FACE-Q® | CRANIOFACIAL

A User's Guide for Researchers and Clinicians

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1. What is FACE-Q | Craniofacial?

The FACE-Q is a rigorously developed patient-reported outcome (PRO) measure that can be used to collect and compare evidence-based outcomes data from patients aged 8 to 29 years of age with a visible and/or functional facial difference. For patients with facial paralysis, there is no upper age limit. FACE-Q is composed of 27 independently functioning scales/checklists that measure 4 overarching domains: appearance, facial function, health-related quality of life (HRQOL), and adverse effects of treatment. These domains form the basis of the FACE-Q conceptual framework (Figure 1). The use of a modular approach means that only the subset of scales/checklists most relevant to a specific research objective or clinical patient population needs to be administered.

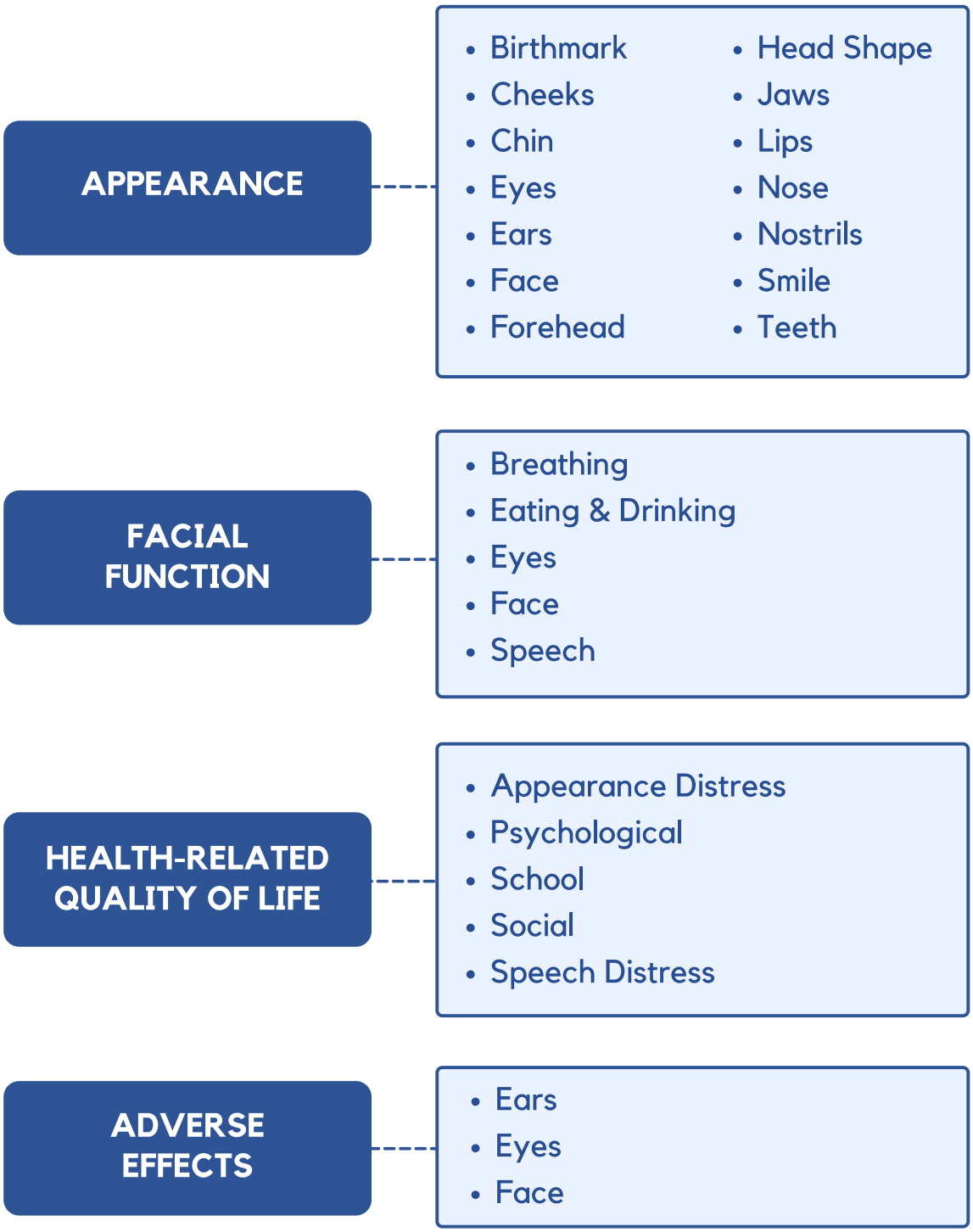
2. How was the FACE-Q | Craniofacial Developed and Validated?

The FACE-Q represents a new generation of PRO instruments developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PRO measure 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.

We followed internationally recommended guidelines for PRO measure development to create the FACE-Q. Figure 2 shows the multiphase mixed methods approach used by our team [1]. Briefly, after developing the CLEFT-Q© [2-9], to address noncleft craniofacial conditions, we interviewed 84 patients aged 8 to 29 years with 28 different congenital and acquired conditions (e.g., microtia, facial paralysis, craniosynostosis, craniofacial microsomia) [10-11]. This qualitative study provided evidence to support the use of the original content from the CLEFT-Q with patients with noncleft craniofacial conditions. The research also identified the need for additional scales to measure constructs not covered by the CLEFT-Q. Our team used the qualitative data to design new scales measuring additional aspects of appearance, facial function, and HRQOL. Figure 1 shows the full set of FACE-Q scales.

In phase 2, field-test data were collected in multiple countries between December 2016 and December 2019. The full field-test sample included 2233 patients aged 8 to 29 years with a broad range of conditions associated with a visible and/or functional facial difference (see Table 1). RMT analysis was used to examine reliability and validity of the scales. The findings are reported in 2 separate publications [12-13].

Figure 1: FACE-Q Craniofacial Conceptual Framework



In the first publication, Differential Item Functioning (DIF) was conducted to determine if the *original* CLEFT-Q scales function the same in cleft and noncleft facial conditions [12]. DIF was found to have negligible impact on scale scoring. In the combined sample of 4743 patients with cleft and noncleft conditions, RMT analysis led to retention of the original content for 10 CLEFT-Q scales, modification of the Teeth scale, and the addition of an Eating/Drinking scale that replaced the CLEFT-Q Eating/Drinking checklist. Table 1 shows the characteristics of the combined sample included in the RMT analysis.

In the second publication, the RMT analysis for the *new* FACE-Q scales not covered by the CLEFT-Q provided evidence for the reliability and validity of 7 appearance scales (Birthmark, Cheeks, Chin, Eyes, Forehead, Head Shape, and Smile), 2 function scales (Breathing and Facial), and an Appearance Distress scale [13]. Table 1 shows the characteristics of the sample of 1495 participants with craniofacial conditions included in the RMT analysis for the new scales.

Figure 2: The multiphase mixed methods approach our team follows to develop a patient-reported outcome instrument. (Reprinted from Wong Riff KW, et al.) International multiphase mixed methods study protocol to develop a cross-cultural patient-reported outcome instrument for children and young adults with cleft lip and/or palate (CLEFT-Q). BMJ Open 2017;7(1):015467.

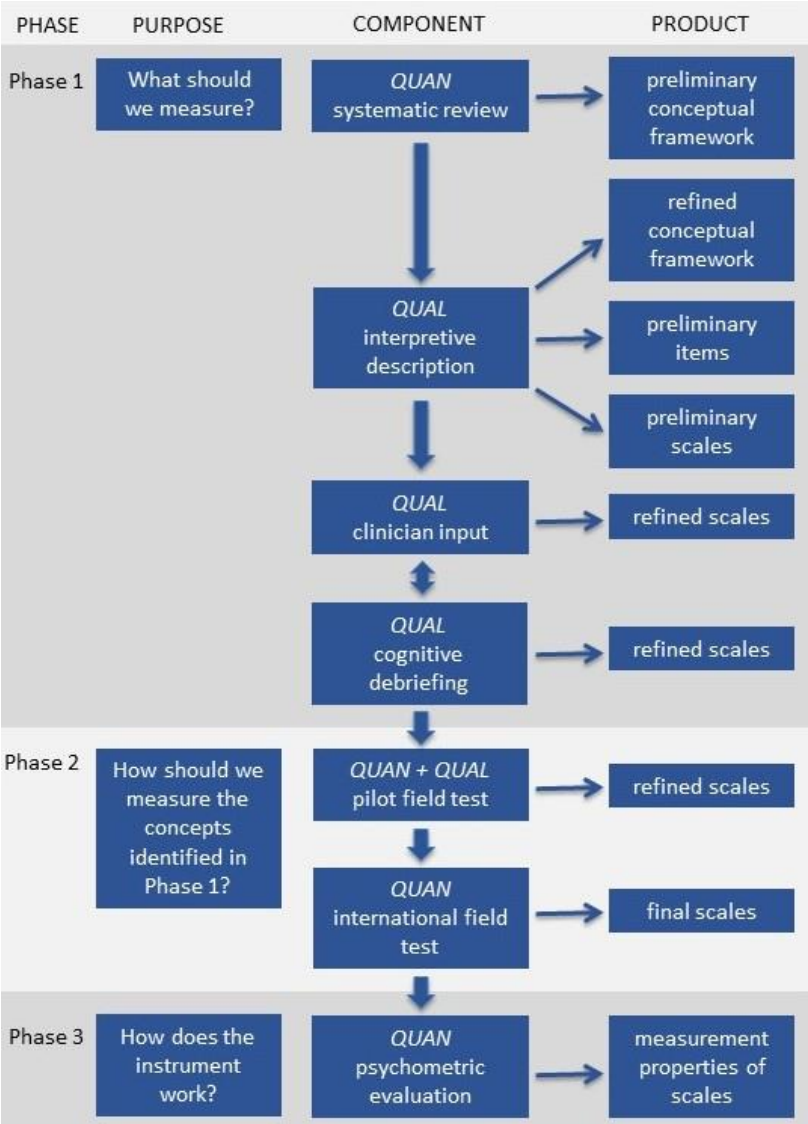


Table 1: Characteristics of participants included in the RMT analyses

		CLEFT-Q scales, N=4743 [12]		FACE-Q scales, N=1495 [13]		FACE-Q sample, N=2233	
		N	%	N	%	N	%
Country	Australia	63	1.3	38	2.5	39	1.7
	Brazil	178	3.8	178	11.9	178	8.0
	Canada	1550	32.7	828	55.4	939	42.0
	Chile	96	2.0	7	0.5	7	0.3
	China	360	7.6	-	-	361	16.2
	Columbia	210	4.4	-	-	-	-
	France	21	0.4	6	0.4	21	0.9
	India	232	4.9	-	-	-	-
	Ireland	213	4.5	113	7.5	113	5.1
	Netherlands	246	5.2	-	-	40	1.8
	Spain	121	2.6	-	-	28	1.3
	Sweden	100	2.1	13	0.9	13	0.6
	Turkey	54	1.1	-	-	-	-
	United Kingdom	756	15.9	185	12.4	350	15.7
	United States	540	11.4	126	8.4	141	6.3
	Other	3	0.1	1	0.1	3	0.1
Language	Chinese	360	7.6	-	-	361	16.1
	English	3132	66.0	1291	86.3	1585	71.0
	Dutch	246	5.2	-	-	40	1.8
	French	21	0.4	6	0.4	21	0.9
	Hindi	232	4.9	-	-	-	-
	Portuguese	178	3.7	178	11.9	178	8.0
	Spanish	420	8.9	7	0.5	35	1.6
	Swedish	100	2.1	13	0.9	13	0.6
	Turkey	54	1.1	-	-	-	-
Age in years	8-10	1216	25.6	335	22.4	526	23.5
	11-13	1148	24.2	355	23.7	607	27.2
	14-17	1293	27.3	429	28.7	614	27.5
	18-29	1085	22.9	376	25.2	486	21.8
	Missing	1	0	-	-	-	-
Gender	Male	2521	53.2	655	43.8	1103	49.4
	Female	2216	46.7	835	55.9	1125	50.4
	Other	3	0.1	4	0.3	4	0.2
	Missing	3	0.1	1	0.1	1	0.0
Main condition	***Birthmark***						
	Congenital melanocytic naevus	39	0.8	44	2.9	44	2.0
	Haemangioma	66	1.4	73	4.9	73	3.3
	Sebaceous naevus	17	0.4	18	1.2	18	0.8
	Vascular malformation	76	1.6	142	9.5	142	6.4
	Birthmark other	4	0.1	4	0.3	5	0.2
	Cleft						
	Cleft lip	272	5.7	-	-	-	-
	Cleft palate	570	12	-	-	-	-
	Cleft lip and palate	1539	32.4	-	-	-	-

	Cleft lip and alveolus	228	4.8	-	-	-	-
	Cleft - type not specified	2	0	-	-	-	-
	Ear condition						
	Microtia	549	11.6	45	3.0	552	24.7
	Prominent ears	146	3.1	37	2.5	146	6.5
	Ear other	34	0.7	10	0.7	34	1.5
	Skeletal						
	Acquired skeletal	55	1.2	55	3.7	55	2.5
	Craniofacial microsomia	79	1.7	78	5.2	80	3.6
	Craniofrontonasal condition	27	0.6	27	1.8	27	1.2
	Craniosynostosis non-syndromic	168	3.5	175	11.7	175	7.8
	Craniosynostosis syndromic	105	2.2	111	7.4	111	5.0
	Fibrous dysplasia	30	0.6	30	2.0	30	1.3
	Mandibular condition	39	0.8	39	2.6	39	1.7
	Multiple bony anomalies	19	0.9	19	1.3	19	0.9
	Post-traumatic bony defect	42	0.3	42	2.8	42	1.9
	Other congenital skeletal	21	0.4	21	1.4	21	0.9
	Soft tissue						
	Acquired soft tissue	30	0.6	30	2.0	30	1.3
	Congenital soft tissue	14	0.3	15	1.0	15	0.7
	Neurofibromatosis type 1	31	0.7	31	2.1	31	1.4
	Parry-Romberg Syndrome	44	0.9	44	2.9	44	2.0
	Soft tissue other	15	0.3	15	1.0	15	0.7
	Trauma						
	Bite	10	0.2	10	0.7	10	0.4
	Fracture	71	1.5	71	4.7	72	3.2
	Laceration	13	0.3	12	0.8	13	0.6
	Burn	20	0.4	20	1.3	20	0.9
	Trauma other	23	0.5	24	1.6	24	1.1
	Other condition						
	Cancer	87	1.8	16	1.1	87	3.9
	Facial paralysis	58	3.2	57	3.8	59	2.6
	Facial paralysis/cancer	25	0.5	6	0.4	25	1.1
	Orthodontic	153	3.2	153	10.2	153	6.9
	Other syndrome	22	0.5	21	1.4	22	1.0

NOTE: For ear conditions, 137 participants had a different craniofacial condition as their main condition. The total number of patients with an ear condition in the field-test sample was 869 (609 microtia, 149 prominent ears, and 111 other). Of these, 6 participants with ear conditions (2 microtia and 4 prominent ears) were excluded from the EAR-Q psychometric publication [14] that reported on 863 participants with ear conditions (607 microtia, 145 prominent ears, and 111 other) because they did not complete the ear-specific scales.

3. FACE-Q | Craniofacial and EAR-Q©

The EAR-Q [14-16] includes 2 ear-specific scales field-tested in the FACE-Q field-test study. These scales measure the appearance of the ears (e.g., size, shape, in photos) and adverse effects (e.g., itchy, painful, numb). There are also 3 single (i.e., stand-alone) items that ask about how the ear scars look and feel, and how hearing aids look. The content for these scales was developed from interviews with 25 patients with microtia (n=14), prominent ears (n=9), or other ear conditions (n=2), and refined with patient and expert input [15]. Data collection took place as part of the FACE-Q field-test study that involved 863 participants: 607 with microtia, 145 with prominent ears, and 111 with another ear condition. The sample provided 960 assessments for the Appearance scale and 137 assessments for the Adverse Effects scale. The RMT analysis provided evidence of scale reliability and validity [14]. The EAR-Q also includes 3 HRQOL scales that were developed as part of the CLEFT-Q [1-9]. These scales evidenced content validity for use in children and young adults with a broad range of craniofacial conditions [10-11]. RMT analysis was performed on a combined sample of 4743 participants with cleft and noncleft craniofacial conditions, including 863 participants with ear conditions [12]. The EAR-Q also includes an Appearance-Related Distress scale that was field-tested in the FACE-Q study with 1495 participants, of whom 223 had an ear condition [13]. More information about the EAR-Q is available in the EAR-Q User's Guide and psychometric publications [14-16].

4. FACE-Q | Craniofacial and FACE-Q | Paralysis

Our findings support the use of a subset of FACE-Q scales/checklists for children aged 8 years and older and adults of any age with facial paralysis. Relevant scales measure appearance (Eyes, Face, Forehead, Lips, Smile), function (Breathing, Eating, Eyes, Facial, Speech), adverse effects (Eyes, Face), and HRQOL (Appearance Distress, Psychological, Social, School, Speech Distress). Briefly, to establish content validity for adult facial paralysis, we combined phase 1 qualitative data from 11 children from the FACE-Q qualitative study [10-11] and 14 adults [17] from a separate study to identify concepts and common themes across age. We reported that many of the concerns expressed by participants were common across the two study samples [18]. In a sample of 235 participants aged 8 to 81 years with facial paralysis, scales relevant to facial paralysis were analyzed using RMT analysis. The findings provided evidence of reliability and validity for the FACE-Q scales in both children and adults with facial paralysis [18]. More information is provided in the FACE-Q | Paralysis User's Guide and psychometric publication [18].

5. FACE-Q | Craniofacial and FACE-Q | Dental

Our findings support the use of a subset of FACE-Q scales for children and young adults aged 8 to 29 years having orthodontic treatment for dental malocclusions. Relevant scales measure appearance (Jaws, Teeth, Smile, Face), function (Eating/Drinking), and HRQOL

(Appearance Distress, Psychological, Social, School, Speech Distress). To establish content validity, we performed a phase 1 cognitive interviewing study involving 15 orthodontic patients with a range of malocclusions traits (e.g., crossbite, crowding, microdontia, overbite, overjet, spacing issues, etc.) [19]. Scales were also shown to 21 clinical experts for feedback. The FACE-Q field-test sample included 153 patients undergoing orthodontic treatment. A psychometric analysis of the performance of these scales in an independent sample of orthodontic patients is forthcoming.

6. Can FACE-Q | Craniofacial be Used in Pediatric Cancer?

Our findings support the use of FACE-Q in children and young adults aged 8 to 29 years whose pediatric cancer and/or its treatment has caused an appearance and/or functional facial difference. To establish content validity, we performed a phase 1 cognitive interviewing study [20]. Six core scales (Face Appearance, Adverse Treatment Effects, Appearance Distress, Psychological, School, and Social) were reviewed by 15 child and young adult childhood cancer survivors. Additional scales were reviewed if applicable to participants based on their facial difference. A sample of 21 experts provided feedback on the full module (except for the Birthmark scale). Feedback showed the core scales were comprehendible, comprehensive, and relevant to participants. The FACE-Q field-test included 73 children (8-17 years of age) and 39 young adults (18-29 years of age) with a history of pediatric head and neck cancer [12-13].

7. FACE-Q | Craniofacial Scales

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

APPEARANCE

Birthmark: This 8-item scale measures how much (not at all, a little bit, quite a bit, very much) someone is bothered by the appearance of a birthmark. This scale can be used to evaluate birthmarks anywhere on the body or face. Items ask about the birthmark's shape, color, size, how it feels to the touch, and how it looks up close.

Cheeks: This 9-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their cheeks look. Items ask about the cheeks in terms of their size, fullness and shape, as well as how they look from the side and in photos.

Chin: This 9-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their chin looks. Items ask about the chin in terms of shape, width and size, as well as how the chin looks from the side, in photos, and when they smile.

Ears: This 10-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their ears look. Items ask about ears in terms of their shape and size, as well as how they look in photos, from the side, and when they wear a hat. In addition to the scale, there are three stand-alone items that can be used to ask how scars after ear surgery look and feel and how hearing aids look.

Table 2: Description of FACE-Q | Craniofacial scales/checklists

Name of scale	Items	Age	Response options	Recall	Scoring	FK
Appearance						
Birthmark	8	8-29	not at all → very much	now	0-100	2.8
Cheeks	9	8-29	not at all → very much	now	0-100	0.0
Chin	9	8-29	not at all → very much	now	0-100	0.4
Ears	10	8-29	not at all → very much	now	0-100	1.3
Eyes	9	8-29	not at all → very much	now	0-100	2.8
Face*	9	8-29	not at all → very much	now	0-100	0.7
Forehead	10	8-29	not at all → very much	now	0-100	3.2
Head Shape	6	8-29	not at all → very much	now	0-100	1.8
Jaws*	7	12-29	not at all → very much	now	0-100	0.3
Lips*	9	8-29	not at all → very much	now	0-100	0.1
Nose*	12	8-29	not at all → very much	now	0-100	0.8
Nostrils*	6	8-29	not at all → very much	now	0-100	1.2
Smile	9	8-29	not at all → very much	now	0-100	0.9
Teeth**	12	8-29	not at all → very much	now	0-100	0.5
Function						
Breathing	7	8-29	always → never	1 week	0-100	0.1
Eating/Drinking**	9	8-29	always → never	1 week	0-100	1.5
Eyes	7	8-29	not at all → very much	1 week	checklist	5.5
Facial	10	8-29	cannot do → can do	1 week	0-100	3.6
Speech*	12	8-29	always → never	1 week	0-100	2.9
Health-Related Quality of Life						
Appearance Distress	8	8-29	always → never	1 week	0-100	3.2
Psychological*	10	8-29	always → never	1 week	0-100	2.2
School*	10	8-18	always → never	1 week	0-100	1.9
Social*	10	8-29	always → never	1 week	0-100	1.8
Speech Distress*	10	8-29	always → never	1 week	0-100	2.5
Adverse Effects						
Ears	10	8-29	not at all → a lot	1 week	0-100	2.0
Eyes	7	8-29	not at all → very much	1 week	checklist	2.0
Face	10	8-29	not at all → very much	1 week	checklist	1.4

*CLEFT-Q scales that can be used to measure outcomes for noncleft craniofacial conditions;
**FACE-Q Teeth and Eating/Drinking differ in content and scoring from the CLEFT-Q versions.

Eyes: This 9-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their eyes and eyelids look. Items ask about the shape and size of the eyes, how the eyes look in photos, as well as how open and even the eyelids look.

Face: This 9-item scale measures how much (not at all, a little, quite a bit, very much) someone likes how their face looks. Items ask about how the face looks in photos, from the side, as well as the shape of the face and how the face looks up close.

Forehead: This 10-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their forehead and eyebrows look. Items ask about the position of the eyebrows, the height and shape of the forehead, as well as how it looks from the side and when the hair is wet or pulled back.

Head Shape: This 6-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes the shape of their head. Items ask about how the shape of their head looks in photos, from the side, in the mirror, and when the hair is wet.

Jaws: This 7-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their jaws look. Items ask about the shape and size of the jaws, how the jaws look in photos, and from the side.

Lips: This 9-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their lips look. Items ask about the shape, size, and fullness of the lips, as well as how their lips look when they smile and up close.

Nose: This 12-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their nose looks. Items ask about the size, shape and length of the nose, as well as how the nose looks in photos, from the side, and when they smile.

Nostrils: This 6-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their nostrils look. Items ask about the size, shape, and width of the nostrils.

Smile: This 9-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their smile looks. Items ask about their smile in terms of how it looks in the mirror, in photos, how big (wide) their smile looks, and how even it looks.

Teeth: This 12-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their teeth look. Items ask about their size, shape, how they line up, how close together they are, how they look in photos, from the side, and when they smile.

FUNCTION

Breathing: This 7-item scale measures how hard it is to breathe in terms of frequency (always, sometimes, never) and in the past week. Items ask about breathing through the nose and mouth, as well as during exercise, sleep, and when eating.

Eating/Drinking: This 9-item scale asks about problems with eating and drinking in terms of frequency (always, sometimes, never) and in the past week. Items ask about avoiding certain foods, eating slowly, as well as having trouble biting and chewing some foods.

Eyes: This 7-point checklist measures problems with eye function in terms of severity (not at all, a little, quite a bit, very much) and in the past week. Items ask about blinking, opening and closing the eyelids all the way, as well as keeping the eyes closed during sleep and vision problems.

Facial: This 10-item scale measures problems with facial movements (cannot do, have some trouble doing, can do) and in the past week. Items ask about having trouble with smiling, eating/drinking, blowing, frowning, and speaking.

Speech: This 12-item scale measures how often (never, sometimes, always) in the past week someone has trouble speaking. Items ask about reading out loud, trouble with specific words or sentences, and the need to use strategies such as speaking slowly or needing to concentrate to speak well.

HEALTH-RELATED QUALITY OF LIFE

Appearance Distress: This 8-item scale measures psychosocial distress caused by appearance in general in terms of frequency (always, sometimes, never) and in the past week. Items ask about social issues (going out, meeting people, covering up) and psychological issues (feeling unhappy or self-conscious about appearance).

Psychological: This 10-item scale measures psychological function in terms of frequency (never, sometimes, often, always) and in the past week. Items are positively worded and ask about self-esteem (e.g., I like myself), body image (e.g., I feel good about how I look), and confidence.

School: This 10-item scale measures social function at school in terms of frequency (never, sometimes, often, always) and in the past week. Items are positively worded and ask about seeing friends at school, feeling safe (not bullied), fitting in, and liking school.

Social: This 10-item scale measures social function in terms of frequency (never, sometimes, often, always) and in the past week. Items are positively worded and ask about having fun with friends, feeling accepted by friends, fitting in, and feeling the same as other people.

Speech Distress: This 10-item scale measures how someone feels about speaking in terms of frequency (always, sometimes, never) and in the past week. Items ask about nervousness, frustration, teasing, embarrassment, and the ability to be understood.

ADVERSE EFFECTS

Ears: This 10-item scale measures how ears feel after surgery. Items ask (not at all, a little, a lot) whether the ears in the past week hurt, felt itchy, were puffy or swollen, felt numb, or were tingly.

Eyes: This 7-item checklist measures how eyes feel in terms of severity (not at all, a little bit, quite a bit, very much) and in the past week. Items ask if their eyes feel itchy, sore, dry and if they twitch or water too much.

Face: This 10-item checklist measures how the face feels in terms of severity (not at all, a little bit, quite a bit, very much) and in the past week. Items ask if the face feels sore, tingly, sensitive, itchy, numb, tight, or firm.

8. Administration of the FACE-Q | Craniofacial

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. Brief instructions and the timeframe for reporting are provided at the start of each scale. FACE-Q was field-tested using two modes of data collection, i.e., online data collection using Research Electronic Data Capture System (REDCap) and 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 and require an e-conversion review and certificate, please email qportfolioteam@gmail.com.

9. Scoring FACE-Q | Craniofacial

There is no overall or total FACE-Q score. The FACE-Q is composed of independently functioning scales, checklists, and stand-alone items (see Table 2).

To score a scale, 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, for each missing item, insert the mean of the completed items prior to computing the total raw score. The total raw score for the scale is then converted to a score that ranges from 0 to 100. The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for FACE-Q scales reflect a better outcome. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

To score a checklist, 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 Rasch analysis for the 3 checklists, they can provide clinically important information, such as monitoring for post-operative complications.

FACE-Q has 3 stand-alone (i.e., single) items. These items ask about how ear scars after surgery look and feel and how hearing aids look. To score single items, the raw score can be used to provide descriptive information about the patient or sample. There is no Conversion Table for the stand-alone items.

10. Conditions of Use

The use of the FACE-Q requires completion of a licensing agreement. The use of the FACE-Q 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, contract research organizations, ePRO companies) is subject to a licensing fee.

To obtain a license to use the FACE-Q, please use the following link:

https://research.mcmaster.ca/industry-and-investors/technologies-available-for-licensing/questionnaire-request-form/

For questions regarding a FACE-Q license, please contact:

Licensing Assistant
McMaster Industry Liaison Office (MILO)
McMaster Innovation Park, Suite 305
175 Longwood Rd S, Hamilton ON L8P 0A1
milo@mcmaster.ca

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 to anyone**
- **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, please contact either:

Karen Wong Riff, MD PhD
Hospital for Sick Children
Toronto, Ontario
Canada
karenw.wong@sickkids.ca

Anne Klassen, DPhil (Oxon)
McMaster University
Hamilton, Ontario
Canada
aklass@mcmaster.ca

11. Frequently Asked Questions

Which FACE-Q | Craniofacial scales are in the International Consortium for Health Outcome Measurement (ICHOM) standard sets?

A number of FACE-Q and CLEFT-Q scales are included in the pediatric ICHOM standard sets for cleft lip and/or palate, craniofacial microsomia, and facial paralysis. More information about these ICHOM standard sets is available on the ICHOM website:

https://www.ichom.org/standard-sets/

To use the FACE-Q as part of an ICHOM standard set, you must sign a licensing agreement. To obtain a license, please use the following link:

https://research.mcmaster.ca/industry-and-investors/technologies-available-for-licensing/questionnaire-request-form/

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

You cannot 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 | Craniofacial 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 that can be used in a publication are shown in Table 3 below. The short forms are from the psychometric publications that describe the FACE-Q field-test study [12-13].

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

Yes, with permission, you can translate the FACE-Q 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 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 | Craniofacial?

Use of FACE-Q scales is free to non-profit users, including use by hospitals. For-profit users should contact McMaster University for information about fees: milo@mcmaster.ca.

12. Acknowledgements

Development of the FACE-Q has involved more than 2000 children and young adults with craniofacial conditions, along with the collaboration of numerous health care professionals and researchers around the world. We are truly grateful for their dedication and help with our research. The FACE-Q study has been generously funded by the following grants:

Phase I: Qualitative

Klassen A, Wong K, Forrest C, Davidge K, Borschell G, Zuker R, Giglia L, Pusic A. Development of the FACE-Q Kids PRO Instrument. The Plastic Surgery Foundation, May 2015 – April 2016.

Phase II: International Field-Test

Klassen A, Wong K, Forrest C, Pusic A. An International Study to Develop a Patient-Reported Outcome Instrument for Conditions Associated with a Facial Difference: FACE-Q Kids, Canadian Institutes of Health Research (FRN 148779), July 2016 – June 2018.

Table 3: Shortened items for FACE-Q scales/checklists to use in a publication

BIRTHMARK	even	laugh	smile	**SPEECH DISTRESS**	speak clearly
shape	shape	mirror	line up	go out	smile fully
color	match	closed	compared	make friends	**SPEECH**
feel	lids open	shape	**APPEAR DISTRESS**	teased	family
difference	lids even	full	going out	frustrated	friends
surface	**FACE**	up close	mirror	embarrassed	read aloud
size	look best	**NOSE**	cover up	avoid	some sentences
noticeable	go out	length	meet people	nervous	avoid
up close	shape	smile	unhappy	worry	phone
CHEEKS	photos	middle	dislike	repeat	new people
cheekbones	match	size	people stare	understood	try hard
mirror	smile	photo	self-conscious	**BREATHING**	repeat
shape	laugh	straight	**PSYCHOLOGICAL**	eat	speak slow
smile	profile	width	happy with life	mouth	concentrate
size	up close	mirror	enjoy life	one side	some words
full	**FOREHEAD**	shape	feel happy	sleep	**AE EARS**
profile	position eyebrows	tip	feel okay	exercise	blood
photos	hairline	profile	believe in self	nose	tingly
match	match	match	proud of self	snore	active
CHIN	shape	**NOSTRILS**	like self	**EATING/DRINKING**	bruised
shape	profile	smile	feel confident	food falls	discolored
bottom	height	mirror	feel great	liquid spills	puffy
smile	frown	size	good look	straw	numb
mirror	smooth	width	**SCHOOL**	open mouth	sleep
photos	wet hair	photo	seeing friends	avoid foods	itchy
size	lift eyebrows	shape	teachers	trouble biting	sensitive
width	**HEAD SHAPE**	**SMILE**	accepted	chew	**AE EYES**
other people	mirror	expresses	liked	small bits	twitch
profile	photos	mirror	happy	eat slow	sore
EARS	wet hair	wide	nice to me	**EYES**	itchy
far away	profile	shape	listen to me	unexpectedly	whites
shape	match	even	safe	open	feels
size	other people	straight	make friends	blink	water
wet hair	smooth	photo	join activities	see	dry
top part	**JAWS**	teeth	**SOCIAL**	close	**AE FACE**
photos	size	other people	friends accept	sleep	bruised
profile	shape	**TEETH**	fun friends	one better	sore
hat on	mirror	size	people listen	**FACIAL**	tingly
up close	photo	close together	treat same	smile spontaneously	sensitive
other people	closed	room	like being with	eat/drink	itchy
far away	smile	shape	confident out	open/close mouth	numb
EYES	profile	gum/teeth	fit in	blow	puffy
suit	**LIPS**	photos	make friends	face moves	uncomfortable
size	smile	profile	same others	frown	tight
photos	size	straight	people look	open/close eyes	firm
smile	photo	top/bottom		raise eyebrows	

13. Publications

1. Wong Riff KW, Tsangaris E, Goodacre T, Forrest CR, Pusic AL, Cano SJ, Klassen AF. International multiphase mixed methods study protocol to develop a cross-cultural patient-reported outcome instrument for children and young adults with cleft lip and/or palate (CLEFT-Q). BMJ Open. 2017 Jan 11;7(1):e015467.
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10. Longmire NM, Wong Riff KWY, Bhoomika P, O'Hara J, Goodacre TEE, Forrest C, Klassen AF. Development of a new module of the FACE-Q for children and young adults with diverse conditions associated with visible and/or functional facial differences. Facial Plast Surg. 2017 Oct;33(5):499-508.

11. Kamran R, Longmire NM, Rae C, Riff KWYW, Forrest CR, O'Hara J, Bulstrode N, Klassen AF. Concepts Important to Patients With Facial Differences: A Qualitative Study Informing a New Module of the FACE-Q for Children and Young Adults. Cleft Palate Craniofac J. 2021 Aug;58(8):1020-1031.

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