Comparative assessment of alignment efficiency and space closure of active and passive self-ligating vs conventional appliances in adolescents: A single-center randomized controlled trial

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Introduction: The aim of this study was to compare the time to initial alignment and extraction space closure using conventional brackets and active and passive self-ligating brackets. **Methods:** One hundred adolescent patients 11 to 18 years of age undergoing maxillary and mandibular fixed appliance therapy after the extraction of 4 premolars were randomized with stratification of 2 age ranges (11-14 and 15-18 years) and 3 maxillomandibular plane angles (high, medium, and low) with an allocation ratio of 1:2:2. Restrictions were applied using a block size of 10. Allocation was to 1 of 3 treatment groups: conventional brackets, active self-ligating, or passive self-ligating brackets. All subjects were treated with the same archwire sequence and space-closing mechanics in a district general hospital setting. The trial was a 3-arm parallel design. Labial-segment alignment and space closure were measured on study models taken every 12 weeks throughout treatment. All measurements were made by 1 operator who was blinded to bracket type. The patients and other operators were not blinded to bracket type during treatment. **Results:** Ninety-eight patients were followed to completion of treatment (conventional, n = 20; active self-ligating brackets, n = 37; passive self-ligating brackets, n = 41). The data were analyzed using linear mixed models and demonstrated a significant effect of bracket type on the time to initial alignment (P = 0.001), which was shorter with the conventional brackets than either of the self-ligating brackets. Sidak's adjustment showed no significant difference in effect size (the difference in average response in millimeters) between the active and passive self-ligating brackets (the results are presented as effect size, 95% confidence intervals, probabilities, and intraclass correlation coefficients) (−0.42 [−1.32, 0.48], 0.600, 0.15), but the conventional bracket was significantly different from both of these (−1.98 [−3.19, −0.76], 0.001, 0.15; and −1.56 [−2.79, −0.32], 0.001, 0.15). There was no statistically significant difference between any of the 3 bracket types with respect to space closure. Space-closure times were shorter in the mandible, except for the Damon 3MX bracket (Ormco, Orange, Calif), where active and total space-closure times were shorter in the maxilla. No adverse events were recorded in the trial. **Conclusions:** Time to initial alignment was significantly shorter for the conventional bracket than for either the active or passive self-ligating brackets. There was no statistically significant difference in passive, active, or total space-closure times among the 3 brackets under investigation. (Am J Orthod Dentofacial Orthop 2014;145:569-78)

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Although the first self-ligating bracket, the Russell lock attachment, was introduced in 1935, it is only more recently that there has been a renewed interest in the use of self-ligating brackets.[1] Currently, 2 main types of self-ligating brackets are available, active and passive, both of which have a number of purported advantages over conventional brackets and over each other. These include fewer treatment visits, reduced overall treatment time, improved esthetics, reduced friction, improved oral hygiene, and full and secure ligation.[2-4]

Previous retrospective research has shown that the use of self-ligating brackets can reduce treatment times by 4 to 6 months and by 4 to 7 visits when compared with conventional brackets.[5,6] In addition, laboratory studies have suggested that friction is reduced,[7-9] particularly with passive self-ligating brackets.[10,11] Although improved treatment efficiency is highly desirable, it has not been a universal finding, particularly for initial alignment and space closure. Some studies have found no difference in the rate of initial alignment with either conventional or self-ligating brackets and have usually compared passive self-ligating brackets with conventional brackets.[12-17] The only study to date that directly compared active with passive self-ligating brackets showed no difference in the time required to complete alignment, although there was no conventional bracket control group.[18] Most previous researchers have also looked only at mandibular labial-segment alignment,[12-16] with relatively few investigating maxillary labial-segment alignment.[17,18]

Studies investigating the rate of space closure have also reported no difference between self-ligating and conventional brackets.[19,20] However, they have only compared passive self-ligating brackets with conventional brackets and either have used a split-mouth design[19,20] or have measured space closure for only a limited time.[17] This has been confirmed by recent systematic reviews highlighting the variability and differences between the studies and recommending that further randomized clinical controlled trials are needed.[21,22]

With these limitations in mind, the aim of this study was to investigate the time to initial alignment of both the maxillary and the mandibular labial-segment teeth along with the time to achieve space closure in the buccal segments when using 1 of 3 types of bracket: Damon 3MX passive self-ligating bracket (Ormco, Glendora, Calif), In-Ovation R active self-ligating bracket (DENTSPLY GAC International, Islandia, NY), and Omni conventional bracket (DENTSPLY GAC International). The null hypotheses were that there are no differences among the 3 bracket types during initial alignment or during space closure, or between the maxillary and mandibular arches (jaws).

MATERIAL AND METHODS

Ethical approval for the trial was granted by the ethics research committee (06/02202/6) of Taunton and Somerset Hospital, Musgrove Park, Taunton, United Kingdom. At the initial planning of this investigation, there were no studies reporting on the time to initial alignment comparing self-ligating and conventional brackets to determine a power calculation. We decided to recruit 90 subjects for the trial: 36 subjects to each self-ligating group and 18 to the conventional bracket group. However, to allow for a 10% dropout rate, 100 subjects were recruited with the following inclusion criteria: less than 18 years of age, ready to commence maxillary and mandibular fixed appliance treatment, intact labial segments, and premolar extractions required in all 4 quadrants. The principal exclusion criteria were the following: subjects who could not understand English, had learning difficulties, and had incomplete labial segments. The flow of the subjects in the trial is shown in the CONSORT diagram (Fig 1), which clearly demonstrates the 3-arm parallel design with its 2:2:1 allocation ratio. In total, 100 patients were recruited into the trial, and 98 were followed to completion of treatment, with 2 dropouts. There were no outcome changes during the trial, and no interim analyses were planned or performed. When this trial began, there was less insistence on trial registration; thus, the trial and its protocol were not registered on a publicly accessible registry. No external funding was received for this trial.

All subjects were treated in the orthodontic department at Musgrove Park Hospital, Taunton, United Kingdom, by 1 of 3 consultants or 5 specialist registrars. Eligible participants and their guardians were given an information sheet before inclusion in the trial and an ample opportunity to ask any relevant questions. Block randomization was used to ensure that each participant was randomly allocated to 1 of the 3 bracket groups: the control group with conventional Omni brackets, or a self-ligation group: Damon 3MX or In-Ovation R. The randomization was carried out by the local research and development office, which was contacted by telephone before the bond-up of each participant. This process allowed allocation concealment from the researchers and prevented the possibility of prediction of the next randomization in each block. The randomization was also stratified to take into account patient age and the Frankfort mandibular plane angle. The participants were divided according to age at the start of the