

Prospective randomized clinical trial to compare pain levels associated with 2 orthodontic fixed bracket systems

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Introduction: In this randomized clinical trial, we compared pain levels associated with 2 fixed appliance systems during initial orthodontic tooth movement. **Methods:** Sixty-six patients (36 female, 30 male) were randomly allocated to either a conventional twin bracket (Tru Straight, Ormco Europe, Amersfoort, The Netherlands) or a self-ligating bracket (Damon 3, Ormco). Both arches were bonded, and a 0.014-in superelastic copper-nickel-titanium archwire was ligated in position. Pain intensity levels were recorded twice a day, over 7 days, by using 10-cm visual analog scales. Patients also recorded whether analgesia was taken. Contact point displacements were measured on study models to calculate Little's irregularity index. **Results:** Fifty-two patients (78.8%) completed the trial (84.8% in the Tru Straight group and 72.7% in the Damon 3 group). Patients in the Damon 3 group reported lower mean maximum pain intensity ($P = 0.053$) and significantly lower mean pain intensity ($P = 0.012$) than did the Tru Straight patients. Patients who consumed analgesics reported significantly higher mean maximum pain intensity and mean pain intensity than those who did not take analgesia ($P < 0.001$). The Damon 3 patients generally reported lower pain intensity than the Tru Straight patients. **Conclusions:** Although there were wide interindividual variations, in this study, the Damon 3 appliance resulted in lower pain intensity, on average, when compared with the Tru Straight appliance. (Am J Orthod Dentofacial Orthop 2009;136:160-7)

A survey of patients who had completed fixed orthodontic treatment found that 91% experienced pain during treatment.¹ Similarly, pain has been reported to be the worst aspect of treatment and the highest-ranking reason for wanting to discontinue care.² Even though pain is a major concern to patients, few recent studies have analyzed and discussed the etiology, manifestations, and consequences of pain from orthodontic treatment.³

The origin of orthodontic-related pain is thought to be in the periodontal ligament by the processes of pressure, ischemia, inflammation, and edema.⁴ Many in-

flammatory mediators shown to elicit hyperalgesia responses, such as histamine, prostaglandins, serotonin, bradykinin, and substance P, have increased levels in the periodontium during orthodontic tooth movement.⁵⁻⁷ Although pain from orthodontic tooth movement has generally been attributed to the periodontium, evidence suggests that elements in the dental pulp can also contribute.^{4,8-11}

There is great interindividual variation in the response to application of an orthodontic force.^{9,12-16} Several studies have proposed that demographic variables (eg, age and sex) might explain interindividual variability; however, the results are often conflicting.^{9,12,13,16-19} Traditionally, there was also believed to be a linear relationship between the severity of contact point displacement and discomfort. Two studies investigated the relationship between contact point displacements and pain intensity but found no significant correlations.^{12,20} Since 1992, there have been no further investigations of the effect of contact point displacements on pain intensity.

Postoperative dental pain (PDP) is frequent after various forms of dental treatment.²¹ The incidence and severity of PDP in adults have been shown to be correlated with specific forms of dental treatment: the highest after endodontic treatment (52.8%) and the lowest after restorations (36.1%).²¹ In addition, women (52.5%)

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reported PDP more often than men (33.7%).²¹ The incidence and severity of PDP in children was also shown to be significantly associated with the dental procedure: the highest after endodontic treatment (62.5%) and preformed stainless steel crowns (60.8%), although sex-related PDP showed conflicting results.²² A common reaction to postoperative pain is to provide an analgesic; however, clinicians and parents often do not seriously consider PDP relief for patients, especially children.²³

According to Damon,^{24,25} his fixed appliance system is superior to other systems because of the combination of a low-friction bracket and a low force generated by superelastic nickel-titanium archwires that result in more efficient tooth movement and less pain. An earlier clinical trial of 60 patients compared the effectiveness and comfort of Damon 2 brackets and conventional twin brackets during initial alignment with a split-mouth design.²⁶ During initial alignment, the conventional twin bracket was less comfortable than the Damon bracket. The authors believed that the Damon 2 bracket was less painful because of incomplete engagement of the archwire. However, pain was recorded only once as either present or absent several days after bond-up; therefore, this does not give a clear understanding of the duration or the severity of pain.

The aims of this study were to compare whether the method of archwire ligation influences pain intensity during the early stages of orthodontic treatment and to investigate the influence of age, ethnicity, sex, and severity of contact point displacement on pain intensity.

MATERIAL AND METHODS

The study was approved by the West Midlands Multi-Centre Research Ethics Committee. Information leaflets were given to eligible patients at least 24 hours before consent; written consent was obtained from all subjects.

The sample size was determined by using the results from a study that evaluated pain perception during orthodontic treatment with fixed appliances.¹⁶ The calculation was based on the number of patients required for a 2-sample *t* test to demonstrate a 20-mm difference in mean maximum pain intensity between the 2 groups on the visual analog scale (VAS). The sample size was calculated as 33 patients per group, based on a significance level of 0.05, a power of 80%, and a standard deviation of 28.3 mm in both groups on the VAS.

The study was a 2-center prospective randomized clinical trial involving 66 patients. Consecutive patients were selected from the orthodontic waiting list at the John Radcliffe Hospital (Oxford, United Kingdom) and the Dental Access Centre (Banbury, United Kingdom).

All treatments began between July 2005 and April 2006, and 7 operators were involved in the study.

Patients who fulfilled the criteria were asked whether they were willing to participate in the study; all who were approached agreed to participate. The following criteria were used: (1) over 10 years of age at the start of treatment with permanent dentition, and (2) maxillary and mandibular fixed appliances required.

Patients who fulfilled at least 1 of the following criteria were excluded from the study: (1) under the age of 16 and not accompanied by a parent or legal guardian, (2) undergoing active headgear treatment, or (3) undergoing maxillary expansion with either a quad-helix, rapid maxillary expansion device or a maxillary removable appliance with a midline expansion screw.

Patients who met the criteria and provided consent were randomized to receive either the Tru Straight bracket (Ormco Europe, Amersfoort, The Netherlands) or the Damon 3 bracket (Ormco). The first permanent molars were banded a week before bond-up.

Simple randomization was done with a computer-generated list of random numbers. Once the patient had consented, a sequentially numbered, opaque, sealed envelope was given to the operator; it contained the name of the bracket system to be used. Because the brackets were visible to both patient and orthodontist, blinding of bracket allocation was impossible.

Each tooth was cleaned with a bristle brush or rubber cup, rinsed thoroughly with water, etched with 37% phosphoric acid for 10 seconds, and rinsed thoroughly with water for 5 seconds. The enamel was dried with clean, oil-free compressed air, and OrthoSolo adhesive (Ormco) was applied to each tooth and air thinned. Bluglo composite (Ormco) was placed on the orthodontic bracket base; the bracket was then placed on the tooth and light cured for a minimum of 10 seconds. A 0.014-in superelastic copper-nickel-titanium archwire (Ormco) was placed in both arches. The wire was engaged in the Damon 3 bracket by closing the slide. All 4 tie-wings of the Tru Straight bracket were engaged with silver elastomeric modules; partial ligation and figure-eight ligation were not permitted. When a patient had, for example, a high buccal canine, the tooth was not fully ligated with either bracket system. Instead, elastic thread was placed from the bracket to the archwire.

A pain diary of 15 questions, each with a VAS, was given to each patient after bond-up. The VAS was an unmarked horizontal 10-cm line, with "no pain" and "extreme pain" at either end. Faces were also used: a happy face for no pain and a sad face for extreme pain. The patients recorded their perceived pain intensity levels before their evening meal on the day of bond-up and before breakfast and the evening meal for the next 7

days. At each time, the patients indicated whether they consumed an analgesic, and, if they did, they recorded its name, dosage, and number of tablets. On return of the questionnaire, the VAS scores were measured from the left margin of the line.

Little's irregularity index,²⁷ defined as the summed displacement of the adjacent anatomic contact points of the 6 mandibular teeth, was used to quantify the degree of alignment from study models by using a digital caliper (150 mm, M110-15DDL, Moore and Wright, Sheffield, Yorkshire, United Kingdom) to the nearest 0.1 mm (caliper resolution, ± 0.01 mm). Maxillary irregularity was recorded by using the same method described by Little. Little's total irregularity index was the combined total of Little's irregularity index and Little's maxillary irregularity index.

Measurement error for the VAS was evaluated by remeasuring the VAS scores from 20 randomly selected questionnaires. Measurement error for the contact point displacement was evaluated by repeating the study model measurements on 20 randomly selected study models. Paired *t* tests on the repeated measurements were used to investigate any systematic effects. Lin's concordance coefficient,^{28,29} with a maximum value of 1.00, was calculated; this combines measurements of both precision and accuracy to determine how far the observed data deviate from the line of perfect concordance (ie, the line at 45° on a square scatter plot when 1 member of the pair of observations is plotted against the other). The Bland and Altman analysis³⁰ was used for each variable, and the 95% limits of agreement and the British standards repeatability coefficient³¹ were determined in each case. The limits of agreement provide an interval within which approximately 95% of the differences between repeated measurements are expected to be, and the British standards repeatability coefficient gives the maximum likely difference between repeated measurements.

Statistical analysis

Data from the VAS and study model analysis were transferred to a spreadsheet, and SPSS for Windows software (version 12.0.1, SPSS, Chicago, Ill) was used for statistical analysis. Data analysis for the main study was undertaken by using (1) maximum pain intensity (the maximum pain score recorded by a patient at any time point on the VAS) and (2) pain intensity (pain recorded at all time points). Data for maximum pain intensity were found to be normally distributed.

Univariable analysis was used (either linear regression or 2-sample *t* tests, as appropriate), with maximum pain intensity for each patient as the dependent variable and the following independent variables: (1) bracket type (Damon 3 or Tru Straight), (2) age, (3) sex, (4)

incisor classification, (5) extraction or nonextraction treatment, (6) Little's irregularity index, (7) Little's maxillary irregularity index, (8) Little's total irregularity index, and (9) analgesic consumption. Independent variables whose coefficients in the univariable regression analyses were statistically significantly different from zero or whose means were significantly different in the 2-sample *t* tests at the 10% level were entered into a multivariable linear regression with maximum pain intensity as the dependent variable.

Pain intensity, from the results at each time point, was analyzed by using a general linear model with univariate hierarchical repeated measures analysis of covariance (ANCOVA) with "patients" (a random factor) nested within "bracket type" (fixed factor) with repeated measures over time (fixed factor); analgesia consumption (presence or absence) was also included as a covariable. Post-hoc tests were undertaken by using the Dunnett pairwise multiple comparison test with the first time point (day 1 before dinner) as the control and the other 14 time points compared with it. The assumptions underlying both the regression analyses and the analysis of variance (ANOVA) were verified by studying the residuals. A significance level of 5% was used throughout, except in the univariable analyses, when the significance level was 10%.

RESULTS

Of the 66 patients enrolled in the study, 52 (78.8%) returned the pain questionnaires (Fig 1). Table I gives the baseline demographics and clinical characteristics in the trial groups.

The results of the repeatability study showed no significant differences ($P > 0.05$) between any sets of repeated measurements, indicating no evidence of systematic effects. The minimum value of Lin's concordance coefficient was 0.98, suggesting very good agreement in all instances. The Bland and Altman method showed, in each case, no funnel effect; this indicates that repeatability was consistent for all magnitudes of the results. In all instances, the repeatability coefficients were clinically acceptable.

The mean maximum pain intensities were 40.92 mm ($n = 24$; 95% CI, 30.40-51.44 mm) for the Damon 3 patients and 55.71 mm ($n = 28$; 95% CI, 45.93-65.50 mm) for the Tru Straight patients. For patients who had consumed analgesics, the mean maximum pain intensity was 58.14 mm ($n = 35$; 95% CI, 50.31-65.98 mm), and, for those who did not consume analgesics, it was 29.82 mm ($n = 17$; 95% CI, 18.75-40.90 mm).

The results of the univariable analyses, with maximum pain as the dependent variable, showed that the following independent variables were significant:

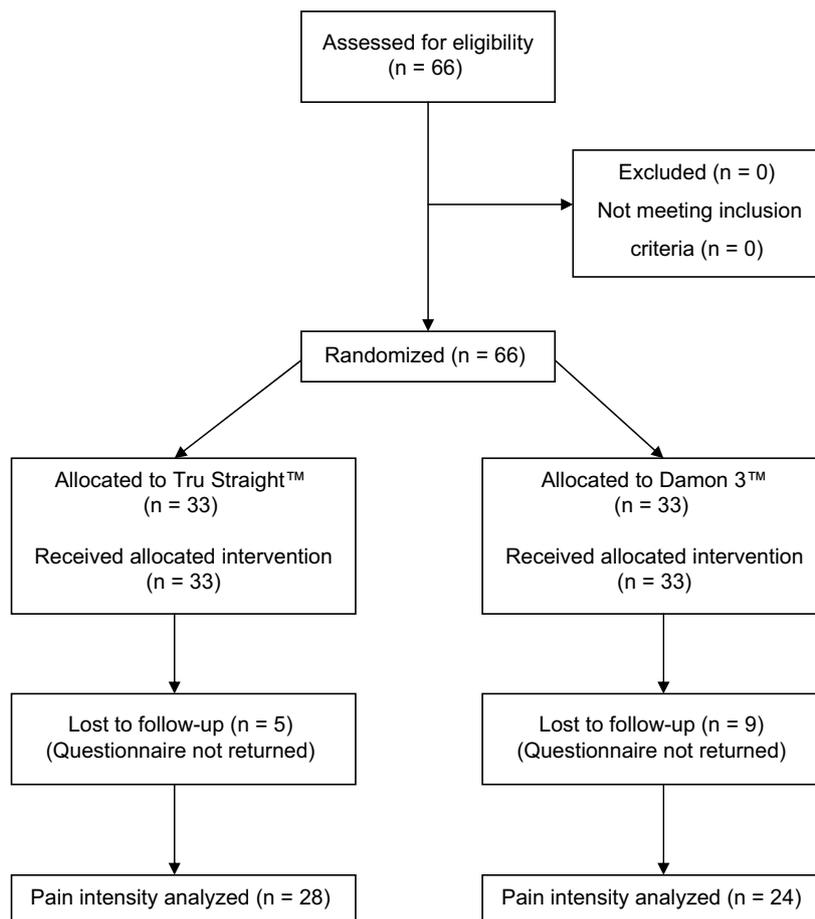


Fig 1. CONSORT diagram showing the progress of the subjects through the trial.

bracket type, Little’s maxillary irregularity index, and analgesia consumption. Table II illustrates the results of the multivariable linear regression, with these variables as covariates. Of the 3 variables, only analgesia consumption was statistically significant at the 5% level; bracket type was marginally significant with a P value of 0.053, and Little’s maxillary irregularity index was close to significance with a P value of 0.062. After adjusting for the other covariates in the model, patients with Damon 3 brackets had lower mean maximum pain intensity than those who had the Tru Straight brackets (difference in means, 11.77 mm; 95% CI, -0.15-23.68 mm; $P = 0.053$), and patients who had consumed analgesics had significantly higher mean maximum pain intensity than those who did not (difference in means, 24.32 mm; 95% CI, 11.35-37.29 mm; $P < 0.001$).

Figure 2 illustrates the mean pain intensity of the 2 groups over 8 days. The general linear model univariate ANCOVA was used as a hierarchical repeated measures ANOVA, with analgesia consumption as a covariable. There was a statistically significant

difference ($P = 0.012$) for the mean pain intensity values between the bracket types, with the Damon 3 patients reporting less pain on average than the Tru Straight group; however, there were wide 95% CIs for both groups. Patients who consumed analgesia reported statistically significantly higher mean pain intensity than those who did not ($P < 0.001$). There was no significant interaction between bracket type and time ($P = 0.312$), but a statistically significant difference in mean pain intensity was noted between the time points ($P < 0.001$). Post-hoc tests were undertaken with the first time point (day 1 before dinner) as the control. The mean pain intensity at each time point was subtracted from day 1 before dinner. Although the mean pain intensity was greater at day 1 before dinner than at day 2 before breakfast, this difference was not statistically significant (95% CI, -10.3-3.0 mm; $P = 0.65$). However, the mean pain intensity was statistically significantly greater at day 1 before dinner than at day 2 before dinner and at each subsequent time point.

Table I. Baseline demographics and clinical characteristics of trial groups

Characteristic	Tru Straight (n = 28)	Damon 3 (n = 24)
Mean age (SD) (y)	16.1 (7.4)	15.2 (6.8)
Sex, n (%)		
Male	15 (53.6)	9 (37.5)
Female	13 (46.4)	15 (62.5)
Ethnicity, n (%)		
White	26 (92.9)	23 (95.8)
Nonwhite	2 (7.1)	1 (4.2)
Incisor classification, n (%)		
Class I	10 (35.7)	6 (25.0)
Class II Division 1	7 (25.0)	13 (54.2)
Class II Division 2	6 (21.4)	2 (8.3)
Class III	5 (17.9)	3 (12.5)
Nonextraction, n (%)	19 (67.9)	16 (66.7)
Extraction, n (%)	9 (32.1)	8 (33.3)
Little's irregularity index mean (SD) (mm)	6.3 (4.0)	6.1 (4.2)
Little's maxillary irregularity index mean (SD) (mm)	8.0 (5.3)	7.1 (6.0)
Little's total irregularity index mean (SD) (mm)	13.9 (7.9)	13.3 (8.9)

No adverse events occurred during the clinical trial.

DISCUSSION

The study was designed to minimize potential bias and errors in accordance with the CONSORT statement.³² After consent and allocation, clinician and patient blinding of the bracket type was impossible. The difference in appearance of the bracket systems might have resulted in overestimation of the treatment effect, because the patients with the Damon 3 bracket could have assumed that, since the bracket was a more contemporary design, they would experience less pain and therefore recorded lower pain intensity. However, there was no way to avoid this.

Patient cooperation in returning the pain questionnaires was essential for the success of the trial. Of the 66 patients enrolled, 52 (78.8%) returned the questionnaire. The return rate compares favorably with previous response rates for randomized trials.³³ In this trial, no additional questionnaires were sent to the patients who failed to return them, because they could not be completed retrospectively. Patients were contacted by phone to remind them to return the completed questionnaires. The number of respondents was lower than that calculated in the sample size calculation. However, a retrospective power calculation showed that the power of this study was more than 80%; therefore, robust conclusions could be drawn.

Table II. Multivariable linear regression with maximum pain as the dependent variable

Variable	Estimated coefficient	95% CI	Test statistic	P value
Constant	90.64	63.62-117.65	—	—
Bracket type (code = 1) Damon 3 (code = 2) Tru Straight	11.77	-0.15-23.68	1.93	0.053
Little's maxillary irregularity index	1.02	-0.53-2.09	1.18	0.062
Analgesia (code = 1) no analgesia (code = 2) analgesia consumed	24.32	11.35-37.29	3.75	<0.001

Model adjusted R^2 : 0.33.

Seven operators were involved in this study, and differences in skill levels might have influenced the findings. However, the effect of the operators was not considered further because this was intended to be a "real-world" trial to establish how pain levels were influenced by several brackets placed by different clinicians.

After adjusting for Little's maxillary irregularity index and analgesia consumption, there was an 11.77-mm (95% CI, -0.15-23.68 mm) difference in mean maximum pain intensity between the 2 bracket groups, with the Damon 3 patients reporting lower mean maximum pain intensity than the Tru Straight patients; this difference was close to significant ($P = 0.053$). However, the clinically relevant difference used in the sample size calculation was 20 mm; therefore, it is unlikely that the difference between the 2 groups is clinically relevant. The lower mean maximum pain intensity with the Damon bracket might be due to the method of ligation and subsequent force applied to the teeth. Closure of the slide on the Damon 3 bracket passively engages the wire in the bracket slot; this might apply less active force than elastic modules (used with Tru Straight); thus, there is the potential for freedom of movement for a 0.014-in wire in the Damon 3 slot. This might be translated to the interbracket area, since the archwire can pass through adjacent brackets without being forced against the slot base, unlike the module that engages each bracket tightly. Furthermore, modules engage the tie-wings around the circumference of the bracket; this further reduces the interbracket span, compared with the Damon 3 slide.

In this study, it was not possible to prove that passive self-ligation (Damon 3) transmits less force to the tooth; currently, no studies (in vivo or in vitro) have compared force levels from different methods of archwire ligation. The force applied to the teeth by the combination of a 0.014-in copper-nickel-titanium archwire and the Damon 3 bracket has been described as "biologically

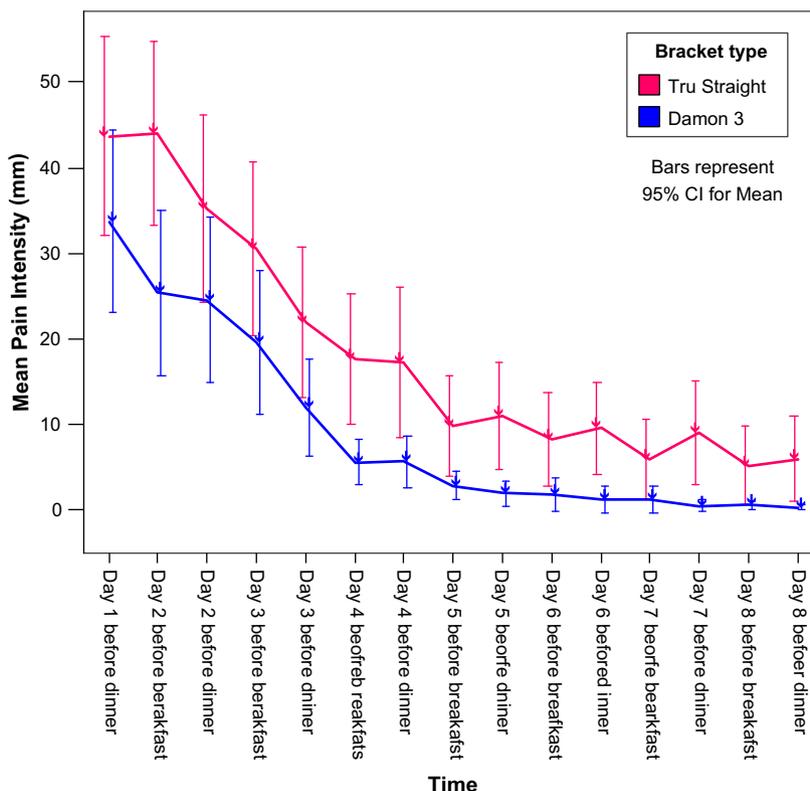


Fig 2. Mean pain intensity of the 2 groups over 8 days.

compatible.”^{12,20} However, the concept of a “biologically compatible” or “optimum” force is merely theoretical; large interindividual variations exist with a standardized force magnitude and, therefore, a lack of definable universal threshold.³⁴

There was no statistically significant difference between mean maximum pain intensity for the sexes; this agrees with some previous studies.^{9,12,16-18} In contrast to our findings, other studies have suggested that, on average, women report higher pain levels than do men.^{13,19}

No maximum age was an inclusion criterion, and, of the 52 patients who completed the trial, 44 (84.6%) were younger than 17 years. No statistically significant result was found between age and mean maximum pain intensity; this agrees with a previous study.⁹ Previous studies reported conflicting results regarding the effect of age on pain perception; several studies reported a significant correlation between age and pain intensity, with adolescents recording lower pain scores than adults.^{12,14,17} Other studies showed that adolescents generally report more pain than patients under 13 years.^{13,18}

Patients who consumed analgesics reported significantly higher ($P < 0.001$) mean maximum pain intensity than those who took none. The difference in mean values, after adjusting for bracket type and Little’s

maxillary irregularity index, was 24.32 mm; this is likely to be of clinical relevance, although there were wide 95% CIs (11.35-37.29 mm). The reason for the higher average pain intensity reported by patients who had consumed analgesics is not as a result of analgesia consumption; it is likely to be the opposite, patients are attempting to relieve pain by consuming analgesia. The association between severe pain and analgesic consumption was also observed in previous studies.^{13,16,17} Consumption of analgesics during the trial might have influenced pain perception and affected the reported pain intensity, but asking the patients not to consume analgesics would have been unethical.

Traditionally, there was believed to be a relationship between the severity of contact point displacement and resultant discomfort. In this study, there was no significant difference in mean maximum pain intensity as a result of irregularity measured with Little’s irregularity index, Little’s maxillary irregularity index, total Little’s irregularity index, or vertical canine displacement. The results agree with 2 studies about this relationship and found with no significant correlations.^{12,20}

Psychological factors might be important in determining a patient’s subjective reaction to orthodontic force, and this is possibly more important than the force

magnitude. This could explain the large variations in pain intensity reported previously and in this study.^{9,12-16} Emotional traits such as extroversion, anxiety, and depression have been shown to predict approximately half of the variability in postoperative outcome measures, including pain.³⁵ Anxiety lowers the pain threshold and can cause the perception of normally nonpainful stimuli as painful; patients reporting pain might be attempting to translate their feelings into a tangible physiologic problem.^{15,18,36} Cognitive factors such as motivation and expectation are also important in orthodontic treatment. Patients who believe their malocclusion is severe can control their emotions and perceive less intense discomfort from orthodontic treatment than those who do not consider their malocclusion severe.³⁷ Perceived pain and the consumption of pain relief might also decrease if the patient is informed about the severity of discomfort to be experienced.¹³

General linear model univariate ANCOVA showed a statistically significant difference ($P = 0.012$) between the mean pain intensity experienced by the 2 bracket types, with the Damon 3 patients reporting less pain, on average, than those in the Tru Straight group. There was no significant interaction between bracket type and time ($P = 0.312$), indicating that the difference between bracket types was consistent for all time points. As discussed previously, the difference in method of ligation is likely to result in less force transmitted to the teeth and therefore result in less pain. Figure 2 illustrates the difference in mean pain intensity between the 2 groups, although there are wide 95% CIs at all time points. As in the univariable analysis, patients who consumed analgesia reported significantly higher mean pain intensity than patients who did not ($P < 0.001$). The post-hoc analysis showed that mean pain intensity at day 1 before dinner was statistically significantly higher than mean pain intensity at day 2 before dinner and all subsequent time points. Mean pain levels appeared to reduce to minimal levels by day 4 as tissue tolerance increased.^{3,12,17}

CONCLUSIONS

1. Patients in the Damon 3 group reported lower mean maximum pain intensity (difference, 11.77 mm; 95% CI, -0.15-23.68 mm) than did the Tru Straight group. The result was close to significant ($P = 0.053$) but unlikely to be clinically relevant.
2. Damon 3 patients reported, on average, statistically significant lower mean pain intensity than did the Tru Straight patients ($P = 0.012$), and the difference between the bracket types was consistent at all time points.
3. Patients who consumed analgesia reported statistically significantly higher mean maximum pain intensity and mean pain intensity than those who took none ($P < 0.001$).
4. Patients reported statistically significant higher pain intensity on day 1 before dinner compared with day 2 before dinner and for all subsequent pain recordings.

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