Patient pain experience after placement of initial aligning archwire using active and passive self-ligating bracket systems: A randomized clinical trial

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Aim: To test whether there is any difference in pain perception during the week following placement of initial aligning archwire in active and passive self-ligating bracket systems. Methods: Seventy patients (mean age ± SD, 16.1 ± 2.3 years; 35 males and 35 females) were enrolled in this prospective randomized clinical trial. After appliance placement and engagement of a 0.016-inch round martensitic nickel-titanium (Ni-Ti) alloy archwire, pain levels were recorded after 4 hours; at bed time on the day of the appointment; after 24 hours; and after 2, 3, 4, 5, 6, and 7 days using a nine-page visual analog system (VAS) questionnaire. The use of pain medication self-administered by the patient was also recorded. Independent sample t tests were used to analyze normally distributed data obtained from VAS measurements. Results: Sixty (85.71%) patients completed the trial. The type of self-ligating bracket had a significant influence on the pain experienced at 4 hours (P = .03), bed time (P = .05), 24 hours (P = .04), and 2 days (P = .05) after placement of initial aligning archwire. Conclusion: The type of self-ligating bracket system had a significant difference on subjective pain experience after placement of the initial aligning archwire. Patients treated with active self-ligating appliances experience significantly higher pain levels until the second day compared with patients treated with passive self-ligating appliances. ORTHODONTICS (CHIC) 2012;13:e58–e65.

Key words: aligning archwire, orthodontic pain, self-ligating

Pain is defined as an unpleasant emotional experience, usually initiated by a noxious stimulus and transmitted over a specialized neural network to the central nervous system, where it is interpreted as such. The application of orthodontic forces causes a disruption of the periodontal tissue, initiating a cascade of events involving the release of inflammatory mediators (such as serotonins, histamines, bradykinins, and prostaglandins) into the local environment, resulting in an inflammatory response that elicits pain. Pain experienced after placement of the initial aligning archwires has been consistently cited as an unpleasant experience by patients undergoing fixed appliance orthodontic therapy, even when compared with other invasive pro-
cedures such as extractions. Peak pain levels experienced after placement of initial aligning archwires have been shown to rise until the second or third day and gradually reduce until the fifth or sixth day. Pain perception during initial orthodontic therapy has been known to influence treatment continuation and compliance. Hence, low pain levels experienced during initial orthodontic therapy would help in improving patient compliance during the later stages of treatment.

Pain during orthodontic treatment has been observed to be influenced by age, sex, archwire material, social class, degree of force applied, dental arch relationships, and dental crowding. The nature of pain perceived has also been shown to be influenced by the type of bracket system used.

The initial stages of fixed appliance orthodontic therapy are primarily concerned with the alignment of individual dental units, which is relative to the wire-bracket relationship. Based on the premise of clinically efficient and rapid alignment, self-ligating brackets were introduced. A self-ligating bracket is “a bracket which utilizes a permanently installed, moveable component to entrap the archwire”. Although self-ligating bracket systems have gained popularity, their origins can be traced back to the 1930s when Charles E. Boyd introduced the Boyd band bracket. However, this particular bracket system did not enjoy much popularity among orthodontics since it was expensive and bulky. In recent years, several new self-ligating bracket designs have been introduced and enjoyed increased popularity.

Self-ligating brackets may be categorized into two groups: active and passive. Active self-ligating brackets have a flexible component that encases the archwire in the slot and stores energy to press against the wire for rotation and torque correction. Passive self-ligating brackets use a rigid moveable component that can be opened or closed to allow for placement or removal of the wire in the slot. This rigid component by itself does not apply any active force on the archwire.

Although earlier studies have investigated patient pain experiences upon placement of initial aligning archwires with self-ligating and conventional brackets, there is, however, no study that has compared pain levels associated with active vs passive self-ligating bracket systems during initial alignment.

The present study was designed to investigate whether there is any significant difference in pain levels after placement of the initial aligning archwire with an active (In-Ovation-R, GAC) vs passive self-ligating bracket system (Damon-MX, Ormco).

METHODS

Subjects
Seventy patients (mean age ± standard deviation [SD], 16.1 ± 2.3 years; 35 males and 35 females) were enrolled in this study from a pool of prospective orthodontic patients from the first author’s office (Fig 1). A minimum overall sample size of 60 patients (power, 80%) was proposed after conducting a power analysis, keeping in mind previous publications on pain experiences with different bracket systems during initial alignment. To allow for drop-out patients and noncompliance with data recording, 10 additional patients were recruited.

Selection criteria were patients who (1) were at least 13 years of age and not older than 20 years of age, (2) were beginning orthodontic treatment for the first time, (3) were not currently using antibiotics or analgesics, and (4) had a Class I malocclusion with mild anterior crowding necessitating a nonextraction treatment protocol in both the maxillary and mandibular arches.
In addition, all patients were required to provide written informed consent for participation in the trial.

Seventy patients were randomly allocated to the two treatment groups: Group A was the active self-ligation group, and group B was the passive self-ligation group. Group A patients received Roth prescription In-Ovation-R brackets, and group B patients were bonded with medium torque Damon-MX brackets. Both brackets had 0.022-inch slots. In all patients, both the maxillary and mandibular arches were bonded. First molar attachments were also bonded. No bands were placed on any teeth. No bite planes, lingual arches, transpalatal arches, quad helices, or headgear were employed for any patient. In all patients, 0.016-inch round martensitic nickel-titanium (Ni-Ti) alloy archwire (3M Unitek) was ligated in all the patients. The archwire was cut distally to the first molar tube and not cinched. All patients were blinded as to which bracket system had been placed in their mouths. All patients were treated by the first author. Patient education booklets with information on appliance maintenance and oral hygiene instructions were distributed to all patients.

Data collection
The visual analog scale (VAS) was chosen to measure the degree of discomfort/pain. A 10-cm horizontal VAS scale was distributed to all the patients, in the form of a nine-page questionnaire booklet. The VAS questionnaire was designed with anchors of no pain at all (0 cm) and worst pain imaginable (10 cm). Patients were asked to rate their expectation of pain consequent to the placement of the initial aligning archwire on this VAS scale. These were recorded by the patients at the following time intervals: 4 hours posttreatment; at bed time on the day of the appointment; after 24 hours; and after 2, 3, 4, 5, 6, and 7 days after the ligation of the initial aligning archwire. Subsequently, measurements were made of the distance from the left margin of the line to the recorded score.
Patients were asked to refrain from taking any analgesics. If any medications were taken within the time frame of the trial, they were asked to make a note of the date, dosage, time, and name of the drug taken in the booklet.

Of the 70 patients who participated in the study, 60 patients returned the completed pain questionnaire booklet (see Fig 1). Of these 60 patients, 38 used some kind of rescue medication (self-prescribed analgesic medication).

**Statistical analysis**
The power calculation for sample size was carried out using Stata Release 9.1 (StataCorp). Data analysis inclusive of descriptive and analytic statistics was performed using SPSS for Windows 10.0 (IBM). Descriptive statistics were measured for pain scores at each time interval as defined earlier for the experimental groups. Comparisons between the two experimental groups were made using the Student $t$ test. Differences between the two groups with regard to pain intensity at different time intervals were measured using the independent sample $t$ test. In this study, the level of significance was determined to be $P < .05$.

**RESULTS**
Seventy subjects, equally distributed between two groups, were enrolled in the trial. Group A patients were bonded with Roth prescription In-Ovation-R (mean age ± SD, 16.7 ± 2.1 years), and group B patients were bonded with medium torque version Damon-MX (mean age ± SD, 15.6 ± 2.9 years).

Ten patients (five from each group) failed to return or complete the pain questionnaire after 7 days and were excluded from the analysis (see Fig 1). The return rate was assessed to be 85.71%. The final sample consisted of 60 patients (see Fig 1). Descriptive statistics for the two experimental groups are given in Table 1. There was no statistical difference between the mean ages of the patients in the three groups. The data (mean pain scores using VAS data measured in the two groups) (Fig 2) were tested for normality using the Shapiro Francia test and was found to be normally distributed. Therefore, an independent sample $t$ test was used to assess whether there were statistically significant differences between the groups at each time interval.

**Intensity of pain**
Mean pain scores by the patients in the two experimental groups are given in Table 2. The findings demonstrate that the changes in pain assessment were clearly perceivable over time. There were significant differences in pain perceived by individuals between the two groups at 4 hours, at bed time, 24 hours, and 2 days after placement of the initial aligning archwire. There were no significant differences at 3, 4, 5, 6, or 7 days after placement of the initial aligning archwire.

<table>
<thead>
<tr>
<th>Group</th>
<th>Type of self-ligating appliance</th>
<th>No. of patients</th>
<th>Mean age</th>
<th>Sex</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Male</td>
</tr>
<tr>
<td>A</td>
<td>Active</td>
<td>30</td>
<td>16.7</td>
<td>2.1</td>
<td>15</td>
</tr>
<tr>
<td>B</td>
<td>Passive</td>
<td>30</td>
<td>15.6</td>
<td>2.9</td>
<td>15</td>
</tr>
</tbody>
</table>

SD, standard deviation.
Patient’s pain after initial placement of aligning archwires.

Table 2 Mean ± SD pain scores using VAS data of experimental groups

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>Group A (In-Ovation R System)</th>
<th>Group B (Damon-MX System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 h</td>
<td>5.3 ± 2.4</td>
<td>4.6 ± 2.4</td>
</tr>
<tr>
<td>At bed time</td>
<td>6.1 ± 2.0</td>
<td>5.1 ± 2.2</td>
</tr>
<tr>
<td>24 h</td>
<td>6.5 ± 1.9</td>
<td>5.9 ± 2.1</td>
</tr>
<tr>
<td>2 d</td>
<td>5.7 ± 2.3</td>
<td>5.2 ± 1.8</td>
</tr>
<tr>
<td>3 d</td>
<td>4.8 ± 2.1</td>
<td>4.4 ± 2.3</td>
</tr>
<tr>
<td>4 d</td>
<td>3.5 ± 1.8</td>
<td>3.2 ± 1.8</td>
</tr>
<tr>
<td>5 d</td>
<td>3.3 ± 1.9</td>
<td>2.9 ± 1.5</td>
</tr>
<tr>
<td>6 d</td>
<td>3.1 ± 2.0</td>
<td>2.7 ± 1.8</td>
</tr>
<tr>
<td>7 d</td>
<td>2.6 ± 1.6</td>
<td>2.4 ± 2.1</td>
</tr>
</tbody>
</table>

SD, standard deviation.

Table 3 Groupwise breakdown of patients reporting usage of self-prescribed analgesic medication

<table>
<thead>
<tr>
<th>Self-prescribed analgesic medication</th>
<th>Group A (n [%])</th>
<th>Group B (n [%])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>21 (70)</td>
<td>17 (56.66)</td>
</tr>
<tr>
<td>Paracetamol once a day for 1 d</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Paracetamol once a day for 2 d</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Paracetamol once a day for 3 d</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Paracetamol twice a day for 1 d</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Paracetamol twice a day for 2 d</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Paracetamol twice a day for 3 d</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ibuprofen once a day for 1 d</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Ibuprofen once a day for 2 d</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ibuprofen once a day for 3 d</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Pain medication
Thirty-eight patients (63.33%) analyzed in this study resorted usage of rescue medication (Table 3). Seventy percent of patients from group A used analgesic medication, while 56.66% of group B used pain medication. The chi-square test corroborated that bracket type had an influence on the level of analgesic medication during the study period. The need for pain medication was highest at the second day after placement of the initial aligning archwire; by the third day, none of the patients used any pain medication in group B. In group A, though, a few patients used analgesic medication on the third day (Table 3).
DISCUSSION

This investigation was designed to analyze the perceived discomfort caused after placement of an initial aligning 0.016-inch round martensitic nickel-titanium (Ni-Ti) alloy archwire (3M Unitek) in patients bonded with active and passive self-ligating bracket systems.

Patients in both groups were asked to record the level of pain/discomfort in a VAS questionnaire booklet at specified time intervals. The VAS scale is one of the most commonly used tools in measurement of perceived pain/discomfort\(^4,17–19\) and has been proven to be a reliable and accurate tool with good reproducibility.\(^20–22\) However, this scale measures the subjective experiences of the patients, thereby providing only a global measure of pain/discomfort and does not help the patient distinguish between the different sources of pain/discomfort.\(^15\)

The use of a self-prescribed analgesic log by the patients gave another independent form of assessment for the degree of pain the subjects were experiencing. The experimental groups had been formed in such a way that there was an equal number of males and females in each group (see Table 1). Care was taken to ensure that patients with similar malocclusions and social backgrounds were selected.\(^23\) Due to the equivalence among the patients in both groups in parameters such as sex distribution, age, and degree of malocclusion, these factors were not likely to have confounded the results.\(^14\)

The initial stage of the orthodontic treatment is a painful process. In this study, it was observed that there was no significant difference in pain experienced by males and females. This is in accordance with previously known findings that sex does not influence perceived pain during orthodontic therapy.\(^4,15\) Analysis of data obtained from VAS records and self-prescribed analgesia records revealed that patients enrolled in group A experienced significantly greater levels of pain/discomfort than patients in group B at 4 hours, bed time, 24 hours, and 2 days after placement of the initial aligning archwire.

Also, it was observed that a large proportion (70\%) of patients bonded with Roth prescription In-Ovation-R brackets resorted to the use of self-prescribed analgesic medication compared with patients who were bonded with the medium torque Damon-MX brackets (see Table 3). The use of self-prescribed analgesic medication was observed until 3 days after placement of the initial aligning archwire in the In-Ovation-R group. The requirement for analgesia in the current study was also high, at more than 63.33\% of participants. This further underscores the severity of orthodontic pain. It would therefore be prudent to prescribe preemptive analgesia, particularly in patients with low pain thresholds.\(^24–26\)

Perceived levels of pain/discomfort experienced after placement of initial aligning archwire peaked 24 hours after the procedure, which gradually abated until the third day—this was in accordance with previous studies.\(^4\) It was observed that the In-Ovation-R group experienced significantly greater levels of discomfort than the Damon-MX group, rendering the Damon-MX appliance more comfortable to the patient. In general, analgesics were mostly used by patients who reported a higher intensity of pain. Although no study has been conducted comparing pain experiences after placement of initial aligning archwires in passive vs active self-ligating bracket systems, the results of our investigation seem to be in agreement with several preceding studies.\(^10,11,15,27\) These studies suggest that passive self-ligating bracket systems are more comfortable and would therefore help increase patient compliance.

Patients treated with passive self-ligating bracket systems recorded significantly lower pain measurements than patients treated with an active self-ligating bracket system (see Table 2), thereby lending credence to the fact that lower
friction may have an effect on tooth movement and result in less pain. With studies reporting no significant differences between active and passive self-ligating bracket systems with respect to treatment duration, crowding alleviation or number of visits required, it would be practical to use a passive self-ligating bracket system in view of lesser pain experienced by the patients during the early stages of treatment, which would help improve patient compliance.

CONCLUSION

The following can be concluded from this study:

- Patients treated with active self-ligating appliance experience significantly higher pain levels until the second day compared with patients treated with passive self-ligating appliances after placement of the initial aligning archwire.
- Sex and age have no effect on perceived pain experienced by patients undergoing fixed appliance orthodontic treatment.
- Perceived peak pain levels after engaging the initial aligning archwire rise until 24 hours after the procedure and then gradually reduce by the third day. Pain is minimal by the seventh day.

REFERENCES