





Reliability and Validity of the CLEFT-Q in a Chinese Context

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Abstract

Objective: To develop an appropriate Chinese version of the CLEFT-Q through translation and cultural adaptation and to evaluate its reliability and validity.

Design: The English CLEFT-Q was translated into Chinese following the International Society for Pharmacoeconomics and Outcomes Research guidelines, including cognitive debriefing interviews, and its reliability and validity were assessed.

Participants: Patients (N = 246) were mostly in active orthodontic treatment, had a mean age of 14.7 ± 4.4 years, 29% were female, and were born with isolated cleft lip ± alveolus (12%), cleft palate (1%), or cleft lip and palate (87%).

Main Outcome Measures: The Chinese CLEFT-Q, including 13 subscales covering Appearance, Health-Related Quality of Life (HRQOL), and Facial Function. Criterion validity instruments included the Negative Physical Self, Satisfaction with Life Scale, and Scale of Positive and Negative Experience.

Results: The wording of 67 items was adapted in the final translation. The internal consistency of the Chinese version of the CLEFT-Q was high based on Cronbach's alphas of 0.85 to 0.98 and split-half reliability of 0.85 to 0.92. Exploratory and confirmatory factor analyses yielded three factors, which demonstrated construct validity by broadly matching the structure of the original CLEFT-Q. The Appearance and HRQOL dimensions had weak to moderate correlations ($r = -0.35$ to 0.67) with the corresponding instruments for criterion validity.

Conclusions: The Chinese version of the CLEFT-Q is a patient-reported outcome measure that can reflect the quality of life of Chinese patients with cleft lip and/or palate with good reliability and validity.

Keywords

CLEFT-Q, cleft lip, cleft palate, quality of life, psychological assessment

Introduction

Cleft lip and/or palate (CL/P) is one of the most common congenital craniofacial diagnoses, with a worldwide incidence of 1.7 per 1000.¹ Patients with CL/P may have malocclusion, altered facial appearance, hearing and/or speech difficulties, and be at risk for psychosocial difficulties. Treatment of patients with CL/P is commonly extended from childhood through adolescence and even into adulthood to improve function and esthetics.² Thus, CL/P is thought to have a significant impact on patients' quality of life, based on the characteristics of the diagnosis and treatment.^{2,3}

To assess the quality of life of patients with CL/P, a patient-reported outcome measure (PROM) is needed. In the literature to date, instruments such as the SF-36, Oral Health Impact Profile, Child Oral Health Impact Profile (COHIP), and Child Oral Health Questionnaire have been used to assess the

quality of life of patients with CL/P.⁴⁻⁷ The instruments mentioned above, however, were not designed specifically for

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patients with CL/P, and their contents may not reflect cleft-specific quality of life. Thus, these instruments may not provide a comprehensive and targeted summary of these patients' situations.

The CLEFT-Q is a PROM that measures the Appearance, Health-Related Quality of Life (HRQOL), and Facial Function of patients with CL/P. It was developed in three phases⁸: the first phase consisted of a systematic review and qualitative interviews to identify key concepts, from which the conceptual framework of the CLEFT-Q was developed.^{9,10} The second phase was a large-scale cross-cultural field-test study, which collected the results of a CLEFT-Q survey of 2434 patients with CL/P from 12 countries, provided normative values of the CLEFT-Q, and validated its reliability and validity.¹¹ The third phase involved further assessment of the reliability, validity, and responsiveness of the CLEFT-Q. Harrison et al.¹² investigated the difference in CLEFT-Q scores between patients with CL/P who were referred for future surgery and those who had undergone surgery to verify its construct validity. Miroshnychenko et al.^{13,14} used the COHIP and Cleft Hearing Appearance and Speech Questionnaire (CHASQ) to verify the cross-sectional construct validity of the CLEFT-Q, and also verified its responsiveness.

In addition, the CLEFT-Q has been recommended as a major component of an international consensus-based core result set.¹⁵ It has been translated into multiple languages, including Arabic, Dutch, Farsi, Finnish, Hindi, Indonesian, Spanish (from Chile, Colombia, and Spain), Swedish, Tagalog, Tamil, Thai, and Turkish, and has been tested for cultural adaptation and psychometrics.^{16–21} However, no Chinese version has been available for use.

This study aimed to develop an appropriate Chinese version of the CLEFT-Q through cross-cultural translation and to assess the reliability (Cronbach's alpha coefficient and split-half reliability) and validity (construct validity and criterion validity) of the Chinese version of CLEFT-Q.

Methods and Materials

This study was ethically approved by the ethics committee of the School of Stomatology, Wuhan University. All participants or their legal guardians signed a written informed consent form.

Translation and Cultural Adaptation of the CLEFT-Q

The translation and cultural adaptation were completed following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines to ensure that the Chinese version conveyed the same meaning as the original English version.²² In short, the entire translation and cultural adaptation process was divided into four steps: forward translation, back translation, harmonization, and cognitive debriefing interviews (Figure 1).^{20–22}

Two Chinese-speaking dentistry students who were fluent in English completed two independent forward translations to obtain *Chinese Version 1* of the CLEFT-Q. A native

English-speaking dentistry student who was fluent in Chinese then back-translated *Chinese version 1*. By harmonizing the differences between the back translation results and the original English version, *Chinese Version 2* of the CLEFT-Q was obtained. Between January 2021 and February 2021, cognitive debriefing interviews were conducted with 30 patients with cleft lip ± palate (CL ± P) (Supplementary Table 1) at the Department of Orthodontics I of Hospital of Stomatology, Wuhan University, and further modifications were made to the CLEFT-Q based on the feedback obtained, yielding *Chinese Version 3*. Based on the cognitive debriefing interviews, it was determined that the meaning of the "jaws" needed to be explained to patients under 12 individually, and patients were thus prompted to observe an illustration of the "jaws" in the original CLEFT-Q. After a thorough conversation with the copyright owners and checking for grammatical problems, the *Final Version* of the CLEFT-Q was approved.

Instruments

Chinese version of the CLEFT-Q. The Chinese version of the CLEFT-Q, which was identical in content to the original CLEFT-Q, consisted of 13 subscales with 119 items.¹¹ It was divided into three dimensions, including Appearance (Face, Nose, Nostrils, Teeth, Lips, Jaws, and Cleft Lip Scar), HRQOL (Psychological Function, Social Function, School Function, and Speech Distress), and Facial Function (Speech Function, Eating and Drinking).¹¹ It was developed for patients with CL/P, aged 8–29 years.¹¹

Negative Physical Self (NPS). The NPS consists of five subscales and was developed for Chinese adolescents and young adults.²³ The Facial Appearance (11 items) and General Appearance (5 items) subscales were used to verify the Appearance dimension. The Facial Appearance subscale is subdivided into dimensions for cognition-affect, behavior, and how they think they are perceived by others, while the General Appearance subscale includes only cognition-affect dimensions.²³ Each item is rated on a 5-point Likert-type scale (0 = strongly agree; 4 = strongly disagree), with lower scores indicating higher satisfaction with body image.²³ The Cronbach's alpha coefficient for the NPS was 0.83 in this study sample.

Satisfaction with Life Scale (SWLS). To assess the HRQOL dimension, the concept of subjective well-being, which is an overall assessment of the quality of life based on self-defined criteria, was used.²⁴ Life satisfaction was measured using the SWLS, which contains five items. Each of the items is rated on a 7-point Likert-type scale (1 = strongly disagree; 7 = strongly agree), with higher scores indicating greater life satisfaction.^{25,26} In this study, the Cronbach's alpha coefficient of the SWLS was 0.89.

Scale of Positive and Negative Experience (SPANE). Participants' positive and negative feeling components were measured using the SPANE, which includes six items to assess positive feelings (SPANE-P) and six items to assess negative feelings (SPANE-N).²⁷ This instrument uses a 5-point Likert scale (1 = very rarely or never; 5 = very often

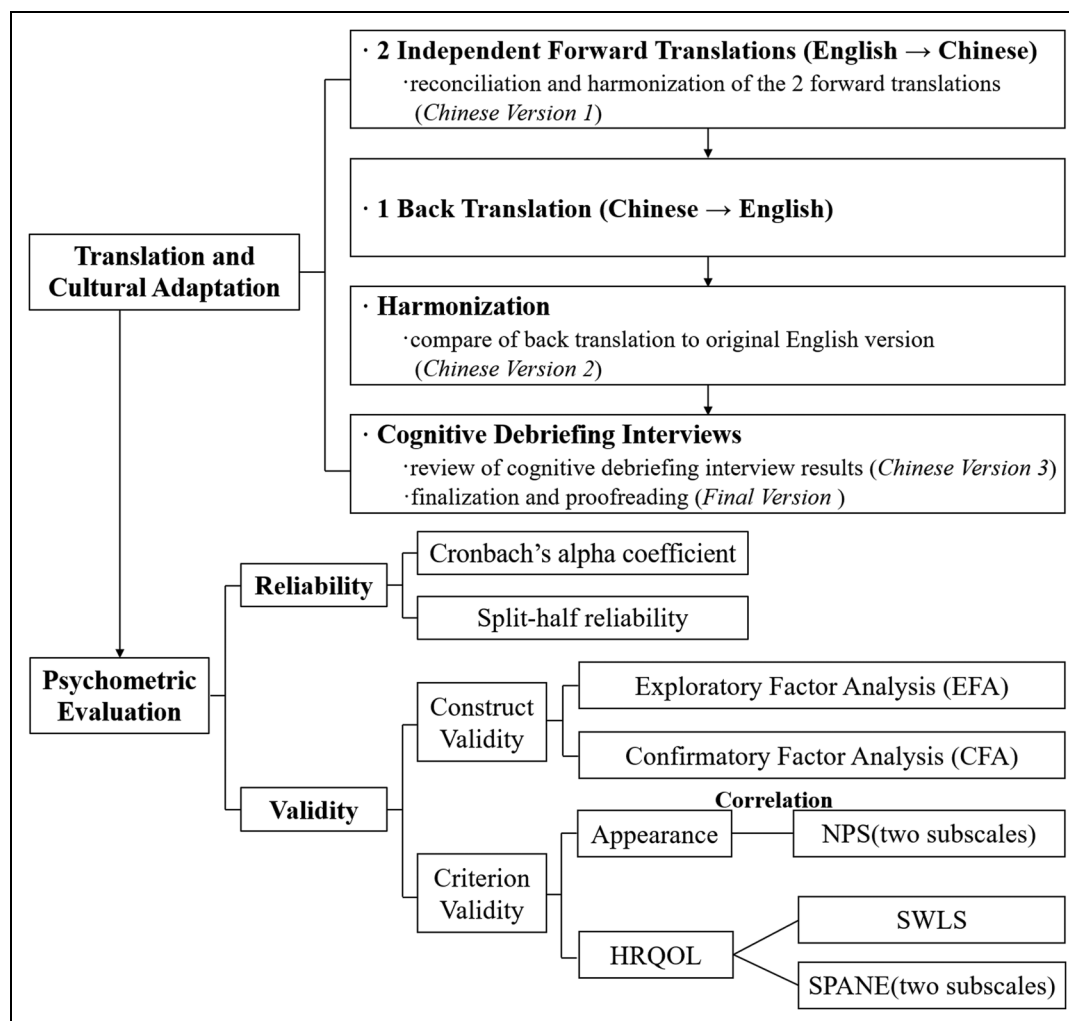


Figure 1. Flow chart of the translation and cross-cultural adaptation steps and psychometric evaluation of the Chinese version of CLEFT-Q. Abbreviations: HRQOL, Health-Related Quality of Life; NPS, Negative Physical Self; SWLS, Satisfaction with Life Scale; SPANE, Scale of Positive and Negative Experience.

or always), with high scores indicating high positive or high negative feelings encountered over the previous 4 weeks.²⁸ In addition, the balance score (SPANE-B) was calculated as (positive feelings – negative feelings).²⁹ In this study, the Cronbach's alpha coefficient of the SPANE subscales were 0.85 (SPANE-P) and 0.84 (SPANE-N).

Sample

Patients with CL/P visiting the Hospital of Stomatology, Wuhan University from July to December 2021 were recruited to complete the Chinese version of CLEFT-Q. The inclusion criteria were age of 8–29 years and non-syndromic CL/P, while the exclusion criteria were an inability to read the Chinese version of the CLEFT-Q and failure to complete the CLEFT-Q. Participants completed measures on paper after the orthodontic visit and they could ask the nearby staff any questions about the questionnaire.

Data Analysis

AMOS software (IBM SPSS Statistics, 24.0, IBM Corp., Armonk, NY, USA) and SPSS software (IBM SPSS Statistics, 25.0, IBM Corp.) were used to analyze the data. The normality of the results was confirmed (Kolmogorov–Smirnov test, $P = 0.089$). The Scar scale value for patients with cleft palate was set to 0. The reliability of the Chinese version of the CLEFT-Q was tested by calculating Cronbach's alpha coefficient and the split-half coefficient. A value of Cronbach's alpha in the range of 0.70–0.95 was considered acceptable,³⁰ and a split-half reliability ≥ 0.7 was considered to indicate high internal consistency.³¹

The construct validity of the Chinese version of the CLEFT-Q was based on structural validity,³² which was quantified using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Prior to factor analysis, Bartlett's spherical test and the Kaiser–Meyer–Olkin (KMO) test were first performed to determine whether items showed sufficient correlation to allow

Table 1. Characteristics of Patients Completing the Instruments.

	No. of participants completing CLEFT-Q (%) N = 246	No. of participants completing CLEFT-Q, NPS, SWLS, and SPANE (%) N = 213
Age		
8–11	75 (30.5%)	60 (28.2%)
12–15	69 (28.0%)	64 (30.0%)
16–19	69 (28.0%)	62 (29.1%)
20–29	33 (13.4%)	27 (12.7%)
Sex		
Male	176 (71.5%)	152 (71.4%)
Female	70 (28.5%)	61 (28.6%)
Cleft type		
Cleft lip/cleft lip and alveolus	30 (12.2%)	25 (11.7%)
Cleft palate only	3 (1.2%)	3 (1.4%)
Cleft lip and palate	213 (86.6%)	185 (86.9%)

Abbreviations: NPS, Negative Physical Self; SWLS, Satisfaction with Life Scale; SPANE, Scale of Positive and Negative Experience.

factor analysis. If $P < 0.05$ for Bartlett's spherical test and $KMO > 0.6$, EFA could be performed.³³ Subsequently, factors with eigenvalues ≥ 1 were first extracted using principal component analysis without rotation. If the cumulative contribution exceeded 60%, the factors were extracted using maximum variance rotation, and the ideal factor loading had to be greater than 0.40.³⁴ Finally, CFA analysis was used to test the model fit using the model derived from EFA. The root mean squared error of approximation (RMSEA), the ratio of cardinality to degrees of freedom (X^2/df), the normalized fit index (NFI), the comparative fit index (CFI), the incremental fit index (IFI), and the Tucker–Lewis index (TLI) were examined. Model fit results were considered excellent if $RMSEA < 0.08$, $X^2/df < 3$, $NFI > 0.90$, $CFI > 0.90$, $IFI > 0.90$, and $TLI > 0.90$.^{35,36}

Criterion validity was analyzed using Pearson's correlation coefficients between the Chinese version of the CLEFT-Q subscales and total scores and each dimension of the NPS, SWLS, and SPANE. In particular, a strong correlation was defined by an r -value between 0.7 and 1.0, a moderate correlation was defined by an r -value between 0.4 and 0.6, and a weak correlation was defined by an r -value between 0 and 0.3.³⁷ Statistical significance was set at $P < 0.05$.

Results

Of the 271 patients with CL \pm P invited to participate, 246 patients completed the Chinese version of the CLEFT-Q only and 213 patients completed the Chinese CLEFT-Q, NPS, SWLS, and SPANE (Table 1).

Translation and Cultural Adaptation

For the translation process, 23 of the back-translated items deviated markedly from the original meaning. In order to make the CLEFT-Q easier to grasp for young patients, many basic words are used. However, when translated directly into

Table 2. The Internal Consistency of the Chinese Version of CLEFT-Q.

Subscales	No. of Items	Cronbach's alpha coefficient	Split-half reliability
Face	9	0.86	0.86
Lips	9	0.91	0.89
Nose	12	0.94	0.92
Nostrils	6	0.92	0.91
Jaws	7	0.92	0.89
Teeth	8	0.91	0.90
Cleft Lip Scar	7	0.94	0.92
Psychological Function	10	0.94	0.91
School Function	10	0.92	0.92
Social Function	10	0.91	0.85
Speech Distress	10	0.92	0.88
Speech Function	12	0.92	0.89
Eating and Drinking	9	0.85	0.85
Total Scale	119	0.98	0.88

Chinese, these words can be challenging to understand. To ensure Chinese participants' comprehension, "speech" was translated as "pronunciation", and "both sides of ... match" as "symmetrical." In addition, words with subtle differences between the two versions were identified and worded for greater clarity, such as "great" or "good", "teased" or "bullied", and "upset" or "frustrated." In terms of cultural adaptation, 44 items were revised for localization by changing sentence patterns and some words. For example, "How much do you like how your lips look when you smile?" was changed into "How much do you like the look of your lips when you smile?" by rephrasing the second "how..." into a declarative sentence. Such revision was also applied to all the other sentences (38 items) with the same sentence patterns.

In terms of vocabulary, words such as “full” (describing the lips) and “meet” (describing the relationship between top and bottom teeth) were modified for language localization.

Reliability

Cronbach’s alpha coefficients of 11 subscales were higher than 0.9, except for 0.86 for the Face subscale and 0.85 for the Eating and Drinking subscale (Table 2). The split-half reliability for the Chinese version as a whole and for each subscale exceeded 0.8 (Table 2). Thus, the Chinese version of CLEFT-Q and all subscales had good internal consistency.

Construct Validity

The results of Bartlett’s sphericity test and KMO test were $P < 0.001$ and $KMO > 0.85$, indicating that factor analysis was possible (Supplementary Table 2). The principal component analysis without rotation yielded three factors with a cumulative contribution of 74.14% (Supplementary Table 3). After five iterations, maximum variance rotation was completed, and three components were identified (Table 3). The EFA findings revealed that the CLEFT-Q question items were set in a clear and focused manner. The modeling for confirmatory factor analysis was based on EFA results (Figure 2). The actual measurement data were observed to fit the conceptual framework and the three-factor model fit well ($RMSEA = 0.07$, $X^2/df = 1.53$, $NFI = 0.92$, $RFI = 0.89$, $IFI = 0.97$, $TLI = 0.96$, $CFI = 0.97$).

Criterion Validity

The total Appearance score was moderately correlated ($P < 0.01$) with the total NPS score ($r = -0.49$) and General Appearance subscale ($r = -0.52$), while it showed a weaker relationship to the

Facial Appearance subscale ($r = -0.35$). Among the NPS dimensions, the correlation coefficients ($P < 0.01$) with total Appearance scores were moderate with cognition-affect ($r = -0.42$) and lower with how participants thought others perceived them ($r = -0.30$). The total HRQOL score was moderately correlated ($P < 0.01$) with the SWLS ($r = 0.59$), SPANE-P ($r = 0.67$), and SPANE-B ($r = 0.62$), while it had a weaker relationship with the SPANE-N ($r = -0.35$).

Discussion

The present study developed an appropriate Chinese version of the CLEFT-Q through a translation and cultural adaptation process. The Chinese version of CLEFT-Q was confirmed to have good validity and reliability in this sample. Adequate internal consistency ensured that the scale had high homogeneity. EFA and CFA results supported a three-factor structure for the Chinese version of CLEFT-Q that is similar to that of the original CLEFT-Q. In terms of criterion validity, the CLEFT-Q showed generally moderate correlations with widely used Chinese measurement instruments. The development of a Chinese version of the CLEFT-Q was crucial to improve the understanding of the quality of life of Chinese patients with CL/P and to provide a theoretical foundation for more appropriate treatments.

For the translation and cultural adaptation process, 23 back-translated items deviated greatly from the original meaning and required modifications and adjustments, while 44 items were modified for localization after the cognitive debriefing interviews. Most of these involved modifications of the same sentence structure. Importantly, many younger patients were unable to understand the meaning of “jaws” during the cognitive debriefing interviews. According to CLEFT-Q requirements, patients under 12 years of age were not required to complete the Jaws subscale. However, this study had to provide complete data because of the need for construct validity. In order to reduce the bias in patients’ understanding of “jaws”, the staff were trained to standardize the wording before collecting the questionnaires. Additionally, the original CLEFT-Q offers a drawing of “jaws” to assist patients’ understanding.

The reliability results of the 13 subscales were good, among which the Cronbach’s alpha coefficient and the split-half reliability of the Eating and Drinking subscale were the lowest (0.85). Klassen et al.¹¹ did not consider the Eating and Drinking subscale to be reliable when they examined the reliability of the original CLEFT-Q, as they considered it to be a simple record of the problems that patients may encounter, rather than a clinical hierarchy. Ajami et al.¹⁶ also found that the Eating and Drinking subscale had the lowest reliability (Cronbach’s alpha coefficient = 0.80, retest reliability ICC = 0.76) in the Farsi version of the CLEFT-Q. However, the reliability of the Eating and Drinking (Cronbach’s alpha coefficient = 0.92) was among the highest in the Indonesian version of the CLEFT-Q, although the authors did not explain the results.¹⁸ In this study, the reliability of the

Table 3. Exploratory Factor Analysis—the Factor Loading of Subscales in the Chinese Version of CLEFT-Q.

	Component		
	Factor 1	Factor 2	Factor 3
Face	0.83		
Lips	0.85		
Nose	0.81	0.30	
Nostrils	0.84		
Jaws	0.73		
Teeth	0.73		
Cleft Lip Scar	0.72		
Psychological Function	0.47	0.70	
School Function		0.86	
Social Function		0.86	
Speech Distress		0.31	0.80
Speech Function		0.31	0.82
Eating and Drinking			0.79

Extraction method: Principal component analysis; Rotation method: Orthogonal rotation method with Kaiser standardization. Only values > 0.3 are displayed in the table.

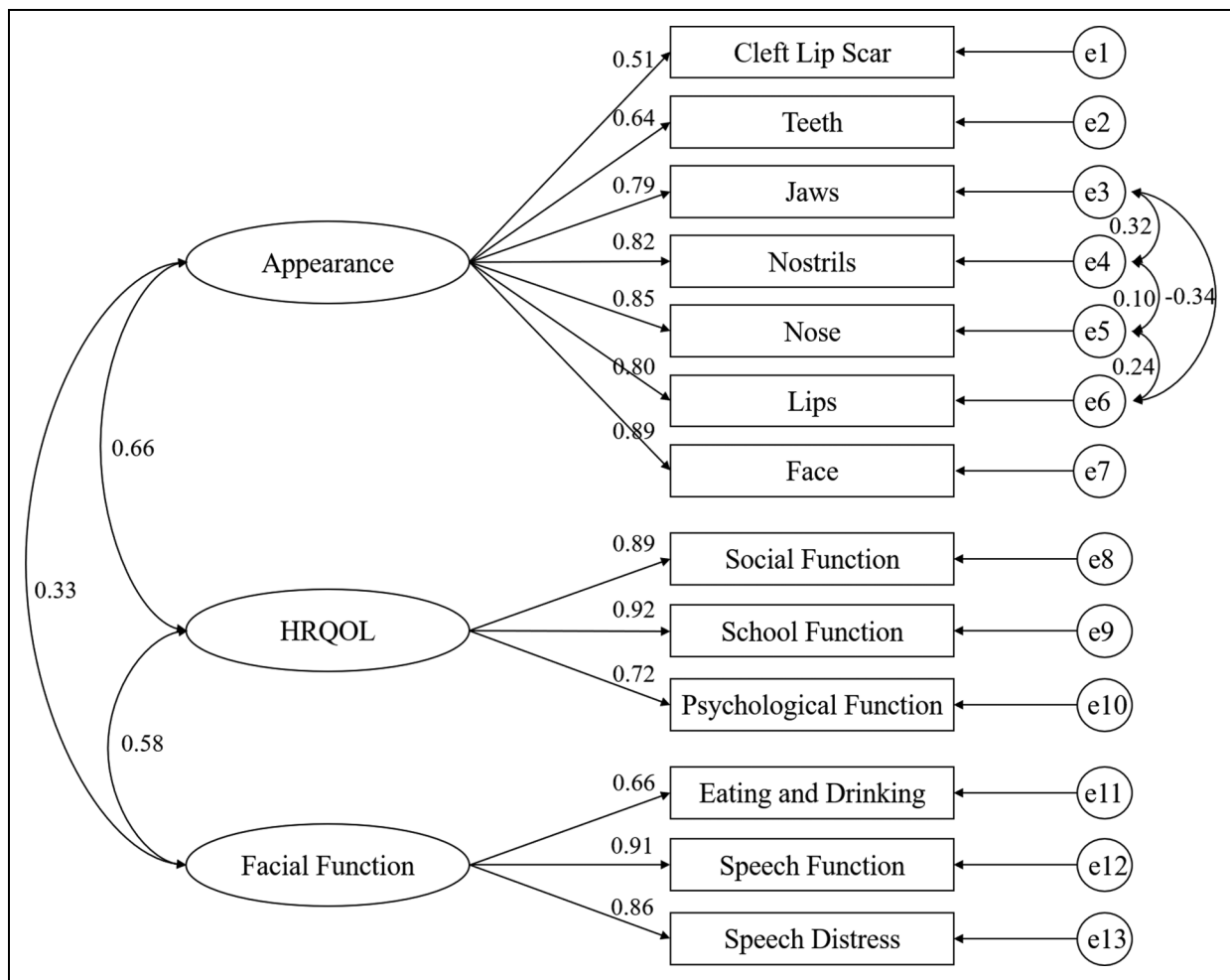


Figure 2. Confirmatory factor analysis model-fitting.
Abbreviation: HRQOL, Health-Related Quality of Life.

Eating and Drinking subscale was good, which could be because the majority of the participants were undergoing orthodontic treatment and had a high degree of homogeneity. They would have similar “eating and drinking” issues, such as the need to eat slowly due to fixed orthodontics.

Retracing the development of the CLEFT-Q revealed that its conceptual framework was derived from a literature review and qualitative interviews (Supplementary Figure 1).^{9,10} This study used factor analysis to investigate the conceptual model of the Chinese version of the CLEFT-Q quantitatively. The EFA results showed that three factors can be extracted, which were broadly in line with the conceptual framework of the original instrument. An exception was the Speech Distress subscale, which was originally included in the HRQOL, but fit best within the Facial Function subscale in this sample. Comparing the item expressions of Speech Function in the Facial Function dimension with those of Speech Distress in the HRQOL dimension, it was clear that the former focused on the patients’ subjective evaluation of function and thus frequently contained expressions such as “It’s hard to understand my speech” and “I

need to speak slowly.” The Speech Distress subscale, however, often described the patients’ feelings, such as “I feel frustrated (embarrassed) when I speak,” and focused on the patients’ attitudes and perceptions of the negative emotion arising from their underlying speech disorder. Consequently, the two subscales are assigned to different dimensions in the original scale. However, considering that “speech” was the subject of both subscales and that the Speech Distress subscale represented an important branch of facial function, assigning Speech Distress to the Facial Function dimension was deemed acceptable, and was subsequently confirmed in the CFA. The construct validity of the CLEFT-Q has been assessed in many studies. Klassen et al.¹¹ used hypothesis testing to demonstrate that lower scores on CLEFT-Q were related to the need for future treatments, unhappiness with the face, and speech problems, providing early evidence of its construct validity. Similarly, Harrison et al.¹² showed that CLEFT-Q could detect differences between groups based on surgical status. Miroshnychenko et al.¹³ used the COHIP and CHASQ to validate the cross-sectional validity of nine subscales (Face, Lips,

Nose, Nostrils, Jaws, Teeth, Cleft Lip Scar, Psychological, and Social) in the CLEFT-Q. Evidence of structural validity of the Chinese version of the CLEFT-Q further supported the validity of this instrument.

Regarding the criterion validity of the Chinese version of CLEFT-Q, this study showed a generally moderate correlation between the two CLEFT-Q dimensions and the instruments for validating criterion validity. The HRQOL correlated more strongly with the SPANE-P and SPANE-B than with the SPANE-N. The HRQOL questions in the CLEFT-Q were designed to measure positive emotions, so that patients did not express negative emotions directly in their responses to the CLEFT-Q, which may have resulted in a weaker correlation with the SPANE-N. The Facial Appearance subscale also had a weak relationship with the CLEFT-Q Appearance score, which may be attributed to the different perspectives of the two question designs. The CLEFT-Q questions are intended to address patients' subjective feelings about their appearance, which is similar to the cognition-affect dimension in the NPS, rather than whether they want to change their appearance in the behavior dimension or how they think others perceive them.

This study had several limitations. Due to a lack of similar Chinese instruments for investigating speech or diet, the criterion validity of the Facial Function section could not be validated. Furthermore, since most of the samples in this study came from the Hospital of Stomatology, Wuhan University, the CL/P types in the study were unevenly distributed, with far fewer patients with isolated cleft palate than in the general Chinese population. Females were also underrepresented in the sample. As most of these patients were undergoing orthodontic treatment, the Eating and Drinking subscale demonstrated high homogeneity, which could have caused a bias in reliability. Additional key differences may exist in cleft populations who are not undergoing orthodontic treatment, which could have influenced the results, such as the degree of malocclusion and motivation for or access to care. Future studies should use the Chinese version of the CLEFT-Q with a large number of patients with CL/P who are representative of the national population and should conduct multi-center evaluations involving other regions.

Conclusion

After translation, cultural adaptation, and reliability and validity testing, the Chinese version of the CLEFT-Q developed here was found to be a PROM that can reflect the quality of life of Chinese children and young people with CL/P with good reliability and validity.

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Supplemental Material

Supplemental material for this article is available online.

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