FACE-Q[®] | AESTHETICS

A User's Guide for Researchers and Clinicians

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1. What is FACE-Q | Aesthetics?

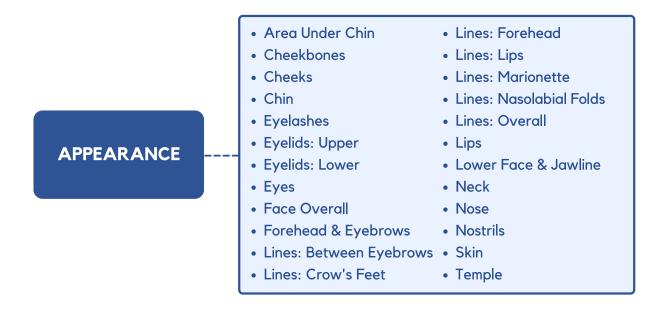
The FACE-Q Aesthetics is a rigorously developed patient-reported outcome measure (PROM) that can be used to evaluate outcomes of aesthetic facial procedures and products from the patient's perspective. The FACE-Q can be used for any type of surgical or minimally invasive facial aesthetic treatment. This PROM has been used to evaluate the safety and effectiveness of facial aesthetic treatments in numerous clinical trials and to inform patient care in clinical practice. The FACE-Q is composed of a set of 40 independently functioning scales/checklists that measure 3 overarching domains: facial appearance, health-related quality of life, and adverse effects. These domains form the basis of the FACE-Q conceptual framework shown below. The FACE-Q modular approach means that only the subset of scales most relevant to a specific research objective or clinical patient population need to be administered.

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

We followed internationally recommended guidelines for patient-reported outcome instrument development to ensure that the FACE-Q meets requirements of regulatory bodies. Our team's mixed methods, multi-phase approach was patient-oriented as we engaged patients and healthcare providers in all phases of our research. Expert and patient input was crucial in designing the content of each FACE-Q scale and its subsequent evaluation. Our goal was to ensure that FACE-Q scales are valid and reliable, not only for health outcomes research, but also for use in clinical care with patients.

In Phase 1, qualitative interviews with patients (n=50) were conducted between January 2008 and February 2009. These interviews were audio recorded, transcribed, and coded using a line-by-line approach. The sample was aged 20 to 79 years, 88% female and 70% Caucasian. Participants had one or more of the following surgical or minimally invasive treatments: Botulinum toxin, skin resurfacing, fillers, blepharoplasty, facelift, rhinoplasty, neck lift, brow lift, and chin implants. The data were used to develop the FACE-Q conceptual framework (Figure 1) and comprehensive item pool. The item pool was used to develop scales that were refined through 35 cognitive interviews with patients who were aged 20 to 68 years, 86% female and 59% Caucasian. To ensure the scales captured all clinically relevant content, they were shown to 15 plastic surgeons, 4 dermatologists, 3 psychologists, and 4 office staff. Feedback was used to finalize the FACE-Q field-test version.

Figure 1: FACE-Q Aesthetics Conceptual Framework







In the Phase 2 international field-test study, we recruited participants between June 2010 and March 2015 from plastic surgery and dermatology clinics in Canada, the United Kingdom, and the USA. Participants were aged 18 years and older and pre- or post-treatment for any facial cosmetic surgery or minimally invasive procedure. Participants were asked to complete the FACE-Q scales relevant to evaluating outcomes for their particular treatment. In the psychometric analysis, for each scale the questions that represent the best indicators of outcome were retained based on their performance against a set of psychometric criteria. Two scales were field-tested in an international sample that included 90 body contouring and 278 facial aesthetics patients. These scales measure expectations and appearance-related distress. The RMT analysis for the 2 scales supported their reliability and validity. Given the large number of scales tested, the psychometric results were published in a series of articles as shown in Table 1.

The FACE-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are each designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, FACE-Q scales can be used with individual patients to inform clinical care.

3. How is FACE-Q | Aesthetics Used?

Each year, millions of people around the world have facial cosmetic surgery procedures and/or minimally invasive procedures. The vast majority of both surgical and nonsurgical cosmetic procedures aimed to rejuvenate facial appearance. While facial products and procedures are continually developed and tested, very little clinical research has included the patient perspective in clinical trials.

Prior to the development of the FACE-Q, few PROMs were available for facial aesthetic research. We previously published a systematic review of PROMs for facial cosmetic surgery and/or nonsurgical facial rejuvenation [1]. From 442 articles, we identified 9 PROMs, but none satisfied best practice guidelines for PROM development and validation.

In a subsequent review commissioned by the UK Department of Health, 9 PRO measures for use in cosmetic surgery were identified, but only 3 followed recommendations for PROM development and validation. The FACE-Q was one of the 3 recommended: https://www.ndph.ox.ac.uk/files/research/cosmetic-surgery-proms-review2013.pdf

The FACE-Q continues to meet the demands for a PROM for facial aesthetics, providing researchers and clinicians worldwide with a rigorously designed comprehensive PROM.

The FACE-Q has been licensed for use by more than 1200 researchers and clinicians in over 50 countries to evaluate facial cosmetic products and treatments from the patient perspective.

The FACE-Q's modular approach provides the ability to select scales targeted to specific facial features, providing flexibility to choose the PRO scales best suited to measure the endpoint of interest in clinical trials. The modular approach taken in the FACE-Q is described in an FDA publication on the value and use of PROs in assessing effects of medical devices (see pg 18): https://www.fda.gov/files/about%20fda/published/Value-and-Use-of-Patient-Reported-Outcomes-%28PROs%29-in-Assessing-Effects-of-Medical-Devices.pdf

In clinical trials, the FACE-Q has been included in at least two FDA approved label claims:

- 1. Juvederm VOLLURE XC, an injectable gel indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as the nasolabial folds) in adults over the age of 21 years. This label reported the findings from the FACE-Q | Aesthetics Recovery Early Symptoms scale as part of their safety endpoint, and findings from the FACE-Q | Aesthetics Appraisal of Nasolabial Folds scale as a secondary effectiveness endpoint. (Allergan, 2017).
- 2. Juvederm VOLBELLA XC, an injectable gel indicated for injection into the lips for lip augmentation and for the correction of perioral rhytides in adults over the age of 21 years. This label included 3 FACE-Q scales. Specifically, the label cites findings for the FACE-Q | Aesthetics Recovery Early Life Impact module as a safety measure, and the FACE-Q | Aesthetics Lip Lines and Satisfaction with Lips scale as secondary measures of effectiveness. (Allergan, 2017).

4. FACE-Q Scales Qualified as Medical Device Development Tools

In April 2022, the US Food and Drug Administration (FDA) qualified 11 FACE-Q Aesthetics scales as a medical device development tool (MDDT). The MDDT program qualifies tools that medical device sponsors can use when developing and evaluating a device. The FDA evaluates the tool to make sure it can be used as intended and will produce sound measurement. Using qualified tools improves the efficiency of regulatory review.

Qualified FACE-Q Self-Perceived Facial Appearance Scales: Cheeks, Face Overall, Lines: Between Eyebrows, Lines: Nasolabial Folds, Lips, Skin.

Qualified FACE-Q Health-Related Quality of Life Scales: Aging Appraisal, Early Life Impact, Outcome, Psychological, Social.

For more information, see: https://www.fda.gov/media/157956/download

Table 1: FACE-Q | Aesthetics Psychometric Publications

SCALES	PUBLICATIONS				
Face Overall	Pusic A, Klassen AF, Scott AM, Cano SJ. Development and psychometric evaluation of the FACE-Q Satisfaction with Appearance Scale: A new patient-reported outcome instrument for facial aesthetics patients. Clin Plast Surg. 2013; 40(2):249-60.				
Aging Appraisal; Age Visual Analogue Scale	Panchapakesan V, Klassen AF, Cano SJ, Scott AM, Pusic AL. Development and Psychometric Evaluation of the FACE-Q Aging Appraisal Scale and Patient-Perceived Age Visual Analog Scale. Aesth Surg J. 2013; 33(8):1099-1109.				
Cheeks; Lines: Nasolabial Folds; Lower Face & Jawline; Area Under Chin; Neck; Adverse Effects: Cheeks, Lower Face & Neck	Klassen AF, Cano SJ, Scott AM, Pusic AL. Measuring Outcomes That Matter to Face-Lift Patients: Development and Validation of FACE-Q Appearance Appraisal Scales and Adverse Effects Checklist for the Lower Face and Neck. Plast Reconstr Surg. 2014; 133(1):21-30.				
Psychological Function; Social Function; Outcome; Decision; Early Life Impact; Recover Early Symptoms	Klassen AF, Cano SJ, Schwitzer J, Scott A, Pusic AL. FACE-Q scales for health-related quality of life, early life impact and satisfaction with outcomes and decision to have treatment: development and validation. Plast Reconstr Surg. 2015; 135(2):375-86.				
Chin; Cheekbones; Forehead & Eyebrows; Adverse Effects: Forehead, Eyebrows, Scalp	Schwitzer J, Klassen AF, Cano SJ, Baker SB, East C, Pusic AL Measuring satisfaction with appearance: Development and validation of the FACE-Q scales for the nose, nostrils, forehead, cheekbones, and chin. Plast Reconstr Surg. 2015. 136(4S-1):140-141.				
Expectations; Appearance Distress	Klassen AF, Cano SJ, Alderman A, East C, Badia L, Baker SB, Robson S, Pusic AL. Self-report scales to measure expectations and appearance-related psychosocial distress in patients seeking cosmetic treatments. Aesthet Surg J. 2016; 36(9):1068-78				
Skin; Lips; Lines: Overall, Forehead, Between Eyebrows, Crow's Feet, Lips, Marionette; Adverse Effects: Skin, Lips Nose; Nostrils; Adverse Effects: Nose	Klassen AF, Cano SJ, Schwitzer JA, Baker SB, Carruthers A, Carruthers J, Chapas A, Pusic AL. Development and Psychometric Validation of the FACE-Q Skin, Lips, and Facial Rhytides Appearance Scales and Adverse Effects Checklists for Cosmetic Procedures. JAMA Dermatol 2016; 152(4): 443-451. Klassen AF, Cano SJ, East CA, Baker SB, Badia L, Schwitzer JA, Pusic AL. Development and Psychometric Evaluation of the FACE-Q Scales for Patients Undergoing Rhinoplasty. JAMA Facial Plast Surg. 2016; 18(1): 27-35.				
Eyes; Eyelashes; Eyelids - Lower; Eyelids - Upper; Adverse Effects: Eyes	Klassen AF, Cano SJ, Grotting JC, Baker SB, Carruthers J, Carruthers A, Van Laeken N, Sykes JM, Schwitzer J, Pusic AL. FACE-Q Eye Module for measuring patient-reported outcomes following cosmetic eye treatments. JAMA Facial Plast Surg. 2017; 19(1):7-14.				

Table 2: Description of FACE-Q | Aesthetics scales and checklists

Name of scale	Domain	Items	Response Options	Recall	FK
Area Under Chin	appearance	5	extremely $ ightarrow$ not at all	past week	2.8
Cheekbones	appearance	10	dissatisfied → satisfied past week		4.1
Cheeks	appearance	5	dissatisfied → satisfied	past week	2.6
Chin	appearance	10	dissatisfied → satisfied	past week	1.1
Eyelashes	appearance	7	dissatisfied → satisfied	past week	6.2
Eyelids - Lower	appearance	7	extremely → not at all	past week	5.0
Eyelids - Upper	appearance	7	extremely $ ightarrow$ not at all	past week	5.7
Eyes	appearance	7	dissatisfied → satisfied	past week	2.1
Face Overall	appearance	10	dissatisfied $ ightarrow$ satisfied	past week	0.9
Forehead & Eyebrows	appearance	6	dissatisfied → satisfied	past week	6.2
Lines: Between eyebrows	appearance	7	extremely → not at all	past week	5.6
Lines: Crow's Feet	appearance	7	extremely → not at all	past week	0.3
Lines: Forehead	appearance	7	extremely → not at all	past week	3.5
Lines: Lips	appearance	6	extremely $ ightarrow$ not at all	past week	2.8
Lines: Marionette	appearance	7	extremely $ ightarrow$ not at all	past week	4.8
Lines: Nasolabial Folds	appearance	5	extremely $ ightarrow$ not at all	past week	6.0
Lines: Overall	appearance	10	extremely → not at all	past week	0.2
Lips	appearance	10	dissatisfied $ ightarrow$ satisfied	past week	1.0
Lower Face & Jawline	appearance	5	dissatisfied → satisfied	past week	3.0
Neck	appearance	10	extremely \rightarrow not at all	past week	1.6
Nose	appearance	10	dissatisfied > satisfied	past week	0.8
Nostrils	appearance	5	dissatisfied → satisfied past w		1.4
Skin	appearance	12	dissatisfied → satisfied past wee		2.5
Temples	appearance	12	dissatisfied → satisfied now		2.3
Aging Appraisal	HRQOL	7	disagree → agree now		2.8
Age Visual Analogue Scale	HRQOL	1	-15 to + 15 years n/a		3.6
Appearance Distress	HRQOL	8	disagree → agree n/a		2.7
Decision	HRQOL	6	disagree → agree n/a		0.2
Early Life Impact	HRQOL	12	most of time → not at all past 2 days		8.4
Expectations	HRQOL	8	disagree → agree n/a		1.5
Outcome	HRQOL	6	disagree → agree n/a		3.0
Psychological Function	HRQOL	10	disagree → agree past week		4.5
Recovery Early Symptoms	HRQOL	17	extremely → not at all past 2 days		6.3
Social Function	HRQOL	8	disagree 🗲 agree	past week	4.9
Cheeks, Lower Face, Neck	AE	15	a lot $ ightarrow$ not at all	past week	4.7
Eyes	AE	6	extremely $ ightarrow$ not at all	past week	9.7
Forehead, Eyebrows, Scalp	AE	12	extremely → not at all past week		7.3
Lips	AE	8	extremely → not at all past week		4.7
Nose	AE	4	extremely → not at all	past week	6.2
Skin	AE	10	extremely → not at all	past week	3.0

AE= adverse effects; FK = Flesch-Kincaid grade level; NOTE: the names of scales may be abbreviated.

5. FACE-Q | Aesthetics Scales

Table 2 shows the FACE-Q scales and checklists, including number of items, response options, recall period, and Flesch-Kincaid (FK) grade reading level. Below is a brief description of the content of each scale and checklist.

APPEARANCE

Area Under Chin: This 5-item scale measures how bothered someone is by the appearance of the area under the chin. Items ask about loose and sagging skin, as well as how the chin looks in profile.

Cheekbones: This 10-item scale measures satisfaction with the appearance of the cheekbones. Items ask about shape, contour and symmetry, as well as how attractive, high, and well-defined the cheekbones look.

Cheeks: This 5-item scale measures satisfaction with the appearance of the cheeks. Items ask about fullness, symmetry, and attractiveness.

Chin: This 10-item scale measures satisfaction with the appearance of the chin. Items ask about size, width and shape, as well as how the chin looks from different angles and in photos.

Eyelashes: This 7-item scale measures satisfaction with the appearance of the eyelashes. Items ask about their fullness, length and color, as well as how attractive and feminine they make the eyes look.

Eyes: This 7-item scale measures satisfaction with the appearance of eyes. Items ask about how youthful, attractive and open the eyes look, as well as their shape.

Eyelids - Lower: This 7-item scale measures how bothered someone is by the appearance of their lower eyelids. Items ask about puffiness and wrinkled skin located in this area, as well as how tired or old the lower eyelids make someone look.

Eyelids - Upper: This 7-item scale measures how bothered someone is by the appearance of their upper eyelids. Items ask how saggy and heavy the upper eyelids look, as well as how tired or old they make someone look.

Face Overall: This 10-item scale measures satisfaction with the appearance of the entire face. Items ask how fresh and rested the face looks, as well as how the face looks from the side, in photos, under bright lights, and at the end of the day.

Forehead & Eyebrows: This 6-item scale measures satisfaction with the appearance the forehead and eyebrows. Items ask about position of the eyebrows, how even they look,

the height of the forehead, as well as how natural, smooth and youthful the forehead looks.

Lines: Between Eyebrows: This 7-item scale measures how bothered someone is by the appearance of lines between their eyebrows. Items ask how deep and noticeable the lines are, how old they make someone look, and how they look when they frown or concentrate.

Lines: Crow's Feet: This 7-item scale measures how bothered someone is by the appearance of crow's feet (i.e., lines at the outer corner of the eyes). Items ask how old or tired they make someone look, and how they look when they smile or squint.

Lines: Forehead: This 7-item scale measures how bothered someone is by the appearance of horizontal forehead lines. Items ask about the number of lines, how deep and noticeable they are, as well as how tired and old they make someone look.

Lines: Lips: This 6-item scale measures how bothered someone is by the appearance of lines around the lips. Items ask about the number of lines, how deep and noticeable they are, as well as how old they make someone look.

Lines: Marionette: This 7-item scale measures how bothered someone is by the appearance of marionette lines (i.e., lines that run downward from the corner of the lips to the chin). Items ask about how angry, sad, old, and tired the lines make someone look.

Lines: Nasolabial Folds: This 5-item scale measures how bothered someone is by the appearance of nasolabial folds (i.e., deep lines that run downward from the sides of the nose). Items ask how deep the lines are, how old they make someone look, and how they look when the face is relaxed.

Lines: Overall: This 10-item scale measures how bothered someone is by the look of lines anywhere on their face. Items ask about the number of lines, how deep and noticeable they are, how they look when someone frowns or smiles, and how they look in the mirror and in photos.

Lips: This 10-item scale measures satisfaction with the appearance of the lips. Items ask about the size and shape of the lips, how full the upper and lower lips look, as well as how nice the lips look when someone smiles.

Lower Face & Jawline: This 5-item scale measures satisfaction with the appearance of the lower face (i.e., lower cheeks and jawline). Items ask about how prominent and sculpted the jawline looks, as well as how the jawline looks in profile.

Neck: This 10-item scale measures how bothered someone is by the appearance of the neck. Items asks about hanging, sagging, and wrinkled skin, as well as how the neck looks from the side and in collared shirts.

Nose: This 10-item scale measures satisfaction with the appearance of the nose. Items ask about the overall size, length and width, the tip and bridge of the nose, as well as how the nose looks from the side, in photos, and from every angle.

Nostrils: This 5-item scale measures satisfaction with the appearance of the nostrils. Items ask about their size, shape, and how even (well-matched) they look.

Skin: This 12-item scale measures satisfaction with appearance of facial skin (complexion). Items ask about how smooth, healthy, refreshed, attractive, even-colored, and hydrated the skin looks, as well as how it looks at the start and the end of the day.

Temples: This 12-item scale measures satisfaction with appearance of the temples. Items in the field-test scale ask about the shape of the temples, how full they look, the age they make someone look, as well as how they look in photos and in a mirror.

HEALTH-RELATED QUALITY OF LIFE

Aging Appraisal: This 7-item scale measures how a respondent feels about the age their face looks. Items ask about age when looking in the mirror and in photos.

Age Visual Analogue Scale: This item measures perceived age in comparison to chronological age on a visual analogue scale that runs from -15 years to +15 years.

Appearance Distress: This 8-item scale measures appearance-related distress in people seeking cosmetic treatments for the body or the face. Item ask someone to agree/disagree with statements about feelings (e.g., unhappy, stressed, down) and behaviors, such as avoiding being around people.

Decision: This 6-item scale measures satisfaction with their decision to undergo a facial procedure. Item ask someone to agree/disagree with statements about the procedure being what was wanted, needed, and worth the time and effort.

Early Life Impact: This 12-item scale measures recovery facial surgery or procedure. Items ask how often someone has experienced difficulty with facial function (e.g., eat, drink, move face or head), trouble sleeping, feeling tired or anxious, and being able to do usual activities.

Expectations: This 8-item scale measures how people seeking cosmetic treatments for the body (e.g., liposuction) or face (e.g., facelift, Botox) expect their appearance and life

might change after treatment, e.g., good things will happen to them and they will look fantastic.

Outcome: This 6-item scale measures satisfaction with the result of a facial procedure. Items ask someone to agree/disagree with statements such the result being great, just as expected, and fantastic.

Psychological Function: This 10-item scale measures psychological function. Items ask respondents to answer with their facial appearance in mind. Items ask about feeling happy, attractive, confident and good about oneself.

Recovery Early Symptoms: This 17-item checklist measures how bothered someone is by adverse effects after a facial surgery or procedure. Items ask about swelling, tenderness, pain, tingling, numbness, and feeling lightheaded or feverish.

Social Function: This 8-item scale measures social function. Items ask respondents to answer with their facial appearance in mind. Items ask about feeling confident when meeting new people, in new social situations, and when participating in group situations.

ADVERSE EFFECTS

Cheeks, Lower Face & Neck: This 15-item checklist asks how bothered someone is by adverse effects specific to the cheeks, lower face, and neck. Items ask about parts of the face feeling numb, tightness, tingling, pulling, swelling, and difficulty with facial movements.

Eyes: This 6-item checklist measures how bothered someone is by eye-specific adverse effects. Items ask about dry eyes, excess tearing, irritation, and difficulty closing the eyes.

Forehead, Eyebrows, Scalp: This 12-item checklist asks how bothered someone is by adverse effects specific to the upper face. Items ask about forehead or scalp pain, tingling, numbness, and difficulty moving the forehead or showing expression.

Lips: This 8-item checklist asks how bothered someone is by lip-specific adverse effects. Items ask about the lips not looking or feeling smooth, swelling, numbness, and difficulty with moving the lips.

Nose: This 4-item checklist asks how bothered someone is by nose-specific concerns. Items ask about tenderness, swelling, and difficulty breathing.

Skin: This 10-item checklist asks how bothered someone is by skin-specific adverse effects. Items ask about redness, parts of the face not looking or feeling smooth to the touch, tightness, and itching.

6. Administration of FACE-Q | Aesthetics Scales

The FACE-Q is designed to be completed by patients on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need to be completed. The FACE-Q scales that measure appearance of face overall and HRQOL are relevant to <u>all</u> facial aesthetic patients. The FACE-Q scales that measure aspects of appearance and adverse effects are <u>specific</u> to facial areas (e.g., eyes, nose, cheeks). The modular approach makes it possible for you to use only the most relevant scales for your patient population or research study. Brief instructions and the timeframe for reporting are provided at the start of each scale.

The FACE-Q was field-tested using online data collection, i.e., Research Electronic Data Capture System (REDCap), as well as paper-and-pencil. 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 data collection, the ePRO company may need a license. If you have had FACE-Q scales converted into an electronic format e-conversion review and certificate, and require an please email qportfolioteam@gmail.com.

7. Scoring FACE-Q | Aesthetics

There is no overall or total FACE-Q score. Instead, the FACE-Q is composed of independently functioning scales that are each scored separately, adverse effects checklists, and a single item visual analogue scale.

To <u>score a scale</u>, the raw scores for the set of items in a scale are added together to produce a total raw score. If missing data is less than 50% of the scale's items, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to ≥ 5 items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to ≤ 4 items, the summed score for this person cannot be computed and is classified as missing data. Importantly, the Conversion Tables are only valid with complete data (i.e., when a person has $\geq 50\%$ completed responses). Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the RMT analysis.

Higher scores for all but 2 FACE-Q scales reflect a better outcome. The 2 scales where higher scores do not mean a better outcome are Expectations and Appearance-Related

Distress. For these 2 scales, higher scores are indicative of expectations that are too high (unrealistic) and more appearance-related distress.

To ensure for all other scales that higher scores represent a better outcome, the raw data need to be scored as shown in the box below. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

To <u>score a checklist</u>, the raw scores for the items in a checklist can be used to identify problems experienced by a patient or a sample. Checklists do not have Rasch Conversion Tables because the set of items did not work together statistically (i.e., the item set did not map out a clinical hierarchy for the concept of interest). Even though there are no Conversion Tables based on the RMT analysis for the checklists, they can provide clinically important information, such as monitoring for post-operative complications.

The FACE-Q has 1 stand-alone (i.e., single) item. To <u>score the single item</u>, the raw score is used. This score measures perceived age in comparison to chronological age on the visual analogue scale that runs from -15 years to +15 years. There is no Conversion Table for the single item.

RAW SCORES FOR SCALE ITEMS

For scales that measure <u>satisfaction with appearance</u>, the raw data needs to be scored as follows: "Very dissatisfied" = 1; "Somewhat dissatisfied" = 2; "Somewhat satisfied" = 3; "Very satisfied" = 4. This includes the following scales: Cheekbones, Cheeks, Chin, Eyelashes, Eyes, Face, Forehead & Eyebrows, Lips, Lower Face & Jawline, Nose, Nostrils, Skin, and Temples.

For the scales that measure <u>bothered by their appearance</u>, the raw data needs to be scored as follows: "Extremely" = 1; "Moderately" = 2; "A little" = 3; "Not at all" = 4. This includes the following scales: Area Under the Chin, Eyelids-Lower, Eyelids-Upper, Lines-Between the Eyebrows, Lines-Crow's Feet, Lines-Forehead, Lines-Lips, Lines-Marionette, Lines-Nasolabial Folds, Lines-Overall, and Neck.

For scales that measure <u>agree/disagree</u>, the raw data needs to be scored as follows: "Definitely agree" = 4; "Somewhat agree" = 3; "Somewhat disagree" = 2; "Definitely disagree" = 1. This includes the following scales: Appearance-Related Distress, Decision, Expectations, Outcome, Psychological Function, and Social Function.

The one exception is Aging Appraisal, which needs to be scored as follows: "Definitely agree" = 1; "Somewhat agree" = 2; "Somewhat disagree" = 3; "Definitely disagree" = 4.

For the scale that measures <u>amount of time</u>, the raw data needs to be scored as follows: "Most of the time" = 1; "Some of the time" = 2; "Not at all" = 3. This includes the following scale: Early Life Impact of Treatment.

8. Conditions of Use

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Non-profit users can access the FACE-Q using the following link: https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3

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

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Memorial Sloan Kettering Cancer Center
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- You will not modify, adapt or create another derivative work from the FACE-Q
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- 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 scales contact either:

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9. Frequently Asked Questions

Do I have to use all of the FACE-Q | Aesthetics scales?

Each scale functions independently, therefore patients can be asked to complete one or all of the FACE-Q scales. It is not necessary for a patient to complete all of the scales or checklists as there is no overall or total FACE-Q score. A researcher or clinician may therefore select a subset of scales depending on the particular purpose of the study or use.

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

You <u>cannot</u> delete or add or change the wording of any items or response options of the FACE-Q. Any modification to the content of the FACE-Q is prohibited under copyright

laws. Also, making any changes to FACE-Q scales would invalidate their psychometric properties.

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

According to the licensing agreement, you cannot reproduce the content of FACE-Q scales 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 in Table 3 below.

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

Yes, with permission, you can translate the FACE-Q into different languages. Before starting a translation, check our translation 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 method you need to follow. Email us at qportfolioteam@gmail.com for more information. Please note that the developers of the FACE-Q own the copyright of all translations of the FACE-Q.

Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points they would like to administer the scales.

Does it cost money to use the FACE-Q | Aesthetics?

Use of FACE-Q is free for non-profit users, including use by hospitals. For-profit users need to pay a licensing fee through Memorial Sloan Kettering Cancer Centre (see conditions of use above).

Table 3: Shortened items for FACE-Q | Aesthetics to use in a publication

APPEARANCE	look tired	noticeable	LOWER FACE	HRQOL	PSYCH	EYES
AREA UC	look old	puckered	prominent	AGING APPRAISAL	like	eyelid scars
fullness	EYES	LINES-MARION	sculpted	don't recognize	positive	dry eyes
contour	shape	angry	profile	look in mirror	okay	eye irritation
sagging	attractive	sad	nice	bothered	happy	excessive tearing
loose	alert	tired	smooth	older	comfortable	look hallowed out
profile	open	relaxed	NECK	worried	accepting	close eyes
CHEEKBONES	bright-eyed	deep	cover up	photos	good	FOREHEAD
symmetric	nice	old .	compared	reflection	confident	pain
high	youthful	noticeable	lines	APP DISTRESS	attractive	tingling
photos	FACE	LINES-NLF	collars	feel unhappy	great	numb
shape	symmetric	compared	hanging	feel stressed	RECOVERY	unnatural
contour	balanced	smile	grimace	feel down	swelling	sensitivity
sculpted	proportioned	old	profile	feel anxious	tenderness	show expression
different angles	end of day	relaxed	wrinkled	look normal	discomfort	move eyebrows
attractive	fresh	deep	old	ugly	bruised	eyebrows uneven
prominent	rested	LINES-OVERALL	sagging	avoid people	sore	eyebrows too high
well-defined	profile	deep	SKIN	doing things	tight	hairline position
CHEEKS	photos	photos	end of day	DECISION	pain	scars look
symmetric	wake-up	relaxed	healthy	time effort	numbness	scars feel
smooth	bright lights	smile	attractive	worth money	stinging	LIPS
attractive	FOREHEAD	number	smooth	wanted	tingling	feel smooth
contour	position	noticeable	clear	needed	throbbing	asymmetric
fullness	even	frown	refreshed	want look	burning	look smooth
CHIN		old			ū	
	forehead height		hydrated	changed life EARLY LIFE IMP	tired	swelling
style	natural	mirror	wake up		itching	unnatural
size	youthful	bright lights	radiant	regret	lightheaded	numbness
width	smooth	NOSE	tone	anxious	headache	moving
suits face	LINES-BE	width	pores	sleeping	feverish	too big
sculpted	relaxed	length	even-colored	worthwhile	SOCIAL	NOSE
shape	old	bridge	SKIN	tired	first impressions	thick skin
profile	angry	suits face	end of day	head movements	new person	tenderness
photos	noticeable	straight	healthy	usual activities	meet people	breathing
projects	deep	size	attractive	facial movements	make friends	bumps
every angle	concentrating	shape	smooth	drinking	group situations	SKIN
EYELASHES	frowning	photos	clear	eating	social situations	redness
nice	LINES-CROW'S	tip	refreshed	social situations	around strangers	skin tone
feminine	Relaxed	every angle	hydrated	intimacy	room of people	sensitivity
dark	noticeable	NOSTRILS	wake up	EXPECTATIONS	ADVERSE EFFECT	blotchy
long	tired	size	radiant	look fantastic	CHEEKS	look smooth
attractive	number	shape	tone	look great	numb	feel smooth
thick	old	show	pores	people proud	tightness	tightness
full	smile	well matched	even-colored	transformed	not smooth	itching
EYELIDS-LOW	squint	overall	TEMPLE	good things	sensitive	scarred
excess fat	LINES-FHEAD	LIPS	compared	fit in	tingling	burning
excess skin	talking	shape lower lip	fit in	relationships	scars feel	
puffiness	relaxed	suit face	compliments	new people	discomfort	
noticeable lines	noticeable	smile	photos	OUTCOME	itching	
crepey skin	tired	full lower lip	light	pleased	scars look	
look old	old	style	age	great	pulling	
look tired	deep	shape upper lip	to side, from side	expected	swelling	
EYELIDS-UP	number	turned up	shape	look in mirror	feeling hard	
skin on lashes	LINES-LIPS	size	mirror	fantastic	expressions	
saggy	compared	relaxed	full	miraculous	bruising	
droopy	old	full upper lip	youthful		movements	
eyelid folds	deep					
	number					

10. Acknowledgements

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Qualitative Phase: Pusic A, Klassen A, Cano S, Corderio P, Hazen A, Hirmand H, Kosowski T, McCarthy C, Rubin L, Stotland M, Van Laeken N, Wilkins EG. Measuring Satisfaction with Facial Appearance. Plastic Surgery Education Foundation Directed-Research Grant. Awarded Jan 2007.

Quantitative Phase: Pusic A, Klassen A, Cano S, Corderio P, Patel S, Shah J. Measuring Patient Satisfaction with Facial Appearance. Plastic Surgery Education Foundation/American Association of Otolaryngology Combined PSEF/AAO-HNSF Research. Awarded July 2006.

11. Publications Related to FACE-Q Development and Validation

- 1. Kosowski TR, McCarthy C, Reavey PL, Scott AM, Wilkins EG, Cano SJ, Klassen AF, Carr N, Cordeiro PG, Pusic AL. A systematic review of patient-reported outcome measures after facial cosmetic surgery and/or nonsurgical facial rejuvenation. Plast Reconstr Surg. 2009 Jun;123(6):1819-27.
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