Development and validation of the Functional Rhinoplasty Outcome Inventory 17 (FROI-17)*

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Abstract

Statement of problem: Quality of life aspects become more and more important in all fields of medicine. There is a lack of such instruments for septorhinoplasty that cover sufficiently both functional and aesthetic aspects.

Methodology: In Phase 1, a group of experts identified 22 questions that represent the symptoms of patients with nasal deformities, which undergo a functional and aesthetic nasal surgery. Forty-one patients filled out the questionnaires before septorhinoplasty. The item assessment and item reduction was performed by a sequential statistical analysis, which included a single item analysis, an assessment of internal consistency, construct validity, the divergence validity and a factor analysis. The resulting 17-item questionnaire was used in a prospective validation study (Phase 2) in which 103 patients were enrolled. Statistical analysis included testing of validity, reliability and responsiveness.

Results: In Phase 2 data analysis revealed a good internal consistency and significant test-retest reliability. A literature survey confirmed that the relevant items were included in the questionnaire. We found significant item-score-correlations. Furthermore, the existence of concurrent validity was confirmed. Standardized Response Mean (SRM) as a measure for sensitivity to change indicated moderate to large effects.

Conclusion: FROI-17 is a valid quality of life instrument for use in septorhinoplasty patients. The instrument is now available for prospective data collection in future septorhinoplasty outcome studies.

Key words: validation, septorhinoplasty, quality of life, validity, reliability

Introduction

Health-related quality of life (HRQL) has an ever increasing importance as outcome parameter. For the proof of the success of a surgical intervention in addition to an improvement in objectively measurable parameters, increasingly, the evidence for an improvement of HRQL is required [1]. For this evidence, the presence of disease-specific instruments is essential [2]. Septorhinoplasty is an operation that addresses both functional and aesthetic impairments of the nose. It follows that the patient may have very different expectations to the operation: Besides patients who only seek to improve function, there is a large number of patients who have both functional and aesthetic impairments. Moreover, a growing demand for purely aesthetic septorhinoplasties has to be noted. Therefore, an outcome measurement tool should be able to measure both functional and aesthetic aspects.

The only HRQL instrument that has been validated for septorhinoplasties is the Rhinoplasty Outcome Evaluation (ROE) [3]. In 5 out of 6 questions it focuses on aesthetic issues. In our view, this instrument does not meet the requirements for all septorhinoplasty patients. For us, this resulted in the task of developing

a measurement instrument that includes both functional and aesthetic issues.

Materials and methods

The Ethics Committee of the Medical Faculty at the University of Heidelberg granted permission to conduct the study (Project No. 409/2006).

Development and testing of FROI-22 (alpha version)

A group of experts identified 22 questions that represent the symptoms of patients with nasal deformities who underwent functional and aesthetic nasal surgery. The individual questions (items) were constructed using a 6-part Likert scale ranging from 0 to 5 (no problem, very mild problem, mild problem, moderate problem, severe problem, problem as worse as it can be). A questionnaire (alpha version) was formulated.

The answers to the items of the alpha-instrument were entered into a JMP file (SAS Institute, JMP 5.1). For this, 41 questionnaires of the alpha version were anonymously filled out by patients before septorhinoplasty. The item assessment and item reduction was performed by a sequential statistical analysis, which included single item analysis, an assessment of internal consistency, construct validity, divergence validity, and factor analysis. The single item analysis included the calculation of mean, median, range, and variance for all 22 items. For optimal distribution the variance should be high, the average near the midpoint (item difficulty), and the range should take advantage of full width. As part of this approach, seven items were identified which had poor distribution with mean values < 1. Six of these items were eliminated from the questionnaire while the item "olfactory impairment" was left in the questionnaire due to its clinical importance (see Table 1).

Table 1. Results for 22 items of the alpha version with mean value and item difficulty.

No.	Item	Mean value	Item difficulty	Decision
1	Nasal obstruction	3.68	0.74	+
2	Sneezing	0.90	0.18	-
3	Constantly running nose	1.07	0.21	+
4	Secretions flow into the throat	1.29	0.26	+
5	Thick mucous nasal discharge	1.19	0.24	+
6	Dry throat	1.37	0.27	+
7	Cough	0.68	0.14	-
8	Feeling of pressure on the ears	1.17	0.23	+
9	Earache	0.76	0.15	-
10	Olfactory impairment	0.92	0.18	+
11	Facial pain, feeling of pressure in the face	0.85	0.17	-
12	Trouble falling asleep	1.63	0.33	+
13	Nocturnal awakening	1.73	0.35	+
14	Daytime sleepiness	1.97	0.39	+
15	Poor concentration	1.73	0.35	+
16	Decreased energy	1.56	0.31	+
17	Irritability	1.41	0.28	+
18	Depression	1.34	0.27	+
19	Low self-esteem	1.50	0.30	+
20	Shape of my nose I'm embarassed	2.09	0.42	+
21	Avoid participation in public events	0.82	0.16	-
22	Avoid participation in family events	0.60	0.12	-

Performing a subsequent factor analysis of the remaining 16 items, we found in the principal component analysis that the first eigenvalue of 6.46 covered 40.4% of the variance of the questionnaire. Another three eigenvalues with values from 2.07 to 1.28 clarified further 31% of the variance. An exploratory factor analysis with varimax rotation showed that 63% of the variance was thus explained. Based on the analysis, three subscores for the beta version were defined: the subscore "Nasal symptoms" (NS) with the items "Nasal obstruction", "Constantly running nose", "Secretions flow into the throat", "Thick mucous nasal discharge", "Dry throat", "Feeling of pressure on the ears" and "Olfactory impairment", the subscore "General symptoms" (GS) with the items "Trouble falling asleep", "Nocturnal awakening", "Daytime sleepiness", "Poor concentration", "Decreased energy", "Irritability" and "Depression" and the subscore "Self confidence" (SC) with the items "Low self-esteem" and "Shape of my nose, I'm embarrassed". The Overall score and the subscores were transformed to a 0-100 scale by dividing the sum of the raw scores of the items by the sum of spans of the items followed by multiplying by 100.

Subsequently, the calculation of Cronbach's alpha to assess the internal consistency for the total score (0.88), the entire subscales (NS: alpha = 0.78; GS: alpha = 0.92) SC: alpha = 0.74) and for subscales with omitted individual items was performed. Construct validity was assessed by calculating the correlations of the items of the subscales with the other items of the subscale

Table 2. Scoring sheet for the Functional Rhinoplasty Outcome Inventory 17 (FROI-17).

To assess how much the individual symptoms have an impact please circle the corresponding point to each question		No problem	Very mild problem	Mild problem	Moderate problem	Large problem	Problem as worse as it can be
1	Nasal obstruction	0	1	2	3	4	5
2	Constantly running nose	0	1	2	3	4	5
3	Secretions flow into the throat	0	1	2	3	4	5
4	Thick mucous nasal discharge	0	1	2	3	4	5
5	Dry throat	0	1	2	3	4	5
6	Feeling of pressure on the ears	0	1	2	3	4	5
7	Olfactory impairment	0	1	2	3	4	5
8	Trouble falling asleep	0	1	2	3	4	5
9	Nocturnal awakening	0	1	2	3	4	5
10	Daytime sleepiness	0	1	2	3	4	5
11	Poor concentration	0	1	2	3	4	5
12	Decreased energy	0	1	2	3	4	5
13	Irritability	0	1	2	3	4	5
14	Depression	0	1	2	3	4	5
15	Low self-esteem	0	1	2	3	4	5
16	Shape of my nose, I'm embarrassed	0	1	2	3	4	5
17	Overall adverse effects from the nose (the form and function)	0	1	2	3	4	5

and a global question on the impact on health. The Spearman correlation coefficient was defined as significant at rho> 0.3. To evaluate the divergence validity correlations of items with items from other subscales on the same criteria were evaluated.
As a result, the 16 selected items showed good distribution parameters, a contribution to a high internal consistency, high item-item and item-subscale correlations and low comprehension problems. A 17th question was added, which is a global issue to assess the overall effect of the nose on quality of life (Table 2).

Validation of FROI-17 (beta version)

To validate this questionnaire, we performed a prospective study on patients undergoing functional and aesthetic septorhinoplasty in our department. All surgeries were performed by two surgeons (I.B. and F.W.).
The recruitment phase for the study started in January 2010 and completed in March 2011. Data collection was completed in March 2012. The study was carried out in accordance with the Declaration of Helsinki as amended in 2004. Patients gave their informed written consent before being subjected to data collection.
To validate FROI-17 we evaluated reliability, validity, and responsiveness of the questionnaire.

Results

Patients

There were 103 patients (52 male and 51 female patients) enrolled in the study. These patients were on average 28.7 ± 11.4 years old. 28% of patients were married, 2% were widowed, and 71% were single. 57% of patients had a secondary school education and 43% had graduation from high school. 32% of the patients were smokers, 19% former smokers and 49% non-smokers.
Three percent of patients reported no impairment of quality

Table 3. Cronbach's alpha for the scores of FROI-17

	pre-op	6 months post-op	12 months post-op
Overall score	0.88	0.90	0.92
Nasal symptoms	0.69	0.78	0.84
General symptoms	0.89	0.88	0.90
Self confidence	0.72	0.56	0.70

Table 4. p-values from Wilcoxon test for split half reliability.

	pre-op	6 months post-op	12 months post-op
Overall score	0.58	0.07	0.73
Nasal symptoms	0.43	0.30	0.58
General symptoms	0.99	0.10	0.61
Self confidence	0.36	0.09	0.97

Table 5. Spearman correlation analysis to determine concurrent validity (accordance with a general item [item 17]).

	pre-op	6 months post-op	12 months post-op
Overall score	0.53	0.77	0.62
Nasal symptoms	0.36	0.65	0.52
General symptoms	0.44	0.69	0.50
Self confidence	0.53	0.51	0.66

Table 6. Standardized Response Mean (SRM).

	6 months post-op	12 months post-op
Overall score	0.93	0.72
Nasal symptoms	0.96	0.71
General symptoms	0.69	0.54
Self confidence	0.67	0.51

of life by the form or a malfunction of the nose, 15% had very mild impairment, 38% had mild impairment, 29% had moderate impairment, 15% had severe impairment and 1% had extreme impairment. Preoperatively, 27% of patients wanted a better function and 7% wanted a more beautiful shape of the nose. For 67% of the patients both aspects were important.

Reliability

The assessment of reliability was performed by determining the internal consistency and test-retest reliability. The internal consistency of the questionnaire was assessed by Cronbach's alpha for the total score and subscores (Table 3). All Crohnbach's alpha values except one were ≥ 0.7 indicating a good internal consistency for all scales at all three measuring time points. Test-retest reliability was determined by calculating split-half reliability (Table 4). All p-values from the Wilcoxon test were >0.5 indicating that there was no significant difference between the two groups.

Validity

The validity of the measuring instrument was evaluated by examining the content validity, item-score-correlations and concurrent validity. To assess the content validity the process of developing the FROI-17 was considered. We surveyed literature to ensure that the developmental process was performed according to the rules and that all relevant items had been considered.

Item-Score-Correlations were calculated with Spearman correlation analysis. All the values were ≥ 0.4, most of them between 0.5 and 0.8.

The concurrent validity was assessed using the correlation analysis of a global disease-specific question (question 17 of the FROI-17) with the scores of FROI-17 (Table 5). All the Spearman correlation coefficients except two were > 0.5 indicating significant correlations.

Responsiveness

The responsiveness of clinical change (sensitivity to change) can be described by the Standardized Response Mean (SRM). It is defined by the ratio of the medium change score and the standard deviation of the change in score. Values < 0.2 indicate minor effects, ≥ 0.2 and <0.5 indicate small effects, ≥ 0.5 - <0.8 medium effects, and ≥ 0.8 large effects [4]. The results of the analysis are presented in Table 6 showing moderate effects for two scales and large effects for the other two scales after 6 months. After 12 months moderate effects were calculated for all scales.

Discussion

The measurement of health-related quality of life gains increasing importance in outcome evaluation in all areas of clinical medicine. Particularly oncology and internal medicine have been studied extensively. Several generic instruments are widely

used, in particular, the SF-36 is applicable. In the field of otolaryngology, several instruments have been developed in the past 20 years to measure disease-specific quality of life, e.g. for use in chronic inflammatory diseases such as chronic otitis media, chronic tonsillitis and chronic rhinosinusitis [5,6,7].

Quality of life measurements in septorhinoplasty patients have so far been carried out only to a small extent. The only validated disease-specific instrument is the Rhinoplasty Outcome Evaluation (ROE) [3]. It consists of 6 items, of which only one is functionally aligned. Studies using this measuring instrument were published only in recent years. Hellings conducted a retrospective study of 90 patients with revision rhinoplasty and was able to demonstrate significantly improved ROE scores [8]. A prospective study of 225 patients could also show improved ROE scores [9]. Another study done in 2012 shows also significantly improved ROE scores, but has significant technical deficiencies (ignoring the response shift phenomenon and little response rate) [10]. More recent studies without using the ROE show an improvement in the quality of life in non-rhinoplasty-specific instruments (SF-36, NOSE and Rosenberg questionnaire) [11] and a high prevalence of moderate to severe Body Dysmorphic Disorder (BDD) in patients seeking aesthetic rhinoplasty [12]. In summary, it must be said that the findings on impairment of health-related quality of life in septorhinoplasty patients are still very patchy and the existing studies only partially meet high quality standards. In addition, to this day, there is no disease-specific instrument that captures the functional limitations of the nose in septorhinoplasty patients adequately. The FROI-17 questionnaire that is presented in this study addresses both function-related and aesthetic impairments of the patients. Moreover, the introduction of subscores in the questionnaire allows a differentiated view on different dimensions of disease-specific quality of life.

Completing the FROI-17 took the patient about 5-10 minutes. This resulted in good acceptance by the patients. Furthermore, the organizational effort for the staff was minimal. Therefore, the FROI-17 is not only characterized by good psychometric properties but also by a practical ease of use.

The present study shows that the FROI-17 is a reliable, valid and sensitive instrument for measuring health-related quality of life in septorhinoplasty patients. The questionnaire measures accurately and reliably the health problems of these patients and captures the sensitivity of the clinical changes.

The assessment of disease-specific quality of life will become more important in the coming years. The use of validated instruments for this purpose is a prerequisite. In this sense, the FROI-17 should be used in future studies.

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Authorship contribution

CB: data collection, manuscript preparation
FW: data collection, literature review
PKP: concept development, manuscript corrections
IB: concept development, statistical analysis, , manuscript preparation.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

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