min a day, the majority of the time (85%). Nine patients (37.5%) in the bite wafer group used rescue medication at least once during the week. Five patients used rescue medication once, 2 patients twice, one three and one four times. All patients who used rescue medication took the initial dose within the first 24 hours after arch wire placement. To control for the effects of the rescue medication, the analyses were re-run removing those responses during the 12 hour period after the medication was taken. As expected, when the

responses were removed for those subjects who experienced sufficient discomfort to require rescue analgesic, the average pain responses for the bite wafer group decreased (Fig 4 and 5).

Pain Responses

For both groups, the average pain level peaked within the first 24 hours after arch wire placement. The response pattern over time for current pain level (Figure 4; P=0.88), average pain level during the day (Figure 5; P=0.90), and the percent of the day with pain (Figure 6; P= 0.84) was similar for the two groups. The average pain control in the bite wafer group was not inferior to that in the OTC group for the overall current pain level (Figure 4; P=0.36); average pain level during the day (Figure 5; P =.10); or the percent of the day with pain (Figure 6; P=0.38). As expected, the current pain level, the average pain level during the day, and the percent of the day with pain decreased significantly over time (P<0.0001).

Table 2 Means and standard deviations for the first two days following arch wire placement for the OTC and bite wafer groups

	2 hours		6 hours		Day 1		24 hours		Day 2	
	M	SD	M	SD	M	SD	M	SD	M	SD
OTC current pain	1.9	2.1	3.7	2.9	4.9	2.6	4.3	2.3	3.6	2.3
BW current pain	1.9	2.3	3.4	2.6	4.0	2.7	3.7	2.3	3.5	2.6
OTC biting front	2.7	2.9	4.8	2.9	6.1	2.9	5.7	2.6	5.1	3.0
BW biting front	2.5	3.1	3.2	2.8	4.4	2.5	4.8	2.4	4.1	3.0
OTC biting back	2.5	2.9	3.4	3.3	4.4	3.2	4.0	3.2	3.9	3.3
BW biting back	2.3	2.6	3.3	2.8	3.8	3.1	3.4	2.7	3.0	2.6
OTC chewing	3.7	3.5	4.3	3.5	6.2	3.4	5.5	2.8	5.6	3.1
BW chewing	2.3	2.5	4.2	3.0	4.7	3.0	5.2	3.3	4.6	3.1
OTC tapping teeth	2.8	3.2	4.6	3.6	5.8	3.3	6.0	2.9	5.4	3.3
BW tapping	1.6	2.1	3.6	3.0	3.5	2.6	3.8	2.9	3.9	3.0

teeth										
OTC % of day with pain					5.0	2.6			5.9	3.2
BW % of day with pain					4.3	2.4			5.3	3.3
OTC average pain for day					5.2	2.2			5.3	2.6
BW average pain for day					4.2	2.5			4.3	2.5
OTC current intensity	4.3	3.4	6.5	4.4	7.8	3.7	7.1	3.5	6.0	3.1
BW current intensity	4.0	3.2	6.7	3.0	6.2	3.0	6.5	3.2	6.5	3.6
OTC worst intensity					8.2	3.8			7.4	3.8
BW worst intensity					7.3	2.6			8.3	3.1
OTC current unpleasantness	3.4	2.8	5.0	3.6	5.8	3.5	6.3	3.6	6.4	3.4
BW current unpleasantness	3.9	2.5	5.5	3.4	5.0	3.2	5.8	3.0	5.5	4.0
OTC worst unpleasantness					6.5	3.8			7.0	3.9
BW worst unpleasantness					5.3	3.2			6.6	3.1

Table 3 P-values associated with the Type III sum of squares for the main effects and pair wise interactions from the general linear model for each outcome

	Group		Gender		Time		Group*Time		Function		Time*Function	
	F	P	F	P	F	P	F	P	F	P	F	P
Current Pain	0.8	0.36	0.7	0.39	37.1	<0.0001	0.4	0.88				
Functions	3.7	0.05	4.5	0.03	74.31	<0.0001	1.5	0.16	24.8	<0.0001	1.1	0.33
% of day with pain	0.7	0.38	0.1	0.74	47.57	<0.0001	0.3	0.84				
Average pain for day	2.7	0.10	0.5	0.48	62.7	<0.0001	0.2	0.90				
Effectiveness of pain management	0.2	0.64	0.7	0.40								
Current intensity	0.2	0.59	0.03	0.86	35.5	<0.0001	0.8	0.54				
Worst intensity	0.08	0.77	0.1	0.75	56.3	<0.0001	1.0	0.36				
Current unpleasantness	0.0	0.94	2.4	0.12	20.9	<0.0001	0.5	0.76				
Worst unpleasantness	0.3	0.54	0.0	0.99	27.9	<0.0001	0.6	0.61				

Figure 4 Average pain scores for "current pain level" for the OTC and bite wafer groups. *The average current pain level for all participants in the bite wafer group and those who did not use rescue medication are displayed.*

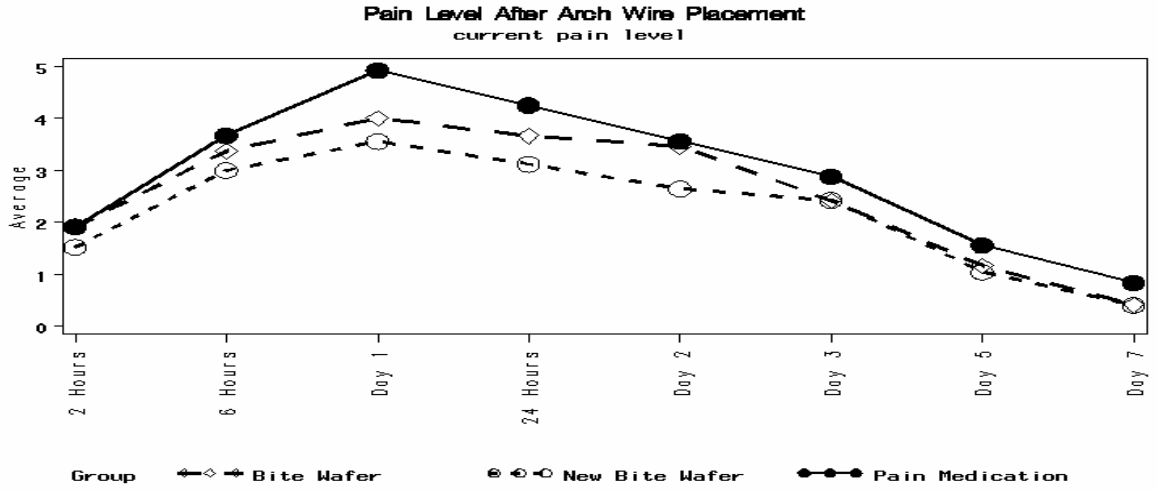


Figure 5 Average pain scores for "average pain level during the day" for the OTC and bite wafer groups. *The average pain level during the day for all participants in the bite wafer group and those who did not use rescue medication are displayed.*

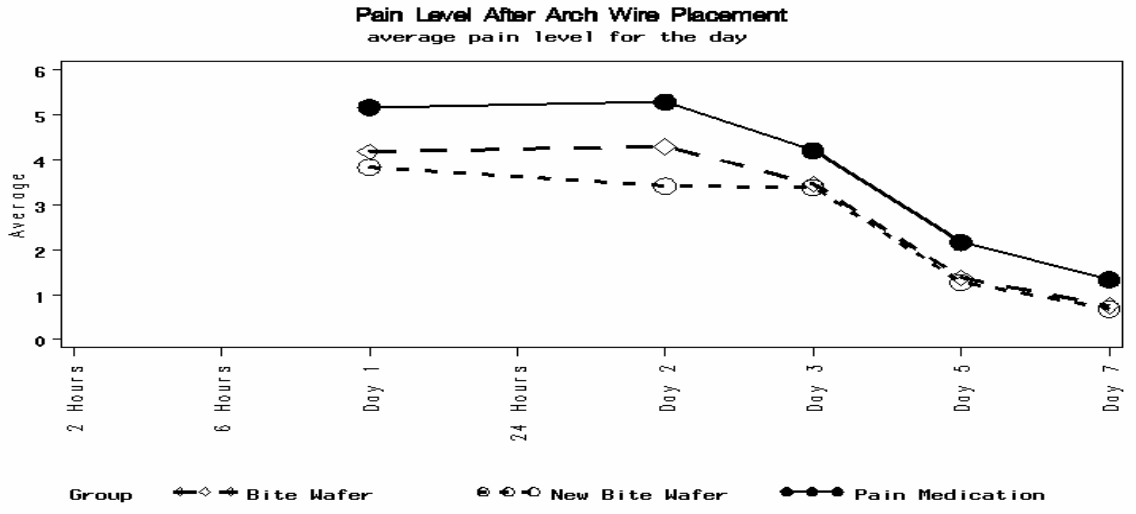
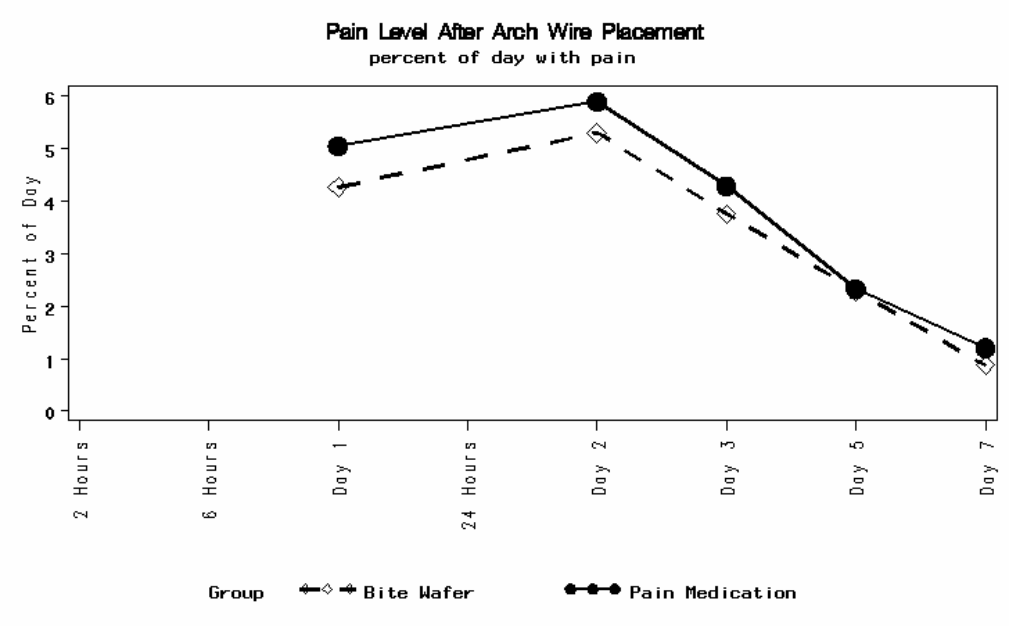


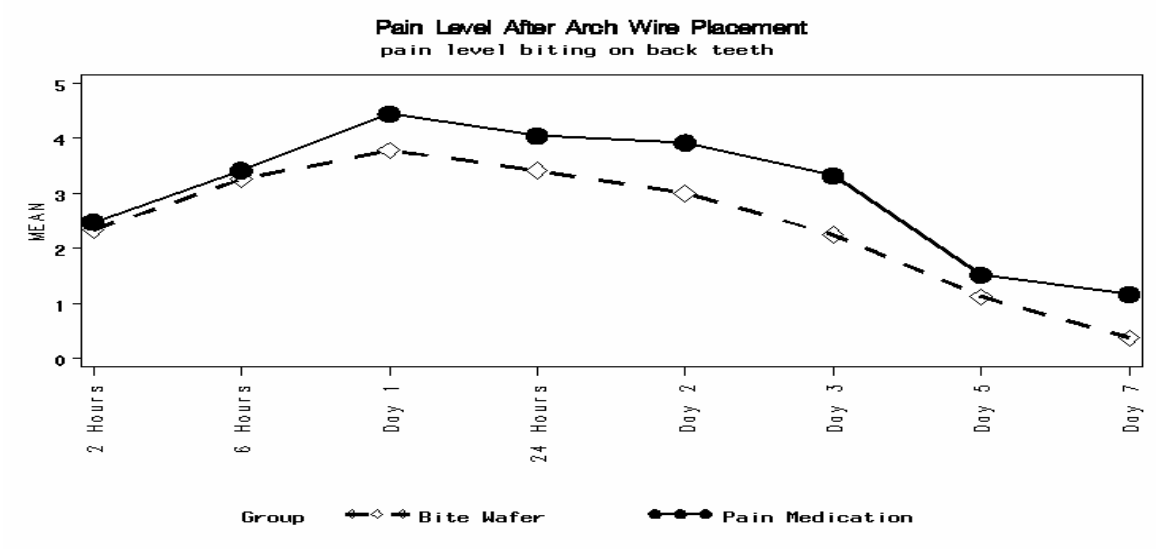
Figure 6 Average "percent of day with pain" for the OTC and bite wafer groups

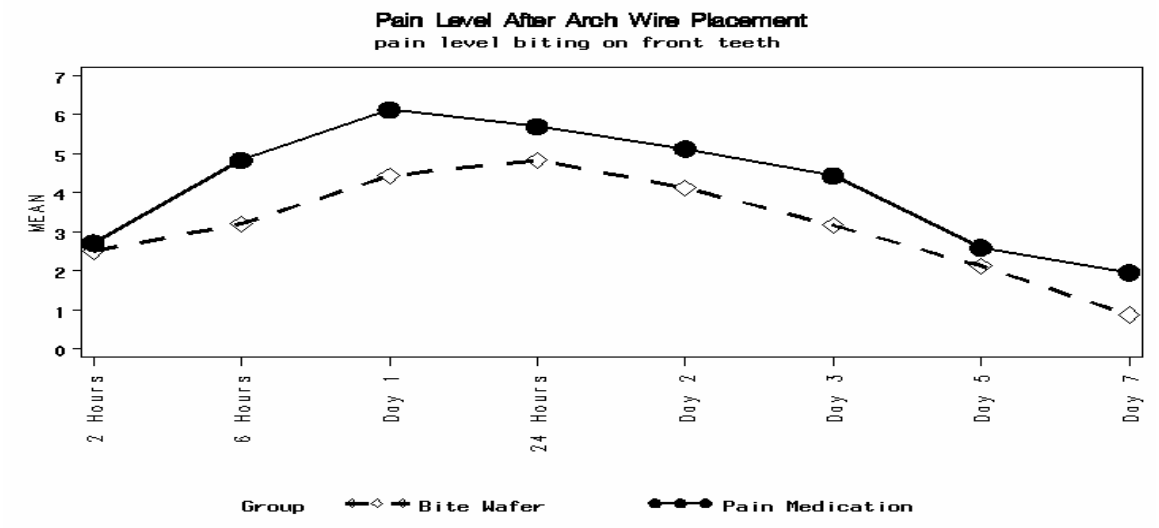


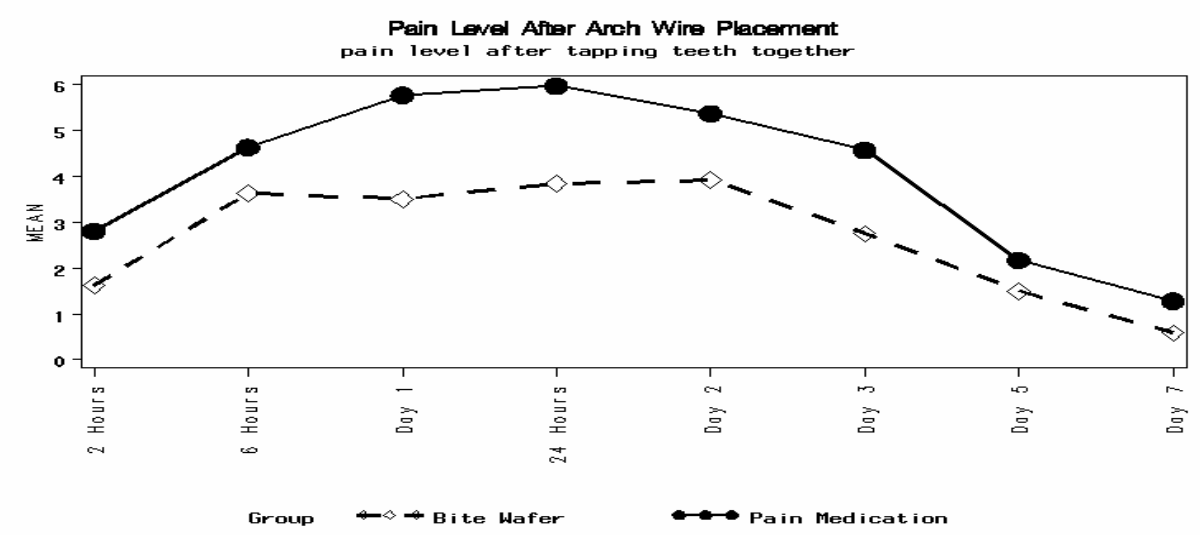
The pattern of pain reported over time was similar for the four functions (biting on front and back teeth, chewing and tapping teeth together) (P=0.33) although the overall pain levels experienced did differ significantly among the four functions (P<0.0001). Pain experienced from biting on the back teeth was significantly lower than that from biting on the front teeth (Figures 7 ; P<0.0001) and chewing was significantly more painful than tapping the teeth together (P<0.0043).

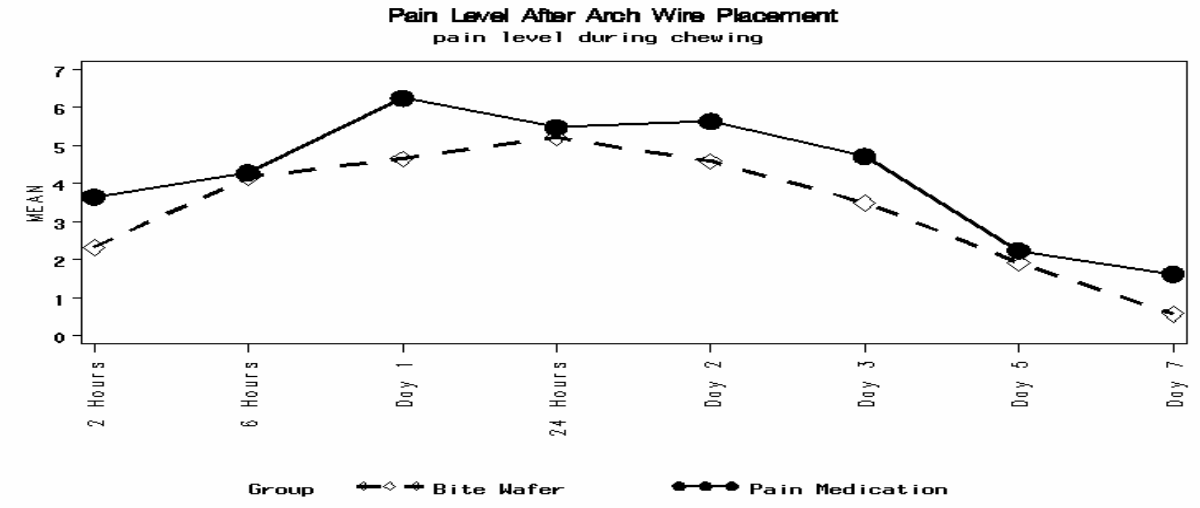
The pattern of pain reported for the functions over time was similar for the two groups (P=0.16) and the overall pain level reported for the functions was not statistically different for the two groups (P=0.06). As expected, the pain level experienced during function decreased significantly over time (P<0.0001).

Figure 7 Average pain responses for the four functions for the OTC and bite wafer groups.









The perceived effectiveness of the pain management for the week was higher, although not significantly (P=0.40), in the bite wafer group (x = 6.1; s = 3.0) than in the OTC group (x=5.7; s = 3.0).

Afferent and Sensory Quality of Pain

The median rankings of the Gracely pain descriptors by the adolescents were similar to the established adult rankings but there was considerable variability in the rankings

associated with the lower intensity and unpleasantness words (Table 4). The variability among the rankings given the words by the subjects supports the use of the individual's baseline ranking as the numerical value for each word.

For current and worst intensity and unpleasantness of the pain experienced during the day, the pattern over time was similar for the two treatment groups (Intensity, P=0.54 and 0.36; Unpleasantness P = 0.76 and 0.94 respectively) and the overall ranking was not statistically different for the two groups (Intensity, P=0.59 and 0.77; Unpleasantness, P =0.94 and 0.54). As expected, the rankings for current and worst intensity and unpleasantness decreased significantly over time (P<0.0001).

Table 4 Rankings of the intensity and unpleasantness words prior to arch wire placement by the bite wafer and the OTC groups

Intensity Words

	Bite Wafer			OTC		
	25th %	Median	75th %	25th %	Median	75th %
No Pain	1.0	1.0	1.0	1.0	1.0	1.0
Faint	2.0	4.0	11.0	2.0	4.0	7.0
Very Weak	2.0	3.0	6.0	2.0	3.0	4.0
Weak	3.0	4.0	6.0	3.0	3.0	4.0
Very Mild	4.0	5.0	6.0	5.0	5.0	6.0
Mild	3.0	5.0	6.0	4.0	5.0	6.0
Moderate	4.0	7.0	9.0	6.0	7.0	7.0
Barely Strong	7.0	8.0	8.0	8.0	8.0	10.0
Slightly Intense	7.0	9.0	10.0	8.0	10.0	10.0
Strong	8.0	9.0	10.0	9.0	9.0	12.0
Intense	8.0	10.0	11.0	8.0	10.0	11.0
Very Intense	9.0	12.0	12.0	9.0	11.0	12.0
Extremely Intense	12.0	13.0	13.0	11.0	12.0	13.0

Unpleasantness Words

	Bite Wafer			OTC		
	25th %	Median	75th %	25th %	Median	75th %
No Pain	1.0	1.0	1.0	1.0	1.0	1.0
Slightly Unpleasant	3.0	5.0	7.0	5.0	6.0	8.0
Slightly Annoying	2.0	5.0	6.0	2.0	4.0	5.0
Unpleasant	3.0	5.5	8.0	5.0	6.0	9.0
Annoying	3.0	3.5	6.0	3.0	4.0	6.0
Slightly Distressing	5.0	8.0	8.0	8.0	8.0	9.0

Very Unpleasant	7.0	8.0	10.0	7.0	7.0	12.0
Distressing	6.0	9.0	9.0	8.0	9.0	9.0
Very Annoying	4.0	6.5	7.0	4.0	7.0	7.0
Slightly Intolerable	7.0	11.0	11.0	5.0	10.0	11.0
Very Distressing	10.0	10.0	11.0	10.0	10.0	10.0
Intolerable	8.0	12.0	12.0	6.0	10.0	11.0
Very Intolerable	10.0	13.0	13.0	7.0	13.0	13.0

DISCUSSION

The discomfort and pain experienced by patients after arch wire placement is of serious concern for both patients and practitioners. Patients in orthodontic treatment often describe the pain or discomfort as a feeling of pressure, tension, ache, and soreness of the teeth (2). Orthodontic forces applied to teeth are transmitted to the bone and surrounding PDL. If this force lasts for more than a few seconds, a pain response is elicited (6). The source of pain is probably the creation of ischemic areas that undergo sterile necrosis within the periodontal ligament (8). Algogens such as histamine, bradykinin, prostaglandins, serotonin, and substance P are released after periodontal ligament compression and activate the inflammatory process (9).

Initial crowding at the start of treatment or the magnitude of force applied to the teeth do not appear to affect the discomfort experienced by patients (16,21). The reports on the influence of age or sex on the pain experienced by patients following an orthodontic procedure have not been consistent (2,15,16). To control for these factors, this study was limited to adolescents and stratification based on sex was used to balance the distribution of males and females in the two groups.

Previous pain management studies in orthodontics have used pre-loading doses of OTC medication before separator or arch wire placement (9,17,18,20) and have reported that OTC analgesics were effective for pain management. However, few clinicians recommend pre-dosing prior to orthodontic procedures but rather instruct patients to take analgesics after

the procedure as needed for the pain. This study was designed to parallel the more common clinical pain management during orthodontic treatment: patients in both groups were asked to record their usage but were not given a specific schedule to follow.

The pain cycle following an orthodontic procedure begins as soon as the appliances are placed and begin to exert forces on the dentition and periodontuim. In this study, current pain level for both groups followed a similar curve: pain increased after 2 hours, peaked at bedtime on day 1, and decreased over the rest of the week (Figure 4). This pattern reflects what has been reported previously (16,27-29). Pain reported by both groups for the tooth functions also showed a peaking of pain at either bedtime day 1 or 24 hours after arch wire placement. This is also consistent with peak pain being reached in the first 24 hours of activation (2,10). Pain experienced from biting on back teeth was significantly lower then that from biting on front teeth for both treatment groups and this is in agreement with studies by Polat (Figure 7). Significantly more pain was reported during chewing then tapping front teeth together; only a few teeth touch when tapping, while chewing calls for maximum intercuspation and contact among the majority of teeth.

The bite wafer was not inferior to OTC analgesics with respect to any of the pain measures or effectiveness. Indeed, the average pain reported by the OTC group was slightly higher than that reported by the bite wafer group for all measures except for biting on front and back teeth at 2 hours. The average current level of pain reported by the OTC group in this study was similar to that reported by Bradley (18). In that study, medication was given 1 hour prior to separator placement and again 6 hours after placement. Data was collected at 2hours, 6 hours, and on days 1, 2, 3, and 7. Likewise, the average current pain reported by the bite wafer group was similar to that reported by Otasevic (26). In that study patients were

instructed to chew on the wafer for 10 minutes immediately after placement of fixed appliances and then whenever they experienced pain. Data was collected in the morning, at lunch time, and in the evening for the next 7 days.

There is a growing concern about medication usage in children and adolescents (24,25). Although quite infrequent, side effects do occur and include, but are not limited to, gastric or duodenal ulceration, bleeding disorders, asthma, renal insufficiency, and drug allergy (22). Another issue that can complicate OTC usage in adolescents is school policy that prohibits the dispensing of medication, even OTC, without a doctor's prescription (23). Alternative pain management methods such as the bite wafer do not have these possible consequences.

CONCLUSIONS

The use of a bite wafer was not inferior to the use of OTC medications for the management of pain after the placement of an arch wire. The bite wafer is a non-pharmacological option for pain management following orthodontic procedures that eliminates the possibility of side effects from the use of analgesics and can easily be used at home or school without adult supervision.

REFERENCES

1. O'Connor PJ. Patients' perceptions before, during, and after orthodontic treatment. J Clin Orthod. 2000 Oct;34(10):591-2.

2. Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. Am J Orthod Dentofacial Orthop. 1989 Jul;96(1):47-53.

3. Lim HM, Lew KK, Tay DK. A clinical investigation of the efficacy of low level laser therapy in reducing orthodontic postadjustment pain. Am J Orthod Dentofacial Orthop. 1995 Dec;108(6):614-22.

4. Roth PM, Thrash WJ. Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement. Am J Orthod Dentofacial Orthop. 1986 Aug;90(2):132-8.

5. Marie SS, Powers M, Sheridan JJ. Vibratory stimulation as a method of reducing pain after orthodontic appliance adjustment. J Clin Orthod. 2003 Apr;37(4):205,8; quiz 203-4.

6. Proffit WR, Fields HW. Contemporary Orthodontics. 3rd ed. Rudolph P, editor. St. Louis: Mosby; 2000.

7. White LW. Pain and cooperation in orthodontic treatment. J Clin Orthod. 1984 Aug;18(8):572-5.

8. Hwang JY, Tee CH, Huang AT, Taft L. Effectiveness of thera-bite wafers in reducing pain. J Clin Orthod. 1994 May;28(5):291-2.

9. Polat O, Karaman AI, Durmus E. Effects of preoperative ibuprofen and naproxen sodium on orthodontic pain. Angle Orthod. 2005 Sep;75(5):791-6.

10. Steen Law SL, Southard KA, Law AS, Logan HL, Jakobsen JR. An evaluation of preoperative ibuprofen for treatment of pain associated with orthodontic separator placement. Am J Orthod Dentofacial Orthop. 2000 Dec;118(6):629-35.

11. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs. 2005 Aug;14(7):798-804.

12. Gracely RH, McGrath P, Dubner R. Validity and sensitivity of ratio scales of sensory and affective verbal pain descriptors: manipulation of affect by diazepam. Pain. 1978 Jun;5(1):19-29.

13. Gracely RH, McGrath F, Dubner R. Ratio scales of sensory and affective verbal pain descriptors. Pain. 1978 Jun;5(1):5-18.

14. Scheurer PA, Firestone AR, Burgin WB. Perception of pain as a results of orthodontic treatment with fixed appliances. Eur J Orthod 1996;18:349-57.

15. Brown DF, Moerenhout RG. The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. Am J Orthod Dentofacial Orthop 1991:100:349-56.

16. Jones M, Chan C. The pain and discomfort experienced during orthodontic treatment: a randomized controlled clinical trial of two initial aligning archwires. Am J Orthod Dentofacial Orthop 1992;102:373-81.

17. Bird SE, Williams K, Kula K. Preoperative acetaminophen vs ibuprofen for control of pain after orthodontic separator placement. Am J Orthod Dentofacial Orthop. 2007 Oct;132(4):504-10.

18. Bradley RL, Ellis PE, Thomas P, Bellis H, Ireland AJ, Sandy JR. A randomized clinical trial comparing the efficacy of ibuprofen and paracetamol in the control of orthodontic pain. Am J Orthod Dentofacial Orthop. 2007 Oct;132(4):511-7.

19. Heft MW, Gracely RH, Dubner R, McGrath PA. A validation model for verbal description scaling of human clinical pain.Pain. 1980 Dec;9(3):363-73.

20. Polat O, Karaman AI. Pain control during fixed orthodontic appliance therapy. Angle Orthod. 2005 Mar;75(2):214-9.

21. Jones ML, Richmond S. Initial tooth movement: force application and pain- A relationship? Am J Orthod 1985;88:111-6.

22. Andreasen JO, Peterson JK, Laskin DM. Textbook and Color Atlas of Tooth Impactions. Copenhagen, Denmark: Munksgaard; 1997:369-437.

23. Awbrey, LM., Juarez, SM. Developing a nursing protocol for over-the-counter medications in high school. J Sch Nurs 2003;19(1):12-15.

24. Mayor S. Warning against overuse of drugs for inattentive children. BMJ 1996 Sept 28; 313(7060):770.

25. Olfson M, Marcus SC, Weissman MM, Jenson PS. National trends in the use of psychotropic medications by children. J Am Acad Child Adolesc Psychiatry 2002 May;41(5): 514-21.

26. Otasevic M, Naini FB, Gill DS, Lee RT. Prospective randomized clinical trial comparing the effects of a masticatory bite wafer and avoidance of hard food on pain associated with initial orthodontic tooth movement. Am J Orthod Dentofacial Orthop 2006;130:6.e9-6.e15.

27. Erdinc AM, Dincer B. Perception of pain during orthodontic treatment with fixed appliances. Eur J Orthod. 2004 Feb;26(1):79-85.

28. Bernhardt MK, Southard KA, Batterson KD, Logan HL, Baker KA, Jakobsen JR. The effect of preemptive and/or postoperative ibuprofen therapy for orthodontic pain. Am J Orthod Dentofacial Orthop. 2001 Jul;120(1):20-7.

29. Fernandes LM, Ogaard B, Skoglund L. Pain and discomfort experienced after placement of a conventional or a superelastic NiTi aligning archwire. A randomized clinical trial. J Orofac Orthop. 1998;59(6):331-9.