Reliability and validity testing for the Child Oral Health Impact Profile-Reduced (COHIP-SF 19)

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Abstract

Objectives: This study assessed the reliability and validity of the Child Oral Health Impact Profile–Short Form 19 (COHIP-SF 19) from the validated 34-item COHIP.
Methods: Participants included 205 pediatric, 107 orthodontic, and 863 patients with craniofacial anomalies (CFAs). Item level evaluations included examining content overlap, distributional properties, and use of the response set. Confirmatory factor analysis identified potential items for deletion. Scale reliability was assessed with Cronbach's alpha. Discriminant validity of the COHIP-SF 19 was evaluated as follows: among pediatric participants, scores were compared with varying amounts of decayed and filled surfaces (DFS) and presence of caries on permanent teeth; for orthodontic patients, scores were correlated with anterior tooth spacing/crowding; and for those with CFA, scores were compared with clinicians' ratings of extent of defect (EOD) for nose and lip and/or speech hypernasality. Convergent validity was assessed by examining the partial Spearman correlation between the COHIP scores and a standard *Global Health* self-rating. Comparisons between the COHIP and the COHIP-SF 19 were completed across samples.
Results: The reduced questionnaire consists of 19 items: Oral Health (five items), Functional Well-Being (four items), and a combined subscale named Socio-Emotional Well-Being (10 items). Internal reliability is $\geq$0.82 for the three samples. Results demonstrate that the COHIP-SF 19 discriminates within and across treatment groups by EOD and within a community-based pediatric sample. The measure is associated with the *Global Health* rating ($P < 0.05$), thereby indicating convergent validity.
Conclusions: Reliability and validity testing demonstrate that the COHIP-SF 19 is a psychometrically sound instrument to measure oral health-related quality of life across school-aged pediatric populations.

Introduction

Oral health-related quality of life (OHRQoL), a multidimensional construct that taps an individual's well-being, is increasingly being recognized as an integral part of general health (1,2). It can play an important role in understanding subjective patient evaluations of and experience with oral health care as well as determining needs assessment. For example, OHRQoL instruments may be used in clinical practice and clinical research as they provide "a better understanding of treatment needs and outcomes from the patient's perspective" (3). OHRQoL instruments can also aid in clinical decision-making and monitor a patient's condition (4-7). Finally, OHRQoL instruments are utilized in epidemiological studies to assess needs of not only the general population but vulnerable populations as well. Such assessments can provide salient information regarding public health issues from environmental impacts (e.g., fluoridation) to health disparities (e.g., unmet dental needs, access to care versus subjective evaluations) (8-10). Thus, incorporating OHRQoL instruments into clinical practice and research can have important benefits for individual patients, community-based dental practices, clinical research, and potentially public health policy (2).

Given these varied applications, it is not surprising that considerable effort has been invested in developing instruments designed to measure OHRQoL (11,12). Even though OHRQoL measures for adults date back to the late 1980s and early 1990s (11), a comprehensive measure of children's OHRQoL was not developed until 2002 (13). In fact, the effort to study children's OHRQoL was largely in response to the 2000 Surgeon General's report and conference entitled, "The Face of the Child: Children and Oral Health," which highlighted the importance of children's oral health to their overall health and well-being and the profound impact that oral health can have on the quality of children's lives (14). The Surgeon General's report emphasized the importance of studying oral health using a health disparities perspective. Some instruments, such as the Michigan Oral Health Related Quality of Life (15) and the Early Childhood Oral Health Impact Score (16), are targeted for preschool children and use caregiver reports for proxies; while other instruments such as the COHIP have developed both caregiver and child instruments. Whether using caregiver or child reports to assess children's OHRQoL, it is critical to include items that take developmental issues (such as cognitive and social factors) into account (17).

The Child Perceptions Questionnaire (CPQ_{11-14}) was the first instrument created for school-aged children using clinical and community samples (18). It has been validated for children ages 11-14 who have a variety of dental, orthodontic, and craniofacial (CF) conditions (13). A 25-item version of the instrument for 8- to 10-year-olds (CPQ_{8-10}) has also been created and validated, although the results were preliminary and based on cross-sectional designs and convenience sampling (19,20). Both versions of the CPQ, however, have yet to be tested longitudinally in evaluative studies. Additionally, questions remain whether the two measures are continuous and can be used in longitudinal studies when children age out of the younger version. Finally, questions also remain regarding the CPQ_{11-14}'s sensitivity and specificity to children's orthodontic needs (21).

Recently, the Pediatric Oral Health-Related Quality of Life (POQL) was created as a brief measure of children's OHRQoL (22). The POQL has four scales (Physical Functioning, Role Functioning, Social Functioning, and Emotional Functioning) and has been validated for use in preschool, school-aged, and preteen children. This tool shows promise for the study of OHRQoL for a number of reasons, including its brevity (it was reduced to only 10 items) and its ability to capture the impact of oral conditions such as caries on both general and vulnerable populations (22). To date, it has not undergone testing for its evaluative properties in a longitudinal study or analyses in large-scale studies (22). Further testing across clinical groups will also be important.

Another OHRQoL measure for school-aged children is the Child Oral Health Impact Profile (COHIP). This 34-item instrument was initially validated with a diverse sample of treatment-seeking school-aged children (ages 8-17) who represented varying oral conditions, health systems, and ethnicities. Creating the COHIP was a multistage process that included psychometric testing, descriptive studies of patient populations, caregiver proxy, and child comparisons, as well as construct validity testing with other psychometric instruments related to well-being and psychological factors (23-26). Additionally, a theoretical framework that incorporates varied factors of OHRQoL (including biological/genetic factors, characteristics of the individual, environmental factors, etc.) played an essential role in developing the COHIP, which is the first children's OHRQoL measure to incorporate positive and negative health impacts (2). With its four domains (School Environment, Self-Image, Social-Emotional Well-Being, and Functional Well-Being), the COHIP is an established instrument for measuring OHRQoL in children and adolescents. The COHIP has been used in a number of ways, including comparing OHRQoL in pediatric, orthodontic, and CF samples of children (23); assessing the relationship between OHRQoL and dental esthetics (27); and understanding OHRQoL in children with chronic conditions such as cleft lip and palate (CLP) (28) and sickle cell disease (29). In a recent study using the COHIP, Broder *et al.* (30) found health disparities (unmet needs) and lower OHRQoL scores among youth with cleft who represent people of color and those without private health insurance compared with whites and Asians with health insurance. Despite having many advantages for studying children's OHRQoL, the COHIP's greatest drawback is its length (31,32).

After sufficient use, developing short forms (SFs) of QoL measures is both advantageous and recommended. Long survey instruments can be burdensome to patients/participants and demand excessive personnel time especially when these participants may be expected to complete multiple survey instruments and health questionnaires. Furthermore, shortened measures are easier to score and interpret and may expand the application of such assessments in clinical research. Generic QOL instruments, such as the SF Health Survey (SF 12) and the World Health Organization Quality of Life instrument, have been reduced (33,34). Furthermore, both child and adult OHRQoL measures have been shortened to ease respondent burden and to reduce the cost of data collection (4,35). The OHIP was shortened from 49 to 14 items (35). Despite the vast reduction in items, the OHIP-14 has been shown to have good statistical properties and validity and can be used to study OHRQoL in a wide variety of clinical/research settings that require a concise and easily administered instrument (35). Regarding children's OHRQoL, the 37-item CPQ_{11-14} was

shortened to 16 and 8 items using item impact and stepwise regression (4).

While shortening instruments for ease of use has practical advantages, it is important that the reduced scale maintains appropriate psychometric properties. Yet, there are no precise guidelines on the ideal number of items to target or on the best method for such item reduction. Some reports recommend keeping at least four items per domain to control for random error and to allow within-domain analysis (4,36), while others require only two items per domain (37). Therefore, when reducing the number of items on a questionnaire, care must be taken to conduct necessary internal reliability as well as construct (36) and content (3) validity testing. Additionally, when deleting items from a scale, preserving the theoretical framework must also be considered.

The goal of the present study is to explore a possible reduction in the number of items on the 34-item COHIP to create a shorter measure for multiple purposes (e.g., needs assessment and clinical research) that retains its strong reliability and validity properties. In this paper, we will describe the process, decision-making, and psychometric testing involved in creating the COHIP–SF.

Methods

Convenience samples were utilized in conjunction with clinical research efforts at pediatric dental (ped), orthodontic (ortho), and CF sites across various locations in the United States. Data were collected in accordance with Institutional Review Board (IRB) specifications at the sites.

Procedures

Pediatric sample

Researchers at University of California (UC) Davis are conducting a population-based health study of agricultural workers in Mendota, California – a small, rural community in the San Joaquin Valley. The UC Davis team invited the UC San Francisco's (UCSF's) National Institutes of Health-funded Center to Address Disparities in Children's Oral Health to collaborate with them and add a dental component to their Mexican Immigration to California: Agricultural Safety and Acculturation study. This study of caries status and OHRQoL of children of agricultural workers strives to uncover the magnitude, extent, and impact of children's oral health problems from clinically determined and self-reported perspectives. A house-to-house enumeration identified households comprised of agricultural workers from which 958 families were randomly selected. Of the random sample, 340 (35 percent) did not meet the UC Davis' inclusion criteria (primary householder age <55 years), and 196 (20 percent) declined to participate. The remaining 421 eligible households consented to participate. The inclusion criteria for the UCSF OHRQoL study included children ages 7-17 who resided in the subset of the 421 households selected by UC Davis for their population-based study.

This project was reviewed and approved by the UCSF Committee on Human Research. Informed consent from each child's parent was obtained prior to administration of the COHIP, parent interview, and dental exam. Each child (seven and older) gave assent prior to administration of the COHIP and dental exam. Spanish and English consent forms were available and a bilingual research staff member facilitated the consent and assent. The questionnaire was printed in English and Spanish and given according to each participant's preference. After explaining the instructions, a brief pretest was given to determine if the child had sufficient literacy level to complete the instrument. As compensation for their time and expression of appreciation, families received a $15 gift certificate to a local food market.

The dental exams followed universal infection control guidelines and were performed in a portable chair with a fiber optic light. One dentist, trained and experienced as a research dental examiner [previously a National Health and Nutrition Examination Survey IV (NHANES IV) study examiner], completed all dental exams. The dental exam yielded markers of clinical oral health including decayed and filled tooth surfaces (DFS index) for permanent teeth and dfs index for primary teeth in children in accordance with NHANES standards. The parental interview also provided the parent's assessment of the child's overall health: "In general, how would you describe the condition of your child's overall health?" Responses were rated using a five-point scale (from poor to excellent) with higher scores reflecting better health.

Orthodontic sample

A nonrandom, convenience sample of children, ages 9-17 years, was recruited in the postgraduate clinic at New York University (NYU) College of Dentistry specifically to examine OHRQoL. The participants consisted of "new patients" who presented for consultation, treatment planning, or initial bonding.

The inclusion criteria specified children between 9 and 17 years of age, children that have no cognitive impairment or other chronic illness, and children that have not begun orthodontic treatment. Exclusion criteria included the following: children that are above or below the specified age, children with cognitive impairment or other chronic illnesses, children with severe oral pain and limited range of motion of the jaws, children who are under psychological treatment, and children who have begun orthodontic treatment. Participants received a $20 financial incentive for participating and the

response rate was 91 percent. Data were collected after gathering initial orthodontic clinical information as consistent with the IRB-approved protocol.

Participants completed the COHIP and clinical data were obtained from chart review. Spacing/crowding in millimeters of misalignment was assessed for each participant and included a simple measurement of overlap (crowding) or spacing between the six anterior maxillary and six anterior mandibular teeth. This measure is an adaptation of the irregularity index (38). The absolute values are added to provide a composite score of both crowding and spacing in both the maxillary and mandibular areas for the orthodontic (ortho) sample.

CF sample

As part of a longitudinal study, the CF sample consisted of treatment-seeking children between the ages of 7 and 18 and their parent/caregiver. Trained research assistants at six established cleft treatment sites in the United States 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, had a mental disorder, or did not read English or Spanish.

Youth assented and caregivers consented to a protocol approved by the IRBs at the respective sites. Participants had the choice of completing the COHIP in English or Spanish. Following uniform verbal instructions, participants independently completed the COHIP. Research assistants were available to provide assistance, if needed. Upon completion of the child and caregiver evaluation packets, a $25 gift card was dispensed to compensate for the participant's time and effort. These assessments are a part of our larger IRB-approved study.

Clinical data were collected by the clinical specialists and research assistants from the medical charts and/or clinical exams. These included whether a surgical recommendation in the next calendar year was recommended, visibility of defect [CLP versus cleft palate only (CPO)], ratings of patients' hypernasality of speech, and the clinician's rating of extent of defect (a Likert-like scale from no difference or normal, mild, moderate to severe) is an adaptation of the severity scale developed by Kuijpers-Jagtman *et al.* (39), which was used in the recent Americleft study (40). Hypernasality was the extent of speech difference rated as normal, mild impairment, moderate, and severe, which is a standard rating scale in cleft research (41). The enrollment rate across CF sites averaged 86 percent (range = 78-93 percent) acceptance. Lack of time was the most prevalent reason for nonparticipation. Missingness of items was <5 percent across sites with no observed specific pattern based on ethnicity, age, gender, or pediatric group.

Instrument

COHIP

The original COHIP consists of 34 items forming five conceptually distinct subscales: *Oral Health, Functional Well-Being, Social-Emotional Well-Being, School Environment*, and *Self-Image* (1). *Oral Health* is comprised of specific oral health symptoms that are not necessarily related to one another (e.g., pain and spots on teeth) (2). *Functional Well-Being* includes items pertaining to the child's ability to carry out specific everyday tasks or activities (e.g., speaking clearly and chewing) (3). *Social-Emotional Well-Being* relates to peer interactions and mood states (4). *School Environment* incorporated items pertaining to tasks associated with the school environment (5). *Self-Image* addresses positive feelings about oneself. The statements are formatted to elicit self-reports from the child. Instructions for the items in the five subscales are as follows: "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 negatively worded items was reversed, while scoring of the positively worded items was not. Thus, higher COHIP scores reflect more positive OHRQoL, while lower scores reflect lower OHRQoL.

Readability statistics

Readability (appropriate US school grade level for language included in the questionnaire) was computed using the Flesch-Kincaid scoring protocol (42). After eliminating the repetitive suffix (because of your teeth, mouth, or face), which is also expressed in the instructions, the original instrument has a 3.5 reading grade level compared with the COHIP-SF 19, which has a 3.2 reading grade level.

Additionally, test formatting to reduce fatigue and response error includes alternating line color, use of a clear font, and use of pictures for younger children. A cue sheet is also available for young children or those with limited attention or reading skills. The test instrument is completed in less than 10 minutes.

Statistical analysis

The development of the original 34-item COHIP has been detailed in previous publications (23,26). The plan was to reduce the 34-item scale, if possible, to a shorter, more convenient final version. The goals of the analyses were the following: a) to eliminate items with a notable amount of content overlap; b) to preserve the strong psychometric

characteristics of the original measure; and c) to maintain good discriminant and face validity. Specifically, we wanted to test the range and frequency of response utilization and distributional properties (e.g., normally distributed, skewed, and kurtotic) at the item level. We applied a second-order confirmatory factor analysis to the original COHIP structure to help identify lower performing items. Loadings less than 0.4 were considered low (43). Expert opinion was also expressed to guide our decisions.

Scale level analyses

Internal consistency was quantified using Cronbach's alpha. The acceptable level for the overall scale was set at 0.80. Also assessed was the ability of the reduced measure to differentiate between groups by clinical severity. *Construct validity* was assessed by examining measures of discriminant and convergent validity.

Discriminant validity was explored by examining the association between the original COHIP and COHIP-SF 19 scores and clinical severity within the pediatric, orthodontic, and CF groups controlling for age, gender, and race/ethnicity. It was expected that greater clinical severity (e.g., increased crowding and spacing in the anterior teeth) would be associated with lower COHIP and COHIP-SF 19 scores – i.e., lower OHRQoL. *Convergent validity* was assessed by examining the partial Spearman correlation between the COHIP and COHIP-SF 19 scores and the single item self-rating of *Global Health* for the orthodontic and CF samples. A positive correlation would indicate that when OHRQoL was higher, *Global Health* was also higher. For the pediatric sample, the parental rating of the child's overall health was assessed using a single item with responses ranging from one to five with higher scores indicating better health. For the Spearman correlations to be considered supportive, statistical significance ($P < 0.05$) was required.

Sample comparisons

Analysis of variance was used to compare the three samples' scores on the original COHIP and the COHIP-SF 19 (overall and subscales).

Results

Item Retention: Notable content overlap between items was identified and investigated as follows:

- Two items captured oral health-related pain experience (had *pain* in your teeth/toothache; had *pain* or *sensitivity* in your teeth with *hot or cold things*).
- Two items assessed oral health-related challenges regarding oral hygiene (had *food sticking in or between* your teeth; had *difficulty* keeping your *teeth clean*).
- Two items measured oral health-related eating challenges (had *trouble biting off or chewing foods* such as apple, carrot, or firm meat; had *difficulty eating foods* you would like to eat).
- Two items included oral health-related challenges with speaking (had *difficultly saying certain words*; had people have difficulty understanding what you were saying).

The first three sets of items had similar distributional properties (normally distributed) and good range of endorsement coverage (all response options were used); additionally, change in alpha reliability upon deletion of either was negligible. The decision was made to retain the more general, less specific item (had pain) over the more specific item (pain or sensitivity . . . hot or cold things). In the case of the last pair of items with content overlap, we retained "difficulty saying certain words" as problems with speech intelligibility tend to subside with age (44).

Confirmatory factor analysis

A number of items on each subscale evidenced weak loadings (Table 2) in one or more samples including the following: Oral Health subscale items – *snoring* (0.09 ped; 0.16 ortho) and *sores* (0.09 ped; 0.07 ortho; 0.08 CF); Emotional Well-Being – *teased* (0.22 ped) and avoided smiling (0.24 ped); School items – *not wanting to go to school* (0.20 ped; 0.06 ortho; 0.21 CF); and Self-Image items – *have good teeth* (0.19 ped; 0.26 ortho; CF 0.22), *feel good about self* (0.12 ped; 0.08 ortho), *will have good teeth* (0.17 ped; 0.08 ortho; 0.17 CF), and *will have good health* (0.10 ped; 0.11 ortho). Those items with the weakest loadings in two or more samples were eliminated from the measure.

Distributional and endorsement considerations

The Oral Health item, *dry mouth or lips*, had low rates of endorsement with 25 percent of each of the samples reporting "never." The School item, "Had difficulty paying attention in school," was skewed (ped = 12.9; ortho = –4.5; CF = –2.08) and kurtotic (ped = 3.64; ortho = 24.6; CF = 4.11), evidencing a ceiling effect (ped > 50 percent; ortho > 70 percent; CF > 50 percent; reporting "never"). Another School item, "Not wanted to go to school," was skewed (ped = –2.94; CF = –2.29) and kurtotic (ped = 6.4; ortho = 2.7; CF = 5.16), evidencing a ceiling effect (ped > 50 percent; ortho > 50 percent; CF > 70 percent; reporting "never"). None of these items were retained in the COHIP-SF 19.

Pediatric sample

The mean [±standard deviation (SD)] age of the 205 children in this sample is 11.8 (±2.9) years. Just over half (55 percent) are male and 97 percent are Latino. Table 1 presents

Table 1 Demographic Characteristics by Participant Group

	Pediatric (n = 205)	Orthodontic (n = 108)	Craniofacial (n = 839)
Age [mean (SD)]	11.8 (2.9)	12.7 (2.0)	11.9 (3.0)
Gender			
Male (%)	55	50	56
Race/ethnicity (%)			
Black	0	22	10
Asian	0	6	10
White	0	12	68
Other	3	4	12
Latino (%)	97	56	14*

* Participants in the CF sample self-described as Latino/not Latino separately from selecting a race designation.
CF, craniofacial; SD, standard deviation.

the demographic description of the sample. To construct group comparisons, DFSs in permanent teeth were grouped as 0 (n = 69, 34.2 percent), 1-3 (n = 43, 21.3 percent), 3-6 (n = 31, 15.3 percent), 6-10 (n = 29, 14.4 percent), and >10 (n = 30, 14.8 percent). Caries in permanent teeth were grouped as absent (n = 159, 78.7 percent) or present (n = 43, 21.3 percent).

Scale level analyses

Internal consistency was assessed using Cronbach's alpha: COHIP Child = 0.87 compared with COHIP-SF 19 = 0.82.

Discriminant validity

COHIP-SF 19 scores were significantly lower for children with the greatest amount of DFS in permanent teeth on Oral Health [F (4,197) = 3.9, $P < 0.005$; DFS = 0 $\bar{x} = 14.6$, DFS > 10 $\bar{x} = 11.7$], Socio-Emotional Well-Being [F (4,197) = 4.65, $P < 0.002$; DFS = 0 $\bar{x} = 26.9$, DFS > 10 $\bar{x} = 22.7$], and the overall COHIP-SF 19 [F (4,197) = −2.0, $P < 0.003$; (DFS = 0 $\bar{x} = 57.3$, DFS > 10 $\bar{x} = 51.2$)]. Functional Well-Being was not significant. These findings are consistent with the COHIP findings where scores were significantly lower for those with the greatest amount of DFS in permanent teeth on Oral Health [F (4,197) = 4.71, $P < 0.001$], Socio-Emotional Well-Being [F (4,197) = 5.82, $P < 0.0002$], Self-Image [F (4,197) = 4.94, $P < 0.001$], and the overall COHIP [F (4,197) = −3.39, $P < 0.01$]. Functional Well-Being and School were not significant.

COHIP-SF 19 scores were significantly lower for participants with caries in permanent teeth (compared with those with none) on Oral Health [F (1,200) = 3.35, $P < 0.05$; no caries $\bar{x} = 14.0$, with caries $\bar{x} = 12.1$] and the overall COHIP-SF 19 [F (1,201) = −3.7, $P < 0.05$; no caries $\bar{x} = 57.2$, with caries $\bar{x} = 53.1$]. Functional and Socio-Emotional Well-Being were not significant. COHIP scores were significantly lower for participants with caries in permanent teeth on Oral Health [F (1,200) = 3.10, $P < 0.05$], Self-Image [F (1,200) = 5.69, $P < 0.01$], and the overall COHIP [F (1,201) = −4.49, $P < 0.05$]. Functional and Socio-Emotional Well-Being were not significant.

Convergent validity

Parental ratings of the child's overall health were significantly positively correlated with scores on the COHIP-SF 19 as follows: Functional Well-Being (r = 0.20, $P < 0.005$), Socio-Emotional Well-Being (r = 0.20, $P < 0.004$), and the overall COHIP-SF 19 (r = 0.20, $P < 0.004$). This is consistent with the results from the COHIP: Functional Well-Being (r = 0.17, $P < 0.02$), Socio-Emotional Well-Being (r = 0.20, $P < 0.007$), School (r = 0.14, $P < 0.05$), and the overall COHIP-SF 19 (r = 0.20, $P < 0.006$).

Orthodontic sample

The sample consists of 108 treatment-seeking youth. The participants averaged 12.7 years (SD = 2.0), and 50 percent were male. The sample was ethnically diverse: 21.7 percent black or African American, 55.6 percent Latino, 12.3 percent white, and 10.4 percent other (mostly Asian) (see Table 1). Clinical severity as measured in millimeters by assessing crowding and spacing in the six anterior maxillary teeth (canine to canine) and in the six anterior mandibular teeth was as follows: maxillary mean score = 3.60 mm (range = 0-12) and mandibular mean score = 4.45 mm (range = 0-12).

Scale level analyses

Internal consistency was assessed using Cronbach's alpha: COHIP Child = 0.86 and COHIP-SF 19 = 0.82.

Discriminant and convergent validity

Significant negative correlations revealed that higher clinical severity was associated with lower OHRQoL as measured by

the COHIP-SF 19 for absolute levels of mandibular and maxilla crowding and spacing. This modified irregularity index revealed these correlations and significance scores for mandibular and maxilla anterior teeth: Oral Health (−0.37, $P < 0.0001$ and −0.31, $P < 0.002$), Functional Well-Being (−0.19, $P < 0.05$ and −0.19, $P < 0.05$), Socio-Emotional Well-Being (−0.25, $P < 0.01$ and −0.24, $P < 0.02$), and the overall COHIP-SF 19 (−0.32, $P < 0.0001$ and −0.30, $P < 0.003$, respectively).

Findings using the COHIP were consistent with correlations for mandibular and maxilla irregularity: Oral Health (−0.40, $P < 0.0001$ and −0.37, $P < 0.002$), Functional Well-Being (−0.21, $P < 0.05$ and −0.23, $P < 0.02$), Socio-Emotional Well-Being (−0.26, $P < 0.01$ and −0.24, $P < 0.02$), and the overall COHIP (−0.34, $P < 0.001$ and −0.31, $P < 0.002$, respectively).

CF sample

Sample characteristics

A total of 863 youth with CF anomalies participated (Table 1). They were recruited from participating sites as follows: Children's Healthcare of Atlanta ($n = 247$); Children's Hospital of Philadelphia ($n = 122$); Lancaster Cleft Palate Clinic ($n = 137$); NYU ($n = 154$); University of Illinois-Chicago ($n = 70$); and University of North Carolina-Chapel Hill ($n = 130$). The sample age range was 7-19 years with an average age of 11.9 (SD = 3.0, mode 8.0, median 11.5). Most ($n = 467$, 56 percent) of the youth participants were male and 204 (29 percent) had a recommendation of surgery within 1 year of the current visit. The ethnic composition of the sample was as follows: 8 percent black or African American, 10 percent Asian, 68 percent white, and 5 percent other.

Scale level analyses

Internal consistency of the COHIP-SF 19 was acceptable as assessed using Cronbach's alpha: child 0.88 and caregiver 0.87. These findings are consistent with the reliability of the original instrument that was also child 0.88 and caregiver 0.87.

Discriminant validity

Based on the clinical evaluation, children with greater defects had positive surgical recommendations compared with those who were clinically acceptable (no surgical recommendation). The results showed that COHIP-SF 19 scores were significantly lower among those children with less optimal clinical status (lower for those having surgical recommendations and higher for those children who had no surgical recommendation) on Functional Well-Being [F (1,862) = 5.0, $P < 0.03$; no surgical recommendation $\bar{x} = 12.7$, surgical recommendation $\bar{x} = 11.9$], Socio-Emotional Well-Being [F (1,862) = 18.4, $P < 0.001$; no surgical recommendation $\bar{x} = 25.9$, surgical recommendation $\bar{x} = 23.1$], and the overall COHIP-SF 19 [F (1,862) = 15.1, $P < 0.0001$; no surgical recommendation $\bar{x} = 55.7$, surgical recommendation $\bar{x} = 51.4$]. There were no significant differences between patients on surgery status for Oral Health [F (1,862) = 1.25, $P > 0.25$]. The findings on the COHIP-SF 19 were similar to those obtained using the original instrument. Original COHIP scores were significantly lower for those children with less optimal clinical status as measured by surgical recommendation on Functional Well-Being [F (1,862) = 5.12, $P < 0.02$], Socio-Emotional Well-Being [F (1,862) = 11.2, $P < 0.001$], School [F (1,862) = 4.81, $P < 0.001$], and the overall COHIP-SF 19 [F (1,862) = 7.74, $P < 0.0005$]. There were no significant differences between patients on surgery status for Oral Health [F (1,862) = 1.94, $P > 0.14$] or Self-Image [F (1,862) = 1.18, $P > 0.30$].

Given that most speech problems are resolved by adolescence (44), speech nasality ratings (none, mild, moderate, and severe) were analyzed among the younger participants between 7.5 and 12 years old. COHIP-SF 19 scores varied significantly by speech production. OHRQoL scores were lowest for those having severe speech problems and highest for those with no speech problems on Oral Health [F (3,470) = 3.14, $P < 0.03$; no problems $\bar{x} = 14.4$, severe $\bar{x} = 12.7$], Functional Well-Being [F (3,470) = 9.4, $P < 0.0001$; no problems $\bar{x} = 13.7$, severe $\bar{x} = 11.9$], Socio-Emotional Well-Being [F (3,470) = 2.9, $P < 0.03$; no problems $\bar{x} = 25.2$, severe $\bar{x} = 22.7$], and the overall COHIP-SF 19 [F (3,470) = 4.8, $P < 0.005$; no problems $\bar{x} = 56.2$, severe $\bar{x} = 51.9$)].

Original COHIP scores followed a similar pattern for speech production: Oral Health [F (3,470) = 4.14, $P < 0.02$], Functional Well-Being [F (3,470) = 8.7, $P < 0.001$], and the overall COHIP-SF 19 [F (3,470) = 3.20, $P < 0.05$] scores were lowest for those individuals having severe speech problems and highest for those with no speech problems.

Based on visibility of cleft defect, COHIP-SF 19 scores were significantly lower for those with CPO compared with those with CLP on Oral Health [F (1,862) = 4.5, $P < 0.05$; CPO $\bar{x} = 14.0$, CLP $\bar{x} = 13.2$], Functional Well-Being [F (1,862) = 5.5, $P < 0.02$; CPO $\bar{x} = 13.0$, CLP $\bar{x} = 12.1$], Socio-Emotional Well-Being [F (1,862) = 32.1, $P < 0.0001$; CPO $\bar{x} = 27.7$, CLP $\bar{x} = 24.2$], and the overall COHIP-SF 19 [F (1,862) = 26.7, $P < 0.0001$; CPO $\bar{x} = 57.9$, CLP $\bar{x} = 52.4$)]. Similarly, original COHIP scores were significantly lower for participants with more extreme defect on Functional Well-Being [F (1,862) = 4.86, $P < 0.03$], Emotional Well-Being [F (1,862) = 34.4, $P < 0.0001$], School [F (1,862) = 12.2, $P < 0.0005$], Self-Image [F (1,862) = 6.63, $P < 0.01$], and the overall COHIP [F (1,862) = 18.6, $P < 0.0001$]. No significant differences were detected on the original COHIP

for Oral Health [$F(1,862) = 4.5, P < 0.05$] based on extent of defect.

Extent of nose defect as measured by the plastic surgeon revealed that COHIP-SF 19 scores were significantly different (lower) for participants with more severe clinicians' rating of extent of nose defect for Functional Well-Being [$F(1,862) = 2.7, P < 0.05$; least defect $\bar{x} = 12.9$, severe defect $\bar{x} = 11.5$], Socio-Emotional Well-Being [$F(1,862) = 15.9, P < 0.0001$; least defect $\bar{x} = 27.5$, severe defect $\bar{x} = 20.3$], and the overall COHIP-SF 19 [$F(1,862) = 11.2, P < 0.0001$; least defect $\bar{x} = 56.9$, severe defect $\bar{x} = 47.6$]. There were no significant differences between participants on extent of nose defect for Oral Health [$F(1,862) = 1.48, P > 0.22$]. This result was largely consistent with the findings using the original COHIP regarding clinician rating of nose defect: lower COHIP for more severe nose defect on Socio-Emotional Well-Being [$F(1,862) = 12.33, P < 0.0001$], School [$F(1,862) = 2.66, P > 0.05$], Self-Image [$F(1,862) = 4.88, P < 0.0007$], and the overall COHIP-SF 19 [$F(1,862) = 6.23, P < 0.0001$]. There were no significant differences between patients on extent of nose defect for Functional Well-Being [$F(1,862) = 1.72, P < 0.14$] or Oral Health [$F(1,862) = 1.23, P > 0.29$].

Extent of lip defect as measured by the plastic surgeon revealed that COHIP-SF 19 scores were significantly different (lower) for participants with more severe clinicians' rating of extent of lip defect for Functional Well-Being [$F(1,862) = 2.9, P < 0.02$; least defect $\bar{x} = 12.9$, severe defect $\bar{x} = 11.4$], Socio-Emotional Well-Being [$F(1,862) = 8.04, P < 0.0001$; least defect $\bar{x} = 27.8$, severe defect $\bar{x} = 24.3$], and the overall COHIP-SF 19 [$F(1,862) = 7.1, P < 0.0001$; least defect $\bar{x} = 57.1$, severe defect $\bar{x} = 51.6$]. No significant differences between patients on rating of extent of lip defect for Oral Health [$F(1,862) = 1.48, P > 0.21$] were found. Original COHIP scores related to Functional Well-Being [$F(1,862) = 2.9, P < 0.02$], Socio-Emotional Well-Being [$F(1,862) = 8.01, P < 0.0001$], Self-Image [$F(1, 862) = 4.94, P < 0.0006$], and the overall COHIP [$F(1,862) = 5.35, P < 0.0003$] were significantly lower in patients with more severe clinicians' rating of lip defect (lower for severe defect). There were no significant differences between patients on extent of defect for lip continuity for Oral Health [$F(1,862) = 0.95, P > 0.40$] or School [$F(1, 862) = 1.55, P > 0.18$].

Convergent validity of the COHIP-SF 19 as assessed using patient's self-rated *Global Health* was significantly correlated (Spearman) with Oral Health ($r = 0.20$, $P < 0.0001$), Functional Well-Being ($r = 0.19$, $P < 0.0001$), Socio-Emotional Well-Being ($r = 0.28$, $P < 0.0001$), and overall COHIP-SF scores ($r = 0.30, P < 0.0001$). These results are similar to those obtained using the COHIP: Oral Health ($r = 0.25$, $P < 0.0001$), Functional Well-Being ($r = 0.23$, $P < 0.0001$), Socio-Emotional Well-Being ($r = 0.26$, $P < 0.0001$), School ($r = 0.22, P < 0.0001$), Self-Image ($r = 0.41, P < 0.0001$), and overall COHIP-SF scores ($r = 0.34, P < 0.0001$). Likewise, caregivers' ratings of their children's *Global Health* were significantly correlated (Spearman) with Oral Health ($r = 0.17$, $P < 0.001$), Functional Well-Being ($r = 0.18$, $P < 0.001$), Socio-Emotional Well-Being ($r = 0.21$, $P < 0.001$), and overall COHIP-SF scores ($r = 0.30, P < 0.001$). These results are similar to those obtained from parents using the COHIP: Oral Health ($r = 0.19$, $P < 0.001$), Functional Well-Being ($r = 0.20, P < 0.001$), Socio-Emotional Well-Being ($r = 0.23$, $P < 0.0001$), Self-Image ($r = 0.41$, $P < 0.0001$), and overall COHIP-SF scores ($r = 0.34, P < 0.0001$).

Comparison of samples

Table 2 includes a comparison of the items and domain scores for the COHIP and COHIP-SF 19 across participant groups. COHIP Oral Health scores for the three samples revealed that the CF sample has significantly lower OHRQoL than the pediatric (ped) sample ($F = 10.9, P < 0.0001$); the COHIP-SF 19 Oral Health scores from the three samples revealed no significant differences on OHRQoL ($F = 1.26, P > 0.28$). A comparison of the COHIP Functional Well-Being scores between the three samples revealed that the ortho and CF samples have significantly lower OHRQoL than the ped sample ($F = 24.8, P < 0.0001$); the findings using the COHIP-SF 19 Oral Health scores were consistent ($F = 9.2, P > 0.28$). A comparison of the COHIP Emotional Well-Being scores between the three samples revealed that the ortho and CF samples have significantly lower OHRQoL than the ped sample ($F = 5.06$, $P < 0.01$). A comparison of the COHIP School scores between the three samples revealed that the ortho and CF samples have significantly lower OHRQoL than the ped sample ($F = 7.2$, $P < 0.001$). A comparison of the COHIP Self-Image scores between the three samples revealed that the ped and ortho samples have significantly lower OHRQoL than the CF sample ($F = 42.6, P < 0.0001$). On the combined COHIP-SF 19 Socio-Emotional Well-Being subscale, the ortho sample had higher scores than the ped or CF samples ($F = 15.9$, $P < 0.0001$). In summary, for both the COHIP Overall ($F = 9.5, P < 0.0001$) and the COHIP-SF 19 ($F = 13.4$, $P < 0.0001$), the CF sample had significantly lower OHRQoL scores than the ped or ortho samples.

Discussion

The results from these three different samples indicate that the COHIP-SF 19 retains very good psychometric properties. Both reliability and validity testing are consistent with those reported in the literature for the original COHIP (23). Thus, the COHIP-SF 19 addresses recommendations for a shorter, more efficient children's OHRQoL instrument, i.e., appropriate for a variety of purposes such as clinical research and epidemiological studies (31,32).

Table 2 Child Oral Health Impact Profile Original and Short Form

Oral Health – Well-Being (original 10 items; five items retained)	Ped	Ortho	CF
	Mean (SD) confirmatory factor analysis loadings		
Had pain in your teeth/toothache	3.0 (1.1) 0.66	3.0 (1.0) 0.12	3.0 (1.1) 0.57
†Been breathing through your mouth or snoring	2.9 (1.2) 0.09	2.8 (1.1) 0.16	2.1 (1.4) 0.47
Had discolored teeth or spots on your teeth	3.3 (1.0) 0.43	3.1 (1.3) 0.44	3.2 (1.1) 0.46
Had crooked teeth or spaces between your teeth	2.6 (1.4) 0.44	2.7 (1.5) 0.27	1.6 (1.5) 0.08
†Had sores or sore spots in or around your mouth	3.1 (1.1) 0.09	3.4 (1.0) 0.07	2.9 (1.1) 0.55
Had bad breath	2.7 (1.1) 0.56	2.7 (1.0) 0.56	2.6 (1.2) 0.52
Had bleeding gums	2.7 (1.1) 0.68	3.0 (1.1) 0.02	3.0 (1.1) 0.59
†Had food sticking in or between your teeth	2.3 (1.1) 0.68	2.3 (1.1) 0.30	2.1 (1.2) 0.20
†Had pain or sensitivity in teeth with hot or cold things	2.5 (1.2) 0.55	2.5 (1.3) 0.29	2.6 (1.4) 0.45
†Had dry mouth or lips	2.5 (1.1) 0.56	2.1 (1.1) 0.61	2.1 (1.2) 0.60
COHIP Oral Health Subscale (original 10 items)	27.6 (6.5)	26.5 (5.5)	25.3 (6.6)
COHIP-SF 19 Oral Health Subscale (five items)	13.8 (2.5)	13.6 (2.9)	13.4 (3.5)
Functional Well-Being (original six items; four items retained)			
†Had trouble biting off or chewing foods such as apple, carrot, or firm meat	3.2 (1.1) 0.59	3.4 (1.0) 0.33	2.8 (1.3) 0.64
Had difficulty eating foods you would like to eat	3.3 (0.9) 0.69	3.4 (1.1) 0.35	3.1 (1.2) 0.73
Had trouble sleeping	3.6 (0.8) 0.66	3.0 (0.2) 0.43	3.6 (0.80) 0.56
Had difficultly saying certain words	3.4 (1.0) 0.70	3.3 (1.0) 0.44	2.7 (1.3) 0.68
†Had people have difficulty understanding what you were saying	3.4 (1.1) 0.69	3.4 (0.9) 0.34	2.7 (1.3) 0.52
Had difficulty keeping your teeth clean	3.0 (1.2) 0.57	2.9 (0.7) 0.45	3.1 (1.1) 0.59
COHIP Functional Well-Being Subscale (original six items)	20.0 (3.8)	19.3 (4.9)	17.9 (4.0)
COHIP-SF 19 Functional Well-Being Subscale (four items)	13.2 (2.6)	12.5 (3.7)	12.4 (2.09)
Social/Emotional Well-Being (original eight items; six items retained)			
Been unhappy or sad	3.0 (1.1) 0.55	2.9 (1.1) 0.73	3.0 (1.2) 0.78
Felt worried or anxious	3.1 (0.09) 0.69	3.0 (1.0) 0.77	3.1 (1.1) 0.75
Avoided smiling or laughing with other children	3.2 (0.08) 0.24	3.7 (1.1) 0.63	3.3 (1.2) 0.64
Felt that you look different	3.3 (1.1) 0.69	3.7 (1.2) 0.59	2.7 (1.3) 0.82
Been worried about what other people think about your . . .	3.0 (1.2) 0.65	3.4 (1.2) 0.08	2.7 (1.4) 0.79
†Felt shy or withdrawn	3.0 (1.0) 0.71	2.3 (1.5) 0.84	3.1 (1.3) 0.63
Been teased, bullied, or called names by other children	3.5 (1.1) 0.22	3.0 (1.0) 0.67	3.1 (1.4) 0.63
†Been upset or uncomfortable with being asked questions about your . . .	3.2 (0.09) 0.72	3.0 (1.3) 0.66	2.8 (1.2) 0.69
COHIP Emotional Well-Being Subscale (original eight items)	25.3 (3.6)	26.9 (4.4)	24.9 (6.8)
School Environment (original four items; two retained)			
Missed school for any reason	3.5 (1.0) 0.55	3.2 (1.1) 0.25	2.9 (0.90) 0.51
†Had difficulty paying attention in school	3.5 (1.1) 0.58	3.0 (1.4) 0.07	3.5 (0.90) 0.37
Not wanted to speak/read out loud in class	3.6 (1.0) 0.80	3.8 (0.5) 0.36	3.3 (1.0) 0.70
†Not wanted to go to school	3.6 (1.1) 0.20	3.4 (1.1) 0.06	3.6 (0.90) 0.21
COHIP School Subscale (original four items)	14.2 (2.3)	13.5 (2.6)	13.4 (2.8)
Self-Image (original six items; two retained)			
Been confident	1.8 (1.0) 0.35	1.8 (1.3) 0.10	2.1 (1.5) 0.48
Felt that you were attractive (good looking)	1.3 (1.3) 0.28	3.3 (1.1) 0.14	1.7 (1.4) 0.49
†I have good teeth	2.2 (1.2) 0.19	1.4 (1.0) 0.26	2.6 (1.3) 0.22
†I feel good about myself	2.9 (1.2) 0.12	2.5 (1.2) 0.08	3.3 (1.1) 0.47
†When I am older, I believe (think) that I will have good teeth	2.6 (1.3) 0.17	3.1 (0.0) 0.08	3.4 (0.90) 0.17
†When I am older, I believe (think) that I will have good health	2.7 (1.3) 0.10	2.7 (1.0) 0.11	3.6 (0.80) 0.62
COHIP Self-Image (original six items)	13.5 (5.1)	15.1 (4.7)	16.7 (4.4)
COHIP-SF 19 Socio-Emotional Well-Being Subscale*	26.0 (5.0)	28.7 (5.6)	25.1 (6.9)
COHIP Total (original items)	**103.5 (16.9)**	**102.2 (13.2)**	**98.3 (13.3)**
COHIP-SF 19 Total	**56.2 (9.3)**	**57.8 (10.3)**	**53.7 (11.4)**

* The retained items from the original Social/Emotional, School, and Self-Image domains are combined to create this subscale on the COHIP-SF 19.

† Items not retained in Short Form.

Questions finish with "because of your teeth, mouth, or face."

CF, craniofacial; COHIP-SF 19, Child Oral Health Impact Profile–Short Form 19; SD, standard deviation. Bolded items depict COHIP total scores.

OHRQoL assessment in children seeks to measure items associated with the teeth, mouth, or face that are understood and meaningful to youth. The 3.2 grade readability level also makes the measure accessible to most school-aged children. Additionally, the ability of the measure to discriminate across clinical groups and within groups by extent of disease/defect highlights the shortened instrument's validity as well as its versatility compared with other children's OHRQoL measures.

One of the limitations of this report is that to date we do not have data on the responsiveness of the measure to change. It is noted that the instrument is currently being utilized as an evaluative measure for a longitudinal outcomes study and data on change following cleft surgery or no surgery will be reported. However, the COHIP, like many recent generic QoL tools, includes positive constructs which should reveal a more robust and responsive outcome measure (17). Another limitation of this research is the mild evidence in support of convergent validity in the nontreatment-seeking pediatric sample as the correlations, while significant, are modest. Further evaluation of the measure in additional pediatric samples is warranted.

The current findings support the position that subjective evaluation of oral health status provides unique data that correlate with clinical outcomes. In fact, the subjective assessment adds a dimension to the relative prevalence and/or importance of the individual or sample. Such data are invaluable when developing interventions and fully assessing the needs of the population. Such findings underscore why QoL measures are now incorporated into almost every area of healthcare and constitute a valuable oral health outcome measure (2).

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