

Duration of treatment and occlusal outcome using Damon3 self-ligated and conventional orthodontic bracket systems in extraction patients: A prospective randomized clinical trial

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Introduction: This was a prospective randomized clinical trial comparing the effect of bracket type on the duration of orthodontic treatment and the occlusal outcome as measured by the peer assessment rating (PAR).

Methods: A multi-center randomized clinical trial was carried out in 2 orthodontic clinics. Sixty-two subjects (32 male, 30 female; mean age, 16.27 years) with a mean pretreatment PAR score of 39.40, mandibular irregularity from 5 to 12 mm, and prescribed extractions including mandibular first premolars were randomly allocated to treatment with either the Damon3 self-ligated or the Synthesis conventional ligated preadjusted bracket systems (both, Ormco, Glendora, Calif). An identical archwire sequence was used in both groups excluding the finishing archwires: 0.014-in, 0.014 × 0.025-in, and 0.018 × 0.025-in copper-nickel-titanium aligning archwires, followed by 0.019 × 0.025-in stainless steel working archwires. Data collected at the start of treatment and after appliance removal included dental study casts, total duration of treatment, number of visits, number of emergency visits and breakages during treatment, and number of failed appointments.

Results: Sixty-two patients were recruited at the start of treatment, and the records of 48 patients were analyzed after appliance removal. Accounting for pretreatment and in-treatment covariates, bracket type had no effect on overall treatment duration, number of visits, or overall percentage of reduction in PAR scores. Time spent in space closure had an effect on treatment duration, and the pretreatment PAR score influenced only the reduction in PAR as a result of treatment. **Conclusions:** Use of the Damon3 bracket does not reduce overall treatment time or total number of visits, or result in a better occlusal outcome when compared with conventional ligated brackets in the treatment of extraction patients with crowding. (Am J Orthod Dentofacial Orthop 2011;139:e111-e116)

In the last decade, there has been a significant increase in the number of self-ligated bracket systems available to orthodontists. Currently, 1 market leader is the Damon system (Ormco, Glendora, Calif), which advocates a treatment philosophy based on the use of a passive self-ligated bracket design and superelastic nickel-titanium

archwires. According to proponents of this system, the low-force and low-friction environment provided by the Damon appliance offers considerable advantages over those with conventional ligation. These include greater patient comfort during treatment, fewer visits to the orthodontist, shorter overall treatment times, less need for extractions, and better outcomes in terms of both occlusal and facial esthetics.¹

To date, these claims have been based on theoretical arguments, isolated case reports,¹ case series,² and retrospective comparisons.^{3,4} Although attempts have been made to achieve equivalence between samples compared retrospectively,⁴ some studies have suffered from poor design, inadequate reporting, and significant bias.⁵ In an attempt to improve the evidence base relating to the Damon system, several prospective randomized clinical trials have been instigated.⁶⁻¹⁰ Some of these have compared pain and discomfort caused by several Damon bracket designs and conventional ligation during the initial alignment phase of treatment and, collectively,

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have shown that the Damon system is not associated with any significant reductions in pain and discomfort compared with conventional appliances.^{8,10,11} They have also reported on the rate of initial tooth alignment, where there is weak evidence that Damon2 brackets can resolve mild crowding more rapidly than conventional appliances when this treatment is carried out on a nonextraction basis.⁶ However, for more severe crowding treated with the Damon3 bracket and first premolar extractions, this is not the case.⁹ In addition, the Damon MX passive self-ligated bracket cannot resolve maxillary anterior crowding any more effectively than an In-Ovation R with active self-ligation.¹² Collectively, these studies have also demonstrated that the Damon appliance does not align teeth in a qualitatively different manner from conventional or active self-ligated appliances; incisor proclination and canine expansion occur just as readily with the Damon system as they do with conventional ligated preadjusted brackets.^{6,7,9,12} Although the literature relating to the clinical use of self-ligated bracket systems is relatively new, currently little objective evidence suggests that they offer significant advantages with regard to treatment efficiency when compared with conventional appliances.^{13,14}

However, the period of initial alignment contributes toward only 1 part of the overall treatment time, which in total depends on many other factors. These can be patient-based, such as age, severity of the underlying malocclusion, and compliance, or treatment-based, including factors such as the decision to extract teeth, the need for overbite reduction, and space closure.¹⁵⁻¹⁷ Therefore, for any investigation of overall treatment effectiveness, it is important to evaluate this over the entire duration, from appliance placement to removal on completion. Moreover, for a sample with pretreatment equivalence, the duration of treatment is relevant only when evaluated in relation to outcome. Treatment outcome can be assessed in many ways, but one of the most recognized is the peer assessment rating (PAR), which provides a validated numeric score based on several occlusal features before and after treatment. The difference in these scores gives an indication of improvement in treatment and whether the occlusal aims were achieved.^{18,19}

The aim of this randomized clinical trial was to compare the efficiency of treatment by using Damon3 self-ligated and conventional bracket systems in terms of overall treatment time, number of visits, and occlusal outcome, as measured by the PAR index.

MATERIAL AND METHODS

Detailed descriptions of the methodology used for this study have been previously reported.^{9,10} Ethical approval was obtained from the Research Ethics Committee (no:

04/Q0704/116) of Guy's Hospital in London, United Kingdom, and written consent was obtained from all parents or guardians and children. The subjects were recruited from a sample of consecutive patients attending the orthodontic departments at Kings College London Dental Institute and Kent and Canterbury Hospital who satisfied the following criteria: (1) under 30 years of age at the start of treatment, (2) no medical contraindications, (3) permanent dentition, (4) mandibular incisor irregularity between 5 and 12 mm, (5) extraction of the mandibular first premolars as part of the normal treatment plan, and (6) absence of a complete overbite.

After we obtained consent, the subjects were randomly allocated for treatment with either the Damon3 passive self-ligated bracket or the Synthesis conventional ligated preadjusted edgewise bracket (both, Ormco) by using a restricted random number table to ensure equivalence of numbers in each group. The bonding method was standardized between the groups, by using conventional etching and BluGloo bracket adhesive (Ormco) according to the manufacturer's instructions. Mandibular dental study casts were taken at appliance placement (T1). After bracket bonding, Damon 0.014-in copper-nickel-titanium archwires were placed and ligated to all teeth by using the self-ligation system for Damon3 or standard elastomeric ligatures for Synthesis. The subjects were reviewed at approximately 6 to 8 week intervals, and a sequence of 0.014 × 0.025-in and 0.018 × 0.025-in copper-nickel-titanium, followed by 0.019 × 0.025-in stainless steel archwires, was used. On placement of the 0.014 × 0.025-in copper-nickel-titanium archwire, a further mandibular dental study cast was taken (T2). Treatment continued, and another mandibular study cast was taken at the end of alignment (T3). Treatment was then continued to completion, as judged ultimately by 2 orthodontic operators (A.T.D. and M.T.C.), and active treatment was recorded as completed on the day of appliance removal. A final set of dental study casts were taken at this point (T4).

For inclusion in the final analysis of treatment outcome at T4, the subjects had to fulfill the following criteria: (1) all records complete, (2) no more than 3 unexplained failed appointments during active treatment, and (3) treatment without orthognathic surgery. Data collection included the total duration of active treatment with fixed appliances, the number of visits (including emergency appointments), before and after PAR scores as recorded from the dental study casts, and the overall improvement in PAR score as a percentage.

Statistical analysis

SPSS software (version 13.0, SPSS for Windows, Chicago, Ill) was used for descriptive and statistical

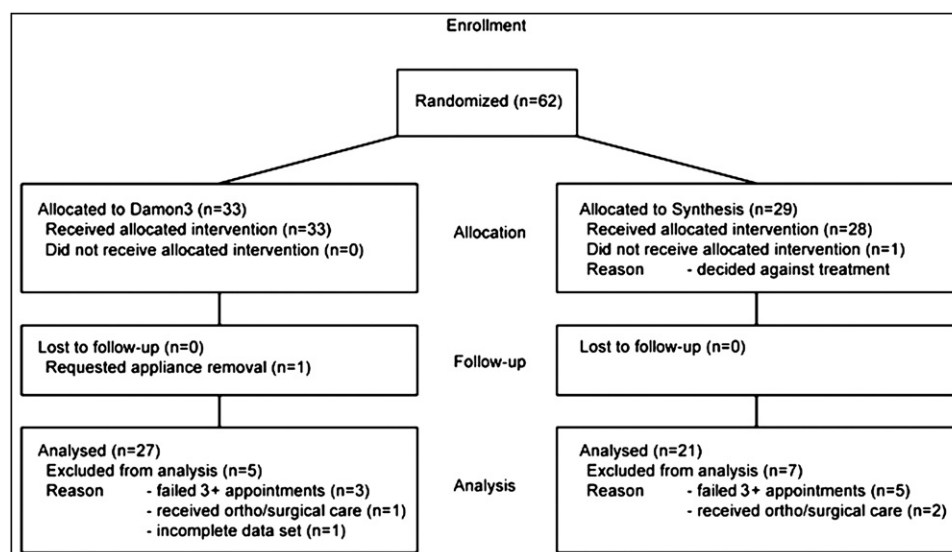


Fig. CONSORT diagram²⁸ showing the flow of patients through the study.

analysis with analysis of covariance (ANCOVA) to compare the treatment effect of the bracket systems while accounting for baseline differences and confounding continuous variables. These included the age of the patient, the initial PAR score, whether ectopic maxillary canines were mechanically erupted during treatment, the number of failed appointments, and the number of breakages during treatment. The level of statistical significance was set at $P < 0.05$. In our initial analysis to determine the effect of sex on treatment duration, we found no statistically significant effect (F ratio 0.057, $P = 0.813$), so further analysis was carried out without discrimination for sex.

RESULTS

Sixty-two patients were recruited to the original study, with 33 (mean age, 16.19 years; SD, 3.68) allocated to treatment with the Damon3 bracket and 29 (mean age, 16.38 years; SD, 5.28) to the Synthesis. The flow of patients through the study and the reasons for excluding patients from the final data set are shown in the Figure. From this original sample, 48 were included in the final analysis at T4 (Table I). In this sample, the range of malocclusions treated by using the 2 appliance systems was broadly similar, except that there were no Class III patients in the Synthesis bracket sample (Table I).

Descriptive statistics for the 2 groups are shown in Table II, including overall treatment times, total numbers of visits (including emergency appointments), pretreatment and posttreatment PAR scores, and the overall percentages of reduction in PAR scores.

Analytic statistics for the 2 groups are shown in Table III. Analysis consisted of ANCOVA to test for differences in means between the 2 groups but accounting for pretreatment factors, including age at T1, the pretreatment PAR score, and confounding variables during treatment, including the number ectopic maxillary canines mechanically erupted, the number of failed appointments, duration of space closure, and the number of breakages. When these factors were covaried out, the effect of the bracket system used on total duration of treatment (F ratio = 0.000; $P = 0.992$) and number of visits (F ratio = 0.956; $P = 0.334$) was not significant. In contrast, the duration of space closure had a significant effect on the duration of treatment ($P = 0.036$) but not on the number of visits ($P = 0.284$). When the pretreatment PAR score was covaried out, the effect of the bracket system on total PAR reduction (F ratio = 1.046; $P = 0.312$) was not significant. The pretreatment PAR score, however, had a significant effect on total PAR reduction ($P = 0.022$).

DISCUSSION

Any orthodontic appliance system that has the potential to significantly reduce treatment duration has clear benefits for both the patient and the orthodontist. There is some evidence that use of the Damon self-ligated bracket system can reduce the total length of orthodontic treatment by up to 6 months and the number of visits by 4 to 7.^{3,4} However, these findings are based on retrospective investigations, which are susceptible to bias. A more

Table I. Demographics of the sample groups at T4 with frequencies as percentages

	<i>Damon3</i>	<i>Synthesis</i>	<i>Total sample</i>
Number randomized	33	29	62
Sample group at T4	27	21	48
Class I	7 (15%)	6 (13%)	13 (28%)
Class II			
Division 1	14 (29%)	13 (27%)	27 (56%)
Division 2	2 (4%)	2 (4%)	4 (8%)
Class III	4 (8%)	0	4 (8%)
Maxillary anchorage support	10 (21%)	9 (19%)	19 (40%)
Maxillary ectopic canines	2 (4%)	2 (4%)	4 (8%)

Table II. Descriptive statistics for treatment duration, visits, breakages, PAR scores, and PAR reduction (standard deviations in parentheses)

	<i>Damon3</i>	<i>Synthesis</i>	<i>Total sample</i>
Treatment duration (mo)	24.48 (6.72)	23.00 (4.86)	23.83 (5.96)
Visits (n)	14.22 (2.64)	14.48 (3.53)	14.33 (3.03)
Breakages (n)	2.74 (2.41)	2.29 (2.74)	
Pretreatment PAR	38.26 (9.91)	40.86 (9.38)	39.40 (9.66)
Posttreatment PAR	5.48 (3.62)	6.43 (3.76)	5.90 (3.67)
PAR reduction (%)	85.19 (8.99)	83.38 (9.41)	84.40 (9.12)

robust method of evaluating any treatment intervention is the prospective randomized clinical trial; to date, none has been reported regarding overall treatment efficiency of the Damon appliance. In this investigation, we randomly allocated patients with moderate and severe crowding who required first premolar extractions to treatment with either Damon3 self-ligated or conventional ligated brackets. Interestingly, the Damon3 bracket was no more efficient than the conventional brackets during initial alignment, either in terms of rate or discomfort to the patient.^{9,10} The findings of these studies are broadly consistent with others carried out prospectively, both with regard to comparison of Damon passive self-ligated bracket and conventional ligated bracket^{13,14} or, more recently, active self-ligated systems.¹² We now report on overall treatment efficiency of Damon3 and Synthesis bracket systems in a patient sample requiring extraction of the first premolars as part of their prescribed orthodontic treatment. The treatment times and numbers of visits in both groups in this study were comparable with average orthodontic treatment times previously reported.¹⁵ However, there were no differences between the bracket groups. Therefore, accounting for confounding pretreatment and in-treatment factors, in our sample the use of Damon3 self-ligated brackets offered no advantage in either reducing overall treatment time or the number of visits during treatment.

It is important to try to understand why the claims relating to treatment efficiency of the Damon bracket

Table III. Adjusted means and influence of bracket type (removing effects of breakages, failed appointments, ectopic maxillary canines, space closure, and pretreatment PAR score) on duration, visits, and PAR reduction

	<i>Damon3</i>	<i>Synthesis</i>	<i>Significance</i>
Treatment duration (mo)	23.84	23.83	0.992
Visits (n)	13.94	14.84	0.334
PAR reduction (%)	85.55	82.92	0.312

have not been justified by our investigation. Advocates of this appliance emphasize the importance of users embracing the philosophy, allowing the light-force, low-friction system to achieve physiologic adaption, aligning crowded arches without the need for extractions and avoiding the use of auxiliaries, such as headgear or palatal expansion devices.² Clearly, in our study, all patients had first premolars extracted, and 40% of the sample also had anchorage reinforcement at some stage during treatment. It could be argued that these subjects do not represent appropriate treatment mechanics for the Damon system, and, as a result, the system could not demonstrate optimum performance. The decision to undertake this study of patients who had mandibular first premolars extracted was to allow standardization of the amount of crowding in the mandibular arch and ensure a level of crowding or malalignment that was significant and measurable. Although many of these patients could have been treated without extractions, this would have been counter to the treatment aims, which were based on clinical diagnoses rather than bracket types. Moreover, these patients were treated to an accepted philosophy of avoiding excessive proclination of the mandibular incisors or expansion of the mandibular intercanine width, both of which are inherently prone to relapse.²⁰⁻²² Proponents might also argue that the Damon bracket would have out-performed those with conventional ligation in terms of overall treatment time if the sample had been treated on a nonextraction basis. However, current evidence has shown that, for patients with irregularity scores greater than 5 mm, any increases in the rapidity of alignment shown by the Damon as opposed to conventional brackets are actually marginally insignificant.⁶ No evidence is currently available for more severely crowded nonextraction patients, but the findings of Pandis et al¹² do not support the idea that the Damon system should necessarily be any quicker than conventional brackets at aligning the dentition in these circumstances; it seems that the most significant factor influencing alignment rate is the degree of tooth displacement, rather than bracket type.^{9,23} Although the Damon philosophy encourages a nonextraction approach, its proponents acknowledge

that some patients require extractions to achieve some treatment goals.² Whereas the nuances of which patients require extractions can be debated, it is reasonable to assume that many of the supposed advantages advocated for the Damon system will still be relevant to patients treated with extractions as part of the treatment plan.

In nonextraction patients with crowding, the mandibular incisors will inevitably procline as these teeth are aligned, irrespective of bracket type. Proclining the mandibular incisors will help to reduce the overbite, and, without extractions, there will be little or no space to close after alignment; both of these factors should reduce the overall treatment time. Therefore, it might be the general modality of treatment that reduces the treatment time with the Damon system and not the brackets.^{9,23} However, in one of the few prospective studies comparing overall treatment times for self-ligated, albeit not Damon, and conventional ligated brackets in primarily nonextraction subjects, no differences were found.²⁴

Clearly, the decision to extract premolars in an orthodontic treatment plan will be a significant determinant of the overall treatment time. With regard to this, it is important to emphasize the equivalence of the 2 samples under investigation. The overall space requirements were similar, there was little difference in mean incisor irregularity, and similar numbers of patients in the 2 samples needed overjet reduction. Currently, few data are available regarding the in-vivo frictional characteristics of self-ligated bracket systems and their influence during orthodontic space closure.²⁵ However, laboratory studies have clearly demonstrated reduced static and kinetic friction associated with self-ligated brackets, and this might be expected to facilitate space closure, particularly during headgear-supported incisor retraction, and positively influence treatment time.^{26,27} Although the time taken for space closure was not formally measured in this investigation, this was not the case in terms of overall treatment time. However, crowding in the sample was high (mean, 11.84 mm); this means that residual space after incisor alignment might be relatively small and therefore negate any potential advantages in the rapidity of space closure. It was also our perception that the Damon3 brackets were more prone to breakage than were the conventional twin brackets used in this study. More specifically, the metal Damon3 bracket slot had a tendency to become detached from the polycarbonate base. Failures associated with the closing mechanism were a feature of earlier Damon brackets and, if present, might have contributed to an extended period of space closure.⁴ However, there was no statistically significant difference in the breakage rates for the 2 bracket systems (independent *t* tests, $P = 0.544$). It may be that the unique nature of the breakage associated with the Damon system

was simply more memorable and therefore perceived as more numerous by the operators. Either way, the breakage rate in both systems would have been unlikely to have a significant impact on the overall treatment time.

The mean percentage of PAR improvement for both groups was over 70%. This means that, for both bracket systems, these patients had great improvements in terms of their static occlusion. This is in part a reflection of the severity of crowding and the numbers of patients with a sagittal discrepancy at the start of treatment, but it also indicates the treatment standard that was achieved irrespective of the preadjusted appliance system used. Static occlusion is only 1 component of the many outcome measures that can be applied to a treated sample of patients, but this demonstrates that, in this investigation, similar occlusal results were achieved with both appliances in a similar time scale. This investigation represents the highest level of evidence currently available for overall treatment efficiency associated with the Damon appliance; we found no evidence to support current claims that this system can achieve faster treatment or a better occlusal outcome.

CONCLUSIONS

In the context of this prospective randomized clinical trial investigating a sample of patients requiring first premolar extractions, the use of the Damon3 self-ligated bracket system conveyed no advantage over a conventional ligated preadjusted twin bracket system in terms of overall treatment duration, number of visits to the orthodontist, or occlusal outcome, as measured by the PAR index.

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