



BREAST-Q® | AUGMENTATION

A User's Guide for Researchers and Clinicians

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Printing History: July 2012
May 2015
November 2017
January 2023

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1. What is the BREAST-Q?

The BREAST-Q is a rigorously developed patient-reported outcome measure (PROM) designed to evaluate outcomes among women undergoing different types of breast surgery from the patient perspective. BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. Version 2.0 was tested in a much larger sample and the scores derived for the two versions are comparable. Appendix 1 shows the minor modifications made for Version 2.0.

2. How was the BREAST-Q Developed and Validated?

The BREAST-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 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, BREAST-Q scales can be used with individual patients to inform clinical care.

We followed internationally recommended guidelines for PROM development to ensure that the BREAST-Q meets requirements for regulatory bodies. The BREAST-Q was developed using an iterative multiphase mixed methods approach. In Phase 1, a systematic literature review was conducted to identify PROMs developed and validated for use in cosmetic and reconstructive breast surgery patients [1]. This study concluded that a valid, reliable, and responsive instrument PROM for breast surgery was lacking.

To develop the BREAST-Q, in 2004, in-depth qualitative interviews were conducted with 48 women who were seeking or had undergone breast surgery [2]. Data were analyzed and used to develop a conceptual framework and preliminary BREAST-Q scales. These scales were shown to clinician experts who were invited to suggest any missing items. The conceptual framework and BREAST-Q scales were refined and shown to 58 women who took part in two separate focus groups. These sessions were used to examine relevance and comprehensiveness of the conceptual framework and draft scales. Further feedback was obtained from clinical experts. Final refinements were made to the BREAST-Q based on cognitive debriefing interviews with 30 women who provided feedback on the relevance, comprehensiveness, and comprehensibility of BREAST-Q items. The content validity of the BREAST-Q was thus well supported by extensive evidence from qualitative studies. Figure 1 shows the BREAST-Q Augmentation conceptual framework, which covers two main domains: quality of life and patient satisfaction.

In phase 2, the BREAST-Q was field-tested in a sample of 1950 participants, 491 of whom also completed a test-retest survey [3,4]. The sample included participants who were

seeking or had breast augmentation (pre=222, post=179), reduction (pre=148, post=316), and reconstruction (pre=295, post=790). Items that did not function well were removed from BREAST-Q scales. RMT analysis of the item-reduced scales supported the summing of the items to form a total score for each scale in each module. Classical test theory and RMT analyses provided evidence to support the validity and reliability of BREAST-Q scales.

In phase 3, the psychometric performance of the BREAST-Q was reexamined in a separate independent sample of 817 women who were seeking or had breast augmentation (n=158), reduction (n=301), or reconstruction (n=358) [5]. BREAST-Q scales exceeded criteria for validity and reliability. Overall, the findings provided support for the use of the BREAST-Q as a tool to study the impact and effectiveness of breast surgery from the patients' perspective.

3. How many BREAST-Q Modules are there?

The BREAST-Q has separate modules to evaluate outcomes and experiences of care for different types of breast surgery, including augmentation, reduction/mastopexy, and breast cancer. This User's Guide describes the BREAST-Q Augmentation module. User's Guides are available for separate BREAST-Q modules for breast reduction/mastopexy and for breast cancer (i.e., Mastectomy, Reconstruction, Breast Conserving Therapy, and Reconstruction Expectations).

4. Is there Normative Data for the BREAST-Q | Augmentation?

Normative data for the BREAST-Q Augmentation module were collected from 1211 women not actively seeking breast augmentation from a large-scale survey [6]. The sample were recruited using the Love Army sample, an online community of women with and without breast cancer. Mean scores were as follows: Satisfaction with Breasts, 54 ± 19 ; Psychosocial Well-being, 66 ± 20 ; Sexual Well-being, 49 ± 20 ; and Physical Well-being, 86 ± 15 . Women with a body mass index of 30 kg/m² or greater and bra cup size of D or greater had lower scores. These data may be used for normative comparison values for those seeking and undergoing surgery. For more information, see our publication [6].

Figure 1: BREAST-Q | Augmentation conceptual framework



5. BREAST-Q | Augmentation Scales

Table 1 shows the Augmentation scales. Information is provided to show the number of items, response options, recall period, scoring, and the Flesch-Kincaid (FK) grade reading level. Below the table is a brief description of the content of each scale.

Table 1: Description of BREAST-Q | Augmentation scales and single items

Scale Name	Items (Pre/Post)	Response options	Recall	Scoring	FK (Pre/Post)
Satisfaction with Breasts	6/15	dissatisfied → satisfied	past week	0-100	0.6/2.3
Satisfaction with Implants	2	dissatisfied → satisfied	past week	single items	4.8
Outcome	8	disagree → agree	n/a	0-100	4.7
Information	16	dissatisfied → satisfied	n/a	0-100	5.5
Surgeon	12	disagree → agree	n/a	0-100	5.7
Medical Team	7	disagree → agree	n/a	0-100	5.1
Office Staff	7	disagree → agree	n/a	0-100	5.1
Psychosocial Well-Being	9	none → all of the time	past week	0-100	7.6
Sexual Well-Being	5	none → all of the time	n/a	0-100	9.4
Physical Well-Being: Chest	5/7	none → all of the time	past week	0-100	9.8/10.5

SATISFACTION

Satisfaction with Breasts: This scale measures body image in terms of a woman's satisfaction with her breasts. Items cover breast appearance (e.g., size, symmetry, softness, implant placement, cleavage) and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. There are also items specific to implants (e.g., rippling) and postoperative issues (e.g., scars).

Satisfaction with Implants: These are implant-specific items (e.g., amount of rippling that can be seen or felt).

Satisfaction with Outcome: This 8-item scale measures a woman's overall appraisal of the outcome of her breast surgery. Items cover whether the woman's expectations were met with respect to the aesthetic outcome, the impact surgery has had upon her life, as well as satisfaction with the decision to have surgery.

Satisfaction with Care

- a. **Information:** This 16-item scale measures satisfaction with information provided about breast augmentation surgery from the surgeon. Items cover complications and risks (e.g., implant leakage, loss of nipple sensation, capsular contracture, rippling), implications for future breast cancer screening and breast-feeding,

healing and recovery time, how the surgery would be done, and breast appearance (e.g., breast size, scars).

- b. Surgeon:** This 12-item scale measures satisfaction with the surgeon. Items ask about the surgeon's manner (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g., easy to talk to). Items also cover the extent to which the patient was involved in the decision-making and her understanding of the process.
- c. Medical Team:** This 7-item scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- d. Office Staff:** This 7-item scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated respectfully.

QUALITY OF LIFE

Psychosocial Well-Being: This 9-item scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.

Sexual Well-Being: This 5-item scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts, and how comfortable or at ease a woman feels during sexual activity.

Physical Well-Being: Chest: This 5-item scale captures negative physical sequelae of the chest and upper body. There are questions about symptoms of pain or tightness in the breast area, as well as difficulty with mobility (e.g., lifting arms) and doing activities (e.g., running, lifting).

6. Administration of the BREAST-Q

Each BREAST-Q scale is designed to function independently. Therefore, patients and research subjects can be asked to complete a subset of scales. The BREAST-Q's modular structure makes it possible for you to use only the most relevant scales for your patient population or research study. The BREAST-Q scales are designed for patients to complete on their own (self-report). Instructions are given at the beginning of each scale. Each scale takes 1-4 minutes to complete, and the entire BREAST-Q Augmentation module can be completed in 10-15 minutes. Women may complete the preoperative scales at any time

prior to surgery (baseline assessment) and the postoperative scales at any time point after surgery (follow-up data). The BREAST-Q may also be administered at a single time point as in a cross-sectional survey. Each researcher or clinician may decide the time points at which they would like to administer the scales.

The BREAST-Q has been tested using two modes of data collection, i.e., online data collection (Research Electronic Data Capture System) and paper-and-pencil [3,6,7]. The BREAST-Q Augmentation module was well-accepted by patients in a qualitative study that examined electronic data collection in community-based cosmetic surgery clinics [8]. 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 BREAST-Q data collection, the ePRO company may need a license. If you have or plan to have an ePRO company convert BREAST-Q scales into an electronic format, e-conversion review and certification is required, please email gportfolioteam@gmail.com.

7. Scoring the BREAST-Q Version 1.0

QScore software is no longer supported. If you need to score BREAST-Q Version 1.0 data, email gportfolioteam@gmail.com.

8. Scoring the BREAST-Q Version 2.0

There is no overall or total BREAST-Q score. Instead, the BREAST-Q Augmentation module is composed of independently functioning scales and two single items. Some scales include the preoperative items in addition to items that address unique postoperative issues. The preoperative and postoperative scales are linked psychometrically to measure change.

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of BREAST-Q. Our suggestion follows the most common method for scoring when there is missing data, which is to impute a missing value using the mean value of responses to completed items if 50% or more of the items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades [12-13]. As such, BREAST-Q scores can be computed if missing data is less than 50% of the scale's items. In this approach, the within-person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, 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.

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 Rasch analysis. Higher scores for BREAST-Q scales reflect 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 provided after each scale and are available after a licensing agreement is signed.

To score stand-alone 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.

RAW SCORES FOR SCALE ITEMS

For scales that measure satisfaction, 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: Satisfaction with Breasts and Information.

For scales that measure agree/disagree, the raw data needs to be scored as follows: “Definitely disagree” = 1; “Somewhat disagree” = 2; “Somewhat agree” = 3; “Definitely agree” = 4. This includes the following scales: Surgeon, Medical Team, and Office Staff.

The one exception is Outcome, which needs to be scored as follows: “Disagree” = 1; “Somewhat agree” = 2; “Definitely agree” = 3

For scales that measure amount of time, the raw data needs to be scored as follows: “None of the time” = 1; “A little of the time” = 2; “Some of the time” = 3; “Most of the time” = 4; “All of the time” = 5. This includes the following scales: Psychosocial and Sexual Well-being.

The one exception is Physical Well-being: Chest, which needs to be scored as follows: “All of the time” = 1; “Some of the time” = 2; “None of the time” = 3.

Below is an example of how to compute a scale score using the BREAST-Q Augmentation Satisfaction with Breasts scale. First, you compute the sum score (total raw score) by adding the raw scores for items a - f. In the example below, the sum score = 17. Second, you will find the sum score in the Satisfaction with Breasts Conversion Table, which is shown below. The sum score of 17 is then converted to a Rasch score (linearized score) of 52.

BREAST-Q® - AUGMENTATION MODULE (PREOPERATIVE) VERSION 2.0:
SATISFACTION WITH BREASTS

With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How you look in the mirror <u>clothed</u> ?	1	2	3	4
b. How your breast size matches the rest of your body?	1	2	3	4
c. How your bras fit?	1	2	3	4
d. How much cleavage you have when you wear a bra?	1	2	3	4
e. The size of your breasts?	1	2	3	4
f. How you look in the mirror <u>unclothed</u> ?	1	2	3	4

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BREAST-Q® - AUGMENTATION MODULE (PREOPERATIVE) VERSION 2.0:
SATISFACTION WITH BREASTS CONVERSION TABLE

Instructions: If missing data is less than 50% of the scale's items, for each missing item, we suggest you calculate and impute the within-person mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best). Higher scores reflect a better outcome.

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
6	0
7	17
8	23
9	28
10	32
11	35
12	38
13	41
14	44
15	47
16	50
17	52
18	55
19	59
20	63
21	67
22	72
23	80
24	100

9. What is a Minimal Importance Difference in BREAST-Q Scores?

The ability of the BREAST-Q Augmentation module to measure clinical change was examined by our team in a sample of 41 patients who completed the scale before and after augmentation [9]. Patients reported that satisfaction with breasts, psychosocial well-being, and sexual well-being were significantly higher following breast augmentation. The change scores were associated with large effect sizes. Distribution based minimally important differences for the BREAST-Q Augmentation module from a sample of 245 women who underwent cosmetic breast augmentation are available in a separate publication [10]. The Breast Implant Follow-up Study is a large ongoing observational study of women who received breast augmentation with silicon-filled or saline-filled breast implants [11]. Based on a sample of 14,514 women, Satisfaction with Breasts and Psychosocial Well-being increased significantly at postoperative year 1 ($p < 0.0001$ for both), and the improvement was sustained at year 4 ($p < 0.0001$ for both). Large effect sizes were observed for Satisfaction with Breasts (2.0 at year 1; 1.8 at year 4) and Psychosocial Well-being (1.2 at year 1; 1.0 at year 4).

10. Conditions of Use

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Use of the BREAST-Q requires completion of a licensing agreement. The use of the BREAST-Q and its modules in non-profit academic research and in clinical care is free of charge. Non-profit users can access and license the BREAST-Q Version 2.0 using the following link:

<https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3>

The use of the BREAST-Q by 'for-profit' organizations (e.g., pharmaceutical companies or sponsored by pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee. For questions regarding fees to be paid by 'for-profit organizations', please contact:

Licensing Manager
Office of Technology Development
Memorial Sloan Kettering Cancer Center

633 3rd Ave, 4th Floor, New York, NY 10016
gotdtrm@mskcc.org

PLEASE NOTE

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

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

For questions regarding study design and optimal use of BREAST-Q scales, please contact:

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11. Frequently Asked Questions

What is the difference between BREAST-Q Version 1.0 and 2.0?

BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. **Appendix 1** shows the minor modifications made. Version 2.0 was tested in a much larger sample and the scores derived for the two versions are comparable.

Do I have to use all the scales?

Each scale functions independently; therefore, patients can be asked to complete one or more scales. It is not necessary for a patient to complete all of the scales as there is no overall or total BREAST-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 BREAST-Q?

You cannot delete or add or change the wording of any items or response options of the BREAST-Q. Any modification to the content of the BREAST-Q is prohibited under copyright laws. Also, making any changes to BREAST-Q scales would invalidate their psychometric properties.

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

According to the licensing agreement, you cannot reproduce the content of BREAST-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 2 below.

Which module do I use for fat grafting procedures?

For patients undergoing fat grafting procedures, either the BREAST-Q Reconstruction or Augmentation modules may be used depending on the indications for the procedure (i.e., correction of defect following oncologic resection or cosmetic augmentation).

Can I translate the BREAST-Q into a new language?

Yes, with permission, you can translate the BREAST-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 BREAST-Q own the copyright of all translations of the BREAST-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 BREAST-Q?

Use of BREAST-Q scales is free for non-profit users, including use by hospitals. For-profit users should contact Memorial Sloan Kettering Cancer Centre for information about fees (gotdtrm@mskcc.org).

12. Acknowledgements

The development of BREAST-Q modules was generously funded by grants from the University of British Columbia (2003), the Plastic Surgery Foundation (2004, 2006),

National Institutes of Health (2007, R03 Research Grant CA128476-01), and Canadian Cancer Society (ADD).

13. Publications Related to BREAST-Q Development and Validation

1. Pusic AL, Chen CM, Cano S, Klassen A, McCarthy C, Collins ED, Cordeiro PG. Measuring quality of life in cosmetic and reconstructive breast surgery: a systematic review of patient-reported outcomes instruments. *Plast Reconstr Surg*. 2007 Sep;120(4):823-37.
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Table 2: Shortened items for BREAST-Q Augmentation scales to use in a publication

PSYCHOSOCIAL	firmness	OUTCOME	confidence
confident social	position implants	good experience	involved you
good	naturally sit	no regrets	reassuring
confident in clothes	evenly positioned	satisfied	answered
equal worth	feel	life better	comfortable
attractive	shape	perfect size	thorough
accepting	size	matched expectations	talk to
self-assured	mirror unclothed	no further surgery	understood
confident body	cleavage	as planned	sensitive
self-confident	close	INFORMATION	made time
SEXUAL WELL-BEING	matched	how surgery	available
attractive in clothes	CHEST (PRE-OP)	complications	MEDICAL TEAM
comfortable	pain	breast-feeding	professional
confident sexually	tightness	leakage	respect
sexy	difficulty lifting objects	risks	knowledgeable
confident unclothed	vigorous activities	loss sensation	friendly
BREASTS (PRE-OP)	difficulty lifting arms	capsular contracture	comfortable
mirror clothed	CHEST (POST-OP)	recovery	thorough
matches body	pain	rippling	made time
bras fit	tightness	scars	OFFICE STAFF
cleavage	shifting	choose size	professional
size	difficulty sleeping	expect look	respect
mirror unclothed	difficulty lifting objects	screening	knowledgeable
BREASTS (POST-OP)	vigorous activities	volume	friendly
bras fit	difficulty lifting arms	size expect	comfortable
mirror clothed	IMPLANTS	other women	thorough
natural	rippling you can see	SURGEON	made time
matches body	rippling you can feel	professional	

APPENDIX 1: Modifications to BREAST-Q Version 1.0 to create BREAST-Q Version 2.0

NOTE: If a scale is not in the list it is because it has not been changed.

Modifications to pre-operative BREAST-Q scales		
Augmentation	Version 1.0	Version 2.0
Changed original stem for all modules	in the past 2 weeks	in the past week
Satisfaction w Breast	a. How bras fit?	a. How your bras fit?
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	5 response options	3 response options

Modifications to post-operative BREAST-Q scales		
Augmentation	Version 1.0	Version 2.0
Changed original stem for all modules	in the past 2 weeks	in the past week
Satisfaction w Breast	a. How bras fit?	a. How your bras fit?
	o. The amount of rippling (wrinkling) of your implant(s) that you can see?	moved to separate section
	p. The amount of rippling (wrinkling) of your implant(s) that you can feel?	moved to separate section
	q. How your scars look?	removed
		added o. How closely matched (similar) your breasts are to each other?
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	5 response options	3 response options