BREAST-Q[©]

A Guide for Researchers and Clinicians

USER'S GUIDE VERSION 2.0 November 2017

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1. What is the BREAST-Q©?

The BREAST-Q© is a rigorously developed patient-reported outcome (PRO) measure designed to evaluate outcomes among women undergoing different types of breast surgery. There are currently 6 BREAST-Q© modules. The Breast Cancer module (comprised of 4 of the 6 modules) is designed to provide clinicians and researchers the ability to tailor their own version of the questionnaire to suit their needs. Each module is divided into multiple scales that can be used independently. The scales are psychometrically linked across the various modules and patient treatment groups and can thus be used for comparison between different patient groups.

- 1) Augmentation Module
- 2) Reduction/Mastopexy Module
- 3) Breast Cancer
 - a. Mastectomy Module
 - b. Reconstruction Module
 - c. Breast Reconstruction Expectations Module
 - d. Breast Conserving Therapy (BCT) Module

All BREAST-Q© modules are based on an underlying conceptual framework developed from extensive qualitative research with breast surgery patients, close examination of the research literature and engagement of healthcare professionals working with breast surgery patients. The conceptual framework of the BREAST-Q© modules is comprised of two overarching themes (or domains). These are 1) Health-related Quality of Life (QOL) and 2) Patient Satisfaction. Under each of these domains, there are six subthemes; QOL: 1) Psychosocial, 2) Physical and 3) Sexual well-being; and Patient Satisfaction: 4) Satisfaction with Breasts, 5) Satisfaction with Outcome and 6) Satisfaction with Care. Body image is an important concept for breast surgery patients. This concept is measured by several of our BREAST-Q© scales.

Expectations: Given before surgery, this module measures expectations of the patient in terms of the process and outcome of surgery.

Psychosocial Well-Being: Measures psychosocial well-being with items that ask about body image and a woman's confidence in social settings.

Sexual Well-Being: Asks about feelings of sexual attractiveness (clothed and unclothed), sexual confidence and comfort level during sex.

Physical Well-Being: Measures pain or tightness and difficulty with mobility, such as lifting arms or running.

Satisfaction with Breasts: Items cover breast appearance, satisfaction with breasts and how bras fit and how the breasts look when clothed or unclothed.

Satisfaction with Outcome: Measures the overall evaluation of the outcome of a woman's surgery and whether or not her expectations were met.

Satisfaction with Care: Measures satisfaction with information about risks, healing and recovery time and details of the procedure from the surgeon.

2. How was the BREAST-Q© Developed?

A description of the development and validation of the BREAST-Q© as well as many publications for further reading is available in Section 9 - BREAST-Q© Publications.

3. BREAST-Q© Scales

The table below shows BREAST-Q© modules and scales including number of items, response options, time frame and the Flesch-Kincaid grade level (FK).

NOTE: The following BREAST-Q© scales in the Mastectomy, Breast Conserving Therapy and Reconstruction modules are exactly the same for <u>all breast cancer patients</u>.

- Preoperative scales: Satisfaction with Breasts, Psychosocial, Sexual and Physical Well-being Chest
- Postoperative scales: Satisfaction with Doctor, Medical Team and Office Staff

Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Augmentation	Psychosocial Well-Being	9	none of the time / all of the time	past week	7.6
(Preoperative)	Sexual Well-Being	5	none of the time / all of the time	past week	9.4
(i reoperative)	Physical Well-Being: Chest	5	none of the time / all of the time	past week	9.8
	Satisfaction with Breasts	6	dissatisfied / satisfied	past week	0.6
	Psychosocial Well-Being	9	none of the time / all of the time	past week	7.6
Augmentation (Postoperative)	Sexual Well-Being	5	none of the time / all of the time	past week	9.4
	Physical Well-Being: Chest	7	none of the time / all of the time	past week	10.5
	Satisfaction with Breasts	15	dissatisfied / satisfied	past week	2.3
	Satisfaction with Implants	2	dissatisfied / satisfied	past week	4.8
	Satisfaction with Outcome	8	disagree / agree	n/a	4.7
	Satisfaction with Information	16	dissatisfied / satisfied	n/a	5.5
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.7
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Reduction	Psychosocial Well-Being	9	none of the time / all of the time	past week	6.2
(Preoperative)	Sexual Well-Being	5	none of the time / all of the time	past week	9.0
(i reoperative)	<u> </u>				
	Physical Well-Being	14	none of the time / all of the time	past week	6.7
	•	14 11	none of the time / all of the time dissatisfied / satisfied	past week past week	6.7 1.0
	Physical Well-Being			•	
Reduction	Physical Well-Being Satisfaction with Breasts	11	dissatisfied / satisfied	past week	1.0
Reduction (Postoperative)	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being	11 9	dissatisfied / satisfied none of the time / all of the time	past week past week	1.0
Reduction (Postoperative)	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being	11 9 5	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time	past week past week past week	1.0 6.2 9.0
	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being Physical Well-Being	11 9 5 14	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time none of the time / all of the time	past week past week past week past week	1.0 6.2 9.0 6.7
	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being Physical Well-Being Satisfaction with Breasts	11 9 5 14 13	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time none of the time / all of the time dissatisfied / satisfied	past week past week past week past week past week past week	1.0 6.2 9.0 6.7 0.9
	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being Physical Well-Being Satisfaction with Breasts Satisfaction with Nipples	11 9 5 14 13 5	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time none of the time / all of the time dissatisfied / satisfied dissatisfied / satisfied	past week	1.0 6.2 9.0 6.7 0.9 4.5
	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being Physical Well-Being Satisfaction with Breasts Satisfaction with Nipples Satisfaction with Outcome	11 9 5 14 13 5	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time none of the time / all of the time dissatisfied / satisfied dissatisfied / satisfied disagree / agree	past week n/a	1.0 6.2 9.0 6.7 0.9 4.5 6.4
	Physical Well-Being Satisfaction with Breasts Psychosocial Well-Being Sexual Well-Being Physical Well-Being Satisfaction with Breasts Satisfaction with Nipples Satisfaction with Outcome Satisfaction with Information	11 9 5 14 13 5 8 13	dissatisfied / satisfied none of the time / all of the time none of the time / all of the time none of the time / all of the time dissatisfied / satisfied dissatisfied / satisfied disagree / agree dissatisfied / satisfied	past week n/a n/a	1.0 6.2 9.0 6.7 0.9 4.5 6.4 5.6

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Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Mastectomy	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
(Preoperative)	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Mastectomy	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
(Postoperative)	Physical Well-Being: Chest	11	none of the time / all of the time	past week	4.6
	Adverse Effects of Radiation	6	not at all / a lot	past week	7.9
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.5
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Document westign	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
Reconstruction (Preoperative)	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
(Freoperative)	Physical Well-Being: Abdomen	4	none of the time / all of the time	past week	13.2
	Physical Well-Being: Shoulder and				
	Back	11	none of the time / all of the time	past week	7.2
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Satisfaction with Abdomen	1	dissatisfied / satisfied	past week	4.4
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
	Physical Well-Being: Chest	11	none of the time / all of the time	past week	4.6
	Physical Well-Being: Abdomen	7	none of the time / all of the time	past week	11.0
	Physical Well-Being: Shoulder and				
Reconstruction	Back	11	none of the time / all of the time	past week	7.2
(Postoperative)	Adverse Effects of Radiation	6	not at all / a lot	past week	7.9
	Satisfaction with Breasts	15	dissatisfied / satisfied	past week	4.6
	Satisfaction with Abdomen	3	dissatisfied / satisfied	past week	8.6
	Satisfaction with Nipple				
	Reconstruction	1	dissatisfied / satisfied	past week	10.3
	Satisfaction with Back	8	none of the time / all of the time	past week	1.2
	Satisfaction with Implants	2	dissatisfied / satisfied	past week	4.8
	Satisfaction with Information	15	dissatisfied / satisfied	n/a	7.7
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.6
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1

Name of Module	Name of Scale	Items	Response Options	Recall period	FK
	Information Needs	1	n/a	preoperative	6.5
	Making Decisions	1	n/a	preoperative	7.3
	Complications	1	n/a	postoperative	7.2
	Support from Medical Staff	5	unlikely/very likely	during process	5.4
Breast	Pain: Postoperative*	6	unlikely/very likely	first week postop	1.4
Reconstruction	Appearance: Chest	1	n/a	after expansion	2.2
Expectations (Preoperative)	Pain: Expander	1	n/a	after placement	3.8
Long Form	Pain: Expansions	1	n/a	after expansion	5.2
	Coping	5	unlikely/very likely	first year	4.0
Note: *indicates	Appearance: Clothed*	5	unlikely/very likely	after 1 year	3.0
the scales and	Appearance: Unclothed	1	n/a	after 1 year	3.3
items included in	Appearance: Breast Symmetry*	1	n/a	after 1 year	5.0
the Expectations	Appearance: Breast Scars	1	n/a	after 1 year	5.0
Short Form	Sensation: Breast*	1	n/a	after 1 year	4.9
	Appearance: Breast Size	1	n/a	after 1 year	5.9
	Appearance: Breast Shape	1	n/a	after 1 year	4.9
	Appearance: Breast Natural	1	n/a	after 1 year	4.2
	Movement: Breast	1	n/a	after 1 year	3.0
	Appearance: Chest Sides	1	n/a	after 1 year	5.8
	Sensation: Chest Sides	1	n/a	after 1 year	4.4
	Appearance: Nipples	1	n/a	after 1 year	6.1
	Sensation: Nipples	1	n/a	after 1 year	5.4
	Sensation: Breasts	5	unlikely/very likely	after 1 year	3.8
	Awareness: Implants	1	n/a	after 1 year	4.6
	Physical: Abdomen	4	unlikely/very likely	after 1 year	7.8
	Appearance: Breast Symmetry*	1	n/a	after 10 years	5.7
	Revision Surgery	1	n/a	after 10 years	5.0
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Breast	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Conserving	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
Therapy	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
(Preoperative)	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
					7.0
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Donast	Psychosocial Well-Being Sexual Well-Being	10 6	none of the time / all of the time none of the time / all of the time	past week past week	9.9
Breast Conserving	Sexual Well-Being	_	none of the time / all of the time	past week	
Conserving	Sexual Well-Being Physical Well-Being: Chest	6	none of the time / all of the time none of the time / all of the time	past week	9.9 5.7
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation	6 9 6	none of the time / all of the time none of the time / all of the time not at all / a lot	past week past week past week	9.9 5.7 7.9
Conserving	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts	6	none of the time / all of the time none of the time / all of the time	past week	9.9 5.7
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts Satisfaction with Information:	6 9 6	none of the time / all of the time none of the time / all of the time not at all / a lot dissatisfied / satisfied	past week past week past week past week past week	9.9 5.7 7.9
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts Satisfaction with Information: Breast Surgeon	6 9 6 11	none of the time / all of the time none of the time / all of the time not at all / a lot	past week past week past week	9.9 5.7 7.9 5.0
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts Satisfaction with Information: Breast Surgeon Satisfaction with Information:	6 9 6 11	none of the time / all of the time none of the time / all of the time not at all / a lot dissatisfied / satisfied dissatisfied / satisfied	past week past week past week past week n/a	9.9 5.7 7.9 5.0
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts Satisfaction with Information: Breast Surgeon Satisfaction with Information: Radiation Oncologist	6 9 6 11	none of the time / all of the time none of the time / all of the time not at all / a lot dissatisfied / satisfied dissatisfied / satisfied dissatisfied / satisfied	past week past week past week past week n/a n/a	9.9 5.7 7.9 5.0
Conserving Therapy	Sexual Well-Being Physical Well-Being: Chest Adverse Effects of Radiation Satisfaction with Breasts Satisfaction with Information: Breast Surgeon Satisfaction with Information:	6 9 6 11 12	none of the time / all of the time none of the time / all of the time not at all / a lot dissatisfied / satisfied dissatisfied / satisfied	past week past week past week past week n/a	9.9 5.7 7.9 5.0 8.4 6.9

3.1 Augmentation Module

Quality of Life Domains

- 1. **Psychosocial Well-being**: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body; attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. **Sexual Well-being**: This 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.
- 3. **Physical Well-being Chest**: This 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).

Satisfaction Domains

- 1. 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).
- 2. **Satisfaction with Outcome**: This 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 and 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").

- a. **Information**: This 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 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 understood the process.
- c. **Medical team:** This scale measures satisfaction with members of the medical team (other than 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 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 in a respectful manner.

3.2 Reduction/Mastopexy Module

Quality of Life Domains

- 1. Psychosocial Well-being: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body; attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. Sexual Well-being: This 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.
- **3. Physical Well-being Chest**: This 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.

Satisfaction Domains

- 1. 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, cleavage), 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).
- **2. Satisfaction with Nipples:** This scale measures satisfaction with the appearance of the nipple and areola complex. Items cover their location on the breast, symmetry, shape and nipple sensation.
- **3. Satisfaction with Outcome**: This 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 and 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").

- a. **Information:** This 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 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 understood the process.
- **c. Medical Team:** This scale measures satisfaction with members of the medical team (other than 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 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 in a respectful manner.

3.3 Mastectomy Module

Quality of Life Domains

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

3. Physical Well-being:

- a. Chest: This scale captures negative physical sequelae of the chest. There are questions about chest muscle pain and breast area discomfort such as tightness, pulling, nagging, tenderness, aching and throbbing. There are also questions asking about activity limitations.
- b. **Adverse Effects of Radiation**: This scales measures physical changes such as soreness and dryness of the skin due to radiation.

Satisfaction Domains

1. **Satisfaction with Breasts**: This scale measures body image in terms of a woman's satisfaction the breast area and asks questions regarding how comfortably bras fit, and how satisfied a woman is with her breast area both clothed and unclothed.

- a. **Surgeon:** This 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 understood the process.
- b. **Medical team:** This scale measures satisfaction with members of the medical team (other than 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.
- c. Office Staff: This 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 in a respectful manner.

3.4 Reconstruction Module

Quality of Life Domains

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

3. Physical Well-being:

- a. Chest: This scale measures physical problems such as chest muscle pain and problems in the breast area (e.g., tightness, pulling, tenderness). Other items ask about activity limitations and sleep problems due to discomfort.
- b. **Adverse Effects of Radiation**: This scale measures physical changes such as soreness and dryness of the skin due to radiation.
- c. Abdomen and Trunk: This scale measures negative physical sequelae of the abdomen following autologous tissue reconstruction (TRAM or DIEP flap). Items cover abdominal discomfort, bloating, bulging and pain as well as difficulty doing certain activities due to abdominal weakness.
- d. **Back and Shoulder**: This scale measures negative physical sequelae such as pain and scarring following latissimus dorsi flap reconstruction (LD flap). Items cover arm and shoulder limitations that lead to difficulty performing certain activities due to arm stiffness and weakness.

Satisfaction Domains

- 1. **Satisfaction with Breasts:** This scale measures body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., size, symmetry, softness) and clothing issues (e.g., how bras fit; being able to wear fitted clothes). There are also implant-specific items (e.g., amount of rippling that can be seen or felt).
- 2. **Satisfaction with Nipples**: This scale measures satisfaction with the appearance of the reconstructed nipple and areola complex.
- 3. **Satisfaction with Abdomen**: This scale measures patient satisfaction with abdominal appearance following autologous tissue breast reconstruction (TRAM or DIEP flap). Items ask about overall appearance as well as position of navel (belly button) and scars.
- 4. **Satisfaction with Back**: This scale measures patient satisfaction with back and back scar appearance following latissimus dorsi flap reconstruction (LD flap). Items ask about overall back and scar appearance as well as location of scar.

5. Satisfaction with Care:

- a. Information: This scale measures satisfaction with information provided about breast reconstruction surgery from the surgeon. Items cover types of breast reconstruction, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done and breast appearance (e.g., breast size, scars).
- b. **Surgeon:** This 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 understood the process.
- c. **Medical team:** This scale measures satisfaction with members of the medical team (other than 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 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 in a respectful manner.

3.5 Breast Reconstruction Expectations Module

These scales are designed to be administered pre-operatively and assess patient expectations for the process and outcome of surgery. The expectations scales compliment the satisfaction and quality-of-life domains of the post-operative reconstruction module. Multi-item and categorical scale structures are used. Five scales provide a 0-100 score:

- 1. **Expectations for Support from Medical Staff:** This scale measures how much time and emotional support the patient is expecting to receive from the medical team and surgeon during the breast reconstruction process.
- 2. **Expectations for Pain:** This scale measures the magnitude of pain the patient is expecting to experience in the first week after reconstruction surgery (e.g., feel sore, great deal of pain).
- 3. **Expectations for Coping:** This scale measures how a patient is anticipating she will cope with the process of breast reconstruction during the first year after surgery (e.g., will get back to my normal life).
- 4. **Expectations for Breast Appearance when Clothed:** This scale measures how a patient expects her breasts to look one year after surgery when she is clothed (e.g., look good in a bra, clothes will hang well).
- 5. **Expectations for Breast Sensation:** This scale measures how a patient expects her breasts to feel when she touches them one year after breast reconstruction (e.g., harder than a natural breast, rippling).

3.6 Breast Conserving Therapy Module

Quality of Life Domains

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

3. Physical Well-being:

- a. Chest: This scale measures problems in the breast area (e.g., tightness, pulling, tenderness, pain). Other items ask about activity limitations and sleep problems due to discomfort.
- b. **Adverse Effects of Radiation**: This scale measures physical changes such as soreness and dryness of the skin due to radiation.

Satisfaction Domains

1. **Satisfaction with Breasts:** This scale measures body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., size, symmetry, softness) and clothing issues (e.g., how bras fit; being able to wear fitted clothes).

- a. **Information: Surgery:** This scale measures satisfaction with information provided about breast surgery from the surgeon. Items cover types of breast surgery, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done and breast appearance (e.g., breast size, scars).
- b. **Information:** Radiation: This scale measures satisfaction with information provided about radiation treatment from the radiation oncologist. Items cover why you need radiation, how the beam will feel, how the radiation might change your skin over time and potential problems.
- c. **Surgeon:** This 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 understood the process.
- d. **Medical team:** This scale measures satisfaction with members of the medical team (other than 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.
- e. Office Staff: This 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 in a respectful manner.

4. Administration of the BREAST-Q©

The BREAST-Q© is a self-administered questionnaire. Each scale takes 1-4 minutes to complete and an entire BREAST-Q© module can be completed in about 10-15 minutes.

Each module has preoperative and postoperative scales. The postoperative scales include all 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. Women may complete the pre-operative 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 he/she would like to administer the scales. Of note, the BREAST-Q© Reconstruction Expectations Module scales differ in that they are designed for pre-operative administration only.

It is important to note that patients do not need to complete all BREAST-Q© scales in any given study or clinical encounter. Each scale can be used independently of the other scales. Patients are given brief instructions at the beginning of each scale. The BREAST-Q© is available in paper and pencil format and REDCap. You may use the paper and pencil format to create your own online version of the BREAST-Q© for ease of administration.

For a detailed description of changes from V1.0 to Version 2.0, please contact the authors.

5. Scoring the BREAST-Q©

There is <u>no overall or total</u> BREAST-Q© score, only scores for each independent scale. All BREAST-Q© scales are transformed into scores that range from 0-100. The scores are computed by adding the response items together and then converting the raw sum scale score to a score from 0-100. For all BREAST-Q© scales, a higher score means greater satisfaction or better QOL (depending on the scale). If missing data is less than 50% of the scales items, insert the mean of the completed items. Use the Conversion Tables available from the authors to convert the raw summed scale score into a score from 0 (worst) to 100 (best).

For instructions on how to score V1.0 of the BREAST-Q using QScore, please contact the authors.

6. Interpretation of the BREAST-Q©

Interpretative data on individual patient's scores is not available, but longitudinal assessment at multiple time points should establish a personal norm for each individual patient. Then changes over time for an individual patient may be best judged in relation to what is 'normal' for that patient. It is also expected that as measurement of QOL and satisfaction becomes more common in clinical settings, intuitive familiarity will develop both through individual and collective experience, as has occurred for more established measures of disease activity and severity. For more information about the BREAST-Q© we direct the reader to Section 9 showing BREAST-Q© publications.

7. Conditions of Use of the BREAST-Q©

Memorial Sloan Kettering Cancer Center and the University of British Columbia hold the copyright of the BREAST-Q© and all its translations (past, on-going and future). To avoid any copyright infringement, a copyright notice shall be included on the original questionnaire and all its derivatives (including but not limited to translations) as follows:

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The use of the BREAST-Q™ and its modules in non-profit academic research and in clinical care is free of charge.

The use of the BREAST-Q© by "for-profit" organizations is subject to a fee per module per protocol.

For questions regarding fees to be paid by 'for-profit organizations', please contact:

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

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8. Frequently Asked Questions

Do I need local ethics board (IRB) approval?

If your intent is to collect BREAST-Q© data for research purposes, a local ethics board must review your methods, patient recruitment, consent and privacy. If you are administering the BREAST-Q© for clinical care, ethics board approval is generally not required. If in doubt, contact your local ethics board.

Do I have to use all the scales?

No, you do not have to use all scales. Each scale functions independently, therefore patients can be asked to complete <u>some or all</u> of a module's BREAST-Q© scales. It is not necessary for a patient to complete all of the scales within a module as there is <u>no overall or total</u> 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 in the BREAST-Q@?

No, you cannot delete or make any changes to the wording of any items or response options in a BREAST-Q© scale. Any modification to the content of the BREAST-Q© by deleting an item within a scale is <u>not acceptable</u>. 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 BREAST-Q© scales. The second reason is that by deleting or adding items, it would then not be possible to score the BREAST-Q© and you would not be able to compare findings with those of other BREAST-Q© studies. Finally, deleting or adding items is prohibited under copyright laws.

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 remodelling, use BCT module).

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, you can translate the BREAST-Q© into different languages. Check our website and with our team first to make sure there is not already a translation in the language you need. You will need to sign a licensing agreement. Please note that the developers of the BREAST-Q© own the copyright of all translation of the BREAST-Q©.

Who helps patients to complete the questionnaire in clinic?

The BREAST-Q© scales were designed for self-completion.

Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points (pre and post-operatively) he or she would like to administer the scales. Each module of the BREAST-Q© has a pre-operative and post-operative version. The post-operative version includes all the pre-operative items in addition to items that address unique postoperative issues (e.g., scars).

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

You may code a version for online administration and data collection, but do not delete, add, or change any items or response options. A template file of the BREAST-Q© is available via the Research Electronic Data Capture (REDCap) portal. Please contact the authors for more information.

What should I do if the patient refuses to fill out the BREAST-Q@?

For research purposes, patients have the right to refuse to participate in a study. If the BREAST-Q© is being used in clinical practice and the patient does not wish to complete the questionnaire, it is helpful to explain to the patient that BREAST-Q© data is being collected to provide their healthcare provider with a complete understanding of their health as it relates to breast surgery. You can

emphasize that the BREAST-Q© is quick and simple to complete. If the patient is still unable to answer the question, it is still possible to score a BREAST-Q© scale with missing data.

What should I do if the patient asks for clarification of a question?

While completing the BREAST-Q©, some patients may ask for clarification of a particular question so that they can better understand and respond to it. You can help by rereading the question verbatim, but do not try to explain what the question means, rather suggest that the patient uses her own interpretation of the question. All patients should answer the questions based on their own understanding of the items.

What should I do if a patient asks why the BREAST-Q© has to be filled out on more than one occasion (if administering the BREAST-Q© prospectively)?

Explain that patients must complete the same BREAST-Q© at additional visits in order to see if their answers change with time. This will give a more complete picture of how her health-related quality of life and satisfaction changes over time.

9. BREAST-Q© Publications

Development & Validation

- 1. 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 Mar 6;33:44-9.
- 2. Cano SJ, Klassen AF, Scott A, Alderman A, Pusic AL. Interpreting Clinical Differences in BREAST-Q Scores: Minimal Important Difference. Plast Reconstr Surg. 2014 Jul;134(1): 173e-5e.
- 3. Cano SJ, Klassen AF, Scott AM, Pusic AL. A closer look at the BREAST-Q©. Clin Plast Surg. 2013 Apr;40(2):287-96.
- 4. McCarthy CM, Cano SJ, Klassen AF, Scott A, Van Laeken N, Lennox PA, Cordeiro PG, Pusic AL. The magnitude of effect of cosmetic breast augmentation on patient satisfaction and health-related quality of life. Plast Reconstr Surg. 2012 Jul;130(1):218-23.
- 5. Pusic AL, Klassen AF, Snell L, Cano SJ, McCarthy C, Scott A, Cemal Y, Rubin LR, Corderio PG. Measuring and managing patient expectations for breast reconstruction: impact on quality of life and patient satisfaction. Expert Rev Pharmacoecon Outcomes Res. 2012 Apr;12(2):149-58.
- 6. Cano SJ, Klassen AF, Scott AM, Cordeiro PG, Pusic AL. The BREAST-Q: Further Validation in Independent Clinical Samples. Plast Reconstr Surg. 2012 Feb;129(2):293-302.
- 7. Chen CM, Cano SJ, Klassen AF, King T, McCarthy C, Cordeiro PG, Morrow M, Pusic AL. Measuring quality of life in oncologic breast surgery: a systematic review of patient-reported outcome measures. Breast J. 2010 Nov-Dec;16(6):587-97.
- 8. Cano S, Klassen AF, Scott A, Thoma A, Feeny D, Pusic A. Health outcome and economic measurement in breast cancer surgery: challenges and opportunities. Expert Rev Pharmacoecon Outcomes Res. 2010 Oct;10(5):583-94.
- 9. Pusic AL, Klassen A, Scott A, Klok J, Cordeiro PG, Cano SJ. Development of a New Patient Reported Outcome Measure for Breast Surgery: The BREAST-Q©. Plast Reconstr Surg. 2009 Aug;124(2):345-53.

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- 10. Klassen A, Pusic AL, Scott A, Klok J, Cano S. Satisfaction and quality of life in women who undergo breast surgery: A qualitative study. BMC Womens Health. 2009 May 1;9:11.
- 11. Pusic AL, Reavey PL, Klassen AF, Scott A, McCarthy C, Cano S. Measuring patient outcomes after breast augmentation: Introducing the BREAST-Q: Augmentation Module. Clin Plast Surg. 2009 Jan;36(1):23-32.
- 12. 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.

Normative Data for BREAST-Q©

- 1. Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Breast cancer and reconstruction: normative data for interpreting the BREAST-Q. Plast Recon Surg. 2017 May;139(5):1046e-1055e.
- 2. Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Normative data for interpreting the BREAST-Q augmentation module. Plast Reconstr Surg. 2017 Apr;139(4):846e-853e.
- Mundy LR, Homa K Klassen AF, Pusic AL, Kerrigan CL. Understanding the health burden of macromastia: normative data for the BREAST-Q reduction module. Plast Reconstr Surg. 2017 Apr;139(4):846e-853e. Focus of video by PRS editor: http://journals.lww.com/plasreconsurg/Pages/videogallery.aspx?videoId=1085&autoPlay=true