

Article

A Prospective Randomized Clinical Trial to Evaluate the Slot Size on Pain and Oral Health-Related Quality of Life (OHRQoL) in Orthodontics during the First Month of Treatment with Conventional and Low-Friction Brackets

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Abstract: The aim of this research project was to analyze the influence of slot size and low-friction on pain and the oral health-related quality of life (OHRQoL) of subjects receiving fixed appliances. A group of 120 patients (61 male, 59 female) were chosen for this randomized clinical trial. Participants were classified into four groups (30 patients in each). We compared conventional (C group) and low-friction (LF group) brackets and 0.018" and 0.022" slots. Pain was assessed at 4 (T0), 8 (T1), and 24 (T2) hours, and 2 (T3), 3 (T4), 4 (T5), 5 (T6), 6 (T7), and 7 (T8) days after the start of treatment by using the visual analogue scale (VAS). OHRQoL was assessed at 1 month using the Oral Health Impact Profile (OHIP-14). Data was analyzed using the analysis of variance (ANOVA) test with post-hoc Bonferroni correction. For pain on the visual analogue scale, statistically significant differences ($p < 0.05$) were found for T0 and T3. For OHRQoL, statistically significant differences ($p < 0.01$) were found in the domains of physical pain, psychological discomfort, psychological disability, and overall OHIP. The group with 0.022" low-friction brackets showed a lower pain score and less impact on OHRQoL. The type of bracket system used and bracket slot size influenced patients' perceptions of pain and their OHRQoL.

Keywords: pain; oral health-related quality of life; orthodontics; oral health

1. Introduction

During fixed orthodontic treatment, patients perceive pain, which is a concern for patients as well as orthodontists. The perception of pain is influenced by different patient characteristics (e.g., gender, age, etc.) [1–3]. Pain during orthodontic treatment peaks between the first and second day of treatment. After seven days the pain described is almost nil [3–5]. Pain is a side effect of orthodontic treatment [6]. Pain indicated by patients can influence patient follow-up during orthodontic treatment [7].

Orthodontics aims to improve oral health-related quality of life (OHRQoL). Improving facial appearance and occlusion are the main objectives of the treatment. Patients' occlusion problems have a negative impact on their OHRQoL. The current scientific literature concludes that the impact of orthodontics on patients has an important psychosocial component and therefore should be measured to assess OHRQoL [8,9]. In the advanced stages of orthodontic treatment, the negative impact on HRQL decreases [9].

Physical pain is the domain of OHRQoL that has the greatest impact on subjects during treatment. This domain presents the worst impact between the first seven days and the first four weeks after starting treatment. From this point on, OHRQoL gradually decreases until reaching baseline values six months after starting treatment. At the end of orthodontic treatment, OHRQoL improves considerably compared to the initial level and during treatment [10].

There is a lack of scientific studies addressing the influence of bracket slot size on pain and OHRQoL during orthodontic treatment. OHRQoL and pain in subjects in treatment with conventional orthodontics and low-friction have not been previously analyzed. Analyzing the data from this research can give us specific information on how the treatment affects the physical, social, and psychological well-being of patients wearing fixed multibrackets. It would also improve the patient's understanding of the potential benefits and decrease the risk factors of orthodontic treatment. Healthcare professionals must know the objectives that patients expect from their orthodontic treatment to provide not only improved oral functioning and health but also enhancement of esthetics, self-esteem, and social life. Thus, this study has evaluated the effect of bracket systems (conventional versus low-friction brackets) and bracket slot size (0.018" versus 0.022") on the perception of pain and on OHRQoL during the first days of orthodontic treatment. The null hypothesis was that intensity of pain and the impact on OHRQoL would not differ in subjects.

2. Materials and Methods

2.1. Bioethics Committee

The patients were treated in the Dental Clinic of the Medical faculty of the University of Salamanca. The Bioethics Committee of the University of Salamanca approved the research project (reference number: 16/060). The study protocol followed the recommendations of the Declaration of Helsinki for human research. Patients who accepted the terms of the study and signed the informed consent form were included in the research project. Subjects were screened before study entry, and their medical and dental history were reviewed.

2.2. Study Sample Size

To calculate the sample size, a review of previously published scientific studies related to pain and quality of life in orthodontics was conducted [4,5,7–9]. It was calculated using the Raosoft online sample size calculation software tool (Raosoft Inc, Seattle, WA, USA). The margin of error was 5% and a 95% confidence level. Based on the data obtained, the estimated sample size was determined to be 120 patients, with a 10% dropout rate.

2.3. Study Design

This study consisted of 120 subjects. The research protocol was defined using the CONSORT 2010 guidelines [11] (Figure 1). The participants were divided into four groups, each group consisting of thirty subjects. The first group in the study was made up of patients wearing conventional fixed orthodontics with a 0.018" slot (C18 group, Victory®, 3M, Saint Paul, MN, USA), the second group with conventional fixed-type multibrackets with a 0.022" slot (C22 group, Victory®, 3M, USA), the third group with low-friction fixed multibrackets with a 0.018" slot (LF18 group, Synergy®, Rocky Mountain Orthodontics, Denver, CO, USA), and the fourth group with low-friction fixed multibrackets with a 0.022" slot (LF22 group, Synergy®, Rocky Mountain Orthodontics). Initially, the orthodontic arch was made of 0.014" superelastic nickel-titanium (Nitinol®, 3M, USA). Elastic ligatures (0.12") were used (G&H Orthodontics, Franklin, IN, USA). Participants were randomly

separated into four groups using a randomization program (<http://www.randomizer.org/form.htm>). This technological tool ensured that patients were equally likely to be assigned to a group. The patients were recruited from April to September 2019 and were treated by the same specialist. The dental bone discrepancy was analyzed for crowding.

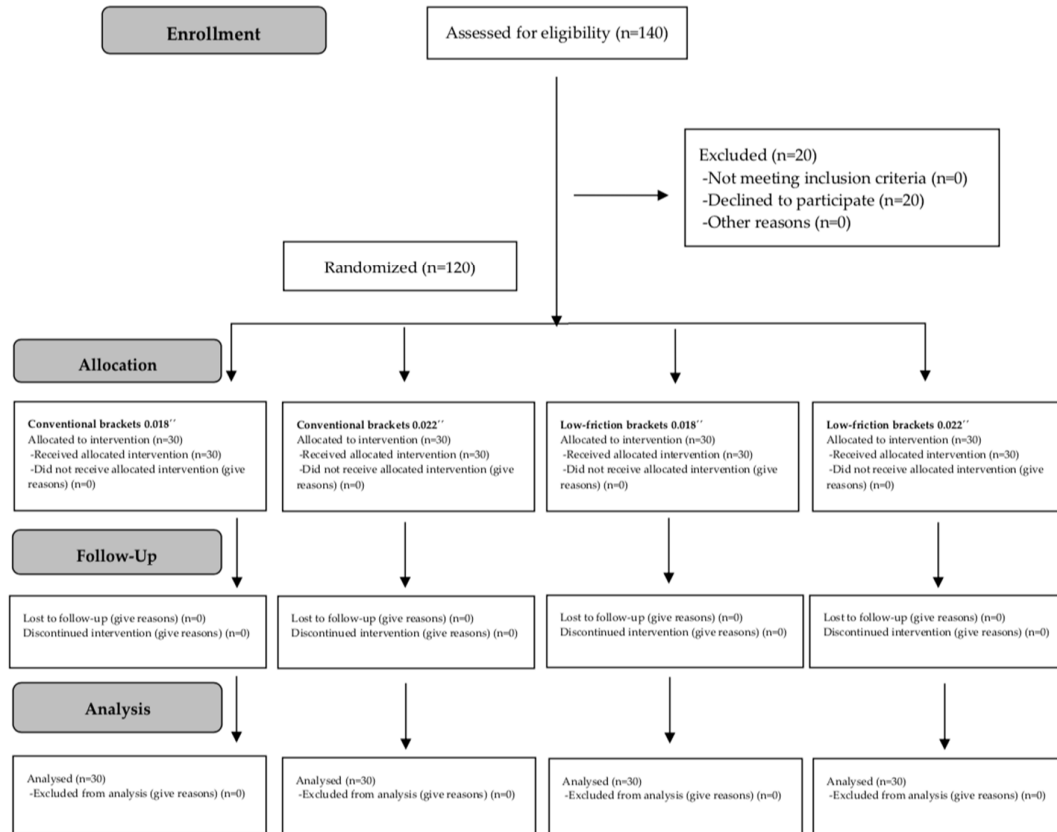


Figure 1. CONSORT flow diagram.

The brackets were bonding on all teeth in both arches, and molar tubes were placed on first and second molars. The blinding of patients was possible in this study. The information about the type of braces was hidden from the patients; however, the operator did know. The results were analyzed in a blind manner, assigning a code number to the patients in the groups. The orthodontic treatment was carried out by one non-blinded experienced orthodontist. All patients were given the same oral hygiene guidelines. The patients were given the questionnaires at the first appointment and were told when to fill out each pain and OHRQoL questionnaire. In the following appointments, the patients gave us the questionnaires.

The following inclusion criteria were considered: permanent dentition, aged between 18 and 40 years, patients without prior orthodontic treatment, no craniofacial anomalies, no missing teeth, with the exception of third molars, dental bone discrepancy between -1.0 and -2.0 mm in both arches, full complement of erupted teeth except for the third molars and skeletal class I or II malocclusion (ANB 0° – 5°) [12]. The exclusion criteria were patients requiring tooth extractions, patients with cognitive disorders or chronic medical conditions, history of orthodontic-surgical treatment, mild or high dental crowding (between -2.1 and -6.8 mm), chronic use of analgesic, antidepressants, and/or anticonvulsant medications, patients with periodontal pathology and/or dental caries, pregnant women, and/or auxiliary orthodontic appliances. The above exclusion criteria were used to ensure that the study sample was homogeneous.

2.4. Assessment of Pain

The patient's pain was evaluated at 4 h (T0), 8 h (T1), 24 h (T2), 2 days (T3), 3 days (T4), 4 days (T5), 5 days (T6), 6 days (T7), and 7 days (T8) after the bracket bonding. This pain was analyzed using the visual analogue scale (VAS), divided from 0 to 10 with the terms "no pain" and "maximum pain" as extremes. The use of VAS is a method commonly used in orthodontic studies [13].

2.5. Assessment of OHRQoL

Study participants were given the Oral Health Impact Profile (OHIP-14) questionnaire (OHIP-14) (Figure 2) 30 days after starting treatment. This OHRQoL questionnaire was created by Slade in 1997 [14] as a reduced version of the OHIP-49 questionnaire (developed by Locker and Miller in 1994) [15]. The Spanish version of the OHIP-14 questionnaire has been previously validated [16].

The items in this questionnaire are scored on a 5-point scale, ranging from = (never) to 4 (always).

The higher scores indicated poor OHRQoL. The OHIP version 14 questionnaire is divided into 7 domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap [17,18].

2.6. Statistical Analysis

The data were described in the tables with the sample (%), and the standard deviations (SD) for the study of the categorical and quantitative variables respectively. The measures to analyze the descriptive data of the study were the SPSS version 20 program (SPSS, Chicago, IL, USA), and the differences of pain and quality of life between Conventional Brackets and Low friction Brackets group were applied with the ANOVA (analysis of variance). A Bonferroni post-hoc test was performed to control and correct the confidence interval. The degree of statistical significance was set at 5%.

3. Results

According to the study's inclusion and exclusion criteria, 140 patients were initially selected; however, 120 expressed interest in participating (Figure 1). In terms of gender, 61 were men (50.8%) and 59 women (49.2%) (Table 1).

ORAL HEALTH IMPACT PROFILE (OHIP-14)	
Have you had any problems or feeling that because of problems with teeth, mouth, dentures?	
DOMAINS	SITUATIONS
Functional limitation	Pronouncing words
	Sense of taste worsened
Physical pain	Painful aching (mouth, teeth)
	Uncomfortable to eat any foods
Psychological discomfort	Been self-conscious
	Felt tense
Physical disability	Diet been unsatisfactory
	Interrupt meals
Psychological disability	Difficult to relax
	Feel a bit embarrassed
Social disability	Irritable with people
	Difficulty doing usual jobs
Handicap	Life in general less satisfying
	Totally unable to function
Scores 0-4	
Summary score 0-56	

Figure 2. Oral Health Impact Profile-14 questionnaire.

Table 1. Descriptive data of the sample divided by groups ($n = 120$).

Groups		Variables		
Conventional Brackets 0.018'' (C18; <i>n</i> = 30)	Age		Mean (years)	SD
			21.7	10.1
	Gender		N	%
		Male	17	56.7
		Female	13	43.3
	Conventional Brackets 0.022'' (C22; <i>n</i> = 30)	Dental Bone Discrepancy		Mean (mm)
Upper			-1.6	0.5
		Lower	-1.7	0.8
Age			Mean (years)	SD
			23.5	12.6
Gender			N	%
	Male	15	50.0	
	Female	15	50.0	
Low-friction Brackets 0.018'' (LF18; <i>n</i> = 30)	Dental Bone Discrepancy		Mean (mm)	SD
		Upper	-1.4	0.3
		Lower	-1.6	0.5
	Age		Mean (years)	SD
			24	9.7
	Gender		N	%
Male		15	50.0	
	Female	15	50.0	
Low-friction Brackets 0.022'' (LF22; <i>n</i> = 30)	Dental Bone Discrepancy		Mean (mm)	SD
		Upper	-1.5	0.2
		Lower	-1.4	0.7
	Age		Mean (years)	SD
			22.6	9.5
	Gender		N	%
Male		14	46.7	
	Female	16	53.3	
All groups (<i>n</i> = 120)	Dental Bone Discrepancy		Mean (mm)	SD
		Upper	-1.5	0.6
		Lower	-1.7	0.4
	Age		Mean (years)	SD
			24.4	11.4
	Gender		N	%
Male		61	50.8	
	Female	59	49.2	
Dental Bone Discrepancy		Mean (mm)	SD	
	Upper	-1.5	0.4	
	Lower	-1.6	0.6	

Analyzing the pain described by the patients on the VAS, statistically significant differences ($p < 0.05$) were observed at 4 h (T0) and 2 days (T3) after starting orthodontic treatment. At other evaluation times, no statistically significant differences were observed between the groups. Patients described their highest pain peak between the first 24 h (T2) and 48 h (T3) after starting orthodontic treatment. At 4 h (T0), the group with conventional brackets (C18 = 3.8 ± 2.3 ; C22 = 3.8 ± 2.9) described the highest level of pain compared to the low-friction bracket group (LF18 = 2.0 ± 1.9 ; LF22 = 2.8 ± 3.1); however, 2 days (T3) after starting orthodontic treatment, the group with low-friction 0.018" brackets described the highest level of pain (5.8 ± 1.9). Throughout the follow-up period, patients with low-friction 0.022" brackets indicated the lowest level of pain (Table 2) (Figure 3).

Table 2. Comparison between groups concerning to visual analogue scale (VAS) measurements at different times. ($n = 120$).

Time		Conventional Brackets 0.018" (C18; $n = 30$)	Conventional Brackets 0.022" (C22; $n = 30$)	Low-Friction Brackets 0.018" (LF18; $n = 30$)	Low-Friction Brackets 0.022" (LF22; $n = 30$)
4 Hours (T0) *	Mean	3.8 ^b	3.8 ^b	2.0 ^a	2.8 ^{a,b}
	SD	2.3	2.9	1.9	3.1
	ANOVA F: 3.337; DF: 3; $p < 0.05$				
8 Hours (T1)	Mean	4.7	4.1	3.4	3.2
	SD	2.3	2.4	2.2	3.1
	ANOVA F: 2.237; DF: 3; $p = 0.088$				
24 Hours (T2)	Mean	5.0	4.5	5.6	4.2
	SD	2.7	2.2	2.0	2.7
	ANOVA F: 2.003; DF: 3; $p = 0.117$				
2 Days (T3) *	Mean	4.6 ^{a,b}	4.6 ^{a,b}	5.8 ^b	4.1 ^a
	SD	2.5	2.6	1.9	2.1
	ANOVA F: 2.773; DF: 3; $p < 0.05$				
3 Days (T4)	Mean	4.4	4.3	4.7	3.6
	SD	3.0	2.6	2.3	2.1
	ANOVA F: 1.124; DF: 3; $p = 0.342$				
4 Days (T5)	Mean	3.4	3.3	4.2	2.9
	SD	2.7	2.5	2.4	2.3
	ANOVA F: 1.442; DF: 3; $p = 0.234$				
5 Days (T6)	Mean	2.7	2.9	3.0	2.6
	SD	2.4	2.5	2.5	2.3
	ANOVA F: 0.146; DF: 3; $p = 0.932$				
6 Days (T7)	Mean	1.8	2.0	2.5	1.7
	SD	1.9	2.2	2.2	2.0
	ANOVA F: 0.758; DF: 3; $p = 0.520$				
7 Days (T8)	Mean	1.3	1.8	1.6	1.3
	SD	1.6	1.9	2.1	1.8
	ANOVA F: 0.450; DF: 3; $p = 0.718$				

Comparison between groups was performed by analysis of variance (ANOVA). The Bonferroni was applied to see the difference between groups with superscript letters ^{a,b} * Statistically significant difference at $p < 0.05$.

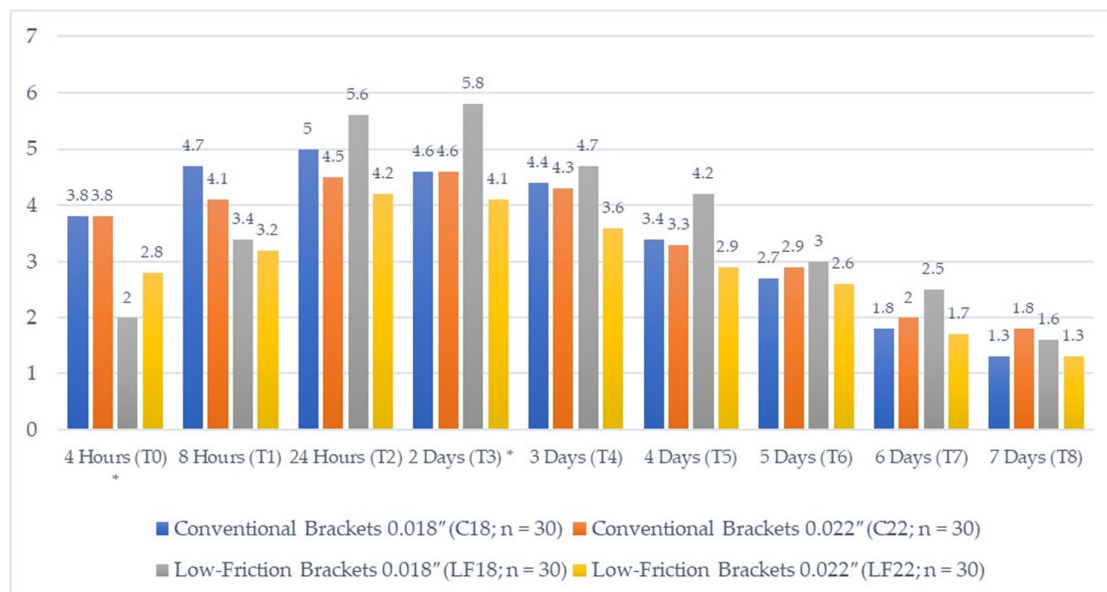


Figure 3. Comparison of pain measures by groups at different times using the VAS (* Statistically significant difference at $p < 0.05$).

In terms of analyzing the results of the impact of orthodontic treatment on patients' oral quality of life, there are statistically significant differences in physical pain, psychological discomfort, psychological disability, and the total OHIP questionnaire score ($p < 0.01$). A trend is observed for LF22, indicating the least impact on their OHRQoL compared to the other groups. In the domains of psychological discomfort (1.3 ± 0.8) and psychological disability (0.8 ± 0.9) and in the OHIP total score (4.5 ± 2.8), the group with low-friction 0.018" brackets showed the worst impact. Physical pain is the domain with the most negative impact on patients, followed by psychological discomfort (Table 3).

Table 3. Comparison of the groups in relation to the domains of the quality of life. ($n = 120$).

Domains		Conventional Brackets 0.018" (C18; $n = 30$)	Conventional Brackets 0.022" (C22; $n = 30$)	Low-Friction Brackets 0.018" (LF18; $n = 30$)	Low-Friction Brackets 0.022" (LF22; $n = 30$)
Functional limitation	Mean	0.4	0.5	0.6	0.3
	SD	0.6	0.7	0.8	0.5
ANOVA F: 1.310; DF: 3; $p = 0.275$					
Physical pain **	Mean	1.6 ^b	1.5 ^b	1.3 ^{a,b}	0.9 ^a
	SD	0.6	0.7	0.8	0.7
ANOVA F: 5.497; DF: 3; $p < 0.01$					
Psychological discomfort **	Mean	0.8 ^b	0.4 ^a	1.3 ^c	0.4 ^a
	SD	0.9	0.6	0.8	0.6
ANOVA F: 9.046; DF: 3; $p < 0.01$					
Physical disability	Mean	0.6	0.4	0.2	0.3
	SD	0.7	0.6	0.5	0.5
ANOVA F: 2.678; DF: 3; $p = 0.05$					
Psychological disability **	Mean	0.3 ^a	0.1 ^a	0.8 ^b	0.1 ^a
	SD	0.5	0.3	0.9	0.2
ANOVA F: 12.176; DF: 3; $p < 0.01$					
Social disability	Mean	0.1	0.1	0.3	0.1
	SD	0.4	0.3	0.5	0.4
ANOVA F: 1.957; DF: 3; $p = 0.124$					
Handicap	Mean	0.0	0.0	0.1	0.0
	SD	0.0	0.0	0.2	0.0
ANOVA F: 1.000; DF: 3; $p = 0.396$					
Total OHIP **	Mean	3.8 ^b	3.0 ^c	4.5 ^d	2.1 ^a
	SD	2.1	1.9	2.8	1.4
ANOVA F: 7.244; DF: 3; $p < 0.01$					

Comparison between groups was performed by ANOVA. The Bonferroni was applied to see the difference between groups with superscript letters ^{a,b,c} ** Statistically significant difference at $p < 0.01$.

A comparison was made evaluating the type of brackets, without taking into account the slot size. Regarding pain scores, statistically significant differences were observed at 4 h (T0; $p < 0.01$) and 8 h (T1; $p < 0.05$), and the group with conventional brackets described a higher level of pain (3.8 ± 2.6 ; 4.4 ± 2.4) than the group with low-friction brackets (2.4 ± 2.6 ; 3.3 ± 2.7). Throughout the follow-up period, there is a trend of the groups with low friction (LF) brackets describing a higher level of pain (Table 4).

Table 4. Pain on the VAS between groups at the different evaluation times ($n = 120$).

Time	Conventional Brackets. C ($n = 60$)		Low-Friction Brackets. LF ($n = 60$)	
	Mean	SD	Mean	SD
4 Hours (T0) **	3.8	2.6	2.4	2.6
8 Hours (T1) *	4.4	2.4	3.3	2.7
24 Hours (T2)	4.8	2.5	5.0	2.5
2 Days (T3)	4.6	2.5	5.0	2.2
3 Days (T4)	4.3	2.8	4.2	2.3
4 Days (T5)	3.4	2.6	3.6	2.4
5 Days (T6)	2.8	2.4	2.8	2.3
6 Days (T7)	1.9	2.1	2.1	2.1
7 Days (T8)	1.5	1.8	1.5	2.0

Comparison between groups applying the Student's *t*-test. * Statistically significant differences at $p < 0.05$. ** Statistically significant differences at $p < 0.01$.

Regarding the impact on the domains of OHRQoL, statistically significant differences are observed in the domains of physical pain ($p < 0.01$), psychological discomfort ($p < 0.05$), physical disability ($p < 0.05$), and psychological disability ($p < 0.05$). The group with conventional brackets described a greater impact in the domains of physical pain and physical disability (1.6 ± 0.6 ; 0.5 ± 0.7); however, the group with low-friction brackets described a greater impact in the domains of psychological discomfort and psychological disability (0.9 ± 0.8 ; 0.4 ± 0.7). We observed a trend of patients in the LF group brackets indicating a greater impact in most domains of OHRQoL compared to patients in the conventional (C) group brackets. The social disability and handicap domains had the least impact on patients (Table 5).

Table 5. Comparison of quality of life measures between treatment groups ($n = 120$).

Domains	Conventional Brackets. C ($n = 60$)		Low-Friction Brackets. LF ($n = 60$)	
	Mean	SD	Mean	SD
Functional limitation	0.4	0.6	0.5	0.6
Physical pain **	1.6	0.6	1.1	0.8
Psychological discomfort *	0.6	0.8	0.9	0.8
Physical disability *	0.5	0.7	0.3	0.5
Psychological disability *	0.2	0.4	0.4	0.7
Social disability	0.1	0.3	0.2	0.4
Handicap	0.0	0.0	0.1	0.1
Total OHIP	3.4	2.0	3.3	2.6

Comparison between groups applying the Student's *t*-test. * Statistically significant differences at $p < 0.05$. ** Statistically significant differences at $p < 0.01$.

4. Discussion

The aim of the study was to evaluate the influence of slot size (0.018" compared to 0.022") and low-friction on patient pain and OHRQoL during the first phases of orthodontic treatment. Due to the design of the study and the planned objectives, it was not possible to carry out a controlled study, since there was no control group without orthodontic treatment. Currently, there are limited published articles in the scientific literature that analyze oral pain and OHRQoL comparing conventional and low-friction brackets and, most importantly, the influence of slot size on these variables. The participants of this study were reasonably comparable, since no significant differences in terms of sex and age were observed. Published studies looking at conventional brackets versus low-friction brackets (Synergy®) are in vitro studies [17,19].

In this study, we used the VAS. The VAS is a useful tool to quantify pain perceived by patients and is widely used in various publications [19–22].

We observed that the peak of pain described by patients occurred between the first and second day after starting orthodontic treatment. The level of pain reached minimum values 7 days after

starting treatment. These results are in line with those of other studies [4,6,19,20,22,23]. This can be understood in terms of the synthesis of various biochemical mediators (such as cytokines and prostaglandins) relative to hyperalgesia, with peaks occurring 24 h after applying force to the teeth [24,25]. Seven days after starting treatment, we observed that the level of pain decreased until reaching minimum values. This coincides with other studies describing similar values to those obtained in this study [19,20,26].

Most of the published studies that quantify pain and the impact of treatment on OHRQoL have used brackets with a 0.022" slot [19,20,22,23], with only a few studies using brackets with a 0.018" slot [27]; hence the justification for analyzing the influence of slot size in this study. El-Angbawi AM et al. analyzed the influence of slot size (0.018" with 0.022") on pain during orthodontic treatment, and concluded that there were no statistically significant differences between the two study groups. In contrast to our study, these authors evaluated pain 6 months after starting treatment [28].

The patient's perception of orthodontic treatment is an important factor to consider. Before and during orthodontic treatment there are changes in the patients' quality of life. A multifactorial concept that helps us to measure these changes is the OHRQoL. To measure these psychosocial factors, there are many questionnaires. The Oral Health Impact Profile-14 (OHIP-14) is the most used questionnaire to evaluate OHRQoL and was used in this work [10,29–32].

Physical pain is the domain of OHRQoL that patients describe as having the greatest impact, followed by psychological discomfort. Social disability and handicap domains have the lowest scores on the OHIP-14 questionnaire. Our results coincide with those observed by other authors, especially during the first phases of orthodontic treatment [29,30,33]. Other authors did not observe statistically significant differences in the impact of orthodontic treatment on OHRQoL when evaluating conventional and self-ligating brackets [33,34].

The literature is scarce regarding information assessing the influence of bracket slot size on pain and OHRQoL in orthodontic patients. The methodology used in this study has been similar to that used in other scientific studies that analyze pain and OHRQoL in orthodontic treatment [6,10,20,22,23,26,29–34].

Depending on the results obtained, we can give the patient information before and during the orthodontic treatment about which factors will have the greatest impact on their quality of life. Therefore, we can achieve greater cooperation from the patient and take preventive measures that will help to have greater success in future fixed orthodontic treatments.

This study has several limitations in terms of sample size, the short follow-up period in relation to the duration of orthodontic treatment, and the absence of OHRQoL evaluation before starting orthodontic treatment. The possibility of generalizing these results could be limited as they are carried out in the same centre; therefore, we would need to carry out a multi-center study with a larger sample size. In the future, a larger sample and randomized studies will be required to evaluate pain and improvements in OHRQoL following orthodontic treatment. It may be helpful to stratify the randomization by age and analyze young people and adults separately in future studies. Further multicenter clinical trials with longer treatment periods are necessary to eliminate the effect of the bias for the results.

5. Conclusions

The results showed that the peak of orthodontic pain perceived by the patients occurs between the first and second day after the initial bonding and placement of the fixed appliances. The level of pain decreases until minimum pain levels are found a week after the placement of the fixed multibrackets. Patients with 0.018" brackets indicate a higher level of pain and a more negative impact on their OHRQoL. Thus, the type of bracket system and the size of the bracket slot had a significant effect on the subjective experience of pain and OHRQoL during the initial stage of orthodontic treatment.

Author Contributions: A.C., A.A., J.M., M.A.-L., D.G., and A.A.-L. conceived and designed the study. Data collection was conducted by A.C. and A.A.-L. Analyses were performed by A.C., A.A., J.M., M.A.-L., D.G., and

A.A.-L. A.C., M.A.-L., and J.M. helped with data interpretation. All authors have read and agreed to the published version of the manuscript.

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