

RHINOLOGY

# How to predict the outcome of septorhinoplasty? A normative study of ROE and FROI-17 scores

## Prevedere l'esito della settorinoplastica? Valori di riferimento per i questionari ROE e FROI-17

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### SUMMARY

**Objective.** Normative values of patient-reported outcome instruments are needed to identify good candidates for rhinoplasty. Rhinoplasty Outcome Evaluation (ROE) and Functional Rhinoplasty Outcome Inventory-17 (FROI-17) are disease-specific questionnaires that evaluate quality of life in patients undergoing rhinoplasty.

**Methods.** The reference cohort contained 1,000 participants, selected from a non-probability panel. Normative ROE and FROI-17 scores from this reference cohort were compared with ROE and FROI-17 scores from a patient cohort before (n = 104) and 6 (n = 55) and 12 months (n = 32) after septorhinoplasty.

**Results.** Mean FROI-17 scores ( $\pm$  SD) were: overall score,  $20.8 \pm 17$ ; nasal symptoms,  $16.8 \pm 7$ ; general symptoms,  $24.8 \pm 22$ ; and self-confidence,  $16.4 \pm 21$ . The ROE total score was  $73.1 \pm 16$ . Normative values differed significantly from the preoperative ROE and FROI-17 scores of septorhinoplasty patients ( $p < 0.01$ ). Except for the FROI-17 general score at 12 months postoperatively ( $p = 0.004$ ), there were no significant differences between normative ROE/FROI-17 and septorhinoplasty scores postoperatively, indicating that they returned to normalcy.

**Conclusions.** Normative scores for ROE and FROI-17 provide a reference point from which to identify patients who are most likely to benefit from rhinoplasty.

**KEY WORDS:** normative score, patient-reported outcome measures, rhinoplasty outcome evaluation, functional rhinoplasty outcome inventory-17, rhinoplasty

### RIASSUNTO

**Obiettivo.** L'identificazione dei valori di riferimento per i questionari di autovalutazione permette di selezionare i candidati migliori per la rinoplastica. Il Rhinoplasty Outcome Evaluation (ROE) e il Functional Rhinoplasty Outcome Inventory-17 (FROI-17) sono questionari che valutano la qualità della vita dei pazienti sottoposti a rinoplastica.

**Metodi.** 1000 volontari sani sono stati reclutati come popolazione di riferimento. I valori standard del ROE e del FROI-17 sono stati poi confrontati con i valori rilevati in un gruppo di pazienti prima dell'intervento di rinosettoplastica (n = 104) e dopo 6 (n = 55) e 12 mesi (n = 32).

**Risultati.** I valori medi del FROI-17 ( $\pm$  SD) sono: punteggio totale  $20,8 \pm 17$ ; sintomi nasali  $16,8 \pm 7$ ; sintomi generali  $24,8 \pm 22$ ; autostima  $16,4 \pm 21$ . Il punteggio totale del ROE è  $73,1 \pm 16$ . I valori standard si sono rivelati significativamente diversi dai valori del ROE e del FROI-17 dei pazienti pre-intervento ( $p < 0,01$ ). Ad eccezione del punteggio totale del FROI-17 a 12 mesi ( $p = 0,004$ ), non si sono evidenziate differenze significative tra i valori standard e i punteggi dichiarati dai pazienti a 6 e a 12 mesi, a indicare il ritorno alla normalità.

**Conclusioni.** La standardizzazione del ROE e del FROI-17 è utile a identificare i pazienti con maggiori probabilità di beneficiare della rinoplastica.

**PAROLE CHIAVE:** standardizzazione dei questionari, questionari di autovalutazione dei pazienti, rhinoplasty outcome evaluation, functional rhinoplasty outcome inventory-17, rinoplastica

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## Introduction

Rhinoplasty is a popular cosmetic surgical procedure and was the fifth most common operation in 2013<sup>1</sup>. Facial symmetry and proportions are important determinants of attractiveness<sup>2</sup>, and the nose is a vital part of a person's appearance and identity<sup>3</sup>. Male gender, young age, minimal deformities, and unrealistic expectations of the surgical results all reduce satisfaction after facial cosmetic surgery<sup>4</sup>. Furthermore, patients with body dysmorphic disorders are almost never fully satisfied with rhinoplasty results<sup>5</sup>. Patient-reported outcome measures are relevant because patient satisfaction and improved quality of life (QoL) are predominant factors for rhinosurgical success<sup>3,6</sup>. Many studies have described that patients benefit physically and psychologically from rhinoplasty and that QoL increases after rhinoplasty<sup>7</sup>. Patient-reported outcome measures in rhinoplasty research are very diverse<sup>8-10</sup>. The Rhinoplasty Outcome Evaluation (ROE) is the most used QoL questionnaire (70.6%)<sup>3</sup>, and focuses on aesthetic outcomes<sup>11</sup>, while the Functional Rhinoplasty Outcome Inventory 17 (FROI-17) evaluates functional and aesthetic outcomes<sup>8</sup>. There are still no normative scores for the ROE and FROI-17 questionnaires. It is not yet known how the QoL of patients undergoing septorhinoplasty compares with that of a control population. This limits our ability to determine the impact of septorhinoplasty on individuals.

Normative scores of the generic and internationally approved instrument, the short form survey 36 (SF-36), for German participants were published in 2005<sup>12</sup>. In 2017, normative scores were also published for the breast surgery-specific and validated patient-reported outcome questionnaire, BREAST-Q<sup>13</sup>. Both are useful interpretive tools for clinicians and researchers.

The main aim of our study was to provide the first normative values for the ROE and FROI-17 questionnaires as a decision-making tool after septorhinoplasty by performing a systematic prospective study on 1,000 healthy participants and comparing these normative values with ROE and FROI-17 scores of septorhinoplasty patients before and after surgery.

## Materials and methods

### *Patient cohort*

1,000 German individuals were recruited via a non-probabilistic online panel. The subset of this panel used for this study was quoted to relevant population distributions of the German Microcensus (an annual 1% probability sample of the German population)<sup>14</sup>. Relevant parameters were age, gender, region and education. Migration was also taken

into account but not quoted for. Participants consented to their data being collected.

Data from the reference cohort (n = 1,000) were compared with data from a patient cohort before septorhinoplasty (n = 104) and 6 (n = 55/54) and 12 months (n = 32/31) after surgery at Department of Ear, Nose and Throat, Head and Neck Surgery, University of Heidelberg, Germany between January 2010 and March 2011.

The Ethics Committee of the Medical Faculty at the University of Heidelberg granted permission to conduct the study (Project No. 409/2006) according to the Declaration of Helsinki on biomedical research involving human subjects. Informed consent was obtained from all patients. Patients were evaluated during an outpatient examination (usually one day before the surgery). They were asked to fill out questionnaires including FROI-17 and ROE. Surgery was performed by one of the authors. With the request to answer the questionnaire again, patients were contacted by mail at 6 months and 1 year after surgery. One hundred and four septorhinoplasty patients were enrolled in this study (53 women, 51 men). After 6 months, 52.4% remained (55 FROI-17/54 ROE answers), and after 12 months 30.3% (31 FROI-17/32 ROE answers) remained. Since this follow-up required a high degree of compliance, patients who did not respond were contacted by telephone. Due to the young and mobile septorhinoplasty patient collective, interest in participation in the study was decreased.

### *Recruitment process*

The reference cohort (n = 1,000) was recruited by September 2018 using the Respondi panel, an international organization for standardisation (ISO)-certified online access panel for market and social science research. Due to the nature of a cohort derived from the general public, that sample size was decided on to ensure a small sampling error and smaller confidence intervals, since the occurrence of participants with low (or high) QoL-measures was expected to be less pronounced than in the clinical cohort. The programming of the questionnaire, quota conditions and quota sizes were programmed by Respondi. Participants were divided into groups in the panel based on the master data information. Before finalising the questionnaire, an internal test run was conducted. On the first day of recruitment, only 200 participants were invited for a first data check after which other participants received reporting access. Sociodemographic questions were asked first. Study participants answered 59 questions, including two disease-specific questionnaires (FROI-17 and ROE), by online access within a mean time of approximately 7 min and 16 sec (arithmetic mean). Raw data were cleansed and converted into a labeled SPSS dataset before checking that questions were complete and rel-

evant quotas were distributed. Test groups were screened to make sure the correct questions had been asked. Statistical analysis was conducted by GESIS (Leibniz Institute for Social Sciences).

#### *Disease-specific questionnaires (ROE and FROI-17)*

ROE and FROI-17 are validated and reliable disease-specific instruments for measuring QoL after septorhinoplasty. The ROE has six questions, each one with five answers, from zero (worst) to four (best). The sum of the scores is then converted into a percentage with a lower score indicating less satisfaction. The FROI-17 includes 17 items. Responses are rated zero (no problem) to five (worst possible). The overall score is then converted into a percentage with a lower score indicating more satisfaction<sup>7,15</sup>.

#### *Statistical analysis*

Data were analysed using the statistical software R (version 3.4.1). Absolute, relative and joint distributions were created for the indices and sociodemographic variables. The five indices (ROE, FROI-17, and the three FROI-17 sub-indices) were tested for independence of sociodemographic characteristics using the Pearson's chi-squared test. A significant p-value (e.g.  $\alpha \leq 0.05$ ) rejected the null hypothesis that variables are independently distributed, and supported a relationship (not necessarily linear) between variables. In this case, p values were calculated via Monte Carlo statistic<sup>16</sup>. Correlation between the FROI indices and the ROE were also assessed.

The (linear) influence of sociodemographic variables was tested via generalised regression. For metric variables, the published coefficients relate to the slope by which a value increases. For non-metric variables (most sociodemographics), model.matrix is used. The coefficients show the increment of increase, when deviating from baseline (first level of a variable; e.g., if male gender is the baseline, the coefficient for the FROI overall index increases by 3.3 if the participant is female). Aside from the coefficients, residual standard errors, Student's t-statistics and p values are also reported.

The calculated indices of the reference cohort were compared with those in the patient cohort before and 6 and 12 months after septorhinoplasty. Comparisons were made using a Student's t-test for unequal variances, and p values are reported. If the p value was not significant, the null hypothesis that there is no difference between the variables was rejected.

## Results

The reference cohort of 1,000 participants included 500 males and 500 females with an average age of  $44.3 \pm 14.2$  years (Tab. I). Since participants belong to a non-probabil-

**Table I.** Demographic characteristics of the study population (n = 1000).

Characteristic	Reference cohort (n = 1000)
<b>Age (years)</b>	44.3 ± 14.2 (range:18-69)
<b>Gender</b>	
Male	500 (50%)
Female	500 (50%)
<b>Marital status</b>	
Single	411 (41.1%)
Married	424 (42.4%)
Separated/divorced	138 (13.8%)
Widowed	27 (2.7%)
<b>Residence (state)</b>	
Baden-Wuerttemberg	71 (7.1%)
Bavaria	137 (13.7%)
Berlin	27 (2.7%)
Brandenburg	25 (2.5%)
Bremen	18 (1.8%)
Hamburg	57 (5.7%)
Hesse	91 (9.1%)
Mecklenburg-Vorpommern	18 (1.8%)
Lower Saxony	93 (9.3%)
North Rhine-Westphalia	161 (16.1%)
Rhineland	82 (8.2%)
Saarland	33 (3.3%)
Saxony	52 (5.2%)
Saxony-Anhalt	28 (2.8%)
Schleswig-Holstein	67 (6.7%)
Thuringia	40 (4.0%)
<b>Country of birth</b>	
Germany	958 (95.8%)
EU country	19 (1.9%)
Non-EU country	23 (2.3%)
<b>Graduation</b>	
No degree	10 (10%)
Certificate of Secondary Education	300 (30%)
General Certificate of Secondary Education	340 (34%)
High school diploma	350 (35%)
<b>Employment</b>	
On leave/temporarily released	24 (2.4%)
Not working or no longer working	292 (29.2%)
Employed occasionally or by the hour	71 (7.1%)
Part-time employment	154 (15.4%)
Full-time employment	459 (45.9%)
<b>Household member</b>	2.5 ± 2.4

istic open access panel with quoted parameters and a fixed sample size, the response rate is not reported. Participants were sampled from an existing (opt-in) access panel until a particular quota was filled.

We also recruited a cohort of patients undergoing septorhinoplasty in our department. At the time of surgery patients were on average  $28.8 \pm 11.5$  years old. The demographic and clinical data are shown in Table II.

The normative ROE and FROI-17 scores differed significantly from the ROE and FROI-17 scores of patients

before septorhinoplasty ( $p < 0.01$ ). There were no significant differences between the normative ROE and FROI-17 scores and those of septorhinoplasty patients at 6 and 12 months after surgery to the reference cohort, except for the FROI-17 general score at 12 months after surgery ( $p = 0.004$ ; Tab. III). However, the substantial loss of participants especially after 12 months, may have impacted the estimator's variance. Such an increase in variance could also explain the lack of significance.

Concerning the impact of sociodemographic factors on the

**Table II.** Demographic characteristics of septorhinoplasty patients before, 6 and 12 months after surgery.

Characteristic	Preoperative (n = 104)	6 months (n = 55)	12 months (n = 32)
Age (years)	$28.8 \pm 11.5$ (range: 16.4-65.6)	$29.4 \pm 11.5$ (range: 17.4-64.2)	$29.0 \pm 12.8$ (range: 16.4-64.2)
<b>Gender</b>			
Male	50%	38%	35%
Female	50%	62%	65%
<b>Marital status</b>			
Married	26.7%	24.4%	24.1%
Separated/divorced	71.3%	73.3%	69.0%
Widowed	2%	2.2%	6.9%
<b>Graduation</b>			
Certificate of Secondary Education	28.7%	17.8%	31.0%
General Certificate of Secondary Education	27.7%	28.9%	24.1%
High school diploma	43.6%	53.3%	44.8%
<b>Employment</b>			
Employed/Self-Employed	46.5%	48.9%	41.4%
Retired	4.0%	4.4%	6.9%
Homemaker	3.0%	0.0%	3.4%
Student	19.8%	20.0%	31.0%
Unemployed	9.0%	6.7%	3.4%
Other	17.8%	20.0%	13.8%
<b>Smoking status</b>			
Currently	31.7%	31.1%	20.7%
Former	18.8%	22.2%	31.0%
Never	49.5%	46.7%	48.3%
<b>Subjective description of the shape of the nose</b>			
Too large			
• no	52.5%	54.5%	58.6%
• indifferent	23.8%	15.9%	31.0%
• yes	23.8%	29.5%	10.3%
Too small			
• no	97.0%	97.7%	93.1%
• yes	3.0%	2.3%	6.9%

continues ►

**Table II.** Demographic characteristics of septorhinoplasty patients before, 6 and 12 months after surgery (*follows*).

Characteristic	Preoperative (n = 104)	6 months (n = 55)	12 months (n = 32)
Too long			
• no	70.3%	75%	72.4%
• indifferent	13.9%	11.4%	13.8%
• yes	15.8%	13.6%	13.8%
Too short			
• no	95.1%	97.0%	97.0%
• yes	4.9%	3.0%	3.0%
Too wide			
• no	64.4%	79.6%	
• indifferent	18.8%	9.1%	NA
• yes	16.8%	11.3%	
Crooked nose			
• no	43.6%	43.6%	43.6%
• indifferent	17.8%	17.8%	17.8%
• yes	38.6%	38.6%	38.6%
Nasal bumps			
• no	40.6%	40.6%	
• indifferent	14.9%	14.9%	NA
• yes	44.6%	44.6%	
Nose tip too clumsy			
• no	74.3%	74.3%	
• indifferent	11.9%	11.9%	NA
• yes	13.9%	13.9%	
Nose tip too pitted			
• no	91.1%		
• indifferent	5.0%	NA	NA
• yes	4.0%		
Nose tip bent			
• no	73.3%	72.2%	
• indifferent	11.9%	20.9%	NA
• yes	14.9%	7.0%	

functional and aesthetic septorhinoplasty outcomes, age and female gender significantly affected the FROI overall and self-confidence scores ( $p < 0.05$ ), whereas no variables influenced the nasal symptom score ( $p > 0.05$ ; Fig. 1). Female participants ( $n = 500$ ) had higher FROI-17 scores (Fig. 1B) and lower ROE (Fig. 2B) scores, and the overall (22.4 vs 19.1), general (27 vs 22.7), and self-confidence (19.8 vs 13.1) FROI-17 scores were significantly different between males and females ( $p < 0.01$ ; Fig. 1B, Tab. IV).

Only age significantly influenced the FROI-17 (Fig. 1A) and ROE (Fig. 2A) scores ( $p < 0.01$ ). Participants older than 50 years had lower FROI-17 scores (negative linear relation) and higher ROE scores (positive linear rela-

tion) ( $p < 0.01$ ). Marital status, residence state, education level and employment status had no effect on the ROE or FROI-17 scores. A migration background only affected the FROI overall score ( $p = 0.037$ ).

For most variables, the chi-square test after Pearson showed that the null hypothesis that variables are independently distributed cannot be rejected, except for the joint distribution of ROE and age as well as FROI confidence and age.

## Discussion

Measuring QoL after plastic surgery has become more important in recent years<sup>7,8,11</sup>. In a systematic literature search

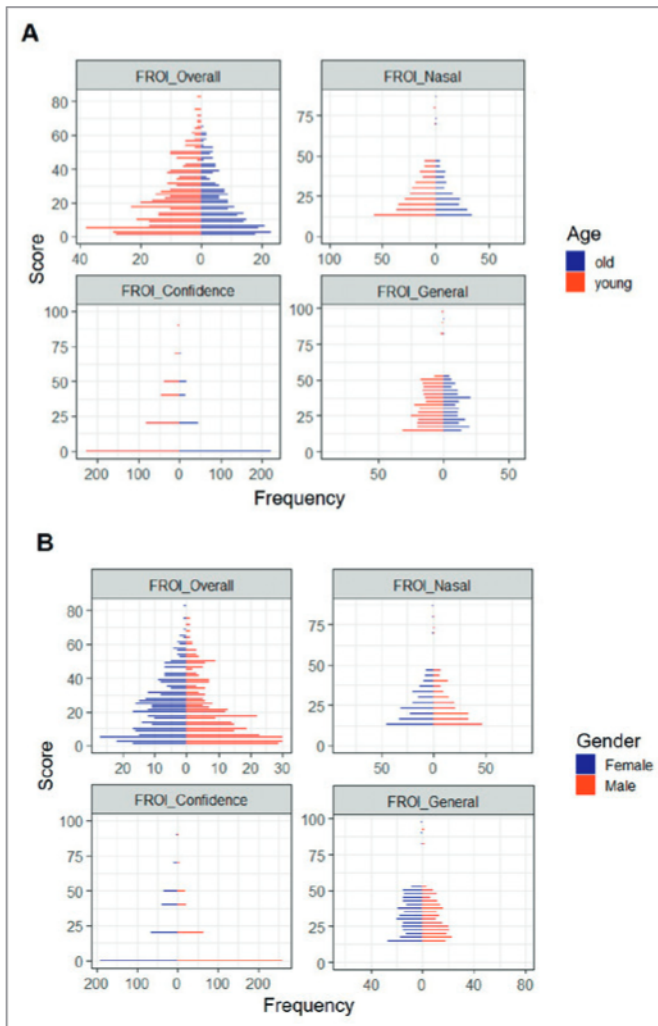
**Table III.** Comparison of ROE and FROI-17 scores between the reference cohort and the patient cohort before and 6 and 12 months after septorhinoplasty.

Disease-specific questionnaires	Reference cohort (n = 1000)		Preoperative (n = 102 F/101R)		p-value	6 months (n = 55 F/54 R)		p-value	12 months (n = 31 F/32 R)		p-value
	Mean	SD	Mean	SD		Mean	SD		Mean	SD	
<b>FROI-17 Index</b>											
Overall score	20.8	17.1	32.3	17.5	< 0.01	18.3	15.0	0.3	17.2	16.4	0.25
Nasal score	16.8	16.6	31.7	17.0	< 0.01	16.9	14.1	1.0	17.2	15.0	0.88
General score	24.8	21.5	33.0	22.8	< 0.01	20.2	19.3	0.1	14.9	17.3	< 0.01
Self-confidence	16.4	21.1	31.5	27.2	< 0.01	14.4	17.5	0.5	13.8	19.3	0.45
<b>ROE Index</b>	73.1	15.9	39.7	15.1	< 0.01	72.4	18.6	0.8	68.5	17.8	0.16

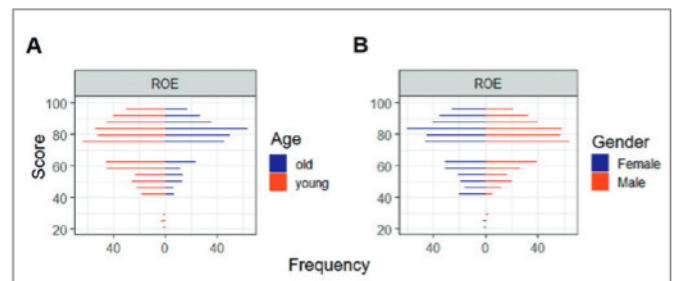
Higher ROE scores and lower FROI-17 scores indicate higher levels of satisfaction. Values are presented as mean ± standard deviation. F: FROI-17; R: ROE.

with the terms “Rhinoplasty” and “Quality of Life” using PubMed/MEDLINE, Google Scholar and Cochrane databases, the authors concluded that the ROE was the most

frequently used QoL questionnaire (70.6%) by focusing on prospective study design, a significant cohort size (at least 50 patients) and a follow-up period of at least 6 months after rhinoplasty. They further reported that the measurement of both satisfaction of appearance and physical function of the nose makes the ROE score, FROI-17 and the novel Standardized Cosmetics and Health Nasal Outcomes Survey (SCHNOS) more eligible for functional and cosmetic rhinoplasty than QoL questionnaires with general functional and/or aesthetic components<sup>3</sup>. Since septorhinoplasty addresses functional and aesthetic impairments of the nose<sup>8</sup>, we specially selected the ROE and the FROI-17 as validated patient-reported outcome measures (PROMs) and not generic instruments (e.g. Short-Form Health Survey (SF-36) questionnaire<sup>17</sup> or non-rhinoplasty-specific questionnaires (e.g. FACE-Q)<sup>9</sup>. Rhinoplasty belongs to aesthetic surgeries with low levels of satisfaction<sup>18</sup>; therefore, identifying patients who are most likely to benefit from the surgery is fundamental for a successful outcome. Identifying patients who can benefit most from rhinoplasty could be simplified by comparing the ROE and FROI-17 scores with normative values by predicting which results will be satisfactory. In addition, rhinoplasty outcomes could be compared between the old and new federal states in Germany as well between Ger-



**Figure 1.** Forest plots showing the association between FROI-17 scores and age (A) and gender (B). The questionnaire score is plotted on the y-axis, and the frequency of score responses on the x-axis.



**Figure 2.** Forest plots showing the association between ROE scores and age (A) and gender (B). The questionnaire score is plotted on the y-axis, and the frequency of score responses on the x-axis.

**Table IV.** Normative ROE and FROI-17 scores from the reference cohort (n = 1000).

Disease-specific questionnaires	All (n = 1000)	Female (n = 500)	Male (n = 500)	< 50 years (n = 619)	> 50 years (n = 381)
<b>FROI-17</b>					
Overall score	20.8 ± 17.1	22.4 ± 17.1	19.1 ± 17.0	22.0 ± 17.6	18.7 ± 16.1
Nasal symptoms	16.8 ± 16.6	17.3 ± 16.8	16.3 ± 16.4	17.7 ± 16.9	15.3 ± 16.0
General symptoms	24.8 ± 21.5	27 ± 21.6	22.7 ± 21.3	25.9 ± 22	23.1 ± 20.7
Self confidence	16.4 ± 21.1	19.8 ± 22.6	13.1 ± 19.0	19.3 ± 22.7	11.7 ± 17.4
<b>ROE</b>	73.1 ± 15.9	72.5 ± 16.6	73.6 ± 15.1	71.1 ± 16.5	76.3 ± 14.3

Values are presented as mean ± standard deviation.

many and other industrialised countries, such as the United States. Alsaraf et al. performed a prospective pilot study of 78 patients treated in three cosmetic surgery centres in the United States and concluded that patient-reported outcome measures are useful to assess cosmetic facial plastic surgery outcomes and provide the surgeon with a more objective means of comparing treatment options<sup>11</sup>. Self-administered questionnaires can be completed quickly and are less expensive, but can be influenced by response shift bias<sup>19</sup>.

In this study, the FROI-17 scores (overall score, nasal symptoms, general symptoms, and self-confidence) and ROE index revealed significantly more functional impairment before rhinoplasty than after rhinoplasty. Herruer et al. (2018) showed that patients seeking rhinoplasty have more distress associated with self-consciousness of appearance than the general unconcerned population<sup>20</sup>. In the present study, we did not find significant differences in aesthetic and functional burden between the reference cohort and postoperative patient cohort, except for the FROI-17 general score which was significantly lower in the patient cohort 12 months after rhinoplasty (14.9 vs 24.8;  $p = 0.004$ ). These findings suggest that rhinoplasty has general benefits. Oedema following rhinoplasty can mask the final result for up to 12 months and can adversely affect patient satisfaction<sup>7,11,21</sup>. Although we lost almost 70% of our septorhinoplasty patients to follow-up at 12 months, we have decided to include these data precisely to take into account the long times obtaining a restitutio ad integrum. The limit of this comparison is the consistent dropout at 12 months that can lead to an increase in the estimator's variance. However, the aim of this study was not to compare groups, but rather establish normative values for the ROE and FROI-17 questionnaires in a European reference cohort as a fundamental help for rhinosurgeons in qualitatively monitoring their own performance and treatment results. Reasons for this dropout rate might be the lack of participants' interest due to the setting for the clinical cohort, since it may be expected that interest in such a study

may decrease after surgery was received. In addition, sociodemographic characteristics such as the participants' age or mobility may also play a role.

We observed that age has a significant influence on the functional and aesthetic outcomes of rhinoplasty. Participants older than 50 years had lower FROI-17 scores and higher ROE scores, indicating higher levels of satisfaction. This finding is supported by the results of Litner et al.<sup>22</sup> and Bulut et al.<sup>7</sup>, who argued that mental impairment affects the physical health of young, healthy individuals. Older people are more accepting of who they are and how they look, and thus are better able to adapt to their new facial appearance and functional disabilities. Contrary to our findings, previous studies reported that younger patients were more satisfied with their QoL following rhinoplasty than patients older than 35-40 years. This may be because patients become less satisfied with their facial appearance as they age, e.g., because of facial lines, loss of cheek fullness, and bags under the eyes<sup>23</sup>. However, it is difficult to compare age-related findings between studies because the age limits are different. In our opinion, being older than 40 does not fall under the definition of old.

Female gender also affected the normative FROI-17 general and self-confidence scores of the reference cohort. Female participants had higher FROI-17 scores and lower ROE scores, indicating lower levels of satisfaction. This may be because females pay more attention to their facial appearance. In addition, their self-image and body satisfaction are negatively affected by unrealistic beauty standards and demands to hide outer imperfections imposed by social media<sup>24</sup>. Global QoL instruments like the SF-36 have shown that women have poorer health scores than men across eight domains<sup>25</sup>. Rohrich et al. (2003) also argued that male patients have less understanding of their health – in this case nose deformity – than women do<sup>26</sup>.

A weakness of our study is that the sample was a non-probabilistic quota sample, so that the data is more suited to descriptive analysis; inference cannot be calculated. Therefore, we have to assume that FROI and ROE scores are

independently distributed between those that opt-in and those that do not. We assumed that the decision to participate in the Respondi panel was not correlated to anything that may affect the FROI and ROE scores. We considered this reference cohort to be a “healthy” cohort in contrast to our patient cohort of individuals undergoing rhinoplastic surgery. Thus, the medical history of facial trauma or nasal surgery was not queried. We observed differences in all index scores between these cohorts. Another limitation of our study is the homogeneity of the European reference cohort presented here, which may not be comparable to a more diverse or ethnic patient population. Minimizing this demographic influence, a proportion of persons with a migration background was included in our participant recruitment. Thus, future research needs to utilise Caucasian and non-Caucasian patient populations to compare patient satisfaction and QoL in the context of race.

However, our study has a number of strengths. We used a well-established study design. In addition, we had a large sample size of 1,000 participants that was representative of industrial countries. The present study suggests that the ROE and FROI-17 questionnaires are reliable and sensitive disease-specific instruments to measure QoL in septorhinoplasty patients and healthy individuals. Even though almost 70% of patients were lost to 12-month follow-up, the study can be useful for rhinoplasty surgeons to evaluate the perception of surgical results in their patients and compare them with normative values. Comparing ROE and FROI-17 scores with normative values explains any differences in scores better than simply comparing scores before and after surgery. Preoperative patients are not “normal” because they carry the physical and psychological burden of nasal deformity. The normative values reported herein can be used in future studies and may help the rhinoplastic surgeon make clinical decisions. These values can be used to compare surgical techniques, quantify positive effects and identify those patients who are most likely to benefit from surgery. They may also determine whether patients have returned to normalcy after septorhinoplasty.

## Conclusions

Patient-reported outcome instruments play a key role in assessing QoL. We present the first normative scores for ROE and FROI-17, which should be of fundamental help to rhinoplastic surgeons and researchers. Using these values, we can now determine whether septorhinoplasty will be associated with a return to normalcy.

## Ethical considerations

The Ethics Committee of the Medical Faculty at the University of Heidelberg granted permission to conduct the study (Project No. 409/2006) according to the Declaration of Helsinki on biomedical research involving human subjects.

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