

Efficiency of a Bite Wafer on Pain Relief after Self-ligating Orthodontic Fixed Appliance Placement in Adolescents: A Single-centre Randomised Controlled Trial

PASCALINE DIEUDONNÉ¹, LAURENCE SEIDEL², ADELIN ALBERT³, ANNICK BRUIER⁴



ABSTRACT

Introduction: The most common treatment proposed to relieve pain and discomfort stemming from the orthodontic treatment is Non Steroidal Anti-inflammatory Drugs (NSAID). Non pharmacological approaches, such as chewing a Bite Wafer (BW), have emerged to manage orthodontic pain to avoid side-effects of ibuprofen or paracetamol in adolescents.

Aim: To compare efficiency between a BW chewing group and a control group to relieve orthodontic pain after the placement of a self-ligating fixed appliance in adolescents.

Materials and Methods: The present single-centre randomised controlled trial in the Department of Orthodontics and Dentofacial Orthopaedics, University Hospital, Liège, Belgium, between August 2019 and December 2020 included 33 teenagers who needed a self-ligating bimaxillary fixed orthodontic appliance. The patients were randomly allocated either to a test group encouraged to first chew on a BW to relieve the pain and then use paracetamol according to need, or to a control group authorised to consume paracetamol only. The BW group was hypothesised to be non inferior to the control group with a margin of 250 mg (one tablet). Data were collected for eight times over a seven-day period. For both groups, pain during four oral

functions (biting with front and back teeth, chewing a piece of apple and tapping teeth together three times) were assessed at each time point through the use of a numerical analog scale. The impact of orthodontic appliance on eating habits and functional limitations was evaluated at the end of the study period. Data was calculated as means and standard deviation for quantitative variables, median and Interquartile Range (IQR) were added for skewed data.

Results: The mean age of study participants was 12.3±1.1 years and 12.9±1.8 years for control group and BW group, respectively. At each time point, no statistically significant difference was observed between the two groups for the paracetamol consumption and the pain reported while the four oral functions. Functional limitations were also comparable. Total average consumption of paracetamol over seven days was lower in the test group (1000±954 mg vs 1150±844 mg) but non inferiority of BW compared to paracetamol only could not be statistically demonstrated. The test group used BW on average 5.6±8.9 times and 12.8±12.4 minutes during the seven days.

Conclusion: No significant difference in consumption of paracetamol was seen between the BW and paracetamol group.

Keywords: Archwire, Copper nickel titanium, ErkoFlex, Numerical analog scale

INTRODUCTION

Orthodontists have to be conscious that pain is an integral part of a fixed appliance treatment. Most orthodontic procedures such as separators, archwires insertion or bracket relief lead to ischaemia and periodontal ligament inflammation [1]. As a result inflammation mediators are released and activate periodontal neuronal terminations. Nociceptive information flows to the brain [2-5]. This is perceived as a pressure, a tightness and a dental hypersensitivity on the affected teeth by the orthodontic treatment [6,7]. In general, pain intensity progressively increases from two to four hours after the beginning of orthodontic force, reaches a peak after 24 hours, decreases after 72 hours and disappears after seven days [8-12].

Pain affects routine activities such as eating or chewing and can go as far as discourage patients from undertaking orthodontic treatment [13-15]. It is not easy to measure the complex and subjective phenomena of pain [16]. The most frequent treatment to relieve pain and discomfort stemming from the orthodontic treatment is NSAIDs intake, such as ibuprofen or paracetamol [17]. However, the risk of overdose or side-effects in children and adolescents are of particular concern and must be taken into account [18]. As a consequence, alternative non pharmacological approaches, such as the chewing of BW have emerged to manage orthodontic pain [19-22]. The analgesic effect of BW is explained by two hypotheses. The first

hypothesis indicates that chewing can restore blood circulation in compressed periodontal area, which decreases the feeling of pain. The second hypothesis is that the chewing rhythm removes nociceptive responses through the inhibitor top-down serotonin (5-HT) way [23]. Investigating the efficacy of BW on pain after self-ligating orthodontic fixed appliance placement has not been reported in the literature. These self-ligating devices are frequently placed in adolescents because of the physiological forces involved. Thus, the primary objective of this single centre randomised controlled trial was to test that paracetamol consumption under BW chewing was not inferior to usual care of pain relief with paracetamol after the fitting of self-ligating fixed appliance. Secondary objectives were to assess the pain felt after four oral functions over a one-week period and to measure the impact of orthodontic treatment on functional limitations.

MATERIALS AND METHODS

The present single-centre randomised controlled trial was conducted in the Department of Orthodontics and Dentofacial Orthopaedics, University Hospital, Liège, Belgium, between August 2019 and December 2020. The study was approved by the Institutional Ethics Committee of the University Hospital of Liège (B7072019400042). The parents of adolescents wearing orthodontic fixed appliance signed an informed consent.

Inclusion criteria: Adolescents between the age group 11-17 years with no previous orthodontic treatment, with Little's index >4 mm [24], with good oral hygiene and patients not on chronic antibiotics or analgesics intake were included in the study.

Exclusion criteria: Subjects with incisor or canine agenesis, with definitive dental extractions and severe liver failure patients were excluded from the study.

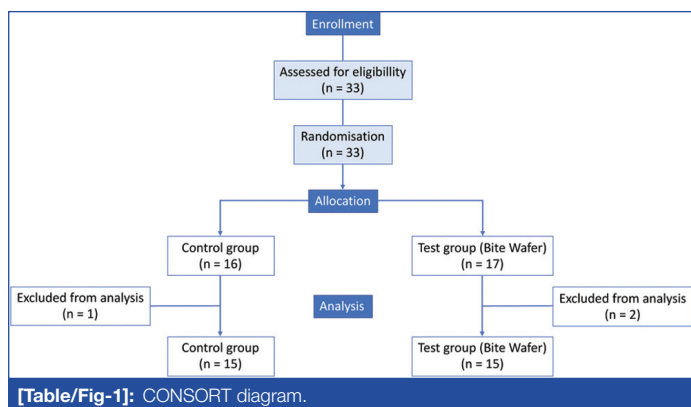
Sample size calculation: Considering total paracetamol consumption as the primary endpoint of the study, a power sample size calculation was based on the hypothesis of non inferiority of the BW group compared to the control group. Assuming an average consumption of paracetamol of 2750 mg (SD 750 mg) obtained in a previous study and a margin of 250 mg (one tablet), it was found that at least 15 adolescents in each group were necessary to evidence non inferiority with 80% power at the 5% critical level [25]. Thirty-three patients of which three were subsequently excluded, therefore 30, were recruited for the present study.

Study Procedure

All patients received self-ligating Damon Q1 (Ormco) fixed appliance in one time on morning using direct bonding technique. The first archwire was 0.014 inches Copper Nickel Titanium (Niti).

Patients were randomly assigned into two groups [Table/Fig-1]:

- Control group: Participants who only used paracetamol 250 mg for pain relief.
- Test group (also called BW) group: Participants who used BW and paracetamol 250 mg, according to need after the first archwire insertion in self-ligating brackets.



The randomisation of subjects was carried out according to a sealed envelopes system. A series of sequentially numbered envelopes contained the group assigned to the subject (C=control group and T=test group). Blocks of 10 envelopes were used, five envelopes contained the C code and five the T code. If at the end of a block of envelopes, there was a deficit, it was possible to assign to the subject the missing C or T. Then, as the subjects were recruited, the envelopes were opened and the code they contained was assigned to the subject.

Pain management: The specific pain management instructions were given to adolescents and parents in each group immediately after the initial archwire placement, including hygiene and standard instructions such as intake of soft diet in the first days and no chewing gum. Adolescents of the control group were allowed to take paracetamol to relieve pain for upto seven days. Adolescents of the test group received a 3 mm thick BW made of Erkoflex (ethyl-vinyl-acetate) and were recommended 20 minutes BW chewing in case of pain and if pain persisted, asked to take oral paracetamol 250 mg [Table/Fig-2]. A notice regarding paracetamol dose (tablet of 250 mg) to take with respect to weight was handed to all participants.



[Table/Fig-2]: Horseshoe shaped Bite Wafer (BW) made in Erkoflex (ethyl-vinyl-acetate).

Pain assessment: To assess pain level, subjects were asked to complete a questionnaire regarding the use and effectiveness of the BW's capacity to relieve orthodontic pain at eight moments after archwire placement (day 1): evening (E) of day 1, morning (M) and evening of day 2 and evenings of day 3-7. They also had to indicate the number of 250 mg paracetamol tablets taken. Adolescents of the BW group were asked to document how many times BW was used and the corresponding total number of minutes. For both groups, quality of life was assessed by the pain level during four oral functions (biting with front and back teeth, chewing a piece of apple, and tapping teeth together three times) at each time point by using a numerical rating scale with smileys associated to each score proposed from "no pain" (0) to "excruciating pain" (10).

Seven days after the fixed appliance placement, the BW group had to complete a satisfaction questionnaire on the BW capacity to relieve orthodontic pain. They also had to indicate on 5-point scale whether they would recommend BW to a friend. At the end of the study, the impact of orthodontic appliance on chewing habits and functional limitations were evaluated. This was evaluated via a questionnaire listing the pain felt in the face and whether or not this pain affected daily activities. The questionnaire was designed on an easy-to-use basis for the adolescents. The numerical scale to quantify pain, numbered from 1-10, was an easy measuring tool to understand and did not require supervision for the adolescents, unlike the visual analog scale. The four oral functions performed to assess pain following device placement were identical to those used in the Murdock S et al., study [19].

STATISTICAL ANALYSIS

Data were summarised as mean and Standard Deviation (SD) for quantitative variables. Median and Interquartile Range (IQR) were added for skewed data. Frequency tables (numbers and percentages) were used for categorical variables. Mean values were compared by the unpaired Student's t-test and proportions by the Chi-square test. To assess the non inferiority of BW, the upper limit of one-sided 95% confidence interval for the difference of the total paracetamol consumption between control and BW groups was compared to the margin of 250 mg. Repeated measures over time were analysed by linear mixed effects models to assess the effect of time and compare the two groups. The statistical analysis was performed using the Statistical Analysis System (SAS) version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Of the 33 adolescents enrolled and randomised in the study, three were excluded (one due to missing reporting and two because of bracket debonding). Thirty patients were finally included in the statistical analysis, 15 in each group. The CONSORT diagram is presented at [Table/Fig-1].

The control and test groups were comparable in terms of age, gender and maxillary/mandible Little's Irregularity Index (LII) as seen as [Table/Fig-3].

Variables		Control group (n=15)	BW group (n=15)	p-value*
Gender	Female (%)	11 (73.3)	9 (60)	0.44
	Male (%)	4 (26.7)	6 (40)	
Age in years (Mean±SD)		12.3±1.1	12.9±1.8	0.24
Maxillary LII (Mean±SD)		6.2±3.4	6.8±2.0	0.58
Mandibular LII (Mean±SD)		4.9±2.0	5.9±2.0	0.19

[Table/Fig-3]: Patient characteristics. *Unpaired Student t-test and Chi-squared test; BW: Bite wafer; SD: Standard deviation

Paracetamol consumption: The total consumption was 1150±844 mg in the control group and 1000±954 mg in the BW group, yielding a mean difference of 150 mg (upper limit of the one-sided 95% CI: 410). Considering a margin of 250 mg, the non inferiority hypothesis was rejected, indicating a lack of efficacy of BW. As seen in [Table/Fig-4], the paracetamol consumption decreased in both groups during the seven-day period. Linear mixed effects modelling of the data confirmed the effect of time (p-value <0.0001) and the lack of difference between BW subjects and controls (p-value=0.65).

Time/day	Control group (Mean±SD)	Test group (Mean±SD)	p-value*
E1	450±343	300±302	0.21
M2	300±316	250±354	0.69
E2	233±306	300±414	0.62
E3	117±281	67±148	0.55
E4	17±65	50±140	0.41
E5	17±65	0±0	0.33
E6	17±65	0±0	0.33
E7	0±0	33±129	0.33
Total	1150±844	1000±954	0.65

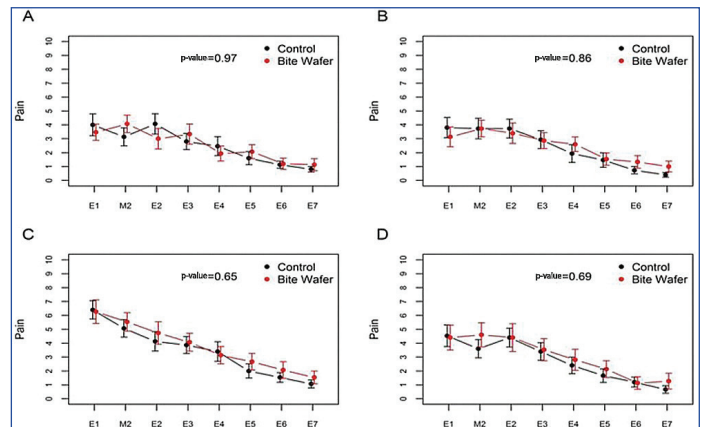
[Table/Fig-4]: Paracetamol consumption (mg) on a seven day-period after self-ligating fixed appliance placement in the control group (N=15) and in the test BW group (N=15). *Unpaired Student t-test; E: Evening; M: Morning; SD: Standard deviation; 1-7: denotes day 1 to day 7

Bite wafer outcomes: The use of BW declined significantly over time (p-value <0.0001) being on average 1.5±0.9 on day 1 and 0.1±0.3 on day 7 [Table/Fig-5]. The mean number of BWs use over one week was 5.6±8.9 (median: 2, IQR: 2-6). In a similar way, the mean BW using time decreased from 12.8±12.4 minutes at day 1 to 0.2±0.8 minutes at day 7 (p-value <0.0001). The mean BW using time over one week was 35±40 minutes (median: 20 minutes, IQR: 5-40 minutes). The satisfaction of participants in using BW averaged 4.1±1.5 on a 1-5 scale, provided they could consume paracetamol in addition to BW if necessary. By contrast, if they could not take paracetamol in addition to BW in case of toothache after fixed appliance placement, their opinion score dropped to 2.9±1.7.

Time	Number of uses		Duration of uses (minutes)	
	Mean±SD	Range	Mean±SD	Range
E1	1.5±0.9	0-3	12.8±12.4	0-40
M2	1.0±1.8	0-7	5.1±7.3	0-20
E2	0.9±1.4	0-5	8.5±12.6	0-45
E3	1.0±2.0	0-7	5.9±13.1	0-50
E4	0.7±2.6	0-10	0.6±1.6	0-5
E5	0.3±0.8	0-3	1.6±5.2	0-20
E6	0.1±0.3	0-1	0.3±1.3	0-5
E7	0.1±0.3	0-1	0.2±0.8	0-3
Total	5.6±8.9	0-36	35.0±39.5	0-140

[Table/Fig-5]: Frequency and duration of uses of Bite Wafer (BW) on a seven day-period after self-ligating fixed appliance placement in the test group (n=15). SD: Standard deviation; E: Evening; M: Morning; 1-7: denotes day 1 to day 7

Their recommendation of BW chewing to a friend was mixed (mean score 3.7±1.4). They felt that they had received enough information concerning BW use (mean score: 4.5±0.8).



[Table/Fig-6]: Evolution of the pain scores for the four oral functions from "no pain" (0) to "excruciating pain" (10) in BW and control groups: a) biting with the front teeth; b) biting with the back teeth; c) chewing; d) three times clenching (all p-values derived from linear mixed model analysis). E: Evening; M: Morning; 1-7: denotes day 1 to day 7

Quality of life outcomes: Regarding pain associated with the four oral functions [Table/Fig-6], linear mixed effects modelling of the pain scores revealed a significant decline over time (p-value <0.001) and no group difference was seen for any of the functions, namely biting with front and back teeth (p-value=0.97 and 0.86), chewing a piece of apple (p-value=0.65), and tapping teeth together three times (p-value=0.69). As far as functional or feeding impact was concerned [Table/Fig-7], no significant difference was noted between controls and BW patients (p-value >0.05).

Item	Question	Control group (n=15) Mean±SD	Test group (n=15) Mean±SD	p-value*
1	Toothache	4.5±1.1	4.4±0.83	0.70
2	Tongue pain	1.1±0.26	1.0±0.0	0.33
3	Lip pain	1.9±1.4	1.9±1.2	1.00
4	Jaw pain	3.1±1.4	2.1±1.6	0.093
5	Pronunciation ("s" and "t" letters) difficulty	2.0±1.5	2.5±1.7	0.37
6	Difficulty brushing teeth	2.5±1.4	2.6±1.4	0.79
7	Free time affected by pain	2.6±1.4	3.2±1.9	0.33
8	Difficulty speaking due to pain	1.8±1.4	2.3±1.5	0.38
9	Difficulty taking a large bite due to pain	4.5±1.1	4.5±0.92	0.86
10	Difficulty chewing hard food due to pain	4.3±1.1	4.3±1.3	0.88
11	Difficulty chewing soft food due to pain	1.3±0.49	1.9±1.2	0.076
12	School work affected by pain	2.3±0.98	2.8±1.3	0.27
13	Difficulty drinking due to pain	1.3±0.80	1.3±0.82	0.82
14	Difficulty laughing because of pain	2.1±1.3	1.6±1.2	0.32
15	Difficulty yawning due to pain	1.5±0.83	1.5±1.1	1.00
16	Difficulty eating bread	3.5±1.6	2.7±1.8	0.24
17	Difficulty eating cereal	3.3±0.88	3.2±0.78	0.83
18	Difficulty eating meat	3.5±1.5	3.0±1.5	0.40
19	Difficulty eating apple	3.5±1.2	4.1±1.1	0.12

[Table/Fig-7]: Impact of orthodontic appliance on eating habits and functional limitations assessed by a 19-item questionnaire at the end of the study. Scores range from 1 to 5; the higher the score, the greater the impact. *Unpaired student t-test

DISCUSSION

To the best of the authors' knowledge, this is the first randomised controlled trial investigating the efficacy of BW on pain after self-ligating

orthodontic fixed appliance placement. It is the most frequently placed orthodontic appliance for teenagers in the last decade because of its low frictional forces. The chosen seven-day period was similar to one other study on fixed orthodontic appliance and pain [26,27]. No evidence-based correlation exists between dental crowding and orthodontic pain after placing first archwire into brackets [28,29]. Nevertheless, the condition of including patients with Little's index above 4 was imposed to optimise the self-ligating fixed appliance use without dental extraction. A controversy also exists about a link between patient's age and orthodontic pain [30]. All patients of the study were teenagers, which was the age of growth peak and then the best age for a successful fixed orthodontic treatment. Paracetamol was taken by adolescents to relieve orthodontic pain and not ibuprofen because of the risk of tooth movement decrease stemming from NSAIDs effect [31,32]. Many authors suggest BW as an alternative to NSAIDs, while other claim that BW chewing is more painful than soft bolus chewing after fixed appliance placement [33].

According to Murdock S et al., maximum analgesic consumption takes place during the first two days after fitting the fixed self-ligating device [19]. Despite the lack of significant difference between the two groups, the slightly lower paracetamol consumption in the test group on day 1 and day 2 may suggest that BW chewing may be more effective during the first two days than over the entire week. This finding is in line with Gomaa NE et al., who found that the BW group consumed less paracetamol during the first 24 hours compared to the control group. Of note, the mean paracetamol consumption over seven days was higher than in the present study, possibly because the Gomaa NE and Ellaithy MM, study population was older [25]. Indeed, Jones M, suggested that pain increases with age [27]. The mean paracetamol difference found in the study between BW and control patients amounted 150 mg less for the BW group. Many studies concluded that BW was as efficient as analgesic consumption to relieve pain after orthodontic procedures [19,20,22,25,26]. According to Otasevic M et al., soft bolus chewing was more effective than BW to relieve pain [33].

Murdock S et al., reported that BW was used three times per day on average with a maximal use during the first two days after fixed appliance placement [19]. Results with self-ligating fixed appliance in the present study were quite different; adolescents did not chew BW more than twice per one week. The average number of intakes was similar between the second and the third day. Nevertheless, BW was mostly chewed on first day. The chewing time was less than 10 minutes from the second day and reached a minimum at the fourth day. The average BW chewing time, less than 20 minutes, was similar to that of study by Murdock S et al., [19].

Numerical scale to quantify pain was an easy measuring tool for the adolescents. However, it was less sensitive than a visual analog scale. Farzanegan F et al., compared a BW group and an ibuprofen group. They gave the same conclusion about pain during four oral functions but Murdock S et al., found slightly higher pain scores in the BW group [19,20]. The maximum pain intensity for the four oral functions was reached on the first evening or 24 hours after self-ligating fixed appliance placement like in others studies. [10,19,20,22]. Except for two studies, significant pain decrease was observed during all four oral functions over one week (p-value <0.0001) [9,10,19,20,22,27,30,33]. As for feeding and functional limitations, no statistically significant differences were found between BW and control patients. This may be explained by instructions given concerning small piece feeding or soft bolus to avoid bracket debonding [13,14].

Limitation(s)

This single-centre randomised study based on a small number of patients is a clear limitation to the generalisation of the findings. BW was made in the laboratory due to the difficulty of obtaining this kind of industrial product in Belgium. The material used was less flexible than an industrial product. Ideally, BW patients should have

been exempt from paracetamol consumption to relieve orthodontic pain but this would be unethical. Data collection two and six hours after fitting self-ligating fixed appliance could have been interesting to analyse pain evolution more precisely.

CONCLUSION(S)

Compared with the use of paracetamol, chewing on a BW had no real clinically relevant effect for managing pain after the placement of self-ligating bimaxillary orthodontic appliance. Nevertheless, BW was mostly chewed on first day to slightly decrease the paracetamol intake in adolescents compared to the control group, which is worth encouraging in order to reduce the possible side-effects of the drugs.

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PARTICULARS OF CONTRIBUTORS:

1. Department of Orthodontics and Dentofacial Orthopaedics, Liege University Hospital, Liege, Belgium.
2. Biostatistics and Research Methods (B-STAT), Liege University Hospital, Liege, Belgium.
3. Biostatistics and Research Methods (B-STAT), Liege University Hospital, Liege, Belgium.
4. Department of Orthodontics and Dentofacial Orthopaedics, Liege University Hospital, Liege, Belgium.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Annick Bruwier,
 Quai G Kurth, 45 B-4020, Liège, Belgium.
 E-mail: Annick.Bruwier@uliege.be

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