Original Article

Self-ligating brackets do not reduce discomfort or pain when compared to conventional orthodontic appliances in Class I patients: a clinical study

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ABSTRACT

Objectives: To compare the intensity, location, and short-term impact of the periodontal discomfort/ pain, as well as the related functional parameters of bite force and masticatory efficiency, between self-ligating and conventional orthodontic appliances.

Materials and Methods: In 20 patients referred for orthodontic treatment, samples were collected from the gingival sulcus to evaluate the level of substance P using enzyme-linked immunosorbent assay. Orthodontic devices were randomly bonded, with self-ligating appliances on one side and conventional brackets on the contralateral side. Pain threshold (PT), maximal bite force (MBF), and masticatory efficiency (ME) were assessed using standard validated techniques at the beginning of the treatment and 24 hours post–orthodontic activation with an 0.016-inch nickel-titanium wire. **Results:** There were no significant differences (P > .05) in the substance P levels, PT, MBF, and

ME between the self-ligating and conventional orthodontic appliances.

Conclusions: There was no difference between conventional and self-ligating appliances in the parameters of pain: substance P and pressure. Functional aspects, such as pain, discomfort, and masticatory efficiency, should not be considered when making a therapeutic decision regarding the use of self-ligating vs conventional orthodontic appliances. (*Angle Orthod.* 2023;93:398–402.)

KEY WORDS: Pain; Orthodontic appliances; Self-ligating brackets

INTRODUCTION

Since the first orthodontic devices were created by Angle, there has been great advancement in orthodontic appliances in order to improve and facilitate adequate patient care. For many years, brackets were tied to the archwire by elastomeric ties or ligatures,¹ but this type of link was shown to have disadvantages and limitations, such as the need for longer time in the chair for the patient and repeated consultations because of loss of ties, inconsistency in the strength of the material, and, consequently, lack of control over the dental material.²⁻⁴ Therefore, self-ligating brackets were created with the premise that brackets that were free of elastomeric ties or ligatures would create much less friction, allowing better dental sliding mechanics with subsequent higher efficiency.⁵ To date, however, there is little evidence regarding pain in patients with self-ligating brackets. In general, pain is the most negative side effect related to orthodontic treatment^{2,3} and is often an argument for lack of patient compliance.6 At the basis of this complaint is the main mechanism related to orthodontic movement, the bone remodeling process, in which mature bone tissue is removed and new bone tissue is formed. Tooth movement is, therefore, initiated as a result of inflammation in the periodontal tissues after the application of orthodontic forces, which underlies such remodeling.^{7–9} Clinical studies¹⁰ indicated that pain is a major concern in orthodontic patients, one that affects their quality of life.

In this context, pain in orthodontic patients with selfligating brackets has not been adequately investigated.

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This oversight is not only due to technical constraints but also to the fact that most of the studies to date have relied on self-reported data and subjective measures, with consideration of the fact that quantification of pain is inherently biased by individual perception. Therefore, there is a lack of high-quality controlled studies objectively assessing this clinically relevant issue. For this reason, the aim of this study was to investigate the differences between self-ligating brackets and conventional brackets in terms of discomfort/pain and the related functional parameters of bite force and masticatory efficiency.

MATERIALS AND METHODS

Type of Study

This study isw a randomized, controlled clinical study comparing conventional and self-ligating brackets.

Study Subjects

Twenty patients aged 15 to 25 years with good general and oral health, without caries or periodontal disease, with permanent dentition, and in whom orthodontic treatment was indicated, were selected to be included in this study. Patients with symptoms of anxiety, depression, or denoted psychological instability were excluded. Patients with dentofacial deformities or temporomandibular joint disorders and those who had used psychotropic drugs, anti-inflammatory drugs, or antibiotics during a period of 6 months prior the beginning of the protocol were also excluded. Among the females, the orthodontic devices were inserted out of the follicular phase of the ovulatory cycle.

To establish the sample size, a difference of 20% was considered between the means of any of the outcome variables (masticatory performance, bite force, or pressure pain), with a 10% standard deviation. Thus, 20 volunteers would be enough to provide a test power greater than 90% (with an alpha of 5%, two-tailed test) in a crossover study.

Experimental Design

All patients included in the present study had a Class I malocclusion and were evaluated by two of the researchers. Straight-wire systems were used, and orthodontic devices were randomly bonded with self-ligating (Damon, slot = 0.022 inches; Ormco Yokohama, Japan) brackets on one side and conventional brackets (Spirit, slot = 0.022 inches; Ormco) on the contralateral side. The type of treatment for each patient was randomized using Microsoft Excel. The measurements recorded before bracket insertion were used as controls. All brackets were metallic with a

similar appearance in order to avoid bias. The conventional appliances had elastomeric ties without esthetic discomfort for the patient. Samples for substance P (SP) level, the pressure-related pain threshold, maximal bite force, and masticatory performance were measured at two timepoints: T1 (before the first activation) and T2 (24 hours after the first activation). The primary outcome was the pain, and the secondary outcome was the pressure.

Gingival Fluid Collection

Collection of gingival fluid from the gingival sulcus for measurement of SP level was performed from the maxilla according to the Offenbacher method. All teeth were first gently washed with water, and the side of the procedure was isolated for minimizing salivary contamination. An endodontic paper cone was then inserted about 1 mm inside the gingival sulcus and was kept there for 1 minute. The volume of fluid absorbed by the paper cone was measured using Periotron 8000 (Harco, Periotron 8000, Amityville, NY), which was calibrated with human serum. All paper cones were stored at a temperature of -30°C until they were processed. The protein concentration was evaluated using the Bradford method, with bovine serum albumin used as a standard.

Enzyme-Linked Immunosorbent Assay

The levels of SP were measured using the enzymelinked immunosorbent assay method (Systems R&D, Minneapolis, Minn), according to the manufacturer's instructions.

Pressure-Related Pain Evaluation

Periodontal pain evaluation was performed using a calibrated mechanical algometer (EMG System, Brazil), which allowed measurement of the pressurerelated pain threshold in each tooth. The circular and flat active tip of the device, measuring 1 cm², was surrounded by a finger rubber and was applied crosssectionally and longitudinally along the long axis of the tooth and in the center and at the occlusal surface of the clinical crowns. The pressure was progressively increased, with constant speed controlled by validated software, and the patients were asked to notify the operator when they felt the pressure was turning into pain. At that time, the test was immediately stopped.

Concomitant with the pain threshold test, the patient was asked to hold with one hand a mechanical device that measures tooth pressure sensation and to hold with the other hand a sensor indicating the subjective feeling in increase in pressure. The calibrated scale from zero (absence of pressure) to 10 (pressure

Table	1.	Mean	(±Standard	Deviation)	of	Substar	nce	Ρ
Measur	eme	nt (ng/m	nL) in the Ging	jival Sulcus b	у Ві	racket Ty	pe a	nd
Evaluat	ion T	Timepoir	nt					

Assessments	Conventional Bracket	Self-Connected Bracket
First evaluation ^a Second evaluation ^b	4.26 (2.64) 3.69 (2.31)	5.33 (2.52) 2.94 (1.46)*

^a Patient without the bracket installed.

 $^{\scriptscriptstyle \rm b}$ Twenty-four hours after the first activation of the 0.16-inch wire orthodontic appliance.

 * Differs from the measurement performed without the bracket, under the same bracket conditions (P < .05).

becoming a pain sensation) indicated the range of sensations. Measurements were performed on premolars and incisors on both sides. Importantly, for this analysis it was required that the patient's head rested in a specific support, with the orbitomeatal plane parallel to the floor, and that the hand holding the sensor was placed at the opposite side of the evaluation in order to avoid head displacement.

Statistical Analysis

First, descriptive and exploratory data analyses were performed. An exploratory analysis of substance P data indicated the presence of four outliers (outliers) that were not considered in the analysis. Then, the mixed-model methodology for repeated measures over time with split mouth was applied. The other variables did not meet the assumptions of the analysis of variance and were analyzed by generalized linear models for repeated measures over time, with a split mouth. Analyses were performed using the R program, considering a significance level of 5%.

Ethical Standards

The risk-benefit ratio was not compromised in this study because orthodontic treatment, when indicated, is important for the patients' functioning and wellbeing. All participants signed an informed consent form. The study was approved by the São Leopoldo Mandic Ethical Committee under project 1.336.037.

RESULTS

Table 1 shows that there was no significant difference in the measurement of substance P between the two devices (P > .05). However, for the self-ligating brackets, the mean in the second assessment (after 24 hours from the first activation) was significantly lower than in the first (before the brackets were installed; P < .05).

There was also no significant difference between the conventional or self-ligating brackets with regard to the time required to reach pain, as measured by the algometer (P > .05), as shown in Table 2. It was also noted that with both brackets there was a significant decrease in the time required to reach pain in the second assessment compared to the first, both in the incisor and premolar regions (P < .05).

Similar results were observed for pressure measurements by the algometer (Table 3). There was no significant difference between the brackets (P > .05), and both brackets showed a significant decrease in pressure threshold (P < .05).

DISCUSSION

Technological innovations are often introduced in the orthodontic market. Among them, self-ligating appliances stand out, as they have been claimed¹¹ to shorten treatment time because of their characteristic of low friction, which facilitates the onset of tooth movement by decreasing the initial resistance to movement. However, there is a lack of evidence regarding objective measures in the evaluation. Therefore, the present study was designed to compare self-ligating to conventional appliances with regard to the pain and discomfort associated with them both.

Different methods have been used to measure the level of pain in orthodontic patients, including tradition-

Table 2. Mean (±Standard Deviation) of the Time to Reach Pain by the Algometer (kpa) by Bracket Type, Location, and Evaluation

		Evaluation	Type of Bracket		
Measure	Tooth		Conventional	Self-Connected	
Cross-sectional	Incisor	First evaluation ^a	10,831.80 (2162.40)	11,384.55 (10,501.23)	
		Second evaluation ^b	4982.85 (3880.28)*	4470.20 (2501.03)*	
	Premolar	First evaluation ^a	16,725.90 (7615.98)	14,505.95 (8619.65)	
		Second evaluation ^b	7181.88 (4764.11) *	7863.43 (5179.44)*	
Longitudinal	Incisor	First evaluation ^a	13,471.51 (8750.90)	18,474.90 (11,759.56)	
		Second evaluation ^b	6960.80 (4637.89)*	8556.55 (6311.84)*	
	Premolar	First evaluation ^a	17,271.10 (10,268.39)	21,305.65 (14,119.29)	
		Second evaluation ^b	10,925.35 (5419.43)*	9394.96 (5630.82)*	

^a Patient without the bracket installed.

^b Twenty-four hours after the first activation of the orthodontic appliance with 0.16-inch wire. There was no significant difference between brackets (P > .05).

* Differs from the measurement performed without the bracket, under the same bracket conditions (P < .05).

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		Evaluation	Type of bracket		
Measure	Tooth		Conventional	Self-Connected	
Cross-sectional	Incisor	First evaluation ^a	35,838 (315.26)	351.13 (269.85)	
		Second evaluation ^b	159.25 (92.38)*	146.41 (67.44)*	
	Premolar	First evaluation ^a	500.68 (205.26)	469.57 (262.42)	
		Second evaluation ^b	249.90 (149.80)*	253.82 (161.67)*	
Longitudinal	Incisor	First evaluation ^a	488.55 (268.89)	611.52 (401.44)	
		Second evaluation ^b	247.56 (153.32)*	304.48 (221.04)*	
	Premolar	First evaluation ^a	597.90 (370.89)	696.95 (460.84)	
		Second evaluation ^b	358.98 (201.40)*	325.57 (180.59)*	

Table 3. Mean (±Standard Deviation) of the Pressure Measurements by the Algometer (kgf) by Bracket Type, Location, and Evaluation

^a Patient without the bracket installed.

^b Twenty-four hours after the first activation of the orthodontic appliance with 0.16-inch wire. There was no significant difference between brackets (P > .05).

* Differs from the measurement performed without the bracket, under the same bracket conditions (P < .05).

al surveys with pretested questionnaires, the Visual Analog Scale (VAS) classification,¹² the McGill pain questionnaire,¹³ the Verbal Rating Scale,¹⁴ and measurement of SP levels in periodontal ligament fluid and using algometers.¹⁵ To reduce these pain variables, pain evaluation in this study was performed based on the SP values, algometer test, and bite force measurements.

Zheng et al.¹⁶ analyzed patients undergoing fixed orthodontic treatment. Patients were interviewed after appliance activation to assess their perception of pain and discomfort in different locations during different activities using a VAS. All patients experienced some pain or discomfort. According to a review by Bergius et al.,¹⁷ a high rate of orthodontic patients report pain during orthodontic treatment; however, it is commonly observed that the pain does not develop until up to 2 hours after the placement of the appliance, and when it does appear, it usually subsides within approximately 3 days. Erdinc and Dincer¹⁸ reported that pain perception during orthodontic treatment with fixed brackets peaked at 24 hours and decreased on the third day, suggesting that the pain perception may be linked to SP release. The late pain develops a few hours later and is caused by increased sensitivity of the nerve fibers to harmful stimuli, such as prostaglandins, histamines, and SP, a neuropeptide released by nociceptors in the damaged tissue region, which also plays a role in increasing the rate of nerve damage.8,15,19 In the present study, pain was present in all patients after orthodontic activation and during the evaluation of pain and SP level.

Yamaguchi et al.²⁰ and Park et al.²¹ found that SP levels in the periodontal ligament were significantly elevated during orthodontic movement in inflammatory response to mechanical force. In the present study, the mean SP values 24 hours after orthodontic appliance activation were significantly lower (inversely proportional values – lower values plus SP) than those in the

control group, but there was no significant difference in the SP values between the self-ligating and the conventional devices. This was contrary to the findings of Yamaguchi et al.,22 who found significantly higher mean SP values for teeth undergoing orthodontic movement than those in controls. Although the SP concentration in teeth with self-ligating brackets in that study was significantly lower than that in teeth with conventional brackets, the SP levels had returned to baseline levels after approximately 168 hours. Based on this finding, the authors suggested that SP participated in a complex network of mediators that regulate inflammation, and that the Damon system is useful for reducing inflammation and pain resulting from orthodontic forces. Peck²³ discussed the purported advantages of the Damon self-ligating system.

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According to Tecco et al.,²⁴ patients treated with conventional brackets reported significantly more "constant" pain than did those treated with self-ligating brackets, who complained of "chewing/biting" pain. Algometry is the most commonly used means for assessing the pain threshold for pressure.²⁵

When self-ligating brackets were developed, even though they represented a more expensive and complicated technique, much was considered about the advantage of generating lower forces and, consequently, the assumption that they would result in less pain caused by tooth movement. However, the findings of the current study reported data similar to those associated with conventional brackets.

In this study, there was no significant difference between the sides with conventional or self-ligating appliances in terms of the time required to reach painful levels, as measured by the algometer. It was also noted that there was a significant decrease in the time required to reach pain thresholds in the second evaluation compared to the first with both appliances, both in the incisor and premolar regions. One limitation of this study was that both types of brackets were bonded in the same dental arch, with the same wire passing through both, and there may have possibly been differences in the force released.

CONCLUSIONS

- There was no difference between conventional and self-ligating appliances in the parameters of pain, substance P, and pressure.
- The results of this study suggest that functional aspects, such as pain and discomfort, should not be considered when making a therapeutic decision regarding the use of self-ligating vs conventional orthodontic appliances.

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