BREAST-Q® | REDUCTION/MASTOPEXY

A User's Guide for Researchers and Clinicians

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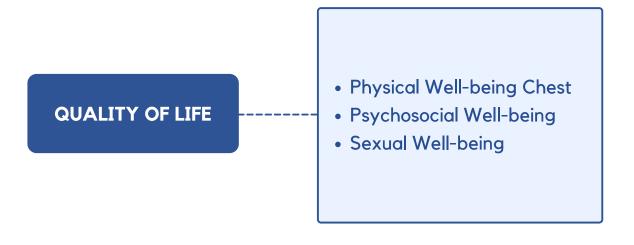
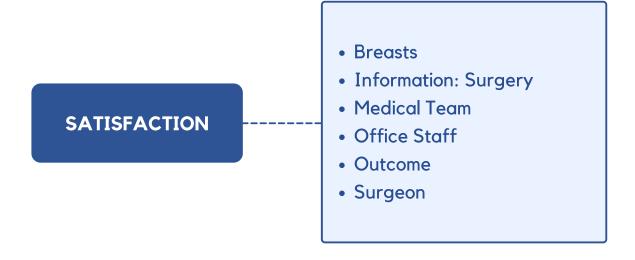## 2. How was the BREAST-Q Developed and Validated?

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 the requirements of 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 Reduction/Mastopexy conceptual framework, which covers two main domains: quality of life and patient satisfaction.

Figure 1: BREAST-Q | Reduction/Mastopexy conceptual framework

QUALITY OF LIFE - - - - - - -
- Physical Well-being Chest
- Psychosocial Well-being
- Sexual Well-being

SATISFACTION - - - - - - -
- Breasts
- Information: Surgery
- Medical Team
- Office Staff
- Outcome
- Surgeon

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]. 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) [4]. 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 Reduction/Mastopexy module. Separate User's Guides are available for BREAST-Q modules for breast augmentation and breast cancer (Mastectomy, Reconstruction, Breast Conserving Therapy, and Reconstruction Expectations).

4. Is there Normative Data for the BREAST-Q | Reduction/Mastopexy?

Normative data for the BREAST-Q Reduction/Mastopexy module were collected from 1206 women not actively seeking breast reduction from a large-scale survey [5]. The sample were recruited using the Love Army sample, an online community of women with and without breast cancer. Mean normative scores were as follows: Satisfaction with Breasts, 57 ± 16; Psychosocial Well-being, 68 ± 19; Sexual Well-being, 55 ± 19; and Physical Well-being, 76 ± 11. Normative scores were lower in women with body mass index ≥ 30 and bra cup size ≥ D. In comparison to normative Love Army scores, published BREAST-Q scores for women undergoing reduction mammaplasty were lower (worse) for preoperative patients and higher (better) for postoperative patients. For more information, see our publication [5].

5. BREAST-Q | Reduction/Mastopexy Scales

Table 1 shows the BREAST-Q scales including number of items, response options, recall period, and grade reading level. Below the table is a brief description of the content of each scale.

Table 1: Description of BREAST-Q | Reduction/Mastopexy scales and single items

Scale Name	Items (Pre/Post)	Response options	Recall	Scoring	FK (Pre/Post)
Satisfaction with Breasts	11/13	dissatisfied → satisfied	past week	0-100	1.0/0.9
Satisfaction with Nipples	5	dissatisfied → satisfied	past week	single items	4.5
Outcome	8	disagree → agree	n/a	0-100	6.4
Information	13	dissatisfied → satisfied	n/a	0-100	5.6
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	6.2
Sexual Well-Being	5	none → all of the time	n/a	0-100	9.0
Physical Well-Being	14	none → all of the time	past week	0-100	6.7

SATISFACTION

Satisfaction with Breasts: This 13-item scale measures body image in terms of a woman's satisfaction with her breasts. Items cover breast appearance (e.g., size, symmetry), and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. There are also postoperative only items (e.g., location and appearance of scars).

Satisfaction with Nipples: These 5 items are about satisfaction with the appearance of the nipples and areola complexes. Items cover their location on the breast, symmetry, shape, and nipple sensation.

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 (e.g., "I would do it again").

Satisfaction with Care

    a. **Information:** This 13-item scale measures satisfaction with information provided about breast reduction surgery from the surgeon. Items cover complications and risks (e.g., loss of nipple sensation), 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 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: This 14-item scale captures physical problems caused by breast size, including pain (e.g., breast, shoulder, back, neck), energy level, rashes, and sleeping problems. There are also questions asking about activity limitations and balance.

6. Administration of the BREAST-Q

Each BREAST-Q scale is designed to function independently. Therefore, patients and research participants 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). Each scale takes only a few minutes to complete. Instructions are given at the beginning of each scale. Each scale takes 1-4 minutes to complete and an entire BREAST-Q module can be completed in about 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 [3,5,6]. 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 BREAST-Q scales converted into an electronic format and require an e-conversion review and certificate, please email qportfolioteam@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 qportfolioteam@gmail.com.

8. Scoring the BREAST-Q Version 2.0

There is no overall or total BREAST-Q score, only scores for each independently functioning scale. The Satisfaction with Breasts scale includes the preoperative items in addition to items that address unique postoperative issues (e.g., scars). 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. If missing data is less than 50% of the scale's items, the within-person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to ≥5 items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to ≤4 items, the summed score for this person cannot be computed and is classified as missing data. Importantly, the Conversion Tables are only valid with complete data (i.e., when a person has ≥50% completed responses). Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the 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 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, which needs to be scored as follows: "All of the time" = 1; "Some of the time" = 2; "None of the time" = 3.

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9. Conditions of Use

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

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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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10. 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 oncoplastic procedures?

For oncoplastic surgery procedures, the BREAST-Q Reduction/Mastopexy module and the BCT module are recommended, depending on the exact nature of the procedure (i.e., for oncoplastic breast reduction, use Reduction module; for oncoplastic lumpectomy/glandular remodeling, use the BCT module).

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 (qotdtrm@mskcc.org).

Table 2: Shortened items for BREAST-Q scales to use in a publication

PSYCHOSOCIAL	mirror	size expect
confident social	hang	loss blood supply
equal worth	normal	incisions
good	mirror unclothed	expect look
self-assured	**BREASTS (POST-OP)**	scars
confident in clothes	in clothes	screening
accepting	matches body	help scarring
appearance matches	size	breast-feeding
confident body	shape bra	**SURGEON (POST-OP)**
attractive	equal	professional
SEXUAL	bras fit	confidence
comfortable	shape not wearing bra	involved you
confident	mirror	reassuring
satisfied	hang	answered
attractive	normal	comfortable
sexy	location scars	thorough
PHYSICAL	scars look	talk to
headaches	mirror unclothed	understood
pain breast	**NIPPLES (POST-OP)**	sensitive
energy	high low	made time
difficulty activities	lined up	available
unbalanced	shape	**MEDICAL TEAM (POST-OP)**
shoulder pain	look	professional
sleeping	sensation	respect
neck pain	**OUTCOME (POST-OP)**	knowledgeable
gouges bra	right decision	friendly
uncomfortable	encourage others	comfortable
rashes	do it again	thorough
back pain	positive	made time
arm pain	changed life	**OFFICE STAFF (POST-OP)**
hands	no regrets	professional
BREASTS (PRE-OP)	matched expectations	respect
in clothes	as planned	knowledgeable
matches body	**INFO (POST-OP)**	friendly
size	how surgery	comfortable
shape bra	complications	thorough
equal	recovery	made time
bras fit	choose size	
shape not wearing bra	loss sensation	

11. Acknowledgements

12. Publications Related to BREAST-Q Development and Validation

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6. Fuzesi S, Cano SJ, Klassen AF, Atisha D, Pusic AL. Validation of the electronic version of the BREAST-Q in the army of women study. Breast. 2017 June; 33:44-49.

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

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

Modifications to pre- and post-operative BREAST-Q scales		
Reduction	**Version 1.0**	**Version 2.0**
Changed original stem for all modules	in the past 2 weeks	in the past week
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	5 response options	3 response options