



FACE-Q® | AESTHETICS ITEM LIBRARIES (IL)

A User's Guide for Researchers and Clinicians

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1. What is FACE-Q | Aesthetics IL?

FACE-Q Aesthetics Item Libraries (IL) are rigorously developed patient-reported outcome measures (PROMs) that can be used to evaluate outcomes of minimally invasive aesthetic facial procedures and products from the patient's perspective [1]. This module of the FACE-Q includes two item libraries. One item library includes 42 items that measure satisfaction with how the *face looks*. The other item library includes 20 items that measure *psychological function*.

In addition to the item libraries, three 10-item short-form scales were derived from the face item library. These scales, which measure facial aging, facial appearance, and facial rejuvenation, were created as examples of how the items can be utilized. These short forms can be used in clinical trials of aesthetic treatments as well as clinical care with patients.

It is also possible to customize a fit-for-purpose short-form scale by choosing a subset of items from the item libraries. Please contact us for more information about scale customization: gportfolioteam@gmail.com.

2. What makes FACE-Q | Aesthetics IL different from Other PROMs?

Standard practice for PROM design has involved the development of short-form scales composed of a small number of items (i.e., questions) for use in a specific context of use. More recently, PROM developers have created item banks and libraries that provide a flexible approach to health outcome assessment. With item banks and libraries, it is possible to customize fit-for-purpose short-form scales by choosing a subset of items that represent the most important concepts for a specific patient population or context of use. This approach aims to maximize content validity and minimize patient burden. Short-form scales can be scored by calibrating scores to the full set of items (i.e., item-bank approach [2-3]), or by using estimates from independent samples (i.e., item-library approach [4-5]).

3. How was FACE-Q | Aesthetics IL Developed and Validated?

To develop the FACE-Q IL, we followed internationally recommended guidelines for PROM development to ensure that it would meet the requirements of regulatory bodies [6-9]. Our team's mixed methods, multi-phase approach to developing the FACE-Q Aesthetics IL is shown in Figure 1. Briefly, between October 2021 to March 2022 we conducted 26 concept elicitation interviews. Table 1 shows sample characteristics and Table 2 shows the sample's treatment history. Concepts from patients were developed into items that were refined with input from 12 experts, 11 clinic patients, and an online sample of 184 Prolific participants. A sample of 1369 Prolific participants completed the full set of appearance and psychological items. The psychometric tests provided evidence of reliability and validity. In addition to the item libraries, short-form scales formed from the 42 appearance items provided examples of item library application. These scales measure facial rejuvenation (e.g., healthy, youthful, rejuvenated), facial appearance (e.g.,

up close, profile, photos), and facial aging (e.g., age, lifted, expression at rest). Further information about the psychometric performance of the item libraries and short-form scales is available in our open access publication [1].

Figure 1: The multiphase mixed methods approach our team followed to develop FACE-Q Aesthetics IL. (Reprinted from Klassen AF, Pusic AL, Kaur M, et al. Extending the range of measurement for minimally invasive treatments by adding new concepts to FACE-Q aesthetics scales. *Plast Reconstr Surg Glob Open.* 2024 Apr 10;12(4):e5736. doi:10.1097/GOX.0000000000005736)

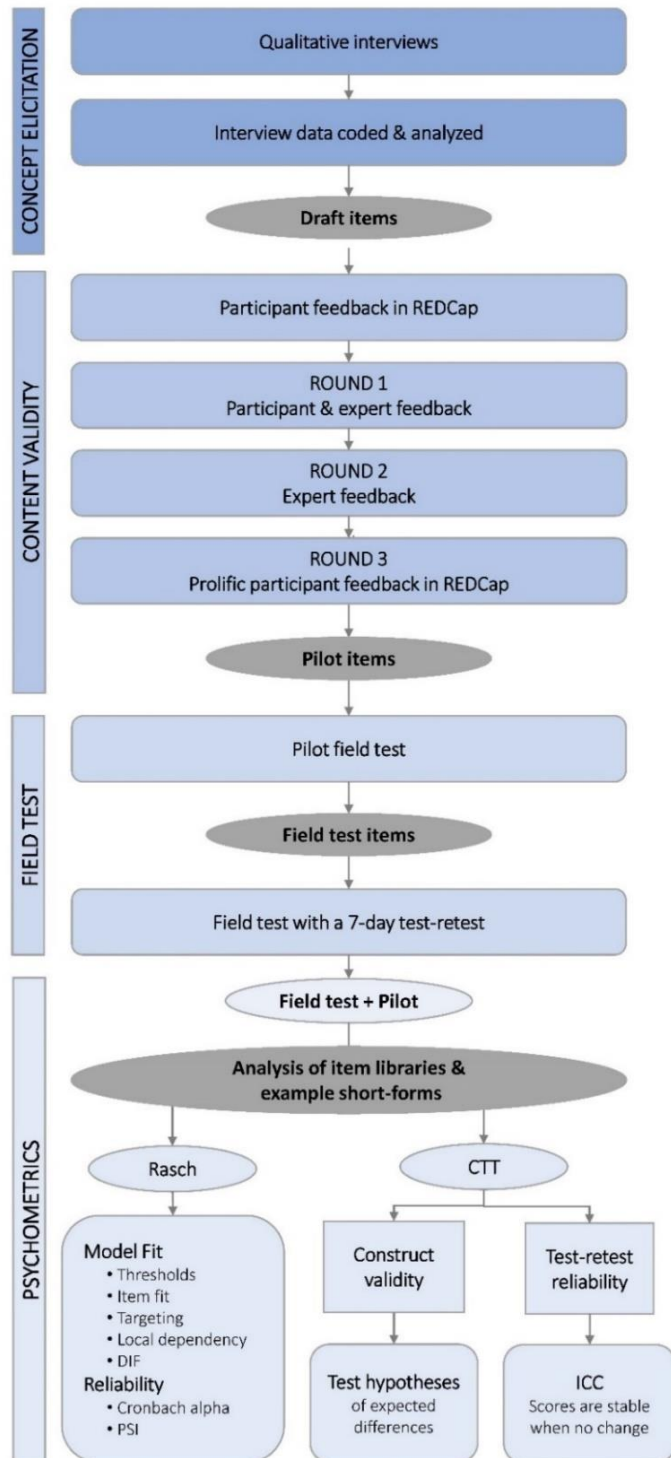


Table 1: Participant characteristics

| | | Qualitative Sample | Prolific | | | |
|-----------------------|--------------------------------------|--------------------|------------------|------|-------------------|------|
| | | | Cognitive Sample | | Field-test Sample | |
| | | N=26 | N=184 | % | N=1369 | % |
| COUNTRY | Canada | 6 | 21 | 11.4 | 107 | 7.8 |
| | UK | 0 | 40 | 21.7 | 721 | 52.7 |
| | USA | 20 | 123 | 66.8 | 540 | 39.4 |
| | Missing | 0 | 0 | 0 | 1 | 0.2 |
| AGE | 20-29 | 3 | 39 | 21.2 | 229 | 16.7 |
| | 30-39 | 6 | 43 | 23.4 | 308 | 22.5 |
| | 40-49 | 7 | 45 | 24.5 | 445 | 32.5 |
| | 50-59 | 6 | 37 | 20.1 | 255 | 18.6 |
| | ≥60 | 4 | 20 | 10.9 | 132 | 9.6 |
| GENDER | Women | 23 | 154 | 83.7 | 1005 | 73.4 |
| | Man | 3 | 28 | 15.2 | 351 | 25.6 |
| | Gender diverse | 0 | 2 | 1.1 | 10 | 0.8 |
| | Prefer to not answer | 0 | 0 | 0 | 3 | 0.2 |
| RACE | White | 22 | 139 | 75.5 | 1048 | 76.6 |
| | Black | 2 | 9 | 4.9 | 96 | 7.0 |
| | Latin American | 0 | 7 | 3.8 | 35 | 2.6 |
| | East Asian | 0 | 6 | 3.3 | 45 | 3.3 |
| | Middle Eastern | 0 | 3 | 1.6 | 10 | 0.7 |
| | South Asian | 1 | 5 | 2.7 | 40 | 2.9 |
| | Southeast Asian | 1 | 2 | 1.1 | 12 | 0.9 |
| | Indigenous | 0 | 1 | 0.5 | 1 | 0.1 |
| | Mixed race | 0 | 10 | 5.4 | 68 | 5.0 |
| | Other/ Missing/ Prefer to not answer | 0 | 2 | 1.0 | 14 | 1.1 |
| MARITAL STATUS | Married/Common Law | 16 | 88 | 47.9 | 753 | 55.0 |
| | Single | 7 | 60 | 32.6 | 428 | 31.3 |
| | Divorced | 2 | 23 | 12.5 | 122 | 8.9 |
| | Separated | 0 | 7 | 3.8 | 35 | 2.6 |
| | Widowed | 1 | 3 | 1.6 | 14 | 1.0 |
| | Other/ Missing/ Prefer to not answer | 0 | 3 | 1.6 | 17 | 1.2 |
| FITZPATRICK SKIN TYPE | Always burn and never tan | 2 | 10 | 5.4 | 98 | 7.2 |
| | Usually burn and minimally tan | 9 | 45 | 24.5 | 371 | 27.1 |
| | Mild burn and then tan | 9 | 81 | 44.0 | 503 | 36.7 |
| | Rarely burn and always tan | 4 | 25 | 13.6 | 264 | 19.3 |
| | Rarely burn and tan very easily | 1 | 16 | 8.7 | 111 | 8.1 |
| | Never burn and never tan | 1 | 4 | 2.2 | 22 | 1.6 |
| | Missing | | 3 | 1.6 | 0 | 0 |
| HIGHEST EDUCATION | Some high school | 0 | 3 | 1.6 | 7 | 0.5 |
| | High school | 1 | 10 | 5.4 | 113 | 8.3 |
| | Some college, trade or university | 4 | 25 | 13.6 | 200 | 14.6 |
| | College, trade or university degree | 9 | 103 | 56.0 | 690 | 50.4 |
| | Some Masters or Doctoral degree | 0 | 7 | 3.8 | 86 | 6.3 |
| | Masters or Doctoral degree | 11 | 36 | 19.6 | 272 | 19.9 |
| | Missing / Prefer to not answer | 1 | 0 | 0 | 1 | 0.1 |

Table 2: Treatment history reported by the qualitative sample and Prolific participants

| | | Qualitative Sample | Prolific | | | |
|-------------------|---------------------------|--------------------|------------------|------|-------------------|------|
| | | | Cognitive Sample | | Field-test Sample | |
| | | N=26 | N=184 | % | N=1369 | % |
| INJECTABLE | Botox | 18 | 124 | 67.4 | 592 | 43.2 |
| | Filler | 17 | 121 | 65.8 | 394 | 28.8 |
| | Platelet-Rich Plasma | 1 | 13 | 7.1 | 58 | 4.2 |
| | Skin Booster | 0 | 17 | 9.3 | 115 | 8.4 |
| SKIN RESUR-FACING | Microdermabrasion | 7 | 81 | 44.0 | 496 | 36.2 |
| | Chemical peel | 16 | 74 | 40.2 | 488 | 35.6 |
| | Hydrafacial | 2 | 65 | 35.3 | 578 | 42.2 |
| | Laser | 14 | 47 | 25.5 | 234 | 17.1 |
| | Microneedling | 2 | 46 | 25.0 | 297 | 21.7 |
| | Light therapy | 14 | 40 | 21.7 | 205 | 15.0 |
| SKIN TIGHTENING | Radio-Frequency | 7 | 21 | 11.4 | 151 | 11.0 |
| | High Intensity Ultrasound | 0 | 17 | 9.2 | 138 | 10.1 |
| | Thread lift | 1 | 13 | 7.1 | 96 | 7.0 |
| FAT REMOVAL | Fat removal injectable | 1 | 14 | 7.6 | 86 | 6.3 |

Note: Tables 1 and 2 were reproduced from Klassen AF, Pusic AL, Kaur M, et al. Extending the range of measurement for minimally invasive treatments by adding new concepts to FACE-Q aesthetics scales. *Plast Reconstr Surg Glob Open*. 2024 Apr 10;12(4):e5736. doi:10.1097/GOX.0000000000005736

4. FACE-Q | Aesthetics II Facial Appearance Items

The Appearance item library includes 42 items. Response options measure satisfaction with how the face looks (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied). The time frame for reporting asks respondents to answer based on NOW. The 42 items shown in Table 3 are organized by the clinical hierarchy from the psychometric analysis (i.e., Rasch Measurement Theory (RMT) analysis [10-11]). People in the sample were most satisfied with the item “how natural your face looks” and least satisfied with the item “how flawless your face looks”.

In Table 3, the items for each short-form are shown. We included the 10-item Face Overall scale from the original FACE-Q Aesthetics set of scales [12]. This scale was qualified as a medical device development tool (MDDT) by the USA Food and Drug Administration in April 2022. More information about the MDDT qualification of FACE-Q Aesthetics scales is available here: <https://www.fda.gov/media/157956/download>. Table 3 also shows the three short-form scales that we published as examples of how the item library could be used. These scales measure Facial Rejuvenation, Facial Appearance, and Facial Aging [1].

Table 3: Satisfaction with Facial Appearance Item Library and short-form scales

| Item Library | Original Face Overall | Short Forms | | |
|--------------------------|-----------------------|---------------------|-------------------|--------------|
| | | Facial Rejuvenation | Facial Appearance | Facial Aging |
| 1. Natural | - | - | - | - |
| 2. Go out | - | - | - | - |
| 3. Look best | - | - | ✓ | - |
| 4. Compare people | - | - | ✓ | ✓ |
| 5. Show expression | - | - | - | ✓ |
| 6. Well-proportioned | ✓ | - | - | - |
| 7. Healthy | - | ✓ | - | - |
| 8. Balanced | ✓ | - | - | - |
| 9. Full (plump youthful) | - | - | - | ✓ |
| 10. Sides match | - | - | - | - |
| 11. Compared gender | - | - | - | - |
| 12. Laugh | - | - | - | - |
| 13. Smile | - | - | - | - |
| 14. Soft | - | - | - | - |
| 15. Age | - | - | - | ✓ |
| 16. Symmetric | ✓ | - | - | - |
| 17. Talk | - | - | - | - |
| 18. Face relaxed | - | - | - | ✓ |
| 19. Shape | - | - | - | - |
| 20. Lifted | - | - | - | ✓ |
| 21. Smooth | - | ✓ | - | ✓ |
| 22. Youthful | - | ✓ | - | ✓ |
| 23. Expression at rest | - | - | - | ✓ |
| 24. Fresh | ✓ | ✓ | - | - |
| 25. Contour | - | - | - | - |
| 26. Radiant | - | ✓ | - | - |
| 27. Resting face | - | - | - | - |
| 28. Attractive | - | - | - | - |
| 29. Rejuvenated | - | ✓ | - | - |
| 30. End of day | ✓ | - | ✓ | - |
| 31. Glows | - | ✓ | - | - |
| 32. Vibrant | - | ✓ | - | - |
| 33. Rested | ✓ | ✓ | - | ✓ |
| 34. Social media | - | - | - | - |
| 35. Different angles | - | - | ✓ | - |
| 36. On screen | - | - | ✓ | - |
| 37. Profile | ✓ | - | ✓ | - |
| 38. Wake up | ✓ | - | ✓ | - |
| 39. Photo | ✓ | - | ✓ | - |
| 40. Up close | - | - | ✓ | - |
| 41. Bright lights | ✓ | - | ✓ | - |
| 42. Flawless | - | ✓ | - | - |

5. FACE-Q | Aesthetics IL Psychological Items

This item library includes 20 items, which effectively doubles the length of the original 10 item Psychological Function scale. Response options measure how much someone agrees

with a series of statements (definitely disagree, somewhat disagree, somewhat agree, definitely agree). The time frame for reporting asks respondents to answer based on the past week. People are asked to respond with their facial appearance in mind. For the item library, we have organized the items by the clinical hierarchy from the RMT analysis. This means that people in the sample agreed the most with “I feel okay about myself” and agreed the least with “I feel at my best”. Table 4 below shows a short form for items in the original 10 item scale. More information about the original Psychological Function scale is available in the FACE-Q Aesthetics User Guide and our publication [13]. This scale was qualified as a medical device development tool (MDDT) by the USA Food and Drug Administration in April 2022. More information about the MDDT qualification of FACE-Q Aesthetics scales is available here: <https://www.fda.gov/media/157956/download>

Table 4: Psychological Function Item Library and short-form scales

| Item Library | Original Psychological Scale |
|---------------------|------------------------------|
| 1. Feel okay | ✓ |
| 2. Like myself | ✓ |
| 3. Feel happy | ✓ |
| 4. Comfortable | ✓ |
| 5. Accepting | ✓ |
| 6. Feel positive | ✓ |
| 7. At peace | - |
| 8. Feel good | ✓ |
| 9. Content | - |
| 10. Satisfied | - |
| 11. Feel confident | ✓ |
| 12. Pleased | - |
| 13. Feel uplifted | - |
| 14. Self-esteem | - |
| 15. Feel great | ✓ |
| 16. Feel vibrant | - |
| 17. Feel attractive | ✓ |
| 18. Feel refreshed | - |
| 19. Feel radiant | - |
| 20. Feel at best | - |

6. Using the FACE-Q | Aesthetics IL

You are able to license to use the FACE-Q Aesthetics IL short-form scales described in this User Guide. In addition, FACE-Q Aesthetics item libraries provide clinicians and researchers with the opportunity to pick a set of items to create a new short-form that will measure outcomes for a procedure or product, or for use in clinical care. This approach reduces patient burden and maximizes content validity.

We anticipate that most researchers and clinicians will use FACE-Q Aesthetics IL published short-form scales. However, if you would like to inquire about the use of either the full item libraries or a customized scale, please email qportfolioteam@gmail.com.

7. Administration of FACE-Q | Aesthetics IL

The FACE-Q Aesthetics IL is designed to be completed by adults on their own (self-report). Brief instructions are provided at the start of each scale. FACE-Q Aesthetics IL was field-tested using a REDCap survey. You may use the paper and pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic).

If you plan to have an ePRO company capture and manage FACE-Q Aesthetics IL data collection, the ePRO company may need a license. If you have had or plan to have an ePRO company convert FACE-Q scales into an electronic format, e-conversion review and certification, please email qportfolioteam@gmail.com.

8. Scoring FACE-Q | Aesthetics IL

The item libraries are independently functioning as they measure different but related constructs (i.e., appearance and psychological function). For both libraries, higher scores represent a better outcome (i.e., higher satisfaction or better function). The full item library can be scored. To obtain a score, the raw scores for the items are added up and linearized using Conversion Tables, which is based on the psychometric analysis. The transformed scores will range from 0 (worst) to 100 (best). To discuss the use of the full item libraries, please contact qportfolioteam@gmail.com.

9. Scoring FACE-Q | Aesthetics IL Short-Form Scales

Each short-form scale is independently functioning. Higher scores represent a better outcome (e.g., higher satisfaction). To obtain a score, the raw scores for the short-form items are added up and linearized using the Conversion Tables we provide, which are based on the Rasch analysis.

When you license the FACE-Q, you will be provided with the Conversion Table(s) to score the short-form scale(s). The scoring algorithm is based on the subset of items in the short-form rather than the full set of items in the item library.

Below is an example of how to compute the score using the FACE-Q Skin Rejuvenation short-form scale from the facial appearance item library.

First, you compute the **sum score** by adding the raw scores for items 1 to 10. In the example below, the sum score = 27. Second, you will find the sum score for the Facial Rejuvenation Conversion Table, which is shown to the right of the scale. The sum score of 27 is then converted to 55.

These questions ask about how your FACE looks. Please answer thinking of how your face looks NOW.

With your FACE in mind, how dissatisfied or satisfied have you been with:

| | VERY dissatisfied | SOMEWHAT dissatisfied | SOMEWHAT satisfied | VERY satisfied |
|--|----------------------|--------------------------|-----------------------|-------------------|
| 1. How <u>healthy</u> your face looks? | 1 | 2 | 3 | 4 |
| 2. How <u>smooth</u> your face looks? | 1 | 2 | 3 | 4 |
| 3. How <u>fresh</u> your face looks? | 1 | 2 | 3 | 4 |
| 4. How <u>youthful</u> your face looks? | 1 | 2 | 3 | 4 |
| 5. How <u>radiant</u> your face looks? | 1 | 2 | 3 | 4 |
| 6. How <u>rejuvenated</u> your face looks? | 1 | 2 | 3 | 4 |
| 7. How <u>vibrant</u> your face looks? | 1 | 2 | 3 | 4 |
| 8. How <u>much</u> your face glows? | 1 | 2 | 3 | 4 |
| 9. How <u>rested</u> your face looks? | 1 | 2 | 3 | 4 |
| 10. How <u>flawless</u> your face looks? | 1 | 2 | 3 | 4 |

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FACE-Q™ - FACIAL REJUVENATION CONVERSION TABLE

| SUM SCORE | RASCH TRANSFORMED SCORE (0 TO 100) |
|-----------|------------------------------------|
| 10 | 0 |
| 11 | 7 |
| 12 | 12 |
| 13 | 15 |
| 14 | 18 |
| 15 | 21 |
| 16 | 24 |
| 17 | 27 |
| 18 | 30 |
| 19 | 33 |
| 20 | 36 |
| 21 | 39 |
| 22 | 41 |
| 23 | 44 |
| 24 | 47 |
| 25 | 49 |
| 26 | 52 |
| 27 | 55 |
| 28 | 58 |
| 29 | 61 |
| 30 | 64 |
| 31 | 68 |
| 32 | 71 |
| 33 | 74 |
| 34 | 77 |
| 35 | 79 |
| 36 | 82 |
| 37 | 85 |
| 38 | 89 |
| 39 | 94 |
| 40 | 100 |

10. How to Deal with Missing Data

The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of FACE-Q. Our suggestion follows the most popular method for scoring when there is missing data, which is to impute a missing value by the mean response to completed items if more than 50% of items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades [14-15]. As such, FACE-Q scores can be computed if missing data is less than 50% of the scale's items. In this approach, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, for the 10-item scale described above, if someone has not responded to all the items, but has responded to ≥ 5 items, all other items for that person could be imputed with the within-person mean (rounded to the nearest integer), and a summed score calculated. Alternatively, for the 10-item scale, if someone has responded to ≤ 4 items, the summed score for this person would be classified as missing data.

11. Conditions of Use

McMaster University, Brigham and Women's Hospital, and Stefan Cano hold the copyright of the FACE-Q Aesthetics IL and all of its translations (past, on-going, and future). To avoid any copyright infringement, please ensure that the copyright notice of the FACE-Q is included in the questionnaire. If you're unsure of the copyright notice for the FACE-Q, our website lists the copyright and trademark notice: <https://qportfolio.org/copyright-information/>

Use of the FACE-Q requires completion of a licensing agreement. The use of the FACE-Q short-form scales in non-profit academic research and in clinical care is free of charge. The use of the FACE-Q by “for-profit” organizations (e.g., pharmaceutical companies or sponsored by pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee.

For questions regarding fees to be paid by ‘for-profit’ organizations, please contact:

Licensing Manager
Office of Technology Development
Memorial Sloan Kettering Cancer Center
633 3rd Ave, 4th Floor, New York, NY 10016
gotdtrm@mskcc.org

Non-profit users can access the FACE-Q Aesthetics IL short-form scales through this link:
<https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3>

PLEASE NOTE

When you sign a FACE-Q license, you agree to the following terms:

- **You will not modify, adapt, or create another derivative work from the FACE-Q**
- **You will not sell, sublicense, rent, loan, or transfer the FACE-Q**
- **You will not reproduce any FACE-Q scales in publications or other materials**
- **You will not translate the FACE-Q without permission from our team**

For questions regarding study design and optimal use of FACE-Q contact either:

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12. Frequently Asked Questions

Do I have to use all items in FACE-Q Aesthetics IL?

Each library functions independently, as do the short-form scales. It is not necessary for a patient to complete all short-form scales described in this User Guide. A researcher or clinician may select any of the short-form scales depending on the particular purpose of the study or use.

Can I delete or add or change any items or response options of FACE-Q Aesthetics IL?

You cannot add or change the wording of any items or response options of FACE-Q Aesthetics IL. Any modification to the content of the FACE-Q Aesthetics IL is prohibited under copyright laws. Making changes to the FACE-Q Aesthetics IL would invalidate its psychometric properties.

Can I reproduce FACE-Q Aesthetics IL in a publication or other document (e.g., PhD thesis)?

According to the licensing agreement, you cannot reproduce the content of FACE-Q Aesthetics IL verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown above in Tables 3 and 4.

Can I translate FACE-Q Aesthetics IL into a new language?

Yes, with permission, you can translate FACE-Q Aesthetics IL into different languages. Before starting a translation, check our translations list on www.qportfolio.org to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the methods you need to follow. Email us at qportfolioteam@gmail.com for more information. Please note that the developers of the FACE-Q Aesthetics IL own the copyright of all translations of the FACE-Q Aesthetics IL.

Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points to use to administer FACE-Q Aesthetics IL.

Does it cost money to use FACE-Q Aesthetics IL?

Use of FACE-Q Aesthetics IL short-form scales described in this User Guide are free for non-profit users. For-profit users should contact Memorial Sloan-Kettering Cancer Center for information about fees for using the item libraries and short-form scales (gotdtrm@mskcc.org).

13. Publications Related to FACE-Q IL Development and Validation

1. Klassen AF, Pusic AL, Kaur M, et al. Extending the range of measurement for minimally invasive treatments by adding new concepts to FACE-Q aesthetics scales. *Plast Reconstr Surg Glob Open*. 2024 Apr 10;12(4):e5736. doi:10.1097/GOX.0000000000005736
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