Original Article

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

Part 1: Treatment efficiency

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ABSTRACT

Objective: To use a two-arm parallel trial to compare treatment efficiency between a self-ligating and a conventional preadjusted edgewise appliance system.

Materials and Methods: A prospective multi-center 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) preadjusted edgewise appliance bracket system using a computer-generated random sequence concealed in opaque envelopes, with stratification for operator and center. Two operators followed a standardized protocol regarding bracket bonding procedure and archwire sequence. Efficiency of each ligation system was assessed by comparing the duration of treatment (months), total number of appointments (scheduled and emergency visits), and number of bracket bond failures.

Results: One hundred thirty-eight subjects (mean age 14 years 11 months) were enrolled in the study, of which 135 subjects (97.8%) completed treatment. The mean treatment time and number of visits were 25.12 months and 19.97 visits in the SmartClip group and 25.80 months and 20.37 visits in the Victory group. The overall bond failure rate was 6.6% for the SmartClip and 7.2% for Victory, with a similar debond distribution between the two appliances. No significant differences were found between the bracket systems in any of the outcome measures. No serious harm was observed from either bracket system.

Conclusions: There was no clinically significant difference in treatment efficiency between treatment with a self-ligating bracket system and a conventional ligation system. (*Angle Orthod.* 2016;86:142–148.)

KEY WORDS: Self-ligating; Treatment efficiency; Bond failure; SmartClip; Treatment time

INTRODUCTION

Self-ligating bracket systems are alleged to reduce friction between the bracket and archwire, thus improving treatment efficiency by reducing the number of appointments and overall treatment time.[1] However self-ligating brackets are more costly to purchase, and if they are to supersede their predecessors, the reduced friction must be proven clinically as well as in vitro.

A number of factors have been shown to affect frictional resistance to tooth movement.[2] These are as follows:

- method of ligation,
- archwire size and material,
- bracket dimensions and material,
- angulation of wire to bracket,
- wet vs dry state, and
- masticatory forces.

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Accepted: February 2015. Submitted: November 2014.
Published Online: April 8, 2015

Table 1. Summary of Previous Studies Evaluating Treatment Efficiency With Self-Ligating (SL) Brackets

Author	Study Design[a]	Appliance	Outcomes[b]	Key Findings
Harradine, 2001[14]	Retrospective matched groups, 60 subjects	Damon SL vs conventional	Total treatment time	SL faster by 4 mo and required 4 fewer visits
Eberting et al., 2001[15]	Retrospective sample group, 215 subjects	Damon SL vs conventional	Total treatment time; patient satisfaction	SL faster by 6 mo and fewer visits required; satisfaction was higher with SL
Miles, 2005[10]	Prospective CCT, parallel groups, 48 subjects	SmartClip vs Victory	Initial alignment of LLS at 10 +20 wk	No difference
Miles et al., 2006[6]	Prospective CCT, split-mouth, 58 subjects	Damon 2 vs conventional	Initial alignment of LLS at 10 +20 wk	No difference
Miles, 2007[11]	Prospective CCT, split-mouth, 13 subjects	SmartClip vs conventional	En-masse space closure	No difference
Pandis et al., 2007[7]	Prospective CCT, parallel groups, 54 subjects	Damon 2 vs conventional	Rate of alignment of LLS	No difference
Scott et al., 2008[8]	RCT, parallel groups, 62 subjects	Damon 3 vs conventional	Rate of alignment of LLS	No difference
Fleming et al., 2010[12]	RCT, parallel groups, 54 subjects	SmartClip vs conventional (Victory)	Treatment duration and number of visits	No difference
Johansson and Lundstrom, 2012[9]	RCT, parallel groups, 90 subjects	Time 2 SL vs conventional	Overall treatment time, number of visits, treatment outcome (ICON)	No difference
Songra et al., 2014[13]	RCT, parallel groups, 98 subjects	Active SL vs passive SL vs conventional	Labial segment alignment and space closure	Initial alignment was quicker with the conventional brackets; no difference in rate of space closure

[a] CCT indicates controlled clinical trial; RCT, randomized controlled trial.
[b] LLS indicates lower labial segment; ICON, index of complexity, outcome, and need.

The findings from laboratory studies suggest that self-ligating brackets exert less friction on the archwire and that lower forces can be employed to achieve tooth movement, reducing the anchorage demand during orthodontic treatment.[3,4] It is difficult to extrapolate these findings to the clinical situation where levels of friction are likely to be complicated by the combined interplay of the aforementioned factors.

A recent systematic review of self-ligating brackets concluded that there is insufficient evidence to suggest that orthodontic treatment is more or less efficient with self-ligating brackets.[5] Table 1 summarizes the findings of other studies that have investigated treatment efficiency of self-ligating brackets. Many of these studies only report a small part of the treatment, for instance initial alignment or space closure. It is much more useful for clinicians to know the effect of the efficiency of an appliance across the whole course of treatment, and in this trial, we report the results from complete treatment.

Although two early retrospective studies found a significant reduction in treatment time, more recent prospective clinical trials have failed to demonstrate such differences. Miles et al.[6] concluded that the Damon brackets performed marginally worse than the conventional brackets during initial alignment of the lower labial segment. Pandis et al.[7] found no difference in the time taken to alleviate mandibular crowding using conventional brackets compared to self-ligating Damon 2 brackets, a finding supported by Scott et al.[8] An alternative self-ligating bracket system, Time 2 brand, found comparable results of no significant difference in treatment efficiency, measured by treatment time and total number of visits, and outcome using the index of complexity, outcome, and need (ICON).[9] Similarly, studies involving SmartClip brackets have demonstrated no statistically significant difference in alignment of the lower labial segment[10] and en-masse space closure[11] compared to a bracket using conventional ligation. A recent randomized controlled trial comparing SmartClip to conventional brackets for treatment efficiency for total treatment duration and number of visits found bracket type accounted for only 6.1% of the variance in treatment duration.[12] Comparison between active and passive self-ligation systems with conventional brackets found that the conventional brackets aligned the labial segment more quickly, and there was no difference in rate of space closure.[13]

The aim of this study was to determine whether a self-ligating bracket system (3M SmartClip) increased the efficiency of treatment as compared to brackets using conventional ligation (3M Victory). The null hypothesis is that there is no difference in the efficiency of treatment with self-ligating brackets as compared to treatment with brackets using conventional ligation,

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 1. Standardized archwire sequence used for all study subjects, as recommended by manufacturer.

in terms of total treatment time, number of visits, and bracket bond failure rate.

MATERIALS AND METHODS

The study was a two-arm, multi-center prospective randomized, controlled clinical trial undertaken from January 2006 to December 2007. Patients were recruited consecutively from the waiting lists of three hospital Orthodontic Departments (Leeds Dental Institute, Leeds Dental Institute, Leeds; Bradford Royal Infirmary, Bradford; and Pinderfields Hospital, Wakefield). All patients requiring upper and lower fixed appliance treatment using preadjusted edgewise appliances, who 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, had hypodontia with more than one missing tooth per quadrant, required orthognathic surgery, or were unwilling to or unable to consent to the trial. No participants had previously undergone orthodontic treatment.

Ethical approval was granted by the Central Office for Research Ethics Committees on December 1, 2006 (Ref: 05/Q1202/146) and independently by the research and development departments at each unit. The rights of the participants were protected during the trial period.

Patients who fulfilled the inclusion criteria and provided consent were allocated to either the study (SmartClip) group or control (Victory) group using block randomization with stratification for each operator.

The study group was bonded with an adhesive precoated SmartClip self-ligating bracket, which consists of two nitinol clips that open and close through elastic deformation of the material when the archwire exerts a force on the clip. The first version of this bracket was used in this study. The control group was bonded with an adhesive precoated Victory bracket, and the wires were engaged with traditional elastomeric modules.

Both operators were specialist registrars who were unfamiliar with both bracket systems but were supervised by consultant trainers. As SmartClip was a new bracket to the market, the specialist registrars attended training sessions hosted by the manufacturer to ensure the best contemporary mechanics were being used.

A standardized procedure was used by both clinicians in all three centers. Bands were used on the molar teeth and brackets were bonded on incisors, canines, and premolars using the following method:

(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, Loughborough, Leicestershire) followed by 5-second air-drying.
(5) – SmartClip APC (3M Unitek, Loughborough, Leicestershire)
(5) – Victory APC (3M Unitek, Loughborough, Leicestershire).
(6) Light polymerization using a light-curing unit according to the manufacturer's guidelines.

The manufacturer's recommended archwire sequence at the time of the study was utilized for each appliance system as far as possible (Figure 1). Any exceptions to this were recorded during data collection.

A sample size calculation was undertaken based on data from a previous study investigating time taken to complete treatment.[14] 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 between the treatment groups. The final agreed 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, and 138 agreed to participate.

Subjects were enrolled by the researchers Drs O'Dywer and Rahman. Once informed consent had been obtained, subjects were allocated to either the study (SmartClip) group or control (Victory) group using a block randomization determined by a 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 the patient was accepted onto 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.

To assess the efficiency of the two bracket systems the following outcomes were measured:

- total duration of treatment (months) from fixed appliance placement to debond;
- total number of appointments, including scheduled and unscheduled visits from start of treatment to debond; and
- number of bracket bond failures, involving only first-time failures for each tooth (multiple breakages on the same tooth were not recorded).

Descriptive and analytical statistical analyses were performed with SPSS software. The normality of the data was confirmed using a frequency histogram. Welch two sample *t*-tests were used to compare the difference in mean treatment duration and number of appointments for SmartClip vs Victory. The 95% confidence interval for the difference in means between the two appliance groups indicated whether there was a statistically significant difference in duration of treatment between the bracket systems. The effect of clinician on both treatment duration and number of appointments was also investigated in this manner. The effect of the center was investigated using a one-way analysis of variance (ANOVA) with a Bonferroni correction.

RESULTS

One hundred thirty-eight subjects were recruited to participate in the study from January 2006 to December 2007. Overall, 135 subjects (97.8%) completed the study; one subject who refused fixed appliance treatment following allocation and two subjects who failed to complete treatment were omitted from the analysis. Subject participation is shown in the CONSORT flow diagram in Figure 2.

The baseline data show there were fewer male subjects in the study and control groups compared to female subjects. The mean age and classification of malocclusion of those who received treatment is shown in Table 2.

Due to the low number of dropouts, analysis was undertaken on a per protocol basis. Table 3 shows a comparison of the treatment efficiency between the bracket systems. The mean treatment time was 25.12 months in the SmartClip group and 25.80 months in the Victory group. The difference of 0.68 months was not found to be statistically significant ($P = .51$, 95% CI, −1.4, 2.7). The mean number of visits was 19.97 and 20.37 for the SmartClip and Victory groups, respectively. The difference of 0.40 visits was not found to be statistically significant ($P = .66$, 95% CI −1.4, 2.2).

The differences in treatment time and number of visits between the two operators were 0.2 months and 1.7 visits, respectively. Neither was found to be statistically significant ($P = .85$, 95% CI −2, −1.8 and $P = .072$, 95% CI −3.4, −0.1). Analysis of the confounding variables indicated a slight difference in treatment time and number of visits between centers. However, this difference of 2.2 months was not statistically significant ($P = .16$). Unsurprisingly, treatment time was shown to be related to the number of visits.

The number and distribution of bracket bond failures, by tooth, is shown in Table 4. Overall, the number of bond failures is skewed toward zero, with 54 participants (40%) experiencing no failures during their treatment and a further 63 participants (47%) having one to two failures. Ten participants (7%) presented with multiple bracket bond failures (six or more), with as many as nine incidents recorded for one subject. The mandibular incisors and premolars showed the greatest number of bracket bond failures, while in both arches, the canines had the fewest. The overall bond failure rate for the 2422 brackets used in the trial was 6.8%. The bond failure rate per appliance was 6.6% for SmartClip and 7.2% for Victory. No statistically significant differences were found between the bracket bond failure rates of the two appliances. No serious harm was observed from either bracket system.

DISCUSSION

No difference was found in treatment efficiency between the two appliance systems, measured in terms of number of visits required and overall treatment time. In a randomized controlled trial similar to the present study, Fleming et al.[12] found very similar results to our study, with no difference between SmartClip and conventional brackets for total treatment duration and number of visits. Bracket type accounted for only 6.1% of the variance in treatment duration.

Initial retrospective studies investigating treatment efficiency reported a significant reduction in treatment time, up to 4 to 6 months, between self-ligating and conventional brackets.[15,16] However, the relatively large standard deviations and expected bias in retrospective studies make these findings less dramatic. More recent prospective clinical trials have failed to demonstrate similar differences, although it must be acknowledged that many of these trials have

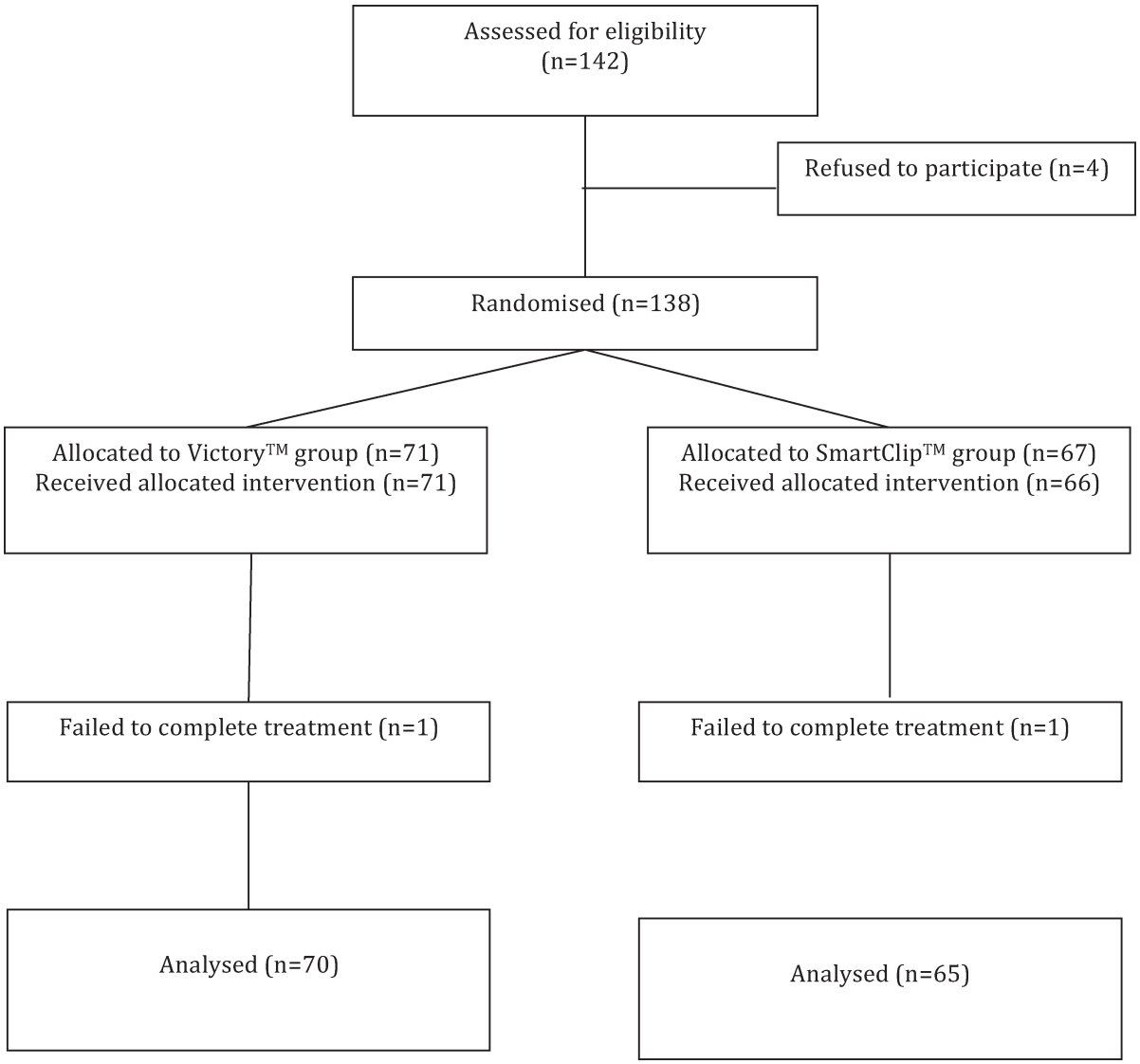

Figure 2. CONSORT flow diagram for subjects through the study.

Table 2. Demographics for All Participants Who Received Treatment (n = 137)

	Self-Ligating (SmartClip)	Conventional (Victory)	Total
Male subjects, n (%)	23 (17)	29 (21)	52
Female subjects, n (%)	43 (31)	42 (31)	85
Minimum age, y	12	10	–
Maximum age, y	29	56	–
Mean age (SD)	15 y 6 mo (3 y 3 mo)	14 y 6 mo (1 y 9 mo)	14 y 11 mo (2 y 7 mo)
Malocclusion			
Class I	12	23	35
Class II division 1	37	31	68
Class II division 2	9	4	13
Class III	8	13	21
Extraction/nonextraction			
Extraction	42	43	85
Nonextraction	25	27	52

Table 3. A Comparison of Treatment Efficiency Between the Bracket Systems, Measured by Treatment Time and Number of Visits

	SmartClip	Victory	Difference Between Groups (95% CI)	Difference Between Operators (95% CI)
Mean treatment time, mo	25.12	25.80	0.68 (−1.4, 2.7)	0.2 (−2, −1.8)
Mean no. of visits	19.97	20.37	0.40 (−1.4, 2.2)	1.7 (−3.4, 0.1)

limitations. The nonrandomized prospective trials by Miles et al.[6] were split-mouth, and the impact of this design on free sliding of the self-ligating brackets and the impact of the selective use of wire ligatures with conventional brackets but not with self-ligating brackets is not known.[10,11]

Two studies evaluating Damon 2 self-ligating brackets found no difference in the time taken to alleviate mandibular crowding, except in those with moderate, rather than severe crowding.[7,8] The authors suggest that any timesaving advantage of self-ligation over conventional ligation is eliminated when crowding exceeds a certain amount, and space within the arch is restricted.[7] The influence of the degree of crowding and extraction pattern on the treatment duration to working archwire was not assessed in the current investigation because it was expected that the randomization process would result in an equal distribution of occlusal features, minimizing the impact these have as confounding factors.

The second parameter used for assessing treatment efficiency was the number of breakages recorded for each appliance. In line with the study by Pandis et al.,[16] only first-time failures were recorded, while multiple failures on the same tooth were excluded. This decision was based on the assumption that multiple fractures on the same tooth are likely to be from patient factors, such as tooth form, occlusion, and habits, rather than a difference in the bracket system. Chapman[17] compared SmartClip to another self-ligating bracket system (In-Ovation R) in 40 patients and found that the bond failure for SmartClip was significantly lower, although both brackets had clinically acceptable bond failure rates. In this study, although the SmartClip appliance had slightly more failures, no statistical or clinical difference was identified. The slightly increased bond failure rate for SmartClip may be a result of operator inexperience when disengaging archwires apply a debonding/shearing force to the brackets.

In the present study, bond failures were highest on the mandibular incisors and premolars at 24.5% of all failures for each group. Previous studies have also reported the highest bond failure rates on the premolar teeth.[18,19] Possible reasons for failure are problems during bonding, increased risk of moisture contamination, and greater masticatory forces in the premolar area.[20] Increased bond failure on the lower incisors may be due to greater initial displacement of these teeth from the line of the arch resulting in a greater force application when the archwire is ligated into the bracket.

Table 4. Distribution of Bracket Failures

Tooth	U1	U2	U3	U4	U5	L1	L2	L3	L4	L5	Total
Left	10	8	5	6	9	11	7	4	5	10	75
Right	8	3	6	4	9	12	12	9	10	17	90
Total	18	11	11	10	18	23	19	13	15	27	165

A randomized controlled clinical trial design was used to minimize errors and bias, and CONSORT guidelines were followed where practicable. Although it was not possible to blind either clinician or subject to the bracket type, the appliance type was not recorded on the data collection sheets in an attempt to minimize bias during data entry and analysis. The number of participants involved is greater than in previous trials investigating self-ligating brackets. The low dropout rate suggests both appliances were acceptable to the participants.

The trial was undertaken in two district general hospital orthodontic departments by orthodontic registrars in the UK. The results may be less applicable to other populations and readers will need to decide if the UK patient mix is similar to their own patient caseload. Additionally, the results of this study apply only to these brackets when used as a system, ie, in conjunction with a particular archwire sequence (Figure 1), and therefore the results may not be generalizable to alternative archwire sequences.

CONCLUSIONS

- No difference was found between SmartClip self-ligating brackets and conventional Victory brackets with regard to the number of visits and overall treatment time.
- Small differences in treatment time were found between the treatment centers, but these were not statistically and clinically insignificant.
- The majority of participants experienced two or fewer bracket bond failures during treatment. No significant difference was found between the numbers of bond failures for each appliance system.

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