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Original Article

Modified short version of the oral health impact profile for patients undergoing orthodontic treatment

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Aim: To derive and validate a short version of the Oral Health Impact Profile (OHIP) in Spanish to measure oral health quality of life (OHRQoL) for subjects wearing fixed orthodontic appliances. **Methods:** Cross-sectional study (data for sensitivity to change analysis were collected longitudinally). The data of 400 subjects (27.34 years, SD 11.66 years, 231 women, and 169 men) were used to develop a short-form instrument, and the data of 126 other subjects (25.95 years, SD 12.39 years, 62 women, and 64 men) were used for its validation. The original OHIPs were translated into Spanish using an iterative forward-backward sequence. After face and content validity were evaluated by an expert committee, an exploratory factorial analysis (EFA) was used to derive the Spanish short-form instrument (OHIP-S14 Ortho). To validate the OHIP-S14 Ortho, validity (content validity assessed by EFA, construct validity assessed by confirmatory factor analysis (CFA), discriminative validity assessed by the Kruskal-Wallis test, and reliability (internal consistency assessed by Cronbach's α test-retest, and inter-observer reliability assessed by correlation coefficients) were evaluated. Sensitivity to change and usefulness of the scale were also evaluated. **Results:** The OHIP-S14 Ortho included only six of the items in Slade´s original OHIP-14 short-form. A two-factor structure with adequate discriminative validity was found. High internal consistency (α=0.912), excellent inter-observer (Lin's correlation=0.97±0.011; rho= 0.97), test-retest agreement (Lin's correlation=0.80±0.059) and adequate sensitivity to change were also found. **Conclusions:** The OHIP-S14 Ortho is a valid and reliable instrument to measure OHRQoL in Spanish-speaking patients with fixed orthodontic appliances.

Keywords: Quality of Life. Reproducibility of results. Orthodontic appliances.

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Introduction

Oral health-related quality of life (OHRQoL) is multidimensional and impacts the functional, psychological, and social aspects of daily life[1]. Individuals seek orthodontic treatment mainly because they are dissatisfied with their appearance, dental malposition, deformity of the teeth, or spaces between them[2]; therefore, OHRQoL after orthodontic treatment tends to improve[3]. However, wearing fixed orthodontic appliances can cause pain and difficulty with eating, speaking, or smiling, and the OHRQoL seems to deteriorate during orthodontic treatment[4,5].

The most widely used instrument to measure OHRQoL is the Oral Health Impact Profile (OHIP), which was proposed by Slade and Spencer[6]. The long-form of this instrument has 49 items (OHIP-49), the short form has 14 items (OHIP-14), and the instrument covers seven dimensions (i.e., functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap). A long questionnaire may not be feasible to administer in clinical settings because it has a high cost of administration and data provision, takes a long time to complete and score, and causes a burden on the respondent, which may lead to the exclusion of a substantial proportion of respondents or problems arising from the need to impute missing data[7]. Because of respondents' different cultural backgrounds, short forms of the OHIP-49 have been derived and validated in different languages and countries[8-13], and most of them were validated in an adult population with oral health or oral rehabilitation needs.

Although the World Health Organization (WHO)[14] does not consider malocclusion an illness and most patients continue to have good oral health during orthodontic treatment, wearing fixed appliances may affect aspects of a patient's quality of life in different ways when compared to patients who have caries, tooth loss, or periodontal disease. Pain is a near pervasive unpleasant experience encountered during orthodontic treatment. Numerous authors[15-18] have linked orthodontic treatment to the experience of pain, finding that orthodontic patients are most likely to experience increased levels of pain for one to three days following the placement of their appliance and subsequent adjustment visits. To date, to the best of our knowledge, a short form of OHIP has not been developed for patients with orthodontic treatment. For this reason, the present research study aims to derive and validate a short form of the OHIP-49 (OHIP-S14 Ortho) in Spanish to measure OHRQoL in patients wearing orthodontic appliances.

Materials and Methods

This was a cross-sectional study. However, the data for sensitivity to change analysis was collected longitudinally. The study included individuals who were wearing fixed orthodontic appliances provided by UniCIEO University in Bogotá, Colombia, between January 2016 and November 2017. This study was approved by the UniCIEO University Ethics Committee. All participants and parents/guardians of minors signed the informed consent form. The research was conducted in full accordance with the World Medical Association Declaration of Helsinki.

From 1,151 eligible subjects during the study period, 400 were chosen by non-probabilistic sampling (for convenience) for the OHIP short version derivation. Additionally, another 126 subjects were chosen for the OHIP-S14 Ortho validation. The sample size was estimated using the criterion recommended by Streiner[19], which recommends that 5 to 10 subjects per variable be included in the sample. For the reliability assessment, the calculation of the sample size for the intraclass correlation coefficient (ICC) was considered to achieve an ICC equal to or greater than 0.6, a confidence interval (CI) of 95% ($\alpha = 0.05$) and 90% power was calculated, resulting in a sample size of 25 subjects.

A total of 126 subjects were included in the internal consistency analysis. Randomly (simple random sampling) selected were 40 for the test-retest reliability analysis, 30 for the inter-observer agreement analysis, 25 for the sensitivity to change analysis, and 50 for the analysis of the instrument's usefulness. The inclusion criteria involved patients who had active orthodontic treatment with fixed orthodontic appliances, who were ≥12 years old, and whose native language is Spanish. Patients with a physical or mental disability that hindered administration of the survey and patients with other oral health conditions (e.g., cavities, muscle pain, periodontal pain) were excluded.

The OHRQoL was measured by the OHIP-49 scale[6]. The questionnaire was self-administered by the participants on paper, except for the assessments related to the sensitivity to change (the scale was administered at three time points: T0=immediately before bracket placement, T1=24 to 48 hours after bracket placement, and T2=2 weeks after bracket placement), interobserver agreement (two observers administered the instrument in 5-minute intervals) and test-retest reliability (application of the instrument repeatedly, at two time points separated by 24 to 48 hours), which were completed through telephone interviews by three researchers previously trained in the implementation of the instrument (Kappa: 0.88). The time intervals were chosen because the changes in the short time of the status of patients wearing fixed orthodontic appliances, due to the activation of the devices, the type of arch, etc.

Demographic variables (i.e., sex; age) were recorded at the time that the questionnaire was applied. Two clinical variables were retrieved from clinical records: the time having worn the fixed appliances at survey's administration, in days, and time since the last orthodontic adjustment visit. Discriminative validity was evaluated by a Visual Analogue Scale for Pain (VAS Pain). Scores were assigned, with 0 corresponding to the absence of pain and 10 corresponding to the highest intensity of pain. The scores were categorized as mild (0 to 2), moderate (3 to 7), or intense (8 to 10). The time required to complete the questionnaire for both the long-form and the short-form was also recorded.

As recommended by WHO, a systematic approach to translation and adaptation was conducted[20]. It requires five steps: forward-translation, expert panel discussion, backward translation, a pre-test, a cognitive briefing, and a consensus on the final version. The English version of the OHIP-49[6] was translated into Spanish by four bilingual professionals (three Colombian and one British professional) using an iterative forward-backward sequence. Four orthodontists and four orthodontic patients assessed the face validity (i.e., Does the test "look like" a measure of the construct of interest?) and content

validity (i.e., Does the test contain items from the desired "content domain"?). A subsequent preliminary fit test was performed with 10 orthodontic patients.

Statistical Analysis

The statistical analysis was performed with STATA14 software (version 14.0; StataCorp, College Station, Tex). The statistical analysis process was conducted in consecutive steps as follows:

1. OHIP-S14 Ortho *Derivation*: To derive a subgroup of 14 questions, an exploratory factor analysis (EFA) was used (assumptions previously verified: sphericity by using Bartlett's sphericity test (P<0.05) and sampling adequacy by using the Kaiser-Meyer-Olkin (KMO) >0.80). The factors to be extracted were determined by the percentage and variance explained (minimum of 80%). The factor loads for each question were estimated to identify those that exceeded 0.4, which was the cutoff point for moderate to high loads. Then, the items that presented the highest factor loads were chosen, and no more than two items of each conceptual dimension were included. To determine whether the removal of the individual items affected the internal consistency of the derived OHIP short version, an analysis using Cronbach's α coefficient was carried out.

2. OHIP-S14 Ortho Validation

2.1 Validity of the OHIP-S14 Ortho:

Content validity was evaluated by exploratory factor analysis (EFA). Construct validity was evaluated by confirmatory factor analysis (CFA) using the maximum likelihood method. The fit of a model was considered adequate when the ratio of the chi-squared value to the degrees of freedom ($\chi 2/df$) <2.0, root mean square error of approximation (RMSEA) <0.10, comparative adjustment index (CFI) >0.90, Tucker-Lewis index (TLI) >0.9 and low values of the Akaike information criterion (AIC), Browne-Cudeck criterion and the Bayes information criterion (BIC) were obtained[21]. Discriminative validity was evaluated by comparing the OHIP-S14 Ortho with a VAS Pain categorized scale (mild, moderate, severe) by the Kruskal Wallis test.

2.2 Reliability of the OHIP-S14 Ortho:

Internal consistency was evaluated by the Cronbach's α coefficient. Intra-observer reliability (test-retest) was evaluated by Lin's concordance correlation coefficient. The inter-observer reliability was evaluated by the Spearman correlation coefficient and Lin's concordance correlation coefficient.

2.3 Sensitivity to change:

This was evaluated by comparing the measurements at T0, T1, and T2 by the Wilcoxon signed-rank test for paired samples.

Our approach to avoiding missing data was to maximize the data collection by explaining to participants the importance of their responses and motivating them to fill out the surveys. However, in the cases where missing data happened, a listwise deletion method was used.

Results

The descriptive statistics of the samples are shown in Table 1. The sample to derivate the OHIP-S14 Ortho was composed of 400 subjects (27.34 years, SD 11.66, 231 women, and 169 men). Another sample of 126 subjects was used for its validation (25.95 years, SD 12.39, 62 women, and 64 men). The mean time spent wearing fixed appliances was 420.76 (SD = 331.46) days for the short version derivation sample and 146.167 (SD = 262.43) days for the OHIP-S14 Ortho validation sample.

The experts' panel removed three of the OHIP-49 questions from the questionnaire; two referred to edentulous patients (Q17 and Q18), and one (Q3: a tooth that does not look good) was redundant and confusing for orthodontic patients. This is because patients seeking orthodontic treatment perceive that crowded teeth do not look good. A modification in the questions related to time was also made; the text was modified to 1 month to match the orthodontic appointment interval.

Table 1. Demographic and clinical characteristics of the subjects

	Sample for short version derivation (n=400)		**Sample for OHIP-S14 Ortho validation (n=126)**	
	Categorical variables			
	n	%	n	%
Sex				
Male	169	42.25	64	50.79
Female	231	57.75	62	49.21
Age categorized				
<18 years old	71	17.75	33	26.19
≥ 18 years old	329	82.25	93	73.81
	Quantitative variables			
	mean (sd)	median (min-max)	mean (sd)	median (min-max)
Age				
Total sample	27.375 (11.633)	24 (12-66)	26.055 (12.440)	22 (12-66)
<18 years old	15.154 (1.348)	15 (12-17)	14.654 (1.486)	14.71 (12-17)
≥ 18 years old	30.012 (11.177)	26 (18-66)	30.101 (12.097)	26 (18-66)
Time wearing fixed appliances (days)	420.76 (331.46)	364 (1-1932)	146.167 (262.43)	80.5 (1-1334)
Time since the last orthodontic adjustment visit (days)	28.81 (14.03)	28 (7-84)	32.18 (25.09)	28 (0-112)
OHIP-49 total score	26.53 (19.591)	23 (0-108)	-	-
<18 years old	21.452 (14.974)	19 (0-64)	-	-
≥ 18 years old	27.626 (20.304)	23 (0-108)	-	-
OHIP-S14 Ortho total score	-	-	10.849 (9.138)	9 (0-45)
<18 years old	-	-	8.333 (7.056)	6 (0-31)
≥ 18 years old	-	-	11.742 (9.647)	10 (0-45)
VAS Pain total score (scale 10mm)	-	-	3.40 (2.43)	3 (0-10)

1. OHIP-S14 Ortho *Derivation*:

EFA was performed after it was verified that the data met the assumptions (Bartlett's sphericity test (X^2 =9808.468, P<0.0001), KMO =0.911). Four factors were extracted by the percentage and variance explained (minimum of 80%); the first had an eigenvalue of 13.06, which accounted for 50.71% of the variance, and the four factors accounted for 80.34% of the variance (Table 2).

Table 2. Exploratory factor analysis OHIP-49 and OHIP-S14 Ortho. The factors were extracted by the percentage and variance explained (minimum of 80%).

OHIP-49				OHIP-S14 Ortho			
Factor	**Eigenvalue**	**% of variability**	**% of cumulative variability**	**Factor**	**Eigenvalue**	**% of variability**	**% of cumulative variability**
1	13.06	50.71	50.71	1	6.50	78.9	78.9
2	3.6	13.98	64.69	2	1.02	12.4	91.23
3	2.46	9.55	74.24				
4	1.57	6.1	80.34				

Table 3 shows the non-response item frequency, item prevalence (% of responses corresponding to occasionally, fairly often, or very often), item severity (item mean), and the OHIP-S14 Ortho development procedure with the highest factorial load questions. EFA correlation loads greater than 0.4 were represented almost entirely by factor 1, except for seven questions (Q2, Q11, Q12, Q25, Q44, Q45, Q48). The 14 items selected according to their factor loads were Q1, Q4, Q16, Q15, Q23, Q22, Q32, Q31, Q34, Q35, Q41, Q42, Q47, and Q46.

Internal consistency (Cronbach's α coefficient) for the OHIP-49 was in total of α= 0.93 (Annex 1).

The comparison of the obtained questions of the OHIP-S14 Ortho with those of the OHIP-14 derived by Slade[22] are shown in table 4. Only six items from Slade's original OHIP-14 version were included in the OHIP-S14 Ortho. OHIP S14- Ortho agreed in six questions with the original OHIP-14 short form.

Table 3. Prevalence, mean, exploratory factor analysis of OHIP long-form questions

Item and conceptual dimension	No response %	% Prevalence	Mean	General factor load
Functional limitation				
Q1 Difficulty chewing	0	46.25	1.28	0.53*
Q2 Difficulty pronouncing words	0	17	0.6	0.4
Q3 Tooth that does not look good	.	.	.	.
Q4 Affected appearance	0.25	20	0.657	0.58*
Q5 Bad breath	0	28	0. 787	0.4
Q6 Worsened taste	0.25	7.25	0.276	0.47
Q7 Stuck Food	0.75	7.25	2.065	0.48
Q8 Digestion worsened	0	5.75	0.255	0.45

Continue

Continuation

Physical Pain				
Q9 Pain in a wound mouth	0	53	1.497	0.51
Q10 Discomfort in the jaw	0.50	21	0.693	0.50
Q11 Headaches	0	9	0. 32	0.38
Q12 Sensitive teeth	0.25	41	1.22	0.36
Q13 Pain in your teeth	0.25	53	1.464	0.45
Q14 Pain in your gums	0.25	24	0.819	0.47
Q15 Eating discomfort	0.25	58	1.569	0.59*
Q16 Painful sites in the mouth	0	45.5	1.28	0.62*
Q17 Unfitted dentures	.	.	.	.
Q18 Uncomfortable dentures	.	.	.	.
Psychological discomfort				
Q19 Worried	0	15	0.522	0.45
Q20 Self-conscious	0	12	0.42	0.65
Q21 Unhappy	0	7.25	0.23	0.60
Q22 Appearance of brackets	0	14.25	0.485	0.67*
Q23 Tense	0	13.75	0.455	0.66*
Physical disability				
Q24 Speak badly	0	15.75	0.545	0.49
Q25 People do not understand my words	0	14.75	0.482	0.37
Q26 Less flavor in food	0	8.25	0.307	0.51
Q27 Unable to brush your teeth	0	35.5	1.04	0.48
Q28 Avoid eating	0.25	61.25	1.697	0.53
Q29 Unsatisfactory diet	0	17.5	0.547	0.54
Q30 Unable to eat	0	17	0.597	0.61
Q31 Avoid smiling	0.50	19.75	0.623	0.67*
Q32 Discontinuing meals	0	21.75	0.685	0.66*
Psychological disability				
Q33 Interrupting sleep	0	6.25	0.26	0.56
Q34 Upset	0	17.25	0.55	0.72*
Q35 Difficulty to relax	0.75	2.5	0.325	0.70*
Q36 Depressed	0	3.75	0.147	0.62
Q37 Affected attention	0	2.25	0.157	0.54
Q38 Ashamed	0.25	11	0.383	0.69
Social disability				
Q39 Avoid leaving	0.50	2.75	0.131	0.58
Q40 Less tolerant with others	0.25	3.25	0.15	0.52
Q41 Interacting with others	0.25	3.75	0.15	0.61*
Q42 Irritable with others	0.25	3.5	0.168	0.59*
Q43 Difficulty of working	0.25	2.25	0.113	0.50
Handicap				
Q44 General affected health	0.25	1.25	0.078	0.31
Q45 Financial loss	0.25	5.75	0.215	0.23
Q46 Enjoy company	0.25	2.75	0.095	0.49*
Q47 Unsatisfactory life	0.25	2.5	0.12	0.54*
Q48 Unable to operate	0.25	0	0.03	0.34
Q49 Unable to work	0.25	1.5	0.083	0.43

* Highest factorial load questions (selected two for each dimension).

Table 4. Comparison of OHIP-14 Original Slade questions and OHIP-S14 Ortho questions

	OHIP -14 (Original Slade)		OHIP- S14 Ortho	
		Question		
Functional limitation	2	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	1	¿En el último mes ha tenido dificultad para masticar algún tipo de comida debido a sus brackets? In the last month have you had difficulty chewing any type of food because of your brackets?
	6	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	4	¿En el último mes ha tenido la sensación de que su apariencia se ve afectada debido a sus brackets? In the last month have you had the feeling that your appearance is affected due to your brackets?
Physical Pain	9	Have you had painful aching in your mouth?	16	¿En el último mes ha tenido sitios dolorosos en su boca debido a sus brackets? In the last month have you had painful sites in your mouth because of your brackets?
	15	Have you found it uncomfortable to eat any foods because of your teeth, mouth or dentures?	15	¿En el último mes ha sentido incomodidad al comer algunos alimentos debido a sus brackets? In the last month have you felt discomfort when eating some foods due to your brackets?
Psychological discomfort	20	Have you been self-conscious because of your teeth, mouth or dentures?	22	¿En el último mes se ha sentido incomodo debido a la apariencia de sus Brackets? In the last month, have you felt uncomfortable due to the appearance of your brackets?
	23	Have you felt tense because of problems with your teeth, mouth or dentures?	23	¿En el último mes se ha sentido tenso debido a sus brackets? In the last month, have you felt tense because of your brackets?
Physical disability	29	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	31	¿En el último mes ha evitado sonreír debido a sus brackets? In the last month have you avoided smiling because of your brackets?
	32	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	32	¿En el último mes ha tenido que interrumpir sus comidas debido a sus brackets? In the last month you had to interrupt your meals because of your brackets?
Psychological disability	35	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	35	¿En el último mes ha encontrado dificultad para relajarse debido a sus brackets? In the last month have you found difficulty relaxing due to your brackets?
	38	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	34	¿En el último mes se ha sentido molesto debido a sus brackets? In the last month, have you felt upset due to your brackets?
Social disability social	42	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	42	¿En el último mes ha estado un poco irritable con otras personas debido a sus brackets? Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
	43	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	41	¿En el último mes ha tenido dificultad para interactuar con otras personas debido a sus brackets? In the last month have you had difficulty interacting with other people because of your brackets?
Handicap	47	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	47	¿En el último mes ha tenido la sensación que su vida en general ha sido menos satisfactoria debido a sus brackets? In the last month you have had the feeling that your life in general has been less satisfactory due to your brackets?
	48	Have you been unable to function because of problems with your teeth, mouth or dentures?	46	¿En el último mes ha sido incapaz de disfrutar de la compañía de otras personas debido a sus brackets? In the last month have you been unable to enjoy the company of other people because of your brackets?

2. OHIP-S14 Ortho Validation

2.1 Validity of the OHIP-S14 Ortho:

Content validity was evaluated by an EFA, and the assumptions were previously verified (Bartlett sphericity test (X^2 =981.003, *P*<0.0001), KMO=0.863). Two factors were extracted, which accounted for 91.23% of the variance (Table 2). Construct validity assessed by the CFA model showed two latent dimensions (functional and social) from the OHIPS14 Ortho. Three bi-dimensional models were evaluated by the chi-squared value (χ^2/df), AIC and TLI. The third model, with associations (Q4, Q46, Q1, Q15, Q34, Q22, Q23) and covariances between most of the items, was deemed best, as it had strong item loadings and a strong model fit (AIC=3711.92; TLI=0.972, χ2/df=1.29, CFI=0.981, RMSA=0.049; SRMR=0.037) (Table 5 and Annex 2).

Table 5. Confirmatory factor analysis (CFA) OHIP-S14 Ortho

	Chi²	X²/df	RMSA	AIC	BIC	CFI	TLI	SRMR	AVE FUNC	AVE SOCIAL
Model 1	223.33	2.93	0.125	3895.58	3946.85	0.84	0.813	0.075	0.51	0.517
Model 2	186.84	2.70	0.117	3803.09	3944.1	0.87	0.835	0.054	0.531	0.533
Model 3	77.67	1.29	0.049	3711.92	3878.31	0.981	0.972	0.037	0.507	0.513

RMSEA (mean square error of approximation); AIC Akaike BIC information criterion (Bayesian information criterion); CFI (comparative adjustment index); TLI (Tucker-Lewis index); SRMR (Root square of the average of the sum of the squares of the residues); AVE (average variance extracted); FUNC (functional).

The mean scores of OHIP-S14 Ortho that showed statistically significant differences by sex were Q15, Q16, and Q42, with higher values in females. The questions with the highest negative impact on the OHRQoL were Q15 and Q16 (Figure 1).

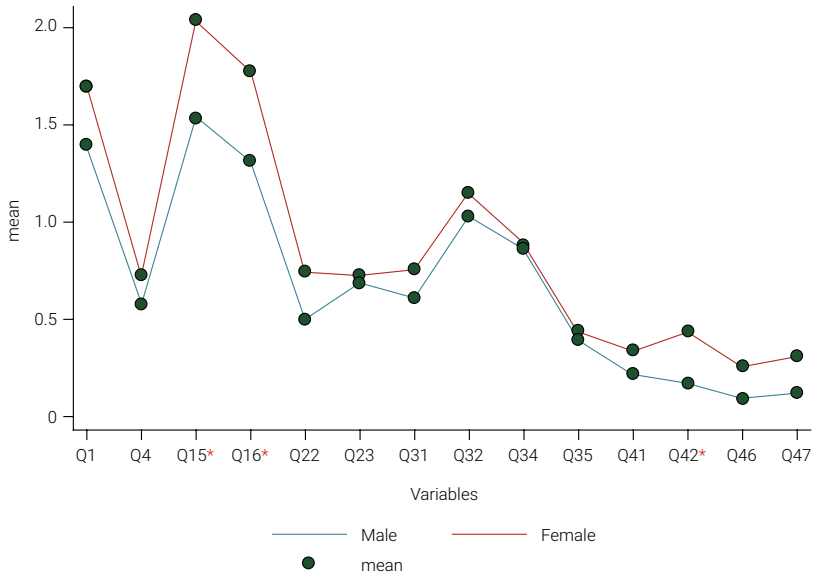

Figure 1. Mean scores of the OHIP-S14 Ortho questions by sex.

Discriminative validity showed significantly (P<0.05) higher OHIP-S14 Ortho scores in the intense pain perception group (19.56) than in the moderate (13.45) and mild (6.1) pain perception groups.

2.2 Reliability of the OHIP-S14 Ortho:

Internal consistency (Cronbach's α coefficient) for the *OHIP-S14 Ortho* was in total of α= 0.91 (Annex 1). The intra-observer reliability assessment (test-retest) showed excellent correlation (Lin's correlation=0.80±0.059; 95% CI:0.68;0.91). The inter-observer agreement analysis showed a high correlation (Lin's correlation=0.97±0.011; 95% CI:0.68;0.91 and Spearman correlation coefficient=0.97).

2.3 Sensitivity to change:

The OHIP-S14 Ortho scores recorded at different time points were T0=2.64, SD 6.59, T1=14, SD 10.27, and T2=11.92, SD 7.76, showing adequate sensitivity to change. There were significant differences (P=0.001) between the OHIP-S14 Ortho scores at T0-T1 and T0-T2, but there were no differences between T1 and T2 (P=0.0937) (Annex 3). Additionally, there was a 6.13-minute reduction in the scale administration time of the OHIP-S14 Ortho compared with that of the long form of the OHIP.

Discussion

OHIP-S14 Ortho Development

According to our results, a version of OHIP-14 was extracted for subjects with fixed orthodontic appliances. The OHIP-S14 Ortho had eight items that were different from those in the original short-form OHIP developed by Slade[22]. Two were from the functional limitation dimension (Q1: difficulty chewing, Q4: "appearance affected"), and six were from each of the other six dimensions (Q16: "sore spots", Q22: "appearance", Q31: "avoid smiling", Q34: "upset", Q41: "trouble getting on with others", and Q46: "unable to enjoy people's company").

Compared with the OHIP-S14 Ortho, a different version in Spanish developed by Castrejón-Perez and Borges-Yañez[9] had seven different items, and another version in Spanish developed by León et al.[13] did not have any matching items. Likewise, other short forms of the OHIP derived by other authors[8,23-26] differ from the original short-form OHIP derived by Slade[22]. The differences might be explained by the cultural distinctiveness of the populations studied, the short-form development methodologies, or the specific impact that fixed orthodontic appliances have on the subject. The OHIP's versions mentioned were about populations with dental needs other than patients wearing fixed orthodontic appliances. Fixed orthodontic appliances affect functional and physical dimensions, making it difficult to consume certain hard and sticky foods, which can cause pain or damage to the appliance. They can also affect appearance, which can generate a social impact on the daily life of patients, preventing them from smiling, and participating in social activities[27,28].

One important aspect to be considered is the different statistical methods used to derive the different OHIP short forms. In our study, we used the statistical methods suggested by Slade and Spencer[6] that were also applied by León et al.[13], (reliability analysis, principal component factor analysis, and least squares regression analysis), whereas other studies used a statistically significant association about the clinical variables[9], the item frequency method[8], or EFA[29]. The sample's age range is another important factor to consider. Most of the studies were conducted with subjects older than 60 years[9,13,22] who had oral rehabilitation needs, while the sample in our research mainly included patients over 11 years old, as adolescents and young adults mostly represent the population undergoing orthodontic treatment.

OHIP specifically evaluates problems with the mouth, teeth, or dentures, as proposed by Slade and Spencer[6]. However, as shown by the results of this study, the scale can be adapted by an appropriate method to another target population, such as patients undergoing orthodontic treatment. Likewise, the scale can be adapted to assess the impact on OHRQoL in the last month, which, in patients with orthodontic treatment, accounts for the most recent impact of orthodontic treatment, whereas, with the original OHIP-49[6,22,30], it was assessed over the previous year.

The two items from each dimension from the original OHIP were maintained in the OHIP 14 S-Ortho. Also, the high Cronbach's alpha (0.912) indicates that the scale measures the same construct. Therefore, we suggest that this number of items satisfactorily evaluates the OHRQoL construct for orthodontic patients[31].

OHIP-S14 Ortho Validation

This study demonstrated appropriate validity of the OHIP-S14 Ortho scale across two main dimensions (functional limitation and social disability) and the associations and covariances between all the items. Santos et al.[32] compared one-dimensional and tri-dimensional structures of the OHIP-14 and reported that the scale measures one single construct. John et al.[33] compared the psychometric performance of three models: a unidimensional model, a four-factor model, and a bifactor model, showing that the model with the best fit was the four-factor model. However, the other two models also showed a good fit, suggesting that one OHIP summary score is sufficient to characterize OHRQoL.

The OHIP-S14 Ortho showed excellent discriminative validity compared with the Visual Analog Scale for Pain (VAS Pain). Other authors used clinical variables such as periodontal status, caries, or missing teeth to evaluate the discriminative validity[8-11,13,22] because these variables affect OHRQoL. Moreover, in orthodontic patients, oral health must be at an optimum level to initiate tooth movement. Pain and discomfort occur as part of orthodontic mechanotherapy, but it is an individual and subjective response dependent on factors such as age, sex, individual pain thresholds, the magnitude of the force applied, the current emotional state and stress, cultural differences, and previous pain experiences[27]. Thus, this research allows clinicians to improve communication with patients so that they can plan treatment and use the OHIP-S14 Ortho in daily practice.

According to the reliability results, the OHIP-S14 Ortho indicated to have very good internal consistency (Cronbach's α coefficient = 0.912), a good level of test-retest agreement (Lin's=0.80; ICC=0.894), and inter-observer agreement (Lin's=0.97; Spearman=0.97). Similar results were reported in other studies[9,13,33].

The scale also demonstrated good sensitivity to change in the initial stages of orthodontic treatment, showing that the OHIP-S14 Ortho has a good capacity to respond to changes in the OHRQoL that occur during orthodontic treatment, but more extensive testing of the measure's responsiveness to change needs to be carried out to confirm this statement. Although in previous studies[8-10,12,13,22] sensitivity to change has not been evaluated, it is important to measure the impact of orthodontic treatment on OHRQoL over time. Mansor et al.[5], found that OHRQoL became highly deteriorated within 24 hours after the placement of fixed orthodontic appliances. Streiner[19] and Johal et al.[28] determined that the initial stages of fixed appliance treatment result in a negative impact on the quality of life and pain experience but that pain and discomfort intensity significantly decrease three days after the bracket's placement and over the following three months. In our study, Q15 (eating discomfort) and Q16 (painful sites in the mouth) had a higher negative impact on the OHRQoL, suggesting that pain and discomfort are the main impact during orthodontic treatment. To assess the impact on OHRQoL in a wide range of time wearing fixed orthodontic appliances since discomfort is experienced in the first 24 hours after brackets placement and subsequent adjustment visits[5,19,28]. However, this assessment could be a limitation due to the inaccuracy which is derived from this aspect, so future research with homogeneous ranges of time of wearing fixed orthodontic appliances is recommended.

Within the limitations of the current study, the data did not show ceiling effects, as the maximum score of 56 of the OHIP-14 scale was not reported by any of the participants. Meanwhile, there were floor effects (scores of 0), which might suggest that the questionnaire is not picking up all the potential impacts of a fixed appliance, and it might be helpful to implement further qualitative work to determine this.

Kettle et al.[34] identified from young people a multi-dimensional social process of managing everyday life with an orthodontic appliance. This study only included subjects wearing buccal fixed appliances; therefore, the impact of other removable appliances, retainers, or lingual brackets was not measured with the OHIP-S14 Ortho, and the results are not generalizable to all kinds of orthodontic treatment. Although the original OHIP-14 version was derived from adult patients, in orthodontics, it has been widely used with patients under 18 years of age[5,28] as it was with our study; however, it would be more appropriate to use the OHIP-14 with individuals' questionnaires developed for young people as is the Child Oral Health Impact Profile (COHIP)[35]. In our results, both OHIP-49 and OHIP-S14 Ortho total scores were higher in adult patients (≥ 18 years old) than in younger patients, suggesting a different impact in the OHRQoL according to age. Further research considering important variables that were not examined in this study, such as socioeconomic status and psychological parameters (self-esteem, depression, and stress), must be done.

Regarding the usefulness of the OHIP-14 scale, in our study, the time to completion of the long-form OHIP was 8.93 minutes, while for the OHIP-S14 Ortho, it was 2.8

minutes. This shows that there was a significant decrease in the time to completion of the questionnaire. Currently, people's time and their compliance with surveys are very important; therefore, long-form questionnaires must be avoided. However, other authors have suggested that reducing the number of questions in the instrument can affect their psychometric properties and that an excessive simplification of the scale can lead to negative interpretations[7]. Conversely, other studies[3,31] have suggested that a reduction in the number of questions does not affect the responsiveness of the instrument, but it does affect its validity and reliability.

Another factor to take into account is the response scale used in this study. Although it is easily quantifiable and understood, it might not measure the true attitudes of respondents, which could underestimates the effects of impacts of high concern to individuals, as the impact of the malocclusion is largely in the emotional and social well-being subscales[34].On the other hand, our study analysis approach was by classical test theory (CTT) instead of the item response theory (IRT), based on the notion that CTT does not invoke a complex theoretical model to relate an examinee's ability to succeed on a particular item and that is easier to apply in many testing situations. However, readers must be aware of the weakness of CTT in terms of its circular dependency on item/person statistics.

As the conclusions of the present study, the OHIP-S14 Ortho is a valid and reliable instrument to measure OHRQoL in Spanish-speaking patients with fixed orthodontic appliances, and the construct validity of the OHIP-S14 Ortho showed a two-dimensional structure with associations and covariances between all the items.

Ethics statement: Individuals who were wearing fixed orthodontic appliances were provided by the UniCIEO University in Bogotá, Colombia. This study was approved by the UniCIEO University Ethics Committee.

Conflicts of interest: None.

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Annex 1**.** Reliability: Cronbach's alpha values for OHIP-49 and OHIP-S14 Ortho

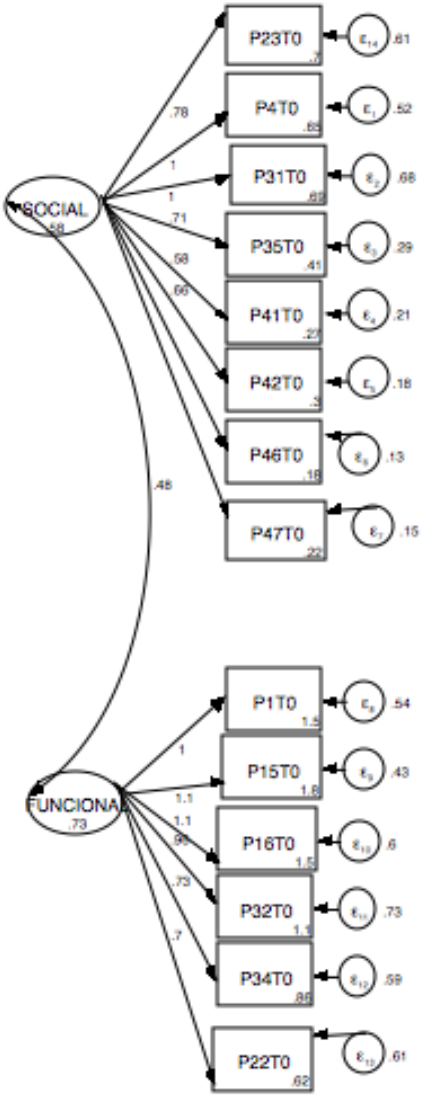
OHIP-49					
Question	Item	Cronbach´s α	Question	Item	Cronbach´s α
Q1	Difficulty chewing	0.93	Q27	Unable to brush your teeth	0.93
Q2	Difficulty pronouncing words	0.93	Q28	Avoid eating	0.93
Q4	Affected appearance	0.93	Q29	Unsatisfactory diet	0.93
Q5	Bad breath	0.93	Q30	Unable to eat	0.93
Q6	Worsened taste	0.93	Q31	Avoid smiling	0.93
Q7	Stuck food	0.93	Q32	Interrupting meals	0.93
Q8	Worsened Digestion	0.93	Q33	Interrupting sleep	0.93
Q9	Pain due to wounded mouth	0.93	Q34	Annoyed	0.93
Q10	Discomfort in the jaw	0.93	Q35	Difficulty to relax	0.93
Q11	Headaches	0.93	Q36	Depressed	0.93
Q12	Sensitive teeth	0.93	Q37	Affected attention	0.93
Q13	Pain in their teeth	0.93	Q38	Ashamed	0.93
Q14	Pain in your gums	0.93	Q39	Avoid leaving	0.93
Q15	Discomfort when eating	0.93	Q40	Less tolerant with others	0.93
Q16	Painful sites in the mouth	0.93	Q41	Interact with others	0.93
Q19	Worried	0.93	Q42	Irritable with others	0.93
Q20	Self-conscious	0.93	Q43	Difficulty working	0.93
Q21	Unhappy	0.93	Q44	General Health Affected	0.93
Q22	Appearance of the brackets	0.93	Q45	Financial loss	0.93
Q23	Tense	0.93	Q46	Enjoy company	0.93
Q24	Speaking badly	0.93	Q47	Unsatisfactory life	0.93
Q25	People do not understand their words	0.93	Q48	Unable to function	0.93
Q26	Less flavor in food	0.93	Q49	Unable to work	0.93
Total					0.93
OHIP-S14 Ortho					
Q1	Difficulty chewing	0.91	Q32	Interrupting meals	0.91
Q4	Affected appearance	0.90	Q34	Annoyed	0.90
Q15	Discomfort when eating	0.90	Q35	Difficulty to relax	0.91
Q16	Painful sites in the mouth	0.90	Q41	Interact with others	0.91
Q22	Appearance of the brackets	0.91	Q42	Irritable with others	0.91
Q23	Tense	0.91	Q46	Enjoy company	0.91
Q31	Avoid smiling	0.91	Q47	Unsatisfactory life	0.91
Total					0.91

Annex 2. Association between OHIP-49, OHIP- S14 Ortho and demographic and clinical characteristics

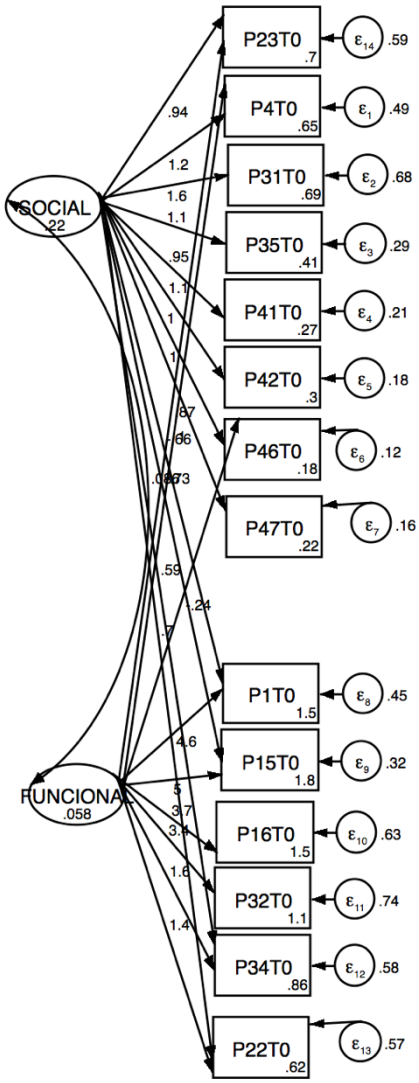
Categorical Variables	**OHIP-49 Mean (ds)**	**OHIP- S14 Ortho Mean (ds)**
Sex		
Male	24.89 (18.84)	7.53 (6.84)
Female	27.72 (20.07)	9.16 (8.0)
P value	0.120	0.059
Occupation		
Unemployed	25.92 (27.09)	7.65 (9.26)
Independent worker	29.92 (27.09)	9.78 (7.89)
Employee	27.21 (19.71)	8.70 (7.97)
Depend on family resources	24.04 (17.42)	7.45 (6.39)
P value	0.132	0.077
Education level		
Primary School	28.67 (20.45)	9.17 (6.71)
Middle school	23.39 (15.10)	6.35 (5.72)
High school	22.73 (19.10)	7.37 (7.52)
Post-secondary education	26.71 (12.10)	8.14 (3.63)
Technical education	25.85 (18.08)	8.02 (6.65)
University education	30.69 (22.92)	10.34 (9.06)
Specialization Course/Master	27.35 (16.59)	8.65 (6.55)
Doctoral degree	12 (4.24)	4.5 (0.719)
P value	0.190	0.128
Orthodontic Technique		
Standard	25.62 (17.62)	7.81 (6.54)
Self-ligating	27.54 (20.55)	9.40 (8.55)
MBT	26.60 (20.65)	8.33 (7.70)
P value	0.889	0.558
Age	0.099	0.125
P value	0.048	0.013
Last Control Time	-0.092	-0.062
P	0.067	0.216
Treatment Time	-0.004	-0.062
P	0.937	0.216

Chi^2 test for categorical variables and independent t-test for quantitative variables

Annex 3.



FCA model 1.


SOCIAL
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P23T0
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P31T0
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P35T0
.41
P41T0
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P42T0
.3
P46T0
.18
P47T0
.22
P1T0
1.5
P15T0
1.8
P16T0
1.5
P32T0
1.1
P34T0
.86
P22T0
.62
.94
1.2
1.6
1.1
.95
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1
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.86
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4.6
5
3.7
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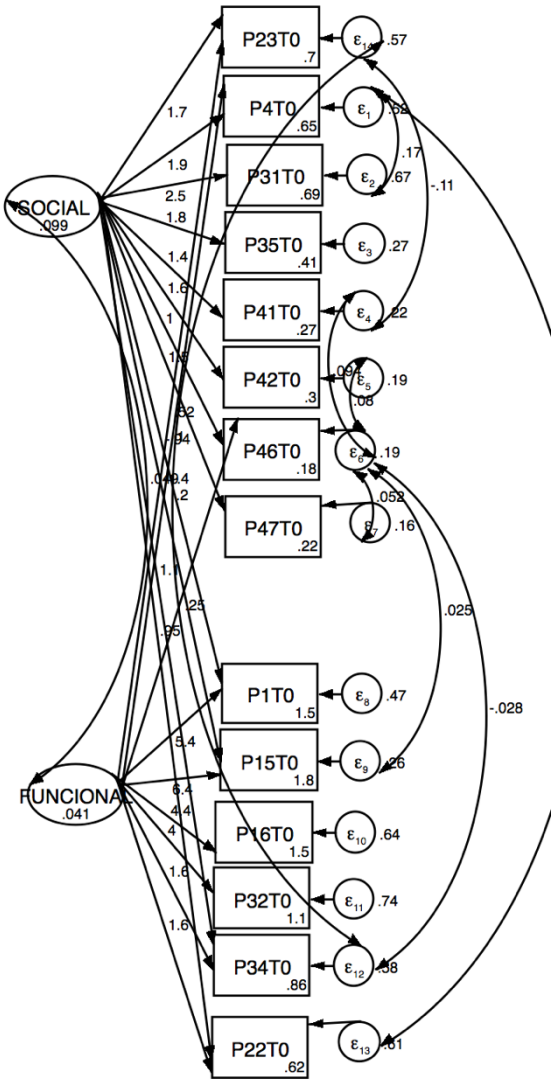
1.6
1.4
ε14 .59
ε1 .49
ε2 .68
ε3 .29
ε4 .21
ε5 .18
ε6 .12
ε7 .16
ε8 .45
ε9 .32
ε10 .63
ε11 .74
ε12 .58
ε13 .57

FCA model 2.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1.4
1.6
1
.57
.17
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-.11
.27
.22
.19
.08
.19
.052
.16
.025
-.028
.47
.26
.64
.74
.58
.61

FCA model 3.

Annex 4. Sensitivity to change. Mean (sd).

	T0	T1	T2	T0- T1	T0- T1	T1-T2
Mean	2.64 (6.59)	14 (10.27)	11.92 (7.76)	0.001[a]	0.001[a]	0.0937[a]

T0 (Before treatment); T1 (24 and 48 hours); T2 (15 days). Signed Wilcoxon rank test of paired samples.
[a] P <0. 05.