



***USERS' MANUAL***

***VERSION 1.0***

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## **1. Why did we develop the BODY-Q©?**

A limitation in the pursuit of evidence-based outcomes data for obesity, bariatric surgery/medicine and body contouring is the lack of a rigorously developed patient-reported outcome (PRO) instrument covering concerns common to obese, bariatric and body contouring patients. Research studies to date have primarily used generic, obesity-specific and/or body contouring-specific PRO instruments to measure outcomes. For example, bariatric research has primarily focused on outcomes related to weight loss, with little attention to the health-related quality of life (HRQL) changes associated with body contouring surgery to remove excess skin. If outcomes data are to be used to inform quality improvement, resource allocation decisions and patient education, well-defined, reliable, valid and responsive patient-reported outcome (PRO) instruments are needed. Such scales should be developed according to rigorous internationally promoted guidelines for PRO instruments development, and measure the concepts of interest (COI) that matter the most to patients.

## **2. What is the BODY-Q©?**

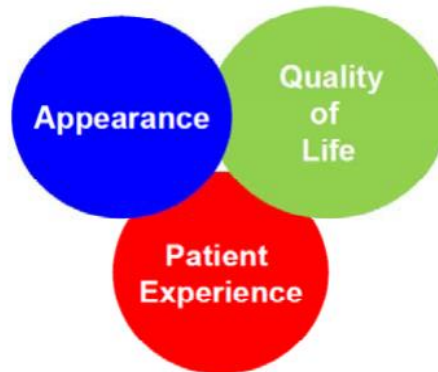
The BODY-Q© is a patient-reported outcome (PRO) instrument (also known as PROM) designed to evaluate outcomes for adult patients who are obese, undergo weight loss through diet, exercise and/or bariatric surgery/medicine, and body contouring patients (following massive weight loss or cosmetic reasons). The BODY-Q© is a self-report tool that should be answered independently by patients themselves, without interpretation by a health-care provider or anyone else. BODY-Q© scales measure appearance (of various body areas), HRQL, and the patient experience of care.

## **3. How was the BODY-Q© developed?**

BODY-Q© scales are based on an underlying conceptual framework developed from extensive qualitative interviews with weight loss and body contouring patients, close examination of the research literature, and engagement of healthcare professionals working with the patient population. Data collected from all three of these sources were used to formulate the BODY-Q© conceptual framework and set of scales. These scales were subsequently tested in a large-scale international field-test.

The conceptual framework of the BODY-Q© scales, presented below, is comprised of three overarching themes as follows: 1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience. Under these domains, there are 18 independently functioning scales that measure important COI. In addition to the 18 scales, there is 1 obesity-specific symptom checklist (see Table 1).

## The BODY-Q framework



**Table 1:** BODY-Q© scales including number of items, response options, time frame, grade reading level

Name of scale	Items	Response options	Recall period	FK grade
Abdomen	7	dissatisfied/ satisfied	past 2 weeks	3.1 (2.2-4.8)
Arms	7	dissatisfied/ satisfied	past 2 weeks	1.4 (0.5-5.2)
Back	4	dissatisfied/ satisfied	past 2 weeks	0 (0-3.9)
Body	10	dissatisfied/ satisfied	past 2 weeks	2.1 (0.5-3.7)
Buttocks	5	dissatisfied/ satisfied	past 2 weeks	1.2 (0.5-3.6)
Hips & Outer Thighs	5	dissatisfied/ satisfied	past 2 weeks	1.2 (0.8-2.3)
Inner thighs	4	dissatisfied/ satisfied	past 2 weeks	0.6 (0.5-1)
Skin	7	not at all/ extremely bothered	past 2 weeks	3.2 (0.5-6.7)
Scars*	10	not at all/ extremely bothered	past 2 weeks	1.2 (0-5.2)
Body Image	7	agree/ disagree	past 2 weeks	2.5 (0.5-6.4)
Physical**	7	all the time/never	past 2 weeks	2.7 (0.5-6.6)
Psychological	10	agree/ disagree	past 2 weeks	3.5 (0.5-9.5)
Sexual	5	agree/ disagree	n/a	5.3 (2.3-6.7)
Social	10	agree/ disagree	past 2 weeks	3.7 (1.0-8.3)
Symptoms**	10	all the time/never	past 2 weeks	2.8 (0.-9.1)
Doctor	10	agree/ disagree	n/a	4.2 (0.5-9.9)
Information	10	dissatisfied/ satisfied	n/a	5 (2.4-11.1)
Medical Team	10	agree/ disagree	n/a	3.6 (0.5-12)
Office Staff	10	agree/ disagree	n/a	3.9 (0.5-12)

\* Scale specific to post-body contouring patients. \*\*Specific to patients with obesity. FK = Flesch-Kincaid grade level.

Rasch Measurement Theory (RMT) a modern psychometric approach, was used to perform item reduction and psychometric validation on the field-test data. For each scale, we identified the subset of items that represent the best indicators of outcome. Decisions

were made about which items to retain on the basis of the results for a series of statistical and graphical tests (e.g., thresholds for item response options, item fit statistics, dependency, stability, targeting, person separation index, etc.) The results are described in full in our development paper [Klassen et al, forthcoming].

#### **4. BODY-Q© Appearance Scales**

**Satisfaction with abdomen:** This 7-item scale measures satisfaction with the appearance of the abdomen. Items ask about abdomen shape, size, how clothes fit, as well as how the abdomen looks inform the side, in a swimsuit and when naked.

**Satisfaction with upper arms:** This 7-item scale measures satisfaction with the appearance of the upper arms. Items ask about upper arm size, shape, skin, as well as how the upper arms look when lifted and when not covered.

**Satisfaction with back:** This 4-item scale measures satisfaction with the appearance of the back. Items ask the back in terms of how toned and smooth the back looks, as well as how the back looks from different angles and when naked.

**Satisfaction with body:** This 10-item scale measures satisfaction with the appearance of the body. Items ask about the body in terms of size, shape, how clothes fit, as well as how the body looks from the side, behind, in a swimsuit and when unclothed.

**Satisfaction with buttocks:** This 5-item scale measures satisfaction with the appearance of the buttocks. Items ask about the size, shape and skin, as well as from the side.

**Satisfaction with hips and outer thighs:** This 5-item scale measures satisfaction with the appearance of the hips and outer thighs. Items ask about size, shape, skin as well as how the hips and outer things look from behind.

**Inner thighs:** This 4-item scale measures satisfaction with the appearance of the inner thighs. Items ask how smooth and toned the inner thighs are, as well as the skin and how the inner things look when naked.

**Appraisal of scars:** This 10-item scale measures being bothered by the appearance of body contouring scars. Items ask about being bothered by the width, location, length and colour of the scars, as well as how noticeable they are and people seeing them.

**Appraisal of excess skin:** This 7-item scale measures being bothered by the appearance of excess skin. Items ask about the amount of skin, how it hangs, having to dress in a way to hide the skin, and how the skin looks when naked.

## **BODY-Q© Quality Of Life Scales**

**Psychological function:** 10-item scale measures psychological function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with feeling happy, feeling confident and feeling in control of his/her life, etc.

**Social function:** This 10-item scale measures social function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with feeling accepted by people, that they make a good first impression, feeling confident in a group situation, etc.

**Body image:** This 7-item scale measures body image. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with being proud of their body, happy with their body, and positive towards their body, etc.

**Sexual wellbeing:** This 7-item scale measures sexual function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with being satisfied with their sex life, comfort with the lights on during sex, and feeling sexually attractive when undressed, etc.

**Physical function:** This 7-item scales asks respondents to indicate how much they have a problem with various physical activities, including getting up from a bed, standing for long periods of time, and doing moderate exercise, etc.

**Physical symptoms related to obesity:** This 10-item checklist asks how often the respondent has experienced obesity-specific symptoms, including feeling tired during the day, back pain, shortness of breath with mild exercise, and excess perspiration, etc.

## **5. BODY-Q© Patient Experience Scales**

**Satisfaction with doctor:** This 10-item scale measures a patient's experience of care in terms of how they were treated by the doctor. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree that the doctor treated them with respect, made them feel comfortable, spent enough time with them, etc.

**Satisfaction with medical team:** This 10-item scale measures a patient experience of care in terms of how they were treated by members of the medical team. Items are positive in both content and phrasing and ask respondents to indicate how much they

agree/disagree that the medical team treated them with respect, were easy to talk to, worked together as a team, etc.

**Satisfaction with information:** This 10-item scale measures the patient experience of care in terms of satisfaction with the information. Items are positive in both content and phrasing and ask respondents to indicate how satisfied they are with information they received about activities to avoid during recovery, options for how the surgery could be done, the kinds of complications that could happen, etc.

**Satisfaction with office staff:** This 10-item scale measures the patient experience of care in terms of how they were treated by members of the office staff. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree that the office staff treated them with respect, were attentive to their needs, welcomed them at the front desk, etc.

### Administration of the BODY-Q©

The BODY-Q© is designed to be completed by patients aged 18 years and older. The entire BODY-Q© can be completed in about 20 minutes. Brief instructions are provided at the start of each scale. The BODY-Q© was field-tested in 734 patients from Canada, USA and UK. We tested two modes of data collection as follows: paper-and-pencil (N=339, 46 percent) and online (N=394, 53.4 percent). The online data were collected using Research Electronic Data Capture System (REDCap).

## **6. Scoring**

The BODY-Q© scales include four different response option sets as follows:

- 1) "Very dissatisfied," "Somewhat dissatisfied," "Somewhat satisfied," "Very satisfied"
- 2) "Extremely," "Moderately," "A little," "Not at all"
- 3) "Definitely disagree," "Somewhat disagree," "Somewhat agree," "Definitely agree."
- 4) "All the time," "Often," "Sometimes," "Never"

## **7. Interpretation**

All BODY-Q© scales are transformed into scores that range from 0-100. The scores are computed from the responses to the items by adding them together and converting the raw score to a scale from 0 to 100. A lookup table for this conversion is available.

## **8. Frequently Asked Questions**

***Do I have to use all the scales?***

Patients can be asked to complete some or all BODY-Q© scales. It is not necessary for a patient to complete all of the scales as there is no overall or total BODY-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 any items to the BODY-Q©?***

You cannot delete or add any items to the BODY-Q©. Any modification to the content of the BODY-Q© by deleting or adding any items within a scale is not acceptable. There are three main reasons why deleting or adding items is not allowed. The first is that deleting or adding items would nullify the psychometric properties of BODY-Q© scales. The second reason is that by deleting or adding items, it would then not be possible to score the BODY-Q© and you would not be able to compare findings with those of other BODY-Q© studies. Finally, adding or deleting items is prohibited under copyright laws.

***Can I change the wording of any item or response options in the BODY-Q©?***

No, you cannot change the wording of any items or response options in a BODY-Q© scale. Any modification to the content of the BODY-Q© by changing an item within a scale or the response options is not acceptable. There are three main reasons why changing items is not allowed. The first is that altering the wording of items or response options in the BODY-Q© would nullify the psychometric properties of BODY-Q© scales. The second reason is by modifying items or response options, it would then not be possible to score the BODY-Q© and you would not be able to compare findings with those of other BODY-Q© studies. Finally, changing the wording of items or response options is prohibited under copyright laws.

***Can I translate the BODY-Q© into a new language?***

For translation of the BODY-Q© scales we suggest you contact MAPI Research Trust <http://www.mapi-trust.org/> or [PROinformation@mapi-trust.org](mailto:PROinformation@mapi-trust.org). This organization can provide you with a current list of available languages of each module, and if a language is not available, the translation guidelines for linguistic validation and translation. Please note that the developers of the BODY-Q© won the copyright of any translation of the BODY-Q©. Current translations completed or in process included Danish, Swedish and Dutch.

***Are there specific time points when patients complete the scales?***

A researcher or clinician can decide the time points he/she would like to administer the scales.



***Is there an electronic version I can use, or can I code a version for online administration with my patients?***

A template file of the BODY-Q© for administration via the Research Electronic Data Capture (REDCap) portal is available. Please contact the authors for more information.

## **9. BODY-Q© Funding**

The BODY-Q© study has been generously funded by the following grants:

### **Phase I: Qualitative**

Pusic A, Cano S, Klassen A. Development and validation of a new patient-reported outcome measure for body contouring patients. National Endowment for Plastic Surgery, \$50,000 USD. 2009, Sept – 2010, Oct

### **Phase II and Phase III: International Field-test and Psychometric Statistical Study**

Klassen, Anne, Cano Stefan, Pusic Andrea, Taylor Valerie, Thoma Achilles, Developing a patient-reported outcome measure for bariatric and body contouring surgery patients: The Body-Q, Grant, Canadian Institutes of Health Research (CIHR), Research - New Project, \$100,000.00. 2012 Oct – 2016 March.

## **10. BODY-Q© Knowledge Translation and Exchange**

### **Journal articles**

1. Klassen AF, Cano SJ, Scott A, Tsangaris E, Pusic AL. Assessing Outcomes in Body Contouring. *Clinics in plastic surgery* 2014; 41(4): 645-654.
2. Klassen AF, Cano SJ, Schwitzer J, Pusic AL. Incorporating the patients' voice in outcomes assessment in cosmetic surgery: Using the BREAST-Q, FACE-Q AND BODY-Q. *Plastic Surgery Pulse News*. 2013; 5(3).  
[http://www.plasticsurgerypulsenews.com/16/article\\_dtl.php?QnCategoryID=152&QnArticleID=313](http://www.plasticsurgerypulsenews.com/16/article_dtl.php?QnCategoryID=152&QnArticleID=313)
3. Klassen AF, Cano SJ, Scott A, Johnson J, Pusic AL. Satisfaction and quality-of-life issues in body contouring surgery patients: a qualitative study. *Obesity surgery* 2012; 22(10): 1527-1534.
4. Reavey PL, Klassen AF, Cano SJ, McCarthy C, Scott A, Rubin JP, et al. Measuring quality of life and patient satisfaction after body contouring: a systematic review of

patient-reported outcome measures. *Aesthetic Surgery Journal* 2011; 31(7): 807-813.

### **Conference Presentations**

1. Klassen A, Alderman A, Soldin M, Robson S, Kaur M, Cano S, Thoma A, Pusic A. Development and Psychometric Validation of a PRO Instrument for Obese, Bariatric and Cosmetic Body Contouring Patients: The BODY-Q. International Society for Quality of Life Research conference. Vancouver, Canada, October 21-24, 2015. Oral Presentation.
2. Klassen A, Cano S, Scotta A, Pusic A. Measuring PROs that matter to bariatric and body contouring surgery: The Body-Q. *Value Health* (2013) 16(7): A386. ISPOR 16<sup>th</sup> Annual European Conference, Dublin Ireland 4th Nov 2013. Poster Presentation/Discussion.
3. Price A, Scott A, Pusic A, Cano S, Johnson J, Lawson J, Cordero P, Klassen A. The BODY-Q: A new patient-reported outcome (PRO) measure for body contouring patients. Canadian Society of Plastic Surgeons meeting June 5-9<sup>th</sup> 2012, Toronto. *Canadian Journal of Plastic Surgery* 20(2):133, 2012. Oral Presentation.
4. Scott A, Pusic A, Cano S, Johnson J, Lawson J, Cordero P, Klassen A,. The BODY-Q: A new patient-reported outcome (PRO) measure for body contouring patients. *Qual Life Res* (2012) 20;1:74. 18<sup>th</sup> Annual Conference of the International Society for Quality of Life Research, Oct 26-29<sup>th</sup> 2011, Denver (USA). Winner of best poster award.
5. Klassen A, Cano S, Pusic A. The BODY-Q: A new patient-reported outcome (PRO) measure for body contouring patients. British Association of Plastic Reconstructive and Aesthetic Surgery Conference, Oxford England July 2011. Oral presentation.

### **Invited Presentations**

1. Klassen AF. Development and Psychometric Validation of a PRO Instrument for Obese, Bariatric and Cosmetic Body Contouring Patients: The BODY-Q. Department of Plastic Surgery. St George's Healthcare NHS Trust, London England, 3 July 2015.
2. Klassen A, Pusic A. Measuring the patient perspective in aesthetics: Face-Q, Breast-Q and Body-Q. Presentation to USA Food and Drug Administration (FDA)/Center for Devices and Radiological Health (CDRH) pre-market review staff. Sept 12, 2014. Silver Spring MD, USA.

3. Klassen A, Development and Validation of New Patient-Reported Outcome Measure: The BODY-Q Field Test. St. George's Healthcare NHS Trust London, United Kingdom. Jun 2, 2014.
4. Klassen A. Q model for Patient Reported Outcomes Measures (PROMs). Presentation to the Clinical Quality and Outcomes Sub-Group of the Cosmetic Surgery Interspeciality Committee (CSIC) of the UK Royal College of Surgeons, London England, 2 June 2014.
5. Klassen A. Introducing the FACE-Q, BREAST-Q and BODY-Q: How to improve your cosmetic practice with Patient-Reported Outcome Measures (PROMs). ACE Conference, London UK, 9<sup>th</sup> March 2014.

### **Suggested further reading about patient-reported outcomes in plastic surgery**

1. Cano SJ, Hobart JC. The problem with health measurement. Patient preference and adherence 2011;5: 279.
2. Pusic AL, Lemaine V, Klassen AF, Scott AM, Cano SJ. Patient-reported outcome measures in plastic surgery; use and interpretation in evidence-based medicine. J Plast Reconstr Aesthet Surg 2011;127(3): 1361-7.
3. Cano SJ, Klassen A, Pusic AL. The science behind quality-of-life measurement: a primer for plastic surgeons. J Plast Reconstr Aesthet Surg 2009;123(3): 98-106.
4. Hobart J, Cano S. Improving the evaluation of therapeutic interventions in multiple sclerosis: the role of new psychometric methods. Health Technol Assess 2009;12: 1-177.
5. Rasch G. Probabilistic Models for Some Intelligence and Attainment Tests. Copenhagen, Denmark: Danish Institute for Education Research; 1960.