Randomized clinical trial of orthodontic treatment efficiency with self-ligating and conventional fixed orthodontic appliances

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Introduction: Our objective was to test the hypotheses that treatment with 2 fixed orthodontic appliances (SmartClip and Victory; 3M Unitek, Monrovia, Calif) would result in no difference in (1) the duration of orthodontic treatment or (2) the number of visits required. Methods: Sixty-six consecutive patients were randomly allocated to treatment with a self-ligating bracket system (SmartClip) or a conventional appliance (Victory). The duration of treatment and the number of visits required in addition to the initial and final peer assessment rating (PAR) scores were recorded. The number of teeth extracted during treatment and the frequency of mechanical eruption of canines were also noted. Analyses of covariance were used to assess the influence of bracket type on treatment durations, visits required, and percentage PAR score reductions. Results: Fifty-four (81.8%) participants completed the study. The duration of treatment was 3 months greater in the group treated with SmartClip. However, bracket type had no statistical influence on treatment duration ($P = 0.076$), total visits required ($P = 0.184$), or percentage PAR score reduction ($P = 0.255$). Conclusions: Neither hypothesis could be rejected. Bracket type did not influence the duration of treatment or the number of visits required. The percentages of PAR score reductions were also unaffected by the choice of appliance. (Am J Orthod Dentofacial Orthop 2010;137:738-42)
Canterbury Hospital, Canterbury, and the Royal London Dental Institute, London, United Kingdom, with subjects recruited after their recall from the orthodontic treatment waiting lists in preparation for active therapy from May to September 2006.

The methodology was partially outlined elsewhere. Based on a retrospective power analysis, a total of 66 patients were required to demonstrate a clinically meaningful difference of 4 months in treatment duration between the appliance systems with a power of 80% and an \( \alpha \) of 0.05, assuming a noncompletion rate of 30%. An unstratified subject allocation sequence was performed using a computer-generated randomization program. The subjects were between 11 and 21 years of age, required treatment with fixed appliances on a nonextraction basis in the mandibular arch, were in the permanent dentition, had mild mandibular incisor crowding, and had study models taken not more than 1 month before placement of the mandibular appliance. Patients were excluded if they had previous orthodontic treatment, had a complex medical history and were taking medications, had cleft lip and palate or other craniofacial anomalies, failed to attend more than 2 appointments, had 3 or more appliance breakages, were undergoing combined orthodontic-surgical treatment or correction of molar relationships, or had hypodontia in the mandibular arch other than third molars.

Two operators (P.S.F. and A.T.D.) treated the participants with both appliances; the vast majority were treated by an orthodontic resident (P.S.F.) who was equally experienced with the 2 appliances. The subjects were randomized to treatment with either a self-ligating (Smart Clip) or a conventional preadjusted edgewise system (Victory) with MBT values for tip and torque and a 0.022-in slot. All subjects followed a predetermined archwire sequence during arch levelling and alignment: 0.016-in nickel-titanium (NiTi), 0.017 × 0.025-in NiTi, 0.019 × 0.025-in NiTi, and 0.019 × 0.025-in stainless steel. Appliances were routinely adjusted at intervals of 8 weeks until the working archwire was passive; however, the 0.017 × 0.025-in NiTi wire was in situ for 6 weeks. Thereafter, treatment mechanics and archwire choices were governed by clinical requirements. Shorter interappointment intervals were used during the finishing stages. The operator was not blinded to appliance type during treatment.

Assessed for eligibility (n=236)  
Excluded (n= 170)  
Not meeting inclusion criteria (n= 170)  
Randomized (n=66)  
Allocated to Victory (n= 33)  
Received allocated intervention (n= 33)  
Did not receive allocated intervention (n= 0)  
Lost to follow-up (n= 1) due to multiple breakages  
Excluded from analysis (n= 6) as had combined orthodontic-surgical care  
Analysed (n= 26)  
Allocated to SmartClip (n= 33)  
Received allocated intervention (n= 33)  
Did not receive allocated intervention (n= 0)  
Lost to follow-up (n= 2) due to:  
Transfer of care (n=1)  
Multiple breakages (n= 1)  
Excluded from analysis (n= 3) due to combined orthodontic-surgical care (n=2) and mandibular arch treatment only (n= 1)  
Analysed (n= 28)  

Fig. CONSORT flow diagram for subjects through the study.
Routine reference models were taken before and after treatment; all models were scored independently by an orthodontic technician. Treatment duration was measured in months from initial placement of the preadjusted edgewise appliances to their removal; the total number of appointments was also recorded. Potential confounding variables, including mechanical eruption of teeth and requirement for extractions, were noted.

Statistical analysis

Descriptive and analytical statistical analyses were performed with SPSS software (release 13.0, SPSS for Windows, SPSS, Chicago, Ill). The 2 groups were tested for differences in their baseline characteristics. Analysis of covariance (ANCOVA) was used to compare the treatment effects of the bracket systems while accounting for baseline differences and confounding continuous variables, including the number of extractions performed as part of the orthodontic plan and the number of maxillary canines erupted as part of the treatment were included in the statistical model (Table II). Preliminary checks were conducted to ensure no violations of the assumptions of the test used.

There was no statistically significant association between the 2 bracket types on treatment duration ($P = 0.076$) or required visits ($P = 0.184$). Based on the multivariate statistical model, bracket type had an effect size of just 6.1% of the variance in treatment duration. Bracket type also had no statistical effect on the percentage PAR score reduction during treatment ($P = 0.255$). In the multivariate model, the number of maxillary canines erupted during treatment had a significant effect on treatment duration ($P = 0.000$) and the number of visits required ($P = 0.000$).

DISCUSSION

Retrospective analyses reported mean reductions of 4 to 7 months in treatment times and 4 to 7 visits during active treatment with self-ligating systems compared with conventional preadjusted edgewise appliances.5,6 Prospective research has been restricted to assessing the rates of initial alignment, examining changes in no more than the initial 20 weeks of treatment,11-15 and assessing the efficiency of space closure.16 These studies failed to determine any compelling advantage for self-ligating brackets with respect to treatment duration; this article corroborates those findings.

Retrospective studies are limited by variations in appointment intervals, appliance mechanics, archwire sequences, and possible selection biases. In this prospective study, appointment intervals and archwire sequences were controlled during arch leveling and alignment.5,6,17 Space closure was performed with sliding mechanics. However, finishing procedures and archwire choices were at the discretion of the clinician based on the occlusal requirements. We thought that this protocol was clinically representative and would produce the most relevant and universally applicable results. Precise matching of subjects based on occlusal

Table I. Demographic baseline characteristics and clinical features of the sample

<table>
<thead>
<tr>
<th>Variable</th>
<th>Victory group</th>
<th>SmartClip group</th>
<th>Overall sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>15.48 (2.38)*</td>
<td>16.11 (2.74)*</td>
<td>15.81 (2.58)*</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7 (26.9%)*</td>
<td>11 (39.3%)*</td>
<td>18 (33.3%)*</td>
</tr>
<tr>
<td>Female</td>
<td>19 (73.1%)*</td>
<td>17 (60.7%)*</td>
<td>36 (66.7%)*</td>
</tr>
<tr>
<td>Total</td>
<td>26 (78.8%)*</td>
<td>28 (84.8%)*</td>
<td>54 (81.8%)*</td>
</tr>
<tr>
<td>Malocclusion type (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>13 (50%)*</td>
<td>10 (35.7%)*</td>
<td>23 (42.5%)*</td>
</tr>
<tr>
<td>Class II Division 2</td>
<td>5 (19.2%)*</td>
<td>7 (25%)*</td>
<td>12 (22.2%)*</td>
</tr>
<tr>
<td>Class II Division 1</td>
<td>5 (19.2%)*</td>
<td>9 (32.1%)*</td>
<td>14 (25.9%)*</td>
</tr>
<tr>
<td>Class III</td>
<td>3 (11.5%)*</td>
<td>2 (7.1%)*</td>
<td>5 (9.3%)*</td>
</tr>
<tr>
<td>Patients having maxillary arch extractions (total)</td>
<td>6 (12)</td>
<td>9 (17)</td>
<td>15 (29)</td>
</tr>
<tr>
<td>Ectopic maxillary canines (total)</td>
<td>3 (4)</td>
<td>5 (7)</td>
<td>8 (11)</td>
</tr>
</tbody>
</table>

*Mean (SD); †Frequency (%).

The mean duration of orthodontic treatment was 19.92 months overall: 18.32 months in the Victory group and 21.41 months in the SmartClip group. A mean of 15.7 visits was required for those treated with Victory, with 2 additional visits for the SmartClip group. The mean pretreatment and posttreatment PAR scores are given in Table II.

ANCOVA was used to assess the influence of the appliance system on treatment duration, required visits, and PAR score reduction. Potential confounding variables including the number of extractions performed as part of the orthodontic plan and the number of maxillary canines erupted as part of the treatment were included in the statistical model (Table II). Preliminary checks were conducted to ensure no violations of the assumptions of the test used.

There was no statistically significant association between the 2 bracket types on treatment duration ($P = 0.076$) or required visits ($P = 0.184$). Based on the multivariate statistical model, bracket type had an effect size of just 6.1% of the variance in treatment duration. Bracket type also had no statistical effect on the percentage PAR score reduction during treatment ($P = 0.255$). In the multivariate model, the number of maxillary canines erupted during treatment had a significant effect on treatment duration ($P = 0.000$) and the number of visits required ($P = 0.000$).
traits was not feasible. Consequently, with the exception of mild mandibular arch crowding amenable to nonextraction treatment, our subjects were unmatched for occlusal traits. However, molar correction with headgear likely to prolong treatment was not attempted on any subject; the number of subjects undergoing extraction of teeth or mechanical eruption of maxillary canines likely to prolong treatment was also similar in both groups. In addition, these occlusal and treatment differences were also accounted for in the statistical model. Subjects undergoing combined orthodontic-surgical treatment were omitted from this part of the trial because this is known to prolong treatment \(^{18}\). Consequently, it can be reasonably assumed that the overriding difference between the subjects was the choice of appliance.

The overall treatment time required in this trial of almost 20 months was comparable to that described in some retrospective research \(^{1,6}\) but considerably shorter than that described by Eberting et al \(^{5}\) using the Damon2 appliance (24.5 months). Similar studies conducted in specialist practices in Australia \(^{15}\) and the United Kingdom \(^{4}\) have, however, highlighted a mean treatment duration of just over 15 months. The discrepancy between those studies and our findings might be related to the complexity of the malocclusion being treated in the hospital service in the United Kingdom; although most participants were treated without extractions in this study (76%), approximately 15% underwent mechanical eruption of at least 1 maxillary canine. Treatment involving eruption of maxillary canines is known to extend orthodontic treatment significantly \(^{19,20}\); this was again confirmed in our clinical study.

It is interesting to note the variations in treatment duration described in the 4 studies, including this one, that have considered the effect of self-ligating brackets on treatment duration. \(^{5,6,16}\) Treatment duration appears to vary considerably between clinicians; however, it seems to be quite uniform for individual operators. It seems unlikely, therefore, that a fixed appliance system would have a significant bearing on the duration of orthodontic treatment or the number of visits required. Moreover, duration is likely to be governed by the skill, experience, and objectives of the treating clinician, in addition to the dictates of the patient’s malocclusion. Therefore, at this stage, the only proven advantage of self-ligating appliances is a modest reduction in chair-side time and less need for chair-side assistance. Self-ligating brackets are considerably more expensive; clinicians must decide whether this advantage counterbalances the additional cost.

### CONCLUSIONS

The self-ligating bracket systems used in this trial neither improved the efficiency of fixed appliance orthodontic treatment nor resulted in fewer treatment visits. Further prospective research investigating the relationship between bracket types and treatment durations in matched subjects would be welcome.

We thank orthodontic technician Guy Thomas for scoring the reference models.

### REFERENCES


