Article published online: 2021-01-27

Dutch Translation and Validation of the FACE-Q Rhinoplasty Module

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Facial Plast Surg 2021;37:296–301.

Abstract

FACE-Q was developed by Klassen et al in 2010 as a validated psychometric evaluation instrument for patients undergoing aesthetic surgery. The aim of this study was to translate, adapt, and validate the FACE-Q rhinoplasty module into a Dutch version of the FACE-Q questionnaire conceptually equivalent to the original English version. "Satisfaction with nose" and "satisfaction with nostrils" questionnaires were used and translated from English into Dutch. The translation process and cross-cultural adaptation were conducted in accordance to the International Society for Pharmacoeconomics and Outcomes Research and World Health Organization guidelines. Psychometric validation was performed prospectively on a patient cohort of 30 patients. Each step in the translation process allowed us to make changes to achieve a conceptual translation equivalent to the original version. Psychometric validation revealed highly significant values for internal consistency, test–retest reliability, and responsiveness. The use of international translation guidelines, with a strict translation–back-translation process, led to a Dutch version of the FACE-Q rhinoplasty module. Statistical validation proved the conceptual correspondence with the original English version. The FACE-Q rhinoplasty module is an adequate instrument for determining successful aesthetic surgery based on patient satisfaction. This tool measures twofold: the degree of success with respect to the patient as well as being an assessment tool for the surgeon. We hope this will provide an additional tool to the clinician evaluating the Dutch-speaking rhinoplasty patient.

Keywords
- patient-reported outcome measures
- rhinoplasty
- Dutch
- FACE-Q
- validation

Septorhinoplasty (SRP) is frequently performed by ear, nose, and throat (ENT) surgeons for both functional and aesthetic reasons. One of the most difficult parts of SRP is to measure the outcomes after surgery.[1] In recent years, there has been an increasing trend to use health-related quality of life questionnaires after surgical procedures. Patient-reported outcome measures (PROMs) are a recommended tool to evaluate the postoperative results.[2] Also, the use of validated subjective scoring tools is strongly advised for future studies on this subject to enhance the reliability of conclusions concerning the correlation between objective and subjective outcomes.[3]

Most aesthetic and quality-of-life questionnaires designed to determine patient-reported outcomes after rhinoplasty are available only in English. According to the overview of Van Zijl et al, only few questionnaires concerning rhinoplasty are available in Dutch (Utrecht Questionnaire and NOSE).[4]

The FACE-Q rhinoplasty module is an instrument designed to evaluate patient-reported outcomes before and after undergoing rhinoplasty. For the English version of the FACE-Q questionnaires, sufficient structural validity and internal consistency have been demonstrated.[5] Adaptation of questionnaires to other languages makes it possible to

published online January 27, 2021

Issue Theme Facial Plastic Surgery Original Research; Guest Editors: Anthony P. Sclafani, MD, MBA, FACS, and Alwyn D'Souza, MBBS, FRCS Eng, FRCS (ORL-HNS)

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DOI https://doi.org/10.1055/s-0040-1721099.
ISSN 0736-6825.

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ensure their conceptual equivalence with the original questionnaire.

The aim of this study is to translate the FACE-Q rhinoplasty module into Dutch and validate its use in a Dutch-speaking population.

Methods

The first part of this research article consists of the Dutch translation and linguistic validation of the English version of the FACE-Q about nose and nostril. In the second part, the Dutch version will be statistically validated.

Development of Dutch Questionnaire

The English version of the FACE-Q was developed by Klassen et al in 2010 as a validated psychometric evaluation instrument for patients undergoing aesthetic surgery and is owned by Memorial Sloan Kettering Cancer Center (New York, NY), which holds the copyright of the original and all translated versions of the questionnaires.[6,7] FACE-Q can measure the impact and effectiveness of facial aesthetic procedures from the patients' perspective and has the potential to support an evidence-based approach to facial aesthetic practice.[8] Two items of the FACE-Q instrument were used for evaluation of SRP and constitute the FACE-Q rhinoplasty module: "satisfaction with nose" contains 10 questions and "satisfaction with nostrils" contains five questions that are scaled on a 4-point Likert scale. The questionnaires have a Flesch–Kincaid grade of 0.8 for the nose and of 1.4 for the nostrils.[6] The raw ordinal score is converted into equivalent linear interval data from 0 to 100, generated by a Rasch transformation. For this transformation, the original equivalent Rasch conversion table of the English version (as provided by Q-Portfolio) was used, with higher scores indicating better outcomes.[6]

Translation and Cross-Cultural Adaptation

"Satisfaction with nose" and "satisfaction with nostrils" questionnaires were used and translated from English, the source language, into Dutch, the target language. The translation process and cross-cultural adaptation were conducted in accordance with international translation recommendations by Q-Portfolio with respect to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and World Health Organization (WHO) guidelines.[6,9,10] The translation and cross-cultural adaptation happened in five steps including direct translation, back-translation, and a pilot comprehension test . An overview of the process is described below in ►**Fig. 1**.

Step 1 consisted of a forward translation. Two individuals independently translated the English version of the original questionnaires into a Dutch version. Both translators had Dutch as their first language and spoke English fluently. The forward translations were reconciled into one single translation by discussing the differences at a reconciliation meeting with both translators and a local coordinator. This process resulted in a first Dutch version of the questionnaires.

Step 2 consisted of a backward translation of the first Dutch version back into the source language. A native English speaker who speaks Dutch fluently translated the Dutch version back into English. Conceptual and cultural rather than literal translation was emphasized. The translator had no knowledge of or access to the original English version. The version created was then reviewed by the developers. Discrepancies were discussed and after re-translation, back-translation, and review, version two of the Dutch FACE-Q questionnaires was created.

Step 3: an expert panel of ENT health care professionals reviewed version two. The expert panel consisted of three ENT surgeons, two translators, and a coordinator, all fluent in Dutch and English. Every translation was discussed openly in the panel. The consensus resulted in Dutch version three.

Step 4 consisted of testing the created translation to determine whether the questionnaires were easy to use

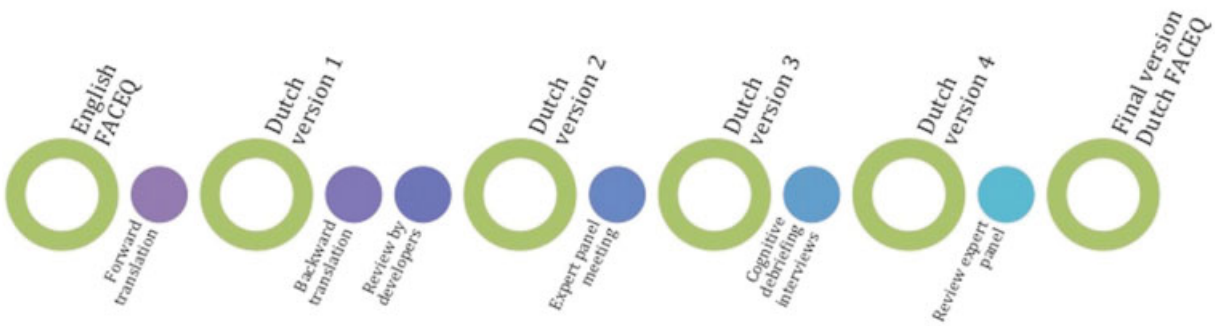

Fig. 1 Overview of the translation process.

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in the target patient population. Cognitive debriefing interviews were held with eight native Dutch-speaking patients. The interviewed patients were rhinoplasty patients, seen at their preoperative or postoperative consultation. The patients were asked to review the questionnaires and explain what they thought was the meaning of each item. In the case of a different interpretation, alternatives of translation were explored. Reconciliation and harmonization led to Dutch version four.

Step 5: after discussing the results of the patient interviews with the expert panel, the final version was created.

Psychometric Validation

Participants

The study design was part of a prospective observational longitudinal outcome cohort study regarding SRP outcome in a single private hospital center. The study was designed and conducted according to the Declaration of Helsinki of 1996.[11] The protocol was registered at Clinicaltrial.gov and approved by the Ethics committee from GZA hospitals (approval number: 190301ACADEM). From March 2019 to November 2019, 30 patients were recruited from the ENT-outpatient department of the St. Vincentius Hospital in Antwerp, Belgium. Participants had to be older than 18 years and master the Dutch language. Those eligible and willing to take part signed an informed consent form. These patients were invited to complete the FACE-Q questionnaires about the satisfaction with the nose and nostrils pre- and postoperatively as part of standard clinical care. The participants provided data at three time points: at the preoperative consultation when the informed consent was signed, at the day of surgery, and at 3 months postoperatively.

Sample Size

Previous studies concerning the effect of SRP surgery on FACE-Q questionnaires showed an effect size of approximately 1.5 standard deviation (SD; Cohen's *d*). Since the current study was performed on a very heterogeneous population, representing a mixture of different ages, ethnical groups, and socio-economic background, we accounted for a possibly lower effect size than previously reported. Assuming an effect size of 0.75 SD in our population, a sample size of 25 individuals, of which both the pre- and postmeasurements are available, would offer a power of 80% at a significance level of 0.01 in a paired *t*-test. Accounting for a possible drop-out of 20%, a sample size of 30 individuals was therefore proposed to be followed up longitudinally. The sample size calculation was performed using the software package R version 3.5.3.

Statistical Analysis

Data were analyzed with SPSS statistical software version 26 (SPSS Inc.) extended with the R eRm package (http://cran.r-project.org).

To determine homogeneity between different items in the questionnaires, internal consistency was calculated using the Cronbach's α coefficient. Cronbach's α is a measure of internal consistency, representing how closely related a set of items is as a group, and is considered a measure of scale reliability. According to Nunnally and Bernstein, Cronbach's α values greater than 0.80 are considered acceptable for applied research.[12] Also, the item–rest correlation was documented. The item–rest correlation shows the strength of a relationship between an item score and the score on the test without that item.

The coefficient of variation (CV) was calculated to document the variation in the data. Test–retest reliability reflects the consistency of the score of a health outcome measure applied in different occasions. The principle of reliability is that recording the PROM in different occasions produces similar results. Test–retest reliability was measured across two time points before surgery: at the preoperative consultation and at the day of surgery. Pearson and intraclass correlation coefficients (ICC) were calculated between the two preoperative time points. The ICCs were based on an individual, absolute-agreement, two-way mixed-effects model (ICC type 3.1). Based on the 95% confidence interval of the ICC estimate, values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively.[13] To exclude systematic bias, a paired *t*-test was conducted. To exclude bias due to the time interval, a linear regression was conducted with the difference in values between the two time points as the dependent variable and the time interval as the independent variable.

Responsiveness is the ability of a PROM tool to detect a change in patients' clinical condition. This is estimated by administering health outcome measures to a group of patients whose clinical condition has changed. First, the scores before the operation were compared with the scores 3 months after surgery applying paired sample *t*-tests. In the present investigation, the responsiveness of the FACE-Q nose and nostrils was also measured by calculating the effect size, using Cohen's *d*. For interpreting effect sizes, the following benchmarks were used: $d = 0.20$, 0.50, and 0.80, indicating small, moderate, and large effects, respectively.[14] Responsiveness was also evaluated by creating receiver operating characteristics (ROC) curves. The area under the ROC curve (AUC) represents the ability of an outcome measure to correctly classify patients as improved or unimproved, across a wide range of cutoff values. The value of the AUC ranges from 0.5 (no ability to discriminating between the improved and unimproved patients) to 1.0 (perfect ability). AUC greater than 0.70 is used as an indicator of acceptable responsiveness.[15]

The minimal clinically important difference (MCID) of a patient-reported outcome represents a threshold value of change in the PROM score deemed to have an implication in clinical management. As reported by Klassen et al,[5] a distribution-based method was used for the calculation of the MCID. For comparison reasons, the MCID was also defined as $1.96 \times$ standard error of mean. Using this formula, the MCID is beyond the 95% confidence interval of the expected random variation in PROM scores, ensuring there is less than a 5% chance that the proposed MCID value is within the expected random variability of PROM scores.[16]

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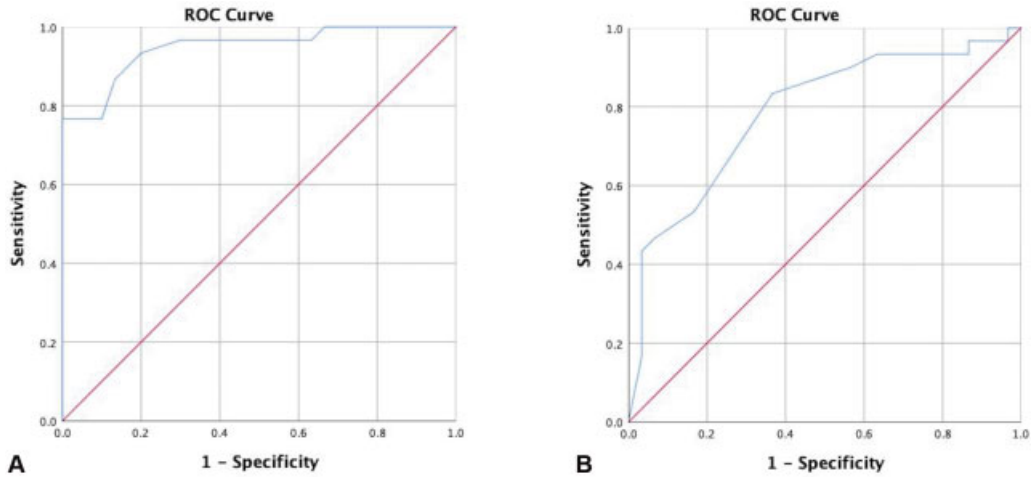

Fig. 2 ROC curves for FACE-Q nose (**A**) and nostrils (**B**). ROC, receiver operating characteristics.

Results

Linguistic Validation

Step 1. Although the two forward translations were very similar, they were prone to synonymous translations resulting in literal rather than conceptual discrepancies. The main differences were noticed in the word order and syntax. Additionally, there were two words translated into different synonyms. Together with the local coordinator, the translations were reconciled and the best synonyms and construction of the sentences were chosen for each discrepancy between the two forward translations.

Step 2. Differences between the back-translation and the original version were also limited. After review by the developers, it was noticed that a part of the question was not included in the forward translation and thus not obtained in the back-translation either.

Step 3. The panel of ENT health care professionals gave us some good alternatives to some words which might not have been easily understandable for all patients (e.g., we changed "Met uw neus in gedachte" to "wanneer u aan uw neus denkt" and we changed "De breedte van de onderzijde van uw neus [van neusgat tot neusgat]?" to "De breedte van de onderzijde van uw neus [van neusvleugel tot neusvleugel])?."

Step 4. The eight native Dutch-speaking rhinoplasty patients who reviewed the questionnaires consisted of 5 females and 3 males with a mean age of 38 years, the youngest patient being 24 years old and the oldest 65 years old.

The cognitive debriefing interviews confirmed that the questionnaires were understandable and easy to use. The interviews confirmed that the changes suggested by the expert panelists were appropriate. The answers were all pretty straightforward for the eight patients. Only when actively asked which items could lead to misinterpretation, some comments were obtained. Most of these suggestions consisted of adding extra information to the questions to further explain what was meant. Concerning the question of "How straight your nose looks," half of the patients could think of several interpretations such as how straight the nose looks in frontal view, from the side, or how straight the nose is positioned in the face. Because all these interpretations were conceptually identical, we decided that no alternative word choice was necessary.

Step 5. Proofreading by clinicians led to no further changes.

The entire translation process took approximately 3 months.

Psychometric Validation

Patient Characteristics

The sample characteristics are summarized in ►**Table 1**. There were an equal number of male and female patients. A total of 30% of our patient population already had a history of a SRP elsewhere and in 47% of the cases a history of nasal trauma was recorded.

Statistical Evaluation

Internal Consistency

Person reliability was measured by the evaluation of the Cronbach's α levels for the Dutch FACE-Q nose and nostrils. The Cronbach's α coefficient was 0.947 for the nose and 0.905 for nostril satisfaction, resulting in a significant internal

Table 1 Patient characteristics

Variable	Value
Gender, number (%)	Male: 15 (50%) Female: 15 (50%)
Age in years, mean (SD) (range)	29.3 (9.5) (18–56)
Race/ethnicity, number (%)	Caucasian: 15 (50%) Middle Eastern/ Mediterranean: 14 (47%) Asian: 1 (3%)

Abbreviation: SD, standard deviation.

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consistency between the different items in both questionnaires. If an item was deleted, the Cronbach's α remained high with a minimum of 0.937 for FACE-Q nose and 0.858 for FACE-Q nostrils.

Test–Retest Reliability

The test–retest reliability was measured by the Pearson correlation coefficient and the ICC type 3.1 at the two preoperative time points. Pearson correlation coefficient *r* was 0.715 for the FACE-Q nose and 0.767 for the FACE-Q nostrils. ICC (type 3.1) was 0.655 (95% confidence interval: 0.391–0.820) for the FACE-Q nose and 0.741 (95% confidence interval: 0.523–0.868) for the FACE-Q nostrils. According to Koo and Li, these correlations can be interpreted as moderate with quite large confidence intervals.[13] A paired *t*-test excluded systematic bias in both questionnaires. The CV was higher for the FACE-Q nostrils than that for the FACE-Q nose. CV was also higher at the first time point (TP1) at the consultation than immediately before surgery (TP2) (CV nose at TP1: 33.73639 and TP2: 28.86177; CV nostrils at TP1: 42.86462 and at TP2: 37.46043).).

Regarding the completion of both questionnaires at the two preoperative time points, there was a mean interval of 52 days (range: 2–192 days). A linear regression excluded bias due to the time interval (FACE-Q nose: $r^2 = 0{,}066$; FACE-Q nostrils: $r^2 = 0.0034$).

Responsiveness

Pre- and postoperative data from FACE-Q nose and nostrils of the SRP patients were compared with paired sample *t*-tests, revealing significant improvements for the nose as well as for the nostrils ($p < 0.0005$). Pre- and postrhinoplasty scores were also evaluated with a Cohen's *d* test and ROC analysis.

A Cohen's *d* of 2.24 (effect size *r*: 0.75) and 1.14 (effect size *r*: 0,50) was found for the FACE-Q nose and nostrils, respectively. Both questionnaires measured consequently large treatment effects.[14]

The AUC was 0.95 (SD: 0.03) and 0.79 (SD: 0.06) for the FACE-Q nose and nostril, respectively, indicating acceptable responsiveness. ROC is a probability curve and AUC represents the degree or measure of separability. The questionnaires can differentiate, with sufficient sensitivity and specificity, between preoperative and postoperative patients (►**Fig. 2**).

MCID measured a value of 7.62 for the FACE-Q nose and 10.17 for the FACE-Q nostrils, suggesting that a change in score on a scale from 0 to 100 of 7.62% for the FACE-Q nose or 10.17% for the FACE-Q nostrils could be seen as clinically important. By comparing the MCID with the change in score after surgery of each patient, a significant improvement was revealed in 87 and 74% of the SRP patients for the FACE-Q nose and FACE-Q nostrils, respectively.

Discussion

Importance of Patient-Reported Outcomes Measures

As SRP is one of the most frequently performed operations in facial plastic surgery, it is important to determine the success of the operation. PROMs are increasingly being used to incorporate the perspective of the patient into the outcome assessment. Surveys such as the FACE-Q allow surgeons to evaluate their ability to deliver and cater to the needs of those seeking or requiring rhinoplasty. Indeed, delivering consistent results in rhinoplasty is a difficult task, as noses are "difficult to predict" and "difficult to construct."[17] Furthermore, the complexity of rhinoplasty procedures has increased tremendously in the last few decades.[1]

The FACE-Q rhinoplasty module was designed to specifically evaluate cosmetic and psychosocial aspects associated with SRP, complies with the requirements of international guidelines, and is specifically validated for rhinoplasty outcome.[5]

Translation Process

Translating this validated PROM into Dutch is important for the evaluation of Dutch-speaking rhinoplasty patients. The FACE-Q rhinoplasty module has already been translated into other languages: at this moment academic translations are available in French, Italian, Norwegian, Spanish, Portuguese, Turkish, and Chinese.[6]

The linguistic validation with cognitive debriefing interviews ensured that nuances of meaning were not lost due to the translation. The translation process and cross-cultural adaptation were conducted in accordance with international translation recommendations by Q-Portfolio with respect to the ISPOR and WHO guidelines and are comparable to the methods other teams used for the translation of the FACE-Q.[18–21]

Psychometric Validation

This article describes a single-surgeon and single-institution-based prospective study, with a limited sample size (30 patients). A considerable number of patients had a history of nasal trauma or had a previous SRP elsewhere. In most studies, a much higher number of females are seeking cosmetic surgery as compared with males. Surprisingly in this study, the number of males seeking SRP was as high as females.

Statistical analysis ensured the internal consistency, test–retest reliability, and responsiveness of the Dutch FACE-Q rhinoplasty module.

The internal consistency, as measured by the Cronbach's α coefficient, was excellent for both the Dutch FACE-Q nose and nostrils. Both questionnaires seem adequately designed to measure the aesthetic satisfaction.

According to Koo and Li, the test–retest reliability could be defined as moderate with quite large 95% confidence intervals.[13] The width of the confidence intervals is probably due to random effects although it also depends to a large extent on the sample size. The consistency of scoring between both time points was higher for the FACE-Q nostrils. Time delay between the preoperative consultation and the day of surgery was statistically not relevant. The dispersion in measurements could be explained by the heterogeneous nature of our patient population (►**Table 1**). The reliability of the French-translated questionnaire, as reported by Radulesco et al, was higher for both questionnaires.[18] However, although we found no statistically significant bias between the two time points, the circumstances were quite different: in our study the first measurement was performed in the outpatient area while the second time point was immediately before surgery. Psychological stress at

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the time of the operation may have influenced these results. Also, some patients might have exaggerated their aesthetic well-being at the time of the preoperative consultation to enforce surgery.

The tests for responsiveness of the Dutch FACE-Q nose and nostrils demonstrated large treatment effects despite previous history of nasal trauma or revision surgery in a considerable number of patients. These results were very comparable to the results of the English version of the FACE-Q.[5,17] Between both questionnaires, the effect size was larger for the nose than for the nostrils. This finding was also in agreement with the study population of Klassen et al (effect size: nose: 2.3 vs. nostrils: 1.1).[5]

Counting for the individual responsiveness, MCIDs showed in our study a higher fraction of significant improvement than that of Klassen et al (74% for the nose and 61% for the nostrils).[5] As there are different approaches in the calculation of the MCID, the interpretation should be taken cautiously as there is no consensus regarding the optimal technique. However, in the present calculation method, the MCID can be interpreted as a change in a cohort's mean pretreatment PROM score that is greater than random variation in PROM scores in a statistically significant manner.[16]

Strengths and Limitations

Strict adherence to international guidelines during the translation led to a Dutch version of the FACE-Q rhinoplasty module, ready to be used in clinical practice. The psychometric validation ensures that the validity of the questionnaires was not affected by the translation. To the best of our knowledge, this is the first study in which an extensive statistical control of the validity was performed after a translation procedure of the FACE-Q rhinoplasty module. Investigation of construct validity by comparing the questionnaires with other commonly used PROMs could be of benefit to further prove their validity. Also, the determination of the MCIDs can help surgeons to evaluate the success of the SRP from the patients' perspective. Additional multi-institutional studies that include patients from all socio-economic backgrounds may be required to further increase the demographical validity of the results.

Conclusion

The use of international translation guidelines, with a strict translation– back-translation process and cognitive debriefing interviews, led to a Dutch version of the FACE-Q rhinoplasty module conceptually corresponding to the original. The statistical analysis attests the efficiency of this questionnaire translated into Dutch. It proves that the translation–back-translation process did not affect its validity. We hope this will provide an additional tool to the clinician evaluating the Dutch-speaking rhinoplasty patient.

Conflict of Interest
None declared.

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