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## FACE-Q eye module for measuring patient-reported outcomes in blepharoplasty surgery: A validation study

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### ABSTRACT

This study aimed to conduct a linguistic validation of all FACE-Q eye module scales in German, and to evaluate the reliability and validity of the scales in patients with blepharoplasty.

According to international recommendations, all FACE-Q scales and checklists were translated from English to German. Psychometric testing of blepharoplasty surgery-related scales of translated versions were administered to patients with blepharochalasis or dermatochalasis and a history of blepharoplasty surgery ( $n = 64$ ; 11 scales) or no history of blepharoplasty surgery ( $n = 65$ ; seven scales), and to a group of control subjects ( $n = 64$ ; seven scales).

Most of the subscales showed acceptable internal consistency, with Cronbach's alphas ranging from 0.75 to 0.97. Intraclass correlation coefficients were high (0.70–0.92), indicating good reliability, with total values of 0.63 (95% CI 0.46–0.76) and 0.68 (95% CI 0.53–0.80) for the upper eyelid and social function scores, respectively. There was good discriminability between pre- and post-blepharoplasty patients and normal subjects ( $p < 0.05$ ).

The German-language version of the FACE-Q eye module is a successfully validated and helpful tool for assessing outcomes after blepharoplasty surgery, especially with respect to 'satisfaction with overall facial appearance', 'psychological well-being, social function', 'decision satisfaction, outcome satisfaction', and 'early-life impact recovery'.

### 1. Introduction

According to the International Society for Aesthetic Plastic Surgery (ISAPS) Global Survey 2022, 1 409 103 blepharoplasty procedures were performed globally in 2022. It is the third most common cosmetic procedure performed in women, and the second most common in men (Campiglio, 2023). Blepharoplasty was the third most common cosmetic procedure in Germany in 2022, with 44 831 procedures performed (Campiglio, 2023).

Blepharoplasty may improve the appearance and function of the upper and lower eyelids by removing excess skin from the upper eyelid and reducing the pouch of the lower eyelid. However, more needs to be done to evaluate the efficacy of this procedure and other ocular

treatments that improve appearance, such as eyelash therapy, from the patient's perspective.

FACE-Q is a recently developed patient-reported outcomes (PRO) tool consisting of more than 40 independently operated scales and checklists for measuring appearance, health-related quality of life, adverse effects of treatment, and patient experience of care (Klassen et al., 2015b). The FACE-Q eye module includes four appearance scales (i.e. eye, upper eyelid, lower eyelid, and eyelashes). The initial development and validation of the English and Finnish FACE-Q eye module scales have been previously reported (Klassen et al., 2017; Homsey et al., 2021). However, a German scale version has yet to be developed and validated. It is necessary to verify the German translation's consistency, reproducibility, and validity before applying it.

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## 2. Materials and methods

A cross-sectional study was performed at the Eye Center of the University of Cologne and approved by the ethical review board (no. 21-1102-1). All subjects provided written consent, following the Declaration of Helsinki.

### 2.1. Subjects

For the linguistic validation phase, five healthy volunteers were recruited. For the psychometric validation phase, three groups of subjects were included: prior to blepharoplasty (pre-BLE group,  $n = 65$ ); subjects at least 3 months after receiving BLE (post-BLE group,  $n = 64$ ), and normal subjects with no facial deformity or history of BLE (control group,  $n = 64$ ). All subjects had German as their mother language.

One senior surgeon (LMH) performed all BLE procedures, following standard planning and surgical principles. Exclusion criteria were subjects with abnormal mentality that would impair the questionnaire application, and those having previous facial/eye trauma, facial/eye surgery, or facial/eye aesthetic procedures.

### 2.2. Translation and linguistic validation of FACE-Q

Ten FACE-Q scales relevant to blepharoplasty were selected for this study (Table 1). The selected original FACE-Q scales were obtained from the authorities of the Q-Portfolio (<https://qportfolio.org>) with the developers' permission. The original English version of the FACE-Q eye module was translated into German, according to the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (Wild et al., 2005). Two native German-speaking medical students with proficiency in English performed forward translations, and consensus was reached based on these translations. Subsequently, an independent native German-speaking medical student fluent in English translated the questionnaires backward. The translation was then compared with the original, and if there were subtle differences, these were resolved by consensus among all interested parties.

The translated scales were tested in a cognitive debriefing interview on a suitable sample of five volunteers per interview, to ensure that the meaning of the instructions, recall period, items, and response options were the same, and that the wording was appropriate (Patrick et al., 2011). The report detailing the forward and backward translation and pilot testing was submitted to the developer of FACE-Q for approval. The translation process is shown in the flowchart in Fig. 1.

### 2.3. Postal survey study

A postal survey was conducted for 193 volunteers, including 65 patients in the pre-BLE group, 64 patients in the post-BLE group, and 64 normal subjects in the control group. The questionnaire package included the ten selected FACE-Q scales. The questionnaires were returned in a prepaid envelope, along with the informed written consent form. The questionnaire with seven scales (Face-Q eye module,

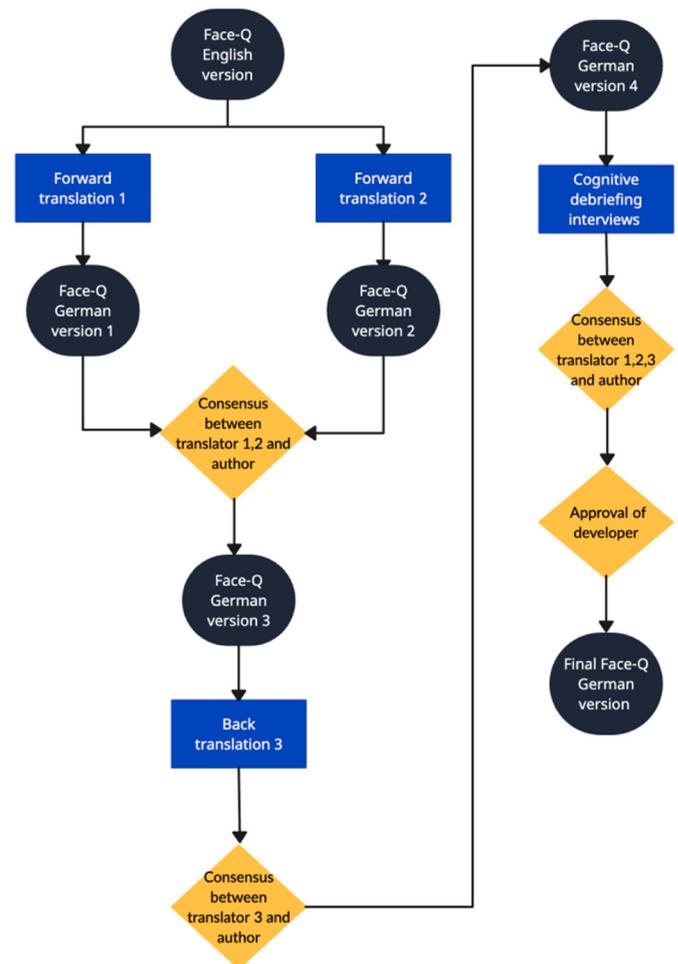


Fig. 1. Flow chart for the translation process.

psychological function, social function, satisfaction with facial appearance) was posted once to pre-BLS and control group volunteers. After receipt of the initial questionnaire, a repeat questionnaire with all ten scales was sent to participants in the post-BLE group. Patients' diagnoses, surgery types, surgery dates, and postoperative complications were recorded retrospectively.

### 2.4. Data analysis

For the descriptive analysis, the metric variables used mean values, and the categorical variables used percentages. Excel (Microsoft Corporation, USA) was used to sum the scores for each FACE-Q scale item, in order to calculate a total score for the scale. The sum score was then converted to an equivalent Rasch score, ranging from 0 to 100, with higher scores indicating a better outcome (Klassen et al., 2010, 2014, 2015b, 2016b; Pusic et al., 2013a). Standard psychometric tests and criteria were adopted to evaluate the reliability and validity (Lamping et al., 2003; Terwee et al., 2007; Reeve et al., 2013). For internal consistency reliability, Cronbach's alpha was calculated for each scale. Cronbach's alpha values  $> 0.70$  are acceptable (Terwee et al., 2007), while those over 0.95 indicate redundancy. For discriminant validity, intergroup comparative analyses (pre-BLE versus post-BLE versus control groups) were performed with paired  $t$ -tests (Schwitzer et al., 2015; Tan et al., 2017). Interscale correlation coefficients were interpreted as high ( $r > 0.70$ ), moderate ( $r = 0.30$ – $0.70$ ), or low ( $r < 0.30$ ) (Lamping et al., 2003; Klassen et al., 2014, 2015b; Tan et al., 2017). Statistically significant differences were defined as two-sided values with  $p < 0.05$ . Statistical analysis and visualization were conducted using SPSS version

Table 1  
Selected FACE-Q scales.

Items	FACE-Q scales
Item 1	Satisfaction with eyes
Item 2	Appraisal of upper eyelids
Item 3	Appraisal of lower eyelids
Item 4	Satisfaction with eyelashes
Item 5	Psychological function
Item 6	Social function
Item 7	Satisfaction with facial appearance
Item 8	Satisfaction with outcome
Item 9	Early life impact of treatment
Item 10	Satisfaction with decision

20.0 (Chicago, IL) and R (4.0.3) statistical software, including the packages 'ggplot2', 'psych', 'rptR', 'rel', 'irr', 'ltm', and 'tidyverse'.

### 3. Results

#### 3.1. Patient characteristics

The characteristics of the participants are shown in Table 2. In total, 193 subjects were enrolled in this study, with 65 in the pre-BLS group (17 males and 48 females, aged  $62.26 \pm 6.90$  years), 64 in the post-BLS group (29 males and 35 females, aged  $64.03 \pm 7.65$  years), and 64 in the control group (29 males and 35 females, aged  $56.84 \pm 12.72$  years). Among the three groups, white participants accounted for 96.9%, 98.4%, and 87.5% ( $n = 63, 63,$  and  $56$ ), respectively, of the pre-BLS group, post-BLS group, and control group. The body mass indices (BMI) were  $26.99 \pm 4.69$ ,  $27.55 \pm 4.58$ , and  $25.99 \pm 5.44$  in the pre-BLS, post-BLS, and control groups, respectively. Regarding smoking habits, 17 (35.4%), 15 (23.4%), and 17 (26.6%) individuals in each respective group reported having a smoking habit.

In the pre-BLS group, 43 patients had no eye or eyelid disease, seven had glaucoma, seven had blepharitis, seven had amaurosis, two had cataracts, and one had dacryocystitis. Additionally, 40 patients were diagnosed with blepharochalasis, 18 with dermatochalasis, and seven with both blepharochalasis and dermatochalasis. In the post-BLS group, 45 individuals had no eye or eyelid disease, seven had glaucoma, one had blepharitis, seven had amaurosis, and 14 had cataracts. Furthermore, 50 patients were diagnosed with blepharochalasis, 13 with dermatochalasis, and one with both blepharochalasis and dermatochalasis. The mean postoperative time for the patients was  $93.13 \pm 55.57$  weeks.

**Table 2**  
Characteristics of the patients.

Characteristics	Pre-BLS group	Post-BLS group	Control group
Participants, $n$	65	64	64
Age, years, $M \pm SD$	$62.26 \pm 6.90$	$64.03 \pm 7.65$	$56.84 \pm 12.72$
Gender, $n$ (%)			
Male	17 (35.4)	29 (82.9)	29 (82.9)
Female	48 (64.6)	35 (17.1)	35 (17.1)
Race/ethnicity, $n$ (%)			
White	63 (96.9)	63 (98.4)	56 (87.5)
Other	2 (3.1)	1 (1.6)	8 (12.5)
BMI	$26.99 \pm 4.69$	$27.55 \pm 4.58$	$25.99 \pm 5.44$
Smoke, $n$ (%)			
Yes	17 (35.4)	15 (23.4)	17 (26.6)
No	48 (64.6)	49 (76.6)	47 (73.4)
Time from BPS to FACE-Q completion, weeks, $M \pm SD$	–	$93.13 \pm 55.57$	–
Eye or eyelid diseases			
No	43	45	64
Glaucoma	7	7	0
Blepharitis	7	1	0
Amaurosis	7	1	0
Cataract	2	14	0
Dacryocystitis	1	0	0
Diagnosis of eyelid			
No	0	0	64
Blepharochalasis: unilateral/bilateral	1/39	1/49	0
Dermatochalasis: unilateral/bilateral	1/17	0/13	0
Bilateral blepharochalasis and dermatochalasis	7	1	0
Other	0	0	0
Previous procedures			
No	65	0	64
Blepharoplasty	0	64	0
Other	0	0	0

BLS: blepharoplasty surgery; pre-BLS group: subjects with no history of BLS; post-BLS group: subjects with history of BLS; M: mean; SD: standard deviation;  $n$ : number of subjects; %: percentage of subjects; –: not applicable.

#### 3.2. Internal consistency

All FACE-Q scales showed floor or ceiling effects (Table 3). Appraisal of upper eyelids, appraisal of lower eyelids, and satisfaction with decision scales displayed a floor effect, with 37.5%, 18.8%, and 43.8% of the patients scoring the minimum possible points, respectively. Satisfaction with eyes, satisfaction with eyelashes, psychological function, social function, satisfaction with facial appearance, satisfaction with outcome, and satisfaction with decision showed a ceiling effect, with 18.8%, 17.2%, 26.6%, 25.0%, 15.6%, 28.1%, and 50.0% of the patients scoring the maximum possible points, respectively.

Internal reliability was measured by evaluating Cronbach's  $\alpha$  levels for the German FACE-Q. All scales displayed high internal consistency, with Cronbach's alphas of 0.75–0.97 (Table 3), implying that the scales performed well at measuring the intended concept. However, Cronbach's alpha for appraisal of upper eyelids, satisfaction with eyes, satisfaction with eyelashes, and psychological function scales indicated item redundancy.

#### 3.3. Test-retest reliability of FACE-Q

On comparing the first and second rounds for the same postoperative patients (Table 3), there were no statistically significant differences in Wilcoxon signed-rank tests for all questionnaires. Test-retest reliability was measured using the Spearman correlation coefficient and the ICC at the two postoperative time points (Fig. 2). The subscales satisfaction with eyes, psychological function, early life impact of treatment, satisfaction with facial appearance, appraisal of lower eyelids, satisfaction with eyelashes, satisfaction with outcome, and satisfaction with decision displayed good reliability on repeat administration, with ICC 0.70–0.92 and  $R$  0.00–0.00, and SEM values below half of the original SEM score. The ICC values for appraisal of upper eyelids and social function were 0.63 (95% CI 0.46–0.76) and 0.68 (95% CI 0.53–0.80), respectively, both with  $R = 0.00$ . However, the SEM scores were acceptable (15.44 with original administration IQR 46.0 and 10.8 with IQR 36.0), both with  $R = 0.00$  (95% CI 0.00–0.00 and 0.00–0.02).

#### 3.4. Validity of FACE-Q

Most FACE-Q scales demonstrated discriminant validity (Table 4). Comparative analyses conducted on matched pre- and post-BLS patients revealed significant differences in the appraisal of upper eyelids ( $p < 0.001$ ), satisfaction with eyelashes ( $p = 0.005$ ), and satisfaction with facial appearance ( $p = 0.013$ ). All scores, except for satisfaction with facial appearance, showed significant differences (all  $p < 0.01$ ) between the pre-BLS and control groups. Aside from for satisfaction with eyes ( $p = 0.020$ ), no scores exhibited significant differences between the post-BLS group and the control group (all  $p > 0.05$ ) (Fig. 3).

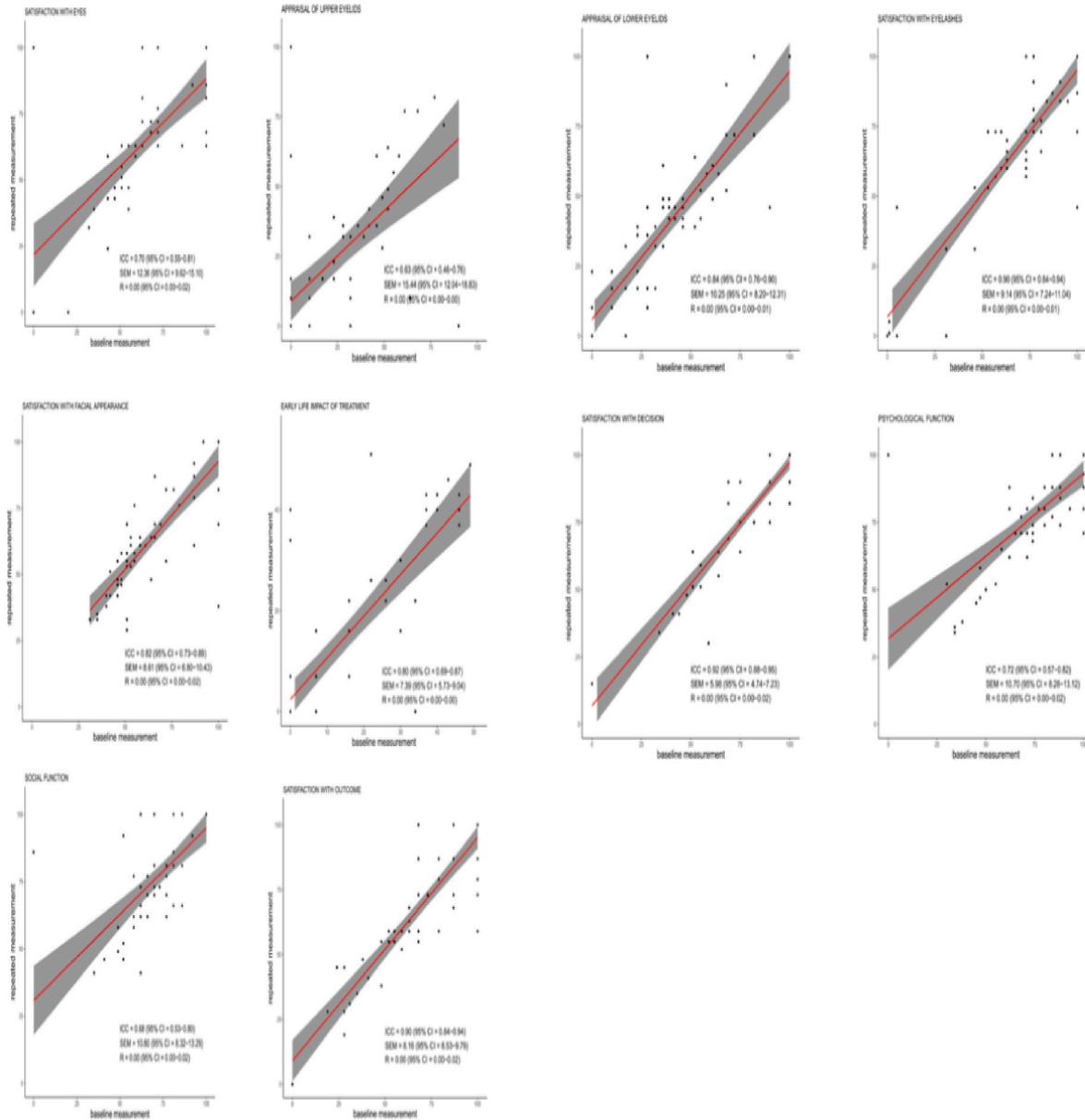
### 4. Discussion

FACE-Q questionnaires are commonly used to provide valuable clinical research information and guide the diagnosis and treatment of surgical diseases (Ioannidis et al., 2014). However, these questionnaires can produce misleading data if misused (Santesso et al., 2020). Therefore, before using such questionnaire tools, their reliability in the target language and culture should be confirmed (Wild et al., 2005). Consideration should also be given to the questionnaire's applicability to a specific patient population.

While the FACE-Q tool has evaluated blepharoplasty outcomes in British and Finnish patients, there has been no German-language version, specifically for the eye module questionnaire (Klassen et al., 2017; Homsey et al., 2021). Consequently, German versions of the eye module scales were developed for FACE-Q: satisfaction with eyes, appraisal of upper eyelids, appraisal of lower eyelids, and satisfaction with eyelashes.

**Table 3**  
FACE-Q subscale scores, and assessment of subscale internal consistency and score reproducibility.

FACE-Q scales	Min (%)	Max (%)	Median score (IQR)	Cronbach's alpha	Comparison of scores in baseline and repeated administrations		
					1	2	p-value
Satisfaction with eyes	3.1	18.8	63.0 (20.0)	0.97	63.0	63.0	0.698
Appraisal of upper eyelids	37.5	1.6	23.0 (46.0)	0.96	23.0	17.0	0.977
Appraisal of lower eyelids	18.8	1.6	32.0 (39.0)	0.95	32.0	39.0	0.593
Satisfaction with eyelashes	4.7	17.2	73.0 (26.0)	0.97	73.0	73.0	0.697
Psychological function	1.6	26.6	78.5 (38.0)	0.96	78.5	80.0	0.644
Social function	1.6	25.0	75.0 (36.0)	0.94	75.0	77.0	0.302
Satisfaction with facial appearance	1.6	15.6	58.0 (34.0)	0.95	58.0	61.0	0.968
Satisfaction with outcome	1.6	28.1	68.0 (48.0)	0.95	68.0	68.0	0.809
Early life impact of treatment	43.8	1.6	7.0 (26.0)	0.75	7.0	7.0	0.906
Satisfaction with decision	1.6	50.0	95.0 (30.0)	0.93	95.0	90.0	0.553



**Fig. 2.** Reliability of the FACE-Q subscales on repeat administration. ICC: intraclass correlation coefficient; SEM: standard error of measurement; R: repeat-ability coefficient.

Our study evaluated the internal consistency of the recently translated and other FACE-Q scales (satisfaction with overall facial appearance, psychological well-being, social function, decision satisfaction,

outcome satisfaction, and early-life impact recovery). These scales performed well in a postoperative patient population with functional or aesthetic problems with the eyelids, and showed high internal

**Table 4**  
Scores and discriminant validity for German FACE-Q scales among groups of subjects.

FACE-Q scales	Pre-BLS group	Post-BLS group	Control group	Pre-BLS group vs post-BLS group	Post-BLS group vs control group	Pre-BLS group vs control group
Satisfaction with eyes	29.83 ± 18.65 (0–63)	64.59 ± 23.01 (0–100)	62.34 ± 21.63 (0–100)	0.799	0.020	0.010
Appraisal of upper eyelids	88.42 ± 14.25 (49–100)	24.58 ± 25.09 (0–90)	30.716 ± 27.54 (0–100)	<0.001	0.496	<0.001
Appraisal of lower eyelids	53.98 ± 28.05 (0–100)	33.77 ± 25.38 (0–100)	29.22 ± 21.17 (0–82)	0.210	0.177	0.007
Satisfaction with eyelashes	46.97 ± 34.08 (0–100)	66.72 ± 28.52 (0–100)	68.91 ± 27.80 (0–100)	0.005	0.698	0.002
Psychological function	61.20 ± 20.85 (0–100)	75.81 ± 21.84 (0–100)	71.75 ± 21.32 (16–100)	0.886	0.781	0.023
Social function	60.14 ± 23.19 (0–100)	74.38 ± 20.42 (0–100)	70.63 ± 21.99 (0–100)	0.338	0.402	0.029
Satisfaction with facial appearance	41.34 ± 16.94 (0–82)	64.83 ± 20.56 (31–100)	58.55 ± 21.55 (0–100)	0.013	0.676	0.072
Satisfaction with outcome	–	69.75 ± 26.07 (0–100)	–	–	–	–
Early life impact of treatment	–	13.69 ± 16.05 (0–49)	–	–	–	–
Satisfaction with decision	–	84.48 ± 21.80 (0–100)	–	–	–	–

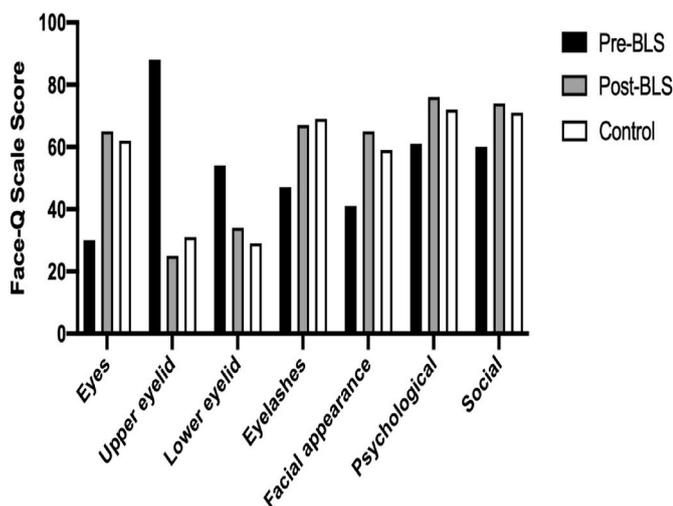


Fig. 3. Mean FACE-Q scale scores.

consistency. This internal consistency was robust across all scales, with Cronbach's alphas of 0.75 or higher. However, minimum or maximum effects were detected across all scales. Our findings may reflect the exclusive use of postoperative patients in our sample, since the scale was initially validated with a group containing both pre- and postoperative patients (Klassen et al., 2017). However, the possibility exists that the scale may not differentiate between subtle differences in treatment outcomes among patients content with their overall eye condition. A Finnish study involving postoperative patients also detected a comparable ceiling effect in the evaluation scale (Homsy et al., 2021).

In our research, no statistically significant differences were observed across all scales when comparing the two postoperative time points. Homsy et al. reported consistent and reproducible results for the Finnish version of the FACE-Q eye module and facial appearance satisfaction, appearance-related psychosocial distress, and outcome satisfaction. Most of the scales in our study also yielded consistent findings, except for the upper eyelid evaluation and social function (Homsy et al., 2021). The study they conducted lacked a social function questionnaire.

It is important to note that our study focused exclusively on patients who underwent upper blepharoplasty. However, their postoperative procedures encompassed treatments such as blepharoplasty, ectropion repair, skin lesion excision, blepharoplasty, brow lift, and others.

Therefore, the findings of our research indicated that there will be alterations in both upper eyelid and social function over time.

The included groups were expected to exhibit differences in between-group comparisons and consequently differ on the FACE-Q scale. This hypothesis was supported by the observation that the post-BLS group scored higher than the pre-BLS group on the three relevant scales. The study conducted by Klassen et al. demonstrated significant variations in results across six questionnaires, except for the eyelash satisfaction questionnaire, when comparing preoperative and postoperative cosmetic eye surgery outcomes (Klassen et al., 2017). Our results generally aligned with these findings; however, they showed a significant difference in eyelash questionnaire scores before and after surgery, while no significant differences were found in psychological questionnaire scores or lower eyelid and eye questionnaire scores. This discrepancy may be attributed to our inclusion of only patients who underwent upper blepharoplasty, whereas the Klassen et al. study encompassed blepharoplasty, facial surgery, and minimally invasive procedures.

Our findings highlighted the importance of utilizing satisfaction survey instruments tailored specifically for distinct patient categories or procedures (Klassen et al., 2010, 2014, 2015a, 2016b, 2017; Pusic et al., 2013b; Schwitzer et al., 2015; Tan et al., 2017). Furthermore, the scores (one scale and six scales) for the BLS postoperative group were higher than or similar to those of the control group. These results were consistent with our expectations, thus indicating that this questionnaire can effectively evaluate patient outcomes following eyelid surgery.

As in previous FACE-Q studies (Panchapakesan et al., 2013; Pusic et al., 2013b; Klassen et al., 2014, 2015a, 2016a, 2016b), our study had certain limitations. Firstly, the sample groups differed in gender, age, and ethnicity, which may have influenced the findings and restricted the exploration of results across different types of study.

Secondly, the study population consisted predominantly of white individuals, and those patients undergoing blepharoplasty were mainly female. Consequently, our study participants were primarily Caucasian, with a higher proportion of women than men. Additionally, for assessing reproducibility in this study, the same postoperative patients were used to avoid the confounding factors mentioned earlier; however, it is important to note that these postoperative patients may have experienced changes over time in terms of their postoperative effects and psychology, which might have introduced some bias into the questionnaire's reproducibility results.

Lastly, all treatments received by patients in this study were limited to blepharoplasty, specifically of the upper eyelids, excluding lower

eyelid surgery or other procedures. This approach partially eliminated interference from different surgical methods on research outcomes, and prevented a comprehensive evaluation of how well the questionnaire tool assessed other types of eyelid surgery.

Therefore, future studies should include samples with diverse gender distributions, ages, ethnicities, and surgical methods to comprehensively evaluate the effectiveness of the German FACE-Q for diagnosing and treating eye diseases.

## 5. Conclusion

In conclusion, the German version of the FACE-Q eye module was developed following established translation and cross-cultural adaptation guidelines. Despite minimal floor or ceiling effects, these scales demonstrated strong internal consistency, reproducibility, and validity. Currently, our translated version of the German FACE-Q eye module scale is readily accessible on the Q-Portfolio website (<https://qportfolio.org>) for both clinical and research purposes. Given the ongoing advancements in oculoplasty worldwide, it is imperative to assess patient outcomes effectively. The FACE-Q eye module can be a reliable and trustworthy tool for oculoplastic surgeons, researchers, and relevant regulatory agencies.

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## Declaration of competing interest

The authors have no conflicts of interest to declare.

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