Original Article

Pain Experience during Initial Alignment with a Self-Ligating and a Conventional Fixed Orthodontic Appliance System

A Randomized Controlled Clinical Trial

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ABSTRACT

Objectives: To test the hypotheses that (1) there is no difference in the pain experience during the week following initial placement of two orthodontic appliances (SmartClip™ and Victory™; 3M Unitek, Monrovia, Calif); and (2) there is no difference in the pain experience during removal and insertion of orthodontic archwires with these brackets.

Materials and Methods: Sixty-six consecutive patients were treated with a self-ligating bracket system (SmartClip™) or a conventional appliance (Victory™) on the basis of computer-generated random allocation. After appliance placement and engagement of a 0.016″ nickel-titanium archwire, pain experience was recorded after 4, 24, and 72 hours and after 7 days with the use of a visual analog system (VAS) questionnaire. At a subsequent visit, participants documented pain experiences during removal and insertion of 0.019 × 0.025″ archwires on an additional 100 mm VAS questionnaire. Independent *t*-tests and analyses of covariance were used to analyze normally distributed data; the Mann-Whitney *U*-test was used for skewed distributions.

Results: Forty-eight (72.2%) and fifty-one (77.3%) subjects completed the first and second parts of the study, respectively. Bracket type had no influence on pain experience at 4 hours ($P = .958$), 24 hours ($P = .289$), 72 hours ($P = .569$), and 7 days ($P = .756$) following appliance placement. However, bracket type significantly influenced pain experience during archwire removal ($P = .001$) and insertion ($P = .013$).

Conclusions: Hypothesis 1 cannot be rejected. The bracket type had no effect on subjective pain experience during the first week after initial placement of two preadjusted orthodontic appliances. Hypothesis 2 was rejected. Significantly greater discomfort was experienced during archwire insertion and removal with the SmartClip™ appliance. (*Angle Orthod.* 2009;79:46–50.)

KEY WORDS: Pain; Orthodontic; Self-ligating; Appliance

INTRODUCTION

Pain and discomfort are commonplace after insertion of an initial archwire during orthodontics[1] and are reported at some stage during treatment by 91% of patients and following each appointment by 39%.[2] The level of pain reported after archwire placement is believed to be greater and more prolonged than that following extraction of teeth.[1] Discomfort peaks on the morning after placement of an archwire remained at this level for 2 to 3 days before abating at 5 to 6 days.[1] The fear of potential pain related to treatment affects the uptake of orthodontic care.[3] Furthermore, treatment discontinuation[4] and poor compliance[5] have been attributed to discomfort experienced in the early stages of appliance therapy.

Pain may be elicited by heavy pressure placed on the tooth with an instrument or by normal mastication, or it may arise spontaneously[6]; pain is known to be influenced by psychological, sociocultural, and environmental factors, making objective evaluation difficult. The experience of pain is measured indirectly,

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and the visual analog scale (VAS) is the most reliable method of measuring pain perception.[7] Nonlinear relationships have been shown between pain experienced after initial archwire placement and archwire material and age; social class; degree of force applied; dental arch relationships; and dental crowding.[1] It is not surprising that the use of preemptive and postoperative analgesia has been shown to reduce pain scores.[8]

Although self-ligating brackets have undergone a recent revival,[9] just one clinical trial that investigated the influence of ligation technique on pain experience has been published.[10] This study involved a split-mouth design, with the conventional twin bracket (Victory™; 3M Unitek, Monrovia, Calif) being more uncomfortable with the initial archwire than the Damon 2™ (Ormco Corporation, Orange, Calif) self-ligating system. However, the conventional Minitwin™ System (Victory, 3M Unitek, Monrovia, CA, USA) also achieved a lower irregularity index than the self-ligating bracket system after initial alignment.

The present study is intended to test whether any significant difference in the pain and discomfort experience could be found during initial alignment with a self-ligating system (SmartClip™; 3M Unitek) vs a conventional preadjusted edgewise bracket system (Victory™) in patients treated without extraction. Additionally, pain experienced with either appliance system during removal and insertion of rectangular archwires was assessed.

MATERIALS AND METHODS

Ethical approval for this study was provided by the South East Research Ethics Committee (06/MRE01/36, April 2006). A randomized, prospective, controlled clinical trial design was adopted and was carried out in two sites: the Royal London Dental Institute and the Kent & Canterbury Hospital UK. From May to September of 2006, patients were recruited for inclusion in the study after they had been recalled from orthodontic treatment waiting lists in preparation for active orthodontic therapy.

A minimum overall sample size of 46 participants was proposed to offer 80% power at a 95% confidence interval to demonstrate a difference in the pain experience of 10 mm in VAS score, with a standard deviation of 12 mm between patients who had received the two appliance systems during this study. To compensate for nonresponse and incomplete data, 20 additional participants were invited to participate. The power calculation was carried out with Stata Release 9.1™ (StataCorp, College Station, Tex).

An unstratified subject allocation sequence was generated by a computer program; random numbers were generated and assignment was concealed from the clinician until the time of the appointment at which the appliance was to be placed. Patients considered eligible for inclusion in this study were aged between 11 and 21 years and required treatment with fixed appliances on a nonextraction basis in the mandibular arch were in the permanent dentition and had mild lower incisor crowding.

Two operators treated participants in both groups who had received one or the other appliance system following a strict treatment protocol, but most patients (97%) were treated by a single operator. Self-ligating preadjusted edgewise brackets (SmartClip™) or conventional preadjusted edgewise brackets (Victory™) with MBT values for tip and torque and a 0.022-inch slot were placed in either group according to random allocation. A 0.016″ round martensitic active nickel-titanium (NiTi) alloy archwire (3M Unitek) was fully ligated in all patients. The archwire was cut distal to the first molar tube and was not cinched; attachments were placed on all teeth from first molar to first molar. No bite planes, lingual arches, intermaxillary elastics, headgears, or active quadhelices were placed or dental extractions undertaken during the study period. Similar oral hygiene and appliance maintenance instructions were given to both groups, and all patients received a supply of relief wax.

Following this appointment, patients were asked to take a questionnaire for completion (T1). The questionnaire consisted of three parts: a record of pain experience during the first week following treatment, a record of medication consumption during this week, and an anxiety scale. Patients were asked to record their experience of pain and discomfort at 4 hours, 24 hours, 3 days, and 1 week after their initial visit. The patient's pain experience was assessed with the use of a VAS that included an unmarked horizontal line 100 mm long and weighted at both ends by the descriptive terminology ''No discomfort'' on the left side and ''Worst pain ever'' on the right. Each patient was asked to place a mark on the line that best corresponded to the level of pain experienced at the appropriate time. Subsequently, measurements were made of the distance from the left margin of the line to the recorded score. Participants also reported any anti-inflammatory medication taken to alleviate orthodontic pain during the study period, providing type, dose, and quantity of medications used. A validated questionnaire with high internal consistency was completed to gauge anxiety status.[11] It comprised six statements that assessed the individual's feelings (eg, ''I am calm''); participants answered by selecting from four available responses ranging from ''Not at all'' to ''Very much.'' Scores were summed, yielding a total that ranged from 6 (not at all anxious) to 24 (very anxious).

Table 1. Demographic and Clinical Characteristics of Participants Returning the Questionnaires at T1 and T2

	Victory™ Group	SmartClip™ Group	Overall Sample
T1			
Age, years	15.65 (2.1)[a]	16.23 (2.91)[a]	15.96 (2.56)[a]
Male, n (%)	6 (12.5)[b]	10 (20.8)[b]	16 (33.3)[b]
Female, n (%)	16 (33.3)[b]	16 (33.3)[b]	32 (66.7)[b]
Irregularity, mm	15.47 (4.45)*	17.43 (3.74)*	16.54 (4.16)*
Anxiety score	9.95 (2.32)[a]	9.77 (2.07)[a]	9.85 (2.16)[a]
Malocclusion, n (%)			
Class I	9 (18.3)[b]	8 (16.3)[b]	17 (34.7)[b]
Class II division 1	4 (8.2)[b]	6 (12.2)[b]	10 (20.4)[b]
Class II division 2	4 (8.2)[b]	10 (20.4)[b]	14 (28.6)[b]
Class III	5 (10.2)[b]	3 (6.1)[b]	8 (16.3)[b]
T2			
Age, years	16.65 (2.49)[a]	16.91 (2.88)[a]	16.78 (2.67)[a]
Male, n (%)	8 (15.7)[b]	10 (19.6)[b]	18 (35.3)[b]
Female, n (%)	17 (33.3)[b]	16 (31.4)[b]	33 (64.7)[b]
Anxiety score	10.2 (2.2)[a]	9.58 (2.12)[a]	9.88 (2.16)[a]

a = SD b = %

Mandibular arch irregularity in the respective groups was measured in three dimensions on pretreatment reference models from first molar to first molar with the use of a Co-ordinate Measuring Machine (Merlin II; International Metrology Systems, Livonia, Mich). Participants also were asked to rate their pain experience in an identical manner immediately after removal of a 0.019 × 0.025″ NiTi wire (3M Unitek) and insertion of a 0.019 × 0.025″ stainless steel archwire (3M Unitek) at a subsequent appointment (T2).

Statistical Methods

Data analysis included descriptive and analytic statistics obtained with the Statistical Package for the Social Sciences (SPSS) software, version 13.0 (SPSS Inc, Chicago, Ill). Descriptive statistics summarized the baseline characteristics of participants. The two groups were tested for baseline differences in irregularity, age, sex, and anxiety scores. Data recording the pain experience at 4 hours, 24 hours, and 3 days followed a normal distribution. An independent two-sample *t*-test was used to assess between-group differences in the pain experience at 4 hours. A one-way between-group analysis of covariance (ANCOVA) was conducted to compare the subjective pain experience related to the two appliances at 24 hours and 3 days following appliance placement; pain at 4 hours was treated as a covariate in the analyses. Data recording the pain experience at 7 days and pain following archwire insertion and removal were not normally distributed, necessitating nonparametric testing. A Mann-Whitney *U*-test was used as a nonparametric alternative to the independent *t*-test. The level of statistical significance was prespecified at $P < .05$.

RESULTS

Sixty-six subjects, equally distributed between two groups, were invited and agreed to participate in the study from April 2006 to October 2006. However, seven subjects in the SmartClip™ group and 11 of those treated with Victory™ failed to return or complete the pain questionnaire and were excluded from additional per-protocol analyses. The final sample consisted of 26 subjects in the SmartClip™ group (78.8%) and 22 subjects in the Victory™ group (66.7%). Baseline demographic and clinical characteristics for the two groups are given in Table 1. Participants who completed the first part of the study initially had similar age distributions (Victory™ group—mean age, 15.65 ± 2.1 years; SmartClip™ group—mean age, 16.23 ± 2.91 years) and sex distributions; these groups also had similar degrees of mandibular arch irregularity measured in three dimensions with the Co-ordinate Measuring Machine. An independent samples *t*-test confirmed no significant differences between the groups in relation to age ($P = .445$), pretreatment irregularity ($P = .104$), and anxiety levels ($P = .771$). A chi-squared test also confirmed no significant sex difference between the respective groups ($P = .413$).

Mean pain scores overall and for each group are given in Table 2. Bracket type had no effect on pain experience at 4 hours ($P = .958$), 24 hours (Table 3; $P = .289$), 72 hours ($P = .569$), and 7 days ($P = .756$) following appliance placement. However, patients who reported higher pain levels at 4 hours were more likely to do so at 24 hours ($P = .005$). More than 60% of patients relied on analgesics for symptomatic relief in the week following appliance placement (Table 4). However, a chi-squared test confirmed that bracket type had no influence on level of anti-inflammatory consumption during the study period ($P = .771$).

Table 2. Mean Pain Scores Using VAS Data are Presented as Mean (SD)

	4 Hours	24 Hours	72 Hours	7 Days	Archwire Removal	Archwire Insertion
Victory™ Group	46.43 (24.07)	67.7 (17.83)	46.45 (24.15)	18.52 (18.31)	15.52 (14.3)	19.74 (17.53)
SmartClip™ Group	46.81 (24.41)	61.46 (25.35)	42.58 (23.87)	17.08 (16.47)	33.65 (21.8)	38.02 (27.47)
Overall Sample	46.64 (24.0)	64.32 (22.22)	44.35 (23.82)	17.74 (17.16)	24.77 (20.49)	29.06 (24.7)

Table 3. Pain Scores by Bracket Type with Adjusted *P* Values; Effect Size is Adjusted For Pain Score at 4 Hours

	Mean			Adjusted Effect Size
	Adjusted	95% CI[a]	*P* Value	
24 hours				
Victory™ Group	67.78	58.96–76.6	.289	0.025
SmartClip™ Group	61.40	53.28–69.52		
3 days				
Victory™ Group	46.96	36.92–56.7	.569	0.007
SmartClip™ Group	42.54	33.16–51.93		

[a] CI indicates confidence interval.

Table 4. Breakdown of Subjects Requiring Analgesia by Treatment Group

Bracket System	Participants Taking Analgesia, n (%)
Victory™	16 (63.6)
SmartClip™	15 (57.7)
Overall	31 (60.8)

Fifty-one subjects completed the second part of the trial (72.3%). A statistically significant difference in the pain experience was found between the two groups, with subjects who received the SmartClip™ type of appliance recording more pain during both wire removal ($P = .001$) and insertion ($P = .013$).

DISCUSSION

Typically, appliance-related pain is believed to peak at 24 hours to 3 days following manipulation of the appliance before reducing to near-baseline levels at 5 to 6 days postoperatively.[1] The current study confirms this pattern; pain experience peaked at 24 hours following appliance placement and subsided significantly within 7 days, mirroring previous findings.[8] The mean levels of pain reported are, however, slightly higher than those reported following separator placement, or indeed in similar studies undertaken to investigate the pain experience during initial alignment with the use of a VAS[1,12]; this may reflect attempts to completely engage a 0.016″ wire in every patient with stainless steel ligatures used when necessary in those treated with conventional appliances. The requirement for analgesia in the current study was also high, at more than 60% of participants; this further underlines the severity of orthodontic pain. The inability of analgesics to control pain adequately lends further support to the use of preemptive analgesia, particularly in those with a low pain threshold.[13,14]

The overall pain experience at each time interval was found to be independent of bracket type. This outcome contrasts with previous findings[10] of greater pain experience with a conventional appliance ligated with both steel ligatures and elastomerics compared with a passive self-ligating system (Damon 2™). The authors[10] related this outcome to incomplete engagement of the aligning archwire with the Damon 2™ appliance, while complete engagement was attempted with the conventional appliance; in the present study, complete engagement of both brackets was attempted.

The influence of anxiety levels on the pain experience was considered due to the potential effect of this confounding variable on reported pain because of the subjective nature of the assessment. This factor was controlled in previous research[10] through the use of a split-mouth design; the disadvantage of this approach involves an inability to locate accurately the source of discomfort, particularly near the midline. In the present study, both groups had almost identical pretreatment anxiety levels, ensuring that anxiety did not affect reported pain; this finding is consistent with previous research.[7] However, elevated anxiety levels assessed using Spielberger's state–trait anxiety questionnaire have been associated with increased pain scores.[15] In the present study, patients who reported greater pain levels at 4 hours also reported increased discomfort at 24 hours, confirming that some individuals may be more physiologically susceptible to pain experience.[16]

A nonlinear relationship is thought to exist between orthodontic pain experience and degree of irregularity, sex, and chronologic age.[16] Studies that considered the influence of age have reported conflicting findings, and many described a positive relationship between increasing age and pain,[1,17,18] although Ngan et al[19] reported no such relationship. Similarly, sex has been shown to be unrelated to the subjective pain experience.[1] In the present study, patients showed pretreatment equivalence with respect to irregularity, sex, and age; therefore, these factors were unlikely to have confounded the results.

Removal and insertion of rectangular archwires resulted in significantly greater pain with the SmartClip™ appliance. This finding, when combined with earlier findings[10] with the Damon 2™ system, suggests that bracket manipulation with self-ligating appliances may result in an enhanced pain experience. Miles et al[10] related this increased pain to greater residual malalignment with the self-ligating system, leading to difficulty in engaging the archwire; however, this was not the case in the present study. Recently, the manufacturers have introduced the SmartClip 2™ system. With this updated system, the engaging clips are more forgiving and SmartClip 2™ is believed to be more comfortable.

CONCLUSIONS

- The subjective pain experience at 4 hours, 24 hours, 3 days, and 7 days following fixed orthodontic appliance placement is independent of bracket type.

- Insertion and removal of rectangular archwires may result in an enhanced pain experience with the SmartClip™ passive self-ligating appliance.

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