

Thai CLEFT-Q: Phase I—A Pilot Study of Translation and Cultural Adaptation in Thailand

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Abstract

Objective: To translate and culturally adapt the original English version of the CLEFT-Q into Thai (Thai CLEFT-Q).

Design: A pilot study.

Setting: A single tertiary referral hospital in Thailand.

Participants: Patients with cleft lip or palate (CL/P) aged between 8 and 29 years.

Interventions: The CLEFT-Q was translated and culturally adapted from English into Thai using the good practice guidelines developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Two forward translations and reconciliation, 1 back translation, and 2 sets of cognitive debriefing interviews with patients were performed to develop the Thai CLEFT-Q.

Results: The English version of the CLEFT-Q consists of 13 scales (119 items) assessing appearance, health-related quality of life (HRQOL), and facial function. The forward translations revealed 33.6% inconsistencies. They were related to narrow meaning (2.5%) and improper (16.8%) or incorrect (14.3%) wording or phrasing of the items. After reconciliation, the back translation showed 5 inconsistencies (4.2%) with the original version. However, no changes were needed because the reconciliation version was consistent with the source version. Sixteen participants underwent cognitive debriefing interviews, which revealed a comprehensive interpretation of the Thai CLEFT-Q. Interim reports revealed fair facial appearance scores, albeit with HRQOL and facial function outcomes.

Conclusions: Translation and cultural adaptation of the Thai CLEFT-Q provided evidence of its transferability and equivalence with the original English version. Feasible comprehension of the Thai version was also achieved.

Keywords

cleft lip or palate, CLEFT-Q, craniofacial abnormalities, patient-reported outcomes, quality of life

Introduction

Cleft lip or palate (CL/P) is one of the most common craniofacial abnormalities. CL/Ps are Thailand's most common craniofacial anomalies, with approximately 1:500 to 600 live births.^{1,2} Patients with CL/P typically require comprehensive multidisciplinary team care and long-term follow-up.³ The principal aims of cleft care are to achieve the best quality of life in terms of function, esthetics, and psychosocial status. In the inceptive era of plastic and reconstructive surgery, “good esthetics” results from surgeons’ perspectives might not match patients’ perceptions. However, the patients’

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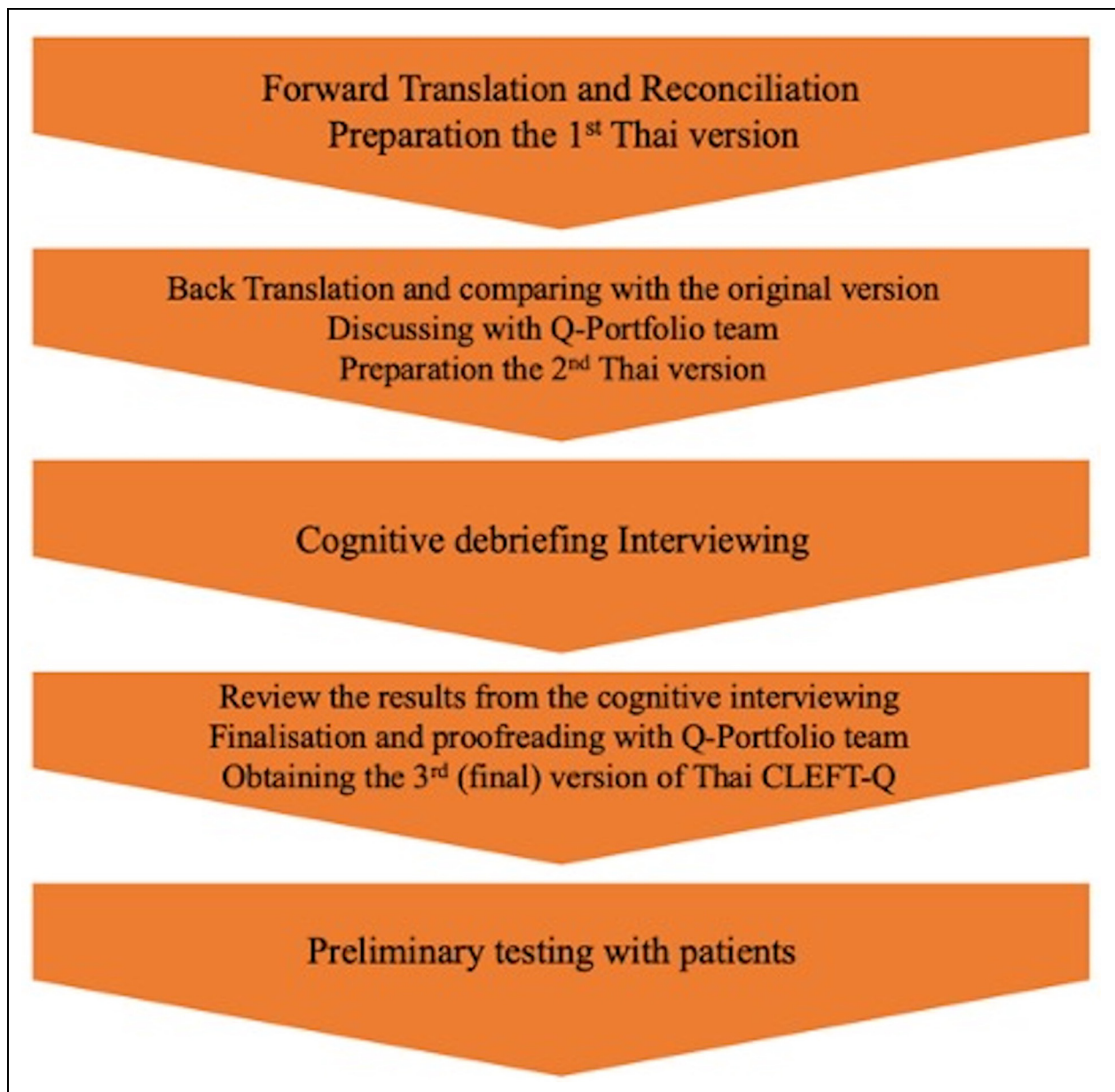


Figure 1. The International Society for Pharmacoeconomics and Outcomes Research guidelines (ISPOR)¹⁵ were used for the translation and cultural adaptation of the CLEFT-Q.⁷ The processes reveal the steps of translating, cognitive debriefing interviewing, and finalizing the Thai version of the CLEFT-Q.

perspective is crucial in defining outcomes in particular conditions. Patient-reported outcomes (PROs) should be the best way to evaluate the final endpoint of treatment effectiveness.⁴

The CLEFT-Q is an English-based PRO tool developed to determine treatment outcomes, including multiple aspects of appearance, speech, psychological function, and health-related quality of life (HRQOL) of patients with CL/P. The CLEFT-Q has been proposed as an international cross-cultural instrument for PRO assessment.⁵ It has gained acceptability worldwide and has been translated into various languages, such as Spanish, Arabic, Dutch, Hindi, Swedish, and Turkish.^{6,7}

The Thai language system differs significantly from English, especially the phonemic system.⁸ Thai is tonal, with

sentences typically comprising a subject, verb, and object. However, unlike in English, the subject is not explicitly stated but is contextually assumed, and the verb has no declensions, tenses, or conjugations.⁹

A group from a university in Thailand developed a QOL questionnaire for patients with cleft in 2010. It comprised 24 questions that addressed 4 aspects: nursing care and service, economics, satisfaction with the clinical outcomes, and self-esteem. However, the authors stated that a limitation was the need for a direct, in-depth family interview for follow-up confirmation.¹⁰

We organized this study to develop a translated version of the CLEFT-Q into Thai (Thai CLEFT-Q) as an alternative

Table 1. Example of Discrepancies of the Back Translation.

Scale	Original English version item	Back translated version item	Reconciled forward Thai version item	Developer's comment	Translator response
Face	... How your face looks up close?	The appearance of your face when seen from a distance?	...ลักษณะของใบหน้าคุณเวลามองใกล้ ?	"Up close" versus "from a distance"—maybe "a short distance?"	Back translation issue was incorrect. The reconciled forward translation meaning was already similar to original version
Nose	... The length of your nose (from the top to the tip)?	The length of your nose (from the bridge to the tip)?	...ความยาวของจมูกคุณ (จากคั้งถึงปลายจมูก) ?	"From the top" versus "from the bridge"; the top of the nose is more precise than the bridge. The bridge refers to the "bony part of the nose."	Back translation issue used improper wording. The reconciled forward translation meaning was similar to original version
Nose	... How the middle part of your nose looks (from the top to the tip)?	The ridge of your nose (from the bridge to the tip)?	...ลักษณะของสันจมูกคุณ (จากคั้งถึงปลายจมูก) ?	It will be good to probe well with patients to see what they are thinking here. Please also refer to the image in the scale and show this to patients	We put in the illustration for better understandable to the patient
Teeth	... How your teeth look up close?	The appearance of your teeth when seen from a distance?	...ลักษณะของฟันของคุณเวลามองใกล้ ๆ ?	This should be "up close" or "from a short distance"	Back translation issue was incorrect. The reconciled forward translation meaning was already similar to original version

tool for PRO assessment after CL/P management. We hoped that the translated version would be culturally and linguistically appropriate for use in Thai culture yet conceptually equivalent to the English version.

Methods

CLEFT-Q

The CLEFT-Q is a self-report PRO instrument developed in 2017 to evaluate the impact of surgery and treatment on patients' appearance, speech, and HRQOL in patients with CL/P aged between 8 and 29 years.⁵ Phase I development involved a literature review¹¹ followed by qualitative interviews with 138 patients from 6 countries.¹² The literature review and qualitative data were used to develop the CLEFT-Q framework concept and a set of scales.¹² Subsequent revisions to the scales (items, instructions, and response options) drew upon patient feedback during a series of cognitive interviews and experts in CL/P.¹³ The CLEFT-Q field test was performed in 30 hospitals across 12 countries. Rasch Measurement Theory analysis was used to refine the CLEFT-Q scales and examine their reliability and validity. The psychometric findings of the final item-reduced CLEFT-Q and normative values for age, gender, and cleft type have been well reported.¹⁴ The mean Flesch-Kincaid (F-K) grade-reading level for the CLEFT-Q items was 1.4, with most below the fifth-grade reading level.¹³

The CLEFT-Q questionnaire used in this study comprises 119 items distributed across 13 scales in 3 modules. The first

module evaluates facial appearance on 7 scales (face, nose, nostrils, teeth, lips, lip scar, and jaws). The second module assesses facial functions, comprising speech function and eating/drinking scales. The last module investigates 4 HRQOL scales (psychological function, school function, social function, and speech-related distress).

With the 7 facial appearance scales, respondents are requested to give their opinion of how particular areas of their faces look. For each area, participants are asked, "How much do you like ...?". They have 4 response options: "Not at all," "A little bit," "Quite a bit," and "Very much" (scored as "1," "2," "3," and "4," respectively).

As for the facial function and HRQOL scales, participants are asked to rate the frequency that various aspects occurred over the past week. In the case of facial functions, the response options for various aspects of their speech function are "Never," "Sometimes," and "Always" (scored as "3," "2," and "1," respectively). However, the eating/drinking scale choices are "Never," "Sometimes," "Often," and "Always" (scored as "4," "3," "2," and "1," respectively). Regarding HRQOL, the frequency response options for 3 of the scales (psychological function, school function, and social function) are "Never," "Sometimes," "Often," and "Always" (scored as "1," "2," "3," and "4," respectively). The fourth scale (speech-related distress) has only 3 choices: "Never," "Sometimes," and "Always" (scored as "3," "2," and "1," respectively).

After obtaining the summation of the raw scores, a conversion table is used to convert the aggregate into the equivalent Rasch-transformed scores (RTS) for an evaluation range from 0 to 100. A higher RTS indicates a better or

Table 2. Demographic Patient Data in Cognitive Debriefing Interviews.

Patient No.	Gender	Age (years)	Diagnosis
1	Male	8	Isolated cleft palate
2	Female	11	Cleft lip and palate
3	Male	12	Cleft lip and palate
4	Female	13	Isolated cleft palate
5	Male	16	Cleft lip and palate
6	Female	21	Cleft lip and palate

more satisfactory rate for each scale. Twelve of the 13 scales have conversion tables. The eating/drinking scale does not have a conversion table and is notably used as an independent scale without the Rasch transformation strategy.

Translation Processes

The project manager recruited 3 translators for English and Thai based on their fluency in each language (Figure 1). The mother tongue of the 2 forward translators was Thai, and each was fluent in English. The third translator, whose mother tongue was English, was fluent in Thai and was recruited as the sole back translator. Suitable in-country representatives who were not involved in the translations were asked to review the final translation to provide feedback. We divided the translation processes into 3 parts and are as follows.

Part 1—Forward Translation

Each forward translator was required to prepare an independent translation of the CLEFT-Q questionnaire. The final translation needed to use straightforward terminology and be conceptually the same as the English version (rather than a literal translation). The 2 forward translators used a Microsoft Excel worksheet to describe any difficulties translating the instructions, items, and response options into the target language. The forward translators compared their translations and produced a reconciled version in consultation with the project manager. Consensus and reconciliation of the forward translations resulted in a combined “Reconciled Thai Version.”

Part 2—Back Translation

The Reconciled Thai Version was copied into an Excel worksheet and sent to the back translator, who had not seen the original English version. The back translator translated the reconciled version from Thai into English and forwarded it to the project manager in a new Excel document.

Part 3—Back Translation Review

The project manager compared the items, instructions, and response options of the back translated and original

English-language versions in terms of their semantic and idiomatic equivalence. A translation report worksheet was then emailed to the Q-Portfolio team (CLEFT-Q developer), whose role was to review the back translation and either approve it or request changes. If changes were needed, the project manager and the forward translators were obliged to review the comments from the Q-Portfolio team. However, if no changes were needed, the project manager could proceed with cognitive debriefing interviews.

Cognitive Debriefing Interviews With Patients

The inclusion criteria for the patient recruitment were patients with CL/P aged between 8 and 29 years who could read and understand the questionnaire by themselves. For some youngsters, their parents could facilitate the interpretation. The principle of assessing the CLEFT-Q results was to let the patients reflect on the outcomes by themselves. The patients with CL/P who underwent surgery in Chiang Rai, Thailand were invited to participate. Consent forms were signed by patients or their parents or legal guardians before the interviews. The sample size was in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommendation (5-8 participants in the target country).¹⁵

Finalizing Translation

The project manager and a representative reviewed findings from the cognitive debriefing interviews, which were used to modify the target Thai version. The project manager double-checked that the new translation was lined up correctly and then emailed the Translation Report to the Q-Portfolio team. The Q-Portfolio team formatted the translation for distribution.

Preliminary Testing of the Thai CLEFT-Q

Another cognitive debriefing interview study was performed to confirm the Thai CLEFT-Q’s comprehension. We invited patients with CL/P aged between 8 and 29 years who were operated in Siriraj Hospital, a tertiary referral hospital in Bangkok, Thailand. Consent forms were signed by patients or legal guardians. The approved final version of the Thai CLEFT-Q was used to interview the participating patients. The converted Rasch score of each patient was evaluated. After finishing the Thai CLEFT-Q interview, each patient or their parents or legal guardians answered another questionnaire to evaluate the understandability and feasibility of the Thai CLEFT-Q. The participants were asked “How much do you understand the Thai version of the CLEFT-Q?”. The feedback was classified as “Not at all,” “Don’t quite understand,” “Quite understand,” and “Understand completely” (scored as “0,” “1,” “2,” and “3” points, respectively).

Statistical Analysis

Categorical variables were summarized using frequencies and percentages. Continuous variables were analyzed with the

Table 3. Demographic Patient Data in the Interim Testing of the Thai CLEFT-Q.

	N
Total	10
Age, mean \pm SD (year)	15.7 \pm 6.7
Gender	
Male	5
Female	5
Diagnosis	
Cleft lip only	1
Unilateral cleft lip and palate	5
Bilateral cleft lip and palate	4
Number of operation, number \pm SD	4 \pm 1.6
CLEFT-Q scores, median (range)	
Facial appearance	52.5 (0–100)
HRQOL except for eating/drinking item	85 (47–100)
Eat/drink (raw score; 9–36)	34 (23–36)

Abbreviation: HRQOL, health-related quality of life; SD, standard deviation.

mean and standard deviation if normally distributed; otherwise, the median with range was used. All statistical analyses were performed with Microsoft Excel 2016 for Windows.

Results

Two of the 3 translators recruited for this study were professional translators who were native speakers of Thai and proficient in English. The third translator was a native speaker of English who was originally from the United States but had been working in Thailand as a professional Thai-to-English translator for 19 years. None of the 3 translators were a health-care provider or had a medical background.

Results of Forward Translation and Reconciliation

Neither of the translators reported having difficulties performing the translations. However, comparing the 2 forward translations revealed inconsistencies in 33.6% of the items (40 of 119). The discrepancies involved a narrowing of the intended meaning (2.5%), improper wording or phrasing (16.8%), and incorrect wording or phrasing (14.3%). An example of narrowing the meaning is that Translator 1 translated the item "... ready to go out (like to a party)" as "... พร้อมจะออกจากงาน (เช่นไปงานเลี้ยง)," but Translator 2 described it in Thai as "... พร้อมจะออกจากบ้าน (เช่นไปงานเลี้ยง)." During the consensus and reconciliation meeting, the 2 forward translators and the project manager agreed that a third version ("... จะออกนอกบ้าน (เช่นไปงานเลี้ยง)") was closest to the source English meaning. As for improper wording, an example is that Translator 1 translated "... how your top and bottom teeth meet when you bite?" as "... ลักษณะ การ สบ กัน ของ ฟัน บน กับ ฟัน ล่าง เวลา ที่ ท่าน เคี้ยว อาหาร?" whereas Translator 2 described it as "การ สบ ของ ฟัน บน และ ล่าง มาก เพียง ใด เมื่อ กัด อาหาร." After discussion, it was agreed that the Thai version should be "... ลักษณะ การ สบ ฟัน?". Regarding incorrect wording,

the translation of the item "... how the tip of your nose looks (the very end of your nose)?" for Translator 1 was "... ลักษณะ ของ ปลาย จมูก ท่าน (ตั้ง จมูก ของ ท่าน)?", while for Translator 2, it was "ปลาย จมูก (สุด ปลาย จมูก) มาก เพียง ใด." The correct was Translator 2's wordings.

Results of Back Translation

Back translation revealed 5 inconsistencies (4.2%) in the words or phrases of the items. One discrepancy revealed no meaning change when compared with the original version. However, the other 4 inconsistent items resulted in different meanings and conceptual equivalence (Table 1). Most of the 5 discrepancies were back translation issues, while the meaning of the reconciled forward translation version was consistent with the original version. However, they required rewording. For instance, the item "... how your face looks up close?" was back translated as "The appearance of your face when seen from a distance?". These translations were considered to have markedly different meanings from the original version and required revision. All discrepancies were resolved through discussion between the project manager and the 3 translators.

Results of Cognitive Debriefing Interviews of Participants

The cognitive debriefing interviews involved 6 participants with cleft lips and/or palates (Table 2). The average age of the 3 males and 3 females was 13.5 years (range 8–21). Participants who were <10 years confused the Thai words for "size" and "shape" ("ขนาด" vs "รูปร่าง"). This age group also experienced the most difficulty interpreting the Thai phrase for "... hard to understand" (ยากที่จะเข้าใจ) and suggested that it should be changed to "... do not understand" (ไม่เข้าใจ). Moreover, participants aged below 14 years could not discern the difference in meaning between the Thai words for "jaw" (ขากรรไกร) and "bite" (การสบฟัน).

Since we had already liaised with the Q-Portfolio team and changing some words would significantly deviate from the original version, no changes were made to the translation or the source version of the Thai CLEFT-Q.

Results of Preliminary Testing of Thai CLEFT-Q with Patients

The preliminary interviews using the Thai CLEFT-Q were performed with 10 patients. The patient demographic data are presented in Table 3. The overall median values for the RTS of appearance and HRQOL scales (except the drinking/eating scale) were 52.5 and 85, respectively. The median raw score of the drinking/eating scale was 34 (out of a total score of 36). In detail, the median RTS of the face, lips, nose, nostrils, jaw, teeth, and cleft lip scar-appearance scales were 57.5, 51, 52.5, 45, 64.5, 46.5, and 59, respectively. Moreover, the median RTS of psychological, school, social, speech distress,

Table 4. Comprehension Score for Assessing Patient Understandability of Each Item of the Thai CLEFT-Q.

Module	Scale	Score; median (range)
Facial appearance	Face	3 (2–3)
	Lips	3 (2–3)
	Nose	2.5 (2–3)
	Nostrils	3 (2–3)
	Jaws	2.5 (2–3)
	Teeth	3 (2–3)
	Cleft lip scar	3 (2–3)
Facial function	Speech function	3 (2–3)
	Eating/drinking	3 (2–3)
Health-related quality of life (HRQOL)	Psychological function	3 (2–3)
	School function	3 (2–3)
	Social function	3 (2–3)
	Speech distress	3 (2–3)

Note. 0, “Not at All”; 1, “Don’t Quite Understand”; 2, “Quite Understand”; and 3, “Understand Completely”.

and speech functions were 84, 85, 87.5, 90, and 72.5, respectively.

The second questionnaire was administered to determine the patients’ comprehension of the Thai CLEFT-Q. The median score for the nose and jaw appearance scales was 2.5 (range: 2-3), while the other scales’ median scores was 3 (range: 2-3; Table 4). With the jaw appearance scale, 1 patient reported becoming confused about the facial appearance. However, the illustrations within the Thai CLEFT-Q helped patients understand the questions. Another patient suggested that some questions might not be suitable for young patients and therefore needed parents’ or guardians’ assistance with interpretation.

Discussion

In this Phase 1 study, we present the protocols used to develop a novel PRO tool for assessing outcomes after CL/P treatment in Thailand. We established the Thai version of the instrument by drawing upon the original English version of the CLEFT-Q,⁵ an internationally accepted and cross-cultural PRO measurement tool. The translation and cultural adaptation steps that we followed¹⁵ can be used to produce new translations of the CLEFT-Q with international acceptance. The features of the Thai language are remarkably different from English; for example, Thai has no verbal tense,⁹ more tonal ranges, and less variety of words with similar meanings. The direct translation of an English assessment tool into Thai may result in expressions and linguistic structures that create misconceptions.^{9,16} Therefore, we followed the guidelines of the ISPOR¹⁵ as the principles of good practice in translation and cultural adaptation of a PRO measurement. The ISPOR guidelines comprise 10 steps: preparation, forward translation, reconciliation, back translation, back translation review,

harmonization, cognitive debriefing, review of cognitive debriefing results and finalization, proofreading, and final report. We followed all these processes, thus ensuring that the Thai CLEFT-Q was produced using a standardized and internationally accepted protocol.

Some discrepancies occurred in the forward translation. The 2 most common errors were using improper and incorrect wordings. However, the improper ones did not alter the meanings of the original version. After meeting with the translators and project manager, the incorrect wordings were discussed and amended to fit the source concepts. The use of incorrect words or phrases was mainly related to the professional translators not having a medical background: they were unfamiliar with medical professions and some terminologies.

As for the back translation process, only a few inconsistencies were revealed. Four major discrepancies that altered the intended meaning of the original English version are described in Table 1. However, 2 items caused incorrect meanings. In each case, the original English version used the phrase “up close,” but the back translation changed the meaning using the phrase “... from a distance.” The Reconciled Thai version used “... มอง ใกล้ ๆ,” which complied with “... up close.” Thus, the back translations for those 2 items were incorrect. Another issue related to the phrases “top of nose” and “bridge of nose.” As mentioned above, unlike Thai, English has a wide range of words with similar or identical meanings. The top of the nose is around the glabellar area, whereas the bridge of the nose is slightly lower from the top. However, no Thai word specifically describes the glabella. Therefore, using “คั้งจมูก,” which means “upper area of the nasal bridge,” appropriately described the area while not altering the meaning of the source version.

The cognitive debriefing interviews revealed that some young patients were confused by several wordings and phrases. Nevertheless, we did not change any particular words or phrases since doing so would have altered the sense of the original questionnaire. To determine whether this would make it difficult for patients to interpret the questionnaire, we organized another cognitive debriefing interview using 10 other patients at our hospital. Its results confirmed the high understandability of the Thai CLEFT-Q among Thai patients (Table 4).

In 2010, a study advocated the development of a quality of life questionnaire called THAICLEFT QoL. The scales covered nursing care and service, economics, clinical-outcome satisfaction, and self-esteem. The questionnaire demonstrated high intra-rater reliability.¹⁰ A subsequent study by the same group revealed that the economic, child relationship, and psychological aspects of the quality of life of young patients with CL/P were low.¹⁷ In comparison, the results of our study interestingly revealed that the patients had moderate satisfaction with their facial appearance RTS. However, they had significantly higher satisfaction levels for HRQOL and facial function RTS. These findings may reflect that, in the Thai culture, people still accept and provide good opportunities for patients with CL/P. In other words, despite their undesired

facial appearances, patients with patients can still enjoy a reasonably good quality of life.

There are many advantages arising from this study's development of the Thai CLEFT-Q. One is that following the translation and cultural adaptation protocols of the ISPOR guidelines during Phase 1 development made the Thai CLEFT-Q reliable and consistent with the original version. Moreover, the double cognitive debriefing interviews confirmed that the Thai CLEFT-Q was comprehensible to Thais. Furthermore, because it did not only assess HRQOL, the Thai CLEFT-Q showed the ability to evaluate other significant modalities, such as function and form satisfaction. Lastly, using the Thai CLEFT-Q enables the organization of international multicenter studies that evaluate patient outcomes after cleft treatment without needing to calibrate score outcomes.

One of the limitations was the small number of participants; thus, this may not fully reflect the reliability of the outcomes from the interim testing. We intend to organize a Phase 2 field test study recruiting many participants to assess the cross-cultural equivalence of the Thai CLEFT-Q.

Conclusions

The translation and cultural adaptation of the Thai CLEFT-Q provided evidence of its transferability and equivalence to the original English version. Feasible comprehension of the Thai version was also achieved.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethics Approval

The Ethics Committee of the Siriraj Institutional Review Board approved this study (approval number 969/2564[IRB2]). All


participants or their parents or legal guardians provided written informed consent.

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