

# Reliability and convergent and discriminant validity of the Child Oral Health Impact Profile (COHIP Child's version)

Broder HL, Wilson-Genderson M. Reliability and convergent and discriminant validity of the Child Oral Health Impact Profile (COHIP Child's Version). Community Dent Oral Epidemiol 2007; 35 (Suppl. 1): 20–31. © 2007 The Authors. Journal compilation © 2007 Blackwell Munksgaard

Abstract - Objectives: The purpose of the current study was to assess the reliability as well as the convergent and discriminant validity of the Child Oral Health Impact Profile (COHIP). The questionnaire consisted of five domains that assessed oral health, functional well-being, social-emotional well-being, school environment, and self-image. COHIP was designed to measure selfreported oral health-related quality of life (OHRQoL) of children between ages 8 and 15 years old, using both positively and negatively worded items. Methods: Children were recruited from pediatric, orthodontic, and craniofacial clinical settings in the USA and Canada. A comparison group of children not seeking dental treatment was recruited from two US elementary schools. Participants included 157 pediatric, 152 orthodontic and 110 patients with craniofacial anomalies, and 104 community-based participants. Scale reliability was assessed with Cronbach's alpha coefficient. Retest reliability was examined by intraclass correlation and paired *t*-test for a subset of participants who did not report a health change. Discriminant validity was assessed in two ways: (i) the COHIP scores of the four groups of children (three clinical and one communitydwelling) were compared by ANOVA and (ii) for two of the clinical groups, the association between COHIP scores and clinical indices was calculated. Convergent validity was examined using partial Spearman correlations between COHIP scores and Global Health Ratings controlling for demographic variables. *Results:* The children (n = 523) averaged 11.6 years (SD = 1.60); 51.6 % were female; and represented diverse ethnicities (black = 22.4%, Latino = 32.1%, white = 35.1%, other 10.4%). Overall COHIP scores ranged from 28 to 135 (mean  $\pm$  SD, 99.0  $\pm$  19.2) for the children. Scale reliability for the overall COHIP was excellent: Cronbach's alpha coefficient = 0.91 for the overall score. The test-retest reliability of the overall COHIP was also excellent (ICC = 0.84) and there was no statistically significant shift in scores over time. Discriminant validity was supported by significant differences (P = 0.003overall COHIP) among the three clinical groups: the craniofacial group reported the lowest overall COHIP quality of life scores of the clinical groups. Within the pediatric dental group, children with greater dental decay reported lower COHIP scores suggesting a lower OHRQoL (r = -0.26, P = 0.02) and within the orthodontic group, children with larger overjet reported lower COHIP scores (r = -0.25, P = 0.005). Controlling for the effect of the participants' age, gender, and ethnicity, the association between the overall COHIP score and Global Health rating was statistically significant (P < 0.05) and similar in strength for the three clinical groups (pediatric dental = 0.29, orthodontic = 0.23, and

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Key words: Children's Oral Health Impact Profile; children's oral health-related quality of life; craniofacial; orthodontics; pediatric dentistry

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All authors declare no conflicts of interest

craniofacial = 0.24) and highest for the community group (0.36).*Conclusion:* The overall COHIP showed excellent scale reliability overall and test–retest reliability. Both discriminant and convergent validity of the COHIP were supported by the comparisons among and within the four groups of children. Further testing will examine the utility of the instrument in both clinical and epidemiological samples.

The World Health Organization Quality of Life Group defined quality of life (QoL) as an 'individual's perceptions of their position in life in the context of culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns' (1). Allen states that one of the principal limitations of the biomedical paradigm of health is that the model only deals with disease. He adds that the socio-environmental model of health recognizes other domains such as cultural, environmental, and psychosocial influences (2). QoL is now recognized as a valid parameter in patient assessment in nearly every area of physical and mental health care including oral health. The desire to capture the patients' QoL in clinical and research settings has led to the development of numerous measures intended to measure this construct. Further, given the disparities in oral health across ethnic groups as well as the thrust to ration health costs, examining the impact of oral conditions among nontreatment-seeking children may be critical. Such information may provide essential information in developing health policy (3, 4).

Recent QoL literature indicates that both positive and negative perceptions of health and health outcomes should be measured (5, 6). Several current adult OHRQoL instruments now include positive aspects of health with the recognition that OHRQoL instruments can potentially capture not only the positive effects of treatment but also the positive influence of oral health and the appearance of the face and teeth on overall health and well-being among patients and the nontreatmentseeking individuals (7–9).

Efforts have recently been made to develop a measure of oral health-related quality of life (OHRQoL) that is appropriate for use with children (10–13). Such measures require attention to developmental issues such as abstract thinking and readability (13–15), as well as to goals set by the WHO definition of health. Given the increasing attention to children and their participation in treatment and clinical research, the necessity for valid OHRQoL measures is growing (16–19).

To date the only published OHRQoL instruments for school-age children are the Child Perception Questionnaire CPQ 8-10 and 11-14 (10, 20, 21). Although these questionnaires appear developmentally appropriate, they do not include positively worded items, positive health concepts and/or have not been validated on US children. Other questionnaires evaluating children's OHRQoL were developed specifically for preschool children (12, 22).

The Child Oral Health Impact Profile (COHIP) was developed to measure OHRQoL in children: parallel forms of the COHIP exist for the child and caregiver, respectively. The COHIP measures *oral health, functional well-being, social-emotional well-being, school environment* and *self-image* as well as the overall OHRQoL of the child. It was designed to be used with a broad age range (8–15 years) across oral conditions and to include positive (e.g., confidence, attractiveness) as well as negative aspects of OHRQoL (see Development Paper for specific details).

The process of developing the COHIP was informed by established guidelines for the development of a new questionnaire as described by Guyatt and colleagues (10, 23, 24). The development of the COHIP is described in detail in another article in this issue. The purpose of this article was to report the results for children only of the reliability, convergent and discriminant validity assessment phase of the COHIP.

# Methods

# Procedures

A convenience sample of male and female children between the ages of 8 and 15 who were seeking pediatric dental or orthodontic treatment were recruited at several locations, including the University of Medicine and Dentistry New Jersey (UMDNJ), McGill University Dental School and Montreal Children's Hospital or New York University (NYU) School of Dentistry and New York University (NYU) Medical Center. Additionally, children seeking craniofacial care at McGill University or NYU were recruited. Trained research assistants approached individuals scheduled for appointments who were identified, whenever possible, in advance as being in the correct age range for the study. Children were excluded if they were enrolled in a special class for mental disabilities or had a mental disorder, or did not read English or Spanish, if recruited in the USA, or English or French if recruited in Canada. Children with craniofacial anomalies who were scheduled for surgery within a 2-week period were excluded. Children in the orthodontic clinics who had previously been banded with orthodontic braces or appliances were also excluded.

After describing the purpose of the study, participating children assented and caregivers consented to a protocol approved by the Institutional Review Boards at the respective sites. Participants had the choice of completing the COHIP in English, Spanish, or French. Uniform verbal instructions were given after which participants independently completed the COHIP. Research assistants were available to provide assistance, if needed. Participants received a monetary incentive for their time and effort. The COHIP was completed first, followed by an oral examination.

A community sample of children attending public schools in Camden and Newark, NJ were also recruited. The median family income in these locations was less than half the state median and the rates of families living below the poverty line were very high at 35.5% and 28.4%, respectively. This and other data indicated that the children in these schools, and therefore this sample, were of low socioeconomic status (25). Arrangements were made with school personnel so that signed consent and assent forms could be obtained. After describing the purpose of the study, participating children assented and caregivers consented to a protocol approved by the Institutional Review Board at UMDNJ. Similar exclusion criteria regarding enrollment in special classes applied to the community sample. Questionnaires were administered at the school sites by the research team.

# Measures

## COHIP

The COHIP consisted of 34 items forming five conceptually distinct subscales: *oral health, functional well-being, social/emotional well-being, school environment* and *self-image.* (i). *Oral health* was composed of specific oral symptoms that are not necessarily related to one another (e.g., pain, spots on teeth). (ii). *Functional well-being* included items related to the child's ability to carry out specific everyday tasks or activities (e.g., speaking clearly, chewing). (iii). Social-emotional well-being pertained to peer interactions and mood states. (iv) School environment incorporated items pertaining to tasks associated with the school environment. (v) Selfimage addressed positive feelings about self. The statements (see Appendix 1) were formatted to elicit self-reports from the child. Instructions for the items in the five subscales were: 'Please read each statement carefully and choose the answer that best describes you in the past 3 months regarding your teeth, mouth or face. We want to know how you really feel'. Responses were recorded as 'never' = 0, 'almost never' = 1, 'sometimes' = 2, 'fairly often' = 3, and 'almost all of the time' = 4. Scoring of the 28 negatively-worded items were reversed. Higher COHIP scores reflect more positive OHRQoL while lower scores reflect lower OHRQoL.

Additionally there were two items regarding treatment expectations and one global health perception item. The instructions for these items and self-image were: 'The following items are about your teeth, mouth or general health. ''Please read each carefully and choose the answer that best describes you. The response set includes 0 ='strongly disagree'; 2 ='somewhat disagree'; 3 ='don't agree or disagree'; 4 ='somewhat agree'; and 5 ='strongly agree'. There are no right or wrong answers.'' The treatment expectations and global health perception items were not included in the COHIP scores but would be used for clinical studies only.

Participants who did not answer at least 75% of the items were not included in the analysis. Of the original 548 child participants, 523 were retained (>95%). The percentage of participants dropped from the analysis due to incomplete data was small (<5%) (see Appendix 2 for details).

Subscale scores were calculated by summing the responses of the items specific to the subscale. The overall OHRQoL score was computed by summing the subscale scores. Treatment expectation scores and the overall health response were not included in the overall COHIP scale as these items would be relevant only when the COHIP is used as part of a treatment assessment. Scores could range from 0 to 136 for the overall scale. If more than two-thirds of the items in a subscale were missing, the subscale and the overall score were set to missing. If fewer items were missing for a subscale, the average of available items used and the sum of the subscale was calculated.

#### Oral health status

For the treatment-seeking participants, all participants underwent a clinical examination subsequent to completing the COHIP. After the clinical data were obtained, the charts were reviewed and data entered into the data collection form developed for this project. Pediatric dentists from the two locations (NY/NJ) were calibrated to 100% agreement ratings for dental surfaces using 'blinded' chart review and live subjects; and the project director from Montreal was solely responsible for chart reviews and data entry at the third location. For the pediatric sample, the clinical variable of interest was decayed surfaces (DS). DS was chosen as a marker for severity of poor oral health status (untreated disease) because tooth decay could reflect poor oral hygiene and lack of preventive care. If left untreated, decay could progress to cause serious harm (26). For the orthodontic sample, the clinical variable of interest was overjet. Overjet was chosen as a marker for severity as it has been reported that it has been associated with peer teasing and negative psychosocial sequelae (27); further extreme overjet required more complicated treatment. Overjet was defined as the horizontal distance between the incisal edge of the most protruded maxillary central incisor and the labial surface of the most protruded mandibular central incisor. The ideal overjet is usually between 2 and 4 mm. Clinical measurement criteria were agreed upon by the research team and clinicians. Calibration exercises were completed to 100% agreement using 10 'live' subjects at NY and NJ. The project director from Montreal was responsible for protocol standardization at the Canadian location. As with the pediatric dental charts, the data were entered from chart reviews of all participants completing the COHIP. For the craniofacial sample, no clinical indicator was utilized as a range of craniofacial conditions were included in the sample. All of the participants with craniofacial anomalies were active treatment-seeking patients.

## Demographic data

Each child participant was asked to report his or her age in years, race/ethnicity, grade in school, and gender. For ethnicity the eight choices presented were Asian, East Indian, Latino, Black, White, Native American, and Other. Because of the very low numbers in several categories, the race/ethnicity categories used herein are Latino, Black, White, and Other.

# Data analysis

#### Item level analyses

Response distributions were examined to determine normality, the range and frequency of response utilization, and percentage of missing responses per item. Missing data were evaluated by identifying the number of items in which >5% of the sample had a missing response.

#### Scale level analyses

Floor and ceiling effects were reviewed using box plots and by examining univariate statistics.

Internal consistency was quantified using Cronbach's alpha. The acceptable level for the overall scale was set at 0.80. Retest reliability was indexed by the intraclass correlation coefficient and the paired *t*-test to examine whether a systematic shift in scores had occurred in the retest period. Testretest participants were included only if the participants denied a change in general or oral health status since their first test. Acceptable test-retest reliability rating was set at 0.70.

Construct validity was assessed by examining measures of discriminant and convergent validity.

Discriminant validity or the ability of the COHIP to differentiate among groups was assessed by comparing the COHIP scores of the four groups (craniofacial, pediatric, and orthodontic clinical groups, and the community group) using the Type III sum of squares from a main effects only factorial analysis of variance model. The type and severity of the oral health status of these groups was expected to be different and thus differences in OHRQoL were likewise expected. The intent was to compare the average COHIP scores among the four groups after controlling for the effects of the demographic characteristics (age, gender, and ethnicity) and the data collection site. The level of significance was set at 0.05. Discriminant validity was further explored by examining the association between COHIP scores and clinical severity within the pediatric dental and orthodontic groups using partial Spearman correlation controlling for age, gender, and race/ethnicity. It was expected that the higher the DS score or overjet, the lower the COHIP score. For the Spearman correlations to be considered supportive, statistical significance (P < 0.05) was required.

Convergent validity was assessed by examining the partial Spearman correlation between the COHIP scores and a self-reported measure of *Global Health*. Partial correlations were used to

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measure the strength of association between COHIP scores and *Global Health* after adjusting for the effect of the participants' age, gender, and ethnicity. A positive correlation between COHIP scores and the *Global Health* rating would indicate that when OHRQoL was higher self-reported *Global Health* was also higher. For the Spearman correlations to be considered supportive, statistical significance (P < 0.05) was required.

# Results

# Sample characteristics

In all, 157 pediatric patients, 152 orthodontic patients, 110 patients with craniofacial anomalies and 104 community-based participants participated. Table 1 presents the demographic characteristics for these groups. The sample age range was 8–15 years with an average age of 11.6 (SD = 1.6). The youngest group, on average, was the community group (M = 10.5, SD = 1.23). The other three groups were, on average, a year older

than the community group (pediatric, M = 11.6, SD = 1.34; orthodontics, M = 12.1, SD = 1.43; craniofacial, M = 12.2, SD = 1.85). The participants were ethnically diverse: 22.4% Black, 32.0% Latino, 35.1% White, and 10.4% other. The pediatric and orthodontic groups were similar in ethnic diversity, while the craniofacial group was predominantly white. The proportion of females overall (51.4%) and in all groups was similar (females: pediatric 47.7%; orthodontic 59.2%; craniofacial 41.8%; community 56.2%).

# Item level analyses

Examination showed that the full range of response choices was utilized by the participants. Item distributions tended to be skewed toward higher OHRQoL. All items for all groups of children had less than 5% missing scores.

# Scale level analyses

Box plots of the overall COHIP, each subscale for each clinical group and the community group was calculated and presented in Figs 1 and 2. Length of

Table 1. Demographic characteristics of the three clinical groups and the community group

	Pediatric, n = 157 (30.0%)	Orthodontic, <i>n</i> = 152 (29.0%)	CF, <i>n</i> = 110 (21.0%)	Community, n = 104 (20.0%)
Gender n (%)				
Male	82 (52.2)	63 (40.8)	64 (40.8)	46 (44.2)
Female	75 (47.8)	90 (59.2)	46 (41.8)	58 (55.8)
Race/ethnicity, $n$ (%)				
Latino	42 (26.8)	58 (38.2)	8 (7.3)	59 (56.7)
Black	41 (26.1)	46 (30.3)	3 (2.7)	27 (26.0)
White	55 (35.0)	43 (28.3)	82 (74.6)	3 (2.9)
Other	19 (12.1)	5 (3.2)	17 (15.4)	15 (14.4)
Education (grade), $n$ (%)				
1–5 <sup>a</sup>	107 (68.24)	112 (74.2)	56 (50.92)	68 (65.5)
≥6 <sup>b</sup>	50 (31.94)	40 (26.6)	54 (49.0)	36 (34.6)
Age (years)				
8	0 (0)	0 (0)	0 (0)	4 (3.2)
9	5 (3.18)	2 (1.3)	5 (4.6)	21 (22.0)
10	32 (20.4)	19 (12.6)	23 (20.9)	27 (25.8)
11	40 (25.5)	38 (25.2)	15 (13.6)	32 (30.5)
12	40 (25.5)	35 (23.2)	17 (15.5)	14 (13.8)
13	24 (15.3)	29 (19.2)	17 (15.5)	6 (5.2)
14	15 (9.6)	22 (14.6)	18 (16.4)	0 (0)
15	1 (0.64)	6 (4.0)	15 (13.6)	0 (0)
Data collection site, $n$ (%)				
Montreal	56 (35.7)	13 (8.6)	16 (15.0)	0 (0)
New Jersey	45 (28.7)	19 (12.5)	0 (0)	104 (100)
New York	56 (35.7)	120 (79.0)	94 (86.0)	0 (0)
Clinical indicators				
Global Health, mean (SD)	3.32 (0.76)	3.09 (0.97)	2.84 (1.16)	3.05 (1.01)
Overjet, mean (SD)		3.92 (2.6)		
Decayed surfaces, mean (SD)	2.8 (3.8)			

<sup>a</sup>Grades 1-5 = elementary school.

<sup>b</sup>Grades  $\geq 6$  = middle/secondary school.

#### Reliability and convergent and discriminant validity of the COHIP

*Fig.* 1. Boxplot representing the distribution of the COHIP subscale scores. Length of the box represents the interquartile range (the distance between the 25th and the 75th percentiles) and the cross and the horizontal lines in the box interior represent the mean and median, respectively. The vertical lines issuing from the box extend to the minimum and maximum utilized values of the scale or subscale.



*Fig.* 2. Boxplot representing the distribution of the of the overall COHIP scores by group. Length of the box represents the interquartile range (the distance between the 25th and the 75th percentiles) and the cross and the horizontal lines in the box interior represent the mean and median, respectively. The vertical lines issuing from the box extend to the minimum and maximum utilized values of the scale or subscale.

the box represented the interquartile range (the distance between the 25th and the 75th percentiles) and the cross and the horizontal line in the box interior represented the mean and median, respectively. The vertical lines issuing from the box extended to the minimum and maximum values of the scale or subscale at which participants scores. With regard to plot 1, the number of items in the subscale varied and thus the maximum value varied with the subscale. The maximums were: oral health 40, functional well-being 32, social-emotional 32, school environment 16, and self-image 42. Examination of plot 1 suggested that the average scores on the functional well-being, social-emotional and school subscales skewed toward positive OHRQoL. The plots of oral health and self-image suggested that the average score is near the middle of the possible range of scores. Plot 2 suggested that the entire range of response scores was utilized and that the mean and median scores were similar for all groups. Plot 2 indicated that the craniofacial group had the widest range of scores and the lowest average OHRQoL.

## Reliability

Results suggested high levels of internal consistency for the overall questionnaire. Cronbach's alpha for the overall COHIP in the sample was 0.91 (See Table 2). Internal consistency of the subscales was acceptable when all groups were combined. When the groups were examined separately, the alpha coefficients for the overall COHIP and the *Social-Emotional Well-being* were excellent (>0.80) within each group. The alpha coefficients for *Oral Health* and *Self-Image* were acceptable (>0.63) for all groups. The coefficients were quite variable for *School Environment* and *Functional Well-being* across the four groups ranging from excellent to poor.

## Test-retest

Forty-four of the eighty-four participants who participated in the test-retest phase and self-com-

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Table 2. Cronbach's alpha for the overall COHIP and subscale by group

Scale (number of items)	Total	Pediatric	Orthodontic	Craniofacial	Community
Oral well-being (10)	0.68	0.69	0.70	0.69	0.67
Functional well-being (6)	0.71	0.66	0.66	0.57	0.80
Social-emotional well-being (8)	0.89	0.91	0.88	0.88	0.90
School environment (4)	0.65	0.71	0.68	0.64	0.50
Self-image (6)	0.73	0.73	0.63	0.69	0.83
Overall scale (34)	0.91	0.89	0.91	0.90	0.92

pleted the COHIP twice at approximately a 3-week interval were included in the test–retest reliability analysis. The 40 participants not included indicated some change in overall physical health or oral health status in the intervening three weeks. The intraclass correlation coefficient indicated excellent consistency for the overall COHIP (0.84) and socialemotional well-being (0.87) and good consistency (>0.58) for the remaining subscales. There were no statistically significant differences in the average scores between the two completions of the questionnaire (data not shown) for the overall or any of the subscales indicating no systematic shift in responses.

#### Discriminant validity

Table 3 shows the results of the ANOVA on known groups for mean ratings of COHIP. These models included child age, gender, race/ethnicity, and data collection site as control variables. The Omnibus

Table 3. Comparison of the mean values (SE) for each subscale and the overall COHIP by treatment group, age, gender, race/ethnicity, site location and the overall model and analysis of variance statistics

	Mean (SE)					
	Functional well-being	Social/emotional well-being	School environment	Overall COHIP		
Treatment group						
Pediatric $(n = 157)$	19.0 (0.44)	24.0 (0.82)	13.3 (0.29)	97.7 (2.1)		
Orthodontic ( $n = 152$ )	18.8 (0.50)	24.1 (0.93)	13.6 (0.33)	97.2 (2.5)		
Craniofacial ( $n = 110$ )	14.7 (0.61)	21.6 (1.2)	11.9 (0.40)	87.1 (3.0)		
Community $(n = 104)$	20.0 (0.62)	25.8 (1.1)	14.4 (0.40)	102.3 (3.0)		
d.f.; <i>F</i> -value; <i>P</i> -value	3; 20.89; 0.0001	2.51; 0.058	7.93; 0.0001	5.56; 0.0009		
Age						
8 (n = 4)	12.5 (2.0)	21.3 (3.8)	10.8 (1.3)	83.2 (9.6)		
9 (n = 33)	17.9 (0.73)	24.9 (1.4)	13.8 (0.48)	97.1 (3.7)		
$10 \ (n = 101)$	18.7 (0.41)	25.2 (0.76)	13.7 (0.27)	100.7 (2.0)		
11 (n = 125)	19.7 (0.39)	24.0 (0.72)	13.9 (0.26)	98.9 (2.0)		
12 (n = 106)	19.8 (0.42)	24.8 (0.77)	14.0 (0.27)	100.7 (2.0)		
13 $(n = 76)$	19.6 (0.48)	24.8 (0.90)	13.7 (0.32)	98.9 (2.4)		
$14 \ (n = 55)$	18.9 (0.58)	23.5 (1.1)	13.6 (0.37)	95.1 (2.8)		
15 (n = 22)	18.0 (0.90)	22.4 (1.7)	13.1 (0.59)	94.3 (4.4)		
d.f.; F-value; P-value	6; 3.03; 0.004	0.76; 0.62	1.23; 0.28	1.17; 0.32		
Gender						
Male $(n = 254)$	18.2 (0.40)	24.7 (0.74)	13.4 (0.26)	97.0 (1.9)		
Female $(n = 269)$	18.1 (0.37)	23.1 (0.69)	13.3 (0.25)	95.0 (1.8)		
d.f.; F-value; P-value	1; 0.19; 0.665	5.77; 0.02	0.12; 0.73	1.59; 0.21		
Race/ethnicity						
White $(n = 183)$	19.5 (0.40)	26.1 (0.75)	14.3 (0.26)	101.7 (1.9)		
African-American ( $n = 117$ )	17.0 (0.51)	22.9 (0.94)	12.8 (0.33)	93.9 (2.4)		
Hispanic ( $n = 167$ )	18.2 (0.47)	22.9 (0.88)	13.0 (0.31)	93.9 (2.3)		
Other $(n = 54)$	17.9 (0.60)	23.5 (1.1)	13.2 (0.40)	94.7 (3.0)		
d.f.; F-value; P-value	2; 7.68; 0.0001	4.71; 0.003	6.52; 0.0002	4.00; 0.008		
Site						
New York $(n = 270)$	18.4 (0.40)	23.8 (0.75)	13.7 (0.27)	97.0 (1.9)		
New Jersey $(n = 168)$	17.5 (0.50)	22.9 (0.92)	13.2 (0.33)	94.0 (2.4)		
Montreal $(n = 85)$	18.5 (0.59)	24.8 (1.1)	13.2 (0.39)	97.3 (2.9)		
d.f.; F-value; P-value	3; 1.25; 0.29	1.11; 0.33	1.25; 0.29	0.65; 0.52		
Overall model ( $n = 523$ )	16; 6.95; 0.0001	2.10; 0.008	2.58; 0.0007	2.29; 0.003		
d.f.; F-value; P-value						

Groups are pediatric, orthodontic, craniofacial, and community.

*F*-test was significant for the overall COHIP score, *Functional Well-being* and *School* subscales and nearly so for the *Social Emotional* subscale. The overall models were not statistically significant for *Oral Health* (P = 0.50) and *Self-Image* (P = 0.11) and these models will not be discussed further. In all cases when the overall model was significant, *post hoc* testing revealed that the craniofacial group reported lower OHRQoL than the other groups. The other two clinical groups (pediatric and orthodontic) did not differ significantly from the community sample, on average.

To further address discriminant validity the relationships between clinical severity within the pediatric and orthodontic groups and the overall COHIP and subscale scores were also examined after controlling for participants' age, gender, race/ethnicity, and data collection site (Table 4). For the pediatric dental group, the number of DS (range = 0-17) was significantly negatively correlated with the overall COHIP scores. Significant negative correlations were also noted between the number of DS and the Oral Health, Functional Wellbeing, and Social Emotional Well-being subscales. For the orthodontic group, the degree of overjet (range = -2 to 15 mm) was significantly negatively correlated with the overall COHIP score, as well as the Social Emotional Well-being and Self-image subscales. Individuals with a larger number of DS and greater overjet tended to report lower OHRQoL scores after controlling for the participant's demographic characteristics.

# Convergent validity

The results of the partial Spearman correlations between COHIP scores and subscale scores and

Table 4. Partial Spearman correlations of clinical severity indicators within the pediatric and orthodontic groups with the overall COHIP and subscale scores

	Pediatric decayed surfaces		Orthodontic overjet	
	$r_{\rm s}$	<i>P</i> -value	$r_{\rm s}$	P-value
Overall COHIP	-0.29	0.02	-0.25	0.005
Oral health	-0.23	0.04	-0.16	0.07
Functional well-being	-0.33	0.005	-0.05	0.61
Social-emotional well-being	-0.25	0.04	-0.30	0.001
School environment	-0.19	0.11	-0.10	0.29
Self-image	-0.16	0.18	-0.25	0.005

The partial Spearman correlations are adjusted for the effects of participants' age, gender, race/ethnicity, and data collection site.

Global Health Ratings after controlling for the participant's age, gender, race/ethnicity, and data collection site are presented in Table 5. The partial Spearman correlations between the overall COHIP score and Global Health Ratings were statistically significant for all four groups and the correlation coefficients were similar for the three clinical groups and highest for the community group. For the subscales, the associations between *Self-image* subscales and *Global Health* was the strongest and statistically significant for all of the groups.

# Discussion

The Cronbach's alphas indicated excellent internal consistency of the overall COHIP. The functional well-being and oral health subscales did not show evidence of high internal consistency. These subscales included a diverse array of symptoms that would not necessarily be expected to either be reported by everyone or 'hang together' empirically (see Development paper, this issue). Given that the COHIP is meant to be used across oral health conditions, these results are not of concern. The test–retest findings suggest very good reproducibility for the Overall COHIP.

Discriminant validity testing on known groups was expected to reveal differences in the OHRQoL such that children with craniofacial anomalies would report lower OHRQoL than children without such conditions. This hypothesis was supported, as the craniofacial group was found to report greater negative impact on their OHRQoL than either the general pediatric or orthodontic patients as demonstrated by the lower Overall COHIP scores, Functional well-being and school subscales and the social emotional subscale approached significance (Table 3.). These data were consistent with prior findings on sequelae associated among school-age children with such oral facial conditions (28, 29).

Not surprisingly, the findings indicated that children with craniofacial conditions did not report lower scores in the area of OHRQoL across all domains. A recent report using the CPQ to measure OHRQoL compared 12-year-old children seeking dental care to those with craniofacial anomalies and found no significant differences in the CPQ overall scale nor on the social and emotional wellbeing subscales (30). This comparison of the two scales highlighted the COHIP's relative discriminative abilities and sensitivity to detect differences.

Table 5. Partial Spearman correlations between the global health status and the overall COHIP and subscale scores separately for each group

	Pediatric		Orthod	Orthodontic		Craniofacial		Community	
	rs	<i>P</i> -value	rs	<i>P</i> -value	rs	<i>P</i> -value	$r_{\rm s}$	<i>P</i> -value	
Overall COHIP	0.25	0.003	0.23	0.008	0.24	0.02	0.36	0.001	
Oral health	0.07	0.40	0.17	0.04	0.02	0.83	0.24	0.03	
Functional well-being	0.03	0.70	0.03	0.74	0.31	0.002	0.22	0.04	
Social-emotional well-being	0.24	0.003	0.23	0.007	0.17	0.09	0.22	0.05	
School environment	0.07	0.37	0.17	0.04	0.02	0.87	0.23	0.04	
Self-image	0.28	0.0006	0.27	0.002	0.39	0.0001	0.32	0.004	

The partial Spearman correlations are adjusted for the effects of participants' age, gender, race/ethnicity, and data collection site.

Another report using the Youth Quality of Life Scale in adolescents with and without craniofacial conditions reported higher social relationship scores among children with facial differences compared to children with chronic conditions and those with other disabilities. The authors suggested that this finding might indicate resilience or social dependence. Given the potential variability within the craniofacial group, it would be important to adjust for the participant's stage of treatment. Some researchers might suggest that an individual with craniofacial differences may make adaptations in his/her self-image and emotional well-being based on the treatment received, or some resilience or coping has occurred within the individual (31–33). This notion is consistent with standardized interview data in which late adolescents report more positive self-image perceptions compared to younger school-age children with craniofacial differences (34, 35).

Further discriminant validity testing to examine whether the extent of a disease or clinical indicator within the pediatric dental and orthodontic groups would be associated with quality of life scores was generally supported. In other words, those individuals with milder conditions had better quality of life scores compared to those with more severe conditions. A significant inverse relationship between extent of overjet and quality of life was found in the orthodontic sample. In addition, greater decay (untreated disease) was associated with lower reported quality of life.

In summary, the findings demonstrate that the COHIP is sensitive to expected differences between clinical conditions, and to differences between those with more and less severe clinical indicators within a clinical condition. These findings are consistent with previous reports examining the relationship between specific areas of impact on both orthodontic and pediatric dental populations (26, 27, 36). The modest correlations between clinical indicators and subjective self-evaluations of oral health imply the unique quality of OHRQoL assessments and the importance of not equating oral health status and related quality of life. Such findings are similar to other investigations (10, 20, 37).

Convergent validity testing was performed with the expectation that when OHRQoL was higher perceived Global Health was also higher. A significant positive, yet modest, relationship was found between self-reported overall health and reported OHRQoL for all clinical groups. This finding underscores the utility of using disease-specific measures of QoL to assess the impact of oral health conditions or concerns among children (36-39). It likewise points to the positive but limited relationship between oral-facial health status as measured by clinical indicators and self-assessed health as supported by previous studies. In summary, a positive, but limited, relationship was found between Global Health and COHIP across groups regardless of site, ethnicity, age, or gender.

Discriminant validity testing on known groups included multiple covariates (e.g., child's age, gender, race/ethnicity, and data collection site). No differences attributable to data collection site were detected. Only one age subscale difference was found in the functional well-being score. Post hoc examination of the scores suggested that the youngest children (age 8) had lower scores than some of the older children (11- and 12-year olds). However, due to the extremely small number of 8-year olds in the sample, this finding should be treated very cautiously. Further, the oldest children (age 15) also had lower scores on functional wellbeing than some of the younger cohorts (11-13 years of age). This later finding may be due to the fact that these adolescents had experienced untreated disease for longer than the

younger participants. Lastly, with regard to race/ethnic differences, the pattern for the functional well-being, social-emotional, school subscales and for the overall COHIP score suggests that Blacks and Latinos have lower scores than whites although these comparisons did not always reach significance levels adjusted for post hoc comparisons. This consistent pattern of Blacks and Latinos reporting lower OHRQoL suggests that ethnic/racial oral health disparities as reported in population-based clinical studies may be reflected in this convenience sample (40, 41). Further testing of ethnic differences will be an important part of to future studies. Finally, the one gender difference for the social-emotional subscale was not found to be significant in *post hoc* testing.

The similarity of the COHIP scores from the low SES community children to those found in the pediatric dental and orthodontic groups is noteworthy. It is unclear from these data whether this finding reflects a general lack of impact in the known clinical groups, or a high level of untreated disease in these economically disadvantaged communities. Such results in nontreatment-seeking children in poor communities require further research. If verified, the findings would be relevant given reduced well-being associated with poor oral health and the presence of oral health-related health disparities suggested by the Surgeon General's report (26).

Some of our findings may be due to limitations in the study. To begin, there were unbalanced samples in the clinical groups, ethnic representation, and ages. Further, the participants represented convenience samples and the data were crosssectional. Replication of the findings in a larger sample is important. Given the lack of ethnic and economic diversity within the craniofacial group, as well as the ethnic/racial differences reported here underscores that well designed studies including multi-center studies for craniofacial children are needed to examine possible sociocultural interaction effects. This goal was emphasized in a recent CDC conference entitled Prioritizing a Research Agenda for Orofacial Clefts (42).

In short, the COHIP demonstrated the ability to discriminate across and within known groups based on the extent of the impact as well as on oral health status. We believe that the COHIP provides a comprehensive measure of OHRQoL in children that is consistent with a strong theoretical position and also presents with good preliminary evidence for its psychometric worthiness. However, hypothesis-driven studies incorporating the COHIP are needed in the future to confirm the utility of the instrument. Regarding clinically meaningful differences using cross-sectional data, comparisons are not altogether indicated.

Assessment of OHRQoL with a valid and reliable instrument is an important adjunct that should be included in health assessments for children seeking care. The COHIP questionnaire was developed for use in epidemiological studies to help instigate potential health policy implications and, as previously stated, further study regarding its use in epidemiological studies among community dwelling, nontreatment-seeking children is needed. Future studies are planned to examine the COHIP as an evaluative tool for clinical trials. Testing the instrument's utility to detect clinically meaningful change in longitudinal studies is necessary and planned. It is a goal in future studies to include healthy controls as well as other means of assessing clinically meaningful differences and change to better inform our interpretation and use of COHIP scores.

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# Appendix 1. Child Oral Health Impact Profile – items by domain

Oral health-well-being (10 items) Had pain in your teeth/toothache Been breathing through your mouth or snoring Had discolored teeth or spots on your teeth Had crooked teeth or spaces between your teeth Had sores or sore spots in or around your mouth Had bad breath Had bleeding gums Had food sticking in or between your teeth Had pain or sensitivity in your teeth with hot or cold things Had dry mouth or lips Functional well-being (6 items) Had trouble biting off or chewing foods such as apple, carrot or firm meat Had difficulty eating foods you would like to eat because of your teeth, mouth, or face Had trouble sleeping because of your teeth, mouth, or face Had difficultly saying certain words because of your teeth, mouth, or face Had people have difficulty understanding what you were saying because of your teeth, mouth or face Had difficulty keeping your teeth clean because of your teeth, mouth or face Social-emotional well-being (8 items) Been unhappy or sad because of your teeth, mouth, or face Felt worried or anxious because of your teeth, mouth, or face Avoided smiling or laughing with other children because of your teeth, mouth or face Felt that you look different because of your teeth, mouth or face Been worried about what other people think about your teeth, mouth or face Felt shy or withdrawn because of your teeth, mouth, or face Been teased, bullied or called names by other children because of your teeth, mouth or face Been upset or uncomfortable with being asked questions about your teeth, mouth, or face School environment (4 items) Missed school for any reason because of your teeth, mouth, or face Had difficulty paying attention in school because of your teeth, mouth, or face Not wanted to speak/read out loud in class because of your teeth, mouth or face Not wanted to go to school because of your teeth, mouth, or face Self-image (6 items) Been confident because of your teeth, mouth, or face Felt that you were attractive (good looking) because of your teeth, mouth or face I have good teeth I feel good about myself

When I am older, I believe (think) that I will have good teeth

When I am older, I believe (think) that I will have good health

Treatment expectancies (2 items)\*

- I will feel better about myself when treatment for my teeth, mouth or face is completed
- I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face

Global Health

Overall I feel my health is ...

\*Treatment expectancies is used primarily in clinical trials and treatment studies

# Appendix 2. Participants retained and dropped from the analysis sample due to missing data

	Retained <i>n</i> (%)	Dropped
Group		
Pediatric	157 (93.4)	11 (6.5)
Orthodontic	152 (95.0)	8 (5.0)
CF	110 (99.0)	1 (1.0)
Community	104 (95.4)	5 (4.5)
Gender, $n$ (%)		
Male	254 (96.2)	10 (3.7)
Female	269 (94.7)	15 (5.2)
Race/ethnicity n (%)		
Asian	21 (87.5)	3 (12.5)
E. Indian	4 (100)	0 (0)
Latino	167 (94.3)	10 (5.6)
Black	117 (99.1)	1 (0.09)
White	183 (94.8)	10 (5.1)
Native American	0 (0)	0 (0)
Other	5 (83.3)	1 (16.7)
None	24 (100)	0 (0)
Education (grade), me	an (SD)	
Ģ	3.76 (2.17)	4.9 (2.12)
Age (years), mean (SE	))	
	11.0 (1.63)	11.64 (1.59)
Data collection site, n	(%)	
Montreal	85 (90.4)	9 (9.6)
New Jersey	168 (96.0)	7 (4.0)
New York	270 (96.7)	9 (3.3)

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