Archives of Orofacial Sciences
The Journal of the School of Dental Sciences
Universiti Sains Malaysia

Arch Orofac Sci (2014), **9**(1): 1-9.

Original Article

Pain experience during initial alignment with self-ligating and conventional brackets

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Revised edition: 15/09/2013. Accepted: 18/02/2014. Published online: 18/02/2014.

Abstract The aim of this study was to compare the pain experience among orthodontic patients treated with self-ligating brackets SmartClip® (3M Unitek, Monrovia, California, USA) and conventional brackets Victory series® (3M Unitek, Monrovia, California, USA). We used a controlled clinical trial study design to compare 69 patients treated with self-ligating to 70 patients treated by conventional brackets. The nickel-titanium archwires 0.012-in were engaged after bonding both arches on the first day; and the visual analogue scale (VAS) was used to assess the pain experience of subjects for the first seven treatment days. The pre-treatment dental study models were assessed by the Little's irregularity index to quantify the groups' malalignment characteristics. The self-ligating brackets reported lower pain experience than the conventional group on the first five treatment days. However, the sixth day showed 1.75 mm higher visual analogue score than conventional brackets, with almost equal pain level on the seventh day. The group differences throughout the first week were neither clinically nor statistically significant. The pain experiences in both groups decreased steadily from the third treatment day to the end of the first week of treatment. Based on the study findings, the pain experience during initial alignment is not influenced by the brackets' ligation type. The pain experience tends to decrease steadily from the third treatment day to the end of the first week of treatment irrespective of the bracket type used.

Keywords: Conventional brackets, orthodontics pain, self-ligating brackets, visual analogue score.

Introduction

The brackets with inbuilt ligating mechanisms have existed since 1935 (Stolzenberg, 1935). More certain archwire engagement, low friction and patients' comfortability are some of the reported characteristics of these self-ligating brackets (SLBs) (Harradine, 2003; Shivapuja and Berger, 1994; Thorstenson and Kusy, 2001), Although they are now widely used (Prettyman *et al*., 2012), their clinical advantages, besides saving chair side time are not clearly demonstrated by clinical trials (Chen *et al*., 2010; Machibya *et al*., 2013; Maijer and Smith, 1990; Paduano *et al*., 2008; Turnbull and Birnie, 2007). Apart from treatment effectiveness, the possible side effects of any therapeutic product in clinical application are among the factors to consider during treatment planning. Self-ligation is thought to have good impact on the patients' pain experience, oral hygiene practices and root resorption associated with fixed orthodontic treatment (Harradine, 2003; Pellegrini *et al*., 2009; Pandis *et al*., 2008; Pandis *at al*., 2010). The experience of discomfort and pain is a common situation during orthodontic treatment (Fernandes *et al*., 1998; Bergius *et al*., 2000). Ninety-one percent of adult patients wearing fixed orthodontic appliances reported pain in Singapore (Lew, 1993); whereas the prospective investigations of both children and adults in Switzerland and Norway revealed that 95% of patients experienced pain during orthodontic treatment (Scheurer *et al*., 1996; Kvam *et al*., 1987). The pain during orthodontic tooth movement is thought to originate from a combination of pressure, ischemia, inflammation, and edema in the surrounding tissues (Furstman and Bernick, 1972). Previous clinical trials have reported inconsistent results on patients' pain perception that causes difficulties for clinicians in making choices of bracket systems (Pringle *et al.,*

2009; Scott *et al.,* 2008; Miles *et al.,* 2006; Fleming *et al.,* 2009). While Scott *et al.* (2008) and Fleming *et al.* (2009) reported no difference between conventional brackets (CBs) and SLBs, Pringle *et al.* (2009) and Miles *et al.* (2006) found lower pain in the SLBs group. A well designed clinical trial with large sample size was recommended to further explore the possible differences between the two bracket groups (Fleming and Johal, 2010). The current study therefore aimed at examining the pain experience among patients treated with the SLBs (SmartClip, 3M Unitek, Monrovia, California, USA) compared to those treated with the conventional brackets CBs (Victory Series, 3M Unitek, Monrovia, California, USA).

Material and methods

The ethical approval for this controlled clinical trial study was obtained and approved by the Jilin University Scientific committee (Dated: 16th July 2011). The research subjects were obtained from a sample of consecutive cases based on the following criteria: patients not younger than 10 years at the beginning of treatment, no tooth extraction indication in the treatment plan, no previous history of orthodontic treatment, patients with permanent vital teeth including first molars; no additional appliance in the first week of active fixed orthodontic treatment, patients without systemic medical conditions, and those not on any regular medication. Based on the previous study (Scott *et al*., 2008), sixty-eight research subjects per group were required to detect the intended minimum clinically significant difference of 10 mm visual analogue scale (VAS) in overall maximum pain experience at 0.05 significance level, 80% power and standard deviation of 23.3 mm VAS. Considering the possibility of subjects' dropout, the present study enrolled 176 patients who attended the orthodontic clinic at the Jilin University Dental Hospital between August 2011 and April 2013. Only 81.25% (143) returned the VAS questionnaires. Of the returned questionnaires, 4 were excluded from the final analysis for indicating use of antibiotics and corticosteroids to treat systemic diseases suffered during data collection. Eventually 139 subjects (110 females and 29 males) were involved in the final analysis (Fig. 1). The subjects' mean age at the start of treatment was 14.97 years. The first group (SLB) consisted of 69 subjects treated by the SmartClip (3M Unitek, Monrovia, California, USA) brackets. The second group (CB) consisted of 70 subjects treated by the conventional pre-adjusted brackets Victory series (3M Unitek, Monrovia, California, USA). One operator (MH) treated all subjects in both groups (SLBs and CBs) following the same treatment protocol.

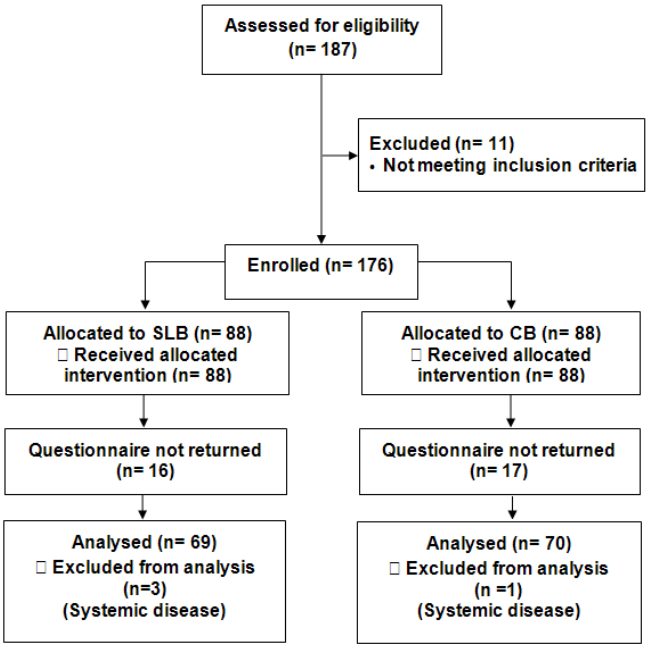

Fig. 1 A CONSORT flow diagram of the progress through the phases of the controlled clinical trial.

The groups were based on the subjects' choice after being educated about the available bracket systems. The pre-adjusted edgewise self-ligating brackets SmartClip (3M Unitek, Monrovia, California, USA) and the conventional Victory series (3M Unitek, Monrovia, California, USA) with the MBT values (MBT Versatile+ Appliance, 3M Unitek, Monrovia, California, USA) for tip and torque with 0.022-inch slot were bonded in the SLBs and CBs groups respectively according to the subjects' choice (Fig. 2 and Fig. 3). After brackets bonding, 0.012-inch round nickel-titanium (NiTi) alloy archwires (3M Unitek, Monrovia, California, USA) were fully engaged in all

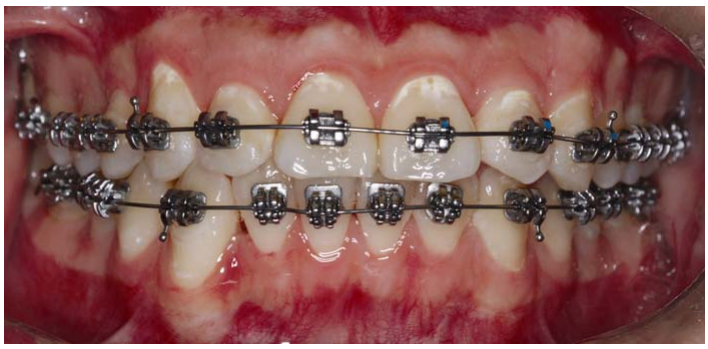

Fig. 2 Self-ligating brackets engaged with 0.012 NiTi archwire in a patient treated by SLBs (SmartClip).

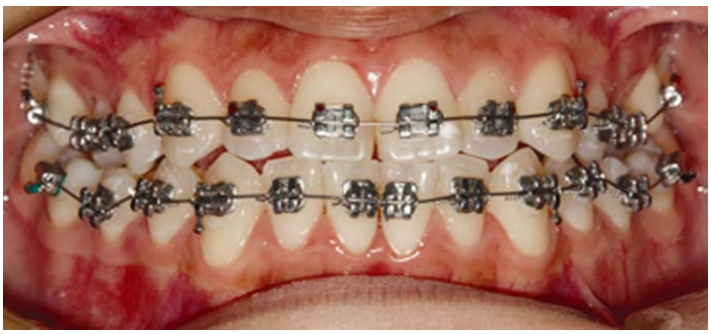

Fig. 3 Stainless steel wire ligation with 0.012 NiTi archwire engaged in a patient treated by CBs (Victory series).

Fig. 4 A 10-cm visual analogue scale used for recording pain experience.

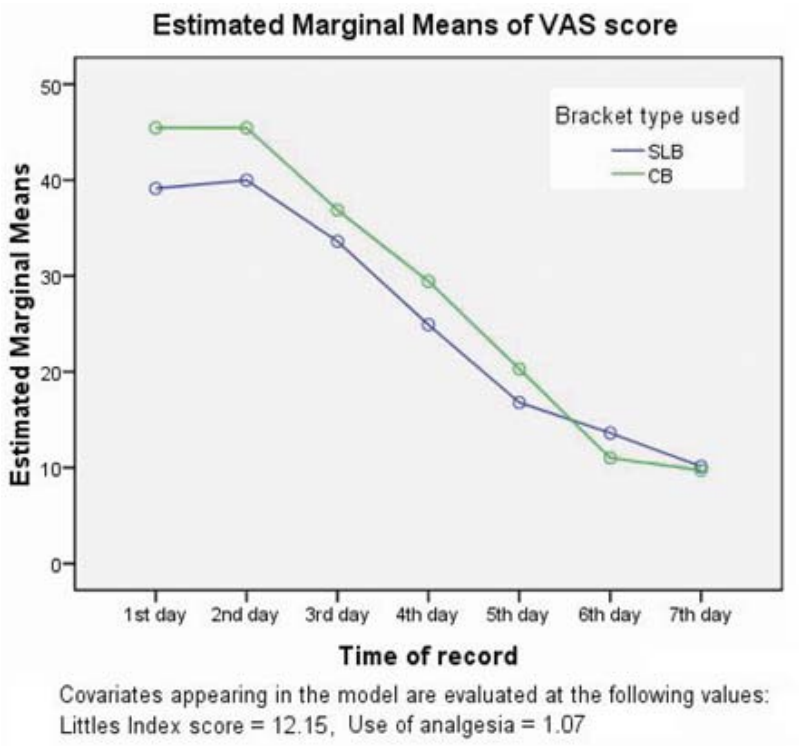

Fig. 5 The adjusted VAS mean score trend for the two groups over seven days.

subjects. The CBs in this study were ligated with 0.010" stainless steel wire (Hangzhou ALS Dental appliance Co., China) (Fig. 3).

Following archwire insertion, the subjects were given oral hygiene and appliance maintenance instructions. Questionnaires were given to all subjects who consented to participate in the study. The questionnaire inquired of the pain experience, intraoral trauma, appliance breakage, medication and systemic illness during the first week of treatment.

The questionnaire was structured to record the subjects' pain experience at the 4^{th} hour following the appliance placement on the first day, and every morning before breakfast on the consecutive days during the first week of fixed orthodontic treatment.

The visual analogy scale (VAS) was used to assess subjects' pain experience. It was made of 3 mm wide, 100 mm long horizontal line labeled "No pain" (at 0 mm) and "Worst pain" (100 mm). The scale was filled with red to green color gradient (Fig. 4). Each subject was asked to place a mark on the line point that best corresponded to the level of pain experienced at the appropriate time.

The subjects also reported any medication taken to alleviate orthodontic pain during the study period, providing type and quantity of medications used. Beside analgesics, the subjects were also requested to record any other medication taken during research period. Intraoral trauma due to orthodontic appliance or other causes and any systemic illness suffered in the first week of treatment were recorded. The subjects were requested to return the completed questionnaire on their next visits.

The averages of three readings of VAS measured using a digital caliper (Dentaurum, Germany) from the 0 mm end to the point marked by the subjects were recorded as pain experience score of an individual subject at that particular time. On the pre-treatment study models, the Little's irregularity index (Little, 1975) was used to quantify the degree of malalignment of the six anterior teeth in the mandible and the maxilla by using a digital caliper (Dentaurum, Germany). All VAS and dental study models measurements were done by the same investigator who was blinded both to the bracket type and subjects' names.

The descriptive and analytical statistics were performed with SPSS for Windows version 13.0 software (SPSS Inc, Chicago, Illinois). The data showed a normal distribution tendency; hence we applied the parametric statistical analysis, with level of statistical significance set at $p<0.05$. We randomly selected 40 dental study models for error study, to test the examiner's accuracy and consistency in evaluating the study models. The dental study models were measured twice at the interval of five days to obtain two sets of data. The paired sample *t* test showed no significant mean differences between the two series of records, with a method error of less than 0.5 mm (Dahlberg, 1940).

Results

A total of 176 patients were enrolled as research subjects in the study, 81.25% (143) returned the pain questionnaires. Four of the returned questionnaires were excluded from the study. Hence, only 139 (79%) patients were included in the final analysis (Fig. 1). Table 1 shows the baseline demographics and clinical characteristics of the subjects. We employed an independent samples *t*-test to compare the age and Little's Irregularity Index score between the two groups. The groups were not statistically significantly different regarding age and pretreatment irregularity ($p=0.96$) and ($p=0.16$) respectively. A chi squared test also confirmed no significant difference between the respective groups by sex ($p=0.53$). Table 2 shows the overall maximum pain score recorded on any day during research period and the daily mean pain scores. The SLB group reported lower pain experience than the CB group on the first five treatment days. However, the sixth day showed 1.75 mm higher VAS score than CB, with almost equal pain level VAS score on the seventh day (Table 2). Nonetheless the analysis of covariance (ANCOVA), using the analgesia consumption and pre-treatment irregularity as co-variables showed no statistically significant difference between the groups (Table 3). The overall maximum pain score

was not affected by the bracket type used (Table 3). Figure 5 illustrates the adjusted VAS mean score trend for the two groups over seven days. The pain experience in both groups decreased steadily from the third day to the end of the first treatment week. The univariable analyses with the overall maximum VAS score as dependent variable showed that the Little's irregularity index had significant correlation with maximum VAS score at $p<0.05$, whereas the pain was not significantly influenced by subjects' gender ($p=0.078$), age ($p=0.17$) and analgesia consumption ($p=0.098$), with only 13.7%(19) of subjects reporting the use of analgesia in our study.

Table 1 The baseline demographics and clinical characteristics of participants

Variables	SLB	CB	Overall
Patients' sex			
Male N (%)	12 (8.6)	17 (12.2)	29 (20.9)
Female N (%)	57 (41.0)	53 (38.1)	110 (79.1)
Patient age at treatment Mean (SD)			
	15.91 (4.76)	15.20 (3.52)	14.97 (4.18)
Little's degree of discrepancy Mean (SD)			
	11.71 (3.96)	12.59 (3.82)	12.15 (4.59)
Malocclusion N (%)			
Class I	45 (32.4)	41 (29.5)	86 (61.9)
Class II	14 (10.1)	24 (17.3)	38 (27.3)
Class III	10 (7.2)	5 (3.6)	15 (10.8)

N = Absolute number

Table 2 The overall maximum pain score recorded on any day during research period and the daily mean pain scores.

Time of record	Bracket type used	Mean	Std. Deviation
Overall Maximum VAS score			
Maximum pain	SLB	47.39	22.27
	CB	49.57	18.83
	Overall	48.49	20.56
Daily mean VAS score			
1st day	SLB	38.70	20.86
	CB	45.86	22.48
	Overall	42.30	21.91
2nd day	SLB	39.56	22.45
	CB	45.86	18.37
	Overall	42.73	20.67
3rd day	SLB	33.19	20.61
	CB	37.28	17.35
	Overall	35.25	19.08
4th day	SLB	24.49	19.44
	CB	29.85	15.17
	Overall	27.19	17.57
5th day	SLB	16.38	16.35
	CB	20.71	14.77
	Overall	18.56	15.67
6th day	SLB	13.18	16.31
	CB	11.43	11.45
	Overall	12.30	14.05
7th day	SLB	9.710	11.87
	CB	10.14	11.22
	Overall	9.928	11.51

Table 3 The adjusted mean and 95% confidence interval (37 SLBs and 36 CBs), ANCOVA with analgesia consumption and Little's Index scores as co-variables.

Bracket type	mean	95% CI			Adjusted effect size
	Adjusted	Lower	Upper	*p*	
Maximum					
SLB	47.21	45.42	48.99	0.102	0.054
CB	49.86	48.09	51.63		
1st day					
SLB	38.57	36.65	40.48	0.086	0.034
CLB	45.97	44.06	47.87		
2nd day					
SLB	39.35	37.59	41.11	0.120	0.084
CB	46.17	44.42	47.92		
3rd day					
SLB	33.08	31.43	34.70	0.346	0.387
CB	37.62	36.00	39.24		
4th day					
SLB	24.39	22.89	25.88	0.115	0.086
CB	30.15	28.67	31.64		
5th day					
SLB	16.25	14.90	17.59	0.128	0.074
CB	20.95	19.61	22.28		
6th day					
SLB	13.10	11.86	14.33	0.434	0.029
CB	11.58	10.35	12.80		
7th day					
SLB	9.68	8.66	10.69	0.896	0.024
CB	10.27	9.26	11.28		

Discussion

This prospective study compared the pain experience after initial placement of the two different pre-adjusted fixed appliance systems (SmartClip and Victory Series). The SmartClip and Victory Series brackets were selected for this study because of their common use by the present research team and have the same MBT Versatile+ Appliance (3M Unitek, Monrovia, Calif, USA) prescription. It was designed to exclude the possible confounders by strict inclusion criteria as mentioned in the methodology section. The criteria excluded patients who might have experienced pain from sources other than the bracket systems such as tooth extraction, systemic diseases, trauma and additional orthodontic appliances like mini-implant, head gear, transpalatal arch, lingual arch, pendulum, twin block and Nance arch in the first week of treatment. The influence of analgesia and the irregularity severity was taken into account by the analysis of variance (ANCOVA) and the consumption of medicaments other than analgesia lead to exclusion from the study. The lack of randomization however is one of the weaknesses of this controlled clinical trial. The patients' preference rather than randomization, may have introduced biasness in our study. Patients who chose the relatively expensive SLBs may have perceived the system to be superior over CBs; this may lead to the group to report lower pain than the actual pain level. Nevertheless, the results are comparable with some previous randomized clinical trials (Scott *et al.*, 2008; Fleming *et al.,* 2009).

The pain experience was measured using VAS, which is one of the most commonly used tools in the measurement of perceived discomfort during orthodontic treatment (Pringle *et al.,* 2009; Scott *et al* 2008; Miles *et al.,* 2006). The tool is said to be reliable and readily understood by most patients, demonstrating good sensitivity between small changes and good reproducibility (Huskisson, 1974; Scott and Huskisson, 1979). However, the method's specificity is low; it does not allow the subject to distinguish between different sources of pain, e.g. pain associated with the mini implant or post extraction; tooth or

soft tissues. The strict inclusion criteria and the analysis for confounding factors are the techniques to improve the validity of the findings.

A number of studies have investigated gender, age and severity of crowding in relation to pain during orthodontic treatment (Fernandes *et al.,* 1998; Pringle *at al.,* 2009; Scott and Huskisson, 1979; Jones and Chan, 1992; Jones, 1984). The current study found no significant correlation between age and the overall maximum VAS score; this is in agreement with previous studies (Pringle *et al.,* 2009; Ngan *et al.,* 1989). On the other hand, some studies reported significant correlation between age and pain intensity, with adolescents experiencing lower pain scores than adults (Fernandes *et al.,* 1998; Jones and Chan, 1992; Jones, 1984). Other studies reported more pain among patients less than 13 years of age (Scheurer *et al.,* 1996; Brown and Moerenhout, 1991).

While some previous studies have suggested that, on average, women report higher pain levels than do men (Scheurer *et al.,* 1996; Kvam *et al.,* 1987); our study found no significant gender difference on pain experience. This agrees with some previous studies (Jones and Chan, 1992; Jones, 1984; Ngan *et al.,* 1989; Brown and Moerenhout, 1991). Moreover, the investigation showed no correlation between pain perceived and analgesic use with only 13.7% of subjects reporting the use of analgesia. This may be due to the use of smallest size of archwire that would cause low pain which can be tolerated by the patients. The finding is consistent with the study by Scott and Huskisson (1979). Conversely; some studies have reported significant association between the perceived discomfort and analgesic consumption (Scheurer, 1996; Pringle *et al.,* 2009; Jones, 1984).

Clinical observations have suggested that there is relationship between the severity of crowding and the forces applied by a fully engaged initial archwire, meaning the more severe the crowding, the heavier the forces exerted; thus the more pain experienced (Bergius *et al*., 2000). In our study, the overall maximum pain was significantly correlated to the degree of irregularity, measured by Little's index (p<0.05). The finding is in contrary to Pringle et al. (2009) who reported no significant difference with P value of 0.062: Hence, the difference may be attributed to the large sample size in the current study. Still, other clinical studies have reported no significant association between the severity of dental displacement and the perceived discomfort during initial orthodontic treatment (Jones and Chan, 1992; Jones, 1984).

Several studies investigating the perceived pain and discomfort between self-ligating and conventional bracket systems have reported contradicting findings (Fernandes *et al.,* 1998; Pringle *et al.,* 2009; Scott *et al.,* 2008; Miles *et al.,* 2006; Fleming *et al.,* 2009). The study designs, subjects and the bracket systems used could be the reasons for the inconsistencies. The elastomeric ligatures used in some studies (Pringle *et al.,* 2009; Miles *et al.,* 2006) for instance, may not have the same archwire pressing effect as that of stainless steel ligation wires; and the SmartClip brackets may cause slight pain during archwire placement and removal which may not be the case with the Damon brackets.

This study found no statistically significant difference between the two groups regarding pain experience on daily records of the first treatment week and the overall maximum VAS score. The outcome of this study is consistent with other studies (Scott *et al.,* 2008; Fleming *et al.,* 2009) which reported no difference in pain experience between SLBs and CBs groups except during archwire engagement and removal which showed significant higher pain in the SmartClip than the Victory group. Our findings are in contrast with Pringle *et al.* (2009) who found lower pain experience in the Damon3 group, and Miles et al. (2006) who reported lower pain in Damon 2 group during initial treatment time. This may be attributed to the difference in slot closure mechanics between the Damon and the SmartClip (SLB) used in the current study; and the difference in type and size of achwires used.

The first two treatment days in our study had the high overall pain experience above 40 mm VAS score, the pain level progressively declined to around 35 mm and 27 mm on the third and fourth days. This reflects the common finding on the appliance-related pain which tend to decline nearing baseline level by the end of the first treatment week (Bergius *et al.,* 2000; Pringle *et al.,* 2009; Scott *et al.,* 2008; Fleming *et al.,* 2009; Jones and Chan, 1992; Jones, 1984). The phenomenon is supported by the physiological studies which reported that the tissue under continuous stimulation tend to adapt; thus, painful experience becomes steadily weaker and may finally disappear (Burns and Dallenbach, 1934; Stone and Dallenbach, 1934). Even so, the physiology of pain adaptation is beyond the scope of this study.

While the differences in VAS scores between the groups on the first and the second treatment days (7.16 mm and 6.30 mm respectively) were relatively higher; the trend declined to 1.75 mm on the sixth day and almost equal pain experience on the seventh day of treatment (Table 2). The observed differences were smaller than the preset minimum clinically significant VAS (10 mm); they were also not statistically significant. Clinicians should therefore consider factors other than pain experience during initial fixed orthodontic treatment for differentiating the two bracket systems' clinical performances.

Conclusions

Based on the findings, the pain experience during initial alignment is not influenced by the brackets' ligation type and tends to decrease steadily from the third treatment day to the end of the first week of treatment irrespectively.

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