Examination of a Theoretical Model for Oral Health–Related Quality of Life Among Youths With Cleft

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Clefting is the second most common birth defect in the United States.[1] A cleft palate affects functional well-being through effects on speech, hearing, dental development, and eating; a cleft of the lip or primary palate also affects facial attractiveness. Such defects can influence youths' sense of self and well-being. We examined well-being and factors theoretically associated with quality of life (QOL) in youths with cleft conditions.

Typically, individuals with cleft experience evaluations and treatment that begin in infancy and often last into young adulthood. Cleft defects are therefore considered chronic conditions that can affect QOL.[2,3] To date, numerous reports suggest that children with cleft have reduced self-concepts and are at risk for depression.[4] Such reports, however, are cross sectional, have small samples, deal with different age groupings, and often lack a conceptual framework. These reports also have inconclusive findings regarding the relationship of oral health–related QOL (OHRQOL) to gender and overall well-being in youths with cleft.

The theoretical perspective underpinning our study is consonant with the World Health Organization's definition of health as more than the absence of disease[5] and with its Quality of Life Group's definition of QOL as an

> individual's perceptions of his/her 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.[6(pp1-2)]

Because QOL is now recognized as an essential in patient assessment in nearly every area of physical and mental health care, including oral health,[7] our goal was to adapt and evaluate a well-respected theoretical model by Wilson and Cleary[8] to examine QOL among youths with cleft. According to the Wilson and Cleary model, the determinants of QOL include biological–physiological factors, symptom and functional status, and general health perceptions within the context of individual and environmental characteristics.

Objectives. We evaluated relationships among physical and psychological indicators and oral health–related quality of life (OHRQOL) in youths with cleft.

Methods. We recruited youths aged 7 to 18 years with cleft palate (n = 282) or cleft lip and palate (n = 918) and their caregivers into a 5-year observational investigation at 6 US treatment centers from 2009 to 2011. At baseline, youths completed surveys to assess psychological status. After clinical evaluation, 433 youths received a recommendation for surgery. We developed structural models from the baseline data incorporating age, gender, race, and cleft diagnosis to examine direct relationships between depressive symptoms and, in separate models, self-concept and sense of mastery and OHRQOL. Subsequent models examined the possible mediating effect of surgical recommendation.

Results. Depressive symptoms were negatively and self-concept and self-efficacy were positively associated with OHRQOL. Surgical recommendation appeared to mediate the effect of psychological well-being, but not depression, on OHRQOL, even after adjustment for cleft diagnosis. In some models, individual-level characteristics were significant.

Conclusions. Path analyses support the theoretical model and underscore the importance of examining positive psychosocial characteristics such as resiliency and self-concept in this patient population. (*Am J Public Health.* 2014;104: 865–871. doi:10.2105/AJPH.2013.301686)

Our adaptation expanded the model to include OHRQOL. Specifically, our model examined how individual characteristics (e.g., age, race, gender), biological function (e.g., type of defect), psychological characteristics, and surgical recommendation (which represents an indicator of current clinical status) were linked to OHRQOL. Further, environmental or contextual factors related to caregiver characteristics (e.g., sociocultural factors) and access to care may also be linked because they may influence children's oral health perceptions and related QOL. Our adaptation of the model allowed us to elaborate on psychosocial factors that are relevant among youths with cleft, who are at risk for negative psychosocial sequelae as a result of their condition.[4] Our model examined negative symptoms such as depression as well as positive psychological characteristics such as resiliency and self-concept, which have been shown to mediate the negative affect associated with a range of chronic conditions, including craniofacial conditions.[9] In sum, we expanded on Wilson and Cleary's

model to create a more comprehensive understanding of these complex interrelationships potentially associated with OHRQOL among this population seeking care. Health service researchers are designing studies to provide empirical data to support the use of this model in health[10-13] and oral health.[14-16]

Over the past 2 decades, several OHRQOL tools have been developed for children and adults.[17-20] These measures broadly conceptualize oral health as a construct that encompasses general well-being and the ability to eat, speak, and socialize with confidence. Traditionally, such QOL measures have focused on measuring the negative impact of chronic conditions or disease. Although many studies that include psychological variables have exclusively examined negative affect such as anxiety and depression, social scientists are increasingly exploring positive factors such as resilience and self-efficacy as well. In fact, health-related QOL experts now recognize that such positive attributes are essential in QOL assessment[21-23] and warrant consideration

during the development of models to examine health outcomes such as QOL.

METHODS

We recruited school-aged, treatment-seeking youths aged 7 to 18 years with cleft into a longitudinal, observational study examining QOL and related outcomes. Here we report baseline cross-sectional data (follow-up data collection is ongoing). We asked youths with cleft evaluated at 1 of 6 prominent and geographically diverse cleft centers in the United States (located in Atlanta, GA, Lancaster, PA, Philadelphia, PA, New York, NY, Chicago, IL, and Chapel Hill, NC) and their caregivers to participate in the study. The average recruitment rate was 90%. Each youth–caregiver dyad received a $40 gift card for their time and effort. Recruitment and data collection occurred between December 2009 and March 2011.

Measures

Demographic characteristics. Youth participants self-reported their age (in years), race, and gender (male = 0, female = 1). Although we collected race/ethnicity data and reported them in the descriptive results for all categories for which participants self-identified, the sample only had sufficient numbers of Black participants to permit model estimation. Therefore, we dummy-coded race for the path analysis (Black = 1, not Black = 0).

Clinical characteristics. We took cleft diagnosis—cleft palate only or cleft lip and palate (CLP)—from the clinical record and dummy-coded it (cleft palate only = 0, CLP = 1). As part of the standard of care, the teams' plastic surgeons conducted clinical evaluations to determine whether the participants had surgical needs warranting surgical intervention within 1 year. The surgeons used criteria (e.g., appearance of the nose, lip, and face; speech) to formulate their surgical recommendations, which were based on their clinical evaluation and consultation with the patients and families. We coded status of this recommendation (which we conceptualized as unmet needs) as 1 if surgery was recommended within the following 12 months and as 0 if not.

Oral health—related quality of life. The Child Oral Health Impact Profile (COHIP) is a 34-item self-report OHRQOL measure with 5

discrete domains[24]: Oral Health contains varied, specific oral symptoms (e.g., tooth pain, bleeding gums); Function Well-Being reveals ability to carry out daily functions (e.g., eating, speaking clearly); Emotional Well-Being addresses peer interactions and mood states; School Environment involves tasks associated with school; and Self-Esteem incorporates positive feelings about oneself. The COHIP has been shown to discriminate within and between diagnostic groups according to the extent of the condition (e.g., orthodontic needs; decayed, missing, and filled surfaces; cleft diagnosis; treatment needs).[24,25] Reports yield excellent psychometric properties (e.g., internal consistency and strong test–retest reliability).[24] The COHIP uses a 5-point Likert scale ranging from never to almost always.

Depressive symptoms. The Beck Depression Inventory for Youth is a 20-item assessment used to identify depressive symptoms in children and adolescents.[26] It includes items that reflect negative thoughts about one's life and future, feelings of sadness, and physiological indications of depression. Internal consistency scores for children ($\alpha = 0.86$) and adolescents (0.92) are excellent. Validity testing is also excellent.[27]

Self-concept. The Beck Self-Concept Inventory for Youth is a 20-item self-report questionnaire designed to measure self-perceptions such as competence and positive self-worth.[26]

It uses a 4-point Likert scale (responses range from never to always), and both reliability testing (e.g., test–retest = 0.81; Cronbach alphas = 0.91) and criterion-referenced validity testing with standard scales (e.g., 0.61 with the Piers Harris Scale) are excellent.[26]

Mastery. The Mastery Scale of the Resiliency Scales for Children and Adolescents is a 20-item self-report questionnaire with responses on a 5-point Likert scale ranging from never to almost always.[28] The scale consists of 3 content areas: optimism (e.g., positive attitudes about life), self-efficacy (i.e., sense that the individual can master his or her environment), and adaptability (e.g., ability to ask for help or problem solve). Internal consistency ($\alpha = 0.91$) is excellent, and validity testing is very good.[28]

Data Analysis

We computed descriptive statistics (in the form of means and standard deviations for continuous variables and frequencies for categorical variables) for all variables in our analysis by cleft diagnosis and for the overall sample; they are presented in Table 1. Bivariate associations are presented in Table 2, which includes Pearson and Spearman correlations where appropriate. To test the model depicted in Figure 1, we first regressed (model 1) the covariates age, race, gender, and cleft diagnosis on surgical recommendation status and surgical recommendation status on OHRQOL

TABLE 1—Study Sample of Youths With Cleft in 6 Treatment Centers by Surgery Recommendation: United States, 2009–2011

Variable	Surgery Recommended (n = 434), Mean ±SD or No. (%)	Surgery Not Recommended (n = 766), Mean ±SD or No. (%)	Total (n = 1200), Mean ±SD or No. (%)
Age, y	11.8 ±3.3	11.5 ±3.0	11.6 ±3.1
Gender			
Male	246 (57)	428 (56)	674 (56)
Female	188 (43)	338 (44)	526 (44)
Diagnosis			
CPO	60 (14)	227 (30)	287 (24)
CLP	374 (86)	539 (70)	913 (76)
Race/ethnicity			
Black	50 (12)	78 (10)	128 (11)
Asian	57 (13)	60 (8)	117 (10)
White	269 (62)	544 (71)	813 (68)
Other	58 (13)	84 (11)	142 (12)

Note. CLP = cleft lip and palate; CPO = cleft palate only.

TABLE 2—Bivariate Correlations Among Model Variables Youths With Cleft in 6 Treatment Centers: United States, 2009–2011

| Variable	Oral Health	Functional Well-Being	Socioemotional Well-Being	School Environment	Self-Esteem	Total COHIP	Beck Self-Concept Inventory for Youth	Beck Depression Inventory for Youth	Mastery Scale[a]	Age	Gender	Race/Ethnicity	Surgery Recommendation	Cleft Diagnosis
Oral health	1													
Functional well-being	0.51***	1												
Socioemotional well-being	0.39***	0.52***	1											
School environment	0.36***	0.59***	0.59***	1										
Self-esteem	0.19***	0.21***	0.37***	0.23***	1									
Total COHIP	0.72***	0.76***	0.83***	0.71***	0.54***	1								
Beck Self-Concept Inventory for Youth	0.26***	0.28***	0.37***	0.27***	0.47***	0.46***	1							
Beck Depression Inventory for Youth	-0.28***	-0.33***	-0.50***	-0.39***	-0.36***	-0.52***	-0.53***	1						
Mastery Scale[a]	0.16***	0.24***	0.32***	0.23***	0.47***	0.38***	0.72***	-0.41***	1					
Age	0.07**	0.01	0.18***	0.05	0.78***	0.12***	0.01	0.17***	-0.05	1				
Gender	0.00	0.00	0.09**	0.001	0.06	0.02	0.00	-0.07*	-0.03	0.01	1			
Race/ethnicity	0.01	0.04	0.08**	-0.08**	0.04	0.04	-0.00	-0.01	-0.05	0.03	0.00	1		
Surgery recommendation	-0.09**	-0.13***	-0.17***	-0.10***	-0.03	-0.15***	-0.08**	0.06*	-0.09**	0.03	-0.01	0.09**	1	
Cleft diagnosis	0.04	0.07*	0.19***	0.11***	0.08**	0.13***	0.04	-0.06*	0.03	0.05	0.13***	-0.01	-0.12***	1

Note. COHIP = Child Oral Health Impact Profile.
[a] From the Resiliency Scales for Children and Adolescents.
*P < .05; **P < .01; ***P < .001.

(1 model was created for each of the subscales on the COHIP and a separate one was created for the COHIP total score). This initial model incorporated a direct path from the psychosocial indicator (e.g., depressive symptoms, self-concept, or mastery) to OHRQOL. Subsequently, we added an indirect path (via surgical recommendation status) from the psychosocial indicator to OHRQOL (model 2). We repeated this process in separate parallel models incorporating the direct and indirect associations between self-concept and OHRQOL and mastery and OHRQOL. We executed these models with MPlus version 6.13 (Muthén and Muthén, Los Angeles, CA) with estimation method weighted least squares, because the model included a dichotomous indicator requiring PARAMETERIZATION = THETA.[29] The results of these models are presented in Table 3.

Further, we reviewed and re-examined all 6 models and included direct paths from age, race, and gender to OHRQOL. Female gender was negatively associated with OHRQOL in both depression models and age was negatively associated with OHRQOL in both the self-concept and mastery models. Inclusion of these direct paths did not alter the significance, magnitude, or interpretation of the models, so we did not include them in the models presented here.

We reported a set of fit indices for these models (Table 2). We reported χ^2 (as is standard); however, for models with many cases (≥ 400), the χ^2 is almost always statistically significant and thus is not the best indicator of model quality. Therefore, we reported relative χ^2, the χ^2 fit index divided by degrees of freedom, as a statistic less dependent on sample size. Acceptable ranges vary widely, with values less than 5 considered to represent plausible model parameters. The Tucker–Lewis Index and comparative fit index have penalties for adding parameters (thus increasing model complexity) and are interpreted similarly, with 0.90 and higher (maximum = 1.0) indicating better-fitting models. Mean square of approximation, the absolute measure of fit, is derived from the noncentrality parameter. It is evaluated as follows: 0.01, 0.05, and 0.08 to indicate excellent, good, and mediocre fit, respectively, with 0.10 usually considered a cutoff for acceptability.[30]
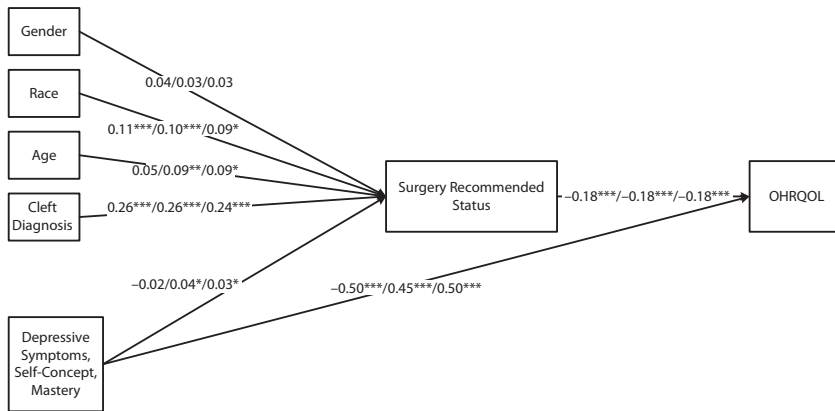
Note. OHRQOL = oral health–related quality of life. Numerical values are the standardized parameters for the identified path and are all from model 2 for depressive symptoms/self-concept/mastery, respectively, including the direct effects.
*$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

FIGURE 1—Path models of psychosocial influences and surgical recommendation status on oral health–related quality of life in youths with cleft in 6 treatment centers: United States, 2009–2011.

RESULTS

The description of the study sample (n = 1200) is presented in Table 1. The table is oriented around the recommendation for surgery because this is a major variable indicative of clinical status. We observed no significant difference in age between the 2 recommendation groups (i.e., youths who were and were not recommended for surgery within 1 year; $t = -1.59$; $df = 1198$; $P = .112$). We also found no significant difference in gender distribution between the 2 groups ($\chi^2 [1] = 0.073$; $P = .787$). However, we detected a significant difference in diagnosis, with a greater percentage of youths with CLP in the surgical recommendation group than among youths not advised to undergo surgery ($\chi^2 [1] = 38.053$; $P < .001$). The groups also differed significantly in racial distribution, with a greater proportion of minorities recommended for surgery (38% vs 29%; $\chi^2 [3] = 13.1$; $P = .004$).

Bivariate correlations (Table 2) showed negative correlations between depressive symptoms ($r = -0.52$; $P < .001$) and COHIP scores as well as significant positive correlations between both self-concept ($r = 0.46$; $P < .001$) and mastery ($r = 0.38$; $P < .001$) and COHIP scores. We observed modest positive correlations with depressive symptoms

($r = 0.06$) and negative correlations with self-concept ($r = -0.07$) and mastery ($r = -0.09$) for surgical recommendation status. We found small negative correlations with depressive symptoms ($r = -0.06$) and positive correlations with self-concept ($r = 0.04$) and mastery ($r = 0.03$) for cleft diagnosis.

The path model findings for all the COHIP subscales (Figure 1) yielded the same interpretation as well as magnitude of parameters as the total COHIP. For the sake of parsimony, we presented only the total COHIP models (full findings available from H. L. B.). In all cases, the fit indices suggested acceptable fit, with the weakest composite lead indicators (0.80) and mean square of approximation (0.08) for mastery models and the weakest χ^2 and df for the self-concept models.

For depressive symptoms in model 1, minority status and CLP were positively associated with a surgical recommendation (Table 3). We observed a negative path from surgical recommendation to OHRQOL as well as a negative direct path from depressive symptoms to OHRQOL. In model 2, the indirect path from depressive symptoms to OHRQOL via surgical recommendation status was not significant, indicating that depressive symptoms had a direct, but not indirect, influence on OHRQOL in this sample. The parameters for

age, race, gender, and cleft diagnosis did not change when we compared model 1 to model 2, which was unexpected because of the addition of an indirect path. Because the indirect path from depressive symptoms to OHRQOL was small and nonsignificant, the inclusion of this path may have had a negligible influence on the entirety of the model. By contrast with the change in the χ^2 for self-concept and mastery, the change in the χ^2 for model 2 (which included depressive symptoms) was quite small.

For self-concept in model 1, female gender, minority status, older age, and CLP were positively associated with surgery being recommended. We observed a negative path from recommendation for surgery to OHRQOL and a positive direct path from self-concept to OHRQOL. The indirect path from self-concept to OHRQOL via surgery-recommended status (model 2) was significant and positive, indicating that self-concept had both a direct and an indirect positive influence on OHRQOL.

Finally, for mastery in model 1, minority status, older age, and CLP were positively associated with surgery being recommended. Results showed a negative path from surgery being recommended to OHRQOL and a positive direct path from mastery to OHRQOL. The indirect path from mastery to OHRQOL via surgery-recommended status (model 2) was significant and positive, indicating that mastery had both a direct and an indirect positive influence on OHRQOL.

DISCUSSION

Our sample of school-aged youths with cleft represented the largest database for this population that incorporated clinical variables as well as subjective patient-oriented variables such as OHRQOL and psychosocial functioning. Our findings support the theoretical model of Wilson and Cleary,[8] which suggests that QOL is an important outcome associated with psychological well-being. We also found that psychological well-being and medical diagnosis were associated with surgical need. Path analysis revealed that resilience and positive self-concept not only had a direct effect, but were also partially mediated by surgical status in influencing OHRQOL, as measured by the COHIP. Although depression had a direct

TABLE 3—Path Model Results for Youths With Cleft in 6 Treatment Centers: United States, 2009–2011

Indicator	Model 1			Model 2		
	B (95% CI)	SE	P	B (95% CI)	SE	P
Depressive symptoms						
Surgical recommendation regressed on						
Female gender	0.04 (−0.13, 0.21)	0.09	.26	0.04 (−0.13, 0.21)	0.09	.26
Black race	0.11 (−0.67, 0.89)	0.40	.001	0.11 (−0.67, 0.89)	0.40	.001
Age	0.05 (0.01, 0.09)	0.02	.14	0.05 (0.01, 0.09)	0.02	.14
Cleft diagnosis	0.26 (−0.97, 1.40)	0.63	.001	0.26 (−0.97, 1.40)	0.63	.001
Psychological well-being				0.05 (0.03, 0.07)	0.01	.16
Direct effect on OHRQOL						
Surgical recommendation	−0.18 (−0.45, 0.09)	−0.14	.001	−0.18 (−0.45, 0.09)	−0.14	.001
Psychological well-being	−0.51 (−2.40, 1.40)	−0.98	.001	−0.50 (−2.40, 1.40)	−0.97	.001
Indirect effect on OHRQOL						
Psychological well-being				−0.02 (−0.03, 0.01)	0.01	.18
Fit indices						
$\chi^2(df)$	17.4 (5)		.001	15.6 (4)		.001
χ^2/df	3.48			3.90		
TLI	0.98			0.98		
CLI	0.96			0.95		
RMSEA	0.05			0.05		
Self-Concept						
Surgical recommendation regressed on						
Female gender	0.03 (−0.04, 0.10)	0.07	.36	0.03 (−0.11, 0.17)	0.07	.36
Black race	0.10 (−0.27, 0.47)	0.37	.001	0.10 (−0.62, 0.82)	0.37	.001
Age	0.10 (0.07, 0.13)	0.03	.01	0.09 (0.03, 0.14)	0.03	.01
Cleft diagnosis	0.26 (−0.39, 1.30)	0.65	.001	0.26 (−1.00, 1.50)	0.65	.001
Psychological well-being				−0.10 (−0.08, 0.12)	−0.01	.01
Direct effect on OHRQOL						
Surgical recommendation	−0.18 (−0.31, 0.001)	−0.16	.001	−0.18 (−0.39, 0.13)	−0.16	.001
Psychological well-being	0.46 (−0.40, 1.30)	0.86	.001	0.45 (−1.10, 2.00)	0.82	.001
Indirect effect on OHRQOL						
Psychological well-being				0.04 (0.02, 0.06)	0.01	.02
Fit indices						
$\chi^2(df)$	43.5 (5)		.001	36.3 (4)		.001
χ^2/df	8.70			9.07		
TLI	0.92			0.93		
CLI	0.81			0.80		
RMSEA	0.08			0.08		
Mastery						
Surgical recommendation regressed on						
Female gender	0.03 (−0.08, 0.14)	0.06	.52	0.03 (−0.08, 0.14)	0.06	.52
Black race	0.09 (−0.53, 0.71)	0.32	.02	0.09 (−0.53, 0.71)	0.32	.02
Age	0.09 (0.03, 0.14)	0.03	.02	0.09 (0.03, 0.14)	0.03	.02
Cleft diagnosis	0.24 (−0.89, 1.40)	0.58	.08	0.24 (−0.89, 1.40)	0.58	.001
Psychological well-being				−0.08 (−0.10, 0.06)	−0.01	.04

Continued

relationship with QOL, it did not show a significant indirect effect on OHRQOL via surgical recommendation status. The findings suggest that youths with oral–facial surgical needs may benefit from the protective effects of mastery skills such as self-efficacy and positive self-esteem.

Our results are consistent with findings in the literature indicating that health disparities exist among children with cleft. Importantly, our findings support previous research that among children with cleft, racial/ethnic minorities are more likely than Whites to have surgical recommendations (i.e., unmet needs) and lower levels of OHRQOL.[25] The association with race may warrant consideration from a health policy perspective, because this is a vulnerable patient population that requires long-term iterative care that can be financially challenging.

Despite tremendous variations in psychosocial functioning among youths with chronic conditions such as asthma, cancer, cystic fibrosis, and migraine headaches, most studies find compromised self-reported social and emotional functioning in such groups.[31] In the past, relatively little was known about the relationship between depression, anxiety, and QOL in children and teens with chronic diseases, including craniofacial conditions.[32] Recent findings, however, have demonstrated the importance of examining the influence of depressive symptoms on QOL among adolescents with craniofacial anomalies.[2] These authors, by contrast with our findings, detected significant mediation of depressive symptoms, and we endorse the relevance of including depression in studies of adolescent QOL.

Our results also underscore the importance of examining positive psychosocial characteristics such as resiliency and self-concept, which have been shown to mediate the negative affect associated with a range of conditions, such as HIV, diabetes, and craniofacial conditions.[9,33–35] Our results, although cross-sectional, support studies linking resiliency and mastery with health outcomes and including positive health variables such as resiliency, optimism, and self-image with measurements of emotional well-being in studies of youths with varying chronic conditions.[28,36–38] School-based mental health programs are being considered

TABLE 3—Continued

Direct effect on OHRQOL						
Surgical recommendation	−0.18 (−0.51, 0.15)	−0.17	.001	−0.18 (−0.53, 0.17)	−0.18	.001
Psychological well-being	0.38 (−0.89, 1.60)	0.65	.001	0.50 (−0.21, 1.20)	0.36	.001
Indirect effect on OHRQOL						
Psychological well-being				0.03 (0.02, 0.04)	0.001	.05
Fit indices						
$\chi^2(df)$	21.6 (5)		.001	17.5 (4)		.001
χ^2/df	4.32			4.27		
TLI	0.94			0.95		
CLI	0.86			0.85		
RMSEA	0.06			0.06		

Note. CI = confidence interval; CLI = composite lead indicators; OHRQOL = oral health–related quality of life; RMSEA = root mean square error of approximation; TLI = Tucker–Lewis Index.

and implemented to create and reinforce positive health attitudes and behaviors for individuals with chronic conditions and their peers.[28,39] Emphasis on such positive psychological attributes has been the subject of numerous articles in the *Cleft Palate/Craniofacial Journal*[40,41] and an entire issue of the *American Psychologist*.[42]

We analyzed baseline cross-sectional data, which did not permit causal influences to be drawn. Future research, including longitudinal and modeling outcomes following surgical intervention, is key for completing a causality design associated with varying types of cleft surgery. Surgeons often assert that secondary surgical revisions carried out during childhood and adolescence improve QOL, yet no data have been produced on such outcomes in cleft habilitation. The depth and size of its database will enable our ongoing investigation to lay the theoretical foundation for future research regarding the efficaciousness of care and, in particular, evaluation of models such as these with prospective longitudinal data. Although a recommendation for surgery may involve functional well-being and aesthetic issues, the results across the total COHIP and each of its subscales demonstrate a significant relationship between unmet clinical needs such as surgical recommendation and OHRQOL. Gender, age, and race may also be potential powerful variables in such outcomes research. Further, the strength of the positive variables related to QOL is extremely noteworthy. These findings support

the few existing studies that have endorsed positive psychological attributes such as mastery, self-concept, and sense of coherence in the oral health, cleft–craniofacial,[40,41,43,44] and chronic conditions[2,45–47] literature.

Our results strongly support the inclusion of personal, medical, and psychological parameters (positive and negative) in a comprehensive theoretical health model for QOL outcomes. Replication of our model will be critical, however, as we move forward with this type of patient-oriented research aimed at creating holistic interventions for individuals with cleft and craniofacial conditions. ∎

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Contributors
H. L. Broder originated the study and led the writing. M. Wilson-Genderson led the analyses and contributed to the writing. L. Sischo contributed to the writing.

Human Participant Protection
All study sites received institutional review board approval. All participants signed consent or assent forms.

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