Measuring Patient-Reported Outcomes in Facial Aesthetic Patients: Development of the FACE-Q

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ABSTRACT

To support the development of new techniques and technology in facial aesthetics, sophisticated ways of measuring outcomes are needed. The objective of this study was to develop the content of a set of patient-reported outcome (PRO) scales for use with facial aesthetic patients. A literature review, patient interviews, and input from experts working with facial aesthetic patients were used to develop a conceptual framework for the outcomes deemed important to facial aesthetic patients and to construct items and a set of preliminary PRO scales. The conceptual framework includes the following themes: satisfaction with facial appearance; health-related quality of life; recovery, early life impact, and adverse effects; and satisfaction with process of care. Separate scales were developed for all parts of the face (e.g., nose, ears, forehead, cheeks, etc.) rather than for particular facial procedures. This new PRO instrument, called the FACE-Q, contains multiple independently scoreable scales with preoperative and postoperative versions. Once psychometric evaluation is completed, the FACE-Q will provide researchers and physicians with the necessary tools to measure the impact and effectiveness of facial aesthetic procedures from the patients' perspective. The FACE-Q has the potential to support advocacy, quality metrics, and an evidence-based approach to facial aesthetic practice.

KEYWORDS: Facial cosmetic surgery, aesthetic surgery, outcomes, quality of life, patient satisfaction, patient-reported outcomes, questionnaire, psychometrics, survey

In facial aesthetic surgery, new techniques and technology are rapidly evolving. At the same time, facial aesthetic patients are increasingly sophisticated consumers who seek meaningful data with which to make informed decisions. They desire valid and reliable information on outcomes when selecting both procedures and physicians. It has thus never been more important for providers to measure rigorously and to report on patient satisfaction and quality of life after aesthetic procedures.

To support progress in facial aesthetics, sophisticated ways of measuring outcomes are needed. Conventional methods, such as the reporting of complications data or photo analysis, represent the health care provider

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perspective. Although these data remain important, they are no longer sufficient when considered alone. A more comprehensive approach involves capturing the patient perspective using questionnaires to measure important patient-reported outcomes.

Patient-reported outcomes (PROs) are any report of the status of a patient's condition that comes directly from the patient without interpretation by a clinician or anyone else.[1] PROs include concepts such as symptoms, satisfaction, and health-related quality of life (a multidimensional umbrella term that represents the patient's general perception of the effect of his or her condition on physical, psychological, and social aspects of life[1]). Understanding and measuring the patients' perspective of the outcome of treatment is especially important for aesthetic facial procedures, as it is the patients' perception of their facial appearance that providers seek to improve.

To appropriately capture PROs, well-defined, reliable, and valid instruments are needed.[2] Such instruments are typically made up of multiple scales that reflect the key aspects of a conceptual framework. This framework defines the concepts to be measured by the PRO instrument and is usually represented as a diagram that maps out the relationship between scales, their items, concepts, and domains (subconcepts).[1]

Identifying all the appropriate items and scales to include in a PRO instrument involves following a stepwise protocol.[1,3] This includes a systematic literature review to identify important themes for any particular patient group, in-depth qualitative interviewing with the patient population, and expert input from health care professionals that work with the patient population. These three sources of information can provide a comprehensive understanding of the important issues for patients and can inform the development of items, domains, and concepts needed to measure PROs in different patient groups.

There are many areas of plastic surgery, dermatology, and otolaryngology where appropriately developed and tested PRO instruments do not exist. Through a systematic review of the literature, we have previously identified a lack of reliable and valid PRO instruments available for measuring the range of issues important to facial aesthetic patients.[4] Our group has now begun to address this issue.[5]

Following internationally accepted guidelines for the development of PRO instruments, we have developed a comprehensive set of scales to measure a range of outcomes that we have identified as being important to facial aesthetic patients. Taken together, these scales belong to a PRO instrument we have named the FACE-Q.[5] This new instrument will make it possible for clinicians and researchers to measure PROs across a wide range of facial aesthetic procedures (surgical and nonsurgical). In this article, we highlight the key steps that were taken to develop the content of the FACE-Q.

METHODS

To develop the content of a set of scales for use with facial aesthetic patients, our team has followed closely a set of recommended guidelines for PROs instrument development.[1,3] In essence, these guidelines describe three distinct phases for item generation, scale formation, and psychometric testing (see Table 1). In this article, we focus only on the first phase, which includes the steps needed to identify the key concepts and to construct items and preliminary scales to measure the concepts forming a conceptual framework. These steps involve the culmination of information from the following three sources:

1. The research literature to identify the key issues, concepts, and existing scales that other researchers have described as important to measurement of facial aesthetic outcomes.[5]
2. Patient viewpoints via in-depth qualitative interviews.

Table 1 Phases of PRO Measure Development

Phase I	A conceptual framework is developed and a pool of items is generated to ensure all important areas are considered for inclusion in the final scales. The conceptual framework and item pool are developed based on in-depth qualitative interviews with patients along with expert opinion and literature review. The item pool is then pretested on a sample of patients to clarify ambiguities in the wording of items, confirm appropriateness, and determine acceptability and completion time.
Phase II	Field testing is performed on a large sample of patients to determine the best items for inclusion in the final measure. Through psychometric evaluation of the field-test data, a lengthy draft questionnaire is converted into a shorter measure that retains only the best items for each of the questionnaire's scales. This ''item-reduction'' process completes the instrument development.
Phase III	Psychometric evaluation of the final measure is performed to understand and describe the strengths and limitations of the new PROs instrument. The PROs instrument, in its final form, is administered to a large population of patients, and tests are conducted to examine data quality, scaling assumptions, targeting, reliability, validity, and responsiveness.

Table 2 Interview Guide

Preoperation issues: timing; influence/opinion/perceptions of partner, friends, and/or family; reason for procedure; motivation; type of procedure chosen; information seeking; Internet; decision making.

Preoperation/postoperation perceptions: feelings going into the procedure; concerns about complications/surgery process; expectations for recovery process; preoperative expectations for results; immediate feelings after operation.

Postoperation symptoms: pain; itchiness; discomfort; fatigue; complications; numbness; swelling; tightness.

Functional ability and role performance: work and normal activities; work impact; ability to participate in sports/fitness/activities; change in level of comfort; energy and vitality.

Aesthetic outcome: facial appearance in general; details of the facial area that was altered; aging concerns.

Psychological well-being and self-concept: mood; confidence; emotional distress, self-consciousness; self-esteem; feelings of normalcy.

Relationships with others: reactions and support of friends, family, and others; difference in treatment or attitude; marital relationship; family relationships; avoidance behavior; confidence in social situations; interference in social activities.

Process of care: satisfaction with care; satisfaction with information (e.g., about healing and recovery); relationship with doctor; surgical setting; clinic; staff; follow-up care.

Expectations: fulfillment of expectations; willingness to repeat and/or recommend procedure; satisfaction with overall appearance; regrets; process better or worse than expected; outcome better or worse than expected.

3. Expert opinion via interviews with physicians, allied health professionals, and psychologists with substantial knowledge and experience in this area.

Literature Review

We have previously performed a systematic literature review to identify PRO instruments for facial cosmetic surgery and/or nonsurgical cosmetic procedures.[4] Our review identified that there are nine PRO instruments developed to measure aspects of patient satisfaction and quality of life after facial cosmetic surgery and nonsurgical facial rejuvenation, but only one that has demonstrated evidence of adequate formal development and validation. Our team used the findings from this systematic review (i.e., inspection of content of other measures) to inform the development of an interview guide for use in the qualitative interviews described below (see Table 2).

Patient Interviews

Prior to starting our study, approval was obtained from the necessary research ethics board at Memorial Sloan-Kettering Cancer Center and The University of British Columbia. Participants were recruited between January 2008 and February 2009 from plastic surgeons and dermatologists working in seven separate offices in New York (United States) and Vancouver (Canada). Interviews took place between January 2008 and February 2009. Potentially eligible participants were either approached by staff working within each participating office or sent a letter of invitation. The research team was notified of any patients interested in participating. These patients were contacted by telephone to set up a location and time for a face-to-face interview. Table 3 shows characteristics of participants.

Before conducting an interview, informed consent was obtained. All consenting patients participated in a semistructured in-person interview that lasted an average of 45 minutes (range, 30 to 90). Interviews began by asking the participant to "tell the story" of the cosmetic procedures they had undergone. Open-ended questions and probes were designed to encourage participants to discuss their feelings and experiences in depth, with a particular emphasis on describing perceived change in their facial appearance. All interviews were digitally

Table 3 Patient Characteristics

Characteristics	Initial Qualitative Interviews ($N=50$)	Cognitive Debriefing Interviews ($N=35$)
Age, years		
Mean	51	45
Range	20–79	20–68
Gender, *n* (%)		
Female	44 (88)	30 (86)
Male	6 (12)	5 (14)
Ethnicity, *n* (%)		
Caucasian	35 (70)	20 (59)
Other	14 (28)	15 (41)
Procedure type, *n* (%)		
Botulinum toxin	20 (40)	15 (43)
Resurfacing	15 (30)	10 (31)
Fillers	15 (30)	9 (26)
Surgery type, *n* (%)		
Blepharoplasty	25 (36)	19 (53)
Face-lift	22 (32)	13 (35)
Rhinoplasty	9 (13)	2 (6)
Neck lift	8 (11)	2 (6)
Brow lift	4 (6)	–
Chin implants	2 (2)	–

recorded and transcribed verbatim with any identifiable information excluded from interview transcripts.

Data collection and analysis took place concurrently, which allowed us to continually revise the interview guide and select new participants to gather data that elaborated and refined emerging categories. NVivo 8 software was used to manage the data. Analysis involved initial line-by-line coding by one member of the research team who applied codes to patient statements and used constant comparison to examine relationships within and across codes to develop a preliminary conceptual framework (see Fig. 1). Interviewing continued until no new themes emerged.

Once the data had been fully coded, potential scales representing the major concepts forming the conceptual model were developed by thematically grouping potential questionnaire items extracted from the coded material. In developing draft items for our field-test scales, we used the words of patients as much as possible to ensure that the items would resonate well with them. Once we had extracted an exhaustive list of items for each of our preliminary scales, we developed Likert scale scoring options for each scale.

Expert Opinion

Our preliminary scales were shown to 26 experts in the field. The sample of experts included 15 plastic surgeons, 4 dermatologists, 3 psychologists, and 4 office staff. Experts were asked to examine the preliminary scales and engage in either a telephone discussion or face-to-face meeting with one or more members of our research team. A total of 43 telephone conference calls and three meetings took place, with some experts engaged in more than one feedback session. Expert opinion helped to ensure that the scales we developed would be useful to clinicians and that all clinically relevant aspects of each concept were captured in the scales.

Figure 1 Satisfaction with facial areas scales.

Cognitive Debriefing Interviews

The preliminary set of scales was shown to 35 patients (12 patients from our initial interviews and 23 new patients identified through the same seven participating plastic surgery offices) in a series of one-on-one cognitive debriefing interviews (see Table 3 for sample characteristics). Findings from these interviews were used to understand how patients interpreted instructions, question stems, the items, and the response categories. Patients were asked to think aloud and describe their thought processes as they read the instructions and answered each question. We used findings from this process to clarify ambiguities in item wording, to confirm appropriateness, and to determine acceptability and completion time of the preliminary scales.

RESULTS

Our literature review, patient interviews, and expert opinion led us to develop a conceptual framework for PROs concepts that are important to facial aesthetic patients (Fig. 2). This led to the generation of clinically meaningful items and preliminary scales for each concept within the conceptual framework. Scales were developed for both preoperative and postoperative patients, with items in the preoperative scales repeated in postoperative scales along with some stand-alone postoperative-only questions (e.g., items about scars). The following are the main major concepts within our framework, for which we have developed one or more scales:

- Satisfaction with facial appearance
- Health-related quality of life
- Recovery, early life impact, and late negative sequelae
- Satisfaction with process of care.

Below we describe each of these concepts and illustrate with examples how the information collected in phase I was synthesized to develop items for scales included in our field-test instrument.

1. Satisfaction with Facial Appearance: Our sample included patients who had undergone a broad range of facial procedures for different facial anatomic areas. To address the challenge of developing meaningful measurement scales for patients undergoing different procedures, we took the approach of developing scales for all parts of the face rather than scales for particular facial procedures (see Fig. 1).

To provide an example of one such scale, we developed a Satisfaction with Nose scale. Though most of the items for this scale were developed from patient data, several items were suggested by an expert panel member who reviewed the scale and recognized that we were missing items asking about satisfaction with the tip

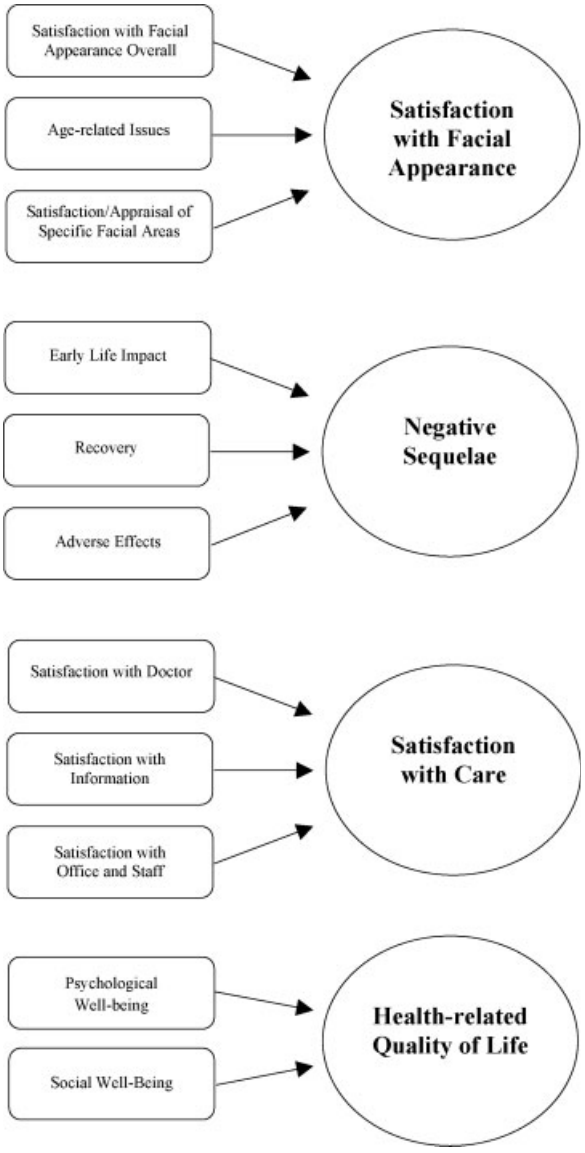

Figure 2 FACE-Q conceptual framework.

of the nose (when smiling or laughing) and about quality of the nose skin. Such items were developed and added by the team. In addition, cognitive debriefing interviews with patients led us to revise our instructions.

A key patient outcome scale in the FACE-Q is our Satisfaction with Facial Appearance Overall scale. This scale was developed to be relevant to all aesthetic facial patients regardless of the number or type of procedures undergone. Patient statements used to develop this scale were taken from statements about their overall facial appearance, such as the following quote from a face-lift patient:

"Yes I knew what I didn't want it to look like. I told them I wanted to look natural. Just take some of the wrinkles out."

We took "look natural" and developed this into the following item in our overall satisfaction with appearance scale: "How natural (not operated on) your face looks?" This scale includes other items such as: "How attractive your face looks," "How refreshed your face looks," "How your profile looks," and "How your face looks in photos."

We also developed a scale to capture age-related issues, given that the aim of many facial aesthetic procedures is to make the patient look younger. A common statement made by patients in our study was to describe a disconnection between what they look like (i.e., old) and how they feel inside (i.e., young). As a patient aged 65 who underwent a face-lift and blepharoplasty explained:

"If you feel young inside then you look in the mirror and you look all sleepy and old and horrible it's not a good thing."

To capture age-related issues, items such as the following were developed: "I'm bothered by how old I look," "In recent photos, I look older than I want to," and "I would be happier if I looked younger."

2. Health-Related Quality of Life: This concept relates to the way that patients described the impact of facial cosmetic procedures on their psychological and social well-being. Patients in all groups described how the change in their facial appearance after an aesthetic procedure had an impact on how they felt about themselves (e.g., higher self-esteem, happier).

In terms of social well-being, a common theme that patients described was to feel more confidence in social situations after treatment. This change was experienced at different levels of social interaction, from being more relaxed around friends and family to feeling comfortable and enjoying attention in group situations or with strangers. As an example, a rhinoplasty patient said the following:

"It's made me more confident. I think when people are more confident they tend to be a little happier. I'm more confident to go out and—not that I locked myself behind bars because of it, but you know it's definitely uplifted me in a sense that I'm more confident, so I'm happier. Totally more content with life."

Data such as this was used to develop items such as the following: "I feel confident in new social situations" and "I am relaxed around people that I don't know well."

3. Negative Sequelae: This theme relates to issues surrounding both recovery during the immediate postprocedure period as well as any longer-term adverse effects that result from treatment. Our Recovery and Early Life Impact scales were developed as scales that are applicable to any patient regardless of the procedure they had. Items included within these scales assess a range of recovery issues

(e.g., pain, swelling, itching, bruising) and early life impact (e.g., avoiding seeing people, difficulty eating or drinking, fatigue). Items within the adverse effects scale, on the other hand, are constructed for particular anatomic areas (e.g., separate scales for the nose, eyes, ears, cheek, and lower face).

4. Satisfaction with Process of Care: Satisfaction with the process of care was an important concept in patients' overall assessment of a procedure and formed an important concept in our conceptual framework. This theme was broad, and we identified several important subthemes within the data that resulted in the development of separate scales to measure satisfaction with information, satisfaction with the care provided by the physician, and satisfaction with the office staff and other members of the medical team. Patients' relationship with their physician, for example, was an important aspect of process of care. Patients talked about their relationship with their doctor, including the extent to which their doctor made them feel comfortable, was caring and reassuring, and understood what they wanted. For example, a rhinoplasty patient talked about their surgeon saying:

"He just made me feel very comfortable and literally from the beginning he made me—like I felt that he had—he shared the same vision of things that he wasn't like, you know, overzealous. And he really saw you rather than taking a cookie cutter nose that's—you know what I mean. So that was very exciting and reassuring to me."

These kinds of concerns were captured by items in our scale entitled Satisfaction with Doctor. More specifically, patients are asked to rate their level of agreement or disagreement with items like: "Made you feel comfortable?" and "Was not pushy or persuading?"

DISCUSSION

In an era of evidence-based medicine and increasingly savvy patient-consumers, high levels of evidence about surgical and nonsurgical techniques and devices is required. PRO data are essential to evaluating the benefits of new and existing treatments. However, the development of PRO instruments to measure concepts important to facial aesthetic patients presents a challenging task. This group represents a clinically heterogeneous population, involving all areas of the face and a wide range of potential treatments. Thus, there is no "typical" facial aesthetic patient, and interventions impact on domains covering the physical, psychosocial, and cosmetic. Sophisticated measurement techniques are therefore needed as this patient population may have different procedures at the same time or at different times adding a further complexity to measurement.

The FACE-Q that our team is developing represents a set of PRO scales for patients undergoing facial aesthetic procedures (both surgical and nonsurgical). Each scale is a stand-alone measure (i.e., scored separately), and therefore only those scales that are relevant to a particular patient and procedure(s) need be completed. As an example, as a minimum, a rhinoplasty patient might only complete the Satisfaction with Nose scale, but depending on the research or clinical question being asked might also complete the Satisfaction with Facial Appearance Overall scale and Negative Sequelae scales to assess early symptoms, early life impact, and adverse effects. This approach to selecting only a subset of scales can help reduce respondent burden and ensure that patients are only asked to complete scales that are relevant to them.

Developing a PRO instrument is a multiphased project.[1,3] Our team has now completed the development of phase I (item generation) and is proceeding with phase II (scale formation) and phase III (psychometric testing) (see Table 1). Once completed, the FACE-Q will provide researchers and clinicians with the necessary tools to measure both the impact and effectiveness of facial aesthetic procedures from the patients' perspective.

As evidence-based medicine is rapidly setting a standard for clinical decision-making among aesthetic patients, PRO data regarding patient satisfaction and quality of life will be essential to aesthetic surgeons and dermatologists. Such data will facilitate comparative effective research, inform discussions with regulatory bodies, and support an evidence-based approach to aesthetic surgery. In addition, PRO information can help inform the patients' decision-making process and may also play an important role in creating realistic expectations toward aesthetic outcomes (e.g., length of recovery, scarring). Routine collection of PRO data in a physician's individual practice can help to identify problems, facilitate communication, and direct appropriate treatment of underappreciated symptoms. For example, by using the FACE-Q, a physician may be able to directly and reliably measure patient satisfaction with his or her facial appearance before and after a face-lift. Collecting PRO data in clinical practice may also help a physician determine whether a dissatisfied patient is upset about the outcome of his or her procedure or some other aspect of his or her treatment experience (e.g., interactions with office staff). In doing so, clinicians may receive feedback from patients about the entire treatment experience and be able to tailor and improve specific aspects of their practices to optimize "customer satisfaction."

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