

A multicenter randomized controlled trial to compare a self-ligating bracket with a conventional bracket in a UK population:

Part 2: Pain perception

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ABSTRACT

Objective: To compare pain experience between self-ligating and conventional preadjusted edgewise appliance systems with a two-arm parallel trial.

Materials and Methods: A prospective multicenter randomized controlled clinical trial was conducted in three hospital orthodontic departments. Subjects were randomly allocated to receive treatment with either a self-ligating (3M SmartClip™) or conventional (3M Victory™) bracket system with stratification for operator and center. Standardized protocol was followed for bracket bonding procedure and archwire sequence. Subject pain was recorded using a Verbal Rating Scale to assess discomfort felt on the teeth and soft tissues at the time of the appointment and 1, 3, and 5 days after each archwire change up to the working archwire. Multilevel modeling was used to analyze the data by blinded assessors.

Results: One hundred thirty-eight subjects (mean age 14 years 11 months) were enrolled in the study, of which 135 subjects (97.8%) completed the study and 113 (82%) returned the required data regarding pain/discomfort. Perceived pain was statistically higher with the SmartClip™ system compared to the Victory™ system, but this difference was not deemed to be clinically significant. Discomfort was greatest after placement of the initial 0.014-inch nickel-titanium archwire, compared with subsequent wires, and was greatest on day 1, less on day 3, and much less on day 5 after each archwire change. Age and gender did not affect the level of discomfort experienced by subjects undergoing fixed appliance treatment.

Conclusion: No clinically significant difference in pain experience was found between patients treated with a self-ligating bracket system compared to those treated with a conventional ligation system. (*Angle Orthod.* 2016;86:149–156.)

KEY WORDS: Self-ligating; Randomized control trial; Pain; SmartClip

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INTRODUCTION

The ideal orthodontic bracket system maximizes the efficiency of tooth movement while minimizing discomfort and irreversible damage to the tooth and periodontal tissues. Pain during orthodontic treatment arises from transient pulpitis, compression of the periodontal ligament, and mechanical trauma to the soft tissues. Direct force from the appliance on the teeth during mastication causes greater discomfort than the soft tissue discomfort related to mechanical irritation of the lips and cheek.¹

A number of factors influence the level of pain experienced during orthodontic treatment. Studies^{2–8} have found that pain intensity increases with time from 4 to 24–48 hours and falls to normal levels at 7 days. Considerable individual variation in pain perception

exists. Jones and Chan⁴ suggested that pain increases with increasing age, while Scheurer et al.¹ found adolescents (13–16 years of age) to have the highest pain levels compared to preadolescents (11–13 years of age) and adults (18+ years of age). However, other studies^{3,6} have failed to demonstrate an association between age and pain experience. Similarly, two studies comparing pain experience with fixed appliances found that female patients reported greater pain intensity levels than did males, while others found no statistically significant gender differences.^{1,4,6,9}

It is claimed that self-ligating brackets reduce the friction on the teeth,¹⁰ and the resulting potential for light forces should reduce pain from the pulp and periodontal ligament. However, the ability of self-ligating systems to reduce discomfort during treatment remains controversial. A systematic review of high-quality studies¹¹ concluded that currently there is insufficient evidence to suggest any difference in pain experience between self-ligating and conventional appliances.

The aim of this study was to compare patients' perception of pain and discomfort between self-ligating (3M SmartClip™) and conventional ligation (3M Victory™) bracket systems, based on the null hypothesis that there was no difference in pain perception between either system. In a separate article, the authors have evaluated treatment efficiency of the bracket systems in terms of number of visits, overall treatment time, and number of bracket bond failures.

MATERIALS AND METHODS

The study was a two-arm, multicenter, prospective, randomized, controlled clinical trial undertaken from January 2006 to December 2007. Ethical approval was granted by the Central Office for Research Ethics Committees and independently by the research and development departments at each participating center. The rights of the participants were protected during the trial period.

Patients were recruited consecutively from the waiting lists of three hospital orthodontic departments. All patients requiring upper and lower fixed appliance treatment using preadjusted edgewise appliances, which were to be treated by the two operators, were invited to participate in the study. Patients were excluded if they had cleft lip/palate and other syndromes, hypodontia (>1 missing tooth/quadrant), required orthognathic surgery, or were unwilling/unable to consent to the trial. No participants had previously undergone orthodontic treatment.

Patients who fulfilled the inclusion criteria and provided consent were allocated to either the study (SmartClip™) group or the control (Victory™) group

using block randomization with stratification for each operator.

The study group was bonded with the first version of the adhesive pre-coated SmartClip™ self-ligating brackets, which consisted of two Nitinol clips that opened and closed through elastic deformation of the material when the archwire exerted a force on the clip. The Nitinol clip secures the archwire in place and is calibrated to release the archwire if forces exceed a predetermined level. The control group was bonded with an adhesive pre-coated Victory™ bracket, and the wires were engaged with traditional elastomeric modules.

Both operators were "Specialist Registrars," unfamiliar with both bracket systems but under the supervision of "Consultant" trainers. As SmartClip™ was a new bracket on the market, the Specialist Registrars attended training sessions hosted by the manufacturer, ensuring use of best contemporary mechanics.

A standardized procedure was used by both clinicians at all three centers (Figure 1). Bands were used on molar teeth and brackets were bonded on remaining teeth. The manufacturer's recommended archwire sequence at the time of the study was utilized for each appliance system, to the extent possible (Figure 2). Any exceptions to this were recorded during data collection.

The outcome of perception of pain/discomfort was measured using a questionnaire given to all subjects following each scheduled appointment; subjects were asked to complete and return the questionnaire at the following visit (Figure 3). This document recorded the amount of discomfort felt on the teeth and soft tissues at the time of the appointment at day 1, day 3, and day 5 following the appointment. Simple, nonleading questions were used so that patients were not discouraged from completing the questionnaire. Using a verbal rating scale of "none," "mild," "moderate," and "severe," questions were graded by the patient accordingly and responses recorded. This outcome measure was assessed at every archwire change up to the working archwire (0.019 × 0.025-inch stainless steel). The pain questionnaire was piloted in the orthodontic department of one of the units involved in the trial, but no formal validation was undertaken. Standard advice was given regarding use of analgesics, and any self-administered analgesia was recorded.

A sample size calculation was undertaken for the primary outcome, treatment efficiency, based on data from a previous study¹² that investigated the time taken to complete treatment. Fifty-three patients per group (106 in total) were calculated as necessary to achieve a significance of 5% and a power of 80% for a clinically significant reduction in treatment time of 3 months

1. Cheek retractors and saliva ejector placed to allow clear access and a dry field
2. 15-second etch with 37% phosphoric acid gel
3. 15-second wash followed by thorough air-drying using a 3-in-1 syringe
4. Application of Transbond™ light cure adhesive primer (3M Unitek) followed by 5-second air-drying
5. Adhesive pre-coated bracket placed onto the buccal surface of the tooth at the midpoint of the long axis of the clinical crown.
 - SmartClip APC™ 3M Unitek
 - Victory APC™ 3M Unitek
6. Light polymerisation using a light-curing unit according to the manufacturer’s guidelines.

Figure 1. Standardized bonding procedure.

between treatment groups. The final agreed-upon sample size was 120 subjects in total (60 per group) to allow for dropouts. During the study period, 142 patients were deemed eligible for inclusion in the trial, of which 138 agreed to participate.

Once informed consent had been obtained, subjects were allocated to either the study (SmartClip™) group or the control (Victory™) group using a block randomization, computer-generated random number table with stratification for operator and center. The appliance type was placed in a sealed, opaque, sequentially numbered envelope that was opened after each patient was accepted into the trial. The generator of the randomization did not participate in patient allocation.

While it was not possible to blind the clinician or patient to the type of bracket system being used, data analysis was carried out at the end of the study with examiner blinding.

Descriptive statistics were carried out using SPSS 13.0 software to assess sample characteristics, such as the number of patients allocated to each appliance system and age and sex distribution. As the data were clustered, longitudinal, categorical data, this analysis was superseded by the use of multilevel modeling (MLM) in MLwiN 2.02 to analyze the statistical significance of any difference in perceived pain

between the appliance systems and to assess simultaneously the effect of factors such as age of the patient, gender, archwire, and operator on the outcomes.

MLM, also known as hierarchical linear modeling, is a statistical method of analyzing hierarchical or clustered data. A large amount of data in dental research exhibits an inherent hierarchy.¹³ Within MLM residual variation is reduced by the inclusion of explanatory variables (covariates), and a partial regression coefficient estimates the effect of each covariate to assess the effect of that factor on the outcome. Outcome variation is measured at each level of the model. Multilevel models are built in several stages. The initial stage of the MLM process was designed to establish the appropriate multilevel structure. This was accomplished by investigating the variation in the outcome variable at each level of the proposed hierarchy. At a given level if the variance did not contribute significantly to the total variance, this level was ignored. Every level in the proposed model was considered to avoid creating an incorrect model structure with errors in the estimated model coefficients. The multilevel model structure was established as shown in Figure 4.

As a result of the low number of dropouts and the use of MLM, the data were analyzed on a per-protocol basis.

Victory™ Appliance System	SmartClip™ Appliance System:
0.014-inch NiTi (conventional)	0.014-inch NiTi (conventional)
0.018-inch NiTi	0.016x0.025-inch NiTi
0.019x0.025-inch NiTi (heat-activated)	0.019x0.025-inch NiTi (heat-activated)
0.019x0.025-inch SS (welded hooks)	0.019x0.025-inch SS (welded hooks)

Figure 2. Standardized archwire sequence used for all study subjects, as recommended by the manufacturer.

Please answer the following questions by ticking ONE of the responses.

After your appointment

What level of discomfort did you experience having the wire changed?

None
Mild
Moderate
Severe

1 Day after your appointment

a. What level of discomfort did you experience of your lips/cheeks against the brace?

None
Mild
Moderate
Severe

b. What level of soreness of your teeth did you experience when eating?

None
Mild
Moderate
Severe

3 Days after your appointment

a. What level of discomfort did you experience of your lips/cheeks against the brace?

None
Mild
Moderate
Severe

b. What level of soreness of your teeth did you experience when eating?

None

Figure 3. Examples of Questions in the Patient Perception of Pain/Discomfort Questionnaire.

RESULTS

Of 142 eligible subjects, 138 agreed to participate. Following randomization, one subject declined treatment for health reasons. Two participants, one per group, were debonded before the final archwire was reached as a result of poor oral hygiene and failure to

comply with treatment ($n = 135$). One further subject was excluded from the analysis on the basis that her age (56 years) did not comply with the fit of the data during MLM. Subject participation through the trial is shown in the CONSORT diagram (Figure 5).

The baseline data show that there were fewer males in the study and control groups than there were

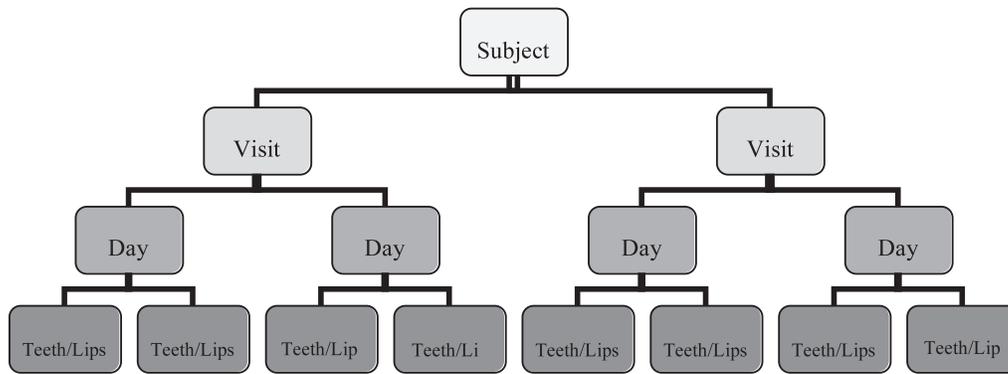


Figure 4. The multilevel model structure (level 1 = teeth/lips, level 2 = day, level 3 = visit, level 4 = subject).

females. The mean age of those who received treatment was 14 years 11 months (± 2 years 7 months) (Table 1). A similar proportion of questionnaires was returned by each gender (Table 2). Overall, 113 subjects (82%) returned the necessary pain data, while 21 subjects failed to return the questionnaire for analysis despite reasonable attempts to follow up with

participants. Participant pain levels reported at major time points up to working archwire are shown in Table 3.

Summary of MLM findings

One “pain unit” was considered to be between each category on the verbal rating scale and was deemed to

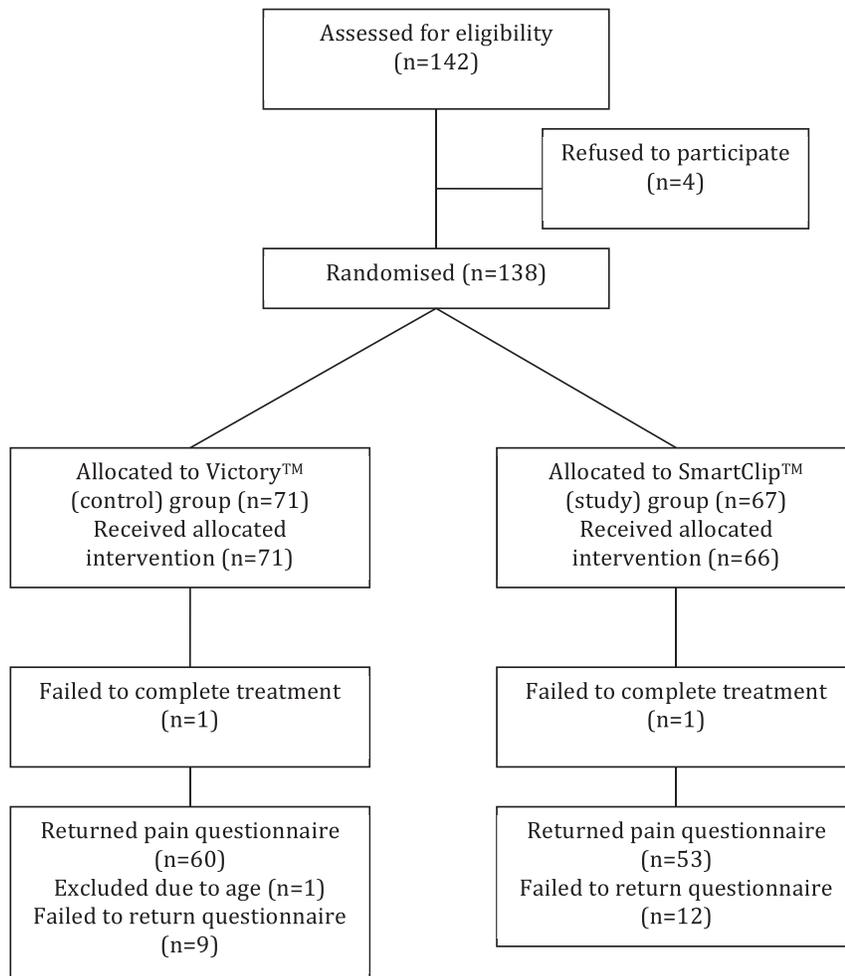


Figure 5. CONSORT diagram to show subject participation through trial.

Table 1. Gender and Age of All Participants Who Received Treatment (n = 137)

		Male	Female	Minimum Age, y	Maximum Age, y	Mean Age, y and mo (±SD) ^a
Group	Victory	29	42	10	56	14 y 6 mo (1 y 9 mo)
	SmartClip	23	43	12	29	15 y 6 mo (3 y 3 mo)
Total		52	85	10	29	14 y 11 mo (2 y 7 mo)

^a SD indicates standard deviation.

Table 2. Gender and Age of Participants Analyzed for Pain Data (n = 113)

		Male	Female	Minimum Age, y	Maximum Age, y	Mean Age, y and mo (±SD) ^a
Group	Victory	22	38	10	21	14 y 5 mo (1 y 9 mo)
	SmartClip	19	34	12	28	15 y 4 mo (3 y 0 mo)
Total		41	72	10	28	14 y 9 mo (2 y 5 mo)

^a SD indicates standard deviation.

be a clinically significant difference. The following findings were derived from the model, which were all statistically significant.

Variable appliance. The coefficient +0.174 suggests SmartClip™ caused 0.174 of a “pain unit” more discomfort than did Victory™. Doubling the standard error (0.068 × 2 = 0.136) is less than the coefficient, suggesting the variable has retained explanatory power within the model.

Variable teeth/lips. The coefficient −0.167, with a standard error of 0.013, indicates that the discomfort on the lips/cheeks was 0.167 of a “pain unit” less than that was felt on the teeth during treatment.

Variable clinician. The coefficient −0.161 indicates that clinician SR had lower pain scores than did clinician LOD.

Variable day. The coefficient +0.193 at day 1 indicates a 0.193 of a “pain unit” increase in pain scores at day 1 after archwire change, which was less on day 3 and much less on day 5.

Variable archwires. The coefficients suggest that initial archwire 0.014-inch nickel-titanium (NiTi) produced the greatest pain scores, as subsequent archwires had negative coefficients, indicating lower pain scores. The first four archwire variables up to the working archwire (0.019 × 0.025-inch stainless steel) retained explanatory power in the model and were statistically significant.

No difference was found between the bracket systems in terms of self-administered analgesia use. No serious harm was observed in either group.

DISCUSSION

Analysis of the pain questionnaires collected after every archwire change showed a statistically significant difference in pain scores between the two appliance types, with SmartClip™ causing more discomfort than Victory™. However, the study was powered for the primary outcome, treatment efficiency (Reference Part One¹⁴), and therefore the results

Table 3. Participant Pain Levels Reported at Major Time Points, Up to Working Archwire

Appliance Group	Level of Pain Reported	Number of Participants														
		After Appointment	Initial Archwire ^a						Transitional Archwire 1 ^b							
			Cheeks/Lips			Teeth			After Appointment	Cheeks/Lips			Teeth			
			Day 1	Day 3	Day 5	Day 1	Day 3	Day 5		Day 1	Day 3	Day 5	Day 1	Day 3	Day 5	
SmartClip (n = 53)	None	12	3	8	20	3	8	23	13	17	30	41	4	21	32	
	Mild	24	21	20	21	13	22	13	23	22	15	7	24	20	15	
	Moderate	13	23	20	7	20	13	13	11	9	6	4	14	10	4	
	Severe	4	6	5	5	17	10	4	6	5	2	2	11	2	2	
Victory (n = 60)	None	16	10	16	35	2	11	27	20	22	29	48	21	34	47	
	Mild	26	28	25	17	19	30	23	31	27	23	10	20	19	12	
	Moderate	15	15	15	7	24	13	8	7	9	8	5	13	5	1	
	Severe	3	7	4	2	15	6	2	2	2	0	0	6	2	0	

^a Initial archwire: 0.014-inch nickel-titanium (NiTi).

^b Transitional archwire 1: SmartClip, 0.016-inch × 0.025-inch NiTi; Victory, 0.018-inch × 0.018-inch NiTi.

^c Transitional archwire 2: 0.019-inch × 0.025-inch NiTi.

^d Working archwire: 0.019-inch × 0.025-inch stainless steel.

regarding pain must be interpreted with caution as a result of the risk of type II error. Pain scores overall were greater on the teeth compared to soft tissues and with clinician LOD. The most pain was encountered on day 1 following archwire placement, with less pain at day 3 and much less pain at day 5. This conforms to the findings of previous studies²⁻⁸ that report that pain intensity increases with time from 4 to 24–48 hours and falls to normal levels at 7 days. The greatest pain experienced from aligning archwire was expected, as the teeth are most displaced initially, and active engagement of the first archwire will apply the greatest degree of force. Subsequent archwires were found to be less painful, on average, by 0.2 of a pain unit.

While statistically significant differences in pain perception were found, these differences were not deemed to reach a clinically significant level, agreed to be a change of one “pain unit.” Both operators felt that patients in the SmartClip™ group experienced more discomfort when engaging/disengaging archwires from the bracket, especially with larger rectangular archwires, when significant pressure was required to engage them. It is possible that this difference may have been greater and might have reached a clinical significance, but patients had no other experiences of fixed appliances on which to base their responses. It should be noted that the SmartClip™ bracket design has since been modified, and the current design, SmartClip™ SL3, is reported to have easier wire engagement and disengagement due to a wider clip gap, angled edges, and a fulcrum point with greater flexibility.

When studying the same two bracket systems, Fleming et al.² found that bracket type did not influence pain experience, but significantly greater discomfort

was experienced during archwire insertion and removal with SmartClip™. Subjective pain experience has been variable in other studies, but direct comparison is difficult as a result of different study designs and brackets. A prospective clinical trial of 60 consecutive patients using a split-mouth design found that Damon 2™ brackets were less painful with the initial archwire than were conventional brackets but was substantially more painful when placing the second archwire. No significant differences were reported in comfort on the lips.¹⁵ Scott et al.³ found that there was no statistically or clinically significant difference in perceived discomfort between Synthesis™ conventional ligation brackets and Damon 3™ SL. In contrast, a randomized clinical trial of 66 patients found that although there was no difference in mean maximum pain intensity, participants treated with the Damon 3™ self-ligating system generally reported lower mean pain intensity at all time points when compared to those with a conventional bracket.¹⁶

Perceived discomfort was measured with a self-administered questionnaire. The questionnaire was piloted but not validated; this is a limitation of the study, and in any future studies the authors would develop questionnaires using guidelines for content validity and test assess validity prior to use. A categorical verbal rating scale for pain (none, mild, moderate, and severe) was used and then converted to nominal data for analysis. This conversion can be criticized, as it results in imprecision, since a score of 2 is not twice as bad as a score of 0. However, as pain is a complex phenomenon with huge subjectivity, it is impossible to assess it precisely, as indicated by the contradictory findings of other studies. A visual analogue scale was not used, as it can give greater precision than raters’

Table 3. Extended.

After Appointment	Transitional Archwire 2 ^c						After Appointment	Working Archwire ^d					
	Cheeks/Lips			Teeth				Cheeks/Lips			Teeth		
	Day 1	Day 3	Day 5	Day 1	Day 3	Day 5		Day 1	Day 3	Day 5	Day 1	Day 3	Day 5
10	16	25	36	10	25	38	10	19	28	41	17	26	39
26	25	18	12	21	17	12	25	18	20	7	13	18	10
12	9	8	3	15	8	2	12	13	2	4	17	6	1
5	3	2	2	7	3	1	5	2	2	0	5	2	2
20	24	35	52	26	40	51	24	28	42	51	17	37	52
29	23	18	7	18	15	7	25	23	12	6	29	17	6
9	9	7	1	8	3	2	9	6	6	3	11	5	1
2	4	0	0	7	2	0	2	2	0	0	3	1	1

ability to discriminate,¹⁷ which may overestimate of the clinical significance of small reported differences. In addition, there is a tendency for central bias as a result of clustering around the midpoint, and as it is a continuous scale, scores may not be distributed among all judges with equal value.¹⁸

The return rate of the questionnaire was 82%. This is the largest randomized controlled trial undertaken to date, and even after accounting for dropouts, the participation rate is considerably higher than that of other similar studies.^{2,3,15,16} Interestingly, the four patients who did not wish to participate in the trial cited a preference for colored elastomeric ligatures during treatment as the reason, indicating that some patients are more concerned with the esthetic appearance of an appliance than they are with treatment time.

Blinding of the treating clinicians and patients was not feasible as a result of obvious differences in the appliances, but the examiner was blinded to bracket type during data analysis. The use of MLM in this study enabled multiple outcomes to be assessed simultaneously while optimizing the estimation of statistical significance and reducing the risk of statistical errors¹³ and enables investigation into the effect of different operators within the study.

The level of experience of both operators was similar and initially limited in the use of SmartClip™ and Victory™ brackets, reducing proficiency bias. The SmartClip™ bracket uses a different door mechanism compared to other self-ligating brackets, making it more difficult to learn, and proficiency with this bracket requires a longer amount of time. Consequently, this steep learning curve may have influenced results. Additionally, bands were used on molar teeth rather than the recommended SmartClip™ molar bonds. It is possible that use of a SmartClip™ bond could have made archwire placement and removal more comfortable.

CONCLUSIONS

- No clinically significant difference in the degree of perceived pain with the use of either SmartClip™ or Victory™ preadjusted edgewise appliance systems up to working archwire was identified in this study.
- The perceived discomfort was greatest on the teeth after placement of an initial 0.014-inch NiTi archwire compared with subsequent wires. Perceived discomfort was worst on day 1 following each archwire placement, less on day 3, and much less on day 5.
- The age and gender of the patient did not affect the level of discomfort.

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