# Orthodontic treatment need, the types of brackets and the oral health-related quality of life

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None declared

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#### **Abstract**

**Background.** Malocclusion can affect the oral health-related quality of life (OHRQoL). The influence of the orthodontic treatment need (OTN) and the type of brackets on OHRQOL is not clear.

**Objectives.** The aim of the present study was to determine the relationships between OTN and the bracket type and OHRQoL during the first 6 months of orthodontic treatment (OT) in adult patients.

**Material and methods.** This cohort study was conducted at the Department of Orthodontics of a private university. A total of 216 patients aged  $\geq$  18 years participated in the study (106 patients with conventional brackets and 110 with self-ligating brackets). The OHRQoL was evaluated using the 14-item Oral Health Impact Profile (OHIP-14) at 5 time points — before OT (T0), and at 24/48 h (T1), 1 month (T2), 3 months (T3), and 6 months (T4) after the installation of the orthodontic appliance. The OTN was evaluated with the dental aesthetic index (DAI) by 2 previously calibrated operators. For the statistical analysis, the  $\chi^2$  test and the Mann—Whitney U test were used. Additionally, Poisson regression models were performed.

**Results.** The evidence of an association between OHRQoL and OTN was found only at T3 (p = 0.0095). No association was found between OHRQoL and the bracket type. However, in the regression models, OHRQoL was statistically significantly worse at T3 in the group with a greater OTN (*IRR* (incidence rate ratio) = 1.34; 95% *CI* (confidence interval): 1.21;1.48) and at T4 in the self-ligation group (*IRR* = 1.23; 95% *CI*: 1.12;1.36).

**Conclusions.** The OHRQoL was affected in the same way at the beginning of OT, regardless of OTN and the bracket type used. However, a worse OHRQoL was observed at 3 months in subjects with greater OTN and at 6 months in patients with self-ligating brackets.

**Keywords:** malocclusion, orthodontic appliances, quality of life, orthodontics, orthodontic brackets

# Introduction

Malocclusion can lead to the discrimination of individuals based on their facial appearance and to low self-esteem, which can affect the oral health-related quality of life (OHRQoL).<sup>1–3</sup> However, orthodontic treatment (OT) with labial fixed appliances can cause a temporary decline in OHRQoL.<sup>4–6</sup> Adult patients undergoing treatment with fixed orthodontic appliances are most likely to experience increased levels of pain for 1–3 days following the placement of the appliance and subsequent visits for adjustments.<sup>7</sup> Chen et al. assessed changes in OHRQoL during fixed orthodontic appliance therapy in Chinese patients, and found that the compromised condition in terms of overall OHRQoL was most severe during the first week after bracket placement.<sup>8</sup> Zhang et al. reported significant improvement in OHRQoL after 6 months of OT.<sup>9</sup>

There are some differences between orthodontic treatment in children and adults due to different basic oral health conditions, therapeutic compliance and oral hygiene. 10–12 Furthermore, adult patients may have compromised occlusion or temporomandibular disorders, which is why more cautious OT should be set up. 13,14 Additionally, there are difficulties in bracket bonding in adult patients due to the presence of prosthetic elements or other conditions in which adhesion could be compromised, like syndromes with impaired tooth mineralization. 15–17

Self-ligating brackets have been advertised to have many reputed advantages with regard to diminishing discomfort and pain levels during initial orthodontic therapy. However, there is no evidence suggesting that self-ligating brackets are more comfortable and lead to less severe pain than conventional brackets. He will be self-ligating brackets on OHRQoL during OT, and no statistically significant differences were found. However, Zhou et al. observed that patients with self-ligating brackets experienced less severe pain and discomfort than those with conventional brackets. Likewise, Othman et al. demonstrated that passive self-ligating, active self-ligating and conventional brackets differed in terms of pain and discomfort at the time of placement. Likewise

Slade and Spencer proposed the Oral Health Impact Profile (OHIP) as an instrument to measure OHRQoL,<sup>24</sup> which is widely used in dentistry and has been validated in numerous languages.<sup>25–31</sup> The long form of this tool has 49 items (OHIP-49) and evaluates 7 dimensions (i.e., functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap).

Although untreated malocclusion has been shown to have a negative impact on OHRQoL, malocclusion severity seems to dictate the need for OT.<sup>2,23</sup> In subjects with mild malocclusion, OT is elective, and minor occlusal traits may not have as large of a negative impact on OHRQoL as severe malocclusion. The influence of both

orthodontic treatment need (OTN) and the bracket type on OHRQOL is not clear. The present study aimed to evaluate the relationships between OTN and the bracket type and OHRQoL during the first 6 months of OT in adult patients.

# Material and methods

This prospective cohort study included a sample of 216 adult patients – 110 patients in the self-ligation group (mean age: 31.75 ±11.63 years; 60 females and 50 males) and 106 patients in the conventional group (mean age: 29.26 ±9.62 years; 61 females and 45 males) (Table 1) who were selected by consecutive sampling and were treated at the Department of Orthodontics of the UniCIEO University, Bogota, Colombia, from December 27, 2016, to May 29, 2019. The study protocol was approved by the ethics committee of the University (No. 007/46 as of November 16, 2016). All patients gave informed written consent for participating in the study. The research was conducted in full accordance with the World Medical Association (WMA) Declaration of Helsinki.

The sample size was calculated based on the data from a pilot study that included 60 patients (35 with self-ligating and 25 with conventional brackets). Epidat 4.2 (Xullo 2016, Consellería de Sanidade, Xunta de Galicia, España; Organización Panamericana da Saúde (OPS-OMS), Universidade CES, Colombia) was used for the calculation, considering a confidence interval (CI) of 95% and a power of 90%. At least 91 subjects were required for each group to detect a mean difference in the 14-item Oral Health Impact Profile (OHIP-14) total score of 2 points (±3.76 and ±4.45 for the self-ligating and conventional brackets, respectively). The inclusion criteria were subjects who were 18 years old or older, and did not have extractions, surgical interventions or mini-screw insertion at the beginning of the treatment or within 1 month before the survey was administered. Patients with craniofacial anomalies, caries, systemic diseases, uncontrolled periodontal disease, OT, cognitive disorders, and those who did not understand the Spanish language were excluded.

The outcome measure was OHRQoL, which was measured with a previously validated Spanish version of OHIP-14.<sup>25</sup> To ensure the transcultural compatibility of OHIP-14, an expert committee (4 orthodontists and 4 orthodontic patients) assessed its face validity (whether the instrument appears to be measuring the variables it claims to measure) and content validity (whether the scale components cover all the attributes to be measured). The OHIP-14 scale was a Likert-type scale with the following scores: 4 – very often; 3 – fairly often; 2 – occasionally; 1 – hardly ever; and 0 – never. The total score was calculated as the sum of the item scores, generating scores from 0 to 56, with a higher score indicating a more negative impact and a lower OHRQoL.<sup>32</sup>

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<b>Table 1.</b> Distribution of the variables in the study groups at baseline	Table 1	. Distribution	of the variab	les in the	study aroups	at baseline
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Variable		Bracket type			OTN		
		conventional ( <i>n</i> = 106)	self-ligating ( <i>n</i> = 110)	<i>p</i> -value	lesser	greater	<i>p</i> -value
Age M ±SD		29.26 ±9.62	31.75 ±11.63	0.1045 <sup>‡</sup>	29.27 ±9.97	33.22 ±11.86	0.0293*‡
Gender	М	45 (47.37)	50 (52.63)	0.6570 <sup>†</sup>	63 (66.32)	32 (33.68)	0.6270 <sup>†</sup>
n (%)	F	61 (50.41)	60 (49.59)	0.0370	84 (69.42)	37 (30.58)	0.0270
DAI (total score) M ±SD		28.39 ±8.62	28.18 ±9.37	0.8308 <sup>‡</sup>			
OTN	lesser	31 (44.93)	38 (55.07)	0.4040 <sup>†</sup>			
n (%)	greater	75 (51.02)	72 (48.98)	0.40401			

M – mean; SD – standard deviation; n – number; M – male; F – female; DAI – dental aesthetic index; OTN – orthodontic treatment need; \* statistically significant (p < 0.05); †  $\chi^2$  test; † M ann – Whitney U test.

The scale was administered by 3 examiners (KLP, MQ and MdPV) at 5 time points: before OT (T0), and at 24/48 h (T1), 1 month (T2), 3 months (T3), and 6 months (T4) after the installation of the orthodontic appliance. To ensure the reliability of the information, the examiners were trained to administer the surveys. The first survey was conducted through personal interviews, and the remaining surveys were completed through telephone interviews by the same researchers.

The predictor variables were OTN and the bracket type. The self-ligating bracket group had a  $0.022 \times 0.027$ -inch slot (50 patients with SmartClip<sup>TM</sup> (3M Unitek, Monrovia, USA) and 60 patients with Carriere<sup>®</sup> SLX (Ortho Organizers, Carlsbad, USA)), and the conventional bracket group had a  $0.022 \times 0.028$ -inch slot and the MBT prescription (Gemini brackets; 3M Unitek). Although the patients were treated by different operators, the operators followed a pre-established clinical protocol with the same treatment philosophy. Additionally, data on the age and gender of the patients were collected from the surveys.

The OTN was evaluated with the dental aesthetic index (DAI) and measured in dental casts by 2 examiners (MQ and MdPV) who were previously trained by an expert operator on the index in accordance with the World Health Organization (WHO) manual methods.33 The DAI measures 10 occlusal traits (the number of visible missing teeth, incisor crowding, the interdental incisor space, the width of the midline diastema, maxillary tooth irregularity, mandibular tooth irregularity, incisor overjet, mandibular overjet, anterior open bite, and the buccal segment relationship), each of which is multiplied by a predetermined statistical weight, and a constant of 13 points is added to obtain the total score of DAI.34 Jenny and Cons established the cut-off points for the following categories to assess malocclusion severity and OTN: no abnormalities or minor malocclusion (13-25); definite malocclusion (26-30); severe malocclusion (31-35); and very severe or handicapping malocclusion (>36).35 In the present study, this variable was dichotomized based on the cut-off score to demarcate the need for orthodontic services that have

been previously defined.<sup>36</sup> Subjects with DAI higher than 30 were considered to have a greater OTN, and subjects with DAI between 13 and 30 were considered to have a lesser OTN.

The reliability of the DAI measurements was determined in 20 cast models randomly selected from the sample and measured on 2 occasions with a 1-week interval. Intra- and interobserver agreement was evaluated with the Bland–Altman plot. Additionally, the method error was estimated with the paired t test (the systematic error) and Dahlberg's formula (the random error).<sup>37</sup>

## Statistical analysis

All analyses were performed with Stata software, v.14 (StataCorp, College Station, USA). To evaluate the associations between categorical variables, the  $\chi^2$  test was applied. Nonparametric tests were used because of the nonnormal distribution of the data. The Mann–Whitney U test was used to evaluate the association between OTN, the bracket type and OHRQoL across the time intervals. Additionally, 5 multiple logistic Poisson regression analyses with the variables OTN and the bracket type included in the model were performed to evaluate their associations with OHRQoL. The significance level was established at p < 0.05.

The random errors were within acceptable limits, and there were no statistically significant systematic errors (p > 0.1). The Bland–Altman plots indicated high intraobserver agreement, with an average error between -0.38 and 0.48 points in the total DAI (95% CI: -0.48–0.70).

## Results

The response rate to the questionnaires was 100%. At baseline, there were no statistically significant differences in age, gender, the total DAI, and OTN between the bracket type groups (p > 0.05). Likewise, there were no significant associations between OTN and gender (Table 1).

The associations between OTN and the bracket type and OHRQoL (OHIP-14 total score) at different time points are reported in Table 2. The only statistically significant association was found between OTN and OHRQoL at T3 (p = 0.0095), showing a worse OHRQoL in the group with greater OTN (8.80) than in the group with lesser OTN (6.54) (Fig. 1A,1B).

The relative changes in OHRQoL at different time points were compared according to the bracket type (Table 3), but there were no statistically significant differences for any of the time intervals. The mean relative changes with 95% *CIs* in OHRQoL across the time intervals are described in Table 4. Greater differences were observed in the T1–T0 (24–48 h after bracket placement) and T2–T0 (1 month after bracket placement) time intervals in the OHIP-14 total scores, and especially for the dimensions of physical pain and physical disability.

The Poisson regression models (one for each time point), which included the OHIP-14 total score as the outcome variable and OTN and the bracket type as the predictor variables, showed that 3 months after appliance placement (T3), having a greater OTN increased the incidence rate ratio (*IRR*) of having a worse OHRQoL by

1.34 times (95% CI: 1.21;1.48). Additionally, patients with self-ligating brackets at 6 months after appliance placement (T4) were more likely to have a worse OHRQoL than those who used conventional brackets (IRR = 1.23; 95% CI: 1.12;1.36) (Table 5).

**Table 3.** Relative changes in the oral health-related quality of life (OHRQoL) at different time points according to the bracket type

OHIP-14 total score	Bracke	n value	
across time intervals	conventional	self-ligating	<i>p</i> -value
T1-T0	5.85 ±8.10	6.37 ±8.70	0.4921
T2-T0	2.93 ±7.98	2.41 ±7.83	0.3598
T3-T0	0.43 ±7.22	0.59 ±8.10	0.9365
T4-T0	0.10 ±8.33	1.22 ±9.64	0.5546
T2-T1	-2.92 ±7.05	-3.95 ±6.12	0.0889
T3-T2	-2.50 ±5.30	-1.83 ±5.24	0.3596
T4-T3	-0.33 ±6.85	0.64 ±8.17	0.6775

Data presented as  $M\pm SD$ . Time points: T0 – before orthodontic treatment (OT); T1 – at 24/48 h after the installation of the orthodontic appliance; T2 – at 1 month after the installation of the orthodontic appliance; T3 – at 3 months after the installation of the orthodontic appliance; and T4 – at 6 months after the installation of the orthodontic appliance. Mann–Whitney U test.

Table 2. Associations between the orthodontic treatment need (OTN) and the bracket type and the oral health-related quality of life (OHRQoL) (OHIP-14 total score) across the time intervals

OHIP-14	OTN		a valva	Bracket type		m value
total score at different time points	lesser	greater	<i>p</i> -value	conventional	self-ligating	<i>p</i> -value
ТО	6.87 ±7.12	6.50 ±5.70	0.9076	6.53 ±7.01	6.96 ±6.39	0.3754
T1	12.70 ±7.98	13.23 ±7.70	0.4073	12.39 ±8.11	13.34 ±7.65	0.2089
T2	9.17 ±6.54	9.94 ±6.21	0.2882	9.46 ±6.32	9.38 ±6.58	0.8924
T3	6.54 ±4.95	8.80 ±6.40	0.0095**	6.96 ±5.55	7.54 ±5.55	0.3244
T4	7.40 ±6.89	7.45 ±6.79	0.8809	6.62 ±6.21	8.69 ±7.34	0.1564

Data presented as  $M \pm SD$ . Time points: T0 – before orthodontic treatment (OT); T1 – at 24/48 h after the installation of the orthodontic appliance; T2 – at 1 month after the installation of the orthodontic appliance; T3 – at 3 months after the installation of the orthodontic appliance; and T4 – at 6 months after the installation of the orthodontic appliance. \*\* statistically significant (p < 0.01); Mann–Whitney U test.

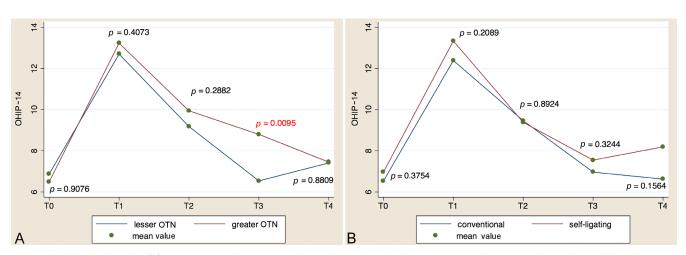


Fig. 1. Oral health-related quality of life (OHRQoL) across the time intervals according to the orthodontic treatment need (OTN) (A) and according to the bracket type (B) Time points: T0 – before orthodontic treatment (OT); T1 – at 24/48 h after the installation of the orthodontic appliance; T2 – at 1 month after the installation of the orthodontic appliance; T3 – at 3 months after the installation of the orthodontic appliance; and T4 – at 6 months after the installation of the orthodontic appliance. OHIP-14 – 14-item Oral Health Impact Profile.

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Table 4 Mean relative changes with 95% confidence interval	(C/s) in the oral health-related quality of life (OHROoL) across the time intervals	5
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Variable	T1–T0	T2-T0	T3-T0	T4-T0	T2-T1	T3-T2	T4-T3
OHIP-14	6.12	2.67	0.51	0.67	-3.45	-2.16	0.16
total score	(4.99;7.24)	(1.61;3.72)	(-0.52;1.54)	(-0.54;1.88)	(-4.33;-2.56)	(-2.86;-1.45)	(–0.85;1.17)
Functional limitation	0.93	0.65	0.50	0.53	-0.28	-0.15	-0.03
	(0.72;1.14)	(0.45;0.85)	(0.31;0.68)	(0.31;0.75)	(-0.48;-0.08)	(-0.33;-0.03)	(-0.18;0.25)
Physical pain	2.94	2.05	1.28	1.27	-0.89	-0.77	-0.10
	(2.59;3.29)	(1.74;2.35)	(0.98;1.58)	(0.94;1.60)	(-1.18;-0.60)	(-1.01;-0.52)	(-0.26;0.02)
Psychological discomfort	-0.49	-0.99	-1.41	-1.27	-0.50	-0.41	0.14
	(-0.80;-0.18)	(-1.32;-0.66)	(-1.70;-1.11)	(-1.58;-0.96)	(-0.73;-0.27)	(-0.61;-0.22)	(-0.11;0.38)
Physical disability	2.61	1.87	1.28	0.93	-0.74	-0.60	-0.34
	(2.29;2.92)	(1.57;2.17)	(0.99;1.56)	(0.64;1.22)	(-1.02;-0.44)	(-0.83;-0.36)	(-0.60;-0.08)
Psychological disability	-0.09	-0.59	-0.91	-0.76	-0.50	-0.31	0.15
	(-0.33;0.15)	(-0.81;-0.38)	(-1.12;-070)	(-0.99;-0.53)	(-0.70;-0.31)	(-0.47;-0.16)	(-0.03;0.32)
Social disability	0.22	-0.09	-0.02	0.04	-0.31	0.07	0.06
	(0.31;0.40)	(-0.24;0.04)	(-0.17;0.12)	(-0.14;0.23)	(-0.46;-0.16)	(-0.05;0.19)	(-0.10;0.23)
Handicap	0.00	-0.18	-0.18	-0.02	-0.18	0.00	0.16
	(-0.16;0.15)	(-0.31;-0.06)	(-0.31;-0.06)	(-0.18;0.13)	(-0.30;-0.06)	(-0.08;0.08)	(0.26;0.30)

Data presented as M (95% CI).

**Table 5.** Multivariate adjusted models using the Poisson regression with the incidence rate ratio (*IRR*) for the association of the oral health-related quality of life (OHRQoL) at different time points with the orthodontic treatment need (OTN) and the bracket type

	Variabl	e	IRR (95% CI)	<i>p</i> -value
OHIP-14	OTN	lesser greater	1 0.94 (0.84;1.05)	0.286
ТО	bracket type	conventional self-ligating	1 1.07 (0.96;1.19)	0.197
OHIP-14	OTN	lesser greater	1 1.04 (0.96;1.12)	0.366
T1	bracket type	conventional self-ligating	1 1.07 (0.10;1.16)	0.059
OHIP-14 T2	OTN	lesser greater	1 1.08 (0.99;1.19)	0.085
	bracket type	conventional self-ligating	1 0.99 (0.90;1.08)	0.772
OHIP-14	OTN	lesser greater	1 1.34 (1.21;1.48)	<0.0001****
T3	bracket type	conventional self-ligating	1 1.07 (0.10;1.18)	0.206
OHIP-14	OTN	lesser greater	1 0.99 (0.89;1.10)	0.891
T4	bracket type	conventional self-ligating	1 1.23 (1.12;1.36)	<0.0001****

<sup>\*\*\*\*</sup> statistically significant (p < 0.0001).

# Discussion

In the present study, we found no significant differences between conventional and self-ligating brackets in terms of their impact on a patient's OHRQoL. However, the mean OHIP-14 overall scores were higher in

the self-ligating bracket group than in the conventional bracket group at T1-T0, T3-T0, T4-T0, T3-T2, and T4-T3. Similar results were found by Lai et al.<sup>21</sup> In contrast, Zhou et al. observed that self-ligating brackets were associated with less severe pain and discomfort at any time point as compared to conventional brackets, but the differences between groups were not significant.<sup>20</sup> Likewise, Othman et al. found no significant differences between the types of brackets; however, the passive self-ligating and active self-ligating bracket groups showed more immediate and delayed effects in the bonding phase, respectively, and the conventional bracket group was affected in both assessments.<sup>22</sup> Many authors have studied the association between OT and the quality of life during different stages of OT. 5,8,9,20,38-40 In orthodontics, the first stage of treatment is alignment and leveling, which usually takes 4-6 months, depending on the amount of crowding, and continues until the stainless-steel archwires are in place. Such archwires are more rigid and help to complete the torque expression. Changing archwires may affect the quality of life through causing more discomfort in the patient. Also, after this stage, the teeth and the smile normally look better, which may influence the OHIP-14 score due to the OHIP-14 scale measuring not only pain and discomfort, but also psychological and social disability.

In the present study, when evaluating the association between OHRQoL and OTN, we found significant declines in OHRQoL at T3 in patients who had a greater OTN (p=0.0095). This result may be explained by the idea that most of the necessary alignment and leveling may have resolved 3 months after bracket installation in individuals with mild to moderate malocclusion. In contrast, it may take longer to resolve crowding or other occlusal traits in individuals with severe malocclusion, and the use of more biomechanics tools or adjustments may lead to a worse OHRQoL. Zheng et al. observed

that changes in OHRQoL followed different patterns among patients with different types of malocclusion. <sup>41</sup> The OHRQoL of Class I malocclusion patients could be significantly improved just after alignment and leveling with OT. Class III patients showed benefits at all stages and Class II patients showed apparent improvement during the space closure stage. <sup>41</sup>

With regard to the relative changes across the time intervals in our study, for almost all the time comparisons with the baseline (T1-T0, T2-T0, T3-T0, and T4-T0), the functional limitation, physical pain and physical disability dimensions showed worse scores at 24-48 h after bracket placement (T1); then, the scores gradually improved and nearly reached the baseline values at 6 months after bracket placement (T4). At T4, the OHIP-14 overall and dimension scores were very low, which suggests that at 6 months after bracket placement, the level of OHRQoL of patients tends to be restored to that before OT. Similar results have been reported by many authors, 9,20-22 and as in this study, the functional limitation, physical pain and physical disability dimensions showed worse scores at 24-48 h after bracket placement (T1-T0). Nevertheless, the social disability and handicap dimensions did not show significant differences over time. Similar results were found in other studies,4,8,20-22,41 which concluded that the main problems during OT were difficulty in chewing foods, tooth pain and sensitivity, the misunderstanding of some words, appearance being affected, and smiling. Social skills (the social disability dimension), financial loss or the inability to function (the handicap dimension) were not affected during OT.

However, one of the main differences between our research and other studies<sup>20-22</sup> is that we included the study variable OTN as a predictor variable in addition to the bracket type, and studied the interaction between these variables and OHRQoL. According to the regression model, in which the bracket type was included, at 3 months after appliance placement (T3), the group with a greater OTN showed an increase in the IRR of having a higher OHIP-14 score (*IRR* = 1.34; 95% *CI*: 1.21;1.48). This finding suggests that at 3 months after bracket placement, subjects with more severe malocclusion had a greater chance of perceiving a poorer OHRQoL than those with less severe malocclusion. Furthermore, at 6 months after appliance placement (T4), a deterioration in the OHIP-14 overall score is expected in patients with self-ligating brackets as compared to those with conventional brackets (IRR = 1.23; 95% CI: 1.12;1.36). This observation may be explained by the standard arch sequence at this time, as rectangular stainless-steel wires are being inserted, which can cause more discomfort and/or pain in patients with self-ligation brackets. Mansor et al. found the highest prevalence and severity of the immediate impact on the OHIP overall score in the conventional bracket group at 6 weeks after bracket placement when rectangular wires were inserted, showing a poorer OHROoL at that time.<sup>42</sup>

## **Limitations and clinical implications**

One limitation of this study was that the appliances used in the self-ligating group comprised those of different brands, including active and passive self-ligation brackets. However, many authors have not found differences between these two appliances in terms of clinical<sup>42</sup> or perceived comfort.22 Also, the short time interval between the observations for the measurement error in DAI could explain the high intraobserver agreement. As to the clinical implications of our findings, patients should be informed that self-ligating brackets are not different from conventional brackets in terms of the resulting OHRQoL, that they are going to suffer a decline in OHRQoL in the first months of OT, which differs according to patients' OTN at 3 months and according to the bracket type at 6 months after appliance installation, and that after 6 months they will feel the same as they did before OT.

## **Conclusions**

No differences were found between the types of brackets during the first 6 months of OT. According to the multinomial regression, OTN and the bracket type led to important changes during OT at 3 months and 6 months, respectively, worsening the patients' OHRQoL at each of the corresponding time intervals. Significant changes in the OHRQoL of the subjects occurred over time after bracket placement – OHRQoL decreased considerably at 24–48 h, and subsequently improved to the baseline value at 6 months after orthodontic appliance insertion.

## Ethics approval and consent to participate

The study protocol was approved by the ethics committee of the University (No. 007/46 as of November 16, 2016). All patients gave informed written consent for participating in the study. The research was conducted in full accordance with the World Medical Association (WMA) Declaration of Helsinki.

## **Data availability**

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request

## **Consent for publication**

Not applicable.

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