

# Perception of discomfort during initial orthodontic tooth alignment using a self-ligating or conventional bracket system: a randomized clinical trial

Paul Scott\*, Martyn Sherriff\*\*, Andrew T. DiBiase\* and Martyn T. Cobourne\*\*\*

\*Department of Orthodontics, East Kent Hospitals Trust and Departments of \*\*Dental Biomaterials and

\*\*\*Orthodontics and Craniofacial Development, King's College London Dental Institute, London, UK

**SUMMARY** The aim of this study was to compare the degree of discomfort experienced during the period of initial orthodontic tooth movement using Damon3™ self-ligating and Synthesis™ conventional ligating pre-adjusted bracket systems. Sixty-two subjects were recruited from two centres (32 males and 30 females; mean age 16 years, 3 months) with lower incisor irregularity between 5 and 12 mm and a prescribed extraction pattern, including lower first premolar teeth. These subjects were randomly allocated for treatment with either bracket system. Fully ligated Damon™ 0.014-inch Cu NiTi archwires were used for initial alignment in both groups. Following archwire insertion, the subjects were given a prepared discomfort diary to complete over the first week, recording discomfort by means of a 100 mm visual analogue scale at 4 hours, 24 hours, 3 days, and 1 week. The subjects also noted any self-prescribed analgesics that were taken during the period of observation. Data were analysed using repeated measures analysis of variance.

There were no statistically significant differences in perceived discomfort levels between the two appliances; discomfort did not differ at the first time point and did not develop differently across subsequent measurement times. Overall, this investigation found no evidence to suggest that Damon3 self-ligating brackets are associated with less discomfort than conventional pre-adjusted brackets during initial tooth alignment, regardless of age or gender.

## Introduction

The first phase of fixed appliance orthodontic treatment is concerned with tooth alignment and relies upon a rapid and predictable response of the appliance system to the aligning archwire. Clinically effective alignment represents a balance between optimal speed of tooth movement and the restriction of potential damage to the tooth and periodontal structures, while inducing the minimum level of discomfort for the patient.

It is well documented that discomfort is a potential side-effect during fixed appliance orthodontic therapy (Kvam *et al.*, 1989; Scheurer *et al.*, 1996) and this can negatively influence the desire to undergo treatment (Oliver and Knapman, 1985), compliance (Sergl *et al.*, 2000), and treatment outcome (Patel, 1992). A number of general factors can influence treatment-related discomfort, including previous pain experiences (Okeson, 1995), gender (Ngan *et al.*, 1989; Jones and Chan, 1992; Fernandes *et al.*, 1998; Bergius *et al.*, 2000), and age (Jones 1984; Scheurer *et al.*, 1996). However, a potentially significant variable is the amount of force applied to the dentition by the orthodontic archwire, particularly during the early stages of treatment. Classical histological studies suggest that light forces are more biologically efficient and less traumatic during orthodontic tooth movement

(Reitan, 1956). Therefore, the use of increased force levels might be expected to be associated with increased discomfort. Moreover, the greater the degree of initial crowding, the more teeth will be actively engaged by the archwire and the greater the potential for high degrees of force. Consistent with this, it has been shown that perceived pain peaks at around 24 hours after initial archwire placement, with reducing levels during the subsequent week (Ngan *et al.*, 1989; Jones and Chan, 1992; Ertan Erdiñç and Dinçer, 2004). However, a clear and direct relationship between applied force and perceived pain is controversial (Jones, 1984).

One of the factors affecting prospective tooth movement and hence the amount of force required is the degree of friction that exists between the archwire and bracket; this frictional resistance being influenced primarily by the physical characteristics of the archwire and bracket materials (Ireland *et al.*, 1991), archwire dimensions (Taylor and Ison, 1996), and the method of archwire ligation (Ireland *et al.*, 1991; Shivapuja and Berger, 1994). Indeed, a number of self-ligating bracket systems have been developed in recent years, including Damon™, In-Ovation™, and SmartClip™ with the proposed benefit of reduced frictional properties (Read-Ward *et al.*, 1997; Thorstenson and Kusy, 2001; Henao and Kusy, 2004). Proponents and manufacturers of

these systems suggest that their physical properties produce lower force levels during tooth alignment and sliding mechanics, a more biologically compatible force level and, therefore, a possible reduction in pain associated with orthodontic tooth movement (Berger and Byloff, 2001; <http://www.damonbraces.com>). To date, there has been only one published clinical trial investigating differences in perceived pain on placement of an initial archwire using self-ligating and conventional brackets (Miles *et al.*, 2006). Interestingly, this split-mouth designed study concluded that Damon2™ brackets were initially less painful than conventional brackets, but more painful when tying in the second archwire.

The aim of this study was to investigate any differences in the degree of discomfort experienced during the initial phase of tooth movement using self-ligating and conventional bracket systems. The null hypothesis tested was that there is no difference in discomfort during the initial phase of tooth alignment between the Damon3 self-ligating bracket system and the conventionally ligated Synthesis pre-adjusted edgewise bracket system.

## Subjects and methods

Ethical approval for this investigation was granted by the Guy's Research Ethics Committee (04/Q0704/116).

### Subjects

The study group comprised 62 subjects (32 males and 30 females) treated in the Departments of Orthodontics at the King's College London Dental Institute, Guy's Campus, and the Kent and Canterbury Hospital. The mean age at the start of treatment was 16 years 3 months. The subjects were obtained from a sample of consecutive cases satisfying the following criteria:

1. under 30 years of age at the start of treatment,
2. no medical contraindications,
3. in the permanent dentition,
4. lower incisor irregularity between 5 and 12 mm,
5. extraction pattern of lower first premolars as part of the normal treatment plan, and
6. absence of a complete overbite.

Following informed consent, the subjects were randomly allocated for treatment with either 0.022 inch Damon3™ (Ormco, Orange, California, USA) standard prescription self-ligating brackets or 0.022 inch Roth prescription Synthesis™ (Ormco) pre-adjusted edgewise brackets. Randomization was carried out using a table of random numbers. The bonding method was standardized between the two groups, using conventional etching and BluGloo (Ormco) bracket adhesive, according to the manufacturers' instructions. After bracket bonding, Damon 0.014 inch Cu NiTi (Ormco) archwires were inserted and ligated to all teeth in the mandibular arch. No other intervention was carried out at this stage of treatment.

Following archwire insertion, the subjects were given full instructions and a prepared discomfort diary to complete over the first week (Figure 1). The diary recorded discomfort by means of a 100 mm visual analogue scale (VAS) at 4 hours, 24 hours, 3 days, and 1 week, using the terms 'very comfortable' and 'very uncomfortable' as peripheral weighting (Seymour, 1982). The VAS score is the distance from the left end of the line to the point of the subject's mark, measured to the nearest millimetre. Each VAS score was measured on two separate occasions by the same operator (PS), with the mean taken as the representative value. In addition to the VAS score, the subject also noted any analgesics that were taken during the period of observation. Each patient was free to take non-prescription analgesia as required. The diary was completed by the subject and returned at the following appointment.

### Statistical analysis

Data were analysed using Stata (Stata Statistical Software: Release 9.1. College Station, Texas, USA). Significance was pre-determined at  $\alpha = 0.05$ . Repeated measures analysis of variance (ANOVA) was used to compare the bracket groups for differences in perceived pain levels. This technique allows both for differences in conditions at the same time point, differential development across subsequent times, and the general effect of time on perceived pain. Contrasts were used to study differences at two subsequent time points (Milliken and Johnson, 1992).

## Results

Patient recruitment is detailed in Table 1. A total of 62 patients were recruited into the study, with 33 in the Damon3 and 29 in the Synthesis groups. The mean age of the Damon3 group was 16.19 years [standard deviation (SD) = 3.68] and of the Synthesis group 16.38 years (SD = 5.28). Within the sample, 60 patients returned their diary, which gave a return rate of 96.8 per cent.

**Table 1** Patient allocation to the two groups.

	Male		Female
Total number of subjects	62	32	30
Subjects allocated to Damon3	33	12	21
Subjects allocated to Synthesis	29	20	9
Total number of subjects returning discomfort diary	60	30	30
Subjects returning discomfort diary with Damon3	33	12	21
Subjects returning discomfort diary with Synthesis	27	18	9

Date..... Patient Study ID.....

**Please fill out this form and bring along to your next appointment**

**Please make a small vertical line on each of the horizontal lines to indicate how much discomfort you are experiencing at certain times after your brace is adjusted**

**4 hours after appointment....**

Very comfortable  Very uncomfortable

**24 hours after appointment...**

Very comfortable  Very uncomfortable

**3 days after appointment...**

Very comfortable  Very uncomfortable

**1 week after appointment....**

Very comfortable  Very uncomfortable

**Did you take any pain killers?**

Date.....Type.....Dose.....

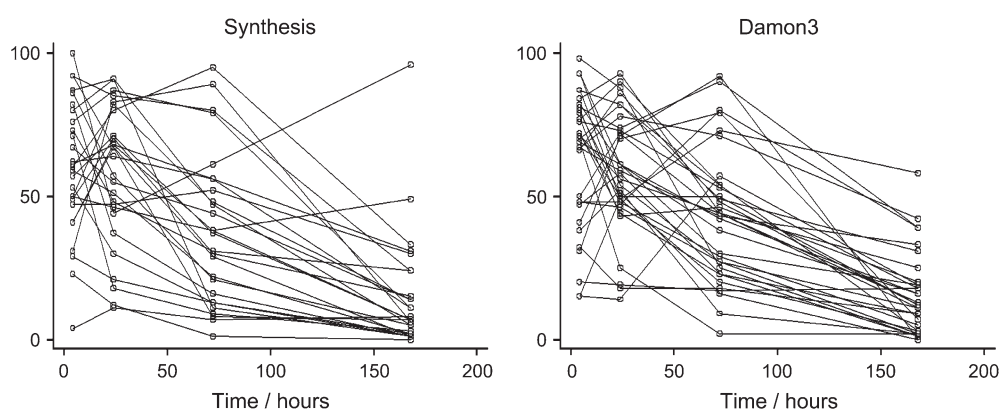
Date.....Type.....Dose.....

Date.....Type.....Dose.....

Date.....Type.....Dose.....

Date.....Type.....Dose.....

**Figure 1** Discomfort score diary allocated to subjects at appliance fitting.



**Figure 2** Individual profile plots of visual analogue score (mm) versus time (hours) for each appliance system.

### Visual analogue scale

The summary statistics for each group are shown in Table 2. The individual profile plots for discomfort with each appliance versus time demonstrated that, as a general trend, perceived discomfort decreased as a function of time for both appliances over the observation period (Figure 2).

Repeated measures ANOVA showed no significant effect of appliance, gender, or coded age ( $\leq 16$  or  $> 16$ ) as main factors or any of their interactions on perceived discomfort. The only significant factor was time ( $P = 0.001$ ; Table 3). Subsequent analysis using contrasts showed that there was no significant difference in discomfort score between 4 and

**Table 2** Mean discomfort score over time for each appliance system.

Appliance	4 hours (SD)	24 hours (SD)	3 days (SD)	7 days (SD)
Synthesis	60.11 (23.3)	57.44 (24.24)	38.19 (26.43)	15.11 (20.32)
Damon3	63.67 (23.18)	58.3 (20.74)	42.94 (23.08)	15.12 (14.32)

SD, standard deviation.

**Table 3** Effect of age and gender on perceived discomfort using repeated measures analysis of variance.

Term	<i>P</i>
Time	0.001
Time $\times$ gender	0.207
Time $\times$ age	0.371
Time $\times$ gender $\times$ age	0.598

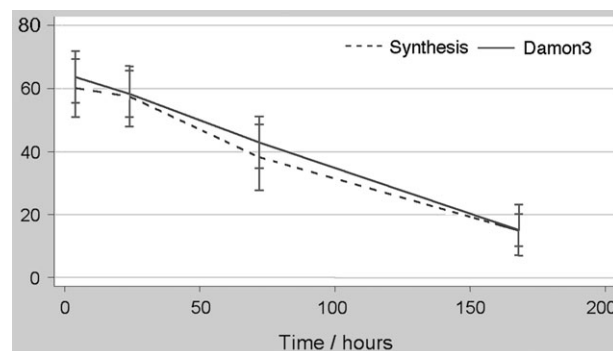
24 hours, but at 24–72 and 72–168 hours, the scores were significantly different. Although there were no significant differences between appliance type, a plot of mean discomfort as a function of time showed the Synthesis group to exhibit a lower level of perceived discomfort than the Damon3, at all time periods (Figure 3).

#### Analgesic use

The diary also allowed the subject to note any analgesia used during the study period. A total of 20 patients (60.6%) in the Damon3 group and 11 patients (40.7%) in the Synthesis group used self-prescribed analgesics (Table 4). There was no significant difference in analgesic use between the two groups ( $x = 2.35$ ;  $P = 0.102$ ). This value was assessed using permutation techniques to allow for the relatively small sample size.

#### Discussion

This study analysed perceived discomfort after initial placement of two different pre-adjusted fixed appliance systems. Discomfort was measured using a VAS, which is one of the most commonly used tools in the measurement of perceived discomfort during orthodontic treatment (Ngan *et al.*, 1989; Jones and Chan, 1992; Fernandes *et al.*, 1998; Ertan Erdiñç and Dinçer, 2004). This system is readily understood by most patients and is reliable, demonstrating good sensitivity between small changes and good reproducibility (Huskişon, 1974; Scott and Huskişon, 1979). However, this scale provides a global measure of discomfort and, for different bracket designs, does not allow the subject to distinguish between different sources of discomfort, e.g. associated with the tooth or soft tissues. The use of a self-prescribed analgesics log by the subjects gave a second independent form of assessment for the

**Figure 3** Plot of mean visual analogue score as a function of time for the two appliance systems.**Table 4** Analgesic usage for each group.

Analgesics taken	Synthesis	Damon3
Total	11 (40.7%)	20 (60.6%)
None	16	13
Paracetamol 1 day	2	2
Paracetamol 2 days	2	3
Paracetamol 3 days	1	2
Paracetamol 4 days	0	1
Paracetamol 5 days	1	1
Ibuprofen 1 day	0	3
Ibuprofen 2 days	2	5
Ibuprofen 3 days	2	1
Ibuprofen 4 days	0	2
Aspirin 2 days	1	0

amount of discomfort participants in the study were experiencing. There was a high return rate of the diaries issued, which was almost certainly due to them being provided at the very start of treatment when subject compliance is likely to be at a premium. However, in spite of randomization, the gender distribution was different, with twice as many females present in the Damon3 group as in the Synthesis group.

It is common for patients to experience discomfort on placement of fixed orthodontic appliances (Ngan *et al.*, 1989; Wilson *et al.*, 1989; Mandall *et al.*, 2006). In this investigation, there were no significant difference in the levels of perceived discomfort for males and females with regard to both the VAS and analgesia logbook. This is in agreement with previous studies, which have shown that gender does not affect perceived pain during orthodontic treatment (Ngan *et al.*, 1989; Jones and Chan, 1992; Fernandes *et al.*, 1998; Ertan Erdiñç and Dinçer, 2004). Gender discrimination was therefore excluded and both males and females were evaluated together for the rest of the data. Significantly, analysis of both the VAS and analgesia data also showed no significant difference between the perceived discomfort level for the Damon3 or Synthesis appliance systems at any time interval. This is in contrast to



previous claims made by the manufacturers of Damon3 and other self-ligating bracket systems that reduced friction allows free movement of the teeth, lighter forces, and hence less discomfort to the patient (<http://www.damonbraces.com>). These results also contradict a report that Damon2 brackets are initially less painful when tying in the first archwire (Miles *et al.*, 2006).

In this study, a split-mouth design was used and subjects noted which side was the most tender on questioning. However, no attempt was made to quantify the levels of pain experience with any form of scale and a far greater number of teeth were left initially unligated in the Damon2 bracket sample, which would suggest less overall force on the remaining teeth on that side (Miles *et al.*, 2006). A correlation between perceived discomfort and analgesic use has been previously reported (Jones, 1984; Scheurer *et al.*, 1996) and while not statistically significant, a plot of the mean discomfort score as a function of time showed the Synthesis group to exhibit a slightly lower level of perceived discomfort than the Damon3 group. Consistent with this, a lower proportion of the Synthesis subjects (40.7%) used self-prescribed analgesics compared with the Damon3 group (60.6%). However, no statistically significant differences were found in the amount of analgesics taken in each group, which is in agreement with the results from the VAS.

As there were no statistically significant differences in discomfort reported between the two appliance systems, the data for perceived discomfort with respect to time were evaluated together to give a larger sample size. Perceived discomfort peaked at 4 and 24 hours, with no significant difference between the levels of discomfort between these two time points. However, this was followed by a statistically significant reduction at 3 days and a further reduction at 7 days. These findings are in general agreement with several investigations that show pain levels following archwire placement to peak at around 24 hours and return to a minimal base line level by 7 days (Wilson *et al.*, 1989; Jones and Chan, 1992; Scheurer *et al.*, 1996; Fernandes *et al.*, 1998). In addition, no significant differences were found between appliance systems when the groups were combined to give a larger sample size, with no effect on perceived discomfort by age. This is in disagreement with previous research that has shown patients over the age of 16 years to have higher pain scores (Jones, 1984) and patients under the age of 13 years experience less perceived pain (Scheurer *et al.*, 1996). Overall, the results of this investigation would suggest that the Damon3 appliance system offers no advantage over conventional ligation in relation to patient discomfort during the first week following placement of initial aligning archwires.

## Conclusions

1. There is no difference in perceived discomfort experienced by subjects during initial tooth alignment when using a

Damon3 self-ligating bracket system or the Synthesis conventional pre-adjusted edgewise appliance system.

2. Gender has no effect on perceived discomfort experienced by subjects undergoing fixed appliance orthodontic treatment.
3. Peak orthodontic perceived discomfort occurs between 4 and 24 hours following initial archwire placement. This decreases by 3 days and is at a minimal baseline level by 7 days.
4. Age does not affect the level of discomfort experienced by subjects undergoing fixed orthodontic treatment.

## Address for correspondence

Dr Martyn Cobourne  
Department of Orthodontics and Craniofacial Development  
King's College London Dental Institute  
Floor 22, Guy's Tower  
Guy's Hospital  
London SE 1 9RT  
UK  
E-mail: [martyn.cobourne@kcl.ac.uk](mailto:martyn.cobourne@kcl.ac.uk)

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